

Short Form Order

NEW YORK SUPREME COURT - QUEENS COUNTY

PRESENT: HON. ORIN R. KITZES
Justice

PART 17

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ELYSA SHATOFF,

Plaintiff,

-against-

Index No. 18876/07
Motion Date: 7/15/09
Motion Cal. No. 51

STEVEN COHEN, M.D., EVAN B. SHAPIRO, M.D.,
WOMEN’S HEALTH & WELLNESS OF QUEENS,
PLLC, WOMEN’S HEALTH & WELLNESS OF
LONG ISLAND PLCC, ADVANCED MEDICAL
IMAGING OF LONG ISLAND, P.C., SHIRLEY BOW,
M.D., INSIGHTEC, INC., EXABLATE OF
METROPOLITAN NEW YORK, L.P., KAREN
GOLDSON, R.N., KARIN BEECHER,
JAMES O’CONNOR, M.D., LONG ISLAND
JEWISH MEDICAL CENTER,

Defendants.

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The following papers numbered 1 to 15 read on this application by defendant **INSIGHTEC, INC** (hereinafter, “Insightec”) for an order pursuant to CPLR 3124 compelling defendant **EXABLATE OF METROPOLITAN NEW YORK, L.P.** (hereinafter, “Exablate”) to produce or permit Insightec to inspect and copy those items which particulars have been sought but not delivered.

	<u>PAPERS NUMBERED</u>
Order to Show Cause -Affirmation-Exhibits.....	1
Affirmation-Exhibits.....	2-3
Memorandum of Law.....	4
Affidavits of Service.....	5
Affirmation in Opposition-Affidavit-Exhibits.....	6-9
Reply Affirmation-Exhibits.....	10-12
Reply Memorandum-Exhibits.....	13-15

Upon the foregoing papers it is ordered that this application is decided as follows:

According to the complaint and non-refuted documents, this action is a medical malpractice/negligence case involving injuries caused to Plaintiff, Ms. Shatoff, while undergoing the ExAblate 2000 procedure to relieve her discomfort associated with uterine fibroid tumors. Plaintiff alleges that these injuries were caused by the malpractice of the treating physician, and insufficient training of that physician for the underlying procedure. The moving party here, InSightec, is the manufacturer of the subject medical device. The device targets and ablates

uterine fibroid tissue using MRI-guided focused ultrasound surgery. ExAblate is a New York limited partnership with several limited partners, including co-defendants Steven Cohen, M.D. and Evan Shapiro, M.D. Sound Medical Solutions, Inc., a Texas corporation, is the general partner and holder of a 1% interest in ExAblate. Charles S. Cohen was President and a Director of Sound Medical Solutions. Deployed Medical Solutions, Inc. (“Deployed Medical Solutions”), also a Texas corporation, is the principal owner (with a 39% interest) and a limited partner of ExAblate. Moreover, Sound Medical Solutions is a wholly-owned subsidiary of Deployed Medical Solutions. Charles S. Cohen was also President and a Director of Deployed Medical Solutions. In 2005, ExAblate purchased the subject medical device from InSightec. As part of the purchase agreement, InSightec agreed to provide application training and application support to the ExAblate physicians purchasing the device. ExAblate began conducting ablation procedures using the device in 2006. Plaintiff was treated in September 2006 by co-defendant and ExAblate limited partner Dr. Evan Shapiro. During the procedure, Plaintiff suffered a perforation of her bowel.

As a result of her injury, Plaintiff brought this case, alleging medical malpractice and negligence claims against the co-defendants. Only the fourth, fifth, and seventh causes of action are against InSightec. The fourth cause of action alleges that the defendants’ negligent supervision, retention, hiring, instructing, and training caused her injuries. The fifth cause of action sounds in product liability claiming InSightec supplied the device and the individual defendants were trained and certified by InSightec and used the Exablate pursuant to InSightec’s training and parameters. InSightec failed to see to proper training, certification, and qualifications of providers and users of equipment and the enforcement of proper treatment and protocols and parameters. The seventh cause of action sounds in negligence and claims InSightec negligently misrepresented in advertising to the general public that the device enabled a safe, non-invasive permanent fibroid removal and the individual defendants were qualified, trained and certified to offer this service. Plaintiff detrimentally relied on these misrepresentations.

Disclosure, including written discovery and depositions, has been on-going pursuant to this Court’s earlier orders. InSightec has served two Demands for Production on ExAblate, on January 22, 2009 and April 14, 2009 and ExAblate produced documents in response to InSightec’s original Demand for Production, but objected to each of InSightec’s supplemental demands.

In particular, InSightec seeks the following: Training materials regarding the ExAblate 2000 device, the ablation procedure and related correspondence; Marketing documents or correspondence relating to the promotion of the ExAblate procedure; the training, skill, or knowledge of its physicians; and the success of ExAblate’s general partners; Accounting records from the Long Island site and all other U.S. sites; Documents “relating to or arising from

complaints, grievances, or concerns from potential, current or former partners of Sound Medical Solutions, Inc. or Deployed Medical Solutions, Inc. including but not limited to those regarding accounting issues, business growth or opportunities, and business revenue.” Insightec claims the above items are related to issues in this case and are discoverable.

Defendant ExAblate opposes this motion claiming that it does not maintain records of Sound, Deployed or other ExAblate facilities throughout the United States and thus these records cannot be produced. ExAblate also claims it does not control these other entities and thus has no duty to produce their records. ExAblate also claims that InSightec’s Demands seek discovery that is not “material and necessary” to the prosecution or defense of this action. Finally, ExAblate claims that the Demands related to records of “all other ExAblate treatment Centers in the U.S.” are unduly burdensome, overly broad and vague and therefore outside the scope of discovery.

It is well settled that there is to be liberal discovery in civil actions. CPLR 3101 (a) provides for discovery of all "material and necessary" evidence. Discovery is limited by the test of materiality to one of usefulness and reason and includes "any facts bearing on the controversy which will assist preparation for trial by sharpening the issues and reducing delay and prolixity." [Allen v Crowell-Collier Publ. Co., 21 NY2d 403, 406 \(1968\)](#).

In the instant case, the defendants have made a sufficient showing that the requested screening is material and necessary for the preparation of their action. *Id. See also, [Datacom Systems Corp. v. New York Medical College, 151 A.D.2d 455 \(2d Dept 1989.\)](#)* Initially, contrary to ExAblate’s claims, a review of the record shows it has not produced all the documents and that Mr. Cohen’s testimony shows that ExAblate of NY is in custody or control of a number of documents directly related to ExAblate of NY and the plaintiff’s procedure that have not been produced. Moreover, contrary to ExAblate of NY counsel’s assertions, a variety of responsive documents regarding the various entities (ExAblate of NY, Deployed Medical Solutions, and Sound Medical Solutions) have not been produced. Moreover, the argument by ExAblate regarding control of the entities is misplaced. Under New York law, the relevant inquiry is not on control of the possessing entities, but rather on control of the documents. CPLR 3120(1)(I). Here, the entities at issue, ExAblate of NY, Sound Medical Solutions, and Deployed Medical Solutions have equal control and possession over the documents. Based on the submitted evidence, these documents are stored in a storage locker in Houston, Texas, as per court order and ExAblate of NY controls these documents. This is shown by the fact that its previous productions came from the very facility it now claims it does not have control or custody of and discussions between the parties regarding document exchange. Finally, ExAblate of NY’s primary witness, Mr. Cohen, confirmed that he has access, custody, and control over the documents at his examination before trial on June 16-17, 2009. Based on the above, it is clear that the requested documents are capable of being provided by ExAblate. Thus the inquiry must

focus on whether these items are properly discoverable.

Regarding the training records, InSightec's training and support of its technology have been put into issue by the claims in the complaint, the testimony of Dr. Shapiro and the already produced documents of ExAblate. These have put into issue whether and how ExAblate complied with or objected to InSightec's training program. Significantly, Deployed Medical Solutions and Sound Medical Solutions purchased InSightec's device and support for sites other than the one at which Plaintiff was treated, and other site's compliance with InSightec's training program is relevant to this litigation. There are documents already produced that suggest Mr. Cohen believed that InSightec's training program was flawed. As such, these records are material and necessary. However, the Court finds all facilities' training records regarding scheduling training is not material and relevant and is unduly burdensome. As such, ExAblate must provide InSightec all correspondence (electronic and otherwise) from its New York management team regarding their current allegations of deficiencies in the training program.

Regarding the marketing materials, these are material and necessary because they directly address how the physicians' competency to perform the procedure based on their training was presented to the public. Additionally, ExAblate of NY alleges that InSightec was to provide radiology training to physicians performing the procedure at issue, and marketing materials would likely include representations as to the physicians' specialized training on the device or with diagnostic radiology. Accordingly, ExAblate must provide InSightec with all marketing material that was presented to the public.

Regarding the Accounting records, these are not material and necessary. InSightec claims these would show if the training program was "fully funded", would show the interrelatedness of the corporate entities at issue here, and whether the financial pressures of securing medical insurance approval may have prompted procedures to be performed prematurely would also be revealed by the accounting records, and is centrally relevant to this litigation. There is no claim or defense, nor any suggestion that the training was not properly funded. In fact, it seems that the training was included in the price paid for the ExAblate 2000 terminal. Nor is there any claim or defense that brings into issue the relatedness of the entities or the financial concerns of the owners of ExAblate and its affiliated entities that requires production of these records.

Regarding business complaints received by related entities, these are material and necessary to the extent that they concern the training and services provided by Dr. Shapiro. There is sufficient evidence Sound Medical Solutions was the general partner of and had control over numerous ExAblate facilities around the country, all using the same medical devices and InSightec training materials and personnel. The overlapping nature of these entities makes the business complaints regarding training received by all entities relevant to this litigation, which involves claims against InSightec for, *inter alia*, its training of Dr. Shapiro. Given this close

affiliation, and the apparently similar training provided by Insightec, complaints about training at one facility would be relatable to the training at other facilities, including the training of Dr. Shapiro. Accordingly, ExAblate shall provide Insightec with records of business complaints regarding the training by Insightec, in ExAblate of NY's possession or control from sites with which it is affiliated, not from other unrelated sites that have purchased medical devices from InSightec.

The Court finds no basis to sanction ExAblate at this time.

A copy of this order is being sent to the parties by way of facsimile transmission on July 20, 2009.

Dated: July 20, 2009

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ORIN R. KITZES, J.S.C.