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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ABRAXIS BIOSCIENCE, LLC, **Plaintiff,** **v.** **SUN PHARMA ADVANCED RESEARCH COMPANY, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., and SUN PHARMACEUTICAL INDUSTRIES LIMITED,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Abraxis BioScience, LLC ("Abraxis"), by its undersigned attorneys, for its Complaint against defendants Sun Pharma Advanced Research Company, Ltd. ("Sun Advanced"), Sun Pharmaceutical Industries, Inc. ("Sun Inc."), and Sun Pharmaceutical Industries, Ltd. ("Sun Ltd.") (collectively, "Sun"), 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 Sun Advanced's filing of New Drug Application ("NDA") No. 211599 ("Sun's NDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Abraxis's Abraxane®

drug product ("Sun's Proposed Product") prior to the expiration of United States Patent Nos. 7,758,891 ("'891 patent"), 7,820,788 ("'788 patent"), 7,923,536 ("'536 patent"), 8,034,375 ("'375 patent"), 8,138,229 ("'229 patent"), 8,268,348 ("'348 patent"), 8,314,156 ("'156 patent"), 8,853,260 ("'260 patent"), 9,101,543 ("'543 patent"), 9,393,318 ("'318 patent"), 9,511,046 ("'046 patent"), and 9,597,409 ("'409 patent"), all owned by Abraxis (collectively, the "patents-in-suit").

The Parties

2. 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, Defendant Sun Pharma Advanced Research Company, Ltd. is a corporation organized under the laws of the India, having a principal place of business at 17-B Mahal Industrial Estate, Off Mahakall Caves Road, Andherl (East), Mumbai 400 093, India.

4. On information and belief, Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 2 Independence Way, Princeton, New Jersey 08540. On information and belief, Sun Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd.

5. On information and belief, Sun Pharmaceutical Industries Limited is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400 063, Maharashtra, India.

Jurisdiction and Venue

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

7. This Court has personal jurisdiction over Sun Advanced, Sun Inc., and Sun Ltd. because of, *inter alia*, their systematic and continuous contacts with the State of New Jersey.

8. On information and belief, Sun Advanced, Sun Inc., and Sun Ltd. develop, manufacture, distribute, market, offer to sell, and sell pharmaceutical products, including generic drug products, for sale and use throughout the United States, including in this Judicial District.

9. On information and belief, Sun Advanced, Sun Inc., and Sun Ltd. prepare and/or aid in the submission of NDAs or abbreviated new drug applications to the FDA.

10. On information and belief, Sun Advanced, Sun Inc., and Sun Ltd. derive substantial revenue from selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

11. This Court has personal jurisdiction over Sun Advanced by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Advanced purposefully has conducted and continues to conduct business in this Judicial District.

12. On information and belief, Sun Advanced 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.

13. On information and belief, Sun Advanced, alone or through Sun Ltd. and/or Sun Inc., or through distributors, retailers, and/or wholesalers, manufactures and/or distributes pharmaceutical products, including generic drug products, for sale and use throughout the United States, including in this Judicial District.

14. This Court also has personal jurisdiction over Sun Advanced because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Abraxis, a corporation whose principal place of business is in New Jersey. On information and belief, Sun Advanced 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.

15. This Court also has personal jurisdiction over Sun Advanced because Sun Advanced has taken the significant step of filing Sun's NDA seeking approval to market its infringing drug product prior to the expiration of the patents-in-suit. Sun's NDA seeks approval to sell Sun's Proposed Product throughout the United States, including in the State of New Jersey.

16. On information and belief, Sun Advanced, alone or through Sun Ltd. and/or Sun Inc., plans to direct sales of Sun's Proposed Product into this Judicial District, where it would cause harm to Abraxis. Therefore, this cause of action arises out of Sun Advanced's contacts with the State of New Jersey.

17. In the alternative, this Court has personal jurisdiction over Sun Advanced because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Abraxis' claims arise under federal law; (b) Sun Advanced is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sun Advanced has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting NDAs and/or 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 Sun Advanced satisfies due process.

18. This Court has personal jurisdiction over Sun Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Inc. purposefully has conducted and continues to conduct business in this Judicial District.

19. On information and belief, Sun Inc. 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.

20. On information and belief, Sun Inc., alone or through Sun Ltd. and/or Sun Advanced, or through distributors, retailers, and/or wholesalers, manufactures and/or distributes pharmaceutical products, including generic drug products, for sale and use throughout the United States, including in this Judicial District. Sun Inc. is registered as a manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5003437, and is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID Nos. 0100954087 and/or 0100970132.

21. On information and belief, Sun Inc., alone or through Sun Ltd. and/or Sun Advanced, plans to direct sales of Sun's Proposed Product into this Judicial District, where it would cause harm to Abraxis. Therefore, this cause of action arises out of Sun Inc.'s contacts with the State of New Jersey.

22. This Court also has personal jurisdiction over Sun Inc. because it has availed itself of the protections afforded by this Judicial District by asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *Celgene Corp. v. Sun Pharm. Indus., Inc., et al.*, No. 18-11630 (SDW)(LDW); *Janssen Pharm. Inc. v. Sun Pharma Global FZE, et al.*, No. 11-6089 (SRC)(CLW); *Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd., et al.*, No. 14-4307 (JBS)(KMW); *Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd.*, No. 14-6397 (JBS)(KMW).

23. On information and belief, Sun Advanced and Sun Inc. act for the benefit of and at the direction of Sun Ltd., and are agents and/or alter egos of Sun Ltd. For example, Mr. Dilip Shanghvi is the Chairman & Managing Director of Sun Advanced as well as Managing Director of Sun Ltd.

24. This Court has personal jurisdiction over Sun Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Inc. purposefully has conducted and continues to conduct business in this Judicial District.

25. On information and belief, Sun Ltd. 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.

26. On information and belief, Sun Ltd., alone or through Sun Ltd. and/or Sun Advanced, or through distributors, retailers, and/or wholesalers, manufactures and/or distributes pharmaceutical products, including generic drug products, for sale and use throughout the United States, including in this Judicial District.

27. On information and belief, Sun Ltd., alone or through Sun Ltd. and/or Sun Advanced, plans to direct sales of Sun's Proposed Product into this Judicial District, where it would cause harm to Abraxis. Therefore, this cause of action arises out of Sun Ltd.'s contacts with the State of New Jersey.

28. This Court also has personal jurisdiction over Sun Ltd. because Sun Ltd. has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Ltd. regularly and continuously transacts business within New Jersey, including by offering

pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey.

29. This Court also has personal jurisdiction over Sun Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Sun Inc., a company registered as a manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5003437 and registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID Nos. 0100954087 and/or 0100970132; and (2) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey, including through, directly or indirectly, Sun Inc. On information and belief, Sun Inc. acts at the direction, and for the benefit, of Sun Ltd., and is controlled and/or dominated by Sun Ltd.

30. On information and belief, Sun Ltd. has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases. Sun Ltd. has previously been sued in this Judicial District and has availed itself of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, and has not challenged personal jurisdiction. *See, e.g.*, *Celgene Corp. v. Sun Pharm. Indus., Inc., et al.*, No. 18-11630 (SDW)(LDW); *Jazz Pharms., Inc., et al. v. Sun Pharm. Indus. Ltd., et al.*, No. 15-8229 (ES)(JAD); *Boehringer Ingelheim Pharms. Inc., et al. v. Sun Pharm. Indus. Ltd., et al.*, No. 15-5982 (PGS)(TJB); *Jazz Pharms., Inc. v. Sun Pharm. Indus. Ltd., et al.*, No. 15-3217 (ES)(JAD); *Otsuka Pharm. Co., Ltd. v. Sun Pharm. Indus. Ltd., et al.*, No. 14-6397 (JBS)(KMW); *Otsuka Pharm. Co., Ltd. v. Sun Pharm. Indus., Inc., et al.*, No. 14-4307 (JBS)(KMW); *Cephalon, Inc. v.*

Sun Pharm. Indus., Inc., et al., No. 11-5474 (FLW)(DEA); *Depomed, Inc., et al. v. Sun Pharm. Indus., Inc., et al.*, No. 11-3553 (JAP)(TJB).

31. Sun Ltd. has further availed itself of the jurisdiction of this Judicial District by initiating litigation in this Judicial District. *See, e.g., Sun Pharm. Indus. Ltd., et al. v. Altana Pharma AG, et al.*, No. 05-2391 (KSH)(PS).

32. In the alternative, this Court has personal jurisdiction over Sun Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Abraxis' claims arise under federal law; (b) Sun Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sun Ltd. 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 Sun Ltd. satisfies due process.

33. This Court also has personal jurisdiction over Sun Inc. and Sun Ltd. because they have purposefully availed themselves of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Inc. and Sun Ltd. regularly and continuously transact business within New Jersey, directly or indirectly, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. For example, www.sunpharma.com states that "[o]ur US headquarters are in Cranbury, New Jersey," that "we have distribution and customer service teams at multiple locations across the country," and that "Sun Pharma's latest acquisition of a majority interest in Ranbaxy Laboratories Limited (Ranbaxy) and its Ohm Laboratories facilities

in the [sic] New Jersey makes it the largest Indian pharma company in the US market . . . ." http://www.sunpharma.com/usa (last visited August 1, 2019).

34. On information and belief, Sun Advanced, Sun. Inc., and Sun Ltd. will work in concert with one another, and/or other affiliates or subsidiaries, towards regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of pharmaceutical products, including Sun's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

35. The State of New Jersey has an interest in providing a forum to resolve disputes, like this one, that involve the unlawful marketing of infringing generic drug products in the State of New Jersey and harm to companies, like Abraxis, that have a principal places of business in, and are doing business in, the State of New Jersey.

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

The Patents-in-Suit

37. On July 20, 2010, the United States Patent and Trademark Office ("PTO") 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.

38. On October 26, 2010, the PTO 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.

39. On April, 12, 2011, the PTO 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.

40. On October 11, 2011, the PTO 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.

41. On March 20, 2012, the PTO 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.

42. On September 18, 2012, the PTO 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.

43. On November 20, 2012, the PTO 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.

44. On October 7, 2014, the PTO duly and lawfully issued the ’260 patent, titled, “Formulations of Pharmacological Agents, Methods for the Preparation Thereof and Methods for the Use Thereof.” The ’260 patent is assigned to Abraxis. A copy of the ’260 patent is attached hereto as Exhibit H.

45. On August 11, 2015, the PTO 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 I.

46. On July 19, 2016, the PTO 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 J.

47. On December 6, 2016, the PTO 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 K.

48. On March 21, 2017, the PTO 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 L.

The Abraxane® Drug Product

49. Abraxis, a wholly-owned subsidiary of Celgene Corporation, holds an approved 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®.

50. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") in connection with Abraxane®.

51. 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.

Acts Giving Rise to This Suit

52. Pursuant to Section 505 of the FFDCA, Sun's NDA seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Sun's Proposed Product, before the patents-in-suit expire.

53. On information and belief, in connection with the filing of Sun's NDA as described in the preceding paragraph, Sun sent a written certification to the FDA pursuant to 21 U.S.C. § 355(b)(2)(A)(vii)(IV) ("Sun's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Sun's NDA.

54. No earlier than June 27, 2019, Abraxis received written notice of Sun Paragraph IV Certification ("Sun's Notice Letter") pursuant to 21 U.S.C. § 355(b)(2)(A). Sun's Notice Letter alleged that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Sun's NDA. Sun's Notice Letter also informed Abraxis that Sun seeks approval to market Sun's Proposed Product before the patents-in-suit expire.

Count I: Infringement of the '891 Patent

55. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

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

57. There is a justiciable controversy between the parties hereto as to the infringement of the ’891 patent.

58. Unless enjoined by this Court, upon FDA approval of Sun’s NDA, Sun 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 Sun’s Proposed Product in the United States.

59. Unless enjoined by this Court, upon FDA approval of Sun’s NDA, Sun will induce infringement 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 Sun’s Proposed Product in the United States. On information and belief, upon FDA approval of Sun’s NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the ’891 patent and knowledge that its acts are encouraging infringement.

60. Unless enjoined by this Court, upon FDA approval of Sun’s NDA, Sun 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 Sun’s Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun’s Proposed 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 Sun’s Proposed Product.

61. Abraxis will be substantially and irreparably damaged and harmed if Sun’s infringement of the ’891 patent is not enjoined.

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

63. 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

64. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

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

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

67. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States.

68. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '788 patent and knowledge that its acts are encouraging infringement.

69. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed 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 Sun's Proposed Product.

70. Abraxis will be substantially and irreparably damaged and harmed if Sun's infringement of the '788 patent is not enjoined.

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

72. 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

73. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

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

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

76. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States.

77. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '536 patent and knowledge that its acts are encouraging infringement.

78. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's

Proposed 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 Sun's Proposed Product.

79. Abraxis will be substantially and irreparably damaged and harmed if Sun's infringement of the '536 patent is not enjoined.

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

81. 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

82. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

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

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

85. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States.

86. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '375 patent and knowledge that its acts are encouraging infringement.

87. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed 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 Sun's Proposed Product.

88. Abraxis will be substantially and irreparably damaged and harmed if Sun's infringement of the '375 patent is not enjoined.

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

90. 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

91. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

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

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

94. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States.

95. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '229 patent and knowledge that its acts are encouraging infringement.

96. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed 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 Sun's Proposed Product.

97. Abraxis will be substantially and irreparably damaged and harmed if Sun's infringement of the '229 patent is not enjoined.

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

99. 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

100. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

101. Sun's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the expiration of the '348 patent, constitutes infringement of one or more 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 '348 patent.

103. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States.

104. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '348 patent and knowledge that its acts are encouraging infringement.

105. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed 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 Sun's Proposed Product.

106. Abraxis will be substantially and irreparably damaged and harmed if Sun's infringement of the '348 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 VII: Infringement of the '156 Patent

109. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

110. Sun's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed

Product, prior to the expiration of the '156 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

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

112. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States.

113. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '156 patent and knowledge that its acts are encouraging infringement.

114. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed 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 Sun's Proposed Product.

115. Abraxis will be substantially and irreparably damaged and harmed if Sun's infringement of the '156 patent is not enjoined.

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

117. 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 '260 Patent

118. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

119. Sun's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed Product, prior to the expiration of the '260 patent, constitutes infringement of the one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

120. There is a justiciable controversy between the parties hereto as to the infringement of the '260 patent.

121. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun will infringe one or more claims of the '260 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States.

122. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun will induce infringement of one or more claims of the '260 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '260 patent and knowledge that its acts are encouraging infringement.

123. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun will contributorily infringe one or more claims of the '260 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Sun's Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's

Proposed Product is especially adapted for a use that infringes one or more claims of the ’260 patent and that there is no substantial non-infringing use for Sun’s Proposed Product.

124. Abraxis will be substantially and irreparably damaged and harmed if Sun’s infringement of the ’260 patent is not enjoined.

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

126. 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 ’543 Patent

127. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

128. Sun’s submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun’s Proposed Product, prior to the expiration of the ’543 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

129. There is a justiciable controversy between the parties hereto as to the infringement of the ’543 patent.

130. Unless enjoined by this Court, upon FDA approval of Sun’s NDA, Sun 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 Sun’s Proposed Product in the United States.

131. Unless enjoined by this Court, upon FDA approval of Sun’s NDA, Sun 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 Sun’s Proposed Product in the United States. On information and belief, upon FDA approval of Sun’s NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the ’543 patent and knowledge that its acts are encouraging infringement.

132. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed 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 Sun's Proposed Product.

133. Abraxis will be substantially and irreparably damaged and harmed if Sun's infringement of the '543 patent is not enjoined.

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

135. 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 '318 Patent

136. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

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

138. There is a justiciable controversy between the parties hereto as to the infringement of the '318 patent.

139. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States.

140. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '318 patent and knowledge that its acts are encouraging infringement.

141. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed 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 Sun's Proposed Product.

142. Abraxis will be substantially and irreparably damaged and harmed if Sun's infringement of the '318 patent is not enjoined.

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

144. 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 '046 Patent

145. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

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

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

148. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States.

149. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, upon FDA approval of Sun's NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the '046 patent and knowledge that its acts are encouraging infringement.

150. Unless enjoined by this Court, upon FDA approval of Sun's NDA, Sun 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 Sun's Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun's Proposed 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 Sun's Proposed Product.

151. Abraxis will be substantially and irreparably damaged and harmed if Sun's infringement of the '046 patent is not enjoined.

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

153. 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 XII: Infringement of the '409 Patent

154. Abraxis repeats and realleges the foregoing allegations as if fully set forth herein.

155. Sun's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed

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

156. There is a justiciable controversy between the parties hereto as to the infringement of the ’409 patent.

157. Unless enjoined by this Court, upon FDA approval of Sun’s NDA, Sun 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 Sun’s Proposed Product in the United States.

158. Unless enjoined by this Court, upon FDA approval of Sun’s NDA, Sun 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 Sun’s Proposed Product in the United States. On information and belief, upon FDA approval of Sun’s NDA, Sun will intentionally encourage acts of direct infringement with knowledge of the ’409 patent and knowledge that its acts are encouraging infringement.

159. Unless enjoined by this Court, upon FDA approval of Sun’s NDA, Sun 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 Sun’s Proposed Product in the United States. On information and belief, Sun has had and continues to have knowledge that Sun’s Proposed 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 Sun’s Proposed Product.

160. Abraxis will be substantially and irreparably damaged and harmed if Sun’s infringement of the ’409 patent is not enjoined.

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

162. 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, Abraxis respectfully requests the following relief:

(A) A Judgment be entered that Sun has infringed the patents-in-suit by submitting NDA No. 211599;

(B) A Judgment be entered that Sun has infringed, and that Sun's making, using, offering to sell, selling, or importing Sun's Proposed Product will infringe one or more claims of the patents-in-suit;

(C) An Order be entered that the effective date of FDA approval of NDA No. 211599 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 be issued enjoining Sun 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 Sun's Proposed 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 be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Sun, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as 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 Abraxis is or becomes entitled;

(F) A Judgment be entered that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Sun's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Sun has committed any acts with respect to the compositions and methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment be entered awarding Abraxis damages for such acts;

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

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

(J) A Judgment be entered awarding Abraxis its costs and expenses incurred in this action; and

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

Dated: August 8, 2019

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that the matter in controversy involves the same plaintiff, same drug product, and some of the same patents (United States Patent Nos. 7,820,788, 7,923,536, 8,138,229, and 8,853,260) that were at issue in the matters captioned *Abraxis Bioscience, LLC, et al. v. Actavis LLC,* Civil Action No. 16-1925 (JMV)(MF) and *Abraxis Bioscience, LLC, et al. v. Cipla Ltd.*, Civil Action No. 16-9074 (JMV)(MF). These cases were filed on April 6, 2016 and December 7, 2016, respectively, and dismissed by the Hon. John Michael Vazquez, U.S.D.J. on January 26, 2018 and October 9, 2018, respectively.

The matter in controversy also involves the same plaintiff, same drug product, and same patents that are currently at issue in the matter captioned *Abraxis Bioscience, LLC v. HBT Labs., Inc.,* Civil Action No. 18-2019 (RGA), which is currently pending in the District of Delaware.

To the best of my knowledge, this matter is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: August 8, 2019

By: s/ Charles M. Lizza

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