IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ELAN PHARMA INTERNATIONAL LIMITED, Plaintiff, v. ABRAXIS BIOSCIENCE, INC., Defendant.	)	Civil Action No. 06-438-GMS **Redacted Version - Publicly Filed**

AMENDED ANSWER TO COMPLAINT AND COUNTERCLAIMS BY DEFENDANT ABRAXIS BIOSCIENCE, INC.

DEMAND FOR JURY TRIAL

Defendant Abraxis BioScience, Inc. ("Abraxis"), by its attorneys, hereby serves its First Amended Answer to Plaintiff Elan Pharma International Limited's ("Elan") Complaint for patent infringement dated July 19, 2006 as follows:

THE PARTIES

1. Abraxis is without sufficient information to admit or deny the allegations of Paragraph 1 and on that basis denies each and every allegation in Paragraph 1 of the Complaint.

2. Abraxis admits that it is a corporation organized and existing under the laws of the State of Delaware. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 2 of the Complaint.

JURISDICTION AND VENUE

3. Abraxis admits that claims for infringement of a United States patent are governed by the patent laws of the United States, Title 35 of the United States Code. Abraxis

admits that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) over patent infringement actions brought pursuant to the patent laws of the United States, Title 35 of the United States Code. Abraxis denies that Elan has a cause of action against Abraxis for patent infringement. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 3 of the Complaint.

4. Abraxis admits that this Court has personal jurisdiction over Abraxis. Abraxis denies that it has committed acts of patent infringement in this or any other judicial district. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 4 of the Complaint.

5. Abraxis denies each and every allegation of Paragraph 5 of the Complaint.

6. Abraxis admits that venue is proper in this judicial district. Abraxis denies that it has engaged in any infringing activity in this or any other judicial district. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 6 of the Complaint.

FACTUAL BACKGROUND

7. Abraxis admits that United States Patent No. 5,399,363 ("the '363 patent") is entitled "Surface Modified Anticancer Nanoparticles". Abraxis admits that the face of the '363 patent lists Gary G. Liversidge, Elaine Liversidge, and Pramod P. Sarpotdar as inventors. Abraxis admits that the face of the '363 patent lists March 21, 1995 as the date of patent. Abraxis admits that Exhibit A to the Complaint is a document that on its face purports to be the '363 patent. Abraxis is without sufficient information to admit or deny the allegation of Paragraph 7 of the Complaint that "Elan is the owner by assignment of all right, title, and interest in and to" the '363 patent and on that basis denies that allegation. Abraxis denies that the '363 patent was duly and legally issued. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 7 of the Complaint.

8. Abraxis admits that United States Patent No. 5,834,025 ("the '025 patent") is entitled "Reduction Of Intravenously Administered Nanoparticulate-Formulation-Induced Adverse Physiological Reactions". Abraxis admits that the face of the '025 patent lists Lawrence de Garavilla, Elaine M. Liversidge, and Gary G. Liversidge as inventors. Abraxis admits that the face of the '025 patent lists November 10, 1998 as the date of patent. Abraxis admits that Exhibit B to the Complaint is a document that on its face purports to be the '025 patent. Abraxis is without sufficient information to admit or deny the allegation of Paragraph 8 of the Complaint that "Elan is the owner by assignment of all right, title, and interest in and to" the '025 patent and on that basis denies that allegation. Abraxis denies that the '025 patent was duly and legally issued. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 8 of the Complaint.

9. Abraxis admits that the United States Food and Drug Administration ("FDA") approved the sale of Abraxane™ in the United States for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy, where prior therapy included an anthracycline unless clinically contraindicated. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 9 of the Complaint.

10. Abraxis admits that Abraxane® is a particulate formulation of paclitaxel. Abraxis admits that Abraxane® is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant therapy, where prior therapy included an anthracycline unless clinically contraindicated. Abraxis admits that Abraxane® "is intravenously administered to patients for the treatment of breast cancer." Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 10 of the Complaint.

11. Abraxis admits that Abraxane® is a product offered for sale or sold by Abraxis within this judicial district. Abraxis admits that it has title to doses of Abraxane® within this

judicial district before delivery to purchasers within this judicial district. Abraxis denies that Abraxane® is a product manufactured by Abraxis within this judicial district. Except as expressly admitted, Abraxis denies each and every allegation in Paragraph 11 of the Complaint.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 5,399,363

12. Abraxis incorporates by reference its answers in paragraphs 1-11 above. Abraxis further denies any implication or allegation purportedly contained in the heading immediately preceding Paragraph 12 of the Complaint.

13. Abraxis denies each and every allegation in Paragraph 13 of the Complaint.

14. Abraxis denies each and every allegation in Paragraph 14 of the Complaint.

15. Abraxis denies each and every allegation in Paragraph 15 of the Complaint.

16. Abraxis denies each and every allegation in Paragraph 16 of the Complaint.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 5,834,025

17. Abraxis incorporates by reference its answers in paragraphs 1-16 above. Abraxis further denies any implication or allegation purportedly contained in the heading immediately preceding Paragraph 17 of the Complaint.

18. Abraxis denies each and every allegation in Paragraph 18 of the Complaint.

19. Abraxis denies each and every allegation in Paragraph 19 of the Complaint.

20. Abraxis denies each and every allegation in Paragraph 20 of the Complaint.

21. Abraxis denies each and every allegation in Paragraph 21 of the Complaint.

ADDITIONAL DEFENSES

22. For its further and separate defenses to the allegations in the Complaint, and without assuming any burden of proof it would not otherwise bear under applicable law, Abraxis pleads as follows:

FIRST ADDITIONAL DEFENSE
('363 patent — Noninfringement)

23. Abraxis does not and has not infringed, either directly or indirectly, any valid claim of the '363 patent.

SECOND ADDITIONAL DEFENSE
('025 patent — Noninfringement)

24. Abraxis does not and has not infringed, either directly or indirectly, any valid claim of the '025 patent.

THIRD ADDITIONAL DEFENSE
('363 Patent — Invalidity)

25. The '363 patent is invalid and void for failure to comply with one or more of the provisions of Part II of Title 35 of the United States Code, including without limitation sections 102, 103, and/or 112.

FOURTH ADDITIONAL DEFENSE
('025 Patent — Invalidity)

26. The '025 patent is invalid and void for failure to comply with one or more of the provisions of Part II of Title 35 of the United States Code, including without limitation sections 102, 103, and/or 112.

FIFTH ADDITIONAL DEFENSE
(Prosecution History Estoppel)

27. Elan is barred by the doctrine of prosecution history estoppel from contending that any claim of the '363 or '025 patents covers any product manufactured, used, sold, or offered for sale by Abraxis.

SIXTH ADDITIONAL DEFENSE
('363 Patent — Inequitable Conduct)

28. The '363 patent is unenforceable due to inequitable conduct in its prosecution before the United States Patent and Trademark Office (the "PTO"), as more particularly alleged below.

29. The application that led to the '363 patent, U.S. Patent Application No. 07/908,125 ("'363 Application"), was filed on July 1, 1992. The PTO issued the '363 patent on March 21, 1995. The named inventors of the '363 patent are Gary G. Liversidge ("Gary Liversidge"), Elaine Liversidge ("Elaine Liversidge"), and Pramod P. Sarpotdar ("Sarpotdar") (collectively, the "'363 Applicants"). The attorneys who prosecuted the '363 patent included Arthur H. Rosenstein ("Rosenstein") and William J. Davis ("Davis").

30. The '363 Applicants filed the '363 Application as a continuation-in-part of U.S. Patent No. 5,145,684 (the '684 patent).

31. The application that led to the '684 patent, U.S. Patent Application No. 07/647,105 (the "'684 Application"), was filed on January 25, 1991. The named inventors of the '684 patent are Gary Liversidge, Kenneth C. Cundy ("Cundy"), John F. Bishop ("Bishop") and David A. Czekai ("Czekai"). The attorneys who prosecuted the '684 Application included Rosenstein and Davis.

32. The inventors, the attorneys who prepared or prosecuted the application, and others involved in the prosecution of a patent application are required to disclose to the PTO information available to them which is material to the patentability of an application.

Failure to Disclose the Domb Reference

33. Rosenstein and Davis had actual knowledge of material, undisclosed prior art during pendency of the '363 Application. They violated their duty of candor and good faith in dealing with the PTO by failing to bring the substance of this prior art to the Examiner's attention during prosecution of the '363 Application. The withheld information was highly

material. On information and belief, this information was withheld with the intent to deceive the PTO.

34. Rosenstein and Davis's failure to disclose U.S. Patent No. 5,188,837 (the "Domb Reference") to the PTO during prosecution of the '363 Application constitutes inequitable conduct which renders the '363 patent unenforceable, as shown below:

35. As the attorneys who prosecuted the '363 Application, Rosenstein and Davis were required to disclose to the PTO information available to them that was material to the patentability of the claims of the '363 Application.

36. As demonstrated by the prosecution history of other patents Rosenstein and Davis were prosecuting during pendency of the '363 Application, Rosenstein and Davis were aware of the Domb Reference. Rosenstein and Davis prosecuted U.S. Patent Application No. 08/240,309 (the "'309 Application"), filed May 10, 1994. That same day – well before the '363 patent issued – Davis submitted an information disclosure statement to the PTO in connection with prosecuting the '309 Application listing the Domb Reference. Davis also prosecuted U.S. Patent Application No. 07/989,281, filed December 11, 1992 (the "'281 Application"). During the prosecution of the '281 Application, the PTO cited the Domb Reference on April 14, 1993 – also well before the '363 patent issued.

37. The Domb reference was material to patentability of the '363 Application because the combination of Haynes U.S. Patent No. 5,091,188 ("Haynes") and the Domb reference makes claim 1 of the '363 patent obvious. Haynes discloses particles meeting all the limitations of claim 1 except for explicit disclosure of a chemotherapeutic agent. The Domb reference discloses particles of a solid, water-insoluble chemotherapeutic agent and a non-crosslinked phospholipid coating on the surface of the drug, with particle sizes of less than 1000 nm.

38. The Domb Reference was not cumulative to other references that the PTO considered during pendency of the '363 Application.

39. Despite being aware of the highly material Domb Reference, Rosenstein and Davis did not disclose the Domb Reference to the PTO during the prosecution of the '363 Application. Rosenstein and Davis violated their duty of candor and good faith in dealing with the PTO by failing to disclose the Domb Reference. Upon information and belief, the Applicants, Rosenstein and Davis intended to deceive the PTO by failing to disclose the Domb Reference.

Misstatements and Withheld Information Material to Enablement

40. As more particularly alleged below, during prosecution of the '363 Application Davis and the '363 Applicants further breached their duty of candor to the PTO with respect to that application by withholding and misstating information material to the enablement requirement of 35 U.S.C. Section 112.

41. Specifically, the '363 Applicants knew that many combinations of drug and surface modifier covered by the claims of the '363 patent could not form usable nanoparticles. Davis and the '363 Applicants withheld this material information and made misleading arguments to the PTO Examiner suggesting enablement that did not exist. On information and belief, Davis and the '363 Applicants made these omissions and misstatements with the intent to deceive the PTO.

42. Claim 1 of the '363 patent, from which all other claims depend, requires particles consisting in part of a "surface modifier." Column 3 of the '363 patent specification states that "[s]uitable surface modifiers can preferably be selected from known organic and inorganic pharmaceutical excipients", which include "various polymers, low molecular weight oligomers, natural products and surfactants."

43. Claim 1 of the '363 patent requires "an average effective particle size of less than 1000 nm." Claims 2 and 3 of the '363 patent require "an average effective particle size of less than" 400 nm, and 300 nm, respectively.

44. Page 12 of the '684 Application, submitted by Davis to the PTO on January 25, 1991, states "[a]s indicated by the following examples, not every combination of surface modifier and drug substance provides the desired results. Consequently, the applicants have developed a simple screening process whereby compatible surface modifiers and drug substances can be selected which provide stable dispersions of the desired particles." This statement appears in Column 7 of the '684 patent.

53. Davis and the '363 Applicants omitted every example in the '684 Application from the '363 Application.

54. Davis and the '363 Applicants also deliberately omitted from the '363 Application the statement in the '684 Application and '684 patent that "[a]s indicated by the following examples, not every combination of surface modifier and drug substance provides the desired results."

59. In an office action mailed by the PTO Examiner on December 22, 1993, pending claims 1-6, 16, and 24-33 (issued Claims 1-17) were rejected in part under 35 U.S.C. section 112, first paragraph, for being enabling only as to four surface modifiers: polyvinylpyrrolidone, Pluronic F108, polyvinyl alcohol and gum acacia.

60. In response to the non-enablement rejection set forth in the December 22, 1993 Office Action, on June 22, 1994 Davis argued to the Examiner in part that "Applicants' specification teaches that a wide variety of surface modifiers are useful. Indeed, Applicants have shown that the invention can be practiced with a wide variety of surface modifiers. *In*

addition to the numerous surface modifiers exemplified in Applicants' specification and working examples, additional surface modifiers tested in varying amounts have been demonstrated to be useful. Moreover, Applicants' specification (page 10, line 24 – page 12, line 13) readily enables one skilled in the art to select surface modifiers for any poorly soluble medicament. *The evidence demonstrates conclusively that the instant invention can be practiced with a wide variety of surface modifiers.* Thus, one skilled in the art is readily able to practice the claimed invention, particularly in view of the teaching in Applicants' specification. Accordingly, withdrawal of the rejection under §112, first paragraph, is respectfully requested." (June 22, 1994 Amendment (emphasis added).)

61. At the time these false and misleading statements were made, on information and belief it was known to the '363 Applicants and Davis that tests demonstrated many surface modifier and medicament combinations did not work.

This highly material information was withheld during the examination of the '363 Application. On information and belief, the foregoing information was withheld, and the misleading and false statements were made, with the intent to deceive the PTO.

SEVENTH ADDITIONAL DEFENSE
('025 Patent — Inequitable Conduct)

62. The '025 patent is unenforceable due to inequitable conduct in its prosecution before the PTO, as more particularly alleged below.

63. The application that led to the '025 patent, U.S. Patent Application No. 08/696754 ("'025 Application"), was filed on August 14, 1996. The PTO issued the '025 patent on November 10, 1998. The named inventors of the '025 patent are Gary G. Liversidge ("Gary Liversidge"), Elaine Liversidge ("Elaine Liversidge"), and Lawrence de Garavilla ("Garavilla") (collectively, the "'025 Applicants").

64. The '025 Applicants and their attorneys falsely stated to the Examiner during prosecution of the '025 Application that the infusion rate claimed in at least Claims 1-3 and 13-15 of the '025 patent was a patentably distinct feature resulting in dramatic and unexpected results. At the time these statements were made, at least Gary Liversidge and Garavilla knew them to be false.

65. At least Gary Liversidge and Garavilla failed to disclose to the Examiner that the hemodynamic effects the Applicants reported at particular infusion rates in the '025 patent were "species-specific," in that the effects they observed were found only in experiments with dogs, not in other mammalian species such as rabbits.

66. Claims 1-3 and 13-15 of the '025 patent are generally directed to a method of administering a nanoparticulate drug composition at an infusion rate not exceeding 10mg/min, wherein said drug composition comprises a crystalline organic drug substance. Although the experiments reported in the '025 patent involve hemodynamic effects observed in dogs under certain experimental conditions, Claims 1-3 and 13-15 of the '025 patent encompass use of the claimed methods in all mammalian species.

67. On September 30, 1997, the Examiner of the '025 Application mailed an office action that rejected all pending claims as obvious in view of U.S. Patent No. 5,565,188.

68. On February 4, 1998, in successfully overcoming that rejection, the '025 Applicants argued that the infusion rate specified in the claims was not taught in the prior art. The '025 Applicants further argued that "the use of an infusion rate of less than 10 mg/ml <sic> is not merely an optimization of an administration variable, as the use of this specific infusion rate results in dramatic, unexpected results, *i.e.*, the reduction or elimination of hemodynamic side effects."

69. These statements were highly material to the Examiner's decision to allow the pending claims to issue.

70. At the time these statements were made, at least Gary Liversidge and Garavilla knew them to be false. On information and belief, Gary Liversidge and Garavilla made these statements to the PTO with the intent to deceive the PTO, in violation of their duty of candor.

71. Gary Liversidge is a named inventor of U.S. Patent No. 5,318,767 (the "'767 patent"), which issued June 7, 1994.

72. The '025 patent teaches that the claimed "crystalline organic drug substance" may be WIN 8883. (*See* '025 patent, column 4.)

73. Example 1 of the '767 patent states a nanoparticulate suspension of WIN 8883 was "injected via syringe into the ear vein of approximately 3kg rabbits...." Dose was varied from 30mg/kg to 300mg/kg.

74. No hemodynamic effects were reported from these experiments, and the example noted follow-up studies at 7 and 22 days after the initial administration.

75. An injection of 900mg of a nanoparticulate suspension of WIN 8883 "via syringe" far exceeds the maximum infusion rate of 10mg/min the '025 Applicants argued was a patentably distinguishing feature of the claimed invention. For a 900mg infusion to meet the infusion rate limitation of Claims 1-3 and 13-15 of the '025 patent, the infusion time must equal or exceed 90 minutes.

80. During prosecution of the '025 patent, neither Gary Liversidge, Garavilla, nor the other Applicants cited the '767 patent . They also did not disclose to the PTO that the 10 mg/min infusion rate did not apply to species other than dogs. For example, they did not disclose that occurrence of hemodynamic effects in dogs could not be used to predict the effects in other mammalian species, such as rabbits and humans, at the same infusion rates. Instead, they falsely and misleadingly claimed that the specific infusion rate they derived from experiments with dogs was a patentably distinguishing feature of the claimed invention for all mammalian species.

EIGHTH ADDITIONAL DEFENSE
('363 Patent — Reverse Doctrine of Equivalents)

81. Under the reverse doctrine of equivalents, Abraxis does not and has not infringed, either directly or indirectly, any valid claim of the '363 patent.

NINTH ADDITIONAL DEFENSE
('025 Patent — Reverse Doctrine of Equivalents)

82. Under the reverse doctrine of equivalents, Abraxis does not and has not infringed, either directly or indirectly, any valid claim of the '025 patent.

TENTH ADDITIONAL DEFENSE
('363 and '025 Patents — Patent Misuse)

83. One or both of the '363 and '025 patents are unenforceable due to Plaintiff's misuse and attempted misuse of the patents.

84. Elan brought this suit in bad faith and for an improper purpose, knowing the '363 and/or '025 patents to be invalid, unenforceable, and/or non-infringed. For example, at the time this suit was filed, Elan had no good faith belief that the paclitaxel in Abraxane is crystalline, a requirement of every asserted patent claim.

85. Elan's attempt to construe the '363 and/or '025 patents to cover Abraxane is an impermissible attempt to expand the physical scope of its patents. On information and belief, Elan brought this suit to cause anticompetitive effects.

ELEVENTH ADDITIONAL DEFENSE
('363 and '025 Patents — Unclean Hands)

86. The '363 and/or '025 patents are unenforceable due to Plaintiff's unclean hands.

TWELFTH ADDITIONAL DEFENSE
('363 Patent — Obviousness-Type Double Patenting)

87. One or more claims of the '363 patent are invalid for obviousness-type double patenting in view of the '684 patent.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

THE PARTIES

88. Counterclaim-Plaintiff Abraxis BioScience, Inc. ("Abraxis") is a Delaware corporation with its principal place of business at 11755 Wilshire Blvd., 20th Floor, Los Angeles, CA 90025.

89. According to the Complaint it filed in this action, Counterclaim-Defendant Elan Pharma International Limited ("Elan") is a company organized and existing under the laws of Ireland, having a business address at Monksland, Athlone, Co. Westmeath, Ireland.

90. This Court has jurisdiction of these Counterclaims for declaratory relief under the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, under the laws of the United States concerning actions relating to patents, 28 U.S.C. § 1338(a), and under 28 U.S.C. § 1331.

91. As set forth in the Complaint and in the Answer to which these Counterclaims are appended, a justiciable controversy has arisen and exists between Counterclaim-Plaintiff and Counterclaim-Defendant concerning the validity, scope and enforceability of the '363 and '025 patents and Abraxis's liability for alleged infringement thereof. Venue properly lies in this judicial district by virtue of Counterclaim-Defendant having filed its Complaint therein.

COUNT I: NONINFRINGEMENT OF THE '363 AND '025 PATENTS

92. Abraxis incorporates the allegations of paragraphs 1-91 as if fully set forth herein.

93. Elan has alleged and claimed that it owns all right title and interest in, and has standing to sue for infringement of, the '363 and '025 patents.

94. Elan has alleged and claimed that Abraxis infringes the '363 and '025 patents.

95. Abraxis has not and does not infringe, either directly or indirectly, any valid claim of the '363 and '025 patents.

96. A declaration of the parties' respective rights is proper and appropriate.

COUNT II: INVALIDITY OF THE '363 AND '025 PATENTS

97. Abraxis incorporates the allegations of paragraphs 1-96 as if fully set forth herein.

98. Elan has alleged and claimed that the '363 and '025 patents were duly and legally issued.

99. On information and belief, one or more claims of the '363 and '025 patents are invalid and void for failure to comply with one or more of the provisions of Part II of Title 35 of the United States Code, including without limitation sections 102, 103, and/or 112. In addition, one or more claims of the '363 patent are invalid for obviousness-type double patenting in view of the '684 patent.

100. A declaration of the parties' respective rights is proper and appropriate.

COUNT III: UNENFORCEABILITY OF THE '363 AND '025 PATENTS

101. Abraxis incorporates the allegations of paragraphs 1-100 as if fully set forth herein.

102. The actions, schemes, conduct, and specific intent alleged above constitute patent misuse and/or unclean hands for which equitable principles require that the '363 patent and/or '025 patent be declared unenforceable against Abraxis.

103. The actions, schemes, conduct, and intent to deceive the PTO in connection with the prosecution of the '363 patent and '025 patent alleged above constitute inequitable conduct for which equitable principles require that these patents be declared unenforceable against any party.

PRAYER FOR RELIEF

WHEREFORE, Abraxis asks this Court to enter judgment against Elan and in Abraxis's favor on all claims in the Complaint, dismissing the Complaint with prejudice, and further:

A. that the Court declare United States Patent No. 5,399,363 to be invalid, void, unenforceable, and/or not infringed by Abraxis;

B. that the Court declare United States Patent No. 5,834,025 to be invalid, void, unenforceable, and/or not infringed by Abraxis;

C. that the Court declare this to be an exceptional case under 35 U.S.C. § 285 and award Abraxis its costs and reasonable attorneys' fees; and

D. that the Court award Abraxis such other relief as it may deem appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b) and Local Rule 38.1, Abraxis hereby demands a jury trial for all issues in this case that are properly subject to a jury trial.

Dated: December 5, 2007

YOUNG CONAWAY STARGATT & TAYLOR, LLP

By: /s/ *Josy W. Ingersoll*

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CERTIFICATE OF SERVICE

I, Jeffrey T. Castellano, Esquire, hereby certify that on December 6, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on December 6, 2007**,** I caused a true and correct copy of the foregoing document to be served by e-mail on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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EXHIBITS 1-3

REDACTED IN THEIR ENTIRETY