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.	)	

PLAINTIFF ELAN PHARMA INTERNATIONAL LIMITED'S ANSWERING BRIEF TO DEFENDANT ABRAXIS BIOSCIENCE INC.'S MOTION TO COMPEL PRODUCTION OF DAMAGES DISCOVERY

AND

PLAINTIFF'S OPENING BRIEF IN SUPPORT OF ITS CROSS-MOTION TO LIMIT BY PROTECTIVE ORDER DEFENDANT'S FED. R. CIV. P. 30(b)(6) DEPOSITION OF PLAINTIFF

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I. Nature And Stage Of Proceedings

On July 19, 2006, Plaintiff Elan Pharma International Limited ("Elan") filed suit alleging that Abraxis BioScience, Inc. ("Abraxis") infringes U.S. Patent Nos. 5,399,363 (the "'363 Patent") and 5,834,025 (the "'025 Patent") (collectively, the "Patents-In-Suit"). Elan's '363 Patent is directed to a nanoparticulate anticancer drug composition; and Elan's '025 Patent is directed to an intravenuous method of administering a nanoparticulate drug composition so as to avoid eliciting adverse hemodynamic effects. The accused product, Abraxane®, is a nanoparticulate anticancer drug composition, which is intravenously administered.

During fact discovery, which concluded on August 13, 2007, Abraxis propounded nine (9) requests for production directed to damages and served Elan with a deposition notice, also directed to damages, pursuant to Federal Rule of Civil Procedure 30(b)(6). Elan fully complied with the Federal Rules of Civil Procedure and the parties' Stipulated Protective Order in responding to Abraxis's discovery requests and Rule 30(b)(6) deposition notice. Nevertheless, on August 8, 2007 — mere days before the end of fact discovery — Abraxis filed an unwarranted motion to compel production of damages discovery (the "Motion"). Elan hereby responds to Abraxis's Motion and files a cross-motion for partial protection from Abraxis's Rule 30(b)(6) deposition notice.

II. Summary Of Argument And Relief Requested

It is undisputed that Abraxis is entitled to discover relevant information concerning the extent to which Elan has been, and continues to be, damaged by Abraxis's infringement of the Patents-In-Suit. The crux of the dispute between the parties is whether Abraxis's discovery should be limited as prescribed by the Federal Rules of Civil Procedure; or, whether Abraxis is entitled to delve into every aspect of Elan's financial history, and into every term of Elan's agreements with non-parties, regardless of any relevance to the issues at hand and

regardless of whether such an inquiry will significantly encroach on the confidential information of non-parties to whom Elan owes a duty of non-disclosure.

Elan seeks a reasonable royalty and a reasonable percentage of the upfront payments Abraxis has already received for its licensing of Abraxane as damages for Abraxis's infringement of the Patents-In-Suit. Controlling authority is abundantly clear that a reasonable royalty determination must be based upon circumstances existing in the marketplace at the time when infringement began. Precedent — including case law cited by Abraxis — also emphasizes that if an established royalty is shown to exist, for example from an existing license granted by the patentee, such royalty is the best measure of damages for infringement of the Patents-In-Suit.[1]

Despite this authority, Abraxis cites to *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970), modified and aff'd, 446 F.2d 295 (2d. Cir.) to support its purported entitlement to temporally-unlimited discovery on each and every one of fifteen factors that the *Georgia-Pacific* court noted were *potentially* relevant to a reasonable royalty determination. Even a cursory review of *Georgia-Pacific*, however, reveals that its reference to a broad spectrum of potential relevant evidentiary factors need occur *only* when there is no established royalty for the patents-in-suit. Here, the Patents-In-Suit have been routinely licensed, and those licenses executed around the time infringement began more than suffice to establish the reasonable royalty rate for purposes of this litigation.

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1 Elan has produced or is in the process of producing, under appropriate terms of confidentiality pursuant to the Stipulated Protective Order, substantial licensing documents relating to the Patents-In-Suit and specifically, to their commercialization and licensing during the periods contemporaneous with Abraxis's infringement of them. These materials should more than suffice to inform Abraxis of the relevant commercial terms that case law establishes will be a principal basis for calculating Elan's damages.

Ignoring the clear mandate of *Georgia-Pacific* (and subsequent Federal Circuit case law), Abraxis seeks to discover through document requests and a Rule 30(b)(6) deposition *all* of Elan's non-party agreements, including those regarding "Particulate Composition Patents" and "pharmaceutical or diagnostic compositions or methods." Abraxis's definition of "Particulate Composition Patents" sweeps into its purview **REDACTED** of Elan's patents, regardless of whether the patents are directly related to the technology claimed in the Patents-In-Suit, or whether licenses of those patents were executed in close proximity to the time Abraxis's infringement began.

Abraxis's discovery request aimed at licenses concerning "pharmaceutical or diagnostic compositions or methods" casts an even wider net. Such a request seeks licenses without limitation as to any specific drug, any specific formulation, any dosage form, any specific diagnostic, any particular dosage regimen, any particular method of administration, or even any drug particle size. Indeed, such a request extends to licenses for macro (i.e., non-nanometer-scale) technology, even though the Patents-In-Suit concern nanoparticulate technology only. *Every* license that Elan has executed over its thirty-year history constitutes a "license concerning pharmaceutical or diagnostic compositions or methods." Abraxis's request for such discovery is therefore inherently overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Abraxis also seeks to discover other agreements and/or documents that Elan is contractually bound not to disclose. Notably, a great many of the documents listed on Elan's confidentiality log, such as the test reports and laboratory notebooks cited by Abraxis at page 8 of its Motion, have nothing to do with damages. In pure sleight of hand, Abraxis folds such

documents into its so-called "Motion To Compel Damages Discovery" but there is no independent or compelling reason why they should be discovered.

Without reference to any authority, Abraxis claims that Elan should be compelled to produce documents merely because they appear on Elan's confidentiality log, and, therefore, must be relevant. Abraxis fails to mention that Elan lodged multiple objections to producing these documents, the least of which pertain to their confidential nature. Abraxis essentially asks the Court to issue a blanket order overruling *all* of Elan's objections to the production of these documents, without particularized inquiry into whether Elan's objections to Abraxis's individual document requests were appropriately lodged. Such a request is unprecedented and should be denied.

Abraxis also obscures the fact that it used Elan's confidentiality log months ago to serve subpoenas upon non-parties for many or all of the agreements, licenses, and documents that Abraxis now seeks to compel from Elan. Because Abraxis has already obtained these documents from the non-parties, the discovery that Abraxis seeks from Elan is unreasonably cumulative and duplicative, and, its Motion in this regard is borderline abusive.

Elan does not shirk its obligation to provide discovery regarding the damages it has sustained. Rather, Elan seeks an order limiting Abraxis's damages discovery to that which is relevant — licenses to the Patents-In-Suit executed at or around the time that Abraxis's infringement began and continues. Elan continues to review documents to determine if any additional licensing materials not yet made available to Abraxis can be provided under conditions that adequately protect third-party confidentiality concerns and obligations, and will supplement its production as warranted. Accordingly, Abraxis's Motion should be denied, and its 30(b)(6) deposition topics that seek relevant information should be stricken.

III. Statement Of Facts

A. Elan Fully Complied With The Stipulated Protective Order.

Each of Abraxis's nine discovery requests directed to damages, and many of the topics contained in Abraxis's 30(b)(6) deposition notice to Elan, seek information regarding agreements relating to and/or licensing of the Patents-In-Suit or other patents. As is typical in the pharmaceutical industry, Elan's non-party agreements and licenses contain provisions prohibiting the parties from disclosing each other's trade secrets or proprietary information.

In response to Abraxis's discovery requests, which sought information that Elan is contractually bound not to disclose, Elan followed the procedures prescribed in the Stipulated Protective Order (the "Protective Order"), which governs discovery in this matter. The Protective Order outlines the procedures for addressing discovery material that is subject to a confidentiality agreement with non-parties. The procedures require that if a party receives a request to produce material that is the subject of a confidentiality obligation to a non-party, then the party is required to contact the non-party to determine whether the non-party is willing to disclose the requested material. If the non-party agrees to disclosure, then the material is produced. If the non-party does not agree to disclosure, the party must produce a log listing the name of the non-party, and the reason why the material is being withheld:

> A party may be requested to produce to another party Discovery Material subject to contractual or other obligations of confidentiality owed to a non-party. The party subject to such contractual or other obligation of confidentiality shall timely contact the non-party to determine whether such non-party is willing to permit disclosure of the confidential document or information under the terms of the Protective Order. If the non-party is not willing to permit disclosure, the Requesting Party shall be notified and any documents withheld on the basis of such contractual or other confidentiality obligation shall be identified on a separate index stating the reason for withholding the document and the person to whom the obligation of confidentiality is owed.

> This Protective Order shall not preclude any party from moving the Court for an order compelling production of such material.

D.I. 33 at ¶ 11. Pursuant to the Protective Order, Elan contacted each non-party privy to agreements containing confidential information potentially responsive to Abraxis's discovery requests and requested permission to disclose the information. Some of the parties agreed to complete disclosure, others to partial disclosure, and still others refused to disclose any information at all. In the first two instances, Elan produced the requested information to Abraxis pursuant to instructions received from the non-parties. In the latter instance, and as required by the Protective Order, Elan logged the names of the non-parties, the nature of each document being withheld, and the basis on which it was withheld.

The Protective Order requires nothing further of Elan. Nor is there any Federal Rule of Civil Procedure or statute that would compel Elan to breach its contractual agreements with non-parties absent a court order. Indeed, once Elan produced its confidentiality log, the Protective Order placed the onus on Abraxis to seek a hearing, during which non-parties ostensibly would have had an opportunity to address their confidentiality concerns to the Court.

Rather than follow the procedures prescribed by the Protective Order — and despite participating in four hearings during which Elan's non-party licenses and agreements could have been raised before the Court — Abraxis directly subpoenaed many of the non-parties that Elan had identified, seeking and obtaining production of the licenses, agreements and/or documents that Elan listed in its confidentiality log. *See* D.I. 152, 155, 165, 168-170, 175, 180, 188. Indeed, by virtue of its questionable actions, Abraxis already possesses the documents relevant to a reasonable royalty determination. Moreover, Elan continues to review documents in its possession to determine if any constitute non-cumulative licensing materials that could be produced to Abraxis without breach of Elan's contractual obligations, and will seasonably

supplement its production under appropriate terms of confidentiality to the extent that such documents are identified.

B. Elan Seeks Limited Protection From Abraxis's Notice Of Deposition Pursuant To Federal Rule Of Civil Procedure 30(B)(6).

On July 3, 2007, Abraxis noticed the deposition of Elan pursuant to Federal Rule of Civil Procedure 30(b)(6) on certain topics. *See* D.I. 167, attached as Exhibit A (the "Notice"). Abraxis's Notice included twenty-one (21) separate topics, the overwhelming majority of which are overly broad, unduly burdensome, seek irrelevant information, and are not reasonably calculated to lead to the discovery of admissible evidence. In addition, Abraxis's Notice purports to require Elan to testify concerning third-party trade secrets and proprietary information, which Elan is either contractually obligated not to disclose, or which Abraxis has already discovered through third-party subpoenas.

In response to the overly broad Notice, Elan telephonically *met and conferred* with Abraxis, seeking a compromise that would provide Abraxis with the relevant testimony to which it is entitled without unduly oppressing Elan. Abraxis, however, refused to modify or narrow the topics on which it sought Elan's testimony. Accordingly, Elan has no choice but to seek protection from the Court to partially limit the reach of Abraxis's Rule 30(b)(6) deposition.

IV. Argument And Authorities

A. Federal Rule Of Civil Procedure 26 Makes Clear That Discovery Is Not To Be Used As A Tool For Harassment.

Federal Rules of Civil Procedure 30 and 34 grant parties substantial latitude to depose individuals and/or parties and to discover non-privileged documents during the course of discovery. *See* Fed. R. Civ. P. 30, 34. To temper the breadth of these rules, however, Federal Rule of Civil Procedure 26 imposes certain limitations on discovery. The first limitation, inherent in Rule 26, is that a party is limited to seeking relevant discovery. *See* Fed. R. Civ. P.

26 (b)(1) ("Parties may take discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party.") The second limitation, expressly set forth by Rule 26, precludes discovery that is unreasonably duplicative, burdensome, expensive, or the benefit of which is outweighed by other considerations:

> The frequency or extent of use of the discovery methods otherwise permitted under these rules and by any local rule shall be limited by the court if it determines that (i) the discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity by discovery in the action to obtain the information sought; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issue.

Fed. R. Civ. P. 26(b)(2)(C). To avoid discovery for any of the reasons articulated under Rule 26, a party must demonstrate "that the discovery request is considered likely to oppress an adversary or might otherwise impose an undue burden." *Forest Prods. Nw., Inc. v. United States*, 453 F.3d 1355, 1361 (Fed. Cir. 2006); *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986). Here, Abraxis's requests for the production of documents related to damages are oppressive because they seek more than Elan's licenses of the Patents-In-Suit executed in close proximity to the time that Abraxis's infringement began and continues. Abraxis's Rule 30(b)(6) deposition topics also seek irrelevant information and would impose an onerous burden on Elan by purportedly requiring it to breach non-party contractual agreements for reasons wholly unrelated to the determination of a reasonable royalty rate.

B. Elan's Licenses Of The Patents-In-Suit Executed In Close Proximity To The Time That Infringement Began Establish The Reasonable Royalty Rate For Purposes Of This Litigation.

When infringement has been established, a patentee is entitled to "damages adequate to compensate for infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer." 35 U.S.C. § 284 (1988). Thus, when a patentee is unable to prove entitlement to lost profits, i.e., a loss in market share, the patentee is entitled to "reasonable royalty" damages based upon a hypothetical negotiation between the patentee and the infringer when the infringement began. *See Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1078 (Fed. Cir. 1983) (describing the hypothetical negotiation as one "resulting from arm's length negotiations between a willing licensor and licensee").

The hypothetical negotiation is deemed to take place on the date that the defendant's infringement began. Indeed, even the case law cited by Abraxis establishes that "a reasonable royalty determination for purposes of making a damages evaluation must relate to the time infringement occurred . . . ." *Unisplay, S.A. v. Am. Elec. Sign Co., Inc.*, 69 F.3d 512, 518 (Fed. Cir. 1995).

In *Unisplay*, the court determined that testimony regarding a royalty rate existing at the time of trial did not support the jury's damages verdict because "it was not directed to the time of infringement." *See id.* In reaching its decision, the court noted that: "[t]he key element in setting a reasonable royalty . . . is the necessity for return to the date when the infringement began." *Id.* (citations omitted). Accordingly, the relevant time period for determining Elan's reasonable royalty damages centers around January 2006, when the infringing product, Abraxis's Abraxane®, was first approved by the Food and Drug Administration ("FDA") for sale in the United States.

In determining a reasonable royalty, a court may look to one or more factors affecting the hypothetical negotiation. In *Georgia-Pacific*, a district court for the Southern District of New York listed fifteen of the factors that courts may consider. ("A comprehensive list of evidentiary facts relevant, in general, to the determination of the amount of a reasonable royalty for a patent license may be drawn from a conspectus of the leading cases." *See Georgia-Pacific*, 318 F. Supp. at 1120. The *Georgia-Pacific* court listed a wide range of factors potentially relevant to determining a reasonable royalty, however, *only* because there was no established royalty rate for the patents-in-suit in that case:

> The parties agree that there was no established royalty for USP's Weldtex or GP striated. Consequently, it is necessary to resort to a broad spectrum of other evidentiary factors probative of a reasonable royalty.

Id. at 1121. The Federal Circuit has also long recognized that when there is an established royalty rate, there is no need for further consideration of the remaining *Georgia-Pacific* factors:

> In performing a hypothetical negotiation analysis, it is important to recognize that some of the *Georgia-Pacific* factors may be of minimal or no relevance to a particular case . . . .

Mobil Oil Corp. v. Amoco Chems. Corp., 915 F. Supp. 1333, 1353 (D. Del. 1994).

Here, the Patents-In-Suit have been repeatedly licensed, and licenses executed around the time that infringement began unequivocally establish the reasonable royalty rate that Elan is due for Abraxis's infringement of the Patents-In-Suit. The remaining *Georgia-Pacific* factors simply bear no relevance in light of such an established royalty rate.

C. Abraxis Has Had Ample Opportunity To Discover Elan's Licenses Relevant To A Determination Of A Reasonable Royalty Rate.

As noted above, Abraxis directly subpoenaed many of the non-parties to whom Elan licensed the Patents-In-Suit. *See* D.I. 152, 155, 165, 168-170, 178, 180, 188. In response to its subpoenas, Abraxis obtained production of Elan's licenses with **REDACTED**

REDACTED

Nevertheless, Abraxis seeks to compel Elan to produce the same licenses. Abraxis's Motion to compel a response to requests nos. 61-63 and 106, and to discover from Elan documents already in Abraxis's possession, custody and control, should therefore be denied. Such discovery is unreasonably cumulative and duplicative.[5] *See* Fed. R. Civ. P. 26.

D. Even Assuming Licenses Regarding So-Called "Comparable Patents" Are Relevant To A Reasonable Royalty Determination, Abraxis's Discovery Request Aimed At Such Licenses Is Overly Broad And Unduly Burdensome.

Erroneously claiming that *all* of the *Georgia-Pacific* factors are relevant to *every* reasonable royalty determination, Abraxis seeks to compel Elan to produce purportedly "comparable patents" in response to request no. 64. *See* Motion at 6. Abraxis's discovery request no. 64 seeks non-party license agreements regarding "pharmaceutical or diagnostic compositions or methods:"

> 64. License agreements between (1) Elan or a Previous Owner and (2) any third party concerning pharmaceutical or diagnostic compositions or methods.

See Motion at 5. The over breadth of this request is staggering. First, it encompasses products containing or consisting of particles on the macro (or non-nanometer) scale, as compared to the Patents-In-Suit, which claim only nanoparticles. Second, the term "pharmaceutical or diagnostic compositions or methods" is unlimited as to any specific formulation, any dosage form, any

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[2] Elan granted permission to produce confidential information in response to Abraxis's subpoena on July 31, 2007. **REDACTED**

[3] Elan granted permission to produce confidential information in response to Abraxis's subpoena on July 31, 2007.

[4] Furthermore, Elan granted **REDACTED** permission to produce confidential documents in its possession on July 31, 2007.

[5] When issuing subpoenas to the non-party licensees, Abraxis had the opportunity to seek documents regarding the negotiations of and communications concerning the licenses, but chose not to do so. This raises the question of how important such documents are to Abraxis. It is difficult to imagine their relevance when the licenses, standing alone, establish the reasonable royalty rate.

specific drug, any specific diagnostic, any particular dosage regimen, or any method of administration (let alone any time period contemporaneous with commencement of Abraxis's infringement). This request misses the mark of identifying patents "comparable" to the Patents-In-Suit by miles, rather than by inches. Indeed, Abraxis's request no. 64 would encompass every license agreement executed between a third party and Elan during the 30 year existence of Elan and its predecessor companies — a total of approximately **REDACTED**

Elan should not be compelled to respond to a request that is so overly broad and that would result in an overwhelming production of irrelevant documents.

E. Elan Seeks Limited Protection From Abraxis's Deposition Notice Pursuant To Federal Rule Of Civil Procedure 30(B)(6).

1. Elan Does Not Seek To Quash Abraxis's Deposition Notice.

Elan does not seek to avoid presenting any witness or witnesses in response to Abraxis's Rule 30(b)(6) deposition Notice regarding damages. Indeed, Elan unequivocally stated that it would offer testimony directed to topics 1, 2, 5, 17, 18, and 19-21 of Abraxis's Rule 30(b)(6) Notice. Elan seeks only the limited protection described below.

2. Elan Seeks Partial Protection From Responding To Topics That Seek Information About Agreements With "Third Parties."

Abraxis's deposition Notice places Elan in the unenviable position of either testifying about third-party trade secrets and proprietary information — in breach of binding contractual obligations — or refusing to answer such questions from Abraxis — which would be in violation of Federal Rule of Civil Procedure 30(d)(1), (4) (if not authorized pursuant to an order of protection as is sought here). Placing Elan in such a situation might arguably be understandable if Abraxis's deposition of Elan concerning relevant license agreements were the only method of discovery available. Here, however, Abraxis has already subpoenaed (and in many or all cases obtained) the relevant license agreements directly from Elan's licensees.

3. Elan's Business Involves REDACTED

To understand the burden placed on Elan by Abraxis's Notice, it is first necessary to understand Elan's business model.

REDACTED

4. Elan's Experimentation And Evaluation Agreements Are Highly Confidential.

Elan's "Experimentation And Evaluation Agreements" and "Master Experimentation And Evaluation Agreements" constitute and reflect third-party trade secrets and/or proprietary information for the following reasons:

(a) they contain a proprietary "work plan" and "feasibility screen;" in other words, they describe the particular composition desired, the third-party compound, and Elan's particular technology to be applied to that compound;

(b) they contain proprietary information on the particular surface modifiers chosen for application to a particular compound;

(c) they may contain proprietary information about a target particle size;

(d) they may contain proprietary information about a target concentration of active pharmaceutical ingredient;

(e) they contain proprietary information about a third-party compound; clearly, information about the drug compounds that a third party develops is trade secret, particularly in the highly-competitive pharmaceutical industry;

(f) they may contain proprietary information about what tests are to be used to characterize a particular formulation, including tests based upon or comprising trade-secret processes or know-how of Elan or the third party;

(g) they may contain proprietary information about what conditions Elan or a third party deems important for formulation of a particular composition;

(h) they may contain proprietary information about what tests Elan or a third party deems important to evaluate the suitability of a particular composition's formulation.

Despite their highly sensitive nature, Abraxis has noticed Elan's deposition on all of its Experimentation And Evaluation Agreements and Master Experimentation And Evaluation Agreements, of which Elan has **REDACTED**

5. Elan Seeks Protection From Abraxis's Deposition Topic No. 16.

Abraxis's Topic No. 16 seeks testimony from Elan on:

> Elan's or a Previous Owners' "experimental evaluation agreements" and "master experimental evaluation agreements" with any Third party, as those terms are used by Elan or a previous owner.

This topic is overly broad, unduly burdensome, seeks irrelevant information, and is not reasonably calculated to lead to the discovery of admissible evidence. Moreover, it seeks

information that Elan is contractually bound not to disclose. Accordingly, Elan seeks protection from providing testimony in response to this deposition topic.

Abraxis's Topic No. 16 is overly broad because it is not limited to third-party agreements that concern the diagnostic or pharmaceutical compositions claimed in the Patents-In-Suit, or in any related family patents. It is also overly broad in that it lacks any relevant temporal limitation; but instead, purports to reach all of Elan's experimental and evaluation agreements executed over the history of Elan's existence.

Moreover, Abraxis's Topic No. 16 is unduly burdensome because it would require Elan to testify about third-party trade secrets and proprietary information, in breach of the parties' confidentiality agreements. There has been no showing by Abraxis of a benefit to be derived from obtaining discovery into experiments on third-party compounds (the majority of which are not claimed by the Patents-In-Suit) that outweighs the burden of requiring Elan to breach its contractual obligations. To illustrate this point, in response to Abraxis's document requests directed to this topic, and pursuant to the parties' Stipulated Protective Order, Elan produced a confidentiality log that listed all of Elan's *relevant* experimental and evaluation agreements. Abraxis had ample opportunity to obtain these documents by following the procedures prescribed by the Protective Order, which would have allowed implicated third parties the opportunity to be heard. The very fact that Abraxis spurned these procedures suggests that the discovery it now seeks from Elan is less than necessary, or that Abraxis doubted that the Court would grant its application under the Protective Order.

Finally, Abraxis's Topic No. 16 seeks irrelevant information and is not reasonably calculated to lead to the discovery of admissible evidence. It is undisputed that the Patents-In-Suit involve nanoparticulate technology. Elan's [**REDACTED**

REDACTED technologies that are wholly irrelevant to the claims and defenses of the parties in this lawsuit. Nonetheless, these technologies would be encompassed by Abraxis's request to examine Elan on all Experimental Evaluation Agreements and Master Experimental Evaluation Agreements.

Finally, and most importantly, Elan is at a loss to understand how its experimental agreements with third parties are relevant to a damages assessment, which case law provides is to be determined by reference to the historical record of licensing of the Patents-In-Suit, when such information exists. *See Trell v. Marlee Elecs. Corp.*, 912 F.2d 1443, 1445 (Fed. Cir. 1990). Indeed, even accepting for purposes of argument Abraxis's untenable claim that, notwithstanding extensive licensing history for the Patents-In-Suit, all of the other 15 *Georgia-Pacific* factors are relevant to a reasonable royalty determination, not a single such factor contemplates scrutiny of agreements similar to Elan's experimental and evaluation agreements. *See Georgia-Pacific*, 318 F. Supp. at 1120.

For all of these reasons, Elan requests that it be protected from providing testimony in response to Abraxis's Topic No. 16.

6. Elan Has Over REDACTED Patents That Would Meet Abraxis's Definition Of "Particulate Composition Patents."

Abraxis also seeks testimony from Elan about its third-party agreements and/or licenses concerning "Particulate Composition Patents." "Particulate Composition Patents" are defined by Abraxis as encompassing claims and technologies that go far beyond those in the Patents-In-Suit and relevant family patents.

> The term "Particulate Composition Patent" means any patent having claims that encompass Particulate Compositions, or methods of making or using them, and that are limited to particles (or methods of making or using them) and that are limited to particles with an effective particle size of 1000 nm [nanometers] or

> less as determined by any method for determining particle size, including but not limited to Elan's NanoCrystal® technology.

D.I. 167, Definitions at ¶ 10. To understand the reach of "Particulate Composition Patents," it is necessary to refer to Abraxis's definition of "Particulate Compositions," which encompasses every pharmaceutical or diagnostic agent that is less than 1000 nm in size.

> The term "Particulate Composition" means pharmaceutical or diagnostic compositions containing a pharmaceutical or diagnostic agent and having an average, mean, median or effective particle size of up to 1000nm as determined by any method for calculating particle size.

D.I. 167, Definitions at ¶ 9. By combining the two definitions, it becomes abundantly clear that Abraxis seeks to question Elan about *any* patent:

(a) regardless of whether it: (1) is a U.S. or foreign patent; (2) is owned by Elan or a third party; or (3) claims the same technology as the Patents-In-Suit or the relevant family patent;

(b) that claims *any* pharmaceutical or diagnostic composition, regardless of whether that composition is claimed by the Patents-In-Suit;

(c) that contains *any* pharmaceutical or diagnostic agent, regardless of whether that agent is claimed by the Patents-In-Suit; and

(d) that has an average, mean, median or effective particle size of up to 1000nm.

Elan has **REDACTED** patents that meet this sweeping definition of "Particulate Composition Patents," most of which are irrelevant to the subject matter of this lawsuit and to the claims and defenses of the parties.

7. Elan Seeks Protection From Testifying About Its Third-Party Agreements Regarding "Particulate Composition Patents."

Abraxis's proposed deposition topics regarding "Particulate Composition Patents" are overly broad, unduly burdensome, seek irrelevant information, and are not reasonably calculated to lead to the discovery of admissible evidence. Moreover, as with Topic No. 16,

Abraxis's topics regarding "Particulate Composition Patents" are inconsistent with Elan's contractual obligations to protect the trade secrets and proprietary information of third parties.

Abraxis claims to seek information about Elan's third-party license agreements in order to determine the reasonable royalty due Elan in recompense for Abraxis's infringement. Controlling case law is crystal clear, however, that courts determine a reasonable royalty by looking *first* to license agreements regarding the specific patents-in-suit. *See Trell*, 912 F.2d at 1445. Courts expand their inquiry *only* when a patentee has not licensed the patents-in-suit. *See, e.g., Am. Orig. Corp. v. Jenkins Food Corp.*, 774 F.2d 459, 462 (Fed. Cir. 1985). Even then, consideration is limited to licenses of patents that are *comparable* to the patents-in-suit. *See Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified and aff'd*, 446 F.2d 295 (2d Cir.).

Here, each of the Patents-In-Suit has been licensed, and accordingly there is abundant information about their royalty rate as negotiated in the marketplace. Therefore, Abraxis's attempt to elicit testimony from Elan about other "Particulate Composition Patents" is inherently overbroad and unnecessarily cumulative. *See* Fed. R. Civ. P. 26.

By noticing Elan's deposition on "Particulate Composition Patents," Abraxis seeks testimony about patents that are not even comparable to the Patents-In-Suit. There are two Patents-In-Suit, which claim, respectively: (1) anti-cancer nanoparticulate pharmaceutical and diagnostic compositions; and (2) a method for the intravenous infusion of nanoparticulate organic drug compositions. By contrast, **REDACTED** , would arguably fall under Abraxis's definition of "Particulate Composition Patents," and include, for instance,

REDACTED

REDACTED

The only thing comparable between the patents listed above and the Patents-In-Suit is their common ownership by Elan and their broad inclusion in the pharmaceutical industry, which is a complex and diverse industry far broader than the relevant subject matter of the Patents-In-Suit.

Abraxis is well aware that its deposition topics regarding "Particulate Composition Patents" would capture irrelevant information. Not only have the parties *met and conferred* about the overbreadth of Abraxis's topics, but Elan has also produced several lists of the patents in its portfolio, which — at a mere glance — should have informed Abraxis that its deposition Notice was overreaching.

In addition to being overly broad, Abraxis's topics regarding "Particulate Composition Patents" are unduly burdensome in that they purport to require Elan to testify in breach of its third-party agreements. Abraxis has yet to demonstrate that its interest in discovering irrelevant third-party agreements regarding "Particulate Composition Patents" outweighs the burden that such discovery would impose on Elan. Accordingly, Elan seeks protection from Abraxis's Topics No. 3-4, 6-13, and 15 to the extent that they seek testimony concerning third-party agreements regarding "Particulate Composition Patents."

8. The Only Third-Party License Agreements Regarding The Patents-In-Suit That Are Relevant Are Those Executed Contemporaneously With Abraxis's Entry Into The Marketplace.

Certain of Elan's third-party license agreements regarding the Patents-In-Suit and related family patents are indisputably relevant to determining a reasonable royalty. Those agreements, however, are limited in number. "[T]he hypothetical negotiation required in a reasonable royalty analysis requires the court to envision the terms of a licensing agreement between the patentee and the infringer *at the time infringement began*." *See Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1276 (Fed. Cir. 1999) (citation omitted) (emphasis in

original). Thus, the only licenses of Elan's patents that are relevant to a reasonable royalty determination are those executed around the time that Abraxane® was approved by FDA for sale in the United States market — January 7, 2006.[6] Moreover, such executed licenses are the best evidence of the entirety of the business factors that were relevant to negotiations between the licensor and licensee at the time.

9. Discovery From Elan About Third-Party Licenses Of The Patents-In-Suit Or Related Family Patents Is Unreasonably Cumulative Or Duplicative.

In response to Elan's production of a confidentiality log, Abraxis issued subpoenas to Elan's licensees. *See* D.I. 152, 155, 165, 168-170, 175, 180, 188. In almost every instance, the third party either released Elan from its confidentiality obligations or directly produced the identified licenses to Abraxis. Accordingly, Abraxis has already discovered the best evidence of the royalties received by Elan for licensing the Patents-In-Suit. There is nothing about which Elan might testify that cannot be found in the four corners of these agreements. Therefore, Abraxis's deposition topics directed to third-party agreements regarding the Patents-In-Suit or related family patents are unreasonably cumulative and duplicative. *See* Fed. R. Civ. P. 26. Accordingly, Elan seeks protection from providing testimony in response to Abraxis's Topics No. 3-4, 6, 8-10, and 12 to the extent that they seek information already available to Abraxis about Elan's license agreements, or the negotiations therefor.

[6] The methodology employed in determining a reasonable royalty encompasses "flexibility because it speaks of negotiations as of the time infringement began, yet permits and requires a court to look at facts and events that occurred thereafter and that could not have been known to or predicted by the hypothetical negotiations." *Studiengesellschaft Kohle v. Dart Indus., Inc.*, 862 F.2d 1564, 1572 (Fed. Cir. 1988) (citation omitted). Accordingly, courts routinely look to the profits made by the infringing party in reaching a reasonable royalty determination.

F. Topic No. 14 Is Irrelevant And Grossly Overbroad.

Abraxis's Topic No. 14 is emblematic of the overbreadth of Abraxis's Rule 30(b)(6) Notice. Topic No. 14 seeks testimony regarding the financial affairs of Elan over a twelve-year period:

> Elan's financial history from 1995 to the present, including Elan's capitalization and stock price, Elan's balance sheet and income statements, Elan's revenues, costs and profits, and losses, and the portion of Elan's income attributable to licensing its patents, inventions and any other rights in intellectual property.

D.I. 125 at Topic No. 14. As a threshold matter, it is difficult, if not impossible, to determine how global details stretching across twelve (12) years of Elan's financial history could have any specific relevance to determining a reasonable royalty rate, which is based upon a hypothetical negotiation occurring at the time infringement began. Abraxis nonetheless claims that the 15th *Georgia-Pacific* factor entitles it to unfettered access to Elan's financial affairs. At the risk of repetition, the last *Georgia-Pacific* factor comes into play only when there is no established royalty for the patents-in-suit. Even then, in most cases, it is appropriate for a District Court to consider the *infringer's* actual profits in determining a reasonable royalty, rather than the patentee's financial history. *See, e.g., Fromson v. W. Litho Plate and Supply Co.*, 853 F.2d 1568, 1575 (Fed. Cir. 1988).

Even in the unlikely event that Abraxis could somehow establish the relevance of this topic, it would remain overly broad and unduly burdensome. To prepare a witness or witnesses to testify on this topic, Elan would have to gather twelve years' worth of comprehensive financial information and prepare a tutorial of substantial breadth. Preparation on Elan's stock price alone would require a witness to become familiar with daily price fluctuations that occurred over a 4,380-plus day period. Surely the Federal Rules do not

contemplate imposing such an onerous burden on a party deponent for the mere sake of providing irrelevant testimony.

G. Abraxis's Request To Compel The Production Of All Documents In Elan's Confidentiality Log Is Unavailing.

In what is best characterized as an afterthought in its Motion, Abraxis suggests that the Court indiscriminately compel Elan to produce all of the documents listed in its confidentiality log. In support of its cause, Abraxis claims that: (1) the documents must be relevant or Elan would not have included them in the log; (2) there is a protective order in place to protect any confidentiality concerns of third parties;[7] and (3) third parties have directly produced documents from the log to Abraxis.

Abraxis's analysis is both superficial and fatally flawed. The documents listed in Elan's confidentiality log are responsive to any number of Abraxis's 144 requests for production. In response to all but a few of Abraxis's requests, Elan lodged appropriate objections, and those objections were not limited to concerns regarding the confidential nature of potentially responsive documents. Indeed, the mere listing of a document in the log means only that its confidential nature was *one* of the reasons why it was withheld. As discussed at length above, the great majority of Abraxis's requests were even more fundamentally, and fatally, flawed because of their overbreadth, and lack of any relevance to any issue in this case that could outweigh their extremely burdensome nature. In logging confidential documents subject to one particular objection — confidentiality obligations to Elan's contractual partners — Elan did not

[7] It is particularly curious that Abraxis makes this argument. Abraxis has guarded its supposed "secret manufacturing information" with more fervor than the Allies guarded the details of the Normandy invasion, and has repeatedly rejected the argument that the Protective Order is sufficient to address supposed confidentiality concerns invoked in Abraxis's abusive overuse of this designation. Nor does Elan expect that Abraxis would accede to a mirror image of its own argument on this point, to wit, that, by classifying huge swathes of its documents as "secret manufacturing" information, Abraxis has ipso facto acknowledged that these documents are relevant, and that such "acknowledgement" means there can be no other impediment or objection to their immediate and full production.

in any way imply that these materials were not also the subject of other proper objections. To the contrary, Elan lodges such additional objections, and renews their assertion in the arguments set forth throughout this submission.

Abraxis asks this Court to go where no other court has gone before. Abraxis implicitly asks the Court to overrule, on a wholesale basis, all of Elan's objections to Abraxis's requests for production — without consideration as to whether they were appropriately lodged in response to individual discovery requests — for the sole reason that potentially responsive documents to those requests are listed on a confidentiality log. Abraxis cites no authority for this request, as indeed none exists.

Notably, Abraxis identifies its own request as duplicative, cumulative, and pointless. It makes clear reference to the fact that "Abraxis has also served subpoenas for documents from a number of the very same third parties that Elan identified in its confidentiality log." *See* Motion at 8. Abraxis then unequivocally states that the third parties have produced the requested documents in response to Abraxis's subpoenas. *See id.* Abraxis therefore, clearly admits that it had ample opportunity to discover (and, in fact, did discover) the documents it now seeks to compel from Elan. Thus, by Abraxis's own admission, there is no incremental evidentiary value in the duplicative production Abraxis seeks to compel, certainly not a value sufficient to outweigh the burden on Elan. When a discovery request has no substantial potential to lead to new, relevant evidence, and could by its terms only impose a burden on an opposing party, there is no inference to be drawn other than that the request was brought for, or would wreak, improper burdening, vexation, and harassment of the party from which discovery is sought. *See* Fed. R. Civ. P. 26.

V. Conclusion

Elan is more than prepared to meet its discovery obligations pursuant to the Federal Rules of Civil Procedure. Abraxis's Rule 34 discovery requests and 30(b)(6) deposition Notice, however, go beyond the pale. Abraxis's attempts to seek discovery from Elan about irrelevant, third-party proprietary, or cumulative topics has no rational explanation, and makes sense only in the context of duplicative and overly-burdensome discovery practice for tactical litigation purposes. Accordingly, Abraxis's Motion should be denied and Elan should be protected from testifying in response to those designated portions of Abraxis's deposition Notice that serve as the basis for Elan's request for partial relief, and which constitute nothing more than harassment.

VI. Prayer

For these reasons, Elan seeks an order from the Court that:

1. Elan's objections to Abraxis's Requests for Production Nos. 61-64 and 106 are sustained;

2. Topic No. 16 of Abraxis's Rule 30(b)(6) deposition Notice to Elan is stricken;

3. Elan is relieved of its obligations under the Federal Rules of Civil Procedure to testify in response to Topics No. 3-4, 6-13, and 15 of Abraxis's Rule 30(b)(6) deposition Notice to the extent that they seek information regarding "Particulate Composition Patents" other than the Patents-In-Suit;

4. Elan is relieved of its obligations under the Federal Rules of Civil Procedure to testify in response to Topics No. 3-4, 6, 8-10, and 12 of Abraxis's Rule 30(b)(6) deposition Notice to the extent that they seek information about Elan's confidential license

agreements, or the negotiations thereof, with third parties regarding the Patents-In-Suit or related family patents;

5. Topic No. 14 of Abraxis's Rule 30(b)(6) deposition Notice is stricken;

6. Elan's other objections to Abraxis's Rule 30(b)(6) deposition Notice, which are attached as Exhibit B hereto, are sustained; and

7. Abraxis's Motion to compel the wholesale production of all documents listed in Elan's confidentiality log is denied.

ASHBY & GEDDES

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