IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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

DEFENDANT ABRAXIS BIOSCIENCE, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR JUDGMENT AS A MATTER OF LAW OF NONINFRINGEMENT, INVALIDITY, INEQUITABLE CONDUCT, AND ITS MOTION FOR NEW TRIAL

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I. NATURE AND STAGE OF THE PROCEEDING

In this patent case, the jury returned a verdict in favor of Elan on infringement of the '363 patent (but not willfulness), validity and (advisory) enforceability of the '363 and '025 patents, and for $55,230,000, and the Court entered judgment on June 16, 2008. D.I. 613-4.

II. SUMMARY OF ARGUMENT

On June 30, 2008, Abraxis renewed its motion for judgment under Fed. R. Civ. P. 50(b) on (1) noninfringement ('363 patent), (2) invalidity under the enablement and written description requirements ('363 and '025 patents), (3) inequitable conduct ('363 and '025 patents), and (4) damages. D.I. 633. In the alternative, Abraxis moved for a new trial under Fed. R. Civ. P. 59, because (1) the clear weight of evidence is against Elan on these issues, and (2) Abraxis was prejudiced by Elan's surprise "more-than-one particle" infringement theory and the admission of Dr. Munson's testimony. Abraxis also requested remittitur or new trial on damages. Abraxis files this Opening Brief in support of those motions. 7/2/2008 Order approving D.I. 632.

III. STATEMENT OF FACTS

The pertinent facts are discussed in the Argument sections, as appropriate.

IV. ABRAXIS IS ENTITLED TO JUDGMENT OF NONINFRINGEMENT

A. Even Under Elan's "More-Than-One Particle-In-Trillions" Theory, Elan Failed To Show Infringement of the '363 Patent

Elan's theory of infringement at trial was that there is "more than one" particle in every vial of Abraxane that infringes '363 patent claims 3 and 5. Tr. 1693:13-19.[1] Under Elan's infringement theory, Elan had to clear three hurdles to prove infringement. It presented

[1] For ease of reference, Abraxis has filed an Appendix containing the trial transcript excerpts and excerpts of the trial exhibits cited in this Opening Brief, and in its Opening Brief in Support of its Motion to Amend the Judgment and Enter Findings that Elan Engaged in Inequitable Conduct in Procuring the '363 and '025 Patents (filed concurrently herewith). We explain in Section IV.B. below why Elan's view of claim scope is incorrect.

substantial evidence on none. First, Elan failed to prove that Abraxane particles meet the crystalline limitation. Second, Elan failed to prove that Abraxane particles meet the non-crosslinked limitation. Third, Elan adduced *no evidence or argument* that any of the same particles were *both* crystalline and non-crosslinked.

1. Elan Failed to Prove the Crystalline Limitation

Under Elan's "more than one particle" theory, Elan had to show that Abraxane contained particles in which the *entire* paclitaxel was crystalline. D.I. 569 at 2; D.I. 271 at 2; D.I. 612, Jury Instruction ("J.I.") 4.2.3(l)(2). Lacking evidence, Elan invited impermissible speculation that Abraxane contains entirely crystalline particles based on Dr. Munson's testimony that 8% of Abraxane's *total* paclitaxel is crystalline (which we show below should be given no weight):

> Dr. Munson [testified that e]ight percent of the total paclitaxel within those vials of Abraxane are crystalline. Eight percent of the total. Very important number to remember. Eight percent of the total, because the issue here isn't in this case is there a certain percentage of the total. The question is are there nanoparticles, more than two, amongst 61 trillion, that are, as Judge Sleet has instructed you, that are themselves entirely crystalline.

Tr. 1711:2-12. Dr. Munson's testimony was the most Elan could point to, but it purports to show only the percent crystalline paclitaxel in Abraxane as a whole. Evidence that the paclitaxel in Abraxane as a whole is 8% crystalline does not mean that any Abraxane particle is *entirely* crystalline. Elan offered no evidence how that alleged 8% crystallinity was divided among the Abraxane particles, and hence produced no evidence that any particle was entirely crystalline.

Elan's other crystallinity evidence similarly fails the "entirely" test. No technique quantified or characterized crystallinity in individual Abraxane particles. Tr. 581:21-585:20 (Dr. Manning's DSC testimony that Abraxane "not completely amorphous" because no glass transition); Tr. 951:1-9 (Dr. Berkland's testimony that TEM "cannot tell you if something is amorphous or crystalline"); Tr. 737:9-738:14 (Dr. Danishefsky's testimony that solubilized

paclitaxel "gets amnesia" whether it was ever crystalline). Elan's reliance on pre-2001 laboratory notebook entries referring to crystals is unavailing, because the undisputed evidence is that those entries reflect samples that did not meet the formulation criteria for Abraxane. Tr. 1276:9-1282:17; 1338:10-1348:5. Thus, even viewing the evidence as portrayed by Elan, *at best* Elan offered evidence of some crystallinity somewhere in Abraxane. Nothing showed that Abraxane contained particles of "entirely" crystalline paclitaxel.

2. Elan Failed to Prove the Non-Crosslinked Limitation

To meet its infringement burden, Elan was also required to adduce substantial evidence that the albumin adsorbed on Abraxane nanoparticles was "essentially free of intermolecular crosslinkages." J.I. 4.2.3(l)(3). But Elan did no testing whatsoever relating to albumin crosslinking. Tr. 1577:15-18; 1764:11-14.

In sharp contrast, although Abraxis should not be required to disprove infringement, Abraxis introduced test data that *directly* answered the relevant infringement question and showed that the adsorbed albumin on Abraxane particles is not essentially free of intermolecular crosslinkages. DX107; DX112. Abraxis witnesses Drs. Desai and Amiji testified to this testing without cross-examination by Elan counsel or contradiction by Elan witnesses. Tr. 1285:15-1286:21; 1377:15-1379:14. This pre-litigation Abraxis testing showed that 55% of adsorbed albumin was dimers, oligomers, and polymers (*i.e.*, "non-monomeric" albumin), and hence was crosslinked. *Id.*; *see also* Tr. 1375:11-14.

Elan's trial strategy was to divert the jury's attention from the inquiry mandated by the claims and the Court. Elan primarily argued that the evidence showed the absence of a "strong, permanent interaction or bond" or "covalent bond." Tr. 551:21-23; 561:2-578:16; 1570:2-1573:17; 1575:25-1577:6; 1700:19-1704:6. But the Court's claim construction required that Elan prove the absence *not only* of *strong* intermolecular crosslinkages but of *any*

"intermolecular crosslinkages," whether "strong" or not. D.I. 271; *see also* Tr. 586:23-587:1 (Dr. Manning admitting Court's construction does not distinguish between different types of intermolecular crosslinkages); 1375:15-1377:10. '363 inventor Dr. Sarpotdar also confirmed that "one can form covalent bonds or other types of bonds, but anything that is linking two molecules of the same compound, that could be considered cross-linking." Tr. 1489:21-1490:19.

Another Elan diversion was Dr. Manning's reference to other Abraxis data showing smaller percentages of linkages among *all* albumin in Abraxane (both adsorbed and free). This did not help Elan because it still shows that total albumin changes from ~5% non-monomeric to ~15-20% non-monomeric during Abraxane manufacture. Tr. 561:5-14; 1604:17-1605; JX005 at ABRX0117401; *see also* Tr. 1699:14-1700:18; 1703:17-20. Thus, it was undisputed that Abraxis's manufacturing process creates intermolecular linkages. *See also* 1703:21-25 (Elan acknowledging "close association" of albumin—crosslinking under Court's claim construction). This data means Abraxane does not meet the non-crosslinked limitation.

Finally, Elan did not overcome Abraxis's additional testing evidence that adsorbed albumin in Abraxane in fact was crosslinked by covalent disulfide bonds, and hence was crosslinked even under Elan's narrow reading of the claim construction. DX076; Tr. 596:9-11; 1286:10-1288:5; 1379:15-1381:23. Again, Elan did no testing and did not cross-examine Drs. Amiji or Desai on Abraxis's testing. Dr. Manning's rebuttal was so conclusory that it did not amount to substantial evidence. Tr. 1577:7-1579:21. Elan bore the burden of proving the essential absence of intermolecular albumin crosslinkages, and failed to meet it.

3. Elan Offered No Argument Or Evidence To Show The Existence of Particles That Are Both Crystalline And Non-Crosslinked

Even under Elan's "more-than-one particle" theory, Elan had to prove that Abraxane contains more than one particle meeting *both* the crystalline *and* non-crosslinked limitations.

Thus, even if Elan had shown that some Abraxane particles were entirely crystalline and that some Abraxane particles were largely non-crosslinked (which it did not), Elan still had to show that the *same* particles were *both* entirely crystalline and non-crosslinked.[2] Elan's case required proof of Abraxane particles that, like the mythical Unicorn, combined those two characteristics.

Elan failed to meet this burden, offering no evidence of crystalline, non-crosslinked particles. Nor did Elan propose a permissible inference. Under Elan's theory, Abraxane was overwhelmingly amorphous but contained "more than one" deviant crystalline particle. Because Elan focused on a tiny fraction of deviant particles, it had to provide evidence about those particles. Elan did not do so. Evidence about Abraxane as a whole is insufficient to demonstrate that both limitations are met in any individual particles. Elan did not even argue in closing that both limitations are met in the same particles. This void requires judgment in Abraxis's favor.

B. Under The Proper Claim Scope, Elan Conceded Infringement

Elan's "more-than-one particle" theory conceded that the paclitaxel in Abraxane nanoparticles is overwhelmingly amorphous. But as the Court correctly stated, the "crystalline medicament" limitation "forecloses the argument that a largely amorphous product can infringe the '363 patent." D.I. 569 at 2. Elan acknowledged that, under this construction, it had no infringement case. D.I. 575 at 1, 3 n.1, 12-13.

The intrinsic evidence contradicts Elan's claim scope theory. During claim construction, the Court resoundingly rejected Elan's proposed "portion" construction, noting that it had "no support" in the intrinsic evidence. D.I. 271, at 2 n.4. The claims have an "average effective particle size" limitation, which, according to the specification (and common sense), requires measuring a dispersion or formulation of particles. JX081 at 4:60-5:10 (A484-5). The

[2] Indeed, even under Elan's proffered claim construction requiring less-than-entirely crystalline medicament, Elan failed to prove infringement because it offered no proof of any particles having any amount of crystallinity that *also* were essentially free of crosslinked surface modifier.

specification discloses "a crystalline anticancer agent" that is "present in one or more discrete crystalline phases," and teaches away from the prior art "amorphous phase." JX081 at 1:51; 2:28-34 (A483). The specification discloses dispersions of these crystalline particles, not a few crystalline particles in a dispersion of overwhelmingly amorphous particles. According to the patent, the dispersions are created by grinding and then analyzed to determine the average particle size. JX081 at 5:22-6:39 (A485). The screening process assesses whether "stable dispersions" are created, not whether random particles of the dispersions are stable. *Id.* at 7:5-51. Each of the examples in the '363 and '684 patents discloses only nanoparticulate "dispersions," "formulations," or "suspensions," not individual particles. *Id.* at 8:20-13:68; JX082 at 8:35-15:31. In the '684 patent, Examples 4 and 5 disclose using XRPD to assess crystallinity of the entire dispersion, not individual particles. JX082 at 10:66-11:2, 11:35-37.

The prosecution history reinforces the Court's conclusion. The '363 patent applicants distinguished prior art particles as being amorphous as a population, and did not distinguish on an individual particle basis. *E.g.*, JX081 at 2:28-34 (A483); Tr. 405:19-407:8; JX039 at 42-44 (A149-51). The possibility that some crystalline particles might result from solvent precipitation — precisely Elan's theory about Abraxane — was no obstacle to patentability because Elan relied on the characteristics of the totality of the dispersion, not any particular particles. Elan repeatedly emphasized that amorphous formulations were "radically different" from the claimed particles. JX039 at 275-276 (A156-7).

As the Court indicated, overwhelmingly amorphous formulations cannot be captured now by broadening the infringement inquiry to "more than one particle" out of trillions. *See, e.g.*, *Seachange Int'l, Inc. v. C-Cor Inc.*, 413 F.3d 1361, 1372-73 (Fed. Cir. 2005) ("Where an applicant argues that a claim possesses a feature that the prior art does not possess in order to

overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language."); *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1319 (Fed. Cir. 2006) ("Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question."). As shown in Sections V.A.3 and V.B below, if the claims are not limited as the Court directed, they are invalid. Because the paclitaxel in the Abraxane formulation is overwhelmingly amorphous, there can be no infringement.

V. ABRAXIS IS ENTITLED TO JUDGMENT OF INVALIDITY UNDER § 112

A. The Specifications Fail To Provide An Enabling Disclosure

Abraxis established by clear and convincing evidence that claims 1, 3, 5, 10, and 11 of the '363 patent, and claims 1-3 and 13-15 of the '025 patent are invalid for lack of enablement. Section 112 requires that the specification enable a skilled artisan to make and use the "full scope of the claimed invention" without undue experimentation. J.I. 5.2. "Although the question of undue experimentation entails many factual considerations, enablement is ultimately a question of law." *Martek Biosciences Corp. v. Nutrinova, Inc.*, 520 F. Supp. 2d 537, 556 (D. Del. 2007) (citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)).

1. The '363 Patent Does Not Enable Uncontaminated Nanoparticles

Abraxis presented clear and convincing evidence that the '363 patent does not enable particles that are "essentially free of . . . contaminants," as the claims require. J.I. 4.2.3(l)(1). Elan itself was not able to make uncontaminated particles using the '363 patent; countless Elan documents revealed "unacceptable contamination levels." DX607; *see also* JX053; JX054; JX055; DX238; DX243; Tr. 424:13-436:4; 506:25-509:11; 1425:12-1439:18.

Applying the *Wands* factors reinforces this conclusion. Elan's internal documents reveal that the wet milling method of the '363 patent was so unpredictable that contamination levels varied from 140 to 16,000 ppm, *all of which were unacceptable*. JX053; JX055; DX320; DX244; DX228. There is no guidance in the patent on how to avoid contamination. Elan's one-sentence "cleaning method," relied on by Dr. Liversidge, did not solve the problem. Tr. 463:18-464:2; 1431:13-1432:6. Elan's internal documents confirm that contamination remained a "key hurdle" even with this pre-cleaning method. DX607; JX053; JX055; DX238; DX228; DX320. Nor can Elan point to any "working examples;" none of the examples in the '363 patent reports contamination amounts. JX081; Tr. 1413:9-12; *Martek*, 520 F. Supp. 2d at 556. Elan's response that it solved contamination problems by later developing "polymeric" milling media and adopting "microfluidization," Tr. 465:5-19; 506:25-509:11, underlines the nonenablement of the '363 patent. *See In re Hogan*, 559 F.2d 595, 605 (C.C.P.A. 1977). By definition the experimentation required is undue, as Elan had to resort to techniques not taught by the '363 patent to avoid the contamination problems inherent in the zirconium and glass grinding. Elan's later FDA-approved products are red herrings, as there was no evidence that any were manufactured using the '363 patent teachings or even covered by the patent. Tr. 1468:3-12; 1437:20-1438:7; 221:21-224:21; 418:7-19; 419:1-17; *see also* 855:4-15; 1616:17-1617:21.

2. The '363 Patent Does Not Enable the Full Scope of Claimed Medicament and Surface Modifier Combinations

The record is replete with admissions that the '363 patent's broad claims to innumerable drug combinations were not enabled as of the time the '363 application was filed. Elan's internal documents evidence the extraordinary difficulties Elan confronted in attempting to make stable particles after the '363 application was filed. DX190; DX193; DX238; DX258; DX286; DX327; DX460; DX528; DX607; JX047; JX055; Tr. 438:10-44:10; 509:12-513:5; 531:6-533:8; 1403:23-

1405:25; 1416:17-1425:11. Elan's expert Dr. Manning acknowledged that "years of arduous effort [would be] involved" even to reach preclinical studies. Tr. 1589:23-1590:19; *see also* 1591:13-1593:2. Elan's later patent applications confirm these difficulties: "[t]he choice of a surface stabilizer is non-trivial and usually requires extensive experimentation." DX544; *see also* DX411; DX522; DX528-531; DX533-534; DX538-542; DX561.

Application of the *Wands* factors again reinforces nonenablement. The challenged patent claims are extremely broad, covering millions of combinations of medicaments and surface modifiers in a wide variety of weight ranges. Tr. 1394:6-1399:4; *Pharm. Res., Inc. v. Roxane Labs., Inc.*, 253 Fed. Appx. 26, 31 (Fed. Cir. 2007) (in strikingly similar circumstances, affirming invalidity where patent covered *only one drug* in combination with any surfactant); F.R.A.P. 32.1 (allowing citation to unpublished opinions). As noted above, the quantity of experimentation necessary to identify useful combinations was high. Dr. Gary Liversidge admitted that Elan tests about 520 compounds a year, which means it would take Elan 100 years to screen just 52,000—a tiny fraction of the claims. Tr. 1617:23-1618:15.

Elan's '363 patent promised anti-cancer treatments, which, as experience has shown, is very difficult to develop. Elan claimed that the '363 patent represented a significant advance over the prior art. *See* Tr. 138:8-15 ("first time someone was able to administer crystalline material to patients without having to dissolve it in solvents"); *see also* Tr. 142:6-9. Yet the amount of direction or guidance in the patent was limited. The examples covered only a "miniscule percentage" of claimed combinations, JX081, Tr. 1403:3-22, and Elan's internal documents show even slight variations often failed, DX193; Tr. 509:12-517:2; 1403:23-1405:25; 1416:17-1425:11, demonstrating the limited value of the patent's guidance. Further, the examples on their face do not refer to the claimed "average effective particle size," JX081 at

4:60-5:1 (A484-5), 8:20-13:68 (A486-9), and thus did not show there were any working examples.

As for the patent's screening method, Elan did not dispute that it was "basically trial and error" with a "trivial end point." Tr. 1399:15-1401:23; 1485:6-1486:22; 1488:25-1489:20; 1588:17-25; 1589:23-1590:19; 1594:9-1601:4; 1612:4-9; *Martek*, 520 F. Supp. 2d at 557. As Dr. Manning confirmed, this "initial step" endpoint only means "this looks promising, let's start to do more development work." Tr. 1592:20-23. Thus, the screening method does not enable "useful" nanoparticles. *In re Fisher*, 421 F.3d 1365, 1378-79 (Fed. Cir. 2005) ("[T]he enablement requirement of § 112 incorporates the utility requirement of § 101").

Dr. Manning also admitted unpredictability: "we never know ahead of time which combination of stabilizer and drug will work." Tr. 1592:8-10. Although the Liversidges claimed a "98 percent success rate," Tr. 491:1-3, Elan's own documents contradicted their claim. Confronted with some of these documents, Dr. Elaine Liversidge admitted that 18 of 21 etoposide formulations failed. Tr. 509:21-511:1; JX067-069; *see also* JX053 (6 of 14 paclitaxel formulations failed); DX258 (30 of 30 piposulfan formulations failed); Tr. 436:5-443:20; 509:12-517:2; 531:6-533:8 (failures with "particularly preferred" combinations). Elan's response that "you only need one formulation to make something a product" (Tr. 510:24-25) is insufficient. Elan claimed *every* formulation, not just the one that may ultimately have succeeded. *See Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008) ("Enabling the full scope of each claim is part of the quid pro quo of the patent bargain.").

Neither Elan nor its licensees has commercialized a claimed embodiment, despite years of trying. Tr. 418:7-19; Tr. 536:6-22; 853:8-10; 853:18-20; *see also* 1394:6-1406:3; 1416:17-1425:11. Fifteen years after the '363 application was filed, Elan tried but failed to develop a

formulation with crystalline paclitaxel and human serum albumin—what Elan (incorrectly) called "Generic Abraxane". Tr. 395:20-396:13; 398:13-399:11; 1418:9-1419:3; DX294; DX328; DX315 at 38 ("HSA alone is not a satisfactory stabilizer" with crystalline paclitaxel); *see also* DX302. With a vial of Abraxane in one hand, and the '363 patent (and subsequent development work) in the other, Elan could not make its crystalline formulation. "If an inventor attempts but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement." *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1318-19 (Fed. Cir. 2007); J.I. ¶ 5.2(4) (same). Elan made that very attempt here, and failed. Abraxis's proof of nonenablement is not just clear and convincing, it is overwhelming.

3. The '363 Patent Does Not Enable Mostly Amorphous Formulations

Elan contends that its claims reach a formulation of particles containing overwhelmingly amorphous medicament and only incidental crystalline medicament. But "claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). Such a composition is not enabled. The '363 patent teaches only how to create crystalline particles and disclaims amorphous particles. JX081 at 2:28-34 (A483); D.I. 271, at 2 n.4.

4. '025 Patent Claims 1-3 and 13-15 Are Not Enabled

The '025 patent claims the avoidance of hemodynamic effects in mammals based on a "critical" infusion rate. JX040 at 58-59 (infusion rate "is not merely an optimization of an administration variable, as the use of this specific infusion rate results in dramatic, unexpected results."); *see also* DX015, abstract; 16:56-17:4. But Elan's internal documents provided clear and convincing evidence that there are no hemodynamic effects to avoid for any mammal other than dogs. JX087; DX248; DX291; DX259; DX297; DX301. Elan's response that

hemodynamic effects "were never measured" in mammals other than dogs reinforces its species-specific nature. Tr. 525:3-4. Elan's inventors admitted they never saw hemodynamic effects in man, monkeys, or rabbits; the '025 patent thus did not enable the avoidance of those effects in mammals other than dogs. Tr. 522:17-530:25. The '025 patent also claims administering particles prepared according to the teaching of the '684 patent. DX015 at 1:23-27, 16:56-17:4. Because the '025 patent is not limited to anti-cancer medicaments, the nonenablement bases discussed in Section V.A.1., above, apply with even greater force to the '025 patent.

B. The '363 and '025 Patents Fail to Provide An Adequate Written Description

The Supreme Court has cautioned that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 536 (1966). Thus, the written description rule requires that the patent demonstrate the inventors were in possession of "the full scope of the invention." *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1259 (Fed. Cir. 2004); *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005) (stating written description prohibits "sweeping, overbroad claims"); *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345-46 (Fed. Cir. 2000) (the purpose of the written description requirement "is to ensure that the scope of the right to exclude . . . does not overreach the scope of the inventor's contribution").

The evidence described in Section V.A. above demonstrates Elan's failure to satisfy this requirement. Elan's patents tell the public to "go fish" for combinations of crystalline medicament and non-crosslinked surface modifiers that might or might not work. Elan simply was not in possession of the innumerable combinations claimed or, indeed, any combination that was not contaminated. Nor was Elan in possession of a formulation of particles containing amorphous medicament and only deviant particles containing crystalline medicament. Finally, in the '025 patent, Elan was not in possession of the claimed methods in all mammalian species.

Elan did not claim its nanoparticle invention structurally. Rather Elan claimed it by function — maintaining stable nano-sized particles. But an adequate written description requires more than a "mere wish or plan for obtaining the claimed chemical invention." *Univ. of Rochester v. Pfizer, Inc.*, 358 F. 3d 916, 927 (Fed. Cir. 2004). Elan's few examples do not help here, where unpredictability is undisputed. "[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated." *Noelle v. Lederman*, 355 F.3d 1343, 1350 (Fed. Cir. 2004).

VI. THE '363 AND '025 PATENTS ARE UNENFORCEABLE

Abraxis's accompanying Opening Brief in Support of Motion to Amend the Judgment and Enter Findings that Elan Engaged in Inequitable Conduct in Procuring the '363 and '025 Patents explains why the Court should reject the jury's advisory verdict and find that Elan engaged in inequitable conduct by making material false statements and omitting material information during prosecution with intent to deceive the PTO. J.I. 6.1. While Abraxis believes entering findings of fact and conclusions of law under Rule 52 is the proper procedure, in an abundance of caution Abraxis has also moved, in the alternative, under Rule 50 that judgment as a matter of law be entered on Abraxis's inequitable conduct claims.

Elan falsely represented to the PTO that particles made according to the '363 patent were "free of unacceptable contamination." JX082 at 2:63:66; *see also* JX081 at 6:23-27 (A485). Internally, Elan knew the patent's grinding methods resulted in "unacceptable contamination." DX607 at 17; *see also* JX053-55; DX238; DX243; Tr. 424:1-436:4; 506:25-509:11; 1425:12-1439:18. Elan also falsely represented that "[t]he selection of material for the grinding media is not believed to be critical." JX081 at 6:21-23 (A485). Internally, Elan knew that the selection of

grinding media was critical because the '363's glass and zirconium caused contamination. *See, e.g.*, DX607; JX053-55; DX238; DX243.

The evidence also showed that Elan falsely represented to the PTO that its "invention can be practiced with a wide variety of surface modifiers." JX039 at 428-29 (A168-9); *see generally* JX081. Internally, Elan knew many combinations of drugs and surface modifiers would fail. Tr. 438:22-25; 439:13-15; 443:16-20; 509:12-513:5; 1394:6-1406:3; 1416:17-1425:11.

Elan falsely represented to the PTO that the '025 patent's invention applied to all mammals. *See* DX015; Tr. 447:1-4. Internally, Elan knew that its invention was "species-specific," and applied only to dogs. Tr. 447:15-18; 450:2-16; 522:17-530:25; DX248; DX297.

Elan's own documents and witnesses established that Elan made the above statements and omitted information with intent to deceive. Weighing materiality and intent establishes inequitable conduct, requiring judgment as a matter of law in favor of Abraxis. *See Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006) (summary judgment granted on inequitable conduct) (*citing Bruno Indep. Living Aids*, 394 F. 3d 1348, 1354 (Fed. Cir. 2005)); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1260 (Fed. Cir. 2005) (reversing district court and entering judgment that patentee had engaged in inequitable conduct).

VII. THERE WAS NO EVIDENTIARY BASIS FOR THE DAMAGES AWARD

The jury returned a verdict based on a 6% royalty rate applied to every sale of Abraxane. Elan failed to present substantial evidence to support the royalty rate and its application to the sales of Abraxane as a whole. To calculate damages, Elan relied on prior Elan license agreements concerning NanoCrystal technology and a speculative calculation of Abraxis's profits. *See* Tr. 799:2-804:17. The licenses were not specific to the '363 patent, and included many more-recent patents, as well as technical assistance and know-how. Even then, the royalty rates were predominately lower than 6 percent. Tr. 850:3-856:13. None of these licenses

compared to the situation here, where Elan claimed that only the '363 patent was infringed, and then only by a small, incidental fraction of the product. *See, e.g., Integra Lifesciences Ltd. v. Merck KGaA*, 2003 U.S. App. LEXIS 27796, at *28-30 (Fed. Cir. June 6, 2003), *vacated in part on other grounds*, 545 U.S. 193 (Fed. Cir. 2005) (reversing jury award due to reliance on incomparable license agreements); *Trell v. Marlee Electr. Corp.*, 912 F.2d 1443, 1446-47 (Fed. Cir. 1990) (reversing award because licenses related to broader inventions not comparable to patent in suit). Federal Circuit precedent has rejected reliance on "an estimate of anticipated profits that bore no relation to actual profits." *Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co.*, 895 F.2d 1403, 1407 (Fed. Cir. 1990). Yet Elan relied on a speculative calculation that predicted a *32% profit* when Abraxis has reported millions of dollars in losses in each of the last three years. Tr. 858:10-860:23.

And Elan's "more-than-one particle" theory is legally inconsistent with Elan's royalty calculation. Elan emphasized, "we are not claiming that Abraxane as a product infringes. We are claiming that Abraxane contains particles, that those particles infringe. . . . And the question is, among those 61 trillion [particles], are there *more than one* particle—are there particles that embody the '363 patent and therefore infringe it." Tr. 1693:9-19; *see also* Tr. 1711:9-12. Elan's damages expert acknowledged, however, that his calculations were based on "all the nanoparticles" in every Abraxane vial. Tr. 848:10-18. In closing, Elan analogized the jury's task to finding a few infringing bolts in a fully assembled car. Tr. 1707:4-19. But Elan did not seek a royalty based on the value of the "bolts"—the few allegedly crystalline nanoparticles. It sought a royalty based on the selling price of the car—on sales of the entire Abraxane product.

A patentee that seeks a royalty based on sales of a product that includes both patented and non-patented components *must* show that "the patent related feature is the basis for customer

demand." *Imonex Servs., Inc. v. W.H. Munzprufer Dietmar Trenner GmbH*, 408 F.3d 1374, 1379 (Fed. Cir. 2005). Elan offered no evidence that the few allegedly crystalline nanoparticles contributed in any way to Abraxane, let alone as to how these particles motivated Abraxane purchases. Absent evidence that the allegedly infringing nanoparticles affected customer demand for Abraxane, Elan is not entitled to a royalty based on Abraxane revenues. *See Izumi Prods. Co. v. Koninklijke Philips Elecs. N.V.*, 315 F. Supp. 2d 589, 614-15 (D. Del. 2004) (barring reasonable royalty damages for claim to portion of razor based on sales of entire razor where claimed portion not basis for customer demand).

Because Elan failed to provide a sufficient evidentiary basis for its damages claim, the record does not support the damages award and judgment as a matter of law is appropriate. *Trell*, 912 F.2d at 1446-67; *Devex Corp. v. General Motors Corp.*, 667 F.2d 347, 362-63 (3d Cir. 1981) (awarding no damages in light of evidentiary void).

VIII. ABSENT JMOL, A NEW TRIAL SHOULD BE GRANTED

This Court may grant a new trial under Rule 59 where, for example, the verdict is against the clear weight of the evidence and a miscarriage of justice would result if it were allowed to stand; damages are excessive; there is unfair surprise; or substantial errors were made in admitting evidence. *Estate of Smith v. Ciritella*, C.A. No. 04-1254-GMS, 2008 U.S. Dist. LEXIS 36122, at *3-4 (D. Del. May 5, 2008); *Becton Dickinson & Co. v. Tyco Healthcare Group LP*, C.A. No. 02-1694-GMS, 2006 U.S. Dist. LEXIS 14999, at *7 (D. Del. Mar. 31, 2006). If the Court does not grant Abraxis's motion for JMOL, Abraxis requests a new trial.

A. The Clear Weight Of Evidence Does Not Support The Jury's Verdict

The clear weight of evidence does not support the jury's verdict on infringement, validity, enforceability, or damages.

As to infringement, in addition to the evidence discussed above, Abraxis provided overwhelming XRPD evidence proving that Abraxane's paclitaxel is amorphous. Tr. 1013:8-1016:23; 1056:1-1064:1; 1252:17-1254:7; 1263:13-1271:21; 1340:14-24; 1362:22-1367:6; DX041; DX605; DX653-656; JX006; JX021; JX085. Although Elan's experts agreed that XRPD is the gold standard, Elan provided no XRPD testing evidence. Tr. 1052:14-1055:15; 1749:20-1750:1; 407:13-408:20; DX450; DX627; *see also* 1040:23-1041:13. XRPD is the test Elan routinely used to assess crystallinity, and is the test used in the parent '684 patent (the '363 patent does not report crystallinity testing). Tr. 400:5-408:21; 1064:2-1066:3; JX047; JX058; JX072; JX082; DX241; DX264; DX265; DX295; DX559. Dr. Liversidge admitted that Elan planned to use XRPD to analyze Abraxane, but did not do so only "on advice of counsel." Tr. 408:14-21. Properly viewed, Dr. Munson's ssNMR testing confirmed that the paclitaxel in Abraxane is not crystalline. *Compare* DX644 *with* DX646; *see also* Tr. 1076:5-1081:22. Elan wrongfully withheld "unfavorable" testing evidence from Abraxis. Those "unfavorable" results should have been accorded substantial weight. D.I. 577; J.I. 4.3.

As to invalidity and unenforceabilty, the evidence discussed in the JMOL section above demonstrates that the clear weight of evidence was in Abraxis's favor.

As to damages, the Court should grant Abraxis a new trial or remit the damage award for the reasons discussed above. Elan's damages award is excessive and against the clear weight of the evidence, and the Court should grant a new trial or remit damages consistent with the absence of evidence that any infringing particles contribute to Abraxane. *Lindemann*, 895 F.2d at 1407 (awarding minimal damages due to plaintiff's failures of proof); *Devex Corp.*, 667 F.2d at 362-63 (awarding no damages where record lacked basis for appropriate calculation); *Lucent*

Techs., Inc. v. Gateway Inc., 509 F. Supp. 2d 912, 936-40 (S.D. Cal. 2007) (granting new trial on damages where no evidence showed contribution of patented technology to whole product).

B. Elan's "More-Than-One" Particle Theory Was Trial By Ambush

Once again hiding the ball, D.I. 437 at 3 n.2, Elan based its infringement case at trial on a new "more-than-one particle" theory. During discovery, Elan's consistent theory was that Abraxane infringed as a whole because its particles purportedly contained more than 10% crystallinity. Elan's experts Drs. Munson and Brittain deployed this theory in their expert reports, opining infringement based on 12% crystallinity. A1991-2 (Munson Op. Rpt) ¶¶ 24-25, 27; A1995-2053 (Brittain Op. Rpt). No expert report or deposition testimony opined that Abraxane held "more than one" crystalline particles in trillions, nor that any particle was "entirely crystalline." Likewise, the single paragraph on literal infringement in Elan's Trial Brief stated only that Dr. Munson's testimony would establish that Abraxane contains "the specific amount of crystallinity required by the claims," *i.e.*, between 99.9-10%. D.I. 507-508, Ex. 10 at 8. *See* the Court's Form Final Pretrial Order, at 3 n.7 ("Any theory of liability or defense that is not expressed in a party's trial brief will be deemed waived"); *see also* D. Del. LR 16.3(c)(8).

Elan first unveiled its theory in Dr. Munson's second supplemental expert report, served the week before trial. A2054-8 (Munson Second Supp. Rpt); *see also* D.I. 575 at 9 (Elan Motion for Reconsideration dated May 22, 2008 arguing that "few, if any materials, are found in which the 'entire' material is crystalline"). Abraxis objected to this new report, and the Court agreed, precluding Dr. Munson from testifying to his new theory. D.I. 593, 5/29/08 Hrg. Tr. 10:11-13:19; 21:8-10. Nevertheless, at trial, Elan abandoned its "12% crystallinity" theory and pressed its "more-than-one-crystalline-particle" theory, over Abraxis's objections. *See, e.g.*, Tr. 1711:9-1712:4; *see also* Tr. 9:1-12:3; 670:9-672:14; 716:25-718:16; D.I. 593, 22:16-23:9.

Elan's strategy of "trial by ambush" prejudiced Abraxis, depriving Abraxis of discovery on this theory and the opportunity to have its technical and damages experts consider it before trial. D.I. 593, 13:9-19. Nor could Abraxis and the Court explore the claim construction, invalidity, and damages implications of Elan's theory. Critically, understanding that Elan's theory was directed to Abraxane as a whole, Abraxis agreed that claim limitations such as "average effective particle size" were not in dispute. D.I. 507, Ex. 1 at 4. Had Abraxis known that Elan would focus on a few deviant crystalline particles, Abraxis would have put Elan to its proof on other claim limitations. Elan's entire infringement case was predicated on its new "more than one particle" theory, prejudicing Abraxis by depriving it of a fair trial. *See Becton Dickinson,* 2006 U.S. Dist. LEXIS 14999, at *32-34.

C. Dr. Munson Should Not Have Been Allowed To Testify

Dr. Munson should not have been allowed to offer opinion testimony on crystallinity. His testimony was based on unreliable science and should have been excluded. *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 322 (3d Cir. 2003). Dr. Munson's testimony at trial only reinforced the bases for exclusion argued in Abraxis's Motion in Limine No. 2. *See* D.I. 465 at 6-10. He testified that ssNMR is a "quantitative" technique and claimed that 8% of Abraxane's paclitaxel is crystalline, but he admitted that he "can do much better in terms of quantitation if it's required." Tr. 710:5-712:6. Instead of "doing much better" for the courtroom, however, Dr. Munson acknowledged an unprecedented 50% "best guess estimate" error rate—far higher than any error rate he had previously published. Tr. 710:5-23. But there was no basis even for qualitative testimony from Dr. Munson on crystallinity. As he acknowledged, Elan's claim of crystallinity rested on a "third peak" that his assistant arbitrarily placed in the test results. Tr. 707:8-12; 666:8-668:3; 670:9-24; 704:19-705:3. Dr. Atwood explained that this third peak was improper. DX169; DX505; Tr. 1088:21-1090:5; 1093:1-15; 1095:4-22. Not only

did Elan not rebut Dr. Atwood's testimony, Tr. 1182:19-21, but Elan's expert, Dr. Brittain, agreed that this peak was superfluous. Tr. 1090:7-23. Moreover, Dr. Munson testified that he doubled his initial 3.5%-4.0% crystallinity based on the speculative hypothesis that Abraxane contained a previously unknown form of crystalline paclitaxel. Tr. 707:13-708:20.

Dr. Munson also should not have been allowed to testify to the legal conclusion that particles within Abraxane meet the crystalline limitation, because he had no admissible evidence supporting entirely crystalline particles and that opinion was not in his first two expert reports. D.I. 593, 5/29/08 Hr. Tr. 21:8-10; A1991 (Munson Op. Rpt. at ¶25) (limited to opinions of "*mostly* crystalline" particles and greater than 10% crystallinity in Abraxane as a whole); (Abraxis MIL No. 2); *see also* D.I. 593, 5/29/08 Hrg Tr. 10:14-13:19; *Gen. Elec. Co. v. Nintendo Co.*, 179 F.3d 1350, 1359 n.5 (Fed. Cir. 1999) (conclusory expert testimony cannot satisfy plaintiff's burden); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1311 (Fed. Cir. 2000) ("there must be factual support for an expert's conclusory opinion").

Abraxis was prejudiced by Dr. Munson's testimony. It was the cornerstone of Elan's infringement argument, Tr. 1707:3-1712:19, and its erroneous admission warrants a new trial.

IX. CONCLUSION

This Court should enter judgment as a matter of law for Abraxis on non-infringement of '363 claims 3 and 5, invalidity and unenforceability of '363 claims 1, 3, 5, 10, and 11 and '025 claims 1-3 and 13-15, and damages. In the alternative, the Court should order a new trial on any issue for which judgment is not entered for Abraxis, or, as to damages, remit.

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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:

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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:

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