IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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

DEFENDANT ABRAXIS BIOSCIENCE, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO COMPEL PRODUCTION OF DAMAGES DISCOVERY

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NATURE AND STAGE OF PROCEEDINGS

Over a year ago, on July 19, 2006, Elan filed suit against Abraxis in this Court, alleging infringement of U.S. Patent Nos. 5,399,363 and 5,834,025. Abraxis served Elan with several sets of document requests and a deposition notice pursuant to Rule 30(b)(6) seeking discovery on damages issues. Fact discovery will close within a week on August 13, 2007, but Elan still refuses to produce the requested damages discovery.

SUMMARY OF ARGUMENT AND RELIEF REQUESTED

In this action, Elan seeks as damages an award of a "reasonable royalty." Under the applicable case law, Elan's existing licenses are relevant to this determination. Abraxis has therefore requested documents and deposition testimony regarding Elan's patent licensing. Elan has refused, however, to produce most of its licenses – whether for the patents-in-suit or for other arguably comparable patents. In the few licenses it actually has produced, it has redacted the most important information – the royalty rates, payments, and terms. Similarly, Elan has refused to produce a 30(b)(6) witness in response to Abraxis's deposition notice on damages topics. Because the requested information is relevant to Elan's damages claim, the Court should order its production.

Specifically, Abraxis requests an order: (1) compelling Elan to produce all documents responsive to Abraxis's Requests for Production Nos. 61-64 and 106; (2) overruling Elan's objections to Abraxis's Requests for Production Nos. 61-64 and 106; (3) compelling Elan to produce all documents listed on its Non-Party Confidentiality Log or otherwise withheld on grounds of non-party confidentiality obligations; and (4) requiring Elan to designate and produce a witness in response to Abraxis's Notice of Rule 30(b)(6) Deposition of Elan Pharma International Limited, dated July 3, 2007.

STATEMENT OF FACTS

Over the course of the discovery period, Abraxis has served several requests for production seeking documents related to damages issues. This discovery includes Abraxis's

Requests for Production Nos. 8, 61-64, 106, and 138-144. (Declaration of Eric C. Pai in Support of Abraxis's Motion to Compel Production of Damages Discovery ("Pai Decl.") Ex. A at 4, 13; Ex. B. at 8; Ex. C. at 3-4.) These requests seek documents relating to licenses of the patents-in-suit and comparable licenses, offers to license, licensing negotiations and communications, and various categories of financial information. (*Id.*) In responding to these requests, Elan asserted a variety of boilerplate objections, such as relevance and confidentiality, but otherwise stated that it would produce responsive documents. (Pai Decl. Ex. D at 7, 33-35; Ex. E at 31; Ex. Q at 6-14.) However, Elan did not produce the majority of the requested documents and improperly redacted many of the documents it did produce. The parties discussed this issue in numerous letters, emails, and meet and confer sessions, but Elan refused to compromise or reconsider its position. Instead, it sought to justify its refusal through a half-hearted relevance objection and a third-party confidentiality objection. (*Id.*; *see also* Pai Decl. Ex. F.)

On July 3, 2007, Abraxis served Elan with a deposition notice pursuant to Federal Rule of Civil Procedure 30(b)(6) on several damages-related topics. (Pai Decl. Ex. G.) Elan refused to produce a witness to testify on most of these topics and stated that it would file for a protective order, relying primarily on the same objections it raised against Abraxis's damages-related document requests. (Pai Decl. Exs. H, I.) Having reached an impasse with Elan on damages discovery, Abraxis had no choice but to file this motion to compel.

ARGUMENT

I. ABRAXIS IS SEEKING RELEVANT AND NECESSARY DISCOVERY ON DAMAGES ISSUES.

Federal Rule of Civil Procedure 26(b)(1) provides that a party "may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party." Fed. R. Civ. P. 26(b)(1). Relevance under Rule 26 is interpreted broadly and encompasses not only information that would be admissible at trial, but also information "reasonably calculated to lead to the discovery of admissible evidence." *Id.* In the Third Circuit, "it is well recognized that the federal rules allow broad and liberal discovery." *Corning Inc. v. SRU Biosystems, LLC*,

Civil Action No. 03-633 JFF, 2004 U.S. Dist. LEXIS 14831, at *3 (D. Del. July 7, 2004) (citing *Pacitti v. Macy's*, 193 F.3d 766, 777-78 (3d Cir. 1999)). When a party objects or fails to produce documents responsive to a request for production, or fails to make a designation under Rule 30(b)(6), the requesting party's remedy is a motion to compel the requested discovery. Fed. R. Civ. P. 34(b), 37(a)(2).

Elan alleges that it has suffered monetary damages under the "reasonable royalty" theory of patent damages. (Pai Decl. Ex. J at 22.) The determination of a reasonable royalty is based on a broad inquiry that takes into consideration the fifteen factors set forth in *Georgia-Pacific*, which the Federal Circuit has adopted as a standard approach. *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified on other grounds by*, 446 F.2d 295 (2d Cir. N.Y. 1971); *Unisplay, S.A. v. Am. Elec. Sign Co.*, 69 F.3d 512, 517 n.7 (Fed. Cir. 1995). The factors are directed at calculating the license fee that willing parties would have agreed upon in a hypothetical negotiation when the alleged infringement began. *Georgia-Pacific*, 318 F. Supp. at 1121.

The first and second *Georgia-Pacific* factors look to the royalties received for existing licenses of the patent-in-suit and of comparable patents. *Id.* at 1120. Therefore, Abraxis served requests for production specifically directed at the types of documents that would bear on these factors – licenses for the patents-in-suit and for particulate compositions and technology. (Pai Decl. Ex. A at 4, 13; Ex. B. at 8; Ex. C. at 3-4.) Abraxis also requested documents on offers to license, negotiations and communications about actual or potential licenses, and financial information about Elan's patent licensing and overall business. (*Id.*) Documents containing these types of information are relevant to how Elan would have acted and bargained as a willing licensor in a hypothetical negotiation at the time that the alleged infringement began. These documents bear on the fifteenth *Georgia-Pacific* factor, as well as the conceptual framework underlying a reasonable royalty analysis. 318 F. Supp. at 1120-21.

II. ELAN HAS IMPROPERLY WITHHELD LICENSES AND RELATED DOCUMENTS THAT ARE RELEVANT TO ITS DAMAGES CLAIM.

Instead of producing the documents requested, Elan has engaged in obstructionist tactics that will prevent Abraxis and the Court from conducting a proper damages analysis. First, Elan has flatly refused to produce the majority of the licenses requested, claiming that they are not relevant to the case. Elan's attempt to contest the relevance of its licenses is contradicted by controlling case law. In discussing the second *Georgia-Pacific* factor, the Federal Circuit has stated that evidence of prior license agreements and license proposals for technology comparable to the patent-in-suit "should carry considerable weight in calculating a reasonable royalty rate." *Unisplay*, 69 F.3d at 519. This Court has also explained that it "interprets this factor broadly." *Mobil Oil Corp. v. Amoco Chems. Corp.*, 915 F. Supp. 1333, 1354 (D. Del. 1994).

In light of this broad standard for what can constitute a "comparable" license, Elan's refusal to produce the vast majority of its licenses for nanoparticulate technology is improper. Ultimately, when it comes time to address the substantive determination of a reasonable royalty at trial, the parties will argue about which licenses are most comparable and should carry the most weight in the analysis. However, Elan seeks to prevent Abraxis from seeing those licenses at all during discovery, which would prejudice Abraxis's ability to make arguments at trial about which licenses are comparable and how they should affect the damages calculation. By making itself the sole judge of "relevance," Elan aims to restrict the available evidence to those licenses that are most favorable to its own position as the patent holder. Therefore, the Court should compel Elan to produce all of its licenses to ensure a level playing field at trial.

Moreover, Elan has redacted some of the most important information – the royalty rates, payments, and terms – from the few licenses it actually has produced. [redacted]

[redacted] This is improper. Without the royalty information, these licenses are effectively useless for damages purposes.

Elan should be compelled to produce all of its licenses in full and unredacted form.[1] If Elan has concerns with the confidentiality of the information in these licenses, it can address them using appropriate designations under the Court-entered protective order already in place, which has a "Restricted Confidential" designation that strictly limits disclosure even for purposes of this litigation. (Pai Decl. Ex. M.).

III. ELAN SHOULD BE COMPELLED TO PRODUCE ALL DOCUMENTS RESPONSIVE TO ABRAXIS'S REQUESTS FOR PRODUCTION NOS. 61-64 AND 106.

Abraxis's Requests for Production Nos. 61-64 and 106 seek the following:

> 61. Documents constituting, referring to, or reflecting any licensing of the Patents-In-Suit.
>
> 62. Documents referring to, evidencing, or reflecting negotiations regarding licensing of the Patents-In-Suit.
>
> 63. Documents referring to, evidencing, or reflecting any royalties or other consideration paid by licensees or sublicensees pursuant to any agreement concerning the Patents-In-Suit.
>
> 64. License agreements between: (1) Elan or a Previous Owner and (2) any third party concerning pharmaceutical or diagnostic compositions or methods.
>
> 106. Documents referring to, evidencing or reflecting any license or offer to license the Patents-In-Suit, the '684 Patent, Foreign Counterparts and/or Related Applications and Patents, including any communications or negotiations concerning any such license or potential license.

(Pai Decl. Ex. A at 13; Ex. B. at 8.) These requests seek documents concerning licenses, offers to license, and negotiations and communications about actual or potential licenses for the patents-in-suit and comparable patents. Elan has resisted production of these documents based

[1] For its own part, Abraxis is producing its potentially comparable licenses as requested by Elan, and Abraxis is not redacting royalty information.

on three objections: (1) that the requests directed to comparable licenses were irrelevant and not reasonably calculated to lead to the discovery of admissible evidence; (2) that the requests were overly broad and unduly burdensome; and (3) that it was obligated not to disclose the confidential information of third parties. (Pai Decl. Ex. D at 33-35; Ex. E at 31.) The Court should overrule these objections and order Elan to produce all responsive documents fully and without redactions.

Elan does not deny that licenses of the patents-in-suit themselves are relevant to damages. However, as discussed above, the case law is clear that comparable licenses are also relevant to the determination of a reasonable royalty. Indeed, they are specifically examined under the second *Georgia-Pacific* factor, which the courts give considerable weight and interpret broadly. *Unisplay*, 69 F.3d at 519; *Mobil Oil*, 915 F. Supp. at 1354. Although there will be arguments to be made at trial about which licenses are the most "comparable" and how they should affect a reasonable royalty calculation, it is improper for Elan to make that determination unilaterally during discovery. That determination is the province of the trier of fact, not Elan. *Unisplay*, 69 F.3d at 517.

With respect to the breadth of the requests and the burden imposed, Elan's counsel has claimed that the discovery "literally would be every single license agreement that my client has ever entered into." (Pai Decl. Ex. F at 2.) However, despite repeated inquiries by Abraxis in an attempt to compromise and lessen the burden of this discovery, Elan has been unwilling to reveal just how many licenses it has. [redacted]

More importantly, given the direct relevance of these licenses and the fact that this case presents many complicated issues that require extensive discovery, Elan should not be allowed to withhold responsive documents based on a vague and generic burdensomeness objection. Abraxis itself has produced to Elan over 500,000 pages of documents, many of which were in

response to Elan's complaints and demands for documents that are only tangentially related to this case.

Finally, Elan has relied heavily on its purported confidentiality obligations to third parties to withhold documents responsive to these requests for production and to redact information in the documents it has produced. As discussed in more detail below, this objection should be overruled because this confidential information can be sufficiently protected from improper disclosure through a "Restricted Confidential" designation under the terms of the Stipulated Protective Order, and because it is questionable whether the third parties have actually objected to the production of this information. *See infra* Section IV. Moreover, given that Elan has redacted the most probative information regarding the royalties in the licenses it actually has produced, the Court should order production of unredacted versions of these documents.

Elan's objections to Abraxis's Requests for Production Nos. 61-64 and 106[2] are without merit. Abraxis therefore requests that the Court overrule these objections and order Elan to produce all documents responsive to these requests in unredacted form.

IV. ELAN SHOULD BE COMPELLED TO PRODUCE ALL OF THE DOCUMENTS FROM ITS CONFIDENTIALITY LOG.

Elan has asserted claims of third-party confidentiality over many of its licenses and other documents and withheld them on that basis. It has listed these documents in a "Non-Party Confidentiality Log," which purportedly identifies all of the responsive documents that Elan has withheld because some third party has objected to their production in this litigation. (Pai Decl. Ex. N.) The Court should compel Elan to produce all of these documents for three reasons.

[2] Elan only recently served its objections and responses to Abraxis's Fourth Set of Requests for Production. (Pai Decl. Ex. Q.) Abraxis's Request Nos. 139-144 call for the same types of damages discovery addressed in this motion, and Elan has lodged the same objections discussed here. (*Id.*) The parties have yet to meet and confer on those responses, but Abraxis expects that Elan's position will not have changed. Therefore, it is likely that Abraxis will need relief from the Court with respect to Request Nos. 139-144 as well.

First, based on the limited information Elan's confidentiality log provides about these documents, it is clear that many of these documents fall into categories that are likely relevant to key issues in the case, such as damages, infringement, and invalidity. For example, in the "Doc. Type/Title" column, many of these documents are titled "License Agreement," "Test Report," or "Lab Notebook." (*Id.*) In fact, Elan has not refused to produce these documents on grounds of relevance or otherwise, but solely on grounds of confidentiality. Indeed, Elan itself had to make judgments as to their responsiveness to Abraxis's document requests before determining that they should be entered into its confidentiality log. Since Elan has recognized that these documents are properly discoverable aside from the confidentiality objection, there is every reason to believe they contain information relevant to the issues in the case.

Second, the concerns with respect to the confidential information of third parties are alleviated by the fact that these documents would be produced under a Court-entered protective order and designated with a "Restricted Confidential" status that would strictly limit their disclosure, even for purposes of this litigation. (Pai Decl. Ex. M.) In addressing objections regarding non-party confidentiality, courts have routinely ordered the production of relevant documents when there is a protective order in place to protect the interests of non-parties. *Walker v. County of Contra Costa*, 2004 U.S. Dist. LEXIS 25285, at *2 (N.D. Cal. Dec. 3, 2004); *Rubenstein v. Adm'rs of the Tulane Educ. Fund*, 1996 U.S. Dist. LEXIS 10618, at *4 (E.D. La. July 23, 1996). The protective order in this litigation has numerous safeguards for highly confidential information that will protect the third parties here.

Third, in at least some cases, it is questionable whether the third parties at issue have actually objected to the production of these documents at all. In addition to seeking discovery from Elan, Abraxis has also served subpoenas for documents from a number of the very same third parties that Elan identified in its confidentiality log. However, several of these third parties have either responded by producing documents to Abraxis or explaining that they would have no objection to having Elan produce the documents requested. (Pai Decl. Exs. O, P.) It is unclear

whether this is the result of miscommunication between Elan and these third parties, or an oversight on Elan's part, but it provides another reason for which Elan should be compelled to produce these documents.

V. ELAN SHOULD BE REQUIRED TO PRODUCE A CORPORATE WITNESS TO TESTIFY ON THE DAMAGES TOPICS IN ABRAXIS'S 30(B)(6) DEPOSITION NOTICE.

A party which receives a deposition notice under Federal Rule of Civil Procedure 30(b)(6) must "designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf." Fed. R. Civ. P. 30(b)(6). The designated witnesses "shall testify as to matters known or reasonably available to the organization." *Id.*

Abraxis's 30(b)(6) notice of July 3 seeks Elan's testimony on a number of licensing and financial topics related to damages. (Pai Decl. Ex. G.) Elan served objections to this notice, stated that it would not designate or produce a witness in response to this notice, and indicated that it would seek a protective order from the Court. (Pai Decl. Exs. H, I.) As the originally noticed date for this deposition has now passed, and Elan still has not filed its motion for a protective order, Abraxis seeks an order from the Court compelling Elan to produce a witness in response to Abraxis's 30(b)(6) deposition notice.

The issues are largely similar to those discussed earlier in the context of Elan's failure to produce damages documents. Elan has rested its refusal to offer a 30(b)(6) witness on the same three objections, pitched only slightly differently: (1) that the topics directed to comparable licenses were irrelevant and not reasonably calculated to lead to the discovery of admissible evidence; (2) that the topics were overly broad and unduly burdensome; and (3) that it was obligated not to disclose the confidential information of third parties. (*Id.*) The Court should overrule these objections and require Elan to produce a corporate representative to testify on the topics in Abraxis's notice.

With respect to relevance, Elan has taken its most extreme position yet. In objecting to Topic Nos. 1, 3, 4, 6-13, 15, 20, and 21 of Abraxis's 30(b)(6) notice, Elan claims that the only

licenses that should be discussed are those for the patents-in-suit "and arguably the '684 patent," which issued from the parent application for one of the patents-in-suit. (Pai Decl. Ex. I.) Despite the fact that Abraxis's topics were already limited to licenses for nanoparticulate technology, Elan apparently believes it is entitled to restrict the inquiry solely to licenses of the patents-in-suit themselves. This is improper, as it completely disregards the second *Georgia-Pacific* concerning the significance of comparable licenses in determining a reasonable royalty. *Unisplay*, 69 F.3d at 519; *Mobil Oil*, 915 F. Supp. at 1354. Elan's earlier objections to Abraxis's document requests were unreasonable in attempting to stack the deck of comparable licenses with only those that Elan preferred to introduce into evidence; its objections here are unreasonable because they pretend, contrary to well-established case law, that comparable licenses do not matter at all.

Elan has also lodged an objection claiming that all of Abraxis's 30(b)(6) topics are overly broad and unduly burdensome. With respect to Abraxis's licensing-related topics – Topic Nos. 1, 3, 4, 6-13, 15, 20, and 21 – this objection merely rides along with Elan's relevance objection. (Pai Decl. Ex. I.) In light of the direct relevance and importance of comparable licenses to calculating a reasonable royalty, this overbreadth objection lacks merit and should be overruled. For one of the remaining topics, Elan's objection is slightly different. It claims that Topic No. 14 is overly broad because it seeks information about Elan's financials over the past twelve years "rather than information regarding Elan's specific revenues from the patents-in-suit." (*Id.*)

Again, Elan ignores the legal standard for a reasonable royalty as set forth in *Georgia-Pacific*. The fifteenth factor, as well as the overarching framework for the *Georgia-Pacific* analysis, inquires into the license fee that the parties would have willingly agreed upon in a hypothetical negotiation when the alleged infringement began. *Georgia-Pacific*, 318 F. Supp. at 1120. This inquiry involves a "market place confrontation of the parties" that takes into account "the realities of the bargaining table" and "any other economic factor that normally prudent

businessmen" would consider under similar circumstances. *Id.* at 1121-22. Elan's overall financial condition is relevant to this analysis because it affects the type of bargaining position that Elan would have taken in a hypothetical negotiation. For example, a struggling company and a well-established highly profitable company will likely bargain quite differently under a given set of circumstances.

Finally, Elan has raised the same third-party confidentiality objection as before against Topic Nos. 2-6 and 8-16. Again, because this information can be designated "Restricted Confidential" under the Court-entered protective order to limit its use even for purposes of this litigation, it will be sufficiently protected against improper disclosure. *See supra*, Section IV.

Abraxis's 30(b)(6) deposition notice seeks Elan's testimony on topics that are highly relevant to Elan's claim for damages. The Court should therefore overrule Elan's objections and require Elan to designate and produce a 30(b)(6) witness in response to Abraxis's notice.

CONCLUSION

For the foregoing reasons, Abraxis respectfully requests that the Court grant its motion to compel and order the relief requested.

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Dated: August 8, 2007

CERTIFICATE OF SERVICE

I, Elena C. Norman, Esquire, hereby certify that on August 15, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on August 15, 2007, I caused a true and correct copy of the foregoing document to be served by e-mail on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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