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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ABRAXIS BIOSCIENCE, LLC, **Plaintiff,** **v.** **HAINAN SHUANGCHENG PHARMACEUTICALS CO., LTD.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Abraxis BioScience, LLC ("Abraxis" or "Plaintiff"), by its undersigned attorneys, for its Complaint against defendant Hainan Shuangcheng Pharmaceuticals Co., Ltd. ("HNSP" or "Defendant"), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq*., arising from HNSP's filing of Abbreviated New Drug Application ("ANDA") No. 216355 ("HNSP's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Plaintiff's Abraxane® (paclitaxel protein-bound particles for injectable suspension) drug product ("HNSP's ANDA Product") prior to the expiration of one or more of United States Patent Nos.

7,758,891 ("the '891 Patent"), 7,820,788 ("the '788 Patent"), 7,923,536 ("the '536 Patent"), 8,034,375 ("the '375 Patent"), 8,138,229 ("the '229 Patent"), 8,268,348 ("the '348 Patent"), 8,314,156 ("the '156 Patent"), 9,101,543 ("the '543 Patent"), 9,393,318 ("the '318 Patent"), 9,511,046 ("the '046 Patent"), 9,597,409 ("the '409 Patent") (together, "the Patents-in-Suit"), all owned by Plaintiff.

The Parties

2. Plaintiff Abraxis is a wholly owned subsidiary of Celgene Corporation, which is in turn a wholly owned subsidiary of the Bristol-Myers Squibb Company ("BMS"). Abraxis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. On information and belief, HNSP is a corporation organized and existing under the laws of China with its principal place of business at No. 16 Xingguo Road, Xiuying District, Haikou, Hainan, China.

The Patents-in-Suit

4. On July 20, 2010, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '891 Patent, titled, "Combinations and Modes of Administration of Therapeutic Agents and Combination Therapy." The '891 Patent is assigned to Abraxis. A copy of the '891 Patent is attached hereto as Exhibit A.

5. On October 26, 2010, the USPTO duly and lawfully issued the '788 Patent, titled, "Compositions and Methods of Delivery of Pharmacological Agents." The '788 Patent is assigned to Abraxis. A copy of the '788 Patent is attached hereto as Exhibit B.

6. On April 12, 2011, the USPTO duly and lawfully issued the '536 Patent, titled, "Compositions and Methods of Delivery of Pharmacological Agents." The '536 Patent is assigned to Abraxis. A copy of the '536 Patent is attached hereto as Exhibit C.

7. On October 11, 2011, the USPTO duly and lawfully issued the ’375 Patent, titled, “Combinations and Modes of Administration of Therapeutic Agents and Combination Therapy.” The ’375 Patent is assigned to Abraxis. A copy of the ’375 Patent is attached hereto as Exhibit D.

8. On March 20, 2012, the USPTO duly and lawfully issued the ’229 Patent, titled, “Compositions and Methods of Delivery of Pharmacological Agents.” The ’229 Patent is assigned to Abraxis. A copy of the ’229 Patent is attached hereto as Exhibit E.

9. On September 18, 2012, the USPTO duly and lawfully issued the ’348 Patent, titled, “Combinations and Modes of Administration of Therapeutic Agents and Combination Therapy.” The ’348 Patent is assigned to Abraxis. A copy of the ’348 Patent is attached hereto as Exhibit F.

10. On November 20, 2012, the USPTO duly and lawfully issued the ’156 Patent, titled, “Compositions and Methods of Delivery of Pharmacological Agents.” The ’156 Patent is assigned to Abraxis. A copy of the ’156 Patent is attached hereto as Exhibit G.

11. On August 11, 2015, the USPTO duly and lawfully issued the ’543 Patent, titled, “Combinations and Modes of Administration of Therapeutic Agents and Combination Therapy.” The ’543 Patent is assigned to Abraxis. A copy of the ’543 Patent is attached hereto as Exhibit H.

12. On July 19, 2016, the USPTO duly and lawfully issued the ’318 Patent, titled, “Methods of Treating Cancer.” The ’318 Patent is assigned to Abraxis. A copy of the ’318 Patent is attached hereto as Exhibit I.

13. On December 6, 2016, the USPTO duly and lawfully issued the '046 Patent, titled, "Methods of Treating Pancreatic Cancer." The '046 Patent is assigned to Abraxis. A copy of the '046 Patent is attached hereto as Exhibit J.

14. On March 21, 2017, the USPTO duly and lawfully issued the '409 Patent, titled, "Methods of Treating Cancer." The '409 Patent is assigned to Abraxis. A copy of the '409 Patent is attached hereto as Exhibit K.

The Abraxane® Drug Product

15. Abraxis holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for paclitaxel protein-bound particles for injectable suspension (NDA No. 21-660), which it sells under the trade name Abraxane®. Abraxane® is an FDA-approved prescription medicine used for the treatment of certain hard-to-treat forms of cancer, including: (1) metastatic breast cancer (after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy); (2) locally advanced or metastatic non-small cell lung cancer, as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy; and (3) metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine. The claims of the Patents-in-Suit cover, *inter alia*, pharmaceutical compositions and methods of use and administration of paclitaxel protein-bound particles for injection, including Abraxane®. Abraxis owns the Patents-in-Suit.

16. Pursuant to 21 U.S.C. § 355(b)(1) 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 Abraxane®.

17. The labeling for Abraxane® instructs and encourages physicians, other healthcare workers, and patients to administer Abraxane® according to one or more of the methods claimed in the Patents-in-Suit.

Jurisdiction and Venue

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

19. This Court has personal jurisdiction over HNSP by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, HNSP is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District, through its own actions and through the actions of its agents and subsidiaries. On information and belief, HNSP has purposefully conducted and continues to conduct business in this Judicial District, including the purposeful sale and distribution of drug products. On information and belief, HNSP regularly and continuously transacts business in New Jersey, including through HNSP's partnerships to manufacture and sell pharmaceutical products with entities whose principal place of business is in New Jersey. On information and belief, this Judicial District will be a destination for the generic drug products described in HNSP's ANDA.

20. On information and belief, HNSP prepares and/or aids in the preparation and submission of ANDAs to the FDA. On information and belief, HNSP actively participated in the preparation and/or filing of HNSP's ANDA.

21. On information and belief, HNSP derives substantial revenue from selling generic products throughout the United States, including in this Judicial District.

22. This Court has personal jurisdiction over HNSP because, *inter alia*, it has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its manufacturing partners.

23. This Court has personal jurisdiction over HNSP because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, HNSP intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Abraxis in New Jersey and in this Judicial District. For example, on information and belief, HNSP will work towards the regulatory approval, manufacturing, use, importation, marketing, sale, offer for sale, and distribution of generic pharmaceutical products, including HNSP 's ANDA Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the Patents-in-Suit.

24. In the alternative, this Court has personal jurisdiction over HNSP because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiff's claims arise under federal law; (b) HNSP is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) HNSP has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over HNSP satisfies due process.

25. On information and belief, HNSP seeks approval from the FDA to sell HNSP's ANDA Product throughout the United States, including in this Judicial District, and intends to

market, sell, and/or distribute HNSP's ANDA Product to residents of New Jersey upon approval of HNSP's ANDA.

26. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

27. Venue is proper in this district for HNSP pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, HNSP is a company organized and existing under the laws of China and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

Acts Giving Rise To This Suit

28. Pursuant to Section 505 of the FFDCA, HNSP filed HNSP's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product before the Patents-in-Suit expire.

29. On information and belief, following FDA approval of HNSP's ANDA, HNSP will make, use, offer for sale, or sell HNSP's ANDA Product throughout the United States, or import such generic products into the United States.

30. On information and belief, in connection with the filing of its ANDA as described above, HNSP provided a written certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("HNSP's Paragraph IV Certification"), alleging that the claims of the Patents-in-Suit are invalid.

31. No earlier than December 27, 2022, HNSP sent written notice of its Paragraph IV Certification to Abraxis ("HNSP's Notice Letter"). HNSP's Notice Letter alleged that the claims of the Patents-in-Suit are invalid. HNSP's Notice Letter also informed Abraxis that HNSP seeks approval to market HNSP's ANDA Product before the Patents-in-Suit expire.

Count I: Infringement of the '891 Patent

32. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

33. HNSP, by the submission of HNSP's Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '891 Patent.

34. HNSP's ANDA has been pending before the FDA since at least December 27, 2022, the date that HNSP sent HNSP's Notice Letter to Abraxis.

35. HNSP's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '891 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

36. There is a justiciable controversy between the parties hereto as to the infringement of the '891 Patent.

37. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will infringe one or more claims of the '891 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States.

38. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will induce infringement of one or more claims of the '891 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, upon FDA approval of HNSP's ANDA, HNSP will

intentionally encourage acts of direct infringement with knowledge of the ’891 Patent and knowledge that its acts are encouraging infringement.

39. Unless enjoined by this Court, upon FDA approval of HNSP’s ANDA, HNSP will contributorily infringe one or more claims of the ’891 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HNSP’s ANDA Product in or into the United States. On information and belief, HNSP has had and continues to have knowledge that HNSP’s ANDA Product is especially adapted for a use that infringes one or more claims of the ’891 Patent and that there is no substantial non-infringing use for HNSP’s ANDA Product.

40. Abraxis will be substantially and irreparably damaged and harmed if HNSP’s infringement of the ’891 Patent is not enjoined.

41. Abraxis does not have an adequate remedy at law.

42. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count II: Infringement of the ’788 Patent

43. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

44. HNSP, by the submission of HNSP’s Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP’s ANDA Product, prior to the expiration of the ’788 Patent.

45. HNSP’s ANDA has been pending before the FDA since at least December 27, 2022, the date that HNSP sent HNSP’s Notice Letter to Abraxis.

46. HNSP's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '788 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

47. There is a justiciable controversy between the parties hereto as to the infringement of the '788 Patent.

48. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will infringe one or more claims of the '788 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States.

49. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will induce infringement of one or more claims of the '788 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, upon FDA approval of HNSP's ANDA, HNSP will intentionally encourage acts of direct infringement with knowledge of the '788 Patent and knowledge that its acts are encouraging infringement.

50. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will contributorily infringe one or more claims of the '788 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, HNSP has had and continues to have knowledge that HNSP's ANDA Product is especially adapted for a use that infringes one or more claims of the '788 Patent and that there is no substantial non-infringing use for HNSP's ANDA Product.

51. Abraxis will be substantially and irreparably damaged and harmed if HNSP's infringement of the '788 Patent is not enjoined.

52. Abraxis does not have an adequate remedy at law.

53. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '536 Patent

54. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

55. HNSP, by the submission of HNSP's Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '536 Patent.

56. HNSP's ANDA has been pending before the FDA since at least December 27, 2022, the date that HNSP sent HNSP's Notice Letter to Abraxis.

57. HNSP's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '536 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

58. There is a justiciable controversy between the parties hereto as to the infringement of the '536 Patent.

59. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will infringe one or more claims of the '536 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States.

60. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will induce infringement of one or more claims of the '536 Patent under 35 U.S.C. § 271(b) by

making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, upon FDA approval of HNSP's ANDA, HNSP will intentionally encourage acts of direct infringement with knowledge of the '536 Patent and knowledge that its acts are encouraging infringement.

61. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will contributorily infringe one or more claims of the '536 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, HNSP has had and continues to have knowledge that HNSP's ANDA Product is especially adapted for a use that infringes one or more claims of the '536 Patent and that there is no substantial non-infringing use for HNSP's ANDA Product.

62. Abraxis will be substantially and irreparably damaged and harmed if HNSP's infringement of the '536 Patent is not enjoined.

63. Abraxis does not have an adequate remedy at law.

64. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '375 Patent

65. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

66. HNSP, by the submission of HNSP's Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '375 Patent.

67. HNSP's ANDA has been pending before the FDA since at least December 27, 2022, the date that HNSP sent HNSP's Notice Letter to Abraxis.

68. HNSP's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '375 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

69. There is a justiciable controversy between the parties hereto as to the infringement of the '375 Patent.

70. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will infringe one or more claims of the '375 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States.

71. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will induce infringement of one or more claims of the '375 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, upon FDA approval of HNSP's ANDA, HNSP will intentionally encourage acts of direct infringement with knowledge of the '375 Patent and knowledge that its acts are encouraging infringement.

72. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will contributorily infringe one or more claims of the '375 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, HNSP has had and continues to have knowledge that HNSP's ANDA Product is especially adapted for a use that infringes one or more claims of the '375 Patent and that there is no substantial non-infringing use for HNSP's ANDA Product.

73. Abraxis will be substantially and irreparably damaged and harmed if HNSP's infringement of the '375 Patent is not enjoined.

74. Abraxis does not have an adequate remedy at law.

75. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '229 Patent

76. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

77. HNSP, by the submission of HNSP's Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '229 Patent.

78. HNSP's ANDA has been pending before the FDA since at least December 27, 2022, the date that HNSP sent HNSP's Notice Letter to Abraxis.

79. HNSP's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '229 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

80. There is a justiciable controversy between the parties hereto as to the infringement of the '229 Patent.

81. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will infringe one or more claims of the '229 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States.

82. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will induce infringement of one or more claims of the '229 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, upon FDA approval of HNSP's ANDA, HNSP will intentionally encourage acts of direct infringement with knowledge of the '229 Patent and knowledge that its acts are encouraging infringement.

83. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will contributorily infringe one or more claims of the '229 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, HNSP has had and continues to have knowledge that HNSP's ANDA Product is especially adapted for a use that infringes one or more claims of the '229 Patent and that there is no substantial non-infringing use for HNSP's ANDA Product.

84. Abraxis will be substantially and irreparably damaged and harmed if HNSP's infringement of the '229 Patent is not enjoined.

85. Abraxis does not have an adequate remedy at law.

86. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '348 Patent

87. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

88. HNSP, by the submission of HNSP's Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial

manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '348 Patent.

89. HNSP's ANDA has been pending before the FDA since at least December 27, 2022, the date that HNSP sent HNSP's Notice Letter to Abraxis.

90. HNSP's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '348 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

91. There is a justiciable controversy between the parties hereto as to the infringement of the '348 Patent.

92. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will infringe one or more claims of the '348 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States.

93. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will induce infringement of one or more claims of the '348 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, upon FDA approval of HNSP's ANDA, HNSP will intentionally encourage acts of direct infringement with knowledge of the '348 Patent and knowledge that its acts are encouraging infringement.

94. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will contributorily infringe one or more claims of the '348 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, HNSP has had and continues to have knowledge that

HNSP's ANDA Product is especially adapted for a use that infringes one or more claims of the '348 Patent and that there is no substantial non-infringing use for HNSP's ANDA Product.

95. Abraxis will be substantially and irreparably damaged and harmed if HNSP's infringement of the '348 Patent is not enjoined.

96. Abraxis does not have an adequate remedy at law.

97. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VII: Infringement of the '156 Patent

98. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

99. HNSP, by the submission of HNSP's Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '156 Patent.

100. HNSP's ANDA has been pending before the FDA since at least December 27, 2022, the date that HNSP sent HNSP's Notice Letter to Abraxis.

101. HNSP's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '156 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

102. There is a justiciable controversy between the parties hereto as to the infringement of the '156 Patent.

103. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will infringe one or more claims of the '156 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States.

104. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will induce infringement of one or more claims of the '156 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, upon FDA approval of HNSP's ANDA, HNSP will intentionally encourage acts of direct infringement with knowledge of the '156 Patent and knowledge that its acts are encouraging infringement.

105. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will contributorily infringe one or more claims of the '156 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, HNSP has had and continues to have knowledge that HNSP's ANDA Product is especially adapted for a use that infringes one or more claims of the '156 Patent and that there is no substantial non-infringing use for HNSP's ANDA Product.

106. Abraxis will be substantially and irreparably damaged and harmed if HNSP's infringement of the '156 Patent is not enjoined.

107. Abraxis does not have an adequate remedy at law.

108. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VIII: Infringement of the '543 Patent

109. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

110. HNSP, by the submission of HNSP's Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '543 Patent.

111. HNSP's ANDA has been pending before the FDA since at least December 27, 2022, the date that HNSP sent HNSP's Notice Letter to Abraxis.

112. HNSP's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '543 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

113. There is a justiciable controversy between the parties hereto as to the infringement of the '543 Patent.

114. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will infringe one or more claims of the '543 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States.

115. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will induce infringement of one or more claims of the '543 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, upon FDA approval of HNSP's ANDA, HNSP will intentionally encourage acts of direct infringement with knowledge of the '543 Patent and knowledge that its acts are encouraging infringement.

116. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will contributorily infringe one or more claims of the '543 Patent under 35 U.S.C. § 271(c) by

making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, HNSP has had and continues to have knowledge that HNSP's ANDA Product is especially adapted for a use that infringes one or more claims of the '543 Patent and that there is no substantial non-infringing use for HNSP's ANDA Product.

117. Abraxis will be substantially and irreparably damaged and harmed if HNSP's infringement of the '543 Patent is not enjoined.

118. Abraxis does not have an adequate remedy at law.

119. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IX: Infringement of the '318 Patent

120. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

121. HNSP, by the submission of HNSP's Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '318 Patent.

122. HNSP's ANDA has been pending before the FDA since at least December 27, 2022, the date that HNSP sent HNSP's Notice Letter to Abraxis.

123. HNSP's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '318 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

124. There is a justiciable controversy between the parties hereto as to the infringement of the ’318 Patent.

125. Unless enjoined by this Court, upon FDA approval of HNSP’s ANDA, HNSP will infringe one or more claims of the ’318 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HNSP’s ANDA Product in or into the United States.

126. Unless enjoined by this Court, upon FDA approval of HNSP’s ANDA, HNSP will induce infringement of one or more claims of the ’318 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HNSP’s ANDA Product in or into the United States. On information and belief, upon FDA approval of HNSP’s ANDA, HNSP will intentionally encourage acts of direct infringement with knowledge of the ’318 Patent and knowledge that its acts are encouraging infringement.

127. Unless enjoined by this Court, upon FDA approval of HNSP’s ANDA, HNSP will contributorily infringe one or more claims of the ’318 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HNSP’s ANDA Product in or into the United States. On information and belief, HNSP has had and continues to have knowledge that HNSP’s ANDA Product is especially adapted for a use that infringes one or more claims of the ’318 Patent and that there is no substantial non-infringing use for HNSP’s ANDA Product.

128. Abraxis will be substantially and irreparably damaged and harmed if HNSP’s infringement of the ’318 Patent is not enjoined.

129. Abraxis does not have an adequate remedy at law.

130. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count X: Infringement of the ’046 Patent

131. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

132. HNSP, by the submission of HNSP's Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '046 Patent.

133. HNSP's ANDA has been pending before the FDA since at least December 27, 2022, the date that HNSP sent HNSP's Notice Letter to Abraxis.

134. HNSP's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '046 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

135. There is a justiciable controversy between the parties hereto as to the infringement of the '046 Patent.

136. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will infringe one or more claims of the '046 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States.

137. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will induce infringement of one or more claims of the '046 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, upon FDA approval of HNSP's ANDA, HNSP will intentionally encourage acts of direct infringement with knowledge of the '046 Patent and knowledge that its acts are encouraging infringement.

138. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will contributorily infringe one or more claims of the '046 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, HNSP has had and continues to have knowledge that HNSP's ANDA Product is especially adapted for a use that infringes one or more claims of the '046 Patent and that there is no substantial non-infringing use for HNSP's ANDA Product.

139. Abraxis will be substantially and irreparably damaged and harmed if HNSP's infringement of the '046 Patent is not enjoined.

140. Abraxis does not have an adequate remedy at law.

141. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XI: Infringement of the '409 Patent

142. Abraxis repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

143. HNSP, by the submission of HNSP's Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior to the expiration of the '409 Patent.

144. HNSP's ANDA has been pending before the FDA since at least December 27, 2022, the date that HNSP sent HNSP's Notice Letter to Abraxis.

145. HNSP's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of HNSP's ANDA Product, prior

to the expiration of the '409 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

146. There is a justiciable controversy between the parties hereto as to the infringement of the '409 Patent.

147. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will infringe one or more claims of the '409 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States.

148. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will induce infringement of one or more claims of the '409 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, upon FDA approval of HNSP's ANDA, HNSP will intentionally encourage acts of direct infringement with knowledge of the '409 Patent and knowledge that its acts are encouraging infringement.

149. Unless enjoined by this Court, upon FDA approval of HNSP's ANDA, HNSP will contributorily infringe one or more claims of the '409 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HNSP's ANDA Product in or into the United States. On information and belief, HNSP has had and continues to have knowledge that HNSP's ANDA Product is especially adapted for a use that infringes one or more claims of the '409 Patent and that there is no substantial non-infringing use for HNSP's ANDA Product.

150. Abraxis will be substantially and irreparably damaged and harmed if HNSP's infringement of the '409 Patent is not enjoined.

151. Abraxis does not have an adequate remedy at law.

152. This case is an exceptional one, and Abraxis is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Abraxis respectfully requests the following relief:

(A) A Judgment that HNSP has infringed the Patents-in-Suit by submitting ANDA No. 216355;

(B) A Judgment that HNSP has infringed, and that HNSP's making, using, offering to sell, selling, or importing HNSP's ANDA Product will infringe one or more claims of the Patents-in-Suit;

(C) An Order that the effective date of FDA approval of ANDA No. 216355 be a date which is not earlier than the later of the expiration of the Patents-in-Suit, or any later expiration of exclusivity to which Abraxis is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining HNSP and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing HNSP's ANDA Product until after the expiration of the Patents-in-Suit, or any later expiration of exclusivity to which Abraxis is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining HNSP, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any paclitaxel protein-bound particles for injectable suspension or compositions claimed in the Patents-in-Suit, or from actively inducing or contributing to the infringement of any claim of the Patents-in-Suit, until after the expiration of the Patents-in-Suit, or any later expiration of exclusivity to which HNSP is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of HNSP's ANDA Product will directly infringe, induce and/or contribute to infringement of the Patents-in-Suit;

(G) To the extent that HNSP has committed any acts with respect to the paclitaxel protein-bound particles of injectable suspension compositions claimed in the Patents-in-Suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Abraxis damages for such acts;

(H) If HNSP engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of HNSP's ANDA Product prior to the expiration of the Patents-in-Suit, a Judgment awarding damages to Abraxis resulting from such infringement, together with interest;

(I) A Judgment declaring that the Patents-in-Suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Abraxis its attorneys' fees incurred in this action;

(K) A Judgment awarding Abraxis its costs and expenses incurred in this action; and

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

Dated: February 8, 2023

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 AND 40.1

I hereby certify that the matter in controversy involves one of the same Plaintiffs, the same drug product, and certain of the same patents that were at issue in the matters captioned *Abraxis Bioscience, LLC, et al. v. Actavis LLC*, Civil Action No. 16-1925 (JMV)(MF), *Abraxis Bioscience, LLC, et al. v. Cipla Ltd*., Civil Action No. 16-9074 (JMV)(MF), *Abraxis Bioscience, LLC, et al. v. HBT Labs, Inc.*, Civil Action No. 18-17304 (JMV)(MF), and *Abraxis Bioscience, LLC v. Jiangsu Hengrui Pharmaceuticals Co., Ltd.*, Civil Action No. 22-2745 (FLW)(TJB). These cases were filed on April 6, 2016, December 7, 2016, December 17, 2018, and May 11, 2022, respectively, and dismissed on January 26, 2018, October 9, 2018, February 7, 2019, and November 22, 2022, respectively.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: February 8, 2023

By: s/ Charles M. Lizza

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