

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

MEDTRONIC SOFAMOR DANEK, INC.,)
SOFAMOR DANEK, L.P., and)
SOFAMOR DANEK HOLDINGS, INC.,)
)
Plaintiff,)
)
vs.)
)
)
OSTEOTECH, INC.,)
)
Defendant.)

No. 99-2656-GV

ORDER DENYING DEFENDANT'S MOTION TO COMPEL

The defendant, Osteotech, Inc., has filed a motion to compel the plaintiffs, Medtronic Sofamor Danek, Sofamor Danek, L.P., and Sofamor Danek Holdings, Inc., (collectively referred to as "Danek") to produce certain documents and to allow three additional depositions to be taken. Specifically, Osteotech seeks documents pertaining to the design, development, and production of cylindrical intervertebral spinal fusion devices and instruments and surgical procedures for implanting them in the cervical and thoracolumbar regions of the spine. Additionally, Osteotech seeks the depositions of "not more than" three of Danek's employees who may have information pertaining to any new information regarding these devices and procedures that might be revealed in the requested documents. This motion was filed August 22, 2001, and is

presently before this court for determination. For the reasons that follow, the motion is denied.

BACKGROUND

In this lawsuit, Danek has accused Osteotech of infringing three of its patents (patent numbers '253, '437, and '038) by selling or distributing surgical instruments covered by the patents which instruments were designed to insert interbody spinal fusion implants¹, by distributing surgical manuals that describe methods of performing surgical spinal implants, and by selling or distributing cortical bone dowel products which were designed to be surgically implanted using methods covered by one or more of the claims in the patents. Infringement of the '253 and '437 patents was asserted in the original complaint filed in August 1999, and infringement of the '038 patent was asserted by way of amended complaint in October 2000.

Osteotech served its first Request for Production of Documents on Danek on December 20, 1999; it contends that Danek failed to produce all documents responsive to its request, specifically to Requests No. 27, 28, 29, 34 and 35.² Danek filed its Response to

¹ Interbody spinal fusion implants are fusion implants placed between adjacent vertebrae of the spine.

² The following requests for production are in dispute:
Request No. 27: All documents, including invention disclosures,

Requests for Production of Documents on January 25, 2000, in which it objected both generally and specifically to the requests in question as "irrelevant," "overbroad," and "not calculated to lead to the discovery of admissible evidence." (Pl.'s Resp. to Def.'s Req. for Prod., pp. 15-19.) Danek produced some of the requested documents in March of 2000. Osteotech admits Danek produced some responsive documents, but claims Danek is withholding more

laboratory notebooks, and memoranda, concerning each and every conception, actual or constructive reduction to practice, or experimental work relating to methods you contend are covered by any claim of the Patents-in-Suit and relating to the implantable tissues and/or devices recited in these claims.

Request No. 28: All documents concerning the conception, research, design, development, and testing of instruments and instrument sets or implantable tissues and/or devices for use in spinal fusion surgery including, but not limited to, those actually sold or at any time offered for sale.

Request No. 29: All documents concerning your production of instruments and instrument sets or implantable tissues and/or devices for use in spinal fusion surgery including, but not limited to, those actually sold or at any time offered for sale.

Request No. 34: All documents relating to instruments or instrument sets used for implanting tissues and/or devices into the spine of a patient for the purpose of fusing at least two vertebrae that have been filed or submitted by you to the United States Food and Drug Administration ("FDA").

Request No. 35: All documents relating to implantable tissues and/or devices used in performing spinal fusion that have been filed or submitted by you to the FDA.

(Mem. in Supp. of Def. Osteotech Inc.'s Mot. to Compel, Ex. D, Def.'s First Req. for Prod.)

documents that are pertinent to the subject of this litigation, particularly those concerning interbody spinal fusion devices and instruments for the cervical and thoracolumbar region of the spine. Osteotech contends that the information in the documents regarding the development of spinal fusion devices in all regions of the spine, not just the lumbar region of the spine, is material to its invalidity defense, and therefore the documents pertaining to these matters are relevant. Numerous letters have been sent between the parties regarding the production of the documents in question.

Osteotech allegedly did not become aware of the existence of the disputed documents until the June 5-6, 2001 deposition of Brad Estes, an employee of Danek. Osteotech claims that during the deposition, Estes stated that employees of Danek's research and development group who worked solely on cervical products had been working with a drill sleeve, an instrument used in the surgical method covered by the patents-in-suit, prior to Danek's involvement with Dr. Michelson, the inventor of the techniques covered by the patents in question.³ (Young Aff., Ex. F at 88-89.) Estes also testified that the thoracolumbar division designed interbody fusion

³ In an affidavit submitted in support of Danek's opposition to the motion to compel, Estes points out that the drill sleeve he mentioned during his deposition was not being used for interbody fusion. (Danek's Mem. in Opp. of Def.'s Mtn. to Compel, Ex. 5, Estes Aff. at 2.)

instrumentation sets.⁴ (Young Aff., Ex. F at 88-89.)

In response, Danek argues that it properly objected to the requests at issue. In addition, Danek maintains that the documents do not pertain to the subject matter of this lawsuit and are irrelevant to the patents-in-suit and the defenses of Osteotech. It further contends that, at the least, Osteotech should have requested the documents during the discovery time period in a timely manner after their existence was made known to Osteotech, namely in March of 2000. Danek denies that Osteotech became aware of these documents during the deposition of Brad Estes; rather, Danek believes that Osteotech knew of the existence of the documents in question almost a year and a half ago and made no attempts to secure these documents before the instant motion.

ANALYSIS

The first question is whether Danek properly raised relevancy objections to the requests at issue. In its response to Osteotech's document production request, Danek lodged a general objection stating that Osteotech's requests exceeded the

⁴ In his affidavit, Estes clarifies that the instrumentation he referred to in his deposition is "connected to the outer surfaces of vertebrae and is intended to fuse adjacent vertebrae bodies . . . but does not involve interbody fusion devices (i.e. implants placed between the vertebrae in order to promote fusion)." (Danek's Mem. in Opp. of Def.'s Mtn. to Compel, Ex. 5, Estes Aff. at 1.)

permissible scope of discovery, sought information protected by privileges, and were overly broad and unduly burdensome because they sought information not within Danek's possession. In addition, Danek responded to all the requests at issue, except Request No. 27, in the following manner:

Response: Plaintiffs specifically object to this request as over-broad, encompassing *irrelevant* material, and not calculated to lead to discovery of admissible evidence. Subject to all general and specific objections, Plaintiff will produce documents responsive to this Request at a mutually agreeable time and place.

(Young Aff., Ex. E., Pl.'s Resp. to First Set of Req. for Prod.) (emphasis added). Thus, as to all the requests, except Request No. 27, Danek specifically objected on grounds of relevancy. To Request No. 27, Danek stated it would produce the documents subject to all of its specific and general objections. *Id.* All the requests, except No. 27, seek documents related to "spinal fusion." Unlike the other requests at issue, Request No. 27 seeks documents relating to methods "you contend are covered by any claim of the Patents-in-Suit." From Danek's response, it appears that it is the subjective opinion of Danek that the methods described in the withheld documents are not covered by the patents-in-suit, and therefore no relevancy objection is necessary.

The critical issue is whether documents pertaining to the

development, design, and production of cylindrical intervertebral spinal fusion devices, instruments, and surgical procedures for implantation of the devices in the cervical and thoracolumbar regions of the spine are relevant to claims or defenses of any party or to the subject matter of this litigation. Danek argues that its claims against Osteotech for infringing activities relate to Osteotech's distribution of threaded cortical bone dowels for use solely in the lumbar spine and also that Danek's commercial applications of the patents-in-suit are only for use in the lumbar region of the spine. Osteotech insists that the claims of the patents-in-suit are not limited to a particular region of the spine.

The scope of discovery is set forth in the Rules: "Parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party" Fed. R. Civ. P. 26(b)(1). Relevancy for discovery purposes is extremely broad. The information sought need not be admissible in court in order to be relevant. Rather, the relevancy burden is met if the party can show that the information sought "appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). Nevertheless, discovery does have "ultimate and necessary boundaries," *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) (quoting *Hickman v. Taylor*, 329 U.S. 495, 507

(1947)), and ``it is well established that the scope of discovery is within the sound discretion of the trial court.''' *Coleman v. American Red Cross*, 23 F.3d 1091, 1096 (6th Cir. 1994) (quoting *United States v. Guy*, 978 F.2d 934, 938 (6th Cir. 1992)).

Danek has shown that the documents in question do not relate to claims asserted in its complaint, and Osteotech has offered no proof to demonstrate how the requested documents relate to its defense of invalidity or to prior art. According to Danek, all of the documents requested, save the ones already produced, do not pertain to the patents-in-suit or Osteotech's invalidity defenses, as all of the technology described in those documents was developed after the patents and techniques were created that are at issue in this lawsuit. Danek asserts Osteotech is mistaken in that Danek did not restrict production of documents based on any spinal region, but rather restricted production by date. Simply by looking at the dates in question, it is clear these documents could not aid Osteotech in its defense nor provide any relevant information in this matter.

Danek had no rights to the technology contained in the patents-in-suit until January of 1994, when it entered into a licensing agreement with Dr. Gary Michelson, the inventor of the patents-in-suit, and Danek has represented to the court that it has produced all documents pertaining to interbody fusion devices

leading up to that date. Any documents that came after that date would not be relevant to Osteotech's defenses, as they would no longer involve prior art as it is defined in 35 U.S.C. §§ 102, 103.⁵ The dates that the patents were filed with the U.S. Patent Office were June 13, 1988, for the '253 patent and June 10, 1993, for the '437 and '038 patent. All documents prior to those dates have been produced to Osteotech, and thus any documents originating after those dates are irrelevant to Osteotech's defenses of prior art and invalidity.

Osteotech took the depositions of two Danek employees, Brad Coates, who presided over the cervical division of research and development at Danek, and David Miller, who presided over the thoracolumbar division. Coates testified that he began working on the Cervical InterBody Fusion Device (CIBFD) project in late 1994. According to their testimony, both Coates and Miller were involved in the kickoff meeting for the CIBFD project, but the kickoff meeting was not held until January 19, 1995. Coates' testimony also confirms that Dr. Michelson had nothing to do with the inventions of the cervical devices referenced in the documents in question, namely, the Novus CT, CIBFD, and Affinity. By all

⁵ The provisions explain that a person may not receive a patent or a patent would be invalid and subject to prior art if a prior invention or technique existed. 35 U.S.C. §§ 102, 103.

accounts, these devices were developed separately beginning sometime in late 1994. (Young Aff., Ex. L, Coates' Dep. at 29.) The threaded bone CIFBD did not come into existence until 1999. (Young Aff., Ex. L, Coates Dep. at 30.) Most importantly, none of the abovementioned surgical procedures involved the patents-in-suit. (Danek's Mem. in Opp. of Def.'s Mtn. to Compel, pp. 8-11.) Miller's testimony confirmed that the thoracolumbar division did not develop interbody fusion devices or instruments for interbody fusions.

Finally, Danek insists that Osteotech's motion is untimely. Danek has come forward with compelling evidence that Osteotech was aware of the existence of the documents in question fifteen months ago. (Pl.'s Mem. in Opp. of Def.'s Mtn. to Compel, p. 4.) Osteotech received documents in March of 2000 that related to the work of the cervical and thoracolumbar divisions of Danek's research and development department. These documents formed the basis for Osteotech's request to depose Coates and Miller, and the documents should have alerted Osteotech to the existence of other documents in these areas of research and development. Sheer inadvertence on the part of Osteotech to discover issues it now deems important to its case cannot be used to delay the trial in this manner, especially now that the deadline for discovery has passed. Moreover, the motion to compel was filed with the court on August

22, 2001, one day after the August 21, 2001 discovery deadline had passed.⁶ If for no other reason, the motion should be denied as untimely filed after the discovery deadline.

Discovery is subject to the limitations imposed by Rule 26(b) (2). If one of the factors set forth in Rule 26(b) (2) of the Federal Rules of Civil Procedure is present, then the court should limit the number of depositions or place other such discovery restrictions on the parties. *Pacitti v. Macy's*, 193 F.3d 766, 778 (3d Cir. 1999); see Fed. R. Civ. P. 26(b) (2). According to Federal Rule of Civil Procedure 26(b) (2), a request for discovery may be denied by the court if:

(ii) the party seeking discovery has had ample opportunity by discovery in the action to obtain the information sought; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit, taking into consideration the . . . importance of the proposed discovery in resolving the issues.

Fed. R. Civ. P. R. 26(b) (2) (ii)-(iii). Osteotech had ample opportunity during discovery to obtain the information sought. Osteotech has failed to demonstrate that this additional discovery or three depositions is warranted and has also failed to

⁶ The motion bears a typed date of August 21, 2001, but there is no certificate of service which indicates when the motion was actually served. The motion was stamped filed on August 22, 2001. The court therefore treats the motion as having been served and filed on August 22, 2001, due to lack of information otherwise.

demonstrate that the documents in question would be relevant to its invalidity defense. As stated by the United States Supreme Court in *Sanders*,⁷ as broad as discovery may be, it must have boundaries, and this court finds that to grant Osteotech's motion would be to exceed those boundaries.

CONCLUSION

Osteotech's motion to compel is denied, both its request to compel Danek to produce additional documents as well as in its request for additional depositions.

IT IS SO ORDERED this 21st day of September, 2001.

DIANE K. VESCOVO
UNITED STATES MAGISTRATE JUDGE

⁷ *Sanders*, 437 U.S. at 351.