IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION,	)	
Plaintiffs,	)	**Civil Action No. 08 C 1083**
v.	)	**JUDGE DOW**
PENTECH PHARMACEUTICALS, INC.,	)	**MAGISTRATE JUDGE ASHMAN**
Defendant.	)	

PENTECH'S REPLY BRIEF IN SUPPORT OF DESIGNATING CERTAIN PORTIONS OF ITS ANDA AS HIGHLY CONFIDENTIAL UNDER THE STIPULATED PROTECTIVE ORDER

I. INTRODUCTION

Plaintiffs' request to allow two in-house counsel access to Pentech's trade secrets should be denied because (1) the risk of inadvertent disclosure significantly outweighs any risk of impairing Plaintiffs' litigation efforts and (2) Plaintiffs have not shown a need for in-house counsel to see the trade secrets. Although Plaintiffs' Proposed Stipulated Protective Order ("SPO") fails to identify their two in-house counsel, based on the affidavit submitted by Plaintiffs' Senior Vice President & Chief Patent Counsel Madge Shafmaster, Ph.D., it appears she wants access to Pentech's trade secrets. (*See* Ex. 6 to Plaintiffs' Brief). However, Plaintiffs failed to show that Dr. Shafmaster is not a "competitive decision maker" for Plaintiffs and that she does not have patent prosecution responsibility relating to the subject matter at issue, as required under the proposed SPO.

Plaintiffs have retained two large firms that will have access to Pentech's trade secret related documents and can advise Plaintiffs on litigation strategy. Thus, Pentech is not being

unreasonable. Pentech requests the Court enter the SPO[1] attached hereto as Ex. 1[2] so Plaintiffs' in-house counsel cannot see the trade secrets in the CMC sections of Pentech's ANDA and related documents.

II. ARGUMENT

The key issue is whether Plaintiffs' in-house counsel is considered a "competitive decision maker." That is, whether counsel provides advice or participates in any way in Plaintiffs' competitive business decisions, such as pricing, product design/development, sales or marketing. *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984); Gottschall Op. at 3-4 [3]. In *Connetics v. Pentech,* "[t]he sole bone of contention between the parties" was whether plaintiffs' in-house counsel could have access to Pentech's ANDA at issue. (*Id.* at 1). The trade secrets in that case, like here, concerned the methods and practices used to produce the generic product at issue and Judge Gottschall found that this type of trade secret "if inadvertently disclosed to [plaintiff], might yield it a competitive advantage." (*Id.* at 6). Judge Gottschall pointed out that "a full and proper analysis requires 'a careful and comprehensive inquiry into in-house counsel's actual (not nominal) role in the affairs of the company, his association and relationship with those in the corporate hierarchy who are competitive decision makers, and any other fact that enhances the risk of inadvertent disclosure.'" (*Id.* at 4 citing *Autotech Techs., Ltd. v. Automationdirect.com, Inc.,* 237 F.R.D. 405, 408 (N.D. Ill. 2006).

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1 This SPO is identical to the one attached to the parties' Joint Motion requesting a briefing schedule [Docket No. 40-2], except that Paragraph 1(a) and (b) allow for the CMC sections of Pentech's ANDA and related documents, as well as sections of Plaintiffs' NDA of equivalent sensitivity and related documents, to be designated "Highly Confidential." It is, however, unnecessary for Plaintiffs to designate any of their documents "Highly Confidential" because Pentech does not have in-house counsel.

2 Pentech is aware that under the Notice [Docket No. 43], the parties are to submit a Joint Motion for a Proposed SPO after the Court rules on the disputed SPO issue. However, if the Court agrees with Pentech's position and enters the attached SPO, there will not be a need to burden the Court with the aforementioned Joint Motion.

3 "Gottschall Op." refers to the May 29, 2008 Opinion by Judge Gottschall involving the same Defendant Pentech in *Connetics Corp. et al. v. Pentech* (Case No. 07-C-6297). *See* Silver Declaration [Docket No. 50-2] accompanying Pentech's opening Brief.

A. Plaintiffs' litigation efforts will not be impaired by denying their in-house counsel access to Pentech's trade secret related documents because their outside counsel have access to them.

Plaintiffs ignored Pentech's request to identify their two in-house counsel in the SPO. (*See* Plaintiffs' Brief, Ex. 3 – May 12, 2008 Silver e-mail). In fact, Plaintiffs do not identify their two in-house in their Brief or proposed SPO. (*Id.*, Ex. 2). Presumably, Plaintiffs seek to designate Dr. Shafmaster because her affidavit discusses her alleged need to have access to Pentech's CMC section for the infringement inquiry. (*Id.*, Ex. 6 at ¶¶ 10-11). However, Plaintiffs' two outside law firms have access to Pentech's trade secrets and can advise Plaintiffs on infringement and other litigation strategy. To the extent Plaintiffs' outside counsel need further technical assistance, they can retain scientific experts and share Pentech's trade secrets with them, provided the SPO requirements are satisfied. Thus, there is no merit to Plaintiffs' argument that their in-house counsel needs access to Pentech's trade secrets.

In finding that there was a greater risk of inadvertent disclosure of Pentech's trade secrets compared to the alleged risk of impairing plaintiffs' litigation in *Connetics v. Pentech*, Judge Gottschall noted that plaintiffs "engaged outside counsel of experience and ability to litigate this case" and that in-house counsel, although barred from seeing the ANDA, was not barred from seeing other trial-related materials. (Gottschall Op. at 6). Here, Plaintiffs' in-house counsel would not be barred from seeing the entire ANDA, but only the CMC sections of the ANDA and related documents.

B. Plaintiffs have not shown that Dr. Shafmaster is not involved with Plaintiffs' competitive decision making policies or patent prosecution.

Dr. Shafmaster's affidavit is silent on whether she is involved with Plaintiffs' competitive decision making policies and patent prosecution responsibilities related to the subject matter at issue, as defined in the SPO. Dr. Shafmaster merely states that "my responsibilities ***include*** hiring, supervising and instructing outside litigation counsel. I work with outside counsel to

develop case strategy, including weighing the merits of Genzyme Corporation's case." (Emphasis added). (Plaintiffs' Brief, Ex. 6 at ¶7). Dr. Shafmaster failed to describe ***all*** of her responsibilities and the individuals she reports to.

In *Connetics v. Pentech*, Judge Gottschall found that although plaintiffs' in-house counsel (who was Assistant General Counsel & Intellectual Property Counsel) "does not make business decisions ***directly***, she is in a position, and … has a duty, to advise [plaintiff's] decision makers concerning business development and marketing." (Emphasis added). (Gottschall Op. at 5-6). Judge Gottschall found such duties "fall within the ambit of 'competitive decision making' as set forth in *U.S. Steel*" where both parties were found to be competitors in the relevant field. (*Id.* at 6 citing *U.S. Steel*, 730 F.2d at 1468 n.3). Pentech and Plaintiffs are also direct competitors. (Ronsen Decl. at ¶¶ 7-8) [Docket No. 50-3].

In view of Dr. Shafmaster's senior title, it is difficult to imagine that she does not have any influence over Plaintiffs' competitive decision making policies or interact with individuals who are responsible for competitive decision making policies. After all, Dr. Shafmaster is Senior VP and she likely interacts with other VPs and CEOs who are involved with pricing, product design or development, sales or marketing of Plaintiffs' products. Plaintiffs are wrong that Pentech is seeking a *per se* rule against in-house counsel seeing Pentech's trade secret related documents. (Plaintiffs' Brief at p.4). Based on the limited information provided about Dr. Shafmaster's responsibilities and applying the "competitive decision making" inquiry set forth in *U.S. Steel*, 730 F.2d at 1468 n.3, it is more likely than not that Dr. Shafmaster is associated with Plaintiffs' competitive decision making polices and therefore should not have access to Pentech's trade secrets.

C. Plaintiffs proposed safeguards to prevent inadvertent disclosure of Pentech's trade secrets are insufficient.

Dr. Shafmaster's assurances that she would abide by the terms of the SPO and "take all

necessary and reasonable steps to protect against inadvertent disclosure of Defendant's 'Confidential' information" (whatever that entails) (Plaintiffs' Brief, Ex. 6 at ¶ 12) is insufficient to protect Pentech's trade secrets. In-house counsel in *Connetics v. Pentech* provided similar assurances and Judge Gottschall explained that "such an assurance marks the beginning, not the end, of the analysis because ***the issue is not one of good faith, but rather one of inadvertent disclosure***. (Emphasis added). (Gottschall Op. at 5 citing *Autotech,* 237 F.R.D. at 408; *Andrx Pharm, LLC v. GlaxoSmithKline, PLC*, 236 F.R.D. 583, 585-86 (S.D. Fla. 2006)). Thus the "good faith" gestures expressed in Dr. Shafmaster's affidavit do not safeguard against the risk of inadvertent disclosure of Pentech's trade secrets.

Judge Gottschall found that despite the proposed safeguards, "the potential for inadvertent disclosure of knowledge of Pentech's trade secrets, gained via this litigation, is significant enough to weigh heavily in favor of barring" in-house counsel from access to Pentech's ANDA. (Gottschall Op. at 6). For these reasons, Dr. Shafmaster should not have access to Pentech's trade secrets and Plaintiffs should be barred from identifying a second in-house attorney.

III. CONCLUSION

Pentech respectfully requests that the Court enter the SPO attached hereto as Ex. 1.

Respectfully submitted,

Dated: June 10, 2008

By /s/ Mona Gupta

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of June, 2008, a true and correct copy of the foregoing **PENTECH'S REPLY BRIEF IN SUPPORT OF DESIGNATING CERTAIN PORTIONS OF ITS ANDA AS HIGHLY CONFIDENTIAL UNDER THE PROPOSED STIPULATED PROTECTIVE ORDER** was served on Plaintiffs' counsel via ECF filing with the Court and emailed, as well as mailed, via United States Postal Services, first class mail, postage prepaid in an envelope addressed to:

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