IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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

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

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Abraxis respectfully submits this Reply Brief in support of its Motion to Compel Production of Damages Discovery ("Motion"), filed August 8, 2007, and in response to the Answering Brief opposing the Motion filed by Elan on August 22, 2007.[1]

INTRODUCTION

Throughout its Answering Brief, Elan not only admits but emphasizes the relevance of the license agreements for the patents-in-suit. *See, e.g.*, D.I. 285 at 4, 10-11 (Answering Br.). Yet Elan continues to ignore Abraxis's Requests for Production ("RFP") Nos. 61-63 and 106, which expressly request such documents.[2] Elan has no answer to Abraxis's motion to compel the production of these highly relevant documents, and it should be ordered to produce them. Elan also repeatedly admits that it has not completed its review and production of all relevant licensing documents, *see* D.I. 285 at 2 n.1, 4, 6, and yet claims that it is able to prove an

[1] Elan's submission is styled as an Answering Brief combined with an Opening Brief in support of a cross-motion to limit Abraxis's Rule 30(b)(6) deposition of Elan. However, Elan's cross-motion is untimely as it was filed after the close of fact discovery. *See, e.g., Allergan, Inc. v. Pharmacia Corp.*, Civil Action No. 01-141-SLR, 2002 U.S. Dist. LEXIS 19811, at *8 (D. Del. May 17, 2003) ("Motions that relate to fact discovery must be filed during fact discovery."). Accordingly, Abraxis will treat Elan's combined submission as an Answering Brief only.

[2] Abraxis's RFP Nos. 61-63 and 106 state:

> 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.
>
> 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.

See Exs. A and B to the August 7, 2007, Declaration of Eric C. Pai in Support of Defendant Abraxis BioScience, Inc.'s Motion to Compel Production of Damages Discovery (D.I. 242) ("August 7, 2007, Pai Decl.") (emphases added).

established royalty and dismisses as irrelevant Abraxis's discovery requests (*e.g.*, RFP No. 64)[3] directed to the factors for the determination of a reasonable royalty under *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970), *modified on other grounds by*, 446 F.2d 295 (2d Cir. N.Y. 1971). Elan's positions are not only self-contradictory, but also unfounded. It is by no means certain that Elan will be able to prove at trial that it has an established royalty so as to obviate the need for discovery relating to a reasonable royalty analysis under the *Georgia-Pacific* factors. Furthermore, Elan's assertions that Abraxis's discovery requests are overbroad, burdensome, and seek the disclosure of confidential third-party information have no basis in fact or law.

ARGUMENT

I. ELAN'S OBJECTIONS TO ABRAXIS'S DISCOVERY REQUESTS RELATING TO THE *GEORGIA-PACIFIC* FACTORS ARE UNFOUNDED IN VIEW OF THE APPLICABLE LAW

At issue are Elan's refusal to produce: (1) documents responsive to Abraxis's RFP Nos. 61-64 and 106,[4] which pertain to the licensing of the patents-in-suit and comparable patents; and (2) a designated witness to testify on the damages topics in Abraxis's July 3, 2007, Notice of Rule 30(b)(6) Deposition.[5] Elan argues that these discovery requests—which are directed to the licensing of the patents-in-suit as well as to other licensing documents relating to the *Georgia-Pacific* factors for determining a reasonable royalty—are irrelevant, overbroad, unduly burdensome, and, in some cases, seek disclosure of information subject to third-party confidentiality obligations (this latter point will be addressed in the next section).

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[3] Abraxis's RFP No. 64: License agreements between: (1) Elan or a Previous Owner and (2) any third party concerning pharmaceutical or diagnostic compositions or methods. (August 7, 2007, Pai Decl. Ex. A)

[4] *See* notes 2 and 3, *supra*; August 7, 2007, Pai Decl. Ex. A at 13; Ex. B at 8.

[5] *See* August 7, 2007, Pai Decl. Ex. G.

According to Elan, the damages discovery in this case need not concern the *Georgia-Pacific* factors, but rather should be limited to licenses for the patents-in-suit that were executed around the time Abraxis's alleged infringement began because those licenses are sufficient to determine the established royalty. The irony in Elan's position is its continuing failure to produce in response to Abraxis's RFP Nos. 61-63 and 106 the very licenses for the patents-in-suit on which it relies. Furthermore, Elan's position is unfounded in view of its admission that it has failed to review and produce all relevant licensing documents, despite discovery closing more than three weeks ago. *See* D.I 285 at 2 n.1, 4, 6 (Answering Br.).

Moreover, in order to prove that its royalty is "established," Elan bears a considerable burden. It must show that the negotiated royalties on the patents-in-suit meet five criteria: "(1) they must be paid or secured before the infringement began; (2) they must be paid by a sufficient number of persons to indicate the reasonableness of the rate; (3) they must be uniform in amount; (4) they must not have been paid under threat of suit or in settlement of litigation; and (5) they must be for comparable rights or activity under the patent." *Mobil Oil Corp. v. Amoco Chems. Corp.*, 915 F. Supp. 1333, 1342 (D. Del. 1994). "Because of these stringent criteria, few courts have actually found an established royalty," *id.* at 1342, such that patentees will often have to determine a "reasonable royalty" based on the *Georgia-Pacific* factors. *See Unisplay, S.A. v. Am. Elec. Sign Co.*, 69 F.3d 512, 517 (Fed. Cir. 1995).

Elan is, in essence, asking the Court to decide *in the context of a discovery motion* that it will prevail on its established royalty theory. At best, that is something that might be decided on summary judgment, but it is not appropriate to assume the outcome at this point in the case. Accordingly, Elan should not be allowed to refuse Abraxis discovery going to all *Georgia-Pacific* factors.

In the event that discovery relating to the *Georgia-Pacific* factors is deemed necessary, Elan argues in the alternative that Abraxis's discovery requests directed to Elan's licenses concerning "comparable patents" under the second *Georgia-Pacific* factor (*e.g.*, RFP No. 64 and Topic Nos. 1, 3, 4, 6-13, 15, 20, and 21) are overbroad and unduly burdensome because they allegedly seek information relating to [redacted] patents. To the extent the question is burdensomeness, the relevant question is the number of *licenses*, not the number of patents. In response to Elan's complaints about burdensomeness, Abraxis asked Elan to disclose the number of licenses that fall within the scope of these discovery requests. *See, e.g.*, D.I. 241 at 6 (Opening Br.). Elan refused to provide that information during the meet and confer process, *id.*, and did not provide it in its opposition. The number of patents referenced by Elan are not relevant, [redacted] Elan similarly overstates its argument that the discovery requests are overbroad: not only does this complaint ignore the fact that courts interpret the second *Georgia-Pacific* factor "broadly to include rates for other [comparable] technology," *Mobil Oil*, 915 F. Supp. at 1354, it also disregards the context provided by the patents-in-suit, wherein comparable technologies would be limited to nanoparticulate technology. That is, Abraxis does not seek documents and testimony regarding every license agreement executed between Elan and a third-party, but rather only those licenses for patents directed to nanoparticulate technology. To further ease any perceived burden on Elan, Abraxis will also temporally limit its request for documents concerning the licensing of "comparable patents" to those documents that were created on or after January 1, 2000.[6]

[6] This temporal limit does not apply to documents concerning the licensing of the patents-in-suit.

Similarly, Elan objects to Abraxis's discovery requests relating to its financial information over the past twelve years under the fifteenth *Georgia-Pacific* factor (*e.g.*, Topic No. 14) as irrelevant and overbroad. Elan's irrelevance objection is invalid in view of the nature of the inquiry posed by the fifteenth *Georgia-Pacific* factor: 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. As 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. However, to ease any perceived burden on Elan, for purposes of this motion Abraxis will temporally limit its discovery requests concerning Elan's financial information to those documents and/or events dated on or after January 1, 2000.

II. ELAN HAS NO FACTUAL OR LEGAL BASIS FOR ITS REFUSAL TO PRODUCE THIRD-PARTY CONFIDENTIAL DOCUMENTS FULLY AND UNREDACTED UNDER THE PROTECTIVE ORDER

There is no dispute that there are additional relevant, responsive documents relating to license agreements that Elan has refused to produce. In justifying its refusal, Elan invokes its confidentiality obligations to third-parties and its alleged compliance with the Protective Order. Elan also complains that Abraxis's requests for those documents are cumulative and duplicative in light of Abraxis's subpoenas to the third-parties listed on its Non-Party Confidentiality Log. None of these reasons is sufficient to justify Elan's failure to produce the third-party documents fully and without redactions.

As explained in Abraxis's opening brief, it is well-established that lawful discovery requests trump third-party confidentiality obligations. Courts have routinely ordered the production of relevant non-party documents when there is a protective order in place to protect

the interests of non-parties. *See* D.I. 241 at 8 (Opening Br.), *citing Walker v. County of Contra Costa*, No. C 03-3723 TEH (JL), 2004 U.S. Dist. LEXIS 25285, at *2 (N.D. Cal. Dec. 3, 2004) (holding that third-party's "privacy is adequately ensured by the protective order" and ordering production of documents containing third-party confidential information); *Rubenstein v. Adm'rs of the Tulane Educ. Fund*, Civil Action No. 95-3343 Section "D" (1), 1996 U.S. Dist. LEXIS 10618, at *4 (E.D. La. July 23, 1996) (affirming magistrate judge's order requiring production of "highly confidential information" because order was granted subject to protective order). Elan does not cite any legal authority to the contrary. In the present case, Elan should have produced all relevant third-party confidential documents under the "Restricted Confidential" designation provided in the Protective Order.[7] Elan chose not to do so, and has not proffered any credible reasons why the "Restricted Confidential" designation would be inadequate for its purposes. In any event, an order granting Abraxis's Motion would insulate Elan from any breach-of-confidentiality claims.

Despite its failure to properly use the "Restricted Confidential" designation for its intended purpose—*i.e.*, the production of all relevant third-party confidential documents—Elan insists that it has fulfilled its discovery obligations with respect to those documents by following Paragraph 11 of the Protective Order ("Discovery Material Subject To Confidentiality Agreement With Third Party"),[8] which provides a protocol for polling third-parties for permission to disclose their confidential information, and logging the names of those who object. Ans. Br. at 5-6. Elan overreads Paragraph 11, which does not address the ultimate question whether production of the logged documents is required. Indeed, Paragraph 11 expressly states that "This Protective Order shall not preclude any party from moving the Court for an order

[7] *See* August 7, 2007, Pai Decl. Ex. M (Protective Order) ¶ 4.3.

[8] *See* August 7, 2007, Pai Decl. Ex. M (Protective Order).

compelling production of [third-party confidential] material." Thus, the provisions of Paragraph 11 governing third-party documents do not end the process as to such documents.

It is notable, moreover, that Elan's compliance with those provisions appears to have been deficient. When Abraxis subpoenaed the same third-parties listed on Elan's Non-Party Confidentiality Log, several of them responded that they would have no objection to Elan producing the documents requested. D.I. 242 (August 7, 2007, Pai Decl. Exs. O, P). Indeed, Elan's correspondence to the third-party ChemGenex, Inc. reveals that it actually encouraged the third-parties to block production by not responding, which Elan promised it would assume meant the party affirmatively objected to production, even under the Protective Order. *See, e.g.*, Ex. A to the September 4, 2007, Declaration of Eric C. Pai in support of Abraxis's Reply Brief in support of its Motion to Compel Production of Damages Discovery ("Sept. 4, 2007, Pai Decl.") (June 7, 2007 letter from Elan to ChemGenex, Inc. stating that "If we do not receive a response after two weeks from the date of this letter we will assume ChemGenex, Inc. is not amenable to disclosure of the requested confidential information"). Furthermore, Elan has steadfastly refused to produce its correspondence with the third-parties which would evidence its alleged compliance with the Protective Order's provisions. (Sept. 4, 2007, Pai Decl. Ex. B.) In sum, Paragraph 11 does not protect Elan from the obligation to produce all relevant third-party confidential documents.

Finally, in light of Abraxis's subpoenas to the third-parties listed on its Non-Party Confidentiality Log, Elan complains that Abraxis's requests for the third-party confidential documents it has withheld and/or redacted are now cumulative and duplicative. This complaint ignores the fact that some third-parties did not produce any documents in response to the subpoenas, but rather informed Abraxis that they would not object to their production by Elan.

(August 7, 2007, Pai Decl. Ex. O.) Moreover, it is by no means certain that the production of documents from those third-parties contains all of the documents in Elan's files. Indeed, Elan's complaint is contradicted by its own repeated admissions throughout its Answering Brief that it continues to review third-party documents in its possession for any non-cumulative licensing materials requiring production. *See, e.g.*, D.I. 285 at 2 n.1, 4, 6 (Answering Br.).

CONCLUSION

For the reasons set forth above and in Abraxis's Opening Brief in support of its Motion, Abraxis respectfully requests an order compelling Elan to produce: (1) all documents responsive to Abraxis's Requests for Production Nos. 61-64 and 106; (2) all documents listed on its Non-Party Confidentiality Log or otherwise withheld on grounds of non-party confidentiality obligations; and (3) a designated witness in response to Abraxis's July 3, 2007, Notice of Rule 30(b)(6) Deposition of Elan.

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Dated: September 4, 2007

CERTIFICATE OF SERVICE

I, Jeffrey T. Castellano, Esquire, hereby certify that on September 11, 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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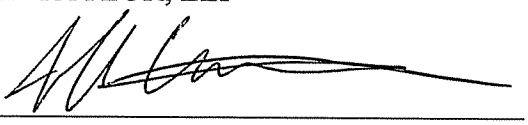
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