IN THE 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

PLAINTIFF ELAN PHARMA INTERNATIONAL LIMITED'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW IN SUPPORT OF THE JURY'S FINDINGS REGARDING INEQUITABLE CONDUCT

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I. PROPOSED FINDINGS OF FACT SUPPORTING THE JURY'S FINDINGS THAT ELAN DID NOT ENGAGE IN INEQUITABLE CONDUCT

1. The patents-in-suit are U.S. Patent No. 5,399,363 (the "'363 patent") (JX081) and U.S. Patent No. 5,834,025 (the "'025 patent") (DX015).

A. Background of the '363 Patent

2. The '363 patent issued March 21, 1995. The application leading to the issuance of the '363 patent, U.S. Patent Application No. 908,125 (the "'125 Application"), was filed on July 1, 1992. This patent claims priority to U.S. Patent Application No. 07/647, which led to the issuance of U.S. Patent No. 5,145,684 (the "'684 patent"). The '125 Application was filed on July 1, 1992.

3. The named inventors of the '363 patent are Gary G. Liversidge, Elaine Liversidge, and Pramod P. Sarpotdar. (JX081.) The attorneys who prosecuted the '363 patent are Arthur H. Rosenstein and William J. Davis. (JX039.)

4. The '684 patent is incorporated by reference into the '363 patent. The named inventors of the '684 patent are Gary G. Liversidge, Kenneth C. Cundy, John F. Bishop, and David A. Czekai. (JX039).

5. The '363 patent describes mixing a surface modifier with a crystalline medicament in the presence of a liquid and then milling until small particles of drug and surface modifier are obtained. (JX081 5:43-6:14.) The specification describes mixing a compatible surface modifier with an anticancer agent to form a premix. (JX081 5:44-55.)

6. The '363 patent teaches that the grinding media for the particle size reduction step can be selected from rigid media preferably spherical or particulate in form having an average size less than about 3 mm, and more preferably, less than 1 mm. (JX081 6:15-19.) It also

teaches that such media desirably can provide the particles of the invention with shorter processing times and impart less wear to the milling equipment. (JX081 6:19-21.)

7. For ball mills, processing times of up to five days or longer may be required. On the other hand, processing times of less than 1 day (residence times of one minute up to several hours) have provided the desired results using a high shear media mill. (JX081 6:34-40.)

8. The '363 patent teaches that for ball milling, the apparent viscosity of the premix is preferably about 1 up to about 100 centipoise and further that such ranges tend to afford an optimal balance between efficient particle fragmentation and media erosion. (JX081 6:11-14.)

9. The '363 patent discloses that zirconium oxide, such as 95% zirconium oxide stabilized with magnesia, zirconium silicate, and glass grinding media provide particles having levels of contamination which are believed to be acceptable for the preparation of pharmaceutical compositions. (JX081 6:23-27.) It also further discloses that other media, such as stainless steel, titania, alumina, and 95% zirconium oxide stabilized with yttrium are expected to be useful. (JX081 6:27-30.)

10. The '684 patent, which is incorporated by reference into the '363 patent, discloses nanoparticles prepared by milling with glass media. (JX082 10:44-47; 11:5-10.) The level of contamination from erosion of the glass grinding media was reported to the PTO. (JX082 at 10:63-66; 11:32-35.)

11. The '363 patent describes a methods for cleaning the grinding media. The specification describes cleaning zirconium oxide beads by rinsing in sulfuric acid followed by rinsing with deionized water, and then drying the media in a vacuum oven at about 100° C overnight. (JX081 8:44-48.)

12. The '684 patent discloses that "[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 8:29-32 (emphasis added); *see also* JX082 2:62-66 ("It is an advantageous feature that a wide variety of *surface modified drug nanoparticles* free of unacceptable contamination can be prepared in accordance with this invention." (emphasis added)).)

13. The '363 patent teaches a screening process for identification of compatible surface modifier and anticancer agent combinations to achieve stable particles of the invention. (JX081 7:5-45.)

B. Findings of Fact Regarding the '363 Patent

14. During prosecution of the '363 patent, inventor Gary Liversidge represented in a declaration that prior art reference U.S. Patent No. 5,049,322 discloses a solvent precipitation technique for preparing nanocapules and that such technique provides particles which are contaminated with solvent. Further, Dr. Liversidge noted that such solvents are often pharmaceutically unacceptable and can be difficult, if not impossible, to adequately remove to pharmaceutically acceptable levels to be practical. (JX039 at 280.)

15. No evidence was presented during the trial that demonstrated any levels of solvent contamination, or any unacceptable contamination of particles by solvents resulting from the teachings of the '363 patent. Therefore, there is no evidence that the statements made by Dr. Gary Liversidge in his declaration to the PTO were false or misleading.

16. There is no evidence in the record that Elan ever represented to the PTO, either during the prosecution of either the '684 patent or the '363 patent, that milling with zirconium oxide beads caused no contamination. Instead, the specification of the '363 and '684 patents states that "[t]he selection of material for the grinding media is not believed to be critical," and

notes that "zirconium oxide, such as 95% ZrO stabilized with magnesia, zirconium silicate, and glass grinding media *provide particles* having levels of contamination which are believed to be acceptable for the preparation of pharmaceutical compositions." (JX081 6-14; 6:39-44 (emphasis added).)

17. Dr. Gary Liversidge testified that he believed the particles taught by the '363 patent have acceptable levels of contamination. He commented that in drug development, "[a]cceptable means the levels are acceptable to regulatory authorities and are safe" but undesirable referred to his goal for the "purest product possible" regardless of whether it was a "regulatory acceptable level." (Tr. 427:21-24.) He explained that he did not think reporting "undesirable" contamination was important to the PTO because it "wouldn't have affected the product getting to the marketplace." (Tr. 228:22-229:2.)

18. Dr. Gary Liversidge explained that Elan provided contamination data to FDA. (Tr. 303:12-19.) Drs. Gary and Elaine Liversidge both testified to the fact that FDA has never reported to Elan that there was a contamination problem with any product formulated by the milling technology taught by the '363 patent. (Tr. 303:12-304:2; Tr. 535:5-11.) This testimony was credible.

19. Dr. Gary Liversidge also testified that Elan had an internal goal for heavy metal contamination which was 10 parts per million ("ppm"). This goal was based on the Japanese Pharmacopeia standard, not the United Sates Pharmacopeia ("USP") standard, which was higher at 20 ppm. (Tr. 432:2-10.) He also explained that the USP standard did not apply to zirconium contamination because zirconium was not listed as a heavy metal in the USP. (Tr. 431:19-22; 433:10-15.) Dr. Liversidge's testimony was credible and Abraxis presented no evidence that refuted his testimony. Dr. Monsoor Amiji's opinion, presented without

foundation, that "I don't think that zirconium oxide is acceptable" (Tr. 1432:25-1433:1) was not credible.

20. Dr. Gary Liversidge's belief that zirconium contamination was not "unacceptable" for regulatory approval was also corroborated by the evidence, a memorandum authored by Dr. Liversidge on September 13, 1990. (DX244, at ELANP0092628 ("There was one abstract in the literature on oral administration of ZrO that gave no data only quantitative statements indicating that Zr was poorly absorbed but accumulated in the ovaries, lung and bone of rats following repeated oral administration. In contrast to the abstract on accumulation of Zr in organs of the rat, ZrO particles are used in humans as a bone cement with no reports of detrimental toxicological consequences.").)

21. Dr. Gary Liversidge also testified that he did not believe zirconium contamination was an issue because the '363 patent described "a simple cleaning procedure in one of the examples in the '363, how to clean up this media." (Tr. 435:17-436:4; Tr. 463:18-464:2; *see* JX081 8:44-47.) The testimony regarding his belief was corroborated by the evidence. (*See* JX053 at ELANP0018478 & 490 ("Reducing Contamination Optimize media preconditioning.").) He also testified that in response to early observations of unacceptable contamination resulting from milling, one of the applicants' key accomplishments was to "develop[] this media such that it gave us no contamination and no pH shifts." (Tr. 465:11-19.) Dr. Liversidge's testimony, corroborated by the evidence, is credible.

22. The exhibits that Abraxis cites as "unambiguous" proof that Elan withheld material information, or made false representations, fall far short of clear and convincing evidence. (*See* JX053, JX054, JX055, DX238 and DX607.) These documents do not demonstrate that *particles* made by the '363 patent's teachings contain unacceptable levels of

contamination. These documents also do not indicate if the particles were created by milling done in accordance with the '363 patent's teachings. For example, all of the documentary evidence is silent on whether the media was precleaned as taught in the '363 patent, or whether the premix viscosity recommendations were followed. Accordingly, these documents do not provide substantial evidence that Elan made any false representations to or withheld material information from, the PTO. "Materiality is defined by what a reasonable examiner would have considered important in deciding whether to allow a patent application." *Innogenetics v. Abbott Labs.*, 512 F.3d 1363, 1378 (Fed. Cir. 2008). Given the vague and ambiguous nature of the statements in the documents, it is unlikely a patent examiner would find the documents or statements in the documents important for patentability.

23. Abraxis's evidence also does not establish that the disclosure in the '363 patent statement that "zirconium oxide, such as 95% ZrO stabilized with magnesia, zirconium silicate, and glass grinding media provide particles having levels of contamination which are believed to be acceptable for the preparation for pharmaceutical compositions" was false, intentionally false, or even material to patentability.

24. In summary, no evidence was presented at trial that proves Elan made false statements or representations to the PTO about contamination or that Elan withheld any information from the PTO that particles made by the teachings of the '363 patent contain unacceptable levels of contamination.

25. The '363 patent also teaches "a simple screening process . . . whereby compatible surface modifiers and anticancer agents can be selected which provide stable dispersions of the desired particles." (JX081 7:5-8.) Dr. Elaine Liversidge, who routinely runs screens in her

laboratory, testified that the screening test for determining compatible surface modifiers with drug compounds was clearly described in the '363 patent. (Tr. 487:14-21; 489:20-25.)

26. Elan told the PTO, and the patent teaches, that "not every combination of surface modifier and drug substance provides the desired results." (JX082 at 721-23.) Dr. Gary Liversidge testified that the '684 patent discloses to whomever reads it that not every combination of surface modifier and drug provides the desired result, and, not surprisingly, that one would not have a screening process if every surface modifier worked. (Tr. 300:13-14.) He explained that the screening process was necessary because not all surface modifiers stabilize a particular drug compound. (Tr. 298:l-13; 300:l-14.)

27. Elan's expert, Dr. Mark Manning testified that the screening process allows one skilled in the art to determine whether there is some ability of the surface modifier to keep the particles from associating. (Tr. 1587:l-1588:4.) The parties stipulated on the meaning of a person of ordinary skill in the art:

> The person of ordinary skill in the art would have a Ph.D. or the equivalent in pharmaceutical sciences, chemistry, chemical engineering, or biological sciences, and at least two years of practical experience in formulating drug compositions at the time the application for the '363 patent was filed.
>
> Alternatively, the person of ordinary skill in the art could be someone with a Master's degree in pharmaceutical sciences, or the equivalent, with two or more years of practical experience, specifically in the development of nanoparticulate pharmaceutical compositions.

(Tr. 1415:19-1416:4.)

28. Dr. Elaine Liversidge explained that Elan screens about ten new compounds per week using the screening process. (Tr. 489:4-11.) Dr. Gary Liversidge corroborated this testimony. (Tr. 1611:19-1612:3.) Dr. Elaine Liversidge testified that over the past 10 years of

conducting screens in her laboratory, Elan has had a 98% success rate in finding compatible surface modifiers to make nanoparticles. (Tr. 490:22-491:5.)

29. Similarly, testimony about the success of companies applying the screening process is credible. Dr. Liversidge explained that five companies had licenses the technology from Elan, and had been applying it to their compounds successfully. (Tr. 1612:16-1613:10.)

30. The evidence also supports that the screening method has been successful with anti-cancer compounds. (Tr. 489:12-24; 490:6-21; 491:6-493:9; JX067, JX068; JX069.) Dr. Gary Liversidge testified that every anticancer drug that Elan attempted to formulate as nanoparticles was so formulated. (Tr. 230:14-24.)

31. The evidence contradicts Abraxis's assertions about piposulfan's failures. In addition to the four examples of successful piposulfan-surface modifier combinations disclosed in the '363 patent using Tween 80, Tween 60, Span 80, and Span 60 (JX081 8:20-9:45), testimony and exhibits presented at trial demonstrated that piposulfan was also stabilized by surface modifiers other than the Tween/Span combinations as suggested by Abraxis. Indeed, human serum albumin ("HSA"), bovine serum albumin, and HSA and tyloxapol combinations and HSA and F-108 combinations also stabilized piposulfan. (Tr. 532:4-6; PX717 at ELANP0014823; JX069 at ELANP018338, JX068 at 18019; PX717 at ELANP0014832, ELANP 0014827.)

32. Elan's representations that "a wide variety of surface modifiers are useful" is also supported by the evidence. The '363 patent discloses 23 examples of anticancer drugs. (JX081 8:20-13:68.) The '684 patent, which is incorporated by reference, discloses an additional 14 examples. (JX082 8:36-13:52.) Furthermore, the Rule 132 declaration in file history of '684 patent discloses an additional 35 examples of successful nanoparticles.

(DX016 at 000134-140.) Abraxis neither alleged, nor presented any evidence that Elan made false representations about any of these examples.

33. Abraxis's assertion that Elan also hid its failures from the PTO is contradicted by the evidence. First, the '363 patent incorporates the disclosure of the '684 patent—its parent. The '684 patent expressly states that "[a]s indicated by the following examples, not every combination of surface modifier and drug substance provides the desired results." (JX082 7:21-23.) Further, examples 13 and 22 of the '363 patent disclose "failures" resulting from flocculation and aggregates. (JX081 12:67; 13:58.) Thus, the evidence convincingly demonstrated that Elan made no secret that unsuccessful combinations of drug-surface modifier combinations existed, nor was this information withheld from the PTO.

34. Abraxis also failed to present any evidence that Elan acted with intent to withhold any material information from the PTO. Abraxis's entire argument presumes that because allegedly material information was withheld, Elan must have acted with intent to deceive the PTO. This is not the law. "Materiality does not presume intent, which is a separate and essential component of inequitable conduct." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1351 (Fed. Cir. 2002). "Intent is a subjective inquiry into whether the inventor knew the information was material and chose not to disclose it." *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1227 (Fed. Cir. 2006). Abraxis failed to present any evidence to support a finding of intent.

35. Furthermore, no inference can be drawn from the absence of testimony from the prosecuting patent attorney, Mr. William Davis. The record is silent as to any allegations, or inferences, that Mr. Davis withheld material information from the PTO.

C. Conclusion of Law Regarding the '363 Patent

36. "Inequitable conduct entails a two-step analysis: first, a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all of the circumstances to determine whether the applicant's conduct is so culpable that the patent should be unenforceable." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 744 (Fed. Cir. 2002).

37. Abraxis's evidence failed to prove that Elan withheld material information from the PTO or that Elan made false statements or omissions of material information from the PTO. Abraxis presented no evidence that anyone with a duty of candor to the PTO believed that grinding media was critical or that zirconium oxide, such as 95% zirconium oxide stabilized by magnesia, zirconium silicate and glass grinding media provided particles having unacceptable levels of contamination for preparation of pharmaceutical compositions. Abraxis did not prove that Elan withheld or misrepresented information about "unacceptable" zirconium contamination. Dr. Liversidge's explanation that he did not believe the contamination issue was material because it would not cause a product from going to market was credible. A plausible or credible explanation can demonstrate that the lack of requisite intent. *See Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005).

38. Furthermore, the evidence demonstrated that the PTO had knowledge that not every surface modifier would work with every drug compound. There is no evidence that the examiner sought additional information from Elan regarding the number of unsuccessful combinations resulting during the screening process, a request that a patent examiner may have made had he deemed it material. "Materiality is defined by what a reasonable examiner would

have considered important in deciding whether to allow a patent application." *Innogenetics*, 512 F.3d at 1378.

39. None of the documentary evidence Abraxis presented contained information that would be material to the PTO during the examination. The vague and ambiguous statements found in presentations and memoranda Abraxis offered into evidence, without context, failed to prove that material information was withheld from the PTO.

40. Finally, to support a finding of inequitable conduct, "there must be evidence sufficient to show, clearly and convincingly, the intent to withhold material information in order to deceive or mislead the examiner." *Jazz Photo Corp. v. U.S. Int'l Trade Comm'n*, 264 F.3d 1094, 1110 (Fed. Cir. 2001). The record contains no such evidence to support this finding.

41. "Inequitable conduct requires not intent to withhold, but rather intent to deceive. Intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons for withholding are plausible." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003). "Intent is a subjective inquiry into whether the inventor knew the information was material and chose not to disclose it." *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1227 (Fed. Cir. 2006). Abraxis failed to prove that the inventors considered the information material, and still chose to withhold it. Inventor Dr. Gary Liversidge and Dr. Elaine Liversidge also both testified that they did not withhold any material information with an intent to deceive the PTO during the prosecution of the '363 patent. (Tr. 467:10-16; 499:14-18.)

42. In summary, Abraxis failed to meet its clear and convincing evidentiary burden and demonstrate that Elan withheld material information from the PTO, or that Elan made false or misleading statements to the PTO during the prosecution of the '363 patent.

43. Considering all the evidence presented at trial, Abraxis failed to prove by clear and convincing evidence that Elan engaged in inequitable conduct during the prosecution of the '363 patent.

II. PROPOSED FINDINGS OF FACT REGARDING INEQUITABLE CONDUCT FOR THE '025 PATENT

A. Background for the '025 Patent

44. The '025 patent issued November 10, 1998. The application leading to the issuance of the '025 patent, U.S. Patent Application No. 08/696,754, was filed on August 14, 1996. The named inventors of the '025 patent are Lawrence de Garavilla, Gary G. Liversidge, and Elaine Liversidge. (DX015.)

45. The '025 patent teaches a method of administering nanoparticles at infusion rates so as to eliminate hemodynamic effects resulting from the infusion. (*See generally* DX015; Tr. 4463-447:4; 495:15-20.)

B. Findings of Fact Regarding the '025 Patent

46. There is no dispute that the '025 patent was issued based on the data developed in a study in dogs (Tr. 496:15-23; 524:8-10), and that the patent examiner issued claims applicable to all mammals, including humans. (Tr. 446:23-447:4.) Abraxis made no allegations, and submitted no evidence, that Elan misrepresented, or failed to fully disclose, any data from the study considered by the PTO. Abraxis also presented no evidence that the examiner requested additional studies or data from Elan during the prosecution.

47. Abraxis's allegations of inequitable conduct regarding the '025 patent are anchored on its assertion that Elan knew the hemodynamic effects observed during the dog study were "species-specific" effects, and therefore, only applicable to dogs. Abraxis's alleges that Elan knowingly withheld this information from the examiner during the '025 patent's prosecution. Abraxis's allegations were not supported by the evidence adduced at trial.

48. Dr. Elaine Liversidge testified that the dog was used as a "very classic model" to study cardiovascular issues and that all the data in the '025 patent was based on the dog model. (Tr. 496:16-25; 524:8-11.) Dr. Gary Liversidge also explained that testing in dogs is applicable to humans: "[T]he dog is used pretty typically as a species for, as a model for the human. If you see this in a dog it is a huge red flag. You have got to really proceed with caution." (Tr. 450:11-13.) The Liversidges' testimony was credible. Abraxis offered no evidence to contradict the Liversidges' testimony.

49. The evidence Abraxis offered as proof that Elan "knew" the data from the dog study was not applicable to other species were general statements in a handful of emails and a presentation to the effect that cardiovascular depressant effects have not been *observed* in other animal species studied such as rats, rabbits or monkeys. (*See* DX248, DX297, DX301.) Both Dr. Gary Liversidge and Dr. Elaine Liversidge, co-inventors on the '025 patent, testified about these statements. They explained that cardiovascular effects had not been observed in those species because they had not been measured in those species. (Tr. 449:15-450:1; Tr. 497:11-23; 527:17-20.) The Liversidges' testimony was credible, and Abraxis presented no evidence to contradict their testimony.

50. Dr. Elaine Liversidge explained that "[b]y 'observing' it means an animal or rodent might have been dosed, but [the idea of] the heart rate and blood pressure were never

measured in these other species." (Tr. 525:3-7.) She stated that "seeing" is not "measuring" and the '025 patent is about measuring the cardiovascular response, measuring the blood pressure, measuring the heart rate. (Tr. 526:3-5.) She also explained that hemodynamic effects had not been observed in rats or monkeys because they had never been measured in these species. (Tr. 497:11-23; 525:3-7.) Statements about observing, without measuring meant that an animal might have been dosed, but the animal's heart rate and the blood pressure were never measured in these other species." (Tr. 525:4-7.) She also testified, that to her knowledge, none of Elan's clients had measured hemodynamic effects during their dosing studies. (Tr. 527:17-529:2.)

51. Dr. Elaine Liversidge testified that measuring hemodynamic effects was a very complicated process requiring a "carefully designed study." (Tr. 495:23-496:10.) She explained that measuring hemodynamic effects was much more than simply monitoring heart rate and blood pressures. She explained that it takes a very carefully designed study to measure hemodynamic effects. To measure these effects, the "animal is basically catheterized" so that arterial heart pressure and heart rate can be measured. (Tr. 495:23-496:10.)

52. Dr. Elaine Liversidge also offered another explanation about why hemodynamic effects had not "observed" in monkeys, rabbits, mice, rats, and humans by Elan or its clients. She believed that hemodynamic effects had not been observed during testing in any species after 1996 was because both Elan and its clients administered nanoparticles following the methods taught by the '025 patent. (Tr. 527:17-529:2.)

53. Dr. Elaine Liversidge was a credible witness, and Abraxis presented no evidence to contradict Dr. Liversidge's testimony.

54. Finally, both Dr. Gary Liversidge and Dr. Elaine Liversidge testified that they never knowingly withheld or misrepresented any information from the PTO regarding the '025 Patent. (Tr. 467:17-20; 499:1-7.)

55. No inference can be drawn from the absence of testimony from inventor Lawrence de Garavilla. The record is silent as to any allegations, or inferences, that Dr. de Garavilla withheld material information from the PTO.

C. Conclusions of Law Regarding the '025 Patent

56. "A patent applicant commits inequitable conduct when, during the prosecution of the application, he makes an affirmative representation of a material fact, fails to disclose material information, or submits false material information, and does so with the intent to deceive." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1358 (Fed. Cir. 2003). "Both intent and materiality are questions of fact, and must be proven by clear and convincing evidence." *Innogenetics v. Abbott Labs.*, 512 F.3d 1363, 1378 (Fed. Cir. 2008)

57. Abraxis's reliance on vague and ambiguous statements to demonstrate that Elan withheld material information from the PTO is not persuasive. "Materiality is defined by what a reasonable examiner would have considered important in deciding whether to allow a patent application." *Innogenetics*, 512 F.3d at 1378. There is no evidence that Elan possessed or withheld any additional information or data that an examiner would have considered important during the prosecution of the '025 patent. Both Dr. Gary Liversidge and Dr. Elaine Liversidge testified that hemodynamic effects had not been observed in other species because they had not been measured. Failing to present non-existent data to the PTO is not withholding material information.

58. The record also contains no evidence that Elan made any false representations or submitted any false information to the PTO. Accordingly, Abraxis failed to meet its evidentiary burden for the first prong of the analysis.

59. "To satisfy the intent to deceive element of inequitable conduct, the 'involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive.'" *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334, 1343 (Fed. Cir. 2008) (quoting *Impax Labs., Inc. v. Aventis Pharmaceuticals, Inc.*, 468 F.3d 1366, 1374-75 (Fed. Cir. 2006)). However, the record is void of evidence proving the requisite intent. "[T]here must be some threshold showing of intent to be balanced; we will not find inequitable conduct on an evidentiary record that is completely devoid of evidence of the patentee's intent to deceive the PTO." *Amgen Inc.*, 314 F.3d at 1358.

60. When questioned about the context of the statements Abraxis claimed were material, Elan's inventors' testimony was not only convincing, but unchallenged. The Liversidges' testimony that Elan had not conducted studies in other species, and therefore, did not have any data on the hemodynamic effects in other species is also credible. A plausible or credible explanation can demonstrate that the lack of requisite intent. *See Bruno Indep. Living Aids*, 394 F.3d at 1354. Accordingly, no intent to withhold information from the PTO was proven at trial, nor can the requisite intent be inferred.

61. In summary, Abraxis offered no evidence at the trial that Elan withheld any material information, nor acted with the requisite intent to withhold information during the prosecution of the '025 patent. The absence of evidence compels the conclusion that Elan did not engage in inequitable conduct during the prosecution of the '025 patent.

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