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October 17, 2007

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

VIA ELECTRONIC FILING

Re: *Elan Pharma International, Ltd. v. Abraxis Bioscience, Inc.*, C.A. No. 06-438-GMS

Dear Chief Judge Sleet:

This letter constitutes Elan Pharma International Limited's ("Elan") response to Abraxis BioScience, Inc.'s ("Abraxis") motion to dismiss newly added infringement contentions pursuant to Fed. R. Civ. P. 16(f)(1)(C) for violation of the Court's Scheduling Order, which was filed on October 10, 2007. (D.I. 363)

A. Pleadings, not contention interrogatories, define the proof admissible at trial.

On July 19, 2006, Elan filed this lawsuit alleging that Abraxis infringes the claims—without limitation—of U.S. Patent Nos. 5,399,363 and 5,834,025. Prior to the completion of the parties' Federal Rule of Civil Procedure 26(f) conference, Abraxis served Elan with Interrogatory No. 1 seeking Elan's infringement contentions and reference to the documents and evidence upon which Elan relies for such contentions:

> Please explain in detail why Elan contends that Abraxis infringes U.S. Patent Nos. 5,399,363 and 5,834,025. Please provide an element-by-element claim chart including your contentions and references to the documents and other evidence upon which Elan relies.

Elan objected that Abraxis's Interrogatory No. 1 prematurely sought expert testimony and information regarding contentions that were not yet fully developed. Elan nonetheless answered the Interrogatory with the information available to it at the time. Since then, Elan has supplemented its response five times at appropriate intervals in compliance with Federal Rule of Civil Procedure 26(e). *See* Fed. R. Civ. P. 26(e). In its most recent supplementation, Elan

included for the first time specific infringement contentions regarding claims 4, 14, 16 and 17 of the '363 Patent.

Despite Elan's pleading, which provided Abraxis with fair notice that Elan was asserting the claims of the '363 Patent, Abraxis now seeks an order dismissing and/or precluding Elan from offering evidence at trial regarding its newly asserted contentions. Abraxis's motion for dismissal and/or preclusion is without merit and should be denied.

As a threshold matter, "[i]nterrogatories do not supersede or supplement pleadings, nor do they bind parties as an allegation or admission in a pleading or pre-trial order." *See Donovan v. Crisostomo*, 689 F.2d 869, 875 (9th Cir. 1982) (citing *Marcoin, Inc. v. Edwin K. Williams & Co., Inc.*, 605 F.2d 1325, 1328 (4th Cir. 1979); *Erie Freed v. Lackawana Ry. Co.*, 445 F.2d 619, 620-21 (6th Cir. 1971) *cert. denied*, 404 U.S. 1017, (1972); *Victory Carriers, Inc. v. Stockton Stevedoring Co.*, 388 F.2d 955, 959 (9th Cir. 1968). This is particularly true in the case of contention interrogatories.

Contention interrogatories are authorized by Federal Rule of Civil Procedure 33 (c), which provides in pertinent part that "[a]n interrogatory otherwise proper is not necessarily objectionable merely because an answer to the interrogatory involves an opinion or contention that relates to fact or the application of law to fact . . . ." When this portion of the rule was added in 1970, it was denominated as Rule 33(b). The Advisory Committee Note to the 1970 Amendment to Rule 33(b) provides that "requests for opinions or contentions that call for the application of law to fact . . . can be most useful in narrowing and sharpening the issues, which is a major purpose of discovery." Fed. R. Civ. P. 33(b) Advisory Committee Note to 1970 Amendment.

Although contention interrogatories serve this laudable purpose, the Advisory Committee noted a potential drawback to the rule. The Advisory Committee stated that "[t]he principal question raised with respect to the cases permitting such interrogatories is whether they reintroduce undesirable aspects of the prior pleading practice, whereby parties were chained to misconceived contentions or theories, and ultimate determination on the merits was frustrated." *Id.* (citing James, Fleming, "The Revival of Bills of Particulars under the Federal Rules," 71 Harv. L. Rev. 1473 (1958)). In attempting to allay the fear that contention interrogatories may frustrate the ultimate determination of a claim on the merits, the Advisory Committee noted that "there are few if any instances in the recorded cases demonstrating that such frustration has occurred." *Id.* This is because:

> the general rule governing the use of answers to interrogatories is that under ordinary circumstances they do not limit proof. *See e.g. McElroy v. United Air Lines, Inc.*, 21 F.R.D. 100 (W.D. Mo. 19[5]7; *Pressley v. Boehlke*, 33 F.R.D. 316, 317 (W.D.N.C. 1963). Although in exceptional circumstances reliance on an answer may cause such prejudice that the court will hold the answering party bound to his answer, *e.g., Zielinski v. Philadelphia Piers, Inc.*, 139 F.Supp. 408 (E.D. Pa. 1956), the interrogating party will not

> ordinarily be entitled to rely on the unchanging character of the answers he receives and cannot base prejudice on such reliance.

Id. Accord Marcoin, 605 F.2d at 1328 ("As a general rule, an answer to an interrogatory does not conclusively bind the answering party in all instances.") (citations omitted); 8A Charles A. Wright, Arthur R. Miller & Richard L. Marcus, Federal Practice & Procedure § 2181 (Thompson West 2007) ("It is quite true that interrogatories often must be answered early in the case before a party has completed its investigation and before it has a full understanding of the case. To hold it to that early understanding, as an occasional case purports to do, would be quite wrong. But the remedy is not to excuse it from answering the interrogatory but to hold that it is not irrevocably bound to the answer it gives.").

Indeed, it is noted by Wright, Miller & Marcus that courts should not permit contention interrogatories to be used as a strategy to maneuver an adverse party into an unfavorable position:

> Answers to interrogatories, as adjuncts to the pleadings, do limit the issues and define the contentions of the parties, but under ordinary circumstances, it is not their function to limit a party's proof in the way that pleadings do. So far as interrogatories require the production of information, parties must disclose the information they have as of the time of the demand of the interrogatories. However, the parties should not be bound by these answers, if in the interim between the time of the answers and trial, they obtain by subsequent investigation new or additional facts. The parties will not be prevented from offering this further information on trial. The discovery rules are not to be employed as a stratagem to maneuver an adverse party into an unfavorable position.

8A Fed. Prac. & Proc. Civ. 2d § 2181 (Thomson/West 2007). Here, there can be no question that Abraxis is attempting to maneuver Elan into an unfavorable position. Abraxis delayed the production of documents and laboratory notebooks, suspended the deposition of its chief medical officer, and has yet to present for deposition Dr. Soon-Shiong and Dr. Desai, two of the named inventors of Abraxane®.[1] Nevertheless, Abraxis asks this Court to find that Elan's answers to Abraxis's contention interrogatories were written in stone prior to a discovery deadline that has now been extended.

B. Case law cited by Abraxis is easily distinguished.

The case law cited by Abraxis in support of its motion to dismiss and/or preclude Elan's contentions is easily distinguished from the facts presented here. First, Abraxis cites *02*

[1] As of this date, Elan still does not have three of Dr. Desai's laboratory notebooks, and Abraxis has yet to produce Dr. Soon-Shiong, Dr. Desai, or Dr. Hawkins for deposition.

Micro International Limited. v. Monolithic Power Systems, Inc., 467 F.3d 1355 (Fed. Cir. 2006) for the proposition that Elan should have amended its answer to Abraxis's Interrogatory No. 1 prior to the now-extended discovery deadline. *See* Motion at 3. Yet, as Abraxis concedes in its motion, *02 Micro* was decided *solely* based on a local rule that prohibited amendments to infringement and invalidity contentions based on new information developed during discovery without a showing of diligence. *See id*; *see also Micro Int'l* at 1359. There is no such requirement in the Scheduling Order in this case or the local rules in this District. Moreover, on Abraxis's theory that the discovery deadline should serve as the drop dead date for amending contentions, a party would be precluded from revising its contentions based on information learned late in the day on the last day scheduled for fact discovery. Such a rule would result in rewarding parties who were intransigent in responding until the very eve of the discovery deadline.

Second, Abraxis's attempt to analogize the facts presented by *Creo Products, Inc. v. Pressteck, Inc.*, 148 F.Supp.2d 416 (D. Del. 2001), which was decided by this Court, to the facts presented here cannot withstand scrutiny. *See* Motion at 3-4. In *Creo Products*, a defendant raised for the first time at the pretrial conference an allegation that certain claims of an asserted patent were infringed. *See Creo Prods.*, 148 F.Supp.2d at 417. This Court precluded the defendant from presenting evidence concerning those claims at trial. *Id.* In doing so, the Court eschewed the defendant's defense that the delay had resulted from plaintiff's discovery tactics, noting that, "Presstek was free to file a motion to compel if it believed Creo's actions were preventing it from prosecuting its case." *Id.* Here, Elan has sought relief from Abraxis's intransigent discovery tactics on more than four occasions. Indeed, it is Abraxis's very obstruction of discovery that led to the late addition of Elan's new contentions.[2]

Far more relevant than the cases cited by Abraxis are Federal Rules of Civil Procedure 26 and 83. Federal Rule of Civil Procedure 26 imposes a duty on parties to seasonably supplement their interrogatory answers, but is devoid of any deadline by which supplementation must cease. Certainly, Rule 26 does not contemplate depriving a litigant of the opportunity to supplement its contentions when, as here, discovery has yet to be completed.

Abraxis erroneously contends that the Scheduling Order entered in this matter provides the deadline lacking in Rule 26. However, the Scheduling Order does not provide actual notice of a deadline, as required by Federal Rule of Civil Procedure 83:

> A judge may regulate practice in any manner consistent with federal law, rules adopted under 28 U.S.C. §§ 2072 and 2075, and local rules of the district. No sanction or other disadvantage may

[2] It is undisputed that in March 2007 Elan had in its possession two documents that support the newly added contentions. *See* Motion at 2. These two documents, however, were the only evidence available to Elan with which to prosecute the new contentions. Elan had planned to deduce additional evidence to support its claims during the depositions of Drs. Desai and Soon-Shiong, named inventors of the accused product Abraxane.® Abraxis, however, has yet to present these witnesses. Abraxis should not be permitted to obstruct discovery and then to reap the benefits from such obstruction.

> be imposed for noncompliance with any requirement not in federal law, federal rules, or the local district rules unless the alleged violator has been furnished in the particular case with *actual* notice of the requirement.

Fed. R. Civ. P. 83(b) (emphasis added). There has been no order, including the Scheduling Order, that would place Elan on actual notice that its infringement contentions would be deemed final by a date certain, or that they could be updated only upon a showing of good cause. Indeed, the Scheduling Order is completely devoid of any suggestion that the discovery deadline is a dual deadline for infringement contentions. Accordingly, Elan should not be sanctioned or disadvantaged for amending its infringement contentions after the close of discovery.

C. Abraxis's contention that "anionic surfactant" needs construing is a red herring.

In a misguided attempt to have this Court preclude infringement contentions without adequate notice to Elan, Abraxis alleges that allowing Elan's new contentions to stand will require the Court to construe the term "anionic surfactant" after conclusion of the Markman process. Nothing could be further from the truth. The Court has already construed the term "surfactant." *See* D.I. 271. Moreover, Abraxis's own motion establishes that "anionic" must be accorded its plain meaning.

As Abraxis concedes, "the patent specification is silent as to how to define an 'anionic surfactant,' mentioning the term only once with no definition or list of representative examples." *See* Motion at 2. Because the patent specification does not reveal that any special definition should be given to the term "anionic" that is difference from what meaning it would otherwise possess, *Philips v. AWH Corporation,* 415 F.3d 1303, 1313-14 (Fed. Cir. 2005) instructs that the term's plain meaning applies. Indeed, "anionic" is not a complex term with varied use. Rather, it is a simple adjective that denotes "a negatively charged ion." THE NEW OXFORD AMERICAN DICTIONARY 62 (2001). Accordingly, Abraxis's contention that "anionic surfactant" requires reopening the Markman process is without merit.

D. Abraxis will not be prejudiced by permitting Elan's contentions to stand.

Abraxis's claim that it will be prejudiced if Elan's recent contentions are permitted to stand is unavailing. The Court has extended the discovery period until November 29, which provides Abraxis with ample opportunity to pose requests for production[3] targeted to Elan's more recent contentions. Furthermore, Abraxis's experts may supplement their reports to address the contentions, if not already addressed in their opening reports. Finally, and most importantly, Abraxis has already conducted discovery on Elan's recently-added contentions. Elan's recent contentions pertain to Claims 4, 14, 16 and 17 of the '363 Patent. These dependant claims can be separated into two groups: (1) Claims 4, 16, and 17 include a limitation directed to the percent by weight of surface modifier; and (2) Claim 14 includes the limitation of an anionic surfactant. Abraxis has undeniably conducted discovery on these limitations. *See e.g.*, Pramod

[3] Abraxis has exceeded the 50 interrogatory limit established in the parties Joint Status Report. *See* D.I. 11 at 7.

Sarpotdar Tr. (Elan Exh. 1)[4] at 74:17-82:5 (discussion of concentration of surface modifier in nanoparticle); 86:14-93:3 (discussion of optimal amount of surface modifier, mention of non-ionic surfactants); 153:22-156:22 (discussion of amount of surface modifier adsorbed on nanoparticles); Nancy Peltier Tr. (Elan Exh. 2) at 237:14-249:20 (discussion of weight percent of surface modifier in nanoparticle and process of choosing surface modifier); E. Liversidge Tr. (Elan Exh. 3) at 80:11-86:2 (discussion of use of pluronic, a non-ionic surfactant, and whether a change in surfactant would similarly effect hemodynamic effects); 173:11-178:13 (discussion of surfactants suitable for nanocrystal formulation); 190:3-191:15 (discussion of TWEEN/SPAN as a surfactant, a non-ionic combination); 237:15-241:19 (discussion of choice of surfactant based on HLB value); G. Liversidge Tr. (Elan Exh. 4) at 48:18-58:25 (discussion of definition of surface modifier; questions directed to particular percentage by weight of surface modifier that may be adsorbed on the surface of a crystalline drug); 183:5-24 (questions regarding amount of surface modifier used to stabilize nanoparticles); 222:11-223:18 (discussion of appropriate surface modifiers/stabilizers); 227:15-22 (definition of surfactant).[5]

E. Conclusion

While contention interrogatories are a valuable tool in discovery, they can also be abused so as to maneuver an adversary into an unfavorable position. Those drafting the Federal Rule of Civil Procedure recognized this potential and ensured through Rule 83(b) that parties would not be held to contention interrogatory answers without actual notice. It is indisputable that the Scheduling Order is silent as to any requirement that Elan finalize its infringement contentions prior to the end of the denominated discovery deadline. Indeed, even if there had been such notice, equity would favor relief for Elan, who has—to this day—still not been given access by Abraxis to two named inventors of Abraxane.®

Respectfully,

/s/ Lauren E. Maguire

LEM/rbg
185051.1

Lauren E. Maguire (I.D. #4261)

cc: Josy W. Ingersoll, Esquire (via electronic mail)
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[4] Citations herein to "Elan Exh. ___" refer to the respective Exhibits attached to the Declaration Of Linda M. Glover submitted contemporaneously herewith.

[5] Notably, Abraxis has not propounded a single discovery request pertaining to Elan's recent contentions since the parties' October 2 hearing. This alone tends to belie Abraxis's allegation that it requires additional discovery on these topics.