IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN PHARMA INTERNATIONAL LIMITED,	)	**REDACTED** **PUBLIC VERSION**
Plaintiff,	)	C.A. No. 06-438-GMS
v.	)	
ABRAXIS BIOSCIENCE, INC.,	)	
Defendant.	)	

ELAN PHARMA INTERNATIONAL LIMITED'S ANSWERING BRIEF TO DEFENDANT ABRAXIS BIOSCIENCE, INC.'S MOTION FOR PROTECTIVE ORDER AGAINST THE DEPOSITIONS OF DRS. SOON-SHIONG AND DESAI
AND
OPENING BRIEF IN SUPPORT OF ITS CROSS-MOTION TO COMPEL THE DEPOSITIONS OF DRS. SOON-SHIONG AND DESAI

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Introduction

Plaintiff Elan Pharma International Limited ("Elan") hereby presents its reasons for opposing, and its Answering Brief in response to, Defendant Abraxis BioScience, Inc.'s ("Abraxis's") Brief In Support Of Its Motion For Protective Order Against The Depositions Of Drs. Soon-Shiong And Desai (the "Motion"), served on August 13, 2007. *See* D.I. 247, D.I. 248. Elan further presents this brief in support of its concurrently-submitted Cross-Motion To Compel The Depositions Of Drs. Soon-Shiong And Desai.

I. Nature And Stage Of The Proceedings

Elan filed this action alleging infringement of U.S. Patent Nos. 5,399,363 and 5,834,025 (collectively, the "Patents-In-Suit") against Abraxis on July 19, 2006. *See* D.I. 1. The product accused of infringement is Abraxane®. During the fact discovery period, Elan timely noticed the depositions of Dr. Patrick Soon-Shiong, Chief Executive Officer of Abraxis, and Dr. Neil Desai, Vice President for Research and Development of Abraxis. *See* D.I. 157, 158, 196, 223. Both are named inventors of patents ostensibly covering Abraxane®, and their knowledge of the infringing product is indispensable to Elan's case in chief.

Elan submits that Abraxis obstructed the course of fact depositions, including by

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refusing to make Drs. Soon-Shiong and Desai available for full deposition on mutually-convenient dates for the parties. Abraxis has now moved for a protective order pursuant to Fed. R. Civ. P. 26(c) that would require Elan to withdraw its Notices Of Deposition of Neil Desai and Patrick Soon-Shiong. *See* D.I. 247. By a Cross-Motion filed herewith, Elan respectfully cross-moves the Court to compel the depositions of Drs. Soon-Shiong and Desai at the earliest possible date.

II. Summary Of Argument

Abraxis seeks to prevent Elan from deposing two key fact witnesses in this case, Drs. Patrick Soon-Shiong and Neil Desai. Elan properly and timely noticed these depositions and the parties had originally scheduled the depositions to take place in July, prior to the close of fact discovery. Abraxis's delayed document production precluded Elan from adequately preparing for and taking these depositions as originally scheduled, thus forcing Elan to postpone these depositions.

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A. Abraxis's Motion For Protective Order Meets Neither Of The Requirements For A Protective Order Under Rule 26(c)

Abraxis's Motion offers no plausible reason for why it should be able to deny Elan the right to take these two depositions. *See generally* D.I. 248. Importantly, Abraxis ignores the requirements of Fed. R. Civ. P. 26(c), which governs protective orders. This Rule requires that Abraxis: (1) in good faith confer or attempt to confer with Elan to resolve the dispute; and (2) show good cause for why a protective order should issue. *See* Fed. R. Civ. P. 26(c). Abraxis fails to meet either of these requirements. Moreover, Abraxis cites *no* applicable legal authority authorizing it to cancel these depositions, which is not surprising because "[t]he circumstances are rare which justify an order that a deposition not be taken at all . . . ." *Scovill Mfg. Co. v. Sunbeam Corp.*, 61 F.R.D. 598, 603 (D. Del. 1973).

B. Elan's Cross-Motion To Compel Depositions Should Be Granted Pursuant to Rule 37

The Court should grant Elan the opportunity to take the depositions of Drs. Patrick Soon-Shiong and Neil Desai at the earliest reasonable date pursuant to Fed. R. Civ. P. 37. These limited depositions, noticed prior to the close of fact discovery, will not place an undue burden on Abraxis or the witnesses. Further, if Elan were precluded from taking the depositions of these very senior and knowledgeable Abraxis employees, it would be severely prejudiced.

III. Statement Of Facts

A. The Chronology Of Events

The following chronology illustrates the relevant timeline of events leading up to Elan's postponement and attempts to reschedule the depositions of Neil Desai and Patrick Soon-Shiong:

Date	Event
6/29/07	Notice of Deposition of Patrick Soon-Shiong for July 13, 2007 served. Abraxis Exh. A,[1] D.I. 157.
6/29/07	Notice of Deposition of Neil Desai for July 19, 2007 served. Abraxis Exh. B, D.I. 158.
7/6/07	Deposition of Abraxis's Chief Medical Officer, Dr. Michael Hawkins took place.

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[1] Citations to "Abraxis Exh. __" refer to the Exhibits attached to the Declaration Of Eric C. Pai In Support Of Defendant Abraxis BioScience, Inc.'s Motion For Protective Order Against The Depositions Of Drs. Patrick Soon-Shiong And Neil Desai. D.I. 251.

[2] Citations to "Elan Exh. __" refer to the Exhibits attached to the Declaration Of Lisa A. Chiarini submitted contemporaneously herewith.

7/10/07 Deposition of Patrick Soon-Shiong postponed by Elan counsel.

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7/16/07 Discovery Teleconference with Judge Sleet.

- Elan sought relief from Abraxis's refusal to permit Elan's lead counsel, Stephen Scheve, access to relevant documents on Abraxis's secret password protected discovery website, Intralinks, and from Abraxis's failure to produce unredacted laboratory notebooks Elan designated as responsive during inspection. Abraxis Exh. T, Telecon. Tr. at 2:19-4:6. Without such information, Mr. Scheve could neither properly prepare for nor effectively conduct the deposition of Dr. Neil Desai on July 19, 2007 as scheduled. Judge Sleet Ordered that Mr. Scheve be

granted access to the Intralinks website and Abraxis's counsel agreed that it would produce any missing laboratory notebooks. *Id.* at 9:13-17; 18:19-25. Judge Sleet further ordered that Abraxis provide Elan counsel one hard copy of the documents to be used at depositions. *Id.* at 12:4-13:6.

- Discovery Deadline extended two weeks to August 13, 2007. *Id.* at 31:18-24.

7/17/07 Deposition of Dr. Neil Desai postponed by Elan counsel.

- Elan postponed Dr. Desai's deposition because, contrary to its representations to the Court, Abraxis failed timely to produce hard copies of all necessary unredacted documents, and Mr. Scheve still had not been granted access to Intralinks, both of which were ordered by the Court to be completed during the July 16, 2007 discovery teleconference. Abraxis Exh. U, e-mail Correspondence.

7/18/07 Amended Notice of Deposition of Dr. Desai for August 8, 2007 served. Abraxis Exh. C, D.I. 196.

- The Amended Notice gave more than sufficient notice time (namely, 21 days) under the Local Rules (which require only seven days notice). *See* D. Del. LR 30.1.

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8/1/07 Amended Notice of Deposition of Patrick Soon-Shiong for August 13, 2007 served. Abraxis Exh. D, D.I. 223.

- The Amended Notice gave more than sufficient notice time (namely, 12 days) under the Local Rules (which require only seven days notice). *See* D. Del. LR 30.1.

8/6/07 Elan's counsel e-mails Abraxis's counsel, memorializing Elan's understanding that Abraxis again refused to make both Neil Desai and Patrick Soon-Shiong available for their depositions as noticed on August 8th and 13th, respectively, a clearly improper obstruction of the depositions. Elan Exh. C, e-mail Correspondence at 1. In telephonic meet-and-confer conversations among counsel, Elan requested, but Abraxis declined, to extend the deposition dates beyond August 13th to accommodate Dr. Desai's reported health problems and Dr. Soon-Shiong's purported business scheduling conflicts for the re-noticed dates.

B. Abraxis's Coercive Tactics In Producing Discoverable Documents

It became apparent to Elan that Abraxis was withholding highly relevant and responsive documents pertaining to the development of Abraxane® during the course of discovery. Elan became aware of Abraxis's obstruction of discovery when it found that Abraxis's document production included only random isolated pages from 65 Abraxis laboratory notebooks, with much of the information on those pages redacted, although Elan's document

requests called for production of *all* laboratory notebooks relating to Abraxane®. Concerned with this inexplicable and seemingly arbitrary failure of production, Elan was forced to demand physical inspection of Abraxis's original laboratory notebooks in order to confirm and seek a remedy for Abraxis's discovery abuse.

Abraxis would only agree to allow five (5) outside attorneys for Elan to inspect the original laboratory notebooks, and each attorney was required to sign an undertaking not to discuss the information contained therein with anyone other than another one of the five designated attorneys. This meant that when Elan designated five associate lawyers for a time-limited review of the notebooks, those associates were, based on Abraxis's arbitrary and onerous terms, not even permitted to report the results of their review to Elan's lead trial counsel, Mr. Scheve. *See* Abraxis Exh. E, Correspondence at 5-7. Moreover, Abraxis unilaterally stated that Elan's opportunity to inspect the laboratory notebooks would expire if not accepted within 24 hours of the "offer" to inspect being made by Abraxis, and further demanded that the laboratory notebooks would not be made available unless Elan agreed to and the Court entered an Interim Protective Order (*see* D.I. 135) containing further onerous restrictions demanded by Abraxis. *See* Abraxis Exh. E, Correspondence at 7.

Even then, Abraxis insisted, the laboratory notebooks would only be made available for a period of one week, which commenced two days after the offer of inspection. *See id.* at 5.

Elan, faced with an incomplete production and Abraxis's strong-arm refusal to make the responsive materials available except on its unilateral and highly unusual terms — it is not generally the party in default of discovery obligations who is allowed to condition his compliance with these obligations on his own arbitrary terms — agreed to the preliminary

Interim Protective Order (*see* D.I. 135) as just that — an *interim* provision to allow confirmation of Abraxis's inadequate production and inappropriate redaction of the laboratory notebooks so that Elan could seek further relief for the incomplete production.

Under the additional terms of the Interim Protective Order, documents designated "Secret Abraxane® Manufacturing Information" are made available only through a secured Internet portal, Intralinks, are not capable of being printed out, and can still only be viewed by five (5) lawyers authorized at any one time within Elan's outside counsel firm. *See id.*

With this Draconian Interim Protective Order in place, Abraxis then proceeded improperly to designate much of its document production under this ultra-restrictive classification (*see* Abraxis Exh. T, Telecon. Tr. at 13:19-23; 14:23-15:4), thus forcing Elan first to sift through this mass of information by designating five associate attorneys for bulk document review, then to change the list of authorized attorneys to include its lead counsel Mr. Scheve so that he could prepare for depositions.[3] It was these onerous procedures, Abraxis's significant over-designation of documents as "Secret Abraxane® Manufacturing Information," and the unwarranted redactions of Abraxis laboratory notebooks that are to blame for any delay in the preparation for Dr. Desai's deposition. *See, e.g.,* Abraxis Exh. U, e-mail Correspondence.

Significantly, even on the constrained review possible under Abraxis's insisted-upon restrictions in the Interim Protective Order, Elan was able rapidly to confirm that numerous responsive and non-privileged portions of the Abraxis laboratory notebooks had been redacted

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[3] Under the original Stipulated Protected Order previously entered herein (*see* D.I. 33), Abraxis also designated vast amounts of information and documents produced as "Restricted Confidential" (an outside-counsel's-eyes only classification level that precluded Elan from, among other things, consulting with in-house counsel or Elan personnel in evaluating the significance of material thus designated). As Elan will establish by separate motion, Abraxis's designation of much of the "Restricted Confidential" information and documents was abusively overbroad, covering as it did, among other things, numerous publicly-available documents.

with no justification and were clearly mis-designated as "Secret Abraxane® Manufacturing Information." Abraxis Exh. T, Telecon. Tr. at 3:23-4:10; 13:19-23.

Notably, Abraxis has to this date steadfastly refused to relax any of the terms of the Interim Protective Order (except to allow limited review by pre-approved Elan experts at Elan's counsel's office, rather than Abraxis's counsel's office), even though the word "Interim" clearly indicates its provisional nature[4] and the parties' mutual intent to replace it with a more permanent and comprehensive solution.

The Amended Notices of Deposition of Drs. Patrick Soon-Shiong and Neil Desai are still outstanding at the present time. *See* Abraxis Exh. C, D.I. 196; Abraxis Exh. D, D.I. 223. Abraxis itself identified these witnesses as likely to have discoverable information that is highly relevant to the determination of infringement in this action. Both Neil Desai and Patrick Soon-Shiong were involved in the development and U.S. Food and Drug Administration approval of Abraxane®, the product accused of infringement in this action. Elan Exh. D, Abraxis's Initial Disclosures at 2.

IV. Argument And Legal Authority

In its Motion, Abraxis provides unfounded argument alleging that Elan has not been diligent in pursuing the depositions of Neil Desai and Patrick Soon-Shiong. *See* D.I. 248 at 6-7. With respect to the deposition of Dr. Desai, Elan waited only as long as it absolutely had to — that is, until Abraxis had made possible meaningful access by Elan to the relevant documents and information necessary for lead counsel to prepare for the deposition. *See, e.g.,* Abraxis Exh. T, Telecon. Tr. at 2:19-3:22, 9:13-17, 12:4-13:6; Abraxis Exh. E, Correspondence at 5-7;

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[4] "**interim** (*adj.*) — intervening; provisional, temporary." CONCISE OXFORD DICTIONARY (9th ed.) (1995).

a deposition, and/or obstructing the legitimate purposes of a deposition.

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accordingly awaited resolution.

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Elan has been quite diligent in pursuit of its discovery against Abraxis, and only sought to refrain from having to take the depositions of these witnesses on more than one occasion because either: (1) Abraxis delayed in making available unredacted relevant documents; or (2) Abraxis

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A. No Protective Order Should Issue Because Abraxis Has Not Met The Requirements Of Rule 26 In Its Tactical Efforts To Deprive Elan Of The Opportunity To Depose Two Highly Relevant Witnesses

Fed. R. Civ. P. 26(c) governs motions for a protective order. Pursuant to that Rule,

> [u]pon motion by a party or by the person from whom discovery is sought, accompanied by a certification that the *movant has in good faith conferred or attempted to confer with other affected parties in an effort to resolve the dispute* without court action, *and for good cause shown*, the court in which the action is pending . . . may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . .

Fed. R. Civ. P. 26(c) (emphasis supplied). Thus, there are two distinct prerequisites set forth by Rule 26 for the issuance of a protective order to be appropriate. Abraxis has not satisfied either of those prerequisites.

1. Abraxis Did Not Confer With Elan In Good Faith In An Effort To Resolve This Dispute

The first requirement of Rule 26(c) mandates that the movant submit a certification that it "*in good faith* conferred or attempted to confer . . . in an effort to resolve the dispute without court action . . ." Fed. R. Civ. P. 26(c) (emphasis supplied). The good faith meet-and-confer requirement contemplated by the Federal Rules envisions actual discussion between the parties in an attempt to resolve disputes. *See, e.g., Williams v. The Art Institute of Atlanta*, No. 1:06-CV-0285, 2006 WL 3694649, at *13 (N.D. Ga. Sept. 1, 2006) (noting that the good faith conference requirement is designed to prevent gamesmanship); *see also Shuffle Master, Inc. v. Progressive Games, Inc.*, 170 F.R.D. 166, 172 (D. Nev. 1996) (finding that party did not confer in good faith when counsel "never personally discussed with opposing counsel a reasonable resolution to their discovery dispute").

Although Abraxis informed Elan of its intent to file a Motion For Protective Order regarding the outstanding deposition notices of Neil Desai and Patrick Soon-Shiong, Abraxis did not present any compromise solution or any alternate dates to accommodate the supposed unavailability of the witnesses on the dates timely re-noticed.

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Abraxis was adamant in its position that if (according to Abraxis), the witnesses were "unavailable" on the noticed dates, Abraxis would not work to find alternate dates beyond the scheduled close of fact discovery.

Elan complied with its portion of the meet-and-confer requirements by stating its willingness to extend the duly-noticed dates **REDACTED**

It should be noted that this exercise in cooperation and

professional courtesy represents a departure from the default rule that compliance with duly-issued deposition notices is not voluntary or optional, as Abraxis appears to believe it is.

Abraxis did not reciprocate this courtesy, instead clearly taking a position that if it could thwart the taking of the depositions prior to the nominal close of discovery, it could run out the clock and establish a substantive entitlement or positive right never to have them taken at all. This is not how discovery works, though. Neither Abraxis nor the witnesses will suffer substantial prejudice by having these depositions take place slightly later than originally noticed.

2. Abraxis Has Not Shown Good Cause For The Imposition Of A Protective Order

"Rule 26(c) places the burden of persuasion on the party seeking the protective order. To overcome the presumption, the party seeking the protective order must show good cause by demonstrating a particular need for protection." *Traynor v. Liu*, No. 06-441-SLR, 2007 WL 2039526, at *7 (D. Del. July 17, 2007) (quoting *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986)). In its Motion, Abraxis does not even state, let alone establish, that good cause exists for the grant of a protective order here. *See generally* D.I. 248.

The entirety of Abraxis's argument appears to be based on the timeliness of Elan's Amended Deposition Notices. *See id.* at 6. Abraxis cites only one case in support of its Motion. *See id.* at 6 (citing *In re Sulfuric Acid Litig.*, 231 F.R.D. 320, 327-28 (N.D. Ill. 2005)). *In re Sulfuric Acid Litig.* is distinguishable from the facts in this case on at least two main grounds. First, it was not decided in the context of a Rule 26(c) motion for a protective order. In that case, instead, the court faced several discovery disputes, including plaintiff's motion to compel depositions. 231 F.R.D. at 327-38. Second, the court denied plaintiff's motion to compel the depositions for several reasons, noting that plaintiff had already obtained *three extensions* of the original discovery deadline — having already extended the discovery deadline

by over *nine months*. *See id.* at 328 n. 8. The plaintiff in that case only noticed the two depositions at issue ten days before the close of discovery, after discovery had been extended three times already. *Id.* at 328.

Abraxis provides no specific reasoning that would justify the grant of a protective order in this instance. Abraxis rather makes the general assertion that permitting Elan to depose Drs. Neil Desai and Patrick Soon-Shiong after the close of discovery,

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, would "encourage[ ] litigants to unnecessarily delay completion of discovery . . . and significantly prejudice Abraxis . . ." D.I. 248 at 7. Abraxis's concern for the precedential effects that an extension of less than a month, for good cause, would have in encouraging dilatory behavior in other litigations is laudable but perhaps not very realistic, especially given the very fact-specific reasons why the slight extension is needed here. Specifically,

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the cumbersome nature of the unusual mechanisms for review of ultra-confidential "Secret Abraxane® Manufacturing Information" upon which Abraxis itself insisted, constitute more than sufficient good cause to permit and order these depositions.

Beyond its improbable assertion that granting Elan the limited relief it needs would imperil the smooth functioning of discovery in future cases, Abraxis does not provide any detail as to how Abraxis itself or the witnesses would be prejudiced in this litigation by having to appear at two additional depositions, which it had initially agreed would take place. "Broad allegations of harm, unsubstantiated by specific examples" are not sufficient to show good cause. *Traynor*, 2007 WL 2039526, at *7 (quoting *Glenmede Trust Co. v. Thompson,* 56 F.3d 476, 483 (3d Cir. 1995)). Abraxis's unsupported assertions do not meet the good cause requirement of

Rule 26(c). *See Emory v. Astrazeneca Pharms.*, No. 02-1466-JJF, 2003 WL 22136301, at *1 (D. Del. Sept. 4, 2003) (noting that under Rule 26(c), "good cause requires a specific showing" that "clearly defined and serious injury" will result). Indeed, "[t]he circumstances are rare which justify an order that a deposition not be taken at all . . ." *Scovill Mfg. Co.*, 61 F.R.D. at 603.

Moreover, the Court should not award Abraxis for creating obstacles to discovery. *See, e.g., supra* § III.B. Thus, Elan respectfully requests that the Court deny Abraxis's Motion.

B. The Depositions Of Neil Desai And Patrick Soon-Shiong Are Highly Relevant To The Issues In This Case And The Court Should Compel Them

Fed. R. Civ. P. 37 governs motions to compel discovery. Pursuant to that Rule, Elan affirmatively seeks by its accompanying Motion, to compel the fact depositions of Drs. Neil Desai and Patrick Soon-Shiong, to take place at the earliest reasonable date that the parties can agree upon. Elan properly and timely served Amended Deposition Notices for these witnesses, whose depositions should have taken place pursuant to these Notices and before the scheduled close of fact discovery, on August 8th and August 13th, respectively. *See* Abraxis Exh. C, D.I. 196; Abraxis Exh. D, D.I. 223.

The relevance under the Federal Rules of the testimony of both Neil Desai and Patrick Soon-Shiong is indisputable. *See* Fed. R. Civ. P. 26(b)(1) ("[p]arties may obtain discovery of any matter, not privileged, that is relevant to the claim or defense of any party . . . .").

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Due to the undisputed relevance of the depositions of Neil Desai and Patrick Soon-Shiong, specifically the fact that the testimony is likely to address issues at the very heart of Elan's infringement case, and Elan's outstanding Notices Of Deposition for these witnesses, Elan requests that the Court order that these depositions take place as soon as practicable.

V. Conclusion And Prayer For Relief

For the foregoing reasons, Elan respectfully requests that the Court:

(1) Deny Abraxis's Motion For Protective Order Against the Depositions of Drs. Patrick Soon-Shiong and Neil Desai;

(2) Grant Elan's Cross-Motion To Compel The Depositions Of Drs. Patrick Soon-Shiong And Neil Desai; and

(3) Award Elan its reasonable expenses in responding to Abraxis's Motion For Protective Order and preparing its Cross-Motion To Compel.

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