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**

ABRAXIS'S RESPONSE TO ELAN'S MOTION IN LIMINE NO. 1 ELAN'S INABILITY TO DEVELOP A COMMERCIAL PRODUCT AND ABRAXIS'S PATENTS ON ABRAXANE

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INTRODUCTION

Elan's motion to exclude its failures to develop a commercial embodiment of the '363 patent ignores recent Federal Circuit authority that such failed attempts are "strong evidence" of non-enablement. Elan's failures are also relevant to issues such as damages and unclean hands.

Elan's separate motion[1] to exclude Abraxis's patents on Abraxane also ignores Federal Circuit authority that a patent on the accused device is strong evidence that it is not an equivalent. Abraxis's patents are also relevant to willfulness and damages, and to respond to Elan's argument that Abraxis's position on cross-linking is "made for litigation."

I. ELAN'S REQUEST TO EXCLUDE EVIDENCE OF ITS INABILITY TO DEVELOP A COMMERCIAL EMBODIMENT IS CONTRARY TO LAW.

Elan's argument that Abraxis should be barred from introducing evidence that Elan failed to create a commercial embodiment of the '363 patent is contrary to law. In *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007), a case not addressed by Elan, the Federal Circuit held that the patentee's failure to create a commercial embodiment was "strong evidence" of a lack of enablement:

> If an inventor attempts but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement.

Here, Abraxis will introduce evidence that [redacted] The methodology disclosed in Elan's patent of attempting to grind a drug in the presence of surface modifier has proven too crude for use in developing a commercial product; indeed, no pharmaceutical product using the '363 patent has *ever* been brought to market in the United States by Elan or its licensees.

[1] Elan's inclusion of two distinct motions in one document is a circumvention of the Court's limit of five motions in limine per party.



Under *Ormco*, Elan's failure to develop a commercial product is "strong evidence" of nonenablement. Elan's failure to develop a commercial formulation due to, *inter alia*, its inability to use the full range of surface modifiers claimed [redacted] is relevant to the validity claims 1, 3 and 5, which are directed to nanoparticulate anticancer particles. It also is relevant to claims 10 and 11, which encompass methods of using the particles of claim 1 wherein "the efficacy is increased" or the "toxicity is decreased" by using the particles of claim 1.

Elan's inability to develop a commercial product is also relevant to other issues. As courts in this district have recognized, the patentee's inability to develop a commercial product is

[2] References to "Ex." are to the exhibits filed with this motion, which include relevant excerpts of the cited documents.

relevant to damages. (Ex. 21, *Enzo Life Sciences, Inc. v. Digene Corp.*, C.A. No. 02-212-JJF, slip op. (D. Del. June 10, 2004) (denying motion in limine to exclude evidence that patentee does not sell a product covered by the patent as "relevant to damages").) As Abraxis's damages expert Musika explained, Elan's inability to develop a commercial product means that in a hypothetical negotiation it would be willing to accept a *lower* royalty rate because it "has no incremental profits to lose" since it has no product and could not reasonably expect to have one given its past failures. (Ex. 5 ¶¶ 19, 31-33, 60, 85, 92.) Elan's damages expert Jarosz also identified the alleged commercialization of the technology as an important factor for calculating damages. (Ex. 6 at 181:6-8, 184:23-185:6, 232:6-10; Ex. 7 at 23-24.)

Abraxis will also demonstrate that after it concluded it could not duplicate Abraxane using its technology, Elan decided to attempt to extract money from Abraxis by pursuing an unfounded lawsuit and engaging in litigation misconduct designed to conceal the lack of support for its case. [redacted]

Elan's self-serving statement that its business was limited to licensing and that it never attempted to develop a commercial drug is factually incorrect. [redacted] Moreover, in addition to Elan's failures, *none* of Elan's licensees has developed a commercial anti-cancer product covered by the '363 patent.[3] The jury is entitled to know that despite [redacted] and the licensing program Elan argues proves the success of its technology, the crude wet milling technology taught by the patent has never been used to successfully develop a commercial anti-cancer product.

[3] Although Elan now touts its licensing program, [redacted]

II. ELAN'S REQUEST TO EXCLUDE EVIDENCE OF ABRAXIS'S PATENTS SHOULD BE DENIED

Elan's motion to exclude evidence of Abraxis's patents should be denied. *Cameo v. La. Cane Mfg.*, the principal case on which Elan relies, is an unpublished 1995 decision from Louisiana that is contrary to controlling Federal Circuit authority that Elan fails to cite, which establishes the relevance of patents to establish lack of equivalency under the doctrine of equivalents. Most recently, in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1379-80 (Fed. Cir. 2007), the Federal Circuit summarized its recent cases holding that the patentability of the accused product is relevant to proving that it is not an "equivalent" under the doctrine of equivalents:

> we have held that when a device that incorporates the purported equivalent is in fact the subject of a separate patent, a finding of equivalency, while perhaps not necessarily legally foreclosed, is at least considerably more difficult to make out. (citations omitted).

The Federal Circuit has thus made it clear that patents on products that incorporate the alleged equivalent are strong evidence that the accused product does not infringe under the doctrine of equivalents. Elan's request to exclude relevant evidence is without merit.

The patents on Abraxane are also relevant to willfulness, damages and non-infringement. Elan's willfulness case relies in part on an argument that [redacted] By that date, however, Abraxis had already filed for patents that Elan acknowledges cover Abraxane. (*E.g.*, Ex. 12 ('686 patent filed Feb. 23, 1993); Ex. 13 ('421 patent filed Feb. 22, 1994).) Moreover, the reasonableness of Abraxis's belief that the '363 patent was directed to crystalline compositions, not Abraxane, is supported by the fact that during prosecution of at least one of these patents the '363 patent was cited and overcome during prosecution on the ground that Abraxis's patent covered non-crystalline amorphous materials that had different physical properties from those claimed in the '363 patent. (Exs. 14-18.)

The patents also support Abraxis's position that it is practicing other technology that contributes more centrally to Abraxane's success than Elan's patents, assuming, *arguendo*,

infringement. This evidence is relevant to at least three factors in the *Georgia Pacific* damages analysis: "The nature of the patented invention…and the benefits to those who have used the invention," "the extent to which the infringer has made use of the invention; and any evidence probative of the value of that use," and "the portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements." *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified on other grounds by*, 446 F.2d 295 (2nd Cir. N.Y. 1971).

Finally, Abraxis's patents, which are identified in the FDA's Orange Book listing of patents covering Abraxane (Ex. 19), are relevant to rebut Elan's argument that Abraxis's position that the human albumin on Abraxane particles is cross-linked is made "for the first time" in this litigation (Elan Motion in Limine No. 4 at 1) and inconsistent with Abraxis's statements to the FDA. (*See, e.g.*, Ex. 20, 10:40-55 ('868 patent filed May 21, 1999) ("crosslinking disulfide bonds"); Ex.12, 4:21-30 ('686 patent filed Feb. 22, 1993) ("substantially crosslinked by way of disulfide bonds").)

Glaros v. H.H. Robertson Co., 797 F.2d 1564, 1572-73 (Fed. Cir. 1986), cited by Elan, is off point. *Glaros* does not address the relevance of patents on the accused device to infringement under the doctrine of equivalents; indeed, there is no discussion anywhere in the opinion regarding the doctrine of equivalents. Nor does it address the relevance of patents to willfulness and damages. The Federal Circuit's affirmance of the district court's exclusion of the defendant's patent, together with other unrelated patent documents, has no application to the circumstances here.

CONCLUSION

For the reasons set forth above, Abraxis respectfully requests that the Court deny Elan's Motion in Limine No. 1.

Dated: April 4, 2008

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CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on April 15, 2008, 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 April 15, 2008**,** 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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