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

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

DEFENDANTS' MOTION AND MEMORANDUM OF LAW IN SUPPORT OF MOTION TO SUSTAIN OBJECTIONS TO ALEXANDER KLIBANOV, ROBERT S. LANGER AND DANIEL G. ANDERSON AS EXPERTS FOR PLAINTIFFS

I. INTRODUCTION

Defendants Pentech Pharmaceuticals, Inc., and Cobrek Pharmaceuticals, Inc. (collectively "Pentech") move for an order to sustain their objections to Drs. Alexander Klibanov, Robert S. Langer and Daniel G. Anderson as experts for Plaintiffs because of conflict of interest, in that the three named experts have a confidential relationship with Pentech, have received confidential information from Pentech, and are serving as experts for Pentech in two other *currently pending* patent litigations in this judicial district. Allowing these individuals to serve as experts *against* Pentech in this case is extremely prejudicial to Pentech, and will continue to cause prejudice to Pentech as the three cases move forward.

II. FACTUAL BACKGROUND

On September 23 and 26, 2008, Plaintiffs disclosed their selected experts in this case to Defendants, namely Drs. Alexander Klibanov, Robert S. Langer, and Daniel G.

Anderson, and provided the experts' signed undertakings pursuant to ¶ 10.a. of the Stipulated Protective Order, Dkt. No. 71 (hereinafter "Protective Order"). On September 29, 2008, Defendants timely served a letter of counsel to Defendants (attached hereto as Exh. A) objecting to Plaintiffs' designation of Drs. Klibanov, Langer and Anderson as Plaintiffs' experts, pursuant to ¶10.b. of the Protective Order, due to conflict of interest. The contents of Defendants' September 29, 2008 letter are incorporated herein by reference, including the attachments, as if fully set forth.

The parties held a "meet-and-confer" telephone conference call on October 7, 2008, but Plaintiffs refused to withdraw their designations of experts Klibanov, Langer and Anderson. Hence, Defendants now file this Motion and Memorandum of Law pursuant to ¶10.b. of the Protective Order.

Pentech is the defendant in three currently pending patent infringement actions in this judicial district. In addition to this case, Pentech is a defendant in *Connetics Corporation, et al. v. Pentech Pharmaceuticals, et al.*, Civil Action No. 07-cv-6297 (N.D. Ill.) (filed Nov. 6, 2007) (*"Connetics I"*), and *Connetics Corporation, et al. v. Pentech Pharmaceuticals, et al.*, Civil No. 08-cv-2230 (N.D. Ill.) (filed April 18, 2008) (*"Connetics II"*).[1] All three cases have been brought pursuant to 35 U.S.C. § 271(e)(2) for the highly artificial acts of patent infringement by Pentech in filing Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration for generic versions of three commercially available drugs. In Answers to the three complaints, Pentech has alleged that the patents in question are invalid and/or would not be infringed

[1] *Connetics I* and *II* both involve U.S. Patent Nos. 6,126,920 and 7,078,058. This case involves U.S. Patent Nos. 6,903,083 and 5,602,116.

by the proposed Pentech ANDA products. All three cases are in the early stages of discovery. No trial dates have been set.

As set forth in the Declaration of William C. Youngblood ("Youngblood Decl.") (Exh. B), one of the outside counsel for Pentech in all three cases, Pentech retained the expert services of Drs. Klibanov, Langer and Anderson in *Connetics I* and *Connetics II* in July 2008, *before* they were retained by Plaintiffs in this case. (Youngblood Decl. ¶¶ 7-12). All three are experts in organic chemistry and drug formulation. (Youngblood Decl. ¶ 8). In *Connetics I* and *II*, these three experts are expected to testify about infringement and validity with respect to the patents-in-suit in those cases. (Youngblood Decl. ¶ 9). Drs. Klibanov and Langer signed confidentiality undertakings in *Connetics I* under the protective order in that case (*see* attachments to Exh. A), which require them to maintain both parties' information confidential. (Youngblood Decl. ¶ 7). Dr. Anderson is an associate and employee of Dr. Langer, and he assists Dr. Langer in litigation matters such as these. (Youngblood Decl. ¶ 7). In addition, there is an understanding with these experts and counsel for Pentech that their opinions are confidential until Pentech authorizes the disclosure of their opinions in expert discovery pursuant to the Federal Rules of Civil Procedure. (Youngblood Decl. ¶ 9). As the Plaintiffs in *Connetics I* did not object to Pentech's retention of Drs. Klibanov, Langer and Anderson, beginning in August, 2008, Pentech provided these experts with Pentech internal confidential information, documents prepared by counsel relating to the validity or infringement of the patents-in-suit in *Connetics I*, and Connetics' confidential information. (Youngblood Decl. ¶ 10). In addition, these experts were involved in conversations with Pentech counsel relating to litigation strategy in *Connetics I*, including discussions of counsels'

legal theories and evaluations of the evidence, *i.e.* classic work product. (Youngblood Decl. ¶ 11). These document disclosures and discussions with counsel occurred *before* Plaintiffs' counsel notified Pentech of Plaintiffs' retention of Drs. Klibanov, Langer and Anderson as experts in this case. (Youngblood Decl. ¶ 12). In addition, Pentech's counsel expects significant involvement of these experts in *Connetics I* and *II* moving forward. (Youngblood Decl. ¶ 13). Further, they have already received payment for their services to date in *Connetics I* and *II*. (Youngblood Decl. ¶ 15).

As set forth in the Declaration of Bruce R. Ronsen, Ph.D. ("Ronsen Decl.") (Exh. C), Pentech Pharmaceuticals, Inc. is a privately-held pharmaceutical company established in 1993, currently with only 12 employees (and just 8 scientists), and it has no inside counsel. (Ronsen Decl. at ¶¶ 2,5,7). Currently, all Pentech litigation matters are coordinated and led by Dr. Ronsen, who serves as Pentech's Vice President of Research and Development. (Ronsen Decl. at ¶¶ 1, 2, 6). Dr. Ronsen is involved in Pentech's litigation decision making and internal activities, including the selection and handling of, and assisting with, experts in all three co-pending Pentech patent litigations, and in assisting outside counsel in all phases of discovery. (Ronsen Decl. at ¶ 8). Dr. Ronsen expects to become involved in expert witness preparation, and in his words, Pentech has certain confidential "approaches and methods of operating when it comes to ANDA litigation matters that are common to all three cases which will invariably be disclosed to or become known by these experts from their involvements in the *Connetics* cases." (Ronsen Decl. at ¶ 9).

Plaintiffs have 10,000 employees, including in-house counsel, with annual revenue exceeding $3 billion.[2] Plaintiffs clearly have the resources and ability to find other organic chemistry/drug formulation experts at this stage of this case.

III. ARGUMENT

In patent infringement cases, the law of the regional circuit should be applied to questions involving disqualification of experts. *Nike, Inc. v. Adidas America, Inc.*, 2006 WL 5111106 at *1 n.1 (E.D. Tex. Sept. 29, 2006), citing *In re Pioneer Hi-Bred Int'l, Inc.*, 238 F.3d 1370, 1374 (Fed. Cir. 2001). In the absence of a Seventh Circuit decision, it is appropriate to examine the law in other circuits.[3]

Federal courts have inherent power to disqualify expert witnesses to protect the integrity of the adversary process, to protect privileges that otherwise may be breached, and to promote confidence in the legal system. *See Campbell Indus. v. M/V Gemini,* 619 F.2d 24, 27 (9th Cir. 1980) (court may exclude expert witness whose trial testimony would unfairly prejudice an opposing party); *Paul v. Rawlings Sporting Goods Co.*, 123 F.R.D. 271, 277-278 (S.D. Ohio 1988).

Courts have adopted a two-part test for whether an expert can be disqualified based on a conflict of interest: "(1) Was it objectively reasonable for the first party who claims to have retained the expert to conclude that a confidential relationship existed? and (2) Was any confidential or privileged information disclosed by the first party to the expert?" *Nike Inc. v. Adidas America Inc.*, No. 9:06-CV-43, 2006 WL 5111106 at *1,

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[2] *See http://www.genzyme.com/2007_ann_rpt/people.asp and http://www.genzyme.com/2007_ann_rpt/fin_highlights.asp.*

[3] Judges in this judicial district have addressed motions to disqualify experts, albeit on dissimilar fact patterns to the case at bar. *E.g., see Great Lakes Dredge & Dock Co. v. Harnischfeger Corp.*, 734 F.Supp. 334 (N.D. Ill. 1990); *Viskase Corp. v. W.R. Grace & Co.*, No. 90 C 7515, 1992 WL 12379 (N.D. Ill. 1992).

citing *Koch Refining Co. v. Jennifer L. Boudreau M/V,* 85 F.3d 1178, 1181 (5th Cir. 1996). If the answers to both questions are in the affirmative, the expert should be disqualified, unless fairness dictates otherwise. *Id.*

In this case, Pentech has an objectively reasonable expectation of confidentiality with the three experts. For example, they signed confidentiality undertakings on behalf of Pentech under the protective order in *Connetics I* requiring them to keep confidential all discovery information disclosed to them of both parties. However, even absent a formal written acknowledgement or agreement of confidentiality, a confidential relationship can still exist. *Hewlett Packard Co v. EMC Corp.*, 330 F.Supp.2d 1087, 1094 (N.D. Cal. 2004). In this case, Pentech's counsel advised all three experts that the Pentech information they would receive is confidential, as were discussions about the cases. (Youngblood Decl. ¶ 14). As a result and in reliance, counsel sent documents produced in discovery to these experts, including Pentech confidential documents, and had discussions with them regarding Pentech's defenses in *Connetics I.* Also, common sense dictates to an expert involved in litigation that his consultancy by its very nature is confidential. Thus, element (1) of the two-part test is satisfied in this case.

As for element (2), as discussed above, Pentech's counsel shared confidential documents with these experts and had confidential discussions with them in the *Connetics I* case. (Youngblood Decl. ¶¶ 10-11). Thus, element (2) is satisfied as well.

The two-part expert disqualification test, in part by necessity, looks back in time as to what relationship has been established and what confidential materials or privileges have been shared with an expert. While the case at bar appears to be one of first impression (in that the experts are for and against Pentech in *simultaneous* litigations),

Pentech urges the court to look forward under these circumstances. The cases are early in discovery, and the moving party is a relatively small organization juggling multiple cases. If confidences and privileges are to be protected, and the integrity of the legal process preserved as required by the case law, a party having the expectation of continued, future work with an expert in confidence in a case should not have to be "on guard" in the event that some confidential information about a companion case slips, or if a strategy common to more than one case has to be developed and discussed. Looking forward in this case, these situations clearly can happen to Pentech's detriment. The chance of this happening cannot be ignored where the situation involves *three* simultaneous cases and *three* experts. The experts are scientists, not trial judges, and it would be unrealistic to assume that confidential information they receive about Pentech in the *Connetics* cases would be banished from their minds with regard to this case. Nor should the experts be permitted to be in a situation where a slip-up on their part could disclose Pentech's confidential information, or otherwise prejudice Pentech.

A situation somewhat similar to the case at bar was presented in *Marvin Lumber & Cedar Co. v. Norton Co.*, 113 F.R.D. 588 (D.Minn. 1986). The defendant's expert, TCT (an independent testing laboratory), was disqualified there because it had a longstanding and on-going consulting arrangement with plaintiff. *Id.* at 590-591. The Court held:

> The rules governing disqualification are designed to protect against the potential breach of such confidences, even without any predicate showing of actual breach. That is the case with respect to expert witnesses. . . just as it is the well-accepted rule with respect to attorney disqualifications. The threat or potential threat that confidences may be disclosed is enough. . . .

Marvin Lumber, 113 F.R.D. at 591 (citations omitted). As noted in *Viskase Corp. v. W.R. Grace & Co.*, 1992 WL 13769 at *3 (N.D. Ill. 1992), "the scientific testing laboratory the plaintiff sought to disqualify [in *Marvin Lumber*] had an actual conflict of interest because it maintained a consulting relationship with the plaintiff at the same time it had been retained by the defendant as an expert witness."

Because Pentech is a relatively small generic drug company, by necessity it has only one point person involved in these three cases, Dr. Ronsen. As Dr. Ronsen will be closely involved in all three cases, making decisions for the client, including decisions about strategy and involving himself with experts, it would be unfair to Pentech to place him in a situation where he is "on guard" with the experts Pentech has retained.

A consideration in disqualifying an expert is whether the "modus operandi, patterns of operations, decision-making process" of the moving party would be disclosed to the expert. *See Koch Refining,* 85 F.3d at 1182; *Marvin Lumber*, 113 F.R.D. at 591. As discussed above, Dr. Ronsen, Pentech's Vice President managing all three of these litigations, states there are common approaches Pentech takes in these three cases (a *modus operandi* or pattern of operation) that invariably will be disclosed or become apparent to the experts retained by Pentech, and Dr. Ronsen rightly asserts these matters are common to the three cases and are confidential. (Ronsen Decl. ¶ 9).

As explained above, the law considers fairness to the non-moving party, too. From Genzyme's point of view, this case is early in discovery. Presumably there has not been any Pentech confidential information shared by Genzyme with any of the three experts, as Pentech objected to these experts being designated by Genzyme under the Protective Order (*see* Pentech's September 29, 2008 letter to counsel for Plaintiffs, Exh.

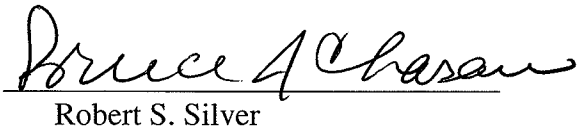
A). In addition, Genzyme with its considerable resources, can readily find alternative organic chemistry/pharmaceutical formulation experts. Thus, if this motion is granted, Genzyme will suffer no prejudice. See also *Nike v. Adidas America Inc.*, 2006 WL 5111106 at *3 (E.D. Tex. 2006) (public interest favored disqualification of expert to prevent conflict of interest and maintain the integrity of the judicial process, especially where the party opposing the motion had time and "ample opportunity" to hire another expert).

IV. CONCLUSION

For the reasons set forth above, Pentech requests the Court to sustain its objections to Drs. Alexander Klibanov, Robert S. Langer and Daniel G. Anderson as experts for Plaintiffs.

Dated: October 14, 2008

Respectfully submitted,

By 

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