Southworth v. SmithKline . . . CV-95-447-SD 07/16/96

UNITED STATES DISTRICT COURT FOR THE

DISTRICT OF NEW HAMPSHIRE

Janice Southworth;
Gregory Southworth

v. Civil No. 95-447-SD

SmithKline Beecham
Pharmaceuticals

O R D E R

Before the court are the issues raised by certain pending motions.

1. Plaintiffs' Motion to Compel Discovery, document 7

This motion seeks production by defendant of a vial of defendant's vaccine from Lot No. 989A4. Defendant objects. Document 11.[1]

The litigation involves a claim by plaintiff Janice Southworth that her vaccination with defendant's hepatitis B vaccine, Engerix B, on October 7, 1992, was causative of the autoimmune disease known as lupus. Plaintiffs seek testing of a

[1]Defendant seeks oral argument, but the court finds that such oral argument would not be of more assistance to it than that found in the documents on file, and therefore denies such request. See Local Rule 7.1(d).

vial of the vaccine from the same lot of vaccine from which Janice Southworth was vaccinated. Such testing is to be conducted by Dr. Arthur Zahalsky, plaintiffs' expert.[2]

Defendant argues that, as the lot of vaccine at issue is beyond its expiration date, production of a vial thereof is neither relevant to the subject matter involved in this litigation nor reasonably calculated to lead to the discovery of admissible evidence. Alternatively, defendant suggests that, if ordered by the court, production of the vaccine should be subject to certain conditions, including confidentiality, the presence of defendant's expert at testing, and payment by plaintiffs of all costs of production of the vaccine from its location in Belgium.[3]

Rule 26, Fed. R. Civ. P., states that a party "may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action, whether it relates to the claim or defense of the party seeking discovery or to the claim or defense of any other party . . . ." Rule 26(b)(1), Fed. R. Civ. P. For Rule 26 purposes, relevance is construed broadly to include "any matter that bears on . . . any

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[2]Dr. Zahalsky is professor emeritus of immunology at Southern Illinois University, where he was a professor of immunology from 1976 to 1994.

[3]Apparently, the lot of vaccine in question exists only in Belgium.

issue that is or may be in the case." Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351 (1978). The information sought through discovery need not itself be admissible at trial, so long as it is "reasonably calculated to lead to the discovery of admissible evidence." Rule 26(b)(1), Fed. R. Civ. P.

However, the court is possessed of broad powers to limit excesses of discovery, Mack v. Great Atlantic & Pacific Tea Co., 871 F.2d 179, 187 (1st Cir. 1989), and under Rule 26(b)(2)(iii) it may limit the scope of discovery where "the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues."

Defendant's initial challenge is to the relevancy and future admissibility of the proposed vaccine testing. It argues that, as the lot of Engerix B expired in the period of time since plaintiff was vaccinated, there are no longer any assurances of its safety, identity, strength, quality, or purity characteristics. While this argument is far from frivolous, it does not serve, at this stage of the litigation, to bar discovery as sought by the plaintiffs.

Designed to encourage the removal of outdated or aged stocks

of drug products, the government regulations requiring that the expiration date be placed on the label of such products, 21 C.F.R. § 211.37, is related to the requirements of 21 C.F.R. § 211.166, a regulation mandating "that manufacturers perform the necessary testing to determine the stability of the drug and its components, and the point in time after which it may be subject to deterioration and loss of effectiveness or safety." National Assoc. of Pharmaceutical Mfrs. v. Department of Health and Human Services, 586 F. Supp. 740, 762 (S.D.N.Y. 1984). However, whether this necessarily means that after the expiration date a drug product loses all characteristics of efficacy which it possessed as of a specific prior date is an issue that will necessarily require the future production of more detailed evidence than is now available to the court.

Defendant also argues that the testing of the vaccine proposed to be conducted by Dr. Zahalsky lacks scientific reliability and therefore cannot lead to the discovery of admissible evidence. This line of argument is premature, for it is far too early in the course of this litigation for the court to assume the "gatekeeping function" assigned to it by Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 592-93 (1993). See Pacamor Bearings, Inc. v. Minebea Co., Ltd., 918 F. Supp. 491, 506-07 (D.N.H. 1996); Grimes v. Hoffmann-LaRoche, Inc., 907

F. Supp. 33, 34-35 (D.N.H. 1995).

The court therefore believes that plaintiffs are entitled to test the vaccine, but also finds that reasonable conditions, as suggested by the defendant, should be imposed on such testing. The first such condition concerns confidentiality; i.e., nondisclosure of testing results until the court has had an opportunity to rule on admissibility.

Defendant's vaccine, Engerix B, has been approved by the FDA, and the Centers for Disease Control have recommended that it be universally administered to children. Accordingly, the reputation of the vaccine and its manufacturer, defendant, would, the court finds, be damaged if the results of Dr. Zahalsky's testing were publicly made prior to the court's having an opportunity to fully consider and rule upon defendant's challenge to the reliability and validity of such testing.

Accordingly, the court herewith orders that plaintiffs, their counsel, and their experts are prohibited from disclosing or otherwise disseminating information concerning the testing of the vaccine or the results derived therefrom until such time as they obtain a ruling from this court as to the admissibility of testing and evidence relating to that testing.

Defendant next seeks the opportunity to have the testing performed at a time mutually convenient to Dr. Zahalsky and

defendant's expert, to have its expert present at such testing, and to seek a time limit for completion of such testing. As it appears that the testing will necessarily be destructive in nature, it falls within the scope of Rule 34, Fed. R. Civ. P., Dabney v. Montgomery & Co., 761 F.2d 494 (8th Cir.), cert. denied, 474 U.S. 904 (1985). In such circumstances, it is appropriate to place reasonable restrictions upon both the production of the matter to be tested and the conduct of the testing itself. Spell v. Kendall-Futuro Co., 155 F.R.D. 587 (E.D. Tex. 1994). Such restrictions have included the requirement of advance notice of testing, submission of a detailed plan of testing for court approval, and presence of the producing party to observe and photograph testing. Sarver v. Barret Ace Hardware, 63 Ill. 2d 454, 349 N.E.2d 28 (1976). Indeed, the presence of a representative of the producing party at testing is not uncommon. Dina v. Lutheran Medical Center, 548 N.Y. Supp. 2d 541 (N.Y. App. Div. 1989); Kelleher v. Omark Indus., Inc., 19 Fed. R. Serv. 2d 725, 727 (D. Mass. 1974).

The court finds and rules that the testing of defendant's vaccine is conditioned on requirements that (1) such testing be scheduled at a time mutually convenient to plaintiffs' and defendant's experts; (2) defendant's expert be permitted to witness all such testing; and (3) all such testing be completed

within 45 days of the date upon which the vaccine is delivered to plaintiffs' expert.

Finally, defendant seeks to have plaintiffs pay the cost of importation and shipping of the vaccine from Belgium to the United States. The court understands that plaintiffs' counsel has no objection to this request.

In any event, in civil litigation, ordinarily each party "bears the ordinary cost of funding his suit," Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 179 (1974); In re Puerto Rico Elec. Power Auth., 687 F.2d 501, 507 (1st Cir. 1982), and orders requiring the requesting party to pay the expenses of production are common. Id. Accordingly, it is ordered that plaintiffs shall pay all fees associated with obtaining the necessary import authorizations and all related shipping expenses of the vaccine to the place of testing.

2. Assented-To Motion of Defendant to Extend Pretrial Deadlines, document 16

At a preliminary pretrial conference held on November 13, 1995, the court tentatively set a trial date of May 1997 and various discovery and motion filing deadlines based on such tentative trial date. Citing the discovery problems hereinabove addressed, defendant has now moved, with the assent of

plaintiffs, to extend the date of plaintiffs' expert disclosure from August 1, 1996, to December 2, 1996; the date of defendant's expert disclosure from October 1, 1996, to January 2, 1997; and the date for filing dispositive motions from September 1, 1996, to January 15, 1997. Such extensions will necessarily move the tentative trial date from May of 1997 to August of 1997, and, conditioned on such extension of trial date, the motion to extend deadlines is herewith granted.

3. Conclusion

For reasons hereinabove outlined, the court has granted plaintiffs' motion to compel, conditioned as set forth in the body of this order. Each party is to bear its own fees and costs in association with such discovery motion.

The court has granted the motion to extend discovery and dispositive motion filing deadlines, conditioned on extension of the tentative trial date from May of 1997 to August of 1997.

SO ORDERED.

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Shane Devine, Senior Judge
United States District Court

July 16, 1996
cc: W. Wright Danenbarger, Esq.
Warren C. Nighswander, Esq.
David A. Barry, Esq.