IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Honorable R. Brooke Jackson

Civil Action No. 10CV1437

ERIC HACKETT,
Plaintiff,

v.

BREG, INC.
Defendant.

ORDER on PENDING MOTIONS

This is one of numerous products liability cases that have been filed by surgical patients concerning pain pumps manufactured and sold by Breg, Inc. The plaintiffs in these cases complain that when the pumps are used to provide a continuous flow of anesthetics into a shoulder or knee joint space over a period of up to two or three days, the anesthetic penetrates and permanently injures cartilage tissue, a condition known as chondrolysis. The case is set for a jury trial beginning on November 7, 2011. Defendant has moved for summary judgment, and if all claims are not dismissed, then for a continuance of the scheduled trial. Plaintiff has moved for leave to amend his complaint to add a prayer for punitive damages. The motions have been fully briefed. The Court vacates the prior order of reference to the Magistrate Judge in order to rule on all pending motions in one order.

Defendant's Motion for Summary Judgment

Plaintiff Eric Hackett underwent shoulder surgery on April 3, 2002. His physician prescribed and implanted a Breg Pain Care 3000 pain pump to administer local anesthetic for post-operative pain control. Plaintiff contends that the continuous injection of the anesthetic into the joint space via the pain pump caused permanent damage to cartilage in his shoulder.

The case was filed in federal court based upon diversity of citizenship. 28 U.S.C. 1362. Plaintiff originally asserted claims against Breg based upon state law theories of strict products liability, negligence and breaches of warranties. He has confessed that his warranty claims are barred by applicable statutory periods of limitation. Therefore, the motion is granted as to claims three, four and five.

Plaintiff's strict liability and negligence claims are based primarily on defendant's alleged failure to adequately warn surgeons and ultimately patients that use of the pain pump for the purpose of continuous injection of anesthetics into the shoulder joint could cause a serious injury. Plaintiff contends that the safety of the device for this use was not adequately

investigated or tested; that the FDA specifically refused to clear the product for this use; and that Breg should have warned orthopedic surgeons either not to use the device for this purpose or, at a minimum, warned the surgeons and patients that permanent cartilage damage could result.

Under Colorado strict liability law, a product is defective and unreasonably dangerous if adequate warnings are not provided. An adequate warning informs the ordinary user of any specific risk of harm that may be involved in the reasonably expected use of the product. However, the product is not defective or unreasonably dangerous if a particular risk was not known or knowable by the manufacturer in light of the generally recognized and prevailing scientific and technical knowledge available at the time of manufacture and distribution. Fiberboard Corp. v. Fenton, 845 P.2d 1168, 1172-74 (Colo. 1993).

A manufacturer is negligent if it fails to warn the user of non-obvious risks of harm of which the manufacturer, in the exercise of reasonable care, knows or reasonably should know. See Fiberboard, supra, 845 P.2d at 1174-75. The defendant's conduct is compared to a standard of care defined by what a reasonably situated manufacturer would do in the same or similar circumstances. Accordingly, while strict liability and negligence concepts are distinguishable even in failure to warn cases, id. at 1175, the concepts of what was "knowable" (strict liability) and what was reasonably foreseeable (negligence) have similarities.

Breg generally denies that the product was defective and denies or at least questions evidence that the pain pump was a cause of the injuries claimed by Mr. Hackett. With respect to its motion for summary judgment, however, Breg relies primarily on the argument that cartilage damage resulting from the continuous injection of anesthetics into the joint space was not known, knowable or reasonably foreseeable to Breg when the device was first distributed in 2000 or at the time of the plaintiff's surgery in April 2002. Breg has produced evidence in the form of deposition excerpts and published articles supporting its position. Breg cites the order of Judge Brimmer of this court in Pavelko v. Breg, Inc., 2011WL782664 (D. Colo. Feb. 28, 2011). The facts concerning the surgery, the use of a pain pump, and the cartilage damage allegedly caused by the pump, were similar to the facts asserted in the present case. The court found that the plaintiff had not shown that there was a genuine dispute regarding whether the risk of pain pumps to cartilage was foreseeable or knowable to Breg in 2003 when that patient's surgery took place. Id. at *1, *6-*8. Defendant notes, as did Judge Brimmer, that other courts had reached similar conclusions. See Krumpelbeck v. Breg, 2010 WL 5475616 (S.D. Ohio Dec. 27, 2010); Monroe v. Zimmer, 2011 WL 534037 (E.D. Cal. Feb. 14, 2011).

Other courts have denied summary judgment motions in these pain pump cases. See Musgrave v. Breg, Inc., 2011 WL 3876529 (S. D. Ohio Sept. 2, 2011); Kildow v. Breg, Inc., 2011 WL 2708292 (D. Or. July 11, 2011); Slavenski v. Breg, Inc., 2011 WL 2709108 (D. Or. July 11, 2011; Hamilton v. Bleg, Inc., 23011 WL 780541 (S.D. Ohio Jan. 20, 2011); Suhn v. Breg, Inc., 2010 WL 5301043 (D.S.D. Dec. 20, 2010); Koch v. Breg, Inc., 2010 WL 5301047 (D. S.D. Dec. 10, 2010). This is not necessarily a reflection of different bodies of state law or even different views of the applicable legal principles. The issue with summary judgment motions is whether the parties in the particular case have presented evidence through affidavits or otherwise that shows that there is at least one issue of material fact that is genuinely disputed. Fed. R. Civ. P. 56(a), (c).

For example, in Pavelko, the plaintiff filed a number of articles and argued that the articles should have raised concerns. The court emphasized the absence of any expert testimony interpreting the literature and supporting the point that the plaintiff inferred from it. 2011 WL 782664 at *5. The court distinguished a Breg pain pump case where summary judgment had been denied on that basis. Id. at *6, n. 5. In the present case, plaintiff presents not just articles but also the affidavit of Dr. Stephen Trippel, an orthopedic surgeon whose qualifications have not been questioned. He reviewed the literature and what he believes was medical knowledge available in 2002 and concluded:

> Prior to 2000, what was known by medical science about joints and the fragility of cartilage would have put a careful and prudent and reasonable medical device maker on notice that continuous infusion of commonly used aesthetics over a period of two to three days into a joint space would likely risk injury to the cartilage. There was enough information available, even before studies investigating the effect of irrigation solutions and local anesthetics on articular cartilage, to raise serious concern that there would likely be a problem if the articular cartilage were continuously exposed to these substances for two to three days.

Trippel Aff., ex. 3A to plaintiff's response brief, at 5.

Without belaboring the point, this Court finds, based on its review of the Trippel affidavit and the other affidavits and materials presented by the plaintiff in opposition to summary judgment, that this plaintiff has made a sufficient showing that there are material facts in genuine dispute concerning what was knowable or foreseeable through literature research and testing to preclude summary disposition. The basic issues in dispute are:

1. Does continuous infusion of common anesthetics into the intra-articular (glanohumeral) joint create a danger of serious damage to articular cartilage in the joint?
2. Was the pain pump a cause of plaintiff's alleged injury?
3. Was the risk of serious damage to the articular cartilage from this use of the pain pump knowable to Breg before the plaintiff's surgery?
4. Was this risk foreseeable to a reasonable manufacturer of pain pumps before the plaintiff's surgery?

The summary judgment motion turns on the knowledge and foreseeability issues rather than the causation issues. Specific fact questions that are material to the resolution of those basic issues include, but are not necessarily limited to:

5. What was the generally recognized and prevailing scientific and technical knowledge concerning the potential impact on cartilage of a continuing infusion of commonly used anesthetics into shoulder (and knee) joints at the time of the plaintiff's surgery?
6. Would a review of medical literature that was available at the time the pain pump was administered to this plaintiff have caused a reasonable manufacturer either not to market the device for orthopedic use or to provide different warnings? Would a reasonable

manufacturer have conducted or obtained such a literature review, and if so, did Breg do this?

7. Would studies or tests specifically addressed to the safety of the device for continuous infusion of anesthetics into an intra-articular joint space have caused a reasonable manufacturer either not to market the device for such use or to provide different warnings? Would a reasonable manufacturer have conducted or obtained such studies or tests at or before the pain pump was administered to the plaintiff, and if so, did Breg do this?
8. Did Breg act reasonably with respect to the testing, marketing or warning of the product for use in intra-articular procedures in light of the FDA's actions prior to the plaintiff's surgery during the 510(k) clearance process?

Because the Court finds that material facts are genuinely disputed, the motion for summary judgment is denied as to the first and second claims for relief.

Motion to Continue

Defendant requests that the trial be continued for a short time. The trial of a similar case against Breg (Musgrave v. Breg, Inc., pending in the Southern District of Ohio) is set to begin on the same date, November 7, 2011. Defendant fears that the same expert witnesses will be needed in two geographically remote jurisdictions at the same time and also expresses concerns regarding possible conflicts for its trial counsel and its company representative. Plaintiff opposes the motion.

It is not disputed that defendant knew of the trial setting in the Ohio case when it agreed to the trial date in this case. Counsel apparently did not, however, disclose the conflict to opposing counsel or the Court until recently. Counsel indicates that they anticipated that one or the other of the cases would settle or otherwise not go to trial as scheduled. However, I do not find it to be reasonable that a "gamble" of that nature should be the basis to cause the plaintiff here to lose his trial date that was set more than a year ago. Moreover, the Court can and will be flexible with the scheduling of witnesses. The Court is willing to take defense witnesses out of order, that is, during the presentation of the plaintiff's case, to accommodate the witnesses' schedules. The Court will expect plaintiff to cooperate in that regard. The Court will do the same thing to accommodate plaintiff's expert witnesses. Counsel should promptly confer and begin the process of scheduling witnesses for both sides with this in mind. There is no reason that a critical witness who is needed by the defense in both trials cannot appear and testify in each court if counsel and the witness cooperate in scheduling.

As for conflicts with trial counsel, Breg has not explained precisely what the conflict is. It acknowledges that it can field more than one trial team. I reviewed the court's order in Musgrave, supra, denying Breg's motion for summary judgment. It lists six lawyers for Breg, only two of whom overlap with Breg's list of five lawyers who represent it in the present case. It appears to the Court that Breg is ably and amply represented in both cases. As for the client representative, Breg does not identify who it will be in either case or why a different person cannot play that role in the two trials. If that individual will be a witness in either case, we can make an accommodation that will permit his or her testimony in both trials.

Thus, while recognizing that Breg has a legitimate interest in its choice of trial counsel and company representative, the Court finds that in the circumstances, those interests, to the extent they are actually affected by the conflicting trial settings, are outweighed by the interest of the plaintiff in maintaining the trial date. These are conflicts that could have been addressed and avoided when the present case was set for trial. The motion to continue the trial is denied.

Motion to Amend

Plaintiff seeks leave to amend his complaint to add a prayer for punitive damages. Although the motion was filed well after the deadline for amending pleadings, plaintiff attempts to justify this on the basis that it was only after receiving recently produced documents, including a document containing statements of Breg's Director of Orthopedic Practice Solutions made in March 2000, that plaintiff had or realized that it had the basis to seek punitive damages. Defendant opposes the motion.

Amendments to pleadings are liberally allowed. See Fed.R.Civ.P. 15(2). However, the Court exercises its discretion to deny the motion. The Court does not find particularly persuasive either the argument that plaintiff's counsel did not have enough information to request the amendment earlier or the defendant's argument that it would be unfairly prejudiced if the amendment is allowed. However, having reviewed the information submitted by the plaintiff, including the reports of plaintiff's experts and the other evidence submitted in opposition to the motion for summary judgment, the Court finds that plaintiff has not made out a prima facie case for the addition of a punitive damages claim. Plaintiff has submitted no affidavits or other evidence that indicate the existence of even a colorable claim that Breg acted in a fraudulent, malicious, or willful and wanton manner in the product's design, testing, marketing or warnings. The absence of a basis for a punitive damages claim is even more evident in light of the high burden of proving the supportive facts beyond a reasonable doubt.

DATED this 3rd day of October, 2011.

BY THE COURT:

R. Brooke Jackson
United States District Judge