UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ELAN PHARMA INTERNATIONAL LIMITED, Plaintiff, v. ABRAXIS BIOSCIENCE, INC., Defendant.	C.A. No. 06-438-GMS

[PROPOSED] FINDINGS OF FACT AND CONCLUSIONS OF LAW REGARDING INEQUITABLE CONDUCT

OF COUNSEL:

Michael A. Jacobs
MORRISON & FOERSTER, LLP
425 Market Street
San Francisco, CA 94105-2482
(415) 268-7000

Emily A. Evans
Eric S. Walters
Erik J. Olson
Paul F. Coyne
Diana B. Kruze
MORRISON & FOERSTER, LLP
755 Page Mill Road
Palo Alto, CA 94304-1018
(650) 813-5600

Anders T. Aannestad
MORRISON & FOERSTER LLP
12531 High Bluff Drive
San Diego, California 92130
(858) 720-5100

YOUNG CONAWAY STARGATT & TAYLOR, LLP
Josy W. Ingersoll (#1088)
Elena C. Norman (#4780)
Karen E. Keller (#4489)
Michele Sherretta Budicak (#4651)
Jeffrey T. Castellano (#4837)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19801
(302) 571-6600
jingersoll@ycst.com
enorman@ycst.com
kkeller@ycst.com
mbudicak@ycst.com
jcastellano@ycst.com

Attorneys for Defendant
ABRAXIS BIOSCIENCE, INC.

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I. PROPOSED FINDINGS OF FACT REGARDING INEQUITABLE CONDUCT

A. Background

1) The patents-in-suit are U.S. Pat. Nos. 5,399,363 (the "'363 patent") (JX081) and 5,834,025 (the "'025 patent") (DX015).

2) The '363 patent issued March 21, 1995. The application leading to the issuance of the '363 patent, U.S. Pat. Appl. No. 908,125 (the "'125 App."), was filed July 1, 1992. The '363 patent claims priority to U.S. Pat. Appl. No. 07/647,105 (the "'105 App."), which led to the issuance of U.S. Pat. No. 5,145,684 and was filed January 25, 1991. The '684 patent is incorporated by reference into the '363 patent. JX081 at 1:8-11 (A483).

3) The named inventors of the '363 patent are Gary G. Liversidge, Elaine Liversidge, and Pramod P. Sarpotdar.[1] The attorneys who prosecuted the '363 patent included Arthur H. Rosenstein and William J. Davis. The named inventors of the '684 patent are Gary Liversidge, Kenneth C. Cundy, John F. Bishop and David A. Czekai. The attorneys who prosecuted the '684 Application included Messrs. Rosenstein and Davis.

4) The '025 patent issued November 10, 1998. The application that led to the '025 patent, U.S. Pat. Appl. No. 08/696,754 (the "'754 App."), was filed on August 14, 1996.

5) The named inventors of the '025 patent are Gary G. Liversidge, Elaine Liversidge, and Lawrence de Garavilla.

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[1] For concision, the Court refers to the persons subject to the Rule 56 requirement of full disclosure collectively as "Elan."

B. Contamination

6) The '363 patent teaches making nanoparticles through wet milling techniques. JX081 at 5:31-7:4 (A485-6). The '363 patent describes mixing a surface modifier with a crystalline medicament in the presence of a liquid and then milling until small crystalline particles of drug and surface modifier are obtained. JX081 at 5:43-6:14 (A485). Several different grinding media are referenced in the '363 patent. JX081 at 6:15-31 (A485).

7) Elan represented to the PTO that "[t]he selection of material for the grinding media is not believed to be critical." JX081 at 6:21-23 (A485). Elan also represented that zirconium oxide and glass grinding media were believed to provide acceptable levels of contamination for drugs. JX081 at 6:23-27 (A485).

8) Zirconium oxide grinding media featured prominently in the remainder of the '363 patent, and is the only grinding media disclosed in the patent examples. *See, e.g.*, JX081 at 8:27-28, 9:34-43, 9:50-58, 9:66-67, 10:3-4 (A486-7).

9) Elan also represented in the '684 patent that the disclosed methods, including the recommended zirconium oxide grinding media, led to acceptable levels of contamination. JX082 at 2:63-66. The '684 patent emphasized freedom from contamination as an unexpected result: "[i]t was surprising that stable drug particles of such a small effective average particle size *and free of unacceptable contamination* could be prepared by the method of this invention." JX082 at 8:29-32 (emphasis added); *see also* JX082 at 2:62-66.

10) During prosecution, Elan repeatedly distinguished its supposedly uncontaminated particles from the "unacceptable contamination" it said resulted from prior art methods such as dry milling, polymerization and solvent precipitation. *See, e.g.,*

JX084, Amendment dated November 18, 1991 at 5-6; JX039 at 0275-276 (A156-7), Amendment dated September 15, 1993; JX039 at 0280 (A161), Rule 132 Declaration of Gary G. Liversidge ¶ 4, dated September 8, 1993.

11) As early as 1990, well before the '684 and '363 applications were filed, Elan internally expressed concern about contamination resulting from the wet milling techniques and grinding media disclosed in the '363 patent. One internal memorandum from the toxicology department stated, "I don't think the zirconium oxide or the zirconium oxide/zirconium silicate are acceptable because there is one report which suggests that zirconium accumulates in certain organs, such as the ovaries." DX243.

12) During a series of development retreats in 1993, while the '363 patent application was pending, Elan internally reported "unacceptable" and "undesirable" contamination using the zirconium and glass beads recommended in the '363 patent. DX607; DX238.

13) Myriad internal reports of high levels of contamination were sent to Elan's inventors both before and throughout the period when Elan was prosecuting the '363 patent. DX607; JX053; JX054; JX055; DX238; DX243. A 1993 Elan memorandum reported that toxicology had recommended the non-use of zirconium grinding media due to concerns about unsafe contamination. JX054 at ELANP033711.

14) Both Drs. Gary and Elaine Liversidge admitted knowing of internal reports regarding unacceptable levels of contamination using glass and zirconium oxide beads. Tr. 429:5-20; 431:7-9; 507:19-508:2; DX607 at ELANP0085236. Dr. Gary Liversidge was sent a 1993 memorandum highlighting problems due to contamination from glass grinding media. JX054 at ELANP033711.

15) Elan's internal documents demonstrate that the techniques disclosed in the '363 patent result in particles contaminated with unacceptable amounts of zirconium and other materials.

16) The "pre-cleaning" procedure disclosed in the patent is, by its own terms, for pre-cleaning media before milling; the procedure neither cleans contaminated particles nor prevents contamination resulting from fragments of grinding media chipping during the milling process. JX081 at 8:44-47 (A486); Tr. 1431:13-1432:6. Elan's internal documents showed that contamination problems continued after July 1992, by which time it had developed its method for pre-cleaning the zirconium beads. DX607; JX053; JX055; DX228; DX238; DX320. Development of the pre-cleaning procedure thus did not resolve the issue of contamination resulting from wet milling as described in the '363 patent.

17) The claims require that the nanoparticles be "essentially free of solvent and other contamina[tion]." J.I. 4.2.3(l)(1).

18) Documents and information regarding the unacceptable levels of contamination in compositions prepared using zirconium and glass grinding media were withheld from the PTO by Elan during prosecution of the application leading to the issuance of the '363 patent.

19) Elan's statements to the PTO that use of zirconium and glass grinding media resulted in particles having acceptable levels of contamination, that "[t]he selection of material for the grinding media is not believed to be critical," that use of the methods disclosed in the patent surprisingly resulted in "particles free from unacceptable contamination" were contradicted by documents and information available to the

applicants before and during prosecution of the application leading to the issuance of the '363 patent. Elan thus misrepresented to the PTO that the levels of contaminants from glass and zirconium grinding media were believed to be acceptable, failed to disclose test data and the internal conclusion that use of the methods disclosed in the '363 patent resulted in unacceptable contamination, and misleadingly represented to the PTO that the disclosed methods resulted in particles superior to those in the prior art because they were free from unacceptable contamination while the prior art particles were not.

20) A reasonable examiner would have considered it important that use of the methods taught by the '363 patent resulted in unacceptable levels of contamination during prosecution of the application leading to the issuance of the '363 patent because it would have, at a minimum, raised serious questions that: (1) those of skill in the art would not have been enabled to practice the claims and (2) the inventors were not in possession of the claimed particles, which must be essentially free of contaminants. Elan's documents and information regarding the unacceptable levels of contamination in compositions prepared using zirconium and glass grinding media establish the '363 patent more likely than not failed to meet the written description and enablement requirements of 35 U.S.C. § 112.

21) That use of the methods taught by the '363 patent resulted in particles with unacceptable contamination was not cumulative to other information before the examiner.

22) For these reasons, the documents and information regarding the unacceptable levels of contamination in compositions prepared using zirconium and glass

grinding media were highly material to the prosecution of the application leading to the issuance of the '363 patent.

23) Elan did not call Dr. Sarpotdar or its patent attorney Mr. William Davis to testify at trial regarding this withheld information.

24) Neither Dr. Gary Liversidge nor Dr. Elaine Liversidge proffered a reasonable explanation at trial for why they told the PTO that glass and zirconium oxide media were believed to result in acceptable levels of contamination. Dr. G. Liversidge acknowledged that the documentary evidence of contamination accurately reflected Elan's belief at the time and admitted that unacceptable contamination was a very serious concern. Tr. 428:16-21; 429:5-20; 431:7-9. Elan's explanations, that it later switched to different milling media (Tr. 507:19-508:6), received no complaints from the FDA about contamination, and had a pre-cleaning method (discussed above), do not provide a reasonable explanation for withholding this material information. That Elan was later forced to switch to new grinding media highlights the importance of the withheld information concerning the contamination resulting from the media disclosed in the patent. The pre-cleaning method is irrelevant to contamination for the reasons discussed above. Elan presented no evidence that any products subject to review by the FDA were made using the methods disclosed in the '363 patent, including the zirconium and glass media, as opposed to later-developed grinding media designed to reduce the contamination problem.

25) In light of the foregoing findings, the high level of materiality of the withheld information regarding contamination, and the inadequate explanations offered

for Elan's misrepresentations, the Court finds that Elan had the requisite intent required for inequitable conduct in the prosecution of the '363 patent.

C. Failed Surface Modifier/Medicament Combinations

26) The '363 patent claims crystalline nanoparticles representing a wide variety of drug/surface modifier combinations, and asserts that these particles can be used in injectable anti-cancer formulations to improve efficacy or reduce toxicity of the anti-cancer drug. *See, e.g.*, JX081 at claims 1, 3, 5, 10, and 11 (A489), Abstract (A482), 2:34-4:52 (A483-4); 8:6-16 (A486).

27) During prosecution of the '363 patent, the PTO rejected the broad claims sought by Elan; the examiner stated that the application supported only limited claims using several specific surface modifiers exemplified. JX039 at 0348-49 (A164-5). In response, Elan represented that the patent taught that a "wide variety of surface modifiers are useful," JX039 at 0428-29 (A168-9), and further argued that "[t]he 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 …." JX039 at 0428-29 (A168-9).

28) At the same time Elan was telling the PTO that skilled artisans could practice the claimed invention with a "wide variety" of surface modifiers, internally it experienced failures with myriad surface modifiers and, in 1993, acknowledged that only a small number of surface modifiers could obtain the requisite size, stability, efficacy and toxicity. DX238 at ELANP085240; DX607 at ELANP085230. By 1994, Elan still had not identified a surfactant of choice for use in parenteral (IV) products. DX190.

29) While reporting its successful experiments, Elan withheld from the PTO its numerous failures. For example, in the exact same set of experiments which underlie

the examples 1 through 4 in the patent, many combinations "failed to reduce the average particle size." JX081; DX193; Tr. 1404:1-1405:25. The only way Elan could stabilize piposulfan with any degree of consistency was to use specific combinations of two surfactants, Tween and Span. JX055 at ELANP083673 (despite extensive milling studies "a viable back-up stabilizer has not been identified"). Only this working combination was disclosed to the PTO. JX081 at 8:20-9:45 (A486-7). Tween and Span were not surfactants that had been proven usable in humans in injectable form. DX286; *see also* JX055.

30) Surface modifiers listed as "particularly preferred" in the patent resulted in unacceptable piposulfan formulations. JX081; DX193; Tr. 1404:1-1405:25. Even the slightest variations of the patent examples, such as "[c]ombinations of Tween 20/Span 20 and Tween 40/Span 40[,] failed." DX193.

31) Elan's statements to the PTO that the invention could be practiced with a wide variety of surface modifiers were contradicted by documents and information available to the applicants during prosecution of the application leading to the issuance of the '363 patent. Elan thus misrepresented to the PTO that the invention could be practiced with a wide variety of surface modifiers.

32) A reasonable examiner would have considered it important that many combinations of drugs and surface modifiers could not be used to prepare the claimed surface-modified nanoparticles because it would have, at a minimum, raised serious questions that: (1) those of skill in the art would not have been enabled to practice the full scope of the claims and (2) the inventors were not in possession of the claimed particles, which cover myriad combinations that were not workable using the methods taught by

the '363 patent. Thus, Elan's documents and information regarding the many failed surface modifier and medicament combinations establish the '363 patent more likely than not failed to meet the written description and enablement requirements of 35 U.S.C. § 112.

33) Elan's failed experiments and its conclusion that only a small number of surface modifiers could obtain the requisite size, stability, efficacy and toxicity were not cumulative to other information before the examiner.

34) For these reasons, the documents and information regarding the many failed surface modifier and medicament combinations were highly material to the prosecution of the application leading to the issuance of the '363 patent.

35) Elan did not call Dr. Sarpotdar or Mr. Davis to testify at trial regarding this withheld information.

36) Neither Dr. Gary Liversidge nor Dr. Elaine Liversidge proffered any explanation whatsoever at trial for why Elan misrepresented that the invention could be practiced with a wide variety of surface modifiers and why Elan withheld highly material documents regarding its many failed attempts from the PTO during prosecution of the application leading to the issuance of the '363 patent.

37) In light of the foregoing findings, the high level of materiality of the withheld information regarding failed attempts to make working embodiments of the claims, and the inadequate explanations offered for Elan's misrepresentations, the Court finds that Elan had the requisite intent required for inequitable conduct in the prosecution of the '363 patent.

D. Species-Specific Nature of Hemodynamic Effects

38) The '025 patent claims intravenous administration of crystalline nanoparticles, in all species of mammals, below a specified infusion rate of 10 mg/min, so long as that administration does not result in adverse hemodynamic effects. D.I. 271 at 3-4. Elan's claims were directed to infusions in mammals generally, and the specification stated that in addition to dogs, there existed other "sensitive" species, including humans. DX015 at 2:66-67.

39) In support of the '025 patent claims and its statements to the PTO, Elan had data from only one specific experiment injecting polystyrene beads into dogs. DX015 at 3:20-7:16.

40) To overcome an obviousness rejection during prosecution, Elan represented that the claimed infusion rate (10 mg/min) was a "**critical**" parameter to avoiding hemodynamic effects. JX040 at 0058, February 4, 1998 Amend. at 5 (emphasis in original). It did not inform the PTO that this parameter was "critical", if at all, only to dogs.

41) At the time Elan was prosecuting the application that led to the issuance of the '025 patent, Elan believed that hemodynamic effects were species-specific. DX248; DX259; DX291; DX297; DX301. Elan withheld the documents and information evidencing its belief that the hemodynamic effects relating to the intravenous administration of nanoparticulate formulations were species-specific.

42) Elan's statements to the PTO that the claimed infusion rate was a "critical parameter" and that there existed other "sensitive species," including humans, were contradicted by the documents and evidence that the parameter was "critical," if at all, only for dogs and that the effects reported in the '025 patent were species specific to dogs.

Thus, Elan misrepresented to the PTO that the claimed infusion rate was a critical parameter to avoiding hemodynamic effects and that humans and other species sensitive to the effects reported in the patent existed.

43) A reasonable examiner would have considered it important that hemodynamic effects relating to the intravenous administration of nanoparticulate formulations were species-specific and believed to occur only in dogs because it would have been important in considering whether the claim could be extended to species other than dogs, including humans, because: (1) those of skill in the art would not have been enabled to practice the full scope of the claims and (2) the inventors were not in possession of the claimed method of avoiding hemodynamic effects in all mammals. Elan's documents setting forth the species-specific nature of hemodynamic effects relating to the intravenous administration of nanoparticulate formulations establish that the '025 patent more likely than not failed to meet the written description and enablement requirements of 35 U.S.C. § 112.

44) The species-specific nature of the hemodynamic effects disclosed in the '025 patent was not cumulative of other information before the examiner.

45) For these reasons, documents and information evidencing Elan's knowledge that hemodynamic effects relating to the intravenous administration of nanoparticulate formulations were species-specific were highly material to the prosecution of the application that led to the issuance of the '025 patent.

46) Elan did not call Dr. de Garavilla to testify at trial regarding Elan's statements to the PTO or this withheld information.

47) Dr. Elaine Liversidge proffered that this information was reasonably withheld from the PTO because the non-canine experiments disclosed in these documents were not designed to measure hemodynamic effects. Tr. 496:15-499:7, 524:15-527:7, 527:11-529:4, 529:8-15, 530:1-4, 530:11-531:5. Elan offered no testimony or other evidence, however, to counter the documentary evidence that Elan believed the hemodynamic effects observed in dogs were species-specific at the time Elan prosecuted the application leading to the issuance of the '025 patent.

48) In light of the foregoing findings, the high level of materiality of the withheld information regarding the species-specific nature of the infusion rate, and the inadequate explanations offered for Elan's misrepresentations, the Court finds that Elan had the requisite intent required for inequitable conduct in the prosecution of the '025 patent.

II. PROPOSED CONCLUSIONS OF LAW REGARDING INEQUITABLE CONDUCT

49) A patent is unenforceable for inequitable conduct if one with a duty of candor and good faith withholds or misrepresents information, or submits false information that is material to the examination of the patent application, with an intent to deceive or mislead the patent office. *See, e.g.*, *Monsanto Co. v. Bayer BioScience N.V.*, 514 F.3d 1229, 1233-34 (Fed. Cir. 2008).

50) Information or statements are material if they contradict or refute a position the applicant took when making an argument to the examiner that the invention was patentable or when opposing an argument by the examiner that the patent was not patentable. *Cargill, Inc. v. Canbra Foods, Ltd*, 476 F.3d 1359, 1364 (Fed. Cir. 2007) (quoting 37 C.F.R. § 1.56(b)).

51) Information is material if there is "a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." *Cargill*, 476 F.3d at 1364 (quoting 37 C.F.R. §1.56(a) (1991)).

52) "Information concealed from the PTO may be material even though it would not invalidate the patent." *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007). Materiality is "not limited to matters reflected in the claims of a patent." *Hoffman-LaRoche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367 (Fed. Cir. 2003).

53) Information or statements are also material if they establish, alone or in combination with other information, that the invention sought to be patented more likely than not failed to satisfy one or more requirements for a patent. *Cargill*, 476 F.3d at 1364 (quoting 37 C.F.R. § 1.56(b)).

54) "[A]ffirmative misrepresentations … in contrast to misleading omissions, are more likely to be regarded as material." *Hoffman-LaRoche*, 323 F.3d at 1367 (misrepresentations about purity of material); *see also Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1583 (Fed.Cir. 1986) (submission of a false affidavit may be "inherently material").

55) Adverse testing data, as well as the applicant's interpretation of that data, can be material if directly relevant to an important issue of patentability. *Cargill*, 476 F.3d at 1365-66.

56) Information that is cumulative to other information before the examiner is not material. *Cargill*, 476 F.3d at 1364 (quoting 37 C.F.R. §1.56(a) (1991)).

57) "The intent element of inequitable conduct requires that 'the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.'" *Cargill*, 476 F.3d at 1364 (quoting *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1374-75 (Fed. Cir. 2006)).

58) Direct evidence of intent to deceive or mislead the patent office is rarely available, and deceptive intent can be inferred from the surrounding circumstances and evidence. *Cargill*, 476 F.3d at 1364. "[I]n the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006), *quoting Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005).

59) When the applicant has knowingly submitted false or misleading information, and the natural consequence of those acts would be to deceive the patent office, an inference of intent to deceive may be appropriate. *See Monsanto*, 514 F.3d at 1241.

60) Once it is demonstrated that information was withheld from the patent office, the Court must balance materiality and intent. In other words, where the materiality of the withheld information is high, the requisite showing of intent is lower, and vice versa. *Cargill*, 476 F.3d at 1364.

61) Abraxis has the burden of proving inequitable conduct by clear and convincing evidence.

62) Balancing materiality and intent, the Court finds Elan engaged in inequitable conduct during prosecution of the '363 patent by its misrepresentations and withholding of information regarding contamination from grinding media.

63) Balancing materiality and intent, the Court finds Elan engaged in inequitable conduct during prosecution of the '363 patent by its misrepresentations and withholding of information regarding myriad failed attempts to create working embodiments of the claims.

64) Balancing materiality and intent, the Court finds Elan engaged in inequitable conduct during prosecution of the '025 patent by its misrepresentations and withholding of information regarding the species-specific nature of the hemodynamic effects reported in the patent and the claimed infusion rate.

YOUNG CONWAY STARGATT & TAYLOR, LLP

Josy W. Ingersoll (#1088)
Elena C. Norman (#4780)
Karen E. Keller (#4489)
Michele Sherretta Budicak (#4651)
Jeffrey T. Castellano (#4837)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600

Attorneys for Defendant
Abraxis BioScience, Inc.

Of Counsel:

Michael A. Jacobs (Admitted *pro hac vice*)
Morrison & Foerster LLP
425 Market Street
San Francisco, California 94105-2482
(415) 268-7000

Emily A. Evans (Admitted *pro hac vice*)
Eric S. Walters (Admitted *pro hac vice*)
Erik J. Olson (Admitted *pro hac vice*)
Paul F. Coyne (Admitted *pro hac vice*)
Diana B. Kruze (Admitted *pro hac vice*)
Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
(650) 813-5600

Anders T. Aannestad (Admitted *pro hac vice*)
Morrison & Foerster LLP
12531 High Bluff Drive
San Diego, California 92130
(858) 720-5100

DATED: July 14, 2008

CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on July 14, 2008, 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:

Steven J. Balick, Esquire
ASHBY & GEDDES
500 Delaware Avenue, 8th Floor
Wilmington, DE 19801

I further certify that on July 14, 2008, I caused a true and correct copy of the foregoing document to be served by e-mail and hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

BY E-MAIL

Linda Glover, Esquire
Stephen Scheve, Esquire
BAKER BOTTS L.L.P.
One Shell Plaza
910 Louisiana Street
Houston, TX 77002-4995
steve.scheve@bakerbotts.com

Paul F. Fehlner, Esquire
BAKER BOTTS L.L.P.
30 Rockefeller Plaza
New York, NY 10112-4498
paul.fehlner@bakerbotts.com

William J. Sipio, Esquire
1375 Brentwood Road
Yardley, PA 19067
sipz25@aol.cm

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

Josy W. Ingersoll (No. 1088)
jingersoll@ycst.com
Elena C. Norman (No. 4780)
enorman@ycst.com
Karen E. Keller (No. 4489)
kkeller@ycst.com
Michele Sherretta Budicak (No. 4651)
mbudicak@ycst.com
Jeffrey T. Castellano (No. 4837)
jcastellano@ycst.com
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19899
(302) 571-6600

Attorneys for Defendant
ABRAXIS BIOSCIENCE, INC.