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October 19, 2007

BY CM/ECF

The Honorable Gregory M. Sleet
United States District Court for the District of Delaware
844 North King Street
Wilmington, DE 19801

Re: Elan Pharma Int'l Ltd. v. Abraxis Bioscience, Inc. – C.A. No. 06-438-GMS

Dear Chief Judge Sleet:

Defendant Abraxis BioScience, Inc. ("Abraxis") hereby replies to plaintiff Elan Pharma Int'l Ltd.'s ("Elan") opposition to Abraxis's October 10, 2007 letter requesting that the Court dismiss Elan's newly added contentions that Abraxis infringes claims 4, 14, 16 and 17.

Despite the considerable length of Elan's letter brief, Elan does not dispute the essential facts set forth in Abraxis's motion. As explained in Abraxis's letter, from December 2006 through the end of fact discovery, Elan stated consistently that the only claims of the '363 patent at issue were 1-3, 5, 8-11 and 15. Elan first asserted that Abraxis infringed claims 4, 14, 16 and 17 of the '363 patent on September 28, 2007, more than six weeks after the close of fact discovery and the day expert reports were due. (Abraxis Letter at 2 (D.I. 363); Elan Opposition at 1-2 (D.I. 370).) Elan waited to do so despite having had all of the information upon which it now relies in support of its new infringement contentions by March 2007, six months earlier. (Abraxis Letter at 2; Elan Opposition at 4, n.2.)

Elan's Delay Until After Fact Discovery Closed to Assert New Claims is Inexcusable

One searches the opposition brief in vain for any conceivable justification for Elan's delay until after the court-ordered fact discovery cutoff to amend its interrogatory responses to add new claims. Its assertion that it has not yet completed the depositions of Drs. Desai and Soon-Shiong and other discovery is a classic red herring – the information it relied upon to assert these claims has been indisputably available and known to Elan since March, and

since these depositions and other discovery had not taken place at the time the claims were added they obviously are not the source of these new allegations. Its argument that the fact discovery cutoff has been extended is equally misplaced: the Court's order explicitly limits the extension to the issues raised in the parties' motions and cross motions. (October 9, 2007 Order amending the Scheduling Order (D.I. 362).)

The Case Law Supports Preclusion

Elan mischaracterizes *O_2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1369-70 (Fed. Cir. 2006), cited by Abraxis, as supposedly turning on the fact that there was a violation of specific local rules regarding amending pleadings. To the contrary, as explained in Abraxis's letter, the Federal Circuit relied on Fed. R. Civ. P. 16 and a violation of case management orders, characterizing the local rules as "essentially a series of case management orders" and noting that "the deadlines for submission of contentions in this case were explicitly included in a supplemental case management order." Thus, *O_2 Micro* is on all fours with this case: both involve a party violating a case management order by amending its contentions to add new claims after the close of discovery, without justification. Elan's argument that to abide by a fact discovery cutoff would prevent a party who learned new facts during the waning days of discovery from supplementing its responses is a non-sequitur – it is undisputed here that Elan had all of the relevant information in March – long before the fact discovery cutoff.

Elan attempts to distinguish this Court's *Creo* case on the grounds that Elan, unlike the defendant in that case, had filed motions to compel. This is truly a distinction without a difference, as Elan's motions to compel have nothing whatsoever to do with the newly added claims, which depend entirely on information available to Elan by March 2007.

Elan's argument that it was not on "notice" that it was impermissible to add new claims after the discovery cutoff because there is no specific local rule or order that so states has no merit. It was on notice of the fact discovery cutoff, and it could not possibly have believed that it could freely amend its interrogatory responses to add new claims after that date based on information that had long been available to it. *See, e.g., Am. Stock Exchange, LLC v. Mopex, Inc.*, 215 F.R.D. 87, 95 (S.D.N.Y. 2002) (granting motion to preclude defendant from asserting additional claim first identified in supplemental interrogatory response served approximately one month after the close of fact discovery and just before exchange of expert reports).

Elan's lengthy discussion of treatises and other authorities discussing interrogatories in general is unavailing. None of these authorities suggests that a party may ignore case management orders, and wait until long after fact discovery closes to assert new patent claims. Elan's argument that the pleadings "control" is meritless; as *O_2 Micro*, *Creo* and *Am. Stock Exchange* make clear, the notice pleading rules do not permit a party to ignore case management orders and the rules of discovery and add new claims after the close of fact discovery.

Elan's Argument that "Anionic Surfactant" Does Not Require Construction is Wrong

Elan does not contest that the term "anionic surfactant" was neither briefed by the parties nor construed by the Court during the Markman proceedings. Nor does it dispute that it would be a significant burden on the Court and the parties if they were forced to go through a second round of Markman briefing and argument to construe this claim term. Indeed, the disruption from this would go even further, requiring not only a new round of briefing and hearing, but possibly supplements to expert reports and additional expert depositions.

Instead, Elan seeks to short-circuit the entire Markman process by throwing out one dictionary definition of the term "anionic" in isolation, without any evidence that one of ordinary skill in the art would interpret the two-word phrase "anionic surfactant" using that definition. Abraxis objects in the strongest possible terms to Elan's attempt to further prejudice it by forcing it to file what amounts to a Markman opposition brief on 48 hours notice. Abraxis has not yet had the opportunity to fully research and develop its claim construction position with respect to the term "anionic surfactant." Elan's attempt to avoid the rigors of the Markman proceedings established by this Court only highlights the prejudice to Abraxis from Elan's late assertion of these claims.

Abraxis Would be Prejudiced by Addition of New Claims After the Close of Fact Discovery

Finally, Elan's argument that Abraxis will not be prejudiced by the assertion of the new claims is plainly wrong. Elan does not contest that it would be fundamentally unfair to prevent Abraxis from conducting fact discovery into these claims. Instead, it seems to argue that Abraxis had soothsaying powers, and conducted discovery into these claims even though they were not in the case. This is nonsense. The deposition questions Elan cites relate to various aspects of surface modifiers (which are of course an element of all of the asserted claims of the '363 patent), but are not directed to the specific ranges of the claims Elan seeks to add (Nos. 4, 16 and 17), or to the anionic surfactants of claim 14. There can be no reasonable dispute that by failing to assert these claims until after the close of fact discovery, Elan has prejudiced Abraxis by precluding it from conducting *any* fact discovery into them. *See, e.g., Am. Stock Exchange*, 215 F.R.D. at 95 (adding additional claims after close of discovery precluded because otherwise plaintiff would be "(1) deprived of the opportunity to pursue needed fact discovery unless it was willing to accept a substantial delay in the case, and (2) compelled to have its expert assess the issue at the last minute without the benefit of fact discovery").

Elan also has no answer to the fact that Abraxis has already served its opening expert reports on validity, and that they did not include the new claims because they were not in the case. Nor does Elan dispute that rebuttal reports are due on October 29 – a little more than a week from today. Elan's late assertion of these claims would wreak havoc with the Court's scheduling order, and put Abraxis at an unfair disadvantage in responding to these claims. It would be fundamentally unfair and extraordinarily disruptive to require Abraxis to develop new expert reports on these late-added claims. Elan's conduct, if condoned, would result in inevitable delays in the completion of expert discovery, duplicative expert depositions, and a cascade of further delays to the remainder of the pretrial schedule.

Conclusion

The record is clear: Elan flouted the Court's case management order by choosing to amend its interrogatory answers an assert four new claims long after the close of discovery. The delay prejudiced Abraxis. Under Fed. R. Civ. P. 16(f)(1)(C) and the Court's inherent authority to enforce its scheduling orders, Elan should be precluded from asserting Claims 4, 14, 16 and 17 of the '363 patent.

Respectfully submitted,

/s/ *Jeffrey T. Castellano*

Jeffrey T. Castellano (#4837)

JTC:mcm

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