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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

APP PHARMACEUTICALS, LLC, Plaintiff, v. NAVINTA LLC, SANDOZ AG, SANDOZ INC., HOSPIRA, INC., SAGENT PHARMACEUTICALS, INC., and STRIDES INC., Defendants.	)	Civil Action No. **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff APP Pharmaceuticals, LLC ("APP"), by way of Complaint against Navinta LLC ("Navinta"), Sandoz AG and Sandoz Inc. ("collectively, Sandoz"), Hospira, Inc. ("Hospira"), Sagent Pharmaceuticals, Inc. ("Sagent"), and Strides Inc. ("Strides"), alleges as follows:

THE PARTIES

1. APP is a limited liability corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1501 East Woodfield Road, Suite 1300 East, Schaumburg, Illinois 60173.

2. On information and belief, Navinta is a limited liability corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 1499 Lower Ferry Road, Ewing, New Jersey 08618.

3. On information and belief, Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

4. On information and belief, Sandoz AG is a company organized and existing under the laws of Switzerland, having a principal place of business at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

5. On information and belief, Hospira is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

6. On information and belief, Sagent is a corporation organized and existing under the laws of the State of Wyoming, having a principal place of business at 1901 N. Roselle Road, Schaumburg, Illinois 60195.

7. On information and belief, Strides is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 201 S. Main St., Suite 3, Lambertville, New Jersey 08530.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action under 35 U.S.C. § 271(e)(2) and 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

9. On information and belief, Navinta is subject to personal jurisdiction within this District because, among other things, Navinta is incorporated in New Jersey, has its principal place of business in New Jersey, and is registered to do business in New Jersey.

10. On information and belief, Sandoz Inc. is subject to personal jurisdiction within this District because, among other things, it has its principal place of business in New Jersey and is registered to do business in New Jersey.

11. On information and belief, Sandoz AG is subject to personal jurisdiction within this District because, among other things, it regularly and systematically conducts business in New Jersey, including through its agent, Sandoz, Inc., and because it has purposefully directed its activities at New Jersey

and purposefully availed itself of the laws of New Jersey through, among other things, its collaboration with Navinta in the development of generic pharmaceuticals, including the ones at issue in this case, and its activities in connection with its role as the exclusive U.S. distributor of generic pharmaceuticals developed by Navinta, including the ones at issue in this case.

12. On information and belief, Hospira is subject to personal jurisdiction within this District because, among other things, Hospira regularly and systematically conducts business in New Jersey, has over thirty distributors in New Jersey, including Hospira Worldwide Contracted Distribution Center in Jersey City, New Jersey, and is registered to do business in New Jersey through its subsidiary, Hospira Worldwide, Inc.

13. On information and belief, Sagent is subject to personal jurisdiction within this District because, among other things, Sagent regularly and systematically conducts business in New Jersey, and because it has purposefully directed its activities at New Jersey and purposefully availed itself of the laws of New Jersey through, among other things, its collaboration with Strides in the development of generic pharmaceuticals, including the ones at issue in this case.

14. On information and belief, Strides is subject to personal jurisdiction within this District because, among other things, it has its principal place of business in New Jersey and is registered to do business in New Jersey.

15. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

NATURE OF THE ACTION

16. This is a civil action for patent infringement that arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., including 35 U.S.C. § 271(e)(2), and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This action relates to at least three Abbreviated New Drug Applications ("ANDAs") which APP is informed and believes have been filed with the United States Food and Drug Administration ("FDA") for approval to market generic versions of APP's ropivacaine hydrochloride injection product, Naropin®. One ANDA which is the subject of this action was filed by Navinta, in collaboration with Sandoz. On information and belief, Sandoz will be the exclusive United States distributor of the generic products for which Navinta's ANDA seeks approval, and will be principally responsible for marketing those products. The second ANDA which is the subject of this action was filed by Hospira. The third ANDA which is the subject of this action was filed by Sagent and Strides.

PATENTS-IN-SUIT

17. APP holds an approved New Drug Application ("NDA") 20-553 for Naropin. Naropin was approved by the FDA on September 24, 1996. The patents-in-suit relate to Naropin and uses of Naropin.

18. United States Patent No. 5,670,524 ("the '524 patent") (attached hereto as Exhibit A), entitled "Methods and Compositions for the Treatment of Pain Utilizing Ropivacaine," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on September 23, 1997.

19. United States Patent No. 5,834,489 ("the '489 patent") (attached hereto as Exhibit B), entitled "Methods and Compositions for the Treatment of Pain Utilizing Ropivacaine," was duly and legally issued by the USPTO on November 10, 1998.

20. APP owns all rights, title and interest in and to the '524 patent and the '489 patent, including the right to sue and recover for patent infringement.

NAVINTA'S AND SANDOZ'S ANDA

21. Navinta has already been found liable for infringement of the '489 and '524 patents based on its filing of a previous ANDA for generic versions of Naropin that were developed with Sandoz and were to be distributed and marketed by Sandoz. *See Abraxis Bioscience, Inc. v. Navinta LLC*, 640 F. Supp. 2d 553 (D.N.J. 2009) (Pisano, J.). In *Abraxis*, the Court ordered that the effective date of approval of the ANDA at issue in that case shall be no earlier than the expiration date of the '489 and '524 patents. *Id*. at 592.

22. On information and belief, Navinta and Sandoz, acting in concert, filed a second ANDA (the "Navinta/Sandoz ANDA") seeking approval to market

generic versions of Naropin (the "Navinta/Sandoz ANDA Products") before the expiration of the '489 and '524 patents. On information and belief, Sandoz will be the exclusive United States distributor of the Navinta/Sandoz ANDA Products, and will be principally responsible for marketing the Navinta/Sandoz ANDA Products.

23. On information and belief, Navinta and Sandoz intend to launch the Navinta/Sandoz ANDA Products on or about September 24, 2010.

HOSPIRA'S ANDA

24. Hospira is a pharmaceutical company that specializes in generic injectable products such as Naropin. On information and belief, Hospira filed an ANDA (the "Hospira ANDA") seeking approval to market generic versions of Naropin (the "Hospira ANDA Products") before the expiration of the '489 and '524 patents.

25. On information and belief, Hospira intends to launch its ANDA Products on or about September 24, 2010.

SAGENT'S AND STRIDES' ANDA

26. Sagent is a pharmaceutical company that specializes in generic injectable products such as Naropin. Strides is the U.S. subsidiary of Strides Arcolab Ltd., an Indian pharmaceutical development and manufacturing company.

27. On information and belief, Sagent and Strides, acting in concert, filed an ANDA (the "Sagent/Strides ANDA") seeking approval to market generic

versions of Naropin (the "Sagent/Strides ANDA Products") before the expiration of the '489 and '524 patents.

28. On information and belief, Sagent and Strides intend to launch their ANDA Products on or about September 24, 2010.

FIRST CLAIM FOR RELIEF

(Infringement Of The '524 Patent Under 35 U.S.C. § 271 Against Navinta And Sandoz)

29. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 28 above.

30. On information and belief, Navinta and Sandoz submitted the Navinta/Sandoz ANDA to the FDA under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of generic versions of Naropin products before the expiration date of the '524 patent.

31. On information and belief, by filing an ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of generic versions of Naropin before the expiration date of the '524 patent, Navinta and Sandoz have committed an act of infringement under 35 U.S.C. § 271, including 35 U.S.C. § 271(e)(2)(A).

32. On information and belief, Navinta's and Sandoz's commercial manufacture, use, and/or sale of the Navinta/Sandoz ANDA Products would infringe one or more claims of the '524 patent under 35 U.S.C. § 271.

33. On information and belief, when Navinta and Sandoz filed their ANDA, they were aware of the '524 patent and were aware that, if the Navinta/Sandoz ANDA were approved, the manufacture, use, and/or sale of the Navinta/Sandoz ANDA Products would infringe the '524 patent.

34. On information and belief, upon FDA approval, Navinta and Sandoz will intentionally and actively induce, encourage, contribute to, and aid and abet activities by others that will infringe the '524 patent, and Navinta and Sandoz will do so with knowledge that the activities by others will infringe the '524 patent.

35. As a result, Navinta and Sandoz are liable for inducing and/or contributing to infringement of the '524 patent under 35 U.S.C. § 271(b) and/or (c).

36. APP will be substantially and irreparably harmed if Navinta and Sandoz are not enjoined from infringing the '524 patent.

37. APP is entitled to the relief provided by 35 U.S.C. § 271, including an injunction preventing Navinta and Sandoz from infringing the '524 patent and/or a Court order that the effective date of any approval of the Navinta/Sandoz ANDA be a date which is not earlier than the expiration date of the '524 patent, including any extensions.

38. On information and belief, Navinta's and Sandoz's infringement of the '524 patent has been and continues to be deliberate and willful, and such

infringement will continue unless it is preliminarily and permanently enjoined by this Court.

SECOND CLAIM FOR RELIEF

(Infringement Of The ’489 Patent Under 35 U.S.C. § 271 Against Navinta And Sandoz)

39. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 38 above.

40. On information and belief, Navinta and Sandoz submitted the Navinta/Sandoz ANDA under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of generic versions of Naropin products before the expiration date of the ’489 patent.

41. On information and belief, by filing an ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of generic versions of Naropin products before the expiration date of the ’489 patent, Navinta and Sandoz have committed an act of infringement under 35 U.S.C. § 271, including 35 U.S.C. § 271(e)(2)(A).

42. On information and belief, Navinta’s and Sandoz’s commercial manufacture, use, and/or sale of the Navinta/Sandoz ANDA Products would infringe one or more claims of the ’489 patent under 35 U.S.C. § 271.

43. On information and belief, when Navinta and Sandoz filed their ANDA, they were aware of the ’489 patent and were aware that, if the

Navinta/Sandoz ANDA were approved, the manufacture, use, and/or sale of the Navinta/Sandoz ANDA Products would infringe the '489 patent.

44. On information and belief, upon FDA approval, Navinta and Sandoz will intentionally and actively induce, encourage, contribute to, aid and abet activities by others that will infringe the '489 patent, and Navinta and Sandoz will do so with knowledge that the activities by others will infringe the '489 patent.

45. As a result, Navinta and Sandoz are liable for inducing and/or contributing to infringement of the '489 patent under 35 U.S.C. § 271(b) and/or (c).

46. APP will be substantially and irreparably harmed if Navinta and Sandoz are not enjoined from infringing the '489 patent.

47. APP is entitled to the relief provided by 35 U.S.C. § 271, including an injunction preventing Navinta and Sandoz from infringing the '489 patent and/or a Court order that the effective date of any approval of the Navinta/Sandoz ANDA be a date which is not earlier than the expiration date of the '489 patent, including any extensions.

48. On information and belief, Navinta's and Sandoz's infringement of the '489 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

THIRD CLAIM FOR RELIEF

(Declaratory Judgment Of Infringement Of The '524 Patent Against Navinta And Sandoz)

49. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 48 above.

50. On information and belief, Navinta and Sandoz have taken significant concrete steps toward infringement of the '524 patent, including submitting the Navinta/Sandoz ANDA for FDA approval and preparing to market and sell the Navinta/Sandoz ANDA Products. APP will be substantially and irreparably harmed if Navinta and Sandoz manufacture, use, sell, offer for sale, and/or import into the United States the Navinta/Sandoz ANDA Products prior to the expiration date of the '524 patent.

51. On information and belief, Navinta's and Sandoz's infringement of the '524 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

FOURTH CLAIM FOR RELIEF

(Declaratory Judgment Of Infringement Of The '489 Patent Against Navinta And Sandoz)

52. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 51 above.

53. On information and belief, Navinta and Sandoz have taken significant concrete steps toward infringement of the '489 patent, including submitting the Navinta/Sandoz ANDA for FDA approval and preparing to market and sell the Navinta/Sandoz ANDA Products. APP will be substantially and irreparably harmed if Navinta and Sandoz manufacture, use, sell, offer for sale, and/or import into the United States the Navinta/Sandoz ANDA Products prior to the expiration date of the '489 patent.

54. On information and belief, Navinta's and Sandoz's infringement of the '489 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

FIFTH CLAIM FOR RELIEF

(Infringement Of The '524 Patent Under 35 U.S.C. § 271 Against Hospira)

55. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 54 above.

56. On information and belief, Hospira submitted its ANDA to the FDA under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of generic versions of Naropin products before the expiration date of the '524 patent.

57. On information and belief, by filing an ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of its generic versions of Naropin products before the expiration date of the '524 patent, Hospira has committed an act of infringement under 35 U.S.C. § 271, including 35 U.S.C. § 271(e)(2)(A).

58. On information and belief, Hospira's commercial manufacture, use, and/or sale of Hospira's ANDA Products would infringe one or more claims of the '524 patent under 35 U.S.C. § 271.

59. On information and belief, when Hospira filed its ANDA, it was aware of the '524 patent and was aware that, if approved, the manufacture, use, and/or sale of Hospira's ANDA Products would infringe the '524 patent.

60. On information and belief, upon FDA approval, Hospira will actively and intentionally induce, encourage, contribute to, and aid and abet activities by others that will infringe the '524 patent, and Hospira will do so with knowledge that the activities by others will infringe the '524 patent.

61. As a result, Hospira is liable for inducing and/or contributing to infringement of the '524 patent under 35 U.S.C. § 271(b) and/or (c).

62. APP will be substantially and irreparably harmed if Hospira is not enjoined from infringing the '524 patent.

63. APP is entitled to the relief provided by 35 U.S.C. § 271, including an injunction preventing Hospira from infringing the ’524 patent and/or a Court order that the effective date of any approval of Hospira’s ANDA be a date which is not earlier than the expiration date of the ’524 patent, including any extensions.

64. On information and belief, Hospira’s infringement of the ’524 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

SIXTH CLAIM FOR RELIEF

(Infringement of the ’489 Patent Under 35 U.S.C. § 271 Against Hospira)

65. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 64 above.

66. On information and belief, Hospira submitted its ANDA to the FDA under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of generic versions of Naropin products before the expiration date of the ’489 patent.

67. On information and belief, by filing an ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of its generic versions of Naropin products before the expiration date of the ’489 patent, Hospira has committed an act of infringement under 35 U.S.C. § 271, including 35 U.S.C. § 271(e)(2)(A).

68. On information and belief, Hospira's commercial manufacture, use, and/or sale of Hospira's ANDA Products would infringe one or more claims of the '489 patent under 35 U.S.C. § 271.

69. On information and belief, when Hospira filed its ANDA, it was aware of the '489 patent and was aware that, if approved, the manufacture, use, and/or sale of Hospira's ANDA Products would infringe the '489 patent.

70. On information and belief, upon FDA approval, Hospira will actively and intentionally induce, encourage, contribute to, aid and abet activities by others that will infringe the '489 patent, and Hospira will do so with knowledge that the activities by others will infringe the '489 patent.

71. As a result, Hospira is liable for inducing and/or contributing to infringement of the '489 patent under 35 U.S.C. § 271(b) and/or (c).

72. APP will be substantially and irreparably harmed if Hospira is not enjoined from infringing the '489 patent.

73. APP is entitled to the relief provided by 35 U.S.C. § 271, including an injunction preventing Hospira from infringing the '489 patent and/or a Court order that the effective date of any approval of Hospira's ANDA be a date which is not earlier than the expiration date of the '489 patent, including any extensions.

74. On information and belief, Hospira's infringement of the '489 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

SEVENTH CLAIM FOR RELIEF

(Declaratory Judgment Of Infringement Of The '524 Patent Against Hospira)

75. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 74 above.

76. On information and belief, Hospira has taken significant concrete steps toward infringement of the '524 patent, including submitting the Hospira ANDA for FDA approval and preparing to market Hospira's ANDA Products. APP will be substantially and irreparably harmed if Hospira manufactures, uses, sells, offers for sale, or imports into the United States Hospira's ANDA Products prior to the expiration date of the '524 patent.

77. On information and belief, Hospira's infringement of the '524 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

EIGHTH CLAIM FOR RELIEF

(Declaratory Judgment Of Infringement Of The '489 Patent Against Hospira)

78. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 77 above.

79. On information and belief, Hospira has taken significant concrete steps toward infringement of the ’489 patent, including submitting Hospira’s ANDA for FDA approval and preparing to market Hospira’s ANDA Products. APP will be substantially and irreparably harmed if Hospira manufactures, uses, sells, offers for sale, or imports into the United States Hospira’s ANDA Products prior to the expiration date of the ’489 patent.

80. On information and belief, Hospira’s infringement of the ’489 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

NINTH CLAIM FOR RELIEF

(Infringement Of The ’524 Patent Under 35 U.S.C. § 271 Against Sagent And Strides)

81. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 80 above.

82. On information and belief, Sagent and Strides submitted the Sagent/Strides ANDA to the FDA under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of generic versions of Naropin products before the expiration date of the ’524 patent.

83. On information and belief, by filing an ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of generic versions of Naropin before the expiration date of

the ’524 patent, Sagent and Strides have committed an act of infringement under 35 U.S.C. § 271, including 35 U.S.C. § 271(e)(2)(A).

84. On information and belief, Sagent’s and Strides’ commercial manufacture, use, and/or sale of the Sagent/Strides ANDA Products would infringe one or more claims of the ’524 patent under 35 U.S.C. § 271.

85. On information and belief, when Sagent and Strides filed their ANDA, they were aware of the ’524 patent and were aware that, if the Sagent/Strides ANDA were approved, the manufacture, use, and/or sale of the Sagent/Strides ANDA Products would infringe the ’524 patent.

86. On information and belief, upon FDA approval, Sagent and Strides will intentionally and actively induce, encourage, contribute to, and aid and abet activities by others that will infringe the ’524 patent, and Sagent and Strides will do so with knowledge that the activities by others will infringe the ’524 patent.

87. As a result, Sagent and Strides are liable for inducing and/or contributing to infringement of the ’524 patent under 35 U.S.C. § 271(b) and/or (c).

88. APP will be substantially and irreparably harmed if Sagent and Strides are not enjoined from infringing the ’524 patent.

89. APP is entitled to the relief provided by 35 U.S.C. § 271, including an injunction preventing Sagent and Strides from infringing the ’524 patent and/or a Court order that the effective date of any approval of the Sagent/Strides ANDA be

a date which is not earlier than the expiration date of the ’524 patent, including any extensions.

90. On information and belief, Sagent’s and Strides’ infringement of the ’524 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

TENTH CLAIM FOR RELIEF

(Infringement Of The ’489 Patent Under 35 U.S.C. § 271 Against Sagent And Strides)

91. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 90 above.

92. On information and belief, Sagent and Strides submitted the Sagent/Strides ANDA under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of generic versions of Naropin products before the expiration date of the ’489 patent.

93. On information and belief, by filing an ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of generic versions of Naropin products before the expiration date of the ’489 patent, Sagent and Strides have committed an act of infringement under 35 U.S.C. § 271, including 35 U.S.C. § 271(e)(2)(A).

94. On information and belief, Sagent's and Strides' commercial manufacture, use, and/or sale of the Sagent/Strides ANDA Products would infringe one or more claims of the '489 patent under 35 U.S.C. § 271.

95. On information and belief, when Sagent and Strides filed their ANDA, they were aware of the '489 patent and were aware that, if the Sagent/Strides ANDA were approved, the manufacture, use, and/or sale of the Sagent/Strides ANDA Products would infringe the '489 patent.

96. On information and belief, upon FDA approval, Sagent and Strides will intentionally and actively induce, encourage, contribute to, aid and abet activities by others that will infringe the '489 patent, and Sagent and Strides will do so with knowledge that the activities by others will infringe the '489 patent.

97. As a result, Sagent and Strides are liable for inducing and/or contributing to infringement of the '489 patent under 35 U.S.C. § 271(b) and/or (c).

98. APP will be substantially and irreparably harmed if Sagent and Strides are not enjoined from infringing the '489 patent.

99. APP is entitled to the relief provided by 35 U.S.C. § 271, including an injunction preventing Sagent and Strides from infringing the '489 patent and/or a Court order that the effective date of any approval of the Sagent/Strides ANDA be a date which is not earlier than the expiration date of the '489 patent, including any extensions.

100. On information and belief, Sagent's and Strides' infringement of the '489 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

ELEVENTH CLAIM FOR RELIEF

(Declaratory Judgment Of Infringement Of The '524 Patent Against Sagent And Strides)

101. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 100 above.

102. On information and belief, Sagent and Strides have taken significant concrete steps toward infringement of the '524 patent, including submitting the Sagent/Strides ANDA for FDA approval and preparing to market and sell the Sagent/Strides ANDA Products. APP will be substantially and irreparably harmed if Sagent and Strides manufacture, use, sell, offer for sale, and/or import into the United States the Sagent/Strides ANDA Products prior to the expiration date of the '524 patent.

103. On information and belief, Sagent's and Strides' infringement of the '524 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

TWELFTH CLAIM FOR RELIEF

(Declaratory Judgment of Infringement of the '489 Patent Against Sagent and Strides)

104. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 103 above.

105. On information and belief, Sagent and Strides have taken significant concrete steps toward infringement of the '489 patent, including submitting the Sagent/Strides ANDA for FDA approval and preparing to market and sell the Sagent/Strides ANDA Products. APP will be substantially and irreparably harmed if Sagent and Strides manufacture, use, sell, offer for sale, and/or import into the United States the Sagent/Strides ANDA Products prior to the expiration date of the '489 patent.

106. On information and belief, Sagent's and Strides' infringement of the '489 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff APP respectfully requests the following relief:

A. Judgment that Navinta and Sandoz have infringed one or more claims of the '524 and/or '489 patents;

B. An order that the effective date of any approval of the Navinta/Sandoz ANDA be a date that is not earlier than the expiration date of the ’524 and ’489 patents, including any extensions;

C. A declaratory judgment that Navinta and Sandoz would infringe one or more claims of the ’524 and/or ’489 patents if they manufacture, use, offer for sale, or sell within the United States, or import into the United States, the Navinta/Sandoz ANDA Products prior to the expiration date of the ’524 and ’489 patents;

D. A preliminary and permanent injunction restraining and enjoining Navinta and Sandoz and their officers, agents, attorneys and employees, and those acting in privity or concert with Navinta and/or Sandoz, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of generic versions of Naropin products as claimed in the ’524 and ’489 patents, prior to the expiration date of the ’524 and ’489 patents, including any extensions;

E. Monetary damages for any acts of infringement by Navinta or Sandoz;

F. Pursuant to 35 U.S.C. § 284, an award increasing damages to three times the amount found or assessed for infringement of the ’489 and ’524 patents due to the willful and deliberate nature of the infringement by Navinta and Sandoz;

G. Judgment that Hospira has infringed one or more claims of the ’524 and/or ’489 patents;

H. An order that the effective date of any approval of Hospira’s ANDA be a date that is not earlier than the expiration date of the ’524 and ’489 patents, including any extensions;

I. A declaratory judgment that Hospira would infringe one or more claims of the ’524 and/or ’489 patents if it manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, Hospira’s ANDA Products prior to the expiration date of the ’524 and ’489 patents;

J. A preliminary and permanent injunction restraining and enjoining Hospira and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of generic versions of Naropin products as claimed in the ’524 and ’489 patents, prior to the expiration date of the ’524 and ’489 patents, including any extensions;

K. Monetary damages for any acts of infringement by Hospira;

L. Pursuant to 35 U.S.C. § 284, an award increasing damages to three times the amount found or assessed for infringement of the ’489 and ’524 patents due to the willful and deliberate nature of the infringement by Hospira;

M. Judgment that Sagent and Strides have infringed one or more claims of the ’524 and/or ’489 patents;

N. An order that the effective date of any approval of the Sagent/Strides ANDA be a date that is not earlier than the expiration date of the ’524 and ’489 patents, including any extensions;

O. A declaratory judgment that Sagent and Strides would infringe one or more claims of the ’524 and/or ’489 patents if they manufacture, use, offer for sale, or sell within the United States, or import into the United States, the Sagent/Strides ANDA Products prior to the expiration date of the ’524 and ’489 patents;

P. A preliminary and permanent injunction restraining and enjoining Sagent and Strides and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of generic versions of Naropin products as claimed in the ’524 and ’489 patents, prior to the expiration date of the ’524 and ’489 patents, including any extensions;

Q. Monetary damages for any acts of infringement by Sagent or Strides;

R. Pursuant to 35 U.S.C. § 284, an award increasing damages to three times the amount found or assessed for infringement of the ’489 and ’524 patents due to the willful and deliberate nature of the infringement by Sagent and Strides;

S. Judgment that this is an exceptional case and that APP is entitled to its reasonable attorneys fees pursuant to 35 U.S.C. § 285;

T. The costs and expenses in this action; and

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

Dated: July 22, 2010

Respectfully submitted,

s/Anthony M. Gruppuso

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