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 FURTHER MOTION TO COMPEL PRODUCTION OF DAMAGES DISCOVERY

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Dated: August 13, 2007

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NATURE AND STAGE OF PROCEEDINGS

On July 19, 2006, Elan filed suit against Abraxis alleging infringement of U.S. Patent Nos. 5,399,363 and 5,834,025 (the "Patents-In-Suit") based on Abraxis's oncology drug Abraxane®. Since that time, Abraxis has served Elan with several sets of document requests, interrogatories and a deposition notice pursuant to Rule 30(b)(6) seeking to understand Elan's claim for damages. Even though fact discovery closes today, Elan has refused to produce documents establishing its damages claim.

SUMMARY OF ARGUMENT AND RELIEF REQUESTED

The issues addressed in this brief are substantially the same as those discussed in Abraxis's Opening Brief in Support of its Motion to Compel Production of Damages Discovery, filed on August 8, 2007 (the "Damages Motion"). (D.I. 241.). This additional motion is necessary due to deficiencies in Elan's response to Abraxis's Fourth Set of Requests for Production. Elan's responses were served on August 6, 2007, and the parties did not have the opportunity to meet and confer until after the Damages Motion was filed. In the interest of efficiency, Abraxis has condensed the overlapping discussion where possible.

Elan seeks as damages an award of a "reasonable royalty." Under the applicable case law, Elan's existing licenses, financial arrangements, and patent valuations are to be used in making the determination of what a reasonable royalty is. Elan has refused to produce most of these documents – whether for the Patents-In-Suit or for other comparable patents it owns and licenses. Because the requested information is relevant to Elan's claim for damages, the Court should order immediate production. Specifically, Abraxis requests an order: (1) compelling Elan to produce all documents responsive to Abraxis's Requests for Production Nos. 139-144; and (2) overruling Elan's objections to Abraxis's Requests for Production Nos. 139-144.

STATEMENT OF FACTS

Abraxis served a number of requests for production seeking documents related to Elan's claim for damages during the fact discovery period. These requests include Abraxis's Requests

for Production Nos. 139-144, served on June 29, 2007. (Declaration of Eric C. Pai in Support of Abraxis's Further Motion to Compel Production of Damages Discovery ("Pai Decl."), Ex. A at 3-4.) The requests seek documents relating to licenses, financial arrangements, and valuations of the Patents-In-Suit and comparable patents. (*Id.*) On August 6, 2007, Elan responded to these requests with a variety of boilerplate objections, but otherwise stated that it would produce responsive documents. (Pai Decl. Ex. B at 7-14.) At least two of these objections – relevance/breadth and third-party confidentiality – are the same objections already addressed in the Damages Motion. (D.I. 241.)

The parties met and conferred on Elan's objections on August 9, 2007. (Pai Decl. ¶ 8.) Abraxis asked if Elan had withheld or intended to withhold any non-privileged documents responsive to Request Nos. 139-144. Elan represented that it would be withholding documents based on its relevance/breadth and third-party confidentiality objections. (*Id.*) For purposes of clarification, Abraxis specifically asked if these were the same objections that Elan had lodged against Abraxis's earlier document requests on damages and licensing and on which Abraxis had moved to compel production. (*Id.*) Elan confirmed that they were the same objections, and that it was not relying on any new or different objections to withhold responsive documents. (*Id.*) The parties agreed that they remained at an impasse on these objections and would seek appropriate relief from the Court.

ARGUMENT

I. ABRAXIS IS SEEKING RELEVANT AND NECESSARY DOCUMENTS REGARDING ELAN'S DAMAGES CLAIM.

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, 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. C at 22.) The determination of a reasonable royalty is based on a broad "hypothetical negotiation" inquiry that takes into consideration the fifteen factors set forth in *Georgia-Pacific*, which the Federal Circuit has adopted. *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 royalty rate that the parties would have agreed to in a hypothetical negotiation at the time the alleged infringement began. *Georgia-Pacific*, 318 F. Supp. at 1121.

The first and second *Georgia-Pacific* factors consider the royalties received for existing licenses of the asserted patents and comparable patents. *Id.* at 1120. The twelfth factor examines the portion of the profit that "may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions." *Id.* The thirteenth factor focuses on the "portion of the realizable profit that should be credited to the invention" rather than other aspects of the product, such as non-patented elements or improvements. *Id.* Therefore, Abraxis served requests for production specifically directed at the types of documents that would allow these factors to be considered by the parties' damages experts – licenses, financial arrangements, and valuations of the Patents-In-Suit and particulate compositions and technology. (Pai Decl. Ex. A at 3-4.) Abraxis also requested documents on financial information about Elan's patent licensing and overall business. (*Id.*) Documents containing this 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 thus 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 SHOULD BE COMPELLED TO PRODUCE ALL DOCUMENTS RESPONSIVE TO ABRAXIS'S REQUESTS FOR PRODUCTION NOS. 139-144.

Abraxis's Requests for Production Nos. 139-144 seek the following:

> 139. Documents constituting or describing financial arrangements and/or Agreements between Elan Pharma International Ltd. and other Elan entities regarding the Patents-In-Suit, the '684 Patent, Related Applications and Patents, and any other patents concerning Particulate Compositions, including Documents describing any formal or informal valuations of the Patents-In-Suit, the '684 Patent, or Related Applications and Patents, by Elan, a Previous Owner, or any third party (including independent consultants).
>
> 140. Documents describing or referring to any analysis, study, or investigation conducted by or on behalf of Elan, a Previous Owner, or their licensees, of the monetary or economic value of the Patents-In-Suit, the '684 Patent, Related Applications and Patents, and any other patents concerning Particulate Compositions, including any audits done by Elan of its licensees.
>
> 141. Documents describing Elan's and/or a Previous Owner's annual income from licensing the Patents-In-Suit, Related Applications and Patents, and any other patents concerning Particulate Compositions.
>
> 142. Documents describing or referencing Elan's financial plans, business plans, and forecasts regarding the monetization, commercialization, or exploitation of the Patents-In-Suit, the '684 Patent, Related Applications and Patents, and any other patents concerning Particulate Compositions.
>
> 143. Documents describing Elan's financial history from 1995 to the present, including Elan's capitalization and stock price, Elan's balance sheets and income statements, Elan's revenues, costs, profits, and losses, and the portion of Elan's income attributable to licensing its patents.
>
> 144. Any development Agreements or partnership Agreements between Elan or any Previous Owner and any third party regarding the marketing, sale, distribution, manufacturing, or production of any products covered by the Patents-In-Suit, the '684 Patent, Related Applications and Patents or any other patents concerning Particulate Compositions.

(Pai Decl. Ex. A at 3-4.) Elan has refused to produce these documents based on two grounds: (1) that the requests are irrelevant, not reasonably calculated to lead to the discovery of admissible evidence, overly broad, and unduly burdensome; and (2) that it was obligated not to disclose the confidential information of third parties. (Pai Decl. Ex. B at 7-14; *id.* ¶ 8.) The Court should

overrule these objections and order Elan to produce all responsive documents fully and without redactions. These objections are the same as those addressed in the Damages Motion, and are wrong for the same reasons.

First, with respect to relevance, Elan's position is contradicted by controlling case law. Abraxis's requests seek documents that are directly related to several of the *Georgia-Pacific* factors for determining a reasonable royalty. 318 F. Supp. at 1120. Request Nos. 141 and 143 seek information about income from licensing the Patents-In-Suit and comparable patents as required by the first and second *Georgia-Pacific* factors. *Id.* Request Nos. 139 and 144 relate to the twelfth factor on the portion of profit customary in the business or comparable businesses for the use of the invention or analogous inventions. *Id.* Documents responsive to Request Nos. 139, 140, 142, and 143 are necessary for determining the incremental monetary or economic value of the patented invention as addressed in the thirteenth factor. *Id.* Finally, Request No. 143 seeks financial information that would affect Elan's behavior as the willing licensor in a hypothetical negotiation, as in the fifteenth factor and the overall *Georgia-Pacific* framework. *Id.* at 1120-21.

Elan's relevance objection seeks to prevent Abraxis from making arguments at trial about which licenses, patents, businesses, and inventions are the most "comparable" and should have the most weight in the determination of a reasonable royalty. Undoubtedly, Elan wishes to avoid producing those licenses showing low royalty rates for its specious patents. Since courts applying the *Georgia-Pacific* analysis interpret comparable licenses and technology broadly, it is improper for Elan to unilaterally restrict its production of these documents during fact discovery. *Mobil Oil Corp. v. Amoco Chems. Corp.*, 915 F. Supp. 1333, 1354 (D. Del. 1994). Without producing all of the relevant documents, Elan could "stack the deck" of licenses and agreements with only those most favorable to Elan. The Court should compel Elan to produce these documents so that the question of comparability can be addressed by both parties' experts and decided by the trier of fact, not only by Elan. *Unisplay*, 69 F.3d at 517.

Second, as with its earlier objections, 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. This objection should be overruled because this confidential information can be sufficiently protected by a "Restricted Confidential" designation under the terms of the Court-entered protective order, which would strictly limit their disclosure, even for purposes of this litigation. (Pai Decl. Ex. D.) 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*, No. C 03-3723 THE (JL), 2004 U.S. Dist. LEXIS 25285, at *2 (N.D. Cal. Dec. 3, 2004); *Rubenstein v. Adm'rs of the Tulane Educ. Fund*, No. 95-3343 Section "D" (1), 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. (*See also* D.I. 241 at 7-9.)

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

CONCLUSION

Elan's objections to Abraxis's Requests for Production Nos. 139-144 are without merit, and should be overruled as a transparent attempt to hide unfavorable damages information from

Abraxis and the trier of fact. Abraxis requests that the Court order Elan to produce all documents responsive to these requests in unredacted form.

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Dated: August 13, 2007

CERTIFICATE OF SERVICE

I, Elena C. Norman, Esquire, hereby certify that on August 20, 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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