IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.
PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 23

(Plaintiffs' Motion to Compel Protegen Documents)

In this multi-district litigation ("MDL") concerning mesh products used to repair pelvic organ prolapse and stress urinary incontinence, the plaintiffs have moved the court to compel Boston Scientific Corp. ("BSC") to produce documents relating to BSC's former, recalled product, ProteGen. The plaintiffs limit their request to those documents which BSC previously produced to litigants in MDL 1387 concerning ProteGen, including deposition and trial transcripts. These documents are located in a document depository at BSC's headquarters in Natick, Massachusetts. (ECF No. 214-18, at 1.)

A brief history of the relevant pelvic mesh products for treating female stress urinary incontinence is necessary. Polypropylene mesh has been used in surgery, notably hernia repair, for more than forty years. (ECF No. 228, at 9.) In 1996, the Food and Drug Administration ("FDA") approved, via the so-called 510(k) process for claims of "substantial equivalence," the use of BSC's ProteGen device for addressing stress urinary incontinence. (*Id*.) ProteGen was a woven polyester sling with pressure injected bovine collagen. (ECF No. 214-6, at 3.) In late 1997, Ethicon, Inc. applied for

and, in early 1998 received, 510(k) approval for its Tension Free Vaginal Tape (TVT) System, composed of polypropylene mesh tape, for treatment of stress urinary incontinence. (ECF No. 232-3, at 2-5.) The 510(k) application asserted that the predicate ("substantially equivalent") device for the TVT System was the ProteGen Sling Collagen Impregnated Material and stated the following:

> Technologically both the new device and predicate device are the same (i.e., both are meshes that provide pubourethral support). Additionally, both devices utilize accessories for use in the surgical procedure. Any differences between the two devices do not raise new questions of safety and effectiveness.

(*Id.*, at 3.)

In 1999, ProteGen was removed from the market by BSC; medical articles reported a 17% urethrovaginal fistula rate and 50% vaginal erosion in 34 patients. (*Id.*) The difficulties associated with the ProteGen device resulted in numerous lawsuits many of which were resolved in MDL 1387, in the U.S. District Court for the District of Maryland.

In 2002, BSC applied for and received 510(k) approval to market its form of Surgical Mesh, based on its claim that the device, a "knitted polypropylene monofilament fiber mesh" intended for treatment of stress urinary incontinence, was substantially equivalent to the TVT device. (ECF No. 214-3, at 1.) In 2004, BSC began marketing its polypropylene mesh slings. (ECF No. 228, at 9.) The majority of cases in this MDL relate to BSC's six transvaginal mesh mid-urethral slings, called Advantage (2004), Advantage Fit (2004), Lynx (2004), Obtryx (2004), Prefyx (2007) and Solyx (2008), all of which are designed to treat stress urinary incontinence.

Positions of the Parties

The plaintiffs make six arguments in support of their position that BSC should produce the ProteGen documents in the MDL 1387 depository to them:

1. ProteGen information is relevant to demonstrate that BSC was on actual notice, based on its experience with ProteGen, that biocompatibility issues existed with respect to surgical meshes implanted in the female pelvis;

2. Documents relating to ProteGen are probative of BSC's knowledge that collagen prevents tissue integration, which results in vaginal erosion and infection;

3. BSC's knowledge of ProteGen's failure rate is directly related to its decision to produce products with the same defects and hazards;

4. BSC's knowledge of ProteGen's failure rate bears on BSC's awareness that the transvaginal approach to repairing pelvic organ prolapse and stress urinary incontinence is itself flawed and unreasonably dangerous;

5. The ProteGen device was the grandfather predicate device for many of the products at issue; and

6. Production does not impose a burden on BSC. (ECF No. 214, at 1-2.)

BSC responds in opposition with three major arguments and three minor points:

1. The polypropylene mesh products in this MDL have significant, undeniable product differences from ProteGen;

2. The requested discovery is not relevant to the plaintiffs' claims and/or to notice;

3. Discovery in this MDL should not be burdened by discovery regarding a decade-old litigation involving a product that is not at issue in these cases;

4. [Minor] The Judicial Panel on Multi-District Litigation concluded that this MDL should not include ProteGen;

5. [Minor] This same motion was briefed and heard in Massachusetts; and

6. [Minor] The plaintiffs filed this motion before a meet and confer. (ECF No. 228, at 1-4.)

The plaintiffs filed a reply which presents three points: their efforts to meet and confer were unsuccessful; the materials sought are relevant; and there is no burden to BSC. (ECF No. 232, at 2, 5.) The court will address the arguments in the order in which BSC presented them.

1. Differences between ProteGen and Current BSC Mesh Products

BSC argues that there are four significant differences between ProteGen and the products which are the subject of this MDL and therefore the ProteGen documents are not relevant. (ECF No. 228, at 7.) The differences are in (1) material, (2) procedures, (3) predicate devices, and (4) regulatory history. (*Id.*)

Material

The parties agree that ProteGen was a "polyester woven sling, coated with pressure-injected bovine collagen and part of a Vesica sling system that also contained bone anchors." (ECF No. 214-2, at 7.) The material used in BSC's current products is "Surgical Mesh," a "knitted polypropylene monofilament fiber mesh." (ECF No. 214-3, at 1.) The FDA has noted that both polyester and polypropylene fall into the general category of non-absorbable synthetic material. FDA Executive Summary, "Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence," Obstetrics & Gynecology Devices Advisory Committee Meeting, September 8-9, 2011 (hereinafter "FDA Summary"), at 7. The FDA Summary did not differentiate among the types of mesh material used to treat stress urinary incontinence, but it noted that "[m]onofilament tape was more effective compared to multifilament

tape." (*Id.*, at 36.) The FDA Summary concluded that the "vast majority of slings evaluated are monofilament polypropylene mesh slings." (*Id.*, at 43.) It found that "between 9% and 17% of all women who had SUI [stress urinary incontinence] treated with surgical mesh reported urinary problems from 6 months postoperatively to 60 months postoperatively," with a similar trend with infection rates. (*Id.*, at 38.) The FDA Summary warned that "there is potential for serious complications with mesh products indicated for SUI repair. The FDA is concerned that safety outcomes may not have been comprehensively evaluated by RCTs [randomized control trials] to date and that the safety of SUI repair with mesh needs to be further considered in evaluating the overall risk to benefit profile of these products." (*Id.*, at 43-44.) ProteGen's coating with bovine collagen may have contributed to its dysfunction, but the complications resulting from it and the current BSC products in some women are the same: pain, erosion, fistula, infection, dyspareunia, urinary retention, etc.

The court finds that because (a) ProteGen and current BSC products were/are made of non-absorbable synthetic materials, (b) the FDA does not differentiate among brands of SUI mesh, and (c) the complications from ProteGen and current BSC SUI products in some women are similar, it is appropriate to consider the ProteGen documents as relevant for the purpose of discovery.

Procedures

Different procedures were/are used to implant and fix ProteGen and the current BSC SUI products within the pelvis, but all the procedures used/use transvaginal insertion. The plaintiffs claim that it is unreasonably dangerous to implant mesh by transvaginal insertion through that so-called "clean contaminated" area, thereby risking

infection, persistent delayed healing and other complications. This is a sufficient showing of relevancy for the purpose of discovery.

Predicate Devices

The court has outlined above the chain of products which led to the current BSC SUI products. Ethicon's TVT sling was approved as substantially equivalent to ProteGen, and BSC's current SUI products were approved as substantially equivalent to TVT. This is a sufficient showing of relevancy for the purpose of discovery.

Regulatory History

BSC argues that the plaintiffs are trying to paint BSC's ProteGen and its current SUI products with the broad brush of negative remarks by the FDA concerning the use of mesh products for treating pelvic organ prolapse ("POP"). (ECF No. 228, at 10.) The court has not been confused.

2. Relevancy

The plaintiffs contend that the ProteGen documents are probative of BSC's knowledge or "notice" that the transvaginal approach to implantation of pelvic mesh to treat either SUI or POP or both was unreasonably dangerous. (ECF No. 214, at 9-10.) They claim that they should be able to explore the role that the transvaginal approach (as opposed to abdominal surgery) plays with respect to the complications experienced by some patients. (*Id.*, at 12.)

BSC responds that the potential complications of which the plaintiffs complain have been the subject of warnings of risks and adverse events since the products were first marketed. (ECF No. 228, at 11.) It contends that ProteGen involved "an entirely different delivery approach" than the current BSC SUI products. (*Id.*, at 12.)

Whether a given product is designed for treatment of SUI or POP, the plaintiffs contend that warnings are insufficient to excuse an allegedly defective design which ignores scientific understanding of the biological effect of mesh on the tissues in a woman's pelvis. In December, 2011, the Committee on Gynecologic Practice of the American College of Obstetricians and Gynecologists, addressing POP, noted that "there seems to be a small but significant group of patients who experience permanent and life-altering sequelae, including pain and dyspareunia, from the use of vaginal mesh." (ECF No. 214-11, at 1.) Unless the ProteGen documents are examined by the plaintiffs, we will not know whether BSC was on notice of the cause of such complications and nevertheless chose to risk marketing its mesh products.

3. Burden on Discovery in this MDL

BSC asserts that the plaintiffs' requested discovery of ProteGen documents would burden the discovery in this MDL and much is available on the public record. The court finds that the production of the ProteGen documents from BSC's depository will not unduly burden the discovery in this MDL. The court cautions the plaintiffs to be circumspect in their questioning of witnesses regarding ProteGen.

4. The Judicial Panel's Comment

On October 1, 2012, the United States Judicial Panel on Multidistrict Litigation vacated a Conditional Transfer Order in *Williams v. Boston Scientific Corp.*, No. 3:12-01080 (N.D. Ohio), a case involving the ProteGen Sling. The Panel noted that "[t]he parties agree, and we are persuaded that, it is unlikely this case will share many factual questions or overlapping discovery with the actions in MDL No. 2326." (ECF No. 228-1, at 1.) The primary reason given was that ProteGen "was manufactured years before the products at issue in MDL No. 2326." (*Id.*) The court finds that the Panel's comment

bears no weight in the determination of whether ProteGen documents may be relevant to subsequently developed products.

5. The Same Motion is before a Massachusetts Court

More than 500 pelvic mesh cases relating to BSC products are pending before the Hon. Diane M. Kottmyer, Judge of the Superior Court Department of the Trial Court, Commonwealth of Massachusetts. (ECF No. 228, at 3; ECF No. 228-2, at 1.) The parties have briefed the same issue relating to the production of the documents in the ProteGen depository, but as of this date, Judge Kottmyer has not entered an Order ruling on the plaintiffs' motion. As of this date, BSC is not subject to inconsistent rulings.

6. Meet and Confer

BSC claims that the plaintiffs filed the instant motion one day before a scheduled meeting to confer on document production issues, and that it was willing to discuss a resolution, such as offering production of the public transcripts of ProteGen trials. (ECF No. 228, at 4.) It also complains that the motion is not specific to particular discovery requests. (*Id.*)

The plaintiffs respond that they have been trying to obtain the ProteGen documents for six months, and the issue was fully briefed before Judge Kottmyer. (ECF No. 232, at 2.) They note that in communications to BSC counsel dated September 13 and 28, and October 5, 2012, the plaintiffs raised anew their arguments for the documents, without success.

Fed. R. Civ. P. 37(a)(1) and our Local Rule 37.1(b) require a party to make a good faith effort to confer or attempt to confer in an effort to obtain the requested discovery without court action. The penalty for failing to attempt to obtain the discovery without

court action is an inability to collect a party's reasonable expenses, including attorney's fees for the motion to compel. Our Local Rule 37.1(b) does not spell out a penalty for failing to meet and confer. Neither the Federal Rule nor the Local Rule provides that a party who fails to meet and confer is disqualified from filing a motion to compel.

The court finds that the plaintiffs made a good faith effort to obtain the ProteGen documents without court action.

It is hereby **ORDERED** that the plaintiffs' Motion to Compel Protegen Documents (ECF No. 214) is granted; BSC is directed to produce the Protegen documents promptly, including all deposition and trial transcripts. The parties shall bear their own costs.

The court **DIRECTS** the Clerk to file a copy of this Pretrial Order # 23 in 2:12-md-2326 and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:12-cv-07764. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: November 15, 2012

Mary E. Stanley
Mary E. Stanley
United States Magistrate Judge