

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

CHARLESTON DIVISION

IN RE: C.R. BARD, INC.
PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION

Case No. 2:10-md-2187

THIS DOCUMENT RELATES TO ALL CASES

**MEMORANDUM OPINION
AND PRETRIAL ORDER # 44**

(Tissue Science Laboratories Ltd.'s Motion to Quash
Subpoena to Produce Documents, ECF No. 255)

In this multi-district litigation (“MDL”) concerning products used to repair pelvic organ prolapse and stress urinary incontinence, on April 23, 2012, the plaintiffs served a subpoena on Instrument Management Associates, L.L.C. (“IMA”), through its registered agent for service, Thomas C. Powell, to produce documents relating to two specifically named civil actions and to other matters involving defendant Tissue Science Laboratories (“TSL”) and its products called Permacol, Pelvicol, PelviLace and Pelvisoft. (ECF No. 244-1, at 2-8.) Permacol is an abdominal and hernia repair product manufactured by TSL. Pelvicol, PelviLace and Pelvisoft are pelvic repair products manufactured by TSL and are among the products at issue in this MDL. Pending before the court is the Motion to Quash Subpoena to Produce Documents (ECF No. 255), filed on July 2, 2012, by TSL. The plaintiffs have responded in opposition (ECF No. 261), and TSL has filed a reply (ECF No. 264).

According to the plaintiffs’ Master Complaint, defendant TSL is a British private limited company which designed, manufactured, packaged and labeled some of the

pelvic repair systems products which are the subject of this MDL (ECF No. 198-1, at 2, 5-6). TSL served its Objections to the subpoena (ECF No. 244), and the plaintiffs filed their Response to the Objections (ECF No. 249). Court staff informally instructed the parties to file an appropriate motion, which is the pending motion to quash, without repeating the arguments in the Objections and Response to Objections.

Background

IMA is a former distributor of Permacol. (ECF No. 244, at 1-2.) IMA was terminated as a distributor for TSL when TSL switched to an internal sales force. *Id.* at 2. After IMA was terminated, its principal and other sales representatives, including Thomas Powell, filed a *qui tam* action against TSL, alleging that TSL engaged in off-label marketing of Permacol, leading to the submission of fraudulent claims to the federal government and injury to patients. *United States ex rel. Stephens v. Tissue Science Laboratories, Inc.*, No. 1:07-cv-2357-ODE (N.D. Ga.) (Order entered Aug. 13, 2009, ECF No. 54). The case was dismissed because the relators were unable to meet the materiality standards of the False Claims Act (*i.e.*, use of Permacol did not affect the amount of reimbursement for hernia repairs). *Id.*, at 13. The Northern District of Georgia further found that there were “no specific allegations regarding a causal link between TSL representatives’ statements and the purchase or use of Permacol.” *Id.*, at 15.

The other specific civil action listed in the subpoena is *Edwards v. Tissue Science Laboratories, Inc.*, No. 1:08-cv-1239 WSD (N.D. Ga.), in which the plaintiffs alleged that Permacol was a defective product improperly marketed to Mr. Edwards’s surgeon and used in Mr. Edwards’s hernia repair. (*Edwards, id.*, Complaint, ECF No. 1-4.) TSL filed a third-party complaint against IMA and Thomas C. Powell, seeking indemnification

and contribution pursuant to their Distribution Agreements. *Id.*, ECF No. 5. IMA and Powell then counterclaimed against TSL, asserting that TSL made false statements to them about Permacol. *Id.*, ECF No. 18. TSL and IMA/Powell filed a Stipulation of Dismissal with Prejudice on April 27, 2009. *Id.*, ECF No. 164. TSL and the Edwardses filed a Stipulation of Dismissal with Prejudice on September 22, 2009. *Id.*, ECF No. 168.

In addition to the documents relating to the specifically named civil actions (Request Nos. 1 and 8), the plaintiffs subpoenaed documents and communications relating to:

2. The termination of IMA's contract with TSL;
3. The first sales training seminar by TSL in May 2002;
4. Seventeen training sessions conducted by IMA employee Stephens between June 2002 and November 2004;
5. The products Permacol, Pelvicol, PelviLace and/or Pelvisoft;
6. The Food and Drug Administration and the products Permacol, Pelvicol, PelviLace and/or Pelvisoft;
7. Distribution agreements entered into by IMA and TSL;
9. Materials produced by IMA in any State or Federal civil action involving a suit against TSL; and
10. Materials produced by IMA in any other State or Federal civil action involving a personal injury claim alleging injury due to the products Permacol, Pelvicol, PelviLace and/or Pelvisoft. (ECF No. 244-1, at 7-8.)

The subpoena commanded the production on May 21, 2012, at the office of the plaintiffs' counsel (Blasingame, Burch, Garrard & Ashley, P.C.) in Athens, Georgia. *Id.*

at 2. The subpoena included a page setting forth Fed. R. Civ. P. 45(c), (d) and (e), including the provision in Rule 45(c)(2)(B) which states: “The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served.” *Id.* at 3. Any objection by IMA was due on May 7, 2012, which was 14 days after the subpoena was served. IMA did not timely object to the subpoena. (ECF No. 261, at 1.)

On July 10, 2012, Thomas C. Powell (IMA’s registered agent), acting *pro se*, sent a letter, via electronic mail, to one of the plaintiffs’ attorneys, Jennifer Register, with copies to TSL’s counsel, which has been filed in this MDL (ECF No. 266, at 2). In the letter, Mr. Powell objects to the subpoena, to producing documents, to the matter being heard by a judge in West Virginia, and to traveling out of state. *Id.* He asserts that he needs “someone” to pay for a lawyer to review the “highly personal and confidential materials” which he has on compact discs. *Id.* Another of the plaintiffs’ attorneys, Josh B. Wages, has submitted his Affidavit, which has been filed. *Id.* at 5-6. Mr. Wages states upon his oath that he had two conversations with Mr. Powell, on May 9 and June 13, 2012, concerning the subpoena and that Mr. Powell told him that “IMA intended to comply with our subpoena and that IMA does not intend to object to the production of the requested materials. However, out of an abundance of caution, Mr. Powell stated that IMA wanted to wait until TSL’s objections could be resolved by a court before producing any materials in response to Plaintiffs’ subpoena.” *Id.*

Mr. Powell’s Objection

The July 10, 2012 letter which Mr. Powell purportedly wrote to Ms. Register (it is not signed), raising objections to the subpoena, is ineffective for several reasons. First and foremost, it is untimely by more than two months. Rule 45(c)(2)(B) is explicit that

an objection “*must*” be served as specified. (Emphasis added.) Second, the subpoena was issued to Instrument Management Associates, L.L.C., not Mr. Powell. A recent check with the Georgia Secretary of State indicates that IMA is an active corporation. There is no indication that Mr. Powell has any authority to act or speak for IMA beyond being its registered agent. Third, Mr. Powell asserts that “the documents include highly personal and confidential materials that need to be reviewed by a lawyer.” Assuming that Mr. Powell is attempting to invoke his personal attorney-client privilege, Rule 45(c)(3)(A)(iii) requires a “timely” motion to quash, filed in the issuing court. There is no reason to believe that such a motion was filed in his behalf in the Northern District of Georgia. Mr. Powell, who is not a lawyer, could not file such a motion to quash on behalf of IMA. Fourth, Mr. Powell’s concern that “there may be trade secret or proprietary materials that TSL could object to,” will be addressed in the context of TSL’s objections and Motion to Quash, not Mr. Powell’s. Finally, Mr. Powell’s desire not to travel out of state is irrelevant; the subpoena commanded production at Athens, Georgia, approximately 76 miles from Marietta. Accordingly, the court will disregard Mr. Powell’s purported letter to Ms. Register.

Positions of the Parties

In its Objections to the subpoena, TSL asserts that the subpoena “exceeds the proper bounds of discovery by: (1) demanding documents from a third party that are irrelevant as well as beyond the scope of discovery in the MDL; (2) duplicating the production of documents that will already be produced in MDL 2187; and/or (3) seeking the disclosure of highly confidential and proprietary documents.” (ECF No. 244, at 2-3.) The Objections address each of the Requests in the subpoena. *Id.* at 3-14. TSL repeatedly refers to the confidentiality provision of its Distribution Agreement with

IMA, but did not initially provide a copy of that Agreement. *Id.* Similarly, with respect to Request No. 8, TSL relies on a “binding confidentiality agreement in that case,” but did not initially provide a copy of that agreement. *Id.* at 11. As to Request No. 10, TSL claims “binding protective orders of confidentiality,” but did not produce them. *Id.* at 14.

In its Motion to Quash, TSL contends that the subpoena “seeks the production of confidential and proprietary material that is protected from disclosure under Fed. R. Civ. P. 45, and attempts to circumvent the discovery protocol agreed upon by the parties in the MDL to seek from a third party information that is wholly irrelevant to the claims in this litigation.” (ECF No. 255, at 1.)

TSL provided a redacted copy of its Distribution Agreement with IMA; the confidentiality provision reads as follows:

All information of Seller which Distributor receives through its operations under this Agreement shall be treated by Distributor as confidential, and shall not be used by Distributor or disclosed by it to any third party except when and to the extent reasonably necessary to comply with the terms of this Agreement. Distributor shall, upon request of Seller, execute, and cause its employees to execute, separate statements acknowledging Seller’s proprietary interest in its confidential information and know-how concerning the Products, in which statements Distributor and its employee or agents shall undertake not to disclose the same except to Distributor’s customers for the purpose and to the extent stated in the preceding sentence.

(ECF No. 255-4, at 3.)

The so-called “binding confidentiality agreement” in the *Edwards* case is not in writing; in fact, it is not an “agreement” at all. In *Edwards*, TSL filed a motion for a protective order and provided a proposed order. *Edwards, id.*, ECF No. 53. IMA and Powell opposed the motion and proposed order as being too broadly written, too restrictive in the use of documents, and too one-sided, noting that TSL had over-

designated documents as “confidential.” *Id.*, ECF No. 61. The *Edwards* presiding judge convened a discovery hearing at which the motion for protective order was “terminated,” neither granted nor denied. *Id.*, ECF No. 89. The judge stated his preferences for provisions in a protective order (*id.*, ECF No. 90) but no agreed protective order was ever entered. The relevant portion of the transcript has been filed in this MDL, at ECF No. 255-3.

TSL asks the court to quash the entire subpoena; in the alternative, TSL requests limiting the subpoena to:

1. **Request No. 6**, narrowing the Request to all documents and communications between IMA and the FDA relating only to Pelvicol, PelviLace and/or Pelvisoft; and
2. **Request No. 10**, narrowing the Request to all documents and communications produced by IMA in any State or Federal Civil Action involving a personal injury claim or cause of action alleging injury relating only to Pelvicol, PelviLace and/or Pelvisoft.

Id. at 5.

In their Response to the Objections, the plaintiffs argue that “a party lacks standing to challenge a subpoena served on a non-party, except to the extent the party may claim privilege in the documents being sought,” citing *Windsor v. Martindale*, 175 F.R.D. 665, 668 (D. Colo. 1997), *U.S. Bank Nat’l Ass’n v. James*, 264 F.R.D. 17, 18-19 (D. Me. 2010), and *Liberty Media Holdings, LLC v. Swarm Sharing Hash File AE340D056012*, 821 F. Supp.2d 444, 450 (D. Mass. 2011). (ECF No. 249, at 1-2.) The plaintiffs note that TSL does not, and cannot, assert any privilege claim in its objections. *Id.* at 2. The plaintiffs contend that the documents are relevant because TSL’s pelvic repair products are made of Permacol, that it is implausible that TSL will produce all of IMA’s documents, and the documents are neither confidential nor proprietary. *Id.* at 2-10. Finally, the plaintiffs point out that the “agreed-upon discovery protocol” in this

MDL addresses the manner of production of documents and ESI and does not limit the rights of any party to engage in discovery under the Rules. *Id.* at 9 n.9. The plaintiffs note the absence of any protective order or confidentiality agreement on the docket in *Stephens* or *Edwards*. *Id.* at 9. The plaintiffs have offered “to allow TSL 30 days from receipt of any IMA production to assert any claim of ‘confidentiality,’” which would trigger the stipulated protective order entered in this MDL. *Id.* at 11. These contentions are repeated in the plaintiffs’ Response to the Motion to Quash (ECF No. 261).

TSL’s Reply asserts its right to protect its confidential, proprietary and otherwise protected material in the possession of IMA, states its intention to produce documents from the *Stephens* and *Edwards* cases “that are responsive based on the criteria and parameters established in MDL 2187,” and relies on the verbal confidentiality preferences expressed by the presiding judge in the *Edwards* case and TSL’s Distribution Agreement with IMA as evidence of the confidential and proprietary nature of the materials sought. (ECF No. 264, at 1-2.)

Analysis

The subpoena was issued by the Clerk of the United States District Court for the Northern District of Georgia, in compliance with Fed. R. Civ. P. 45(a)(2)(C), because IMA is located in Marietta, Georgia. (ECF No. 244-1, at 1.) The parties have agreed to submit this dispute to the undersigned, rather than the issuing court, “for consistency in approach and application of orders governing discovery” in the MDL. (ECF No. 244, at 1 n.1.)

Standing of TSL

The plaintiffs argue the general proposition that a party lacks standing to challenge a subpoena to a non-party, except to the extent the party may claim privilege

or protection in the documents being sought. This principle is well-settled, as set forth in 9A Wright, Miller, Kane & Marcus, *Federal Practice & Procedure* § 2459 (3d ed. 2012).

Rule 45(c)(3)(A)(iii) provides that a court “*must* quash or modify a subpoena that “requires disclosure of privileged or other protected matter, if no exception or waiver applies . . .” (Emphasis supplied.) Rule 45(c)(3)(B)(i) states that “[t]o protect a person . . . affected by a subpoena, the . . . court *may*, on motion, quash or modify the subpoena if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information.” (Emphasis supplied.) The plaintiffs are correct that TSL has not asserted a claim of privilege or protection as trial-preparation material; thus Rule 45(c)(3)(A)(iii) and Rule 45(d)(2) are inapposite. However, TSL has asserted that IMA’s production will result in disclosure of “confidential and proprietary documents.” The court **FINDS** that TSL has standing to file the instant Motion to Quash.

Relevancy

TSL claims that the documents sought from IMA are irrelevant because they relate to Permacol; IMA was never a distributor of Pelvicol, PelviLace and Pelvisoft, the products at issue in this MDL. While asserting that the IMA documents are irrelevant, TSL acknowledges that it will be producing documents in this MDL which were produced in *Stephens* and *Edwards*. It insists that TSL’s production must be limited to those documents which are “responsive based on the criteria and parameters established in MDL 2187,” and therefore the IMA subpoena must be quashed. (ECF No. 264, at 1-2.)

The plaintiffs make a persuasive case that Permacol is the material which is used to make Pelvicol, PelviLace and Pelvisoft. (ECF No. 249, at 2-8.) TSL has not disputed these allegations. The court **FINDS** that Permacol is relevant to this MDL.

This MDL's Discovery Protocol

TSL asserts that the subpoena to IMA “circumvent[s] the established discovery process in MDL 2187 by: (1) demanding documents from a third party that are irrelevant as well as beyond the scope of discovery in the MDL; . . .” (ECF No. 244, at 2-3.) The court assumes that TSL bases this argument on Pretrial Order # 11 (Stipulation for the Production of Documents and Electronically Stored Information Protocols). Pretrial Order # 11 applies to discovery disclosure and production documents prepared by “the parties,” not by non-parties. (ECF No. 58, at 3.) Notably, the last section of the Stipulation states that “[t]his agreement is without waiver or limitation of any rights of any party to discovery under the Federal Rules of Civil Procedure.” *Id.* at 13. The court **FINDS** that there is nothing in the Stipulation which restricts the plaintiffs from serving subpoenas on non-parties; moreover, the Stipulation does not address the “scope of discovery.” If there are disputes concerning whether proposed discovery is irrelevant, the disputes will ultimately be decided by a judicial officer.

Duplication

TSL indicates that it will be producing documents in this MDL which it produced to IMA; thus there will be unnecessary duplication of documents. (ECF No. 244, at 3.) The plaintiffs respond that IMA has its own documents, and may have documents from TSL which TSL no longer has. (ECF No. 249, at 9.)

The court **FINDS** that the possibility of duplication is not a reason for quashing the subpoena. The plaintiffs should not be limited to production of documents only by TSL.

Purported Protective Order in *Edwards*

TSL produced documents which were stamped, “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER IN EDWARDS, CASE NO. 1:08-CV-1239 WSD.” (ECF No. 255-4.) It appears evident from the docket sheet and the transcript in the *Edwards* discovery hearing that there was never a protective order which was signed by the parties and accepted by the presiding judge. (ECF No. 255-3.) TSL acknowledged during the hearing that it had over-designated documents which it produced. *Id.* at 12. Obviously, TSL prematurely stamped the documents as confidential and subject to a protective order. At most, the *Edwards* judge indicated that “every document produced in this case is in this case, period.” *Id.* Such a statement cannot be enforced. Thus the court is left with an unknown set of documents, virtually all of which were stamped as confidential and subject to an unwritten and unenforceable “protective order.” The answer is not to quash the subpoena; after all, it was TSL which over-designated its documents and then neglected to obtain a stipulated protective order. The court **FINDS** that TSL has failed to show that there is a “binding confidentiality agreement” in *Edwards* and to meet its burden of proving that the documents produced in *Edwards* were in fact “trade secrets or other confidential research, development, or commercial information.”

Distribution Agreement with IMA

Paragraph 14 of the Distribution Agreement with IMA provides that “[a]ll information of Seller which Distributor receives through its operations under this

Agreement shall be treated by Distributor as confidential, and shall not be used by Distributor or disclosed by it to any third party . . .” (ECF No. 255-4.) That is, IMA agreed to treat the information as confidential, whether or not it was in fact confidential. TSL has not provided other provisions of the Distribution Agreement, such as its term or its applicability after the termination of the distribution relationship.

Several courts have held that private confidentiality agreements do not preclude the production of documents for the purpose of discovery. *See, e.g., Zoom Imaging, L.P. v. St. Luke’s Hosp. and Health Network*, 513 F. Supp.2d 411, 417 (E.D. Pa. 2007); *Niester v. Moore*, No. 08-5160, 2009 WL 2179356, at *3 (E.D. Pa. July 22, 2009). In *Grumman Aerospace Corp. v. Titanium Metals Corp. of Am.*, 91 F.R.D. 84, 87 (E.D.N.Y. 1981), the court wrote that “confidentiality agreements . . . do not immunize . . . materials from discovery.” In *Volumetrics Medical Imaging, LLC v. Toshiba*, No. 1:05-cv-955, 2011 WL 2470460, at *18 (M.D.N.C. June 20, 2011), the court compelled a party to produce a confidential settlement agreement. “Information and documents are not shielded from discovery merely because they are confidential.” *DirecTV, Inc. v. Puccinelli*, 224 F.R.D. 677, 684-85 (D. Kan. 2004). “There is no privilege for documents merely because they are subject to a confidentiality agreement, and confidentiality agreements do not necessarily bar discovery that is otherwise permissible and relevant.” *National Union Fire Ins. Co. of Pittsburgh, PA v. Porter Hayden Co.*, No. CCB-03-3408, 2012 WL 628493, at *2 (D. Md. Feb. 24, 2012). In *Young v. State Farm Mut. Auto Ins. Co.*, 169 F.R.D. 72, 77-80 (S.D. W. Va. 1996), the undersigned rejected an argument that an agreement is rendered non-discoverable by virtue of its confidentiality provisions. The court **FINDS** that the Distribution Agreement’s confidentiality provision does not constitute a reason for quashing the subject subpoena.

Trade Secrets, Other Confidential Research, Development or Commercial Information

The plaintiffs have offered TSL the opportunity to designate some of IMA's documents produced pursuant to the subpoena as "confidential," pursuant to the Stipulated Protective Order entered in this MDL (Pretrial Order # 7, ECF No. 54). This arrangement provides adequate protection to TSL, particularly as TSL has not yet met its burden of showing that IMA's documents are in fact TSL's trade secrets or other confidential research, development or commercial information.

Ruling

It is hereby **ORDERED** that TSL's Objections to the Subpoena to Produce Documents (ECF No. 244) are **OVERRULED** and TSL's Motion to Quash Subpoena to Produce Documents (ECF No. 255) is **DENIED**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Pretrial Order # 44 in 2:10-md-2187, and to mail a certified copy to Thomas C. Powell, 2261 Chimney Swift Circle, Marietta, Georgia 30062-2883, via certified mail, return receipt requested. This Memorandum Opinion and Pretrial Order # 44 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-03011. 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.wvsc.uscourts.gov.

ENTER: July 12, 2012


Mary E. Stanley
United States Magistrate Judge