

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ORION CORPORATION, BAYER)	
CONSUMER CARE AG, BAYER)	
HEALTHCARE LLC, and)	
BAYER HEALTHCARE)	
PHARMACEUTICALS INC.,)	
)	C.A. No. <u>1:25-cv-01201-UNA</u>
Plaintiffs,)	
)	
v.)	
)	
MSN PHARMACEUTICALS INC. and MSN)	
LABORATORIES PRIVATE LIMITED)	
)	
Defendants.)	

COMPLAINT

Plaintiffs Orion Corporation (“Orion”), Bayer Consumer Care AG (“BCC”), Bayer HealthCare LLC (“BHC”), and Bayer HealthCare Pharmaceuticals Inc. (“BHCPI”) (Orion, BCC, BHC, and BHCPI are collectively referred to herein as “Plaintiffs”), by their attorneys, for their Complaint, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited (collectively, “MSN”) of Abbreviated New Drug Application No. 220822 (“MSN’s ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Plaintiffs’ Nubeqa® (darolutamide) tablets (“MSN’s ANDA Product”) prior to the expiration of U.S. Patent Nos. 10,010,530 (“the ’530 patent”), 10,383,853 (“the ’853

patent”), 10,835,515 (“the ’515 patent”), and 11,168,058 (“the ’058 patent”). These patents are referred to collectively herein as the “patents-in-suit.”

PARTIES

Plaintiffs

2. Plaintiff Orion is a corporation organized under the laws of Finland with a principal place of business at Orionintie 1A, FI-02200 Espoo, Finland. Orion is the owner and assignee of the patents-in-suit.

3. Plaintiff BCC is a Swiss corporation with its principal place of business at Peter Merian-Str. 84, Basel, Switzerland 4052. BCC is an exclusive licensee under the patents-in-suit.

4. Plaintiff BHC is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey. BHC is an exclusive sublicensee under the patents-in-suit.

5. Plaintiff BHCPI is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey. BHCPI is the holder of New Drug Application (“NDA”) No. 212099 for Nubeqa® (darolutamide) tablets.

Defendants

6. Upon information and belief, defendant MSN Laboratories Private Limited is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at MSN House, Plot No. C 24, Sanath Nagar Industrial Estate, Sanathnagar, Hyderabad, Telangana, India, 500018. Upon information and belief, MSN Laboratories Private Limited is in the business of, among other things, manufacturing and selling

generic versions of branded pharmaceutical drugs through various operating subsidiaries, including MSN Pharmaceuticals Inc.

7. Upon information and belief, defendant MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. Upon information and belief, MSN Pharmaceuticals Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

8. Upon information and belief, MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. acted in concert to prepare and submit MSN's ANDA to the FDA. Upon information and belief, MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. know and intend that upon approval of MSN's ANDA, MSN Laboratories Private Limited will manufacture MSN's ANDA Product, and MSN Pharmaceuticals Inc. will directly or indirectly market, sell, and distribute MSN's ANDA Product throughout the United States, including in Delaware.

9. Upon information and belief, MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. 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, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, MSN Pharmaceuticals Inc. participated in, assisted, and cooperated with MSN Laboratories Private Limited in the acts complained of herein.

10. Upon information and belief, following any FDA approval of MSN's ANDA, MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. will act in concert to

distribute and sell MSN's ANDA Product throughout the United States, including within Delaware.

JURISDICTION

11. Jurisdiction is proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

12. This Court has personal jurisdiction over each of MSN Laboratories Private Limited and MSN Pharmaceuticals Inc.

13. MSN Laboratories Private Limited is subject to personal jurisdiction in Delaware because, among other things, MSN Laboratories Private Limited, itself and through its subsidiary MSN Pharmaceuticals Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, MSN Laboratories Private Limited, itself and through its subsidiary MSN Pharmaceuticals Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, MSN Laboratories Private Limited is subject to personal jurisdiction in Delaware because, upon information and belief, it controls MSN Pharmaceuticals Inc. and therefore the activities of MSN Pharmaceuticals Inc. in this jurisdiction are attributed to MSN Laboratories Private Limited.

14. MSN Pharmaceuticals Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of

Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, upon information and belief, MSN Pharmaceuticals Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

15. MSN has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

16. Upon information and belief, MSN, with knowledge of the Hatch-Waxman Act process, directed MSN's Notice Letter to BHCPI, an entity incorporated in Delaware. Upon information and belief, MSN knew when it did so that it was triggering the forty-five-day period for BHCPI to bring an action for patent infringement under the Hatch-Waxman Act.

17. Because BHCPI is incorporated in Delaware and BHC is a limited liability company organized and existing under the laws of Delaware, BHCPI and BHC suffer injury and consequences from MSN's filing of MSN's ANDA, in Delaware. MSN has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending MSN's Notice Letter to BHCPI, a Delaware corporation, and BHC, a Delaware limited liability company, that it would be sued in Delaware for patent infringement.

18. Upon information and belief, if MSN's ANDA is approved, MSN will directly or indirectly manufacture, market, sell, and/or distribute MSN's ANDA Product within the United States, including in Delaware, consistent with MSN's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, MSN regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, MSN's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, MSN's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of the patents-in-suit in the event that MSN's ANDA Product is approved before the patents expire.

19. Upon information and belief, MSN derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by MSN and/or MSN Laboratories Private Limited or MSN Pharmaceuticals Inc. Upon information and belief, various products for which MSN Laboratories Private Limited or MSN Pharmaceuticals Inc. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

20. Alternatively, if MSN Laboratories Private Limited's connections with Delaware, including its connections with MSN Pharmaceuticals Inc., are found to be insufficient to confer personal jurisdiction, then on information and belief, MSN Laboratories Private Limited is not subject to jurisdiction in any State's courts of general jurisdiction, and exercising jurisdiction

over MSN Laboratories Private Limited in Delaware is consistent with the United States Constitution and laws. *See Fed. R. Civ. P. 4(k)(2).*

VENUE

21. Venue is proper in this district as to MSN Pharmaceuticals Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

22. Venue is proper in this district as to MSN Laboratories Private Limited pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, MSN Laboratories Private Limited is a company organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

23. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

The '530 Patent

24. The '530 patent, entitled “Carboxamide Derivative and Its Diastereomers in Stable Crystalline Form,” (Exhibit A hereto), was duly and legally issued on July 3, 2018.

25. The '530 patent lists as inventors Olli Törmäkangas and Terhi Heikkinen.

26. The '530 patent is listed in connection with Nubeqa® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the “Orange Book.”

27. Claim 1 of the '530 patent recites:

Crystalline form I of N—((S)-1-(3-(3-chloro-4-cyanophenyl)-1H-pyrazol-1-yl) propan-2-yl)-5-(1-hydroxyethyl)-1H-pyrazole-3-

carboxamide (I) having an X-ray powder diffraction pattern comprising characteristic peaks at about 8.5, 10.4, 16.6, 16.9, and 24.3 degrees 2-theta.

28. Plaintiffs will be substantially and irreparably damaged by infringement of the '530 patent.

The '853 Patent

29. The '853 patent, entitled "Carboxamide Derivative and Its Diastereomers in Stable Crystalline Form," (Exhibit B hereto), was duly and legally issued on August 20, 2019.

30. The '853 patent lists as inventors Olli Törmäkangas and Terhi Heikkinen.

31. The '853 patent is listed in connection with Nubeqa® in the FDA's Orange Book.

32. Claim 1 of the '853 patent recites:

Crystalline form I of N—((S)-1-(3-(3-chloro-4-cyanophenyl)-1H-pyrazol-1-yl)propan-2-yl)-5-(1-hydroxyethyl)-1H-pyrazole-3-carboxamide (I) having an X-ray powder diffraction pattern comprising characteristic peaks at about 8.5, 10.4, 16.6, and 24.3 degrees 2-theta, wherein the crystalline form I is substantially free of any other crystalline form of N—((S)-1-(3-(3-chloro-4-cyanophenyl)-1H-pyrazol-1-yl)propan-2-yl)-5-(1-hydroxyethyl)-1H-pyrazole-3-carboxamide (I).

33. Plaintiffs will be substantially and irreparably damaged by infringement of the '853 patent.

The '515 Patent

34. The '515 patent, entitled "Carboxamide Derivative and Its Diastereomers in Stable Crystalline Form," (Exhibit C hereto), was duly and legally issued on November 17, 2020.

35. The '515 patent lists as inventors Olli Törmäkangas and Terhi Heikkinen.

36. The '515 patent is listed in connection with Nubeqa® in the FDA's Orange Book.

37. Claim 1 of the '515 patent recites:

A pharmaceutical dosage form in the form of a tablet or a capsule for oral administration comprising crystalline form I of N—((S)-1-(3-(3-chloro-4-cyanophenyl)-1H-pyrazol-1-yl)-propan-2-yl)-5-(1-hydroxyethyl)-1H-pyrazole-3-carboxamide (I) having an X-ray powder diffraction pattern comprising characteristic peaks at about 8.5, 10.4, 16.6, 16.9, and 24.3 degrees 2-theta, together with a pharmaceutical excipient.

38. Plaintiffs will be substantially and irreparably damaged by infringement of the '515 patent.

The '058 Patent

39. The '058 patent, entitled "Manufacture of a Crystalline Pharmaceutical Product," (Exhibit D hereto), was duly and legally issued on November 9, 2021.

40. The '058 patent lists as inventors Merja Reunanan and Anna Staffans.

41. The '058 patent is listed in connection with Nubeqa® in the FDA's Orange Book.

42. Claim 1 of the '058 patent recites:

Crystalline particles of N—((S)-1-(3-(3-chloro-4-cyano-phenyl)-1H-pyrazol-1-yl)-propan-2-yl)-5-(1-hydroxyethyl)-1H-pyrazole-3-carboxamide (I) having a specific surface area (SSA) in a range from about 8 to about 16 m²/g.

43. Claim 10 of the '058 patent recites:

Crystalline particles of N—((S)-1-(3-(3-chloro-4-cyanophenyl)-1H-pyrazol-1-yl)-propan-2-yl)-5-(1-hydroxyethyl)-1H-pyrazole-3-carboxamide (I) having a rounded particle shape and a volume median diameter (D_{v50}) ranging from between 100 µm and 1000 µm.

44. Plaintiffs will be substantially and irreparably damaged by infringement of the '058 patent.

Infringement by MSN

45. By letter dated August 26, 2025 ("MSN's Notice Letter"), MSN notified Plaintiffs that it had submitted to the FDA ANDA No. 220822, seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of MSN's ANDA Product prior to the expiration of the patents-in-suit. On information and belief, the purpose of the submission of ANDA No. 220822 was to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product prior to the expiration of the patents-in-suit.

46. In MSN's Notice Letter, MSN also notified Plaintiffs that, as part of ANDA No. 220822, MSN had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the patents-in-suit. On information and belief, MSN submitted ANDA No. 220822 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product.

47. According to information in MSN's Notice Letter, MSN's ANDA Product is a generic version of Nubeqa® tablets.

48. According to information in MSN's Notice Letter, the dosage form of MSN's ANDA Product is a tablet.

49. According to information in MSN's Notice Letter, the proposed dosage strength of MSN's ANDA Product is 300 mg.

50. On information and belief, MSN's ANDA Product is not publicly available, nor is ANDA No. 220822 accessible to the public.

51. MSN's Notice Letter was accompanied by an Offer of Confidential Access to "information from" ANDA No. 220822. However, the Offer of Confidential Access was subject to unreasonably restrictive confidentiality provisions. In addition, MSN's Notice Letter did not offer to provide additional information beyond "information from" ANDA No. 220822, such as samples of MSN's ANDA Product, which on information and belief is not accessible to the public.

52. Plaintiffs are filing this Complaint within forty-five days of receipt of MSN's Notice Letter.

**COUNT I – INFRINGEMENT BY MSN
OF THE '530 PATENT UNDER 35 U.S.C. § 271(e)(2)**

53. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

54. MSN's submission of MSN's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product prior to the expiration of the '530 patent was an act of infringement of the '530 patent under 35 U.S.C. § 271(e)(2)(A).

55. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product would infringe at least claim 1 of the '530 patent, recited above, literally and/or under the doctrine of equivalents. In MSN's Notice Letter, MSN did not contest that MSN's ANDA Product infringes claim 1 or any other claim of the '530 patent.

56. On information and belief, MSN will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product immediately and imminently upon FDA approval of MSN's ANDA.

57. On information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe at least claim 1 of the '530 patent, recited above.

58. On information and belief, MSN plans and intends to, and will, actively induce infringement of the '530 patent when MSN's ANDA is approved, and plans and intends to, and will, do so after approval.

59. On information and belief, MSN knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '530 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, MSN plans and intends to, and will, contribute to infringement of the '530 patent after approval of MSN's ANDA.

60. The foregoing actions by MSN constitute and/or will constitute infringement of the '530 patent, active inducement of infringement of the '530 patent, and contribution to the infringement by others of the '530 patent.

61. Unless MSN is enjoined from infringing the '530 patent, actively inducing infringement of the '530 patent, and contributing to the infringement by others of the '530 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT II – INFRINGEMENT BY MSN
OF THE '853 PATENT UNDER 35 U.S.C. § 271(e)(2)**

62. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

63. MSN's submission of MSN's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product prior to the expiration of the '853 patent was an act of infringement of the '853 patent under 35 U.S.C. § 271(e)(2)(A).

64. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product would infringe at least claim 1 of the '853 patent, recited above, literally and/or under the doctrine of equivalents.

65. On information and belief, MSN will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product immediately and imminently upon FDA approval of MSN's ANDA.

66. On information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe at least claim 1 of the '853 patent, recited above. In MSN's Notice Letter, MSN did not contest that MSN's ANDA Product infringes claim 1 or any other claim of the '853 patent.

67. On information and belief, MSN plans and intends to, and will, actively induce infringement of the '853 patent when MSN's ANDA is approved, and plans and intends to, and will, do so after approval.

68. On information and belief, MSN knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '853 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, MSN plans and intends to, and will, contribute to infringement of the '853 patent after approval of MSN's ANDA.

69. The foregoing actions by MSN constitute and/or will constitute infringement of the '853 patent, active inducement of infringement of the '853 patent, and contribution to the infringement by others of the '853 patent.

70. Unless MSN is enjoined from infringing the '853 patent, actively inducing infringement of the '853 patent, and contributing to the infringement by others of the '853 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT III – INFRINGEMENT BY MSN
OF THE '515 PATENT UNDER 35 U.S.C. § 271(e)(2)**

71. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

72. MSN's submission of MSN's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product prior to the expiration of the '515 patent was an act of infringement of the '515 patent under 35 U.S.C. § 271(e)(2)(A).

73. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product would infringe at least claim 1 of the '515 patent, recited above, literally and/or under the doctrine of equivalents.

74. On information and belief, MSN will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product immediately and imminently upon FDA approval of MSN's ANDA.

75. On information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe at least claim 1 of the '515 patent, recited above. In MSN's Notice Letter, MSN did not contest that MSN's ANDA Product infringes claim 1 or any other claim of the '515 patent.

76. On information and belief, MSN plans and intends to, and will, actively induce infringement of the '515 patent when MSN's ANDA is approved, and plans and intends to, and will, do so after approval.

77. On information and belief, MSN knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '515 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, MSN plans and intends to, and will, contribute to infringement of the '515 patent after approval of MSN's ANDA.

78. The foregoing actions by MSN constitute and/or will constitute infringement of the '515 patent, active inducement of infringement of the '515 patent, and contribution to the infringement by others of the '515 patent.

79. Unless MSN is enjoined from infringing the '515 patent, actively inducing infringement of the '515 patent, and contributing to the infringement by others of the '515 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT IV – INFRINGEMENT BY MSN
OF THE '058 PATENT UNDER 35 U.S.C. § 271(e)(2)**

80. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

81. MSN's submission of MSN's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product prior to the expiration of the '058 patent was an act of infringement of the '058 patent under 35 U.S.C. § 271(e)(2)(A).

82. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product would infringe at least claim

1 and/or claim 10 of the '058 patent, recited above, literally and/or under the doctrine of equivalents.

83. On information and belief, MSN will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product immediately and imminently upon FDA approval of MSN's ANDA.

84. On information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe at least claim 1 and/or claim 10 of the '058 patent, recited above.

85. On information and belief, MSN plans and intends to, and will, actively induce infringement of the '058 patent when MSN's ANDA is approved, and plans and intends to, and will, do so after approval.

86. On information and belief, MSN knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '058 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, MSN plans and intends to, and will, contribute to infringement of the '058 patent after approval of MSN's ANDA.

87. The foregoing actions by MSN constitute and/or will constitute infringement of the '058 patent, active inducement of infringement of the '058 patent, and contribution to the infringement by others of the '058 patent.

88. Unless MSN is enjoined from infringing the '058 patent, actively inducing infringement of the '058 patent, and contributing to the infringement by others of the '058 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V – DECLARATORY JUDGMENT OF INFRINGEMENT
BY MSN OF THE '530 PATENT

89. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

90. MSN has knowledge of the '530 patent.

91. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product would infringe at least claim 1 of the '530 patent, recited above, literally and/or under the doctrine of equivalents.

92. On information and belief, MSN will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling upon FDA approval of MSN's ANDA.

93. On information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe at least claim 1 of the '530 patent, recited above.

94. On information and belief, MSN plans and intends to, and will, actively induce infringement of the '530 patent when MSN's ANDA is approved, and plans and intends to, and will, do so after approval.

95. On information and belief, MSN knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '530 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, MSN plans and intends to, and will, contribute to infringement of the '530 patent after approval of MSN's ANDA.

96. The foregoing actions by MSN constitute and/or will constitute infringement of the '530 patent, active inducement of infringement of the '530 patent, and contribution to the infringement by others of the '530 patent.

97. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and MSN regarding whether MSN's manufacture, use, sale, offer for sale, or importation into the United States of MSN's ANDA Product with its proposed labeling according to MSN's ANDA will infringe at least claim 1 of the '530 patent, recited above.

98. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of MSN's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '530 patent and that the claims of the '530 patent are valid.

99. MSN should be enjoined from infringing the '530 patent, actively inducing infringement of the '530 patent, and contributing to the infringement by others of the '530 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT
BY MSN OF THE '853 PATENT**

100. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

101. MSN has knowledge of the '853 patent.

102. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product would infringe at least claim 1 of the '853 patent, recited above, literally and/or under the doctrine of equivalents.

103. On information and belief, MSN will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling upon FDA approval of MSN's ANDA.

104. On information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe at least claim 1 of the '853 patent, recited above.

105. On information and belief, MSN plans and intends to, and will, actively induce infringement of the '853 patent when MSN's ANDA is approved, and plans and intends to, and will, do so after approval.

106. On information and belief, MSN knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '853 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, MSN plans and intends to, and will, contribute to infringement of the '853 patent after approval of MSN's ANDA.

107. The foregoing actions by MSN constitute and/or will constitute infringement of the '853 patent, active inducement of infringement of the '853 patent, and contribution to the infringement by others of the '853 patent.

108. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and MSN regarding whether MSN's manufacture, use, sale, offer for sale, or importation into the United States of MSN's ANDA Product with its proposed labeling according to MSN's ANDA will infringe at least claim 1 of the '853 patent, recited above.

109. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of MSN's ANDA Product with its

proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '853 patent and that the claims of the '853 patent are valid.

110. MSN should be enjoined from infringing the '853 patent, actively inducing infringement of the '853 patent, and contributing to the infringement by others of the '853 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VII – DECLARATORY JUDGMENT OF INFRINGEMENT
BY MSN OF THE '515 PATENT**

111. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

112. MSN has knowledge of the '515 patent.

113. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product would infringe at least claim 1 of the '515 patent, recited above, literally and/or under the doctrine of equivalents.

114. On information and belief, MSN will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling upon FDA approval of MSN's ANDA.

115. On information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe at least claim 1 of the '515 patent, recited above.

116. On information and belief, MSN plans and intends to, and will, actively induce infringement of the '515 patent when MSN's ANDA is approved, and plans and intends to, and will, do so after approval.

117. On information and belief, MSN knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '515 patent and that its

ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, MSN plans and intends to, and will, contribute to infringement of the '515 patent after approval of MSN's ANDA.

118. The foregoing actions by MSN constitute and/or will constitute infringement of the '515 patent, active inducement of infringement of the '515 patent, and contribution to the infringement by others of the '515 patent.

119. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and MSN regarding whether MSN's manufacture, use, sale, offer for sale, or importation into the United States of MSN's ANDA Product with its proposed labeling according to MSN's ANDA will infringe at least claim 1 of the '515 patent, recited above.

120. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of MSN's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '515 patent and that the claims of the '515 patent are valid.

121. MSN should be enjoined from infringing the '515 patent, actively inducing infringement of the '515 patent, and contributing to the infringement by others of the '515 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT
BY MSN OF THE '058 PATENT**

122. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

123. MSN has knowledge of the '058 patent.

124. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product would infringe at least claim

1 and/or claim 10 of the '058 patent, recited above, literally and/or under the doctrine of equivalents.

125. On information and belief, MSN will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling upon FDA approval of MSN's ANDA.

126. On information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe at least claim 1 and/or claim 10 of the '058 patent, recited above.

127. On information and belief, MSN plans and intends to, and will, actively induce infringement of the '058 patent when MSN's ANDA is approved, and plans and intends to, and will, do so after approval.

128. On information and belief, MSN knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '058 patent and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, MSN plans and intends to, and will, contribute to infringement of the '058 patent after approval of MSN's ANDA.

129. The foregoing actions by MSN constitute and/or will constitute infringement of the '058 patent, active inducement of infringement of the '058 patent, and contribution to the infringement by others of the '058 patent.

130. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and MSN regarding whether MSN's manufacture, use, sale, offer for sale, or importation into the United States of MSN's ANDA Product with its proposed labeling according to MSN's ANDA will infringe at least claim 1 and/or claim 10 of the '058 patent, recited above.

131. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of MSN's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '058 patent and that the claims of the '058 patent are valid.

132. MSN should be enjoined from infringing the '058 patent, actively inducing infringement of the '058 patent, and contributing to the infringement by others of the '058 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

- (a) A judgment that MSN has infringed, will infringe, and will induce and contribute to the infringement of each of the patents-in-suit;
- (b) A judgment that the patents-in-suit are valid and enforceable;
- (c) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of MSN's ANDA Product be not earlier than the latest of the expiration dates of the patents-in-suit, inclusive of any extension(s) and additional period(s) of exclusivity;
- (d) A preliminary and permanent injunction enjoining MSN, and all persons acting in concert with MSN, from the commercial manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product prior to the latest of the expiration dates of the patents-in-suit, inclusive of any extension(s) and additional period(s) of exclusivity;
- (e) A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product prior to the expiration of the patents-in-suit will infringe, actively induce infringement of, and/or contribute to the infringement by others of the patents-in-suit;

(f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if MSN engages in the manufacture, use, offer for sale, sale, or importation of MSN's ANDA Product prior to the latest of the expiration dates of the patents-in-suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

(g) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(h) Costs and expenses in this action; and

(i) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock
Rodger D. Smith II (#3778)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
rsmith@mnat.com
dfahnestock@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Dov P. Grossman
Shaun P. Mahaffy
Arthur J. Argall III
Christian J. Gladden-Sorensen
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
(202) 434-5000

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