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

DEFENDANT ABRAXIS BIOSCIENCE, INC.'S ANSWERING BRIEF IN OPPOSITION TO ELAN'S CONDITIONAL MOTION FOR NEW TRIAL

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I. NATURE AND STAGE OF THE PROCEEDINGS

The Court granted judgment as a matter of law to Abraxis under Federal Rule of Civil Procedure 50(a) on Elan's claims of inducement and contributory infringement and on infringement under the doctrine of equivalents. The jury returned a verdict in favor of Elan on direct 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.

Abraxis has renewed its motions for judgment as a matter of law of no direct infringement, invalidity, and unenforceability and for a new trial, and has moved that the Court amend the judgment and find that Elan engaged in inequitable conduct. D.I. 633; D.I. 634. Elan did not move for judgment or a new trial on the doctrine of equivalents.[1] Elan has moved, conditionally, for a new trial on inducement and contributory infringement.

II. SUMMARY OF ARGUMENT

1) Elan's Conditional Motion for New Trial on Its Claims of Induced and Contributory Infringement ("Motion"), D.I. 638, should be denied because any alleged error in granting judgment as a matter of law ("JMOL") under Rule 50(a) is not a basis for a new trial under Rule 59 and Elan is improperly seeking reconsideration of the Court's JMOL ruling.

2) Elan's "conditional" Motion should also be denied because the condition of granting Abraxis's Rule 50(b) JMOL would itself defeat the Motion. Elan's Motion is conditioned on this Court or the Federal Circuit "vacat[ing] or modify[ing] the jury verdict and judgment" of direct infringement. However, granting Abraxis's motion for judgment as a matter

[1] Judgment was correctly entered against Elan's theory under the doctrine of equivalents for the reasons set forth in D.I. 605 § III.D.

of law of no direct infringement would establish that a showing of direct infringement by "others" is also not possible, rendering a new trial on indirect infringement futile.

3) This Court correctly held that there is no evidence on which a reasonable jury could find the intent necessary for inducement or contributory infringement. Thus, even if Abraxis is granted a new trial on direct infringement, there is no basis for a retrial of inducement or contributory infringement.

III. STATEMENT OF FACTS

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

IV. ARGUMENT

A. Elan's Motion Improperly Seeks Reconsideration.

Elan's motion for a new trial to reverse this Court's grant of judgment under Rule 50(a) seeks relief that Rule 59 does not provide. While Rule 59 allows a new trial for reasons "heretofore granted in the courts of the United States," Elan cites, and Abraxis has found, no instance of a new trial granted by a district court reversing its own grant of a Rule 50(a) motion, *i.e.*, a pre-jury directed verdict. Elan's reliance on *Smith v. Transworld Drilling Co.* confirms the lack of basis for its motion. *Smith* involved the plaintiff's appeal after two separate jury verdicts reaching different results, not a Rule 50(a) motion granted by the district court. *Smith v. Transworld Drilling Co.*, 773 F.2d 610, 612 (5th Cir. 1985).

Because indirect infringement was not the subject of a jury verdict, as with summary judgment, Elan's proper recourse is appeal. *See* 9B Charles Alan Wright and Arthur R. Miller, Federal Practice and Procedure: Civil § 2531 (3d ed. 2008) ("If either version of the motion for judgment as a matter of law is granted, the case is at an end.").

Elan's Motion is effectively a disguised, and untimely, motion for reconsideration. D. Del. LR 7.1.5.[2] Such motions carry a high burden, not even addressed by Elan's motion, and are granted only "sparingly." *Id.*; *see also Tristrata Tech., Inc. v. ICN Pharms., Inc.*, 313 F.Supp. 2d 405, 407 (D. Del. 2004); *Karr v. Castle*, 768 F. Supp. 1087, 1090 (D. Del. 1991).

B. Granting Abraxis Judgment as a Matter of Law of No Direct Infringement Would Make a Jury Trial on Indirect Infringement Improper.

Elan's Motion is conditioned on the jury verdict and judgment of direct infringement being "vacate[d] or modif[ied]." However, without evidence of direct infringement, indirect infringement cannot be found. *E.g., Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004) (direct infringement necessary for a finding of indirect infringement).

Elan's claims of indirect infringement are based on "the preparation and administration of reconstituted Abraxane®" by "others." D.I. 639 at 2, n.2. But Elan has not explained how it could prove direct infringement by others if this Court grants judgment for Abraxis based on Elan's lack of sufficient evidence of direct infringement of claims 3 and 5 of the '363 patent by Abraxis. The Court would necessarily be finding that the particles in Abraxane powder do not meet all of the claim limitations or that a largely amorphous product cannot infringe. D.I. 642 § IV. Elan presented no evidence that the preparation of Abraxane for administration changes the crystallinity or amorphousness of the paclitaxel, or the crosslinking of the albumin in Abraxane particles. Thus, there is no more evidence of direct infringement by "others" than by Abraxis, and a new trial would be improper.

[2] The Court granted Abraxis's Rule 50(a) motion on June 11, 2008, but Elan did not file the Motion until June 30, 2008, after the ten day deadline for filing motions for reargument under Local Rule 7.1.5. Tr. 1633:1-5.

C. Regardless of the Status of the Direct Infringement Judgment, the Court Correctly Granted Judgment as a Matter of Law of No Indirect Infringement.

Any new trial should not be encumbered by Elan's unsupported claims of indirect infringement. This Court correctly found no legally sufficient evidentiary basis for a reasonable jury to find that Abraxis had induced infringement or contributorily infringed. Tr. 1633:1-5. Abraxis understood the '363 patent to cover crystalline and noncrosslinked particles, and even Elan's theory of the case acknowledged that Abraxis designed and made its particles overwhelmingly amorphous and with crosslinked surface modifiers.

1. Abraxis Did Not Induce Infringement.

For its induced infringement claim, Elan had to prove that Abraxis acted with the "specific intent" of inducing infringement. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) ("the inducer must have an affirmative intent to cause direct infringement"). Elan failed to introduce any evidence of an affirmative intent by Abraxis to create entirely crystalline particles, particles with noncrosslinked surface modifiers, or entirely crystalline particles with noncrosslinked surface modifiers.[3] And it is undisputed that the paclitaxel in Abraxane is at least overwhelmingly amorphous, and that the albumin surface modifiers include dimers, oligomers and polymers. *See* D.I. 642 § IV. The evidence Elan cites—that Abraxis wanted doctors to treat cancer patients using Abraxane and that Abraxis knew of the '363 patent—is insufficient to show a specific intent to induce *infringement*. *See DSU Med. Corp.* at 1305-6 (inducement rule premises liability on "purposeful, culpable expression and conduct" such as "clear expression or other affirmative steps taken to foster infringement"). Elan did not

[3] The jury's finding of nonwillfulness further supports the lack of any intent to induce infringement or to contributorily infringe, making any alleged error in granting Abraxis's Rule 50(a) motion harmless. Elan has not moved for judgment or a new trial on willfulness. Moreover, Abraxis cannot fairly be found to "intentionally" induce infringement under an infringement theory ("one or more particles") that Elan did not concoct until the eve of trial.

carry its burden of proof with evidence of any intent, purposeful conduct, or affirmative steps to foster infringement, and judgment was properly entered for Abraxis.

Though Abraxis should not be required to disprove intent, the uncontradicted documents and testimony of Drs. Soon-Shiong and Desai show Abraxis's intent to avoid crystalline particles. JX006; JX011; JX020; JX021; DX041; DX605; Tr. 1227:9-1229:5; 1232:5-1233:20; 1238:7-1240:19; 1252:17-1254:7; 1263:13-1267:16; 1293:8-1297:7; 1339:13-1340:24; 1366:17-1367:6; 1503:12-1505:10; 1506:18-1513:1. Abraxis's goal of rapid dissolution in the bloodstream is in direct opposition to the presence of slowly dissolving crystalline particles. Tr. 1220:15-1221:19; 1388:19-1389:22; 1506:18-1513:1. Abraxis's data that Abraxane particles include intermolecularly crosslinked albumin dimers, oligomers and polymers provides additional evidence of its belief that Abraxane does not infringe the '363 patent. DX076; DX107; DX112; Tr. 1285:15-1288:5; 1375:11-14; 1377:15-1381:23; 1503:12-1505:10; 1506:18-1513:1, *see also DSU Med. Corp.*, 471 F.3d at 1307 (citing evidence that defendant did not believe its product infringed). Looking at all the evidence, no reasonable jury could find intent to induce infringement, and this Court's entry of judgment against Elan was proper.

While Elan tries to make much of Abraxis's decision not to obtain an opinion of counsel regarding the '363 patent, there is no requirement that an opinion be obtained, and the unchallenged testimony of Drs. Soon-Shiong and Desai was that they understood the differences between Abraxis's amorphous and crosslinked technology and Elan's crystalline and noncrosslinked approach to be "very clear." Tr. 1224:15-1225:16; 1227:9-1229:5; 1513:25-1515:9; 1544:15-1545:12; 1548:11-25. In the willfulness context, this Court has held that whether an opinion of counsel was obtained is merely *part* of the analysis. *See* D.I. 612, Jury

Instruction ("J.I.") 4.6 (whether a reasonable competitor would have secured legal advice one of five nonlimiting factors for willful infringement); *DSU Med. Corp.*, 471 F.3d at 1307. Elan presented no evidence that a reasonable competitor would have obtained an opinion of counsel, and completely ignores the other factors in the Court's instruction, none of which supports intent in this case. *Id.*

2. Abraxis Did Not Contributorily Infringe.

Like inducement, contributory infringement requires a specific mental state for a finding of indirect infringement: "whoever offers to sell or sells…a component of a patented machine, manufacture, combination or composition…*knowing the same to be especially made or especially adapted for use in infringement*…shall be liable as [an] infringer". 35 U.S.C. § 271(c) (emphasis added). As the Federal Circuit held in *Golden Blount, Inc. v. Robert H. Peterson Co.*, Elan had to show that Abraxis "knew that the combination for which its components were especially made was both patented and infringing." 365 F.3d 1054, 1061 (Fed. Cir. 2004) (citations omitted). Elan's purported evidence, the unsurprising facts that Abraxis wants to sell Abraxane for patient use and that it appropriately reviewed patents in the field before marketing Abraxane, does nothing to show the requisite knowledge or intent to infringe. Elan failed to present any evidence that Abraxis believed that the noninfringing particles in Abraxane powder are "especially made or especially adapted" to become infringing when reconstituted (they do not). And there is no evidence that Abraxis knew or believed that the particles in Abraxane met either the crystalline medicament or the noncrosslinked surface modifier limitations, much less that they met both limitations.[4] To the contrary, the evidence establishes that Abraxis knew that its paclitaxel nanoparticles are amorphous and crosslinked, and thus not covered by Elan's patent claims to crystalline, noncrosslinked particles. JX006; JX011; JX020; JX021; DX041; DX107;

[4] Even after a full trial, there is no evidence of any such particles. *See* D.I. 642 §§ IV.A.

DX112; Tr. 1224:15-1225:16; 1227:9-1229:5; 1276:9-1282:17; 1513:25-1515:9; 1544:15-1545:12; 1548:11-25. Abraxis had no reason to further study Abraxane when every "gold standard" XRPD test established the consistent amorphousness of commercial Abraxane.[5] DX041; Tr. 1040:18-1041:13; 1096:23-1097:8; 1266:20-1268:18. Thus, it would be impossible for a reasonable jury to find that Abraxis *knew* of special adaptation or of infringement. The Court correctly granted judgment as a matter of law of no contributory infringement.

Elan's reliance on *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster*, 545 U.S. 913 (2005) for a presumption of intent is misplaced. D.I. 639 at 15. To begin, *Grokster* confirms that "[o]ne infringes contributorily by intentionally inducing or encouraging direct infringement." *Grokster* at 930. As discussed, there is no evidence that Abraxis intentionally induced or encouraged infringement. Contrary to Elan's argument, the *Grokster* Court's statement that a party will be "presumed to intend the natural consequences of his acts" has no application here, where Elan's theory of direct infringement is premised on an undetected "more than one particle" out of 62 trillion. The *Grokster* Court explained that the presumption creates no injustice where the article is "good for nothing else but infringement." *Id.* at 932. Here, even under Elan's view of the evidence, the paclitaxel in Abraxane's nanoparticles is largely amorphous, and any presumption was overcome by overwhelming evidence that Abraxis intended to have amorphous, not crystalline particles. Tr. 1693:7-19; 1711:2-12. Liability for contributory infringement was properly removed from the jury's consideration.

[5] Elan never performed tests on the crystallinity of individual nanoparticles to support its new "one or more particles" infringement theory before or during this litigation, making its characterization of Abraxis as "intransigent" for not performing such tests specious. Tr. 1711:2-12; D.I. 639 at 13.

V. CONCLUSION

For the reasons stated above, this Court should deny Elan's conditional motion as improperly seeking reconsideration and ineffective relief, and because this Court properly granted judgment as a matter of law of no inducement or contributory infringement under Rule 50(a).

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CERTIFICATE OF SERVICE

I, Michele Sherretta Budicak, Esquire, hereby certify that on July 18, 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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