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

CHARLESTON DIVISION

IN RE: AMERICAN MEDICAL SYSTEMS, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2325

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER #62

(Plaintiffs' Request to Modify Stipulated Pretrial Orders to Allow Access and Exchange of Confidential Information Among MDLs)

Currently pending before this court are five separate multidistrict litigations ("MDL") concerning pelvic mesh products manufactured and distributed by the five competing corporations for which the MDLs are named. In each MDL, the parties agreed to the entry of a stipulated protective order ("SPO") that, *inter alia*, allowed the parties to designate documents as "confidential" or "highly confidential" and restricted the use and disclosure of the designated documents to the MDL in which they were produced. Now Plaintiffs in all five MDLs are seeking to modify the protective orders to allow sharing and cross-utilization of the Defendants' "confidential" documents, without a corresponding duty to notify the designating Defendant or allow that Defendant an opportunity to be heard. The parties have filed position statements and their arguments are clear. Having fully considered the matter, and for the reasons that follow, the court **DENIES** Plaintiffs' request for modifications to the stipulated protective orders.

I. Positions of the Parties

Plaintiffs argue that the factual and legal issues in all five MDLs are the same. In each case, Plaintiffs claim that the mesh products were improperly designed, manufactured, and marketed, and the warnings provided by the manufacturers were inadequate and misleading. Plaintiffs state claims of negligence, strict liability, breach of warranty, and punitive damages. According to Plaintiffs, the common characteristics of the various mesh products, the common claims asserted by the Plaintiffs, and the similarities of their injuries are "three reasons why cross-utilization of documents is relevant." To support their position, Plaintiffs point to documents produced in one MDL that have proven relevant in other MDLs. For instance, Plaintiffs contend that some of the experts identified by the Defendants have been industry consultants for manufacturers named in other MDLs; consequently, documents produced in one MDL containing consulting opinions by an expert in another MDL are relevant for impeachment of the expert. In addition, Plaintiffs claim that the Defendants have generated a fair amount of material in which they assess, and often criticize, the mesh products of competing manufacturers. Because a mesh manufacturer is held to the standard of an expert in its industry, "selling against the competitor" information is useful in determining the state of knowledge regarding pelvic mesh at critical points in time.

Plaintiffs further contend that the Defendants have substantially over-designated documents as confidential and cross-utilization would allow the parties "to immediately access and use documents produced in one MDL in another MDL for purposes of [that] litigation only." Plaintiffs stress that courts from around the country regularly allow parties to share the fruits of discovery. Plaintiffs assert that

they would be subject to the existing SPOs; accordingly, allowing them to freely use these documents across MDL lines would not significantly jeopardize the confidentiality of the documents. Plaintiffs argue that removing the requirement of notice to designating Defendants and eliminating the opportunity of the Defendants to be heard before use and disclosure would expedite discovery and preserve resources.[1]

In response, Defendants offer a variety of arguments against modification of the protective orders. First, they contend that the burdens imposed upon them by allowing cross-utilization of documents would vastly outweigh the benefits to the Plaintiffs. Defendants emphasize that, unlike the Plaintiffs who share the same document depository and many of the same counsel and, thus, have ready access to the full range of documents, Defendants do not have access to the information supplied by the other manufacturers. In order to properly prepare a defense, Defendants will be forced to obtain and review hundreds of thousands of pages produced in other MDLs. Moreover, without notice, they will have no way of knowing which of their documents Plaintiffs intend to use against the other Defendants. To prevent misuse of their information, Defendants will be forced to attend depositions scheduled in other MDLs.

Second, Defendants claim that Plaintiffs are attempting to create one "super MDL," which is not what the Judicial Panel on Multidistrict Litigation intended when it separated the MDLs by major manufacturer. Defendants refer to several decisions by the Judicial Panel in which it refused to centralize actions with very similar claims

[1] Plaintiffs agree that they will refrain from sharing and cross-utilizing documents marked "highly confidential."

because the actions involved different manufacturers and different products. In these instances, the Judicial Panel reasoned that the efficiencies to be gained by centralization would be overwhelmed by the individualized issues; therefore, centralization was not beneficial.

Finally, Defendants argue that Plaintiffs have failed to provide good cause to modify the protective orders. Plaintiffs have shown no change of circumstances since entry of the stipulated orders to justify the requested modification. Defendants claim that they have produced millions of documents in reliance on the terms of the SPOs and would be substantially prejudiced if Plaintiffs are permitted, without restraint, to share Defendants' confidential documents with competing manufacturers.

II. <u>The Stipulated Protective Orders</u>

The stipulated protective orders in each of the five MDLs are nearly identical. They are "umbrella" orders intended to "expedite the production, reduce the costs, and avoid the burden on the court of document-by-document adjudication" when the volume of potentially protected materials is large. *See Annotated Manual for Complex Litigation, Fourth,* (MCL 4th), § 11.432 (2004). The SPOs prohibit the use and disclosure of information designated as "confidential" or "highly confidential" for any purpose other than the litigation in which the information is produced. They do not include an exception to the restriction that would allow parties to share discovery with litigants in similar or related cases.[2] However, the orders do not limit the use and disclosure of non-confidential material.

[2] The MCL 4th provides sample language to include in an SPO to address this scenario. MCL 4th § 40.27 (2004).

In addition, each SPO contains a provision allowing a party to challenge the redaction or designation of information as confidential or highly confidential. *See* SPO at Section II.B.4. Under this provision, the challenging party must notify the designating party of an objection to the designation either in writing or by placing the objection on the record at a deposition. The parties must then meet and confer to see if they can resolve the issue, such as by de-designating the information. If agreement is not possible, either party may seek the court's intervention.

III. <u>Standards for Modifying a Protective Order</u>

A district court that enters a protective order retains the right to modify the order as long as it remains in effect. *United States v. (Under Seal),* 794 F.2d 920, 928 n.6 (4th Cir. 1986); *S.E.C. v. Merrill Scott & Assocs., Ltd.,* 600 F.3d 1262 (10th Cir. 2010); *Omega Homes, Inc. v. Citicorp Acceptance Co.,* 656 F.Supp 393 (W.D.Va. 1987); *In re Agent Orange Product Liab. Litig.*, 821 F.2d 139, 147 (2d Cir. 1987). "The party seeking to modify a protective order bears the burden of showing good cause for the modification." *SmithKline Beecham Corp. v. Synthon Pharm., LTD,* 210 F.R.D. 163, 166 (M.D.N.C. 2002) (citing *S.E.C. v. TheStreet.Com,* 273 F.3d 222, 229 (2d Cir. 2001); *see also Jochims v. Isuzu Motors, LTD,* 145 F.R.D. 499, 501 (S.D. Iowa 1992) ("[W]here a party to [a] stipulated protective order seeks to modify that protective order, that party must demonstrate particular good cause to gain relief from the agreed protective order."). Factors that a court should consider when deciding whether to modify a protective order include: "the reason and purpose for a modification, whether a party has alternative means available to acquire the information, the type of protective order which is at issue, and the type of materials or documents which are sought." *SmithKline Beecham Corp.,* 210 F.R.D. at 166.

Ultimately, the court must balance the interests of the parties by weighing the potential for injury to the party opposing modification against the need demonstrated by the party seeking modification.[3]

IV. Analysis

Applying the framework outlined in *SmithKline Beecham*, the undersigned notes that Plaintiffs' primary reasons for requesting modification of the protective orders' use and disclosure limitations are to avoid duplication of discovery and to facilitate sharing of relevant materials that have been improperly designated as confidential. Certainly, avoiding duplication of discovery is a legitimate reason for modifying a protective order; particularly, "when parties in other litigation seek to obtain the discovery in concluded litigation which involved a party to their present lawsuit." *SmithKline Beecham*, 210 F.R.D. at 166. In contrast, Plaintiffs here are not seeking modification in order to share discovery already produced by Defendants in other litigation for use against the same Defendants in this litigation. Instead, Plaintiffs seek permission to use materials produced by a manufacturer in one MDL against manufacturers in the other MDLs. Although the undersigned acknowledges that some portion of a manufacturer's confidential information is probably relevant to issues arising in an MDL not involving that manufacturer, the amount of relevant

[3] There is no unanimity among the circuits as to the correct standard to apply when considering a request to modify a protective order. *Jochims*, 145 F.R.D. at 501-02. Some factors that affect the analysis include the status of the movant (party or intervenor), whether the order was agreed upon by the parties, and whether modification is sought purely for private reasons. *See SRS Tech., Inc. v. Physitron, Inc.*, 216 F.R.D. 525 (N.D. Ala. 2003); *In re Vitamins Antitrust Litig.*, Case No. Misc. 99-197, 2001 WL 34088808, at *6 (D.D.C., Mar. 19, 2001). Under circumstances similar to those present here, however, courts in the Fourth Circuit have placed the burden to show good cause on the moving party and have weighed the factors set forth in *SmithKline Beecham Corp.*, 210 F.R.D. at 166. *See, e.g.*, *Minogue v. Modell*, Civil No. CCB-03-391, 2012 WL 4105312, at *4 (D.Md., Sept. 17, 2012); *United States v. Bailey*, Cae No. 1:11-cr-10, 2012 WL 1340518, at *2 (M.D.N.C., Apr. 18, 2012); *Sepracor, Inc. v. Barr Pharmaceuticals, Inc.*, Case No. 5:08-cv-362H(3), 2010 WL 3210720, at *3 (E.D.N.C., Aug. 9, 2010).

information is likely to be small in comparison to discovery as a whole and, thus, would not significantly reduce Plaintiffs' discovery burden. On the other hand, allowing Plaintiffs free rein to share and use Defendants' confidential material in any MDL would necessarily result in an increased discovery burden on the Defendants. Moreover, without some oversight by the court, Plaintiffs are likely to unintentionally disclose to a manufacturer's competitor proprietary information entitled to protection. Therefore, allowing unfettered use of confidential discovery creates more problems than it solves and significantly prejudices the ability of the manufacturers to prepare their defenses.

The court has considered the cases cited by Plaintiffs, which stand for the proposition that different plaintiffs in different cases should be permitted to share the fruits of their discovery. Clearly, as a general rule, that position makes logical and practical sense. However, a closer review of the cases reveals significant factual differences that render them inapplicable to the question before this court. In two of the cases, the court was concerned with whether good cause supported the issuance of a motion for protective order. In the present matter, the issue is whether an existing stipulated protective order should be modified, which requires a slightly different analysis. *Burlington City Bd. of Educ. V. U.S. Mineral Products Co., Inc.*, 115 F.R.D. 188 (M.D.N.C. 1987); *Nestle Foods Corp. v. Aetna Casualty & Sur. Co.*, 129 F.R.D. 483 (D.N.J. 1990). Another case relied upon by Plaintiffs involves the dissemination of *non-confidential* discovery, which is not a concern in this litigation. *Cipollone v. Liggett Group, Inc.*, 113 F.R.D. 86 (D.N.J. 1986). Finally, in the *Baker* case, the court addressed whether the defendant tobacco companies had demonstrated good cause to include a non-sharing provision in a protective order

that effectively prevented the plaintiffs from disclosing any information received in discovery, including non-confidential materials. *Baker v. Liggett Group, Inc.*, 132 F.R.D. 123 (D. Mass. 1990). The court found that defendants had not shown good cause to restrict the disclosure of non-confidential information and had not shown good cause to prohibit the sharing of confidential information with litigants in similar actions. Significantly, the court entered a protective order that allowed sharing of confidential materials obtained in discovery with other litigants in similar cases, but only after the defendants were given twenty (20) days advance notice of the intended disclosure, the right to meet and confer, and an opportunity to bring any unresolved issues to the court—steps similar to the steps contained in the SPOs here. Accordingly, none of these cases discusses the factors that a court should take into account when asked to remove from a protective order one of the stipulated limitations on the use and disclosure of discovery.

Additionally, Plaintiffs' contention that Defendants have greatly over-designated documents, albeit probable, does not provide a strong basis for modifying the SPOs given that they already anticipate disputes regarding over-designation and provide a procedure to resolve them. While this procedure, which requires notice, negotiation, and an opportunity for judicial intervention, may seem cumbersome, it is no more burdensome than what is already required by the Rules of Civil Procedure. Moreover, challenges to designations need not only be raised on a document-by-document basis but may be directed toward categories of information that have been improperly marked. Simply stated, "[t]he fact that Defendants have designated a significant percentage of their documents [confidential] is, in and of itself, an insufficient basis to warrant modification" of protective orders in litigation which

necessarily requires the exchange of "proprietary and commercially sensitive information among competitors." *Eisai, Inc. v. Sanofi-Aventis U.S., LLC,* Case No. 08-4168 (MLC), 2012 WL 1299701, at *10 (D.N.J., Apr. 16, 2012).

Next, the court examines whether Plaintiffs have alternative means to acquire confidential information produced in other MDLs. As previously indicated, Plaintiffs may pursue de-designation of the confidential material produced in their MDL that they wish to share with litigants in other MDLs. They can also subpoena relevant records from Defendants in other MDLs. Thus, the information is available to the Plaintiffs without modifying the protective orders.

Taking into account that the protective orders at issue are umbrella orders, the court realizes that no party is required to make a good cause showing before designating a document as confidential. Therefore, Plaintiffs may argue that Defendants did not produce documents in reliance on the orders. Nevertheless, Defendants undoubtedly did rely on the "notice and opportunity to be heard" provisions of the orders, which, in turn, allowed more expeditious release of information to the Plaintiffs. Without the orders, the discovery process would be riddled with motions to compel and motions for protective orders, and the likelihood of resolving cases in a reasonable amount of time would be nonexistent. Thus, notice and opportunity to be heard are the *quid pro quo* for the acceleration of discovery and case resolution. Other reasons exist for protecting the terms of the SPOs, as well. As the court points out in *SmithKline Beecham*:

> A court should be hesitant to modify protective orders for matters unrelated to the litigation in front of it because otherwise, in the long run, parties may begin to distrust protective orders. Discovery, in turn, will become more complicated and expensive and settlements will be more difficult ... A natural feeling of unfairness arises when the rules are

> modified during the middle of the game, especially without very good cause.

Id. at 166 (citing *Jochims,* 151 F.R.D. at 343) (internal citations omitted).

In balancing the interests of the parties, the court cannot overlook the fact that Plaintiffs had the opportunity to negotiate inclusion of language in the protective orders that would allow sharing of discovery with litigants in the related MDLs. Courts have found that a party's failure to incorporate a provision in a stipulated protective order to address a reasonably foreseeable circumstance does not constitute a good cause basis to modify the order at a later date. *See Romary Associates, Inc.,* Case No. 1:10-cv-376, 2012 WL 32969, at *4 (N.D. Ind., Jan 6, 2012) ("a party's oversight in not negotiating a provision in the protective order considering a matter which should have been reasonably foreseeable at the time of the agreement has been held not to constitute good cause for relief from the protective order.") (citing *Murata Mfg. Co., v. Bel Fuse, Inc.,* 234 F.R.D. 175, 180 (N.D.Ill. 2006)); *see also Jochims,* 145 F.R.D. at 502. As in these MDLs, the plaintiff in *Jochims* sought to modify a protective order that limited the use of confidential documents to the lawsuit in which they were produced. Plaintiff wished to share the results of his discovery with other plaintiffs making the same product liability claims against defendant, Isuzu Motors. The court denied the request, finding that plaintiff failed to establish good cause for a modification, stating:

> Jochims seeks to modify the stipulated protective order in this case in order to share its discovery with other Plaintiffs' counsel with lawsuits pending against Isuzu. Jochims states that the desired modification of the protective order would reduce the cost and waste of repetitive discovery in similar lawsuits against Isuzu. While there is no doubt truth to this assertion, the circumstances which allegedly require modification should have been apparent to Jochims at the time he entered into the protective order. Even were the court to assume that

> Jochims' case was the first such suit against Isuzu, Jochims' counsel should have surmised that other such lawsuits would follow and counsel in those lawsuits would seek access to the same confidential documents which were the subject of discovery here. Thus, Jochims' counsel should have sought to have a suitable provision permitting [disclosure] incorporated into the protective order.

Id. Like counsel in *Jochims*, counsel in the present litigation should have contemplated the sharing and cross-utilization of information in the pelvic mesh MDLs and should have negotiated a disclosure clause in the SPOs. At a minimum, requesting such a clause would have brought the issue to the forefront *before* the Defendants produced millions of pages of internal documentation and sat for numerous depositions, all while under the impression that confidential information disclosed in discovery would not be disseminated outside of the litigation without notice and an opportunity to be heard.

Weighing the competing interests of the parties, the undersigned finds that (1) the SPOs include an adequate procedure to manage over-designations; (2) Plaintiffs failed to negotiate a sharing clause that was reasonably foreseeable at the time the orders were negotiated; (3) the documents Plaintiffs wish to use are available through alternative means; and (4) it would be fundamentally unfair at this stage in the litigations, after Defendants have provided discovery responses in reliance on the terms of the SPOs, to modify those terms in a manner that removes the Defendants' ability to oversee dissemination and utilization of their presumptively confidential information.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2325 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 2:13-cv-10639. 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 **http://www.wvsd.uscourts.gov.**

ENTERED: May 9, 2013.

Cheryl A. Eifert
United States Magistrate Judge