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BY CM/ECF **PUBLIC VERSION**

The Honorable Gregory M. Sleet
U.S. District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. 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:

Elan's opposition to Abraxis's proposed summary judgment motion of noninfringement on the '363 patent reinforces why summary judgment is appropriate here. Elan's letter confirms the fundamental problem with its case: the particles in Abraxane, even under Elan's experts' view, consist overwhelmingly of amorphous, not crystalline, medicament, but Elan told the Patent Office over and over again that crystallinity was critical to patentability.

(1) Whether Literally Or By Equivalents, The Claims Cannot Cover Particles With Overwhelmingly Amorphous Medicament.

Elan's argument necessarily ignores the many statements in the '363 patent specification and prosecution history where the applicants explicitly distinguished their crystalline particles from amorphous particles, and did so without referring to solvents. (D.I. 446 at 3, n.3 & n.4 (patentee statements).) That crystallinity is a basic and novel property should be determined as a matter of law. Elan's cited case, *AK Steel Corp. v. Sollac*, 344 F.3d 1234 (Fed. Cir. 2003), supports that conclusion. *See id*. at 1239-41 (affirming summary judgment of noninfringement, reasoning that "the specification directly speaks to and conclusively answers that question [i.e., what affects the basic and novel properties of the invention]"; referring to basic and novel property as issue of claim construction).

Elan's assertion that the prosecution history is irrelevant (D.I. 452 ("Elan Opp.") at 3-4) reinforces that Elan must run from the representations made to the Patent Office in order to pursue its claim against Abraxis. This claim of irrelevance, moreover, flies in the face of the close focus Federal Circuit precedent pays to the intrinsic evidence, *including* the prosecution history. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1319 (Fed. Cir. 2005) (en banc), *cert. denied*, 126 S. Ct. 1332 (2006). Elan repeatedly told the Patent Office during prosecution that its crystalline particles were patentable *because they were crystalline*. Elan may not now ignore those representations by asserting legal irrelevance.

Elan's argument that reduced toxicity and enhanced efficacy are important properties of the claimed invention, and hence its *only* "basic and novel properties" misses the point. Toxicity and efficacy are important properties in many pharmaceutical inventions, but Elan cannot explain why crystallinity is not a basic and novel property of *this* invention – particularly when Elan told the Patent Office over and over that it was. As a matter of law, Elan cannot so dramatically contradict itself and now claim that crystallinity is merely incidental, and the amorphousness of Abraxane's particles non-consequential.[1]

Elan's claim that Abraxis would overrule the Court's claim construction (Elan Opp. at 2) mischaracterizes Abraxis's Opening Claim Construction brief. There, we argued that Elan's proposed open-ended use of "include" effectively converted the term "consisting essentially of" into "comprising," and hence was intended to embrace amorphous medicaments. (D.I. 140 (Abraxis's Opening Claim Construction Brief), at 17.) The Court in fact rejected Elan's proposed use of "includes." Abraxis's summary judgment argument, far from seeking to overturn the Court's claim construction, applies it to the evidence viewed in the light most favorable to Elan – which shows that the paclitaxel in Abraxane is at least overwhelmingly amorphous, not crystalline.

The foregoing establishes why Elan has no literal infringement case. Infringement under the doctrine of equivalents suffers from the same basic problem. Elan does not dispute that prosecution history estoppel prevents a patentee from reclaiming subject matter it explicitly disclaimed. Elan argues again that the patentees distinguished only amorphous medicaments contaminated with solvents, as opposed to amorphous medicaments in general. Elan addresses one statement regarding the Devissaguet reference, but ignores that the patentees made numerous statements highlighting crystallinity and disclaiming amorphous particles *in general*. (Elan Opp. at 4.) Elan is legally barred from asserting infringement of the crystalline limitation under the doctrine of equivalents.

(2) Even Assuming the Claims Cover Overwhelmingly Amorphous Particles, Elan Has No Infringement Case Under the At Least 10% By Weight Crystalline Medicament Requirement of the Claims.

Elan's answering letter fails adequately to respond to Abraxis's argument that Munson's "best guess estimate" lacks sufficient probative value to raise a genuine issue of material fact whether Abraxane's particles contain 10% crystalline medicament by weight. Elan does not dispute our quotation of Munson's deposition, nor does Elan point to any bolstering of Munson's

[1] Contrary to Elan's assertion, the court in *Talbert Fuel* affirmed a grant of summary judgment for the defendant on *both* literal infringement and infringement under the doctrine of equivalents. *See, e.g., Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 1375 (Fed. Cir. 2002), *vacated and remanded on other grounds*, 537 U.S. 802 (U.S. 2002), *aff'd on remand*, 347 F.3d 1355 (Fed. Cir. 2003). Strikingly similar to the case at bar, the court rejected the plaintiff's interpretation of "consisting essentially of" as inconsistent with the prosecution history. *Id.*

testimony that would add credence to his "over 8%" contention. Nor does Elan contest Abraxis's observation that Elan failed to properly establish the percentages "by weight" of crystalline medicament and surface modifier in the particles as recited in the claims.

Unable to make a showing as to Abraxane's particles in general, Elan has now shifted its infringement position so that it turns on the purported crystalline content "*in each individual particle*." (Elan Opp. at 5.) (emphasis in original). Elan has no support for this theory.

First, Munson's contention that Abraxane samples "include individual particles that are mostly crystalline" (Munson Report ¶ 27.D) ignores the remaining limitations of the claim. Elan concedes that it measured the particles only "*collectively*," not individually. (Elan Opp. at 4.) (emphasis in original). Elan offers no complete particle-by-particle infringement analysis. Do the individual supposedly crystalline particles contain, for example, the requisite "non-crosslinked surface modifier"? On these issues, Munson, the rest of Elan's experts, and Elan's responses to our infringement contention interrogatories are completely silent.

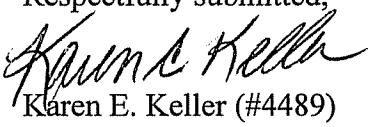
Moreover, as a review of his expert report reveals, Munson's contention that individual particles might be crystalline (even when he purportedly measured only a few percent of crystallinity overall) is not supported, and constitutes mere speculation that is insufficient to defeat summary judgment.

Finally, Elan's assertion that Abraxis conducted no testing of it own to disprove Munson's testing is of no moment. Elan, as the patentee, carries the burden of affirmatively proving infringement. It is now even clearer that Elan cannot meet that burden.

Conclusion

Even under a charitable view of Elan's evidence, the paclitaxel in Abraxane is overwhelmingly amorphous. The '363 patentees made clear that they claimed crystalline, not amorphous, particles as their invention. As a matter of law, particles containing predominantly amorphous paclitaxel do not consist essentially of crystalline drug. Abraxis should be allowed to file a motion for summary judgment of noninfringement and end Elan's infringement claim on summary judgment.

Respectfully submitted,



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