

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

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.

PELVIC REPAIR SYSTEMS

PRODUCT LIABILITY LITIGATION

MDL No. 2187

THIS DOCUMENT RELATES TO
ALL CIVIL CASES

PRETRIAL ORDER #122

(Defendant C. R. Bard's Motion to Quash or Modify Shakespeare Subpoena
or, in the Alternative, for Entry of a Protective Order)

Pending before the court is C. R. Bard's ("Bard") Motion to Quash or Modify Shakespeare Subpoena or, in the Alternative, for Entry of a Protective Order. (ECF No. 825). Plaintiffs have filed a response in opposition to the motion, (ECF No. 847), and Bard has replied. (ECF No. 853). Therefore, the issues are fully briefed and ready for resolution. For the reasons set forth below, the court **DENIES** Bard's motion to quash the subpoena; **DENIES** Bard's motion to modify the subpoena, as framed; and **DENIES** Bard's motion for a protective order, as framed. However, the court **GRANTS** Bard's motion to modify the subpoena and for a protective order in one respect: Plaintiffs' inquiries related to polypropylene shall be limited to Marlex HGX-030-01 polypropylene, rather than to "polypropylene in general."

I. Relevant Background

This multidistrict litigation ("MDL") involves the design, manufacturing, marketing, and distribution of pelvic mesh products by Defendant Bard. Plaintiffs recently served a subpoena to produce documents, information, or objects on non-party,

Shakespeare Monofilament, Inc. (“Shakespeare”), a company that previously supplied polypropylene monofilament to Bard for use in its pelvic and hernia mesh products. Bard objects to the subpoena on several grounds, primary of which is that the subpoena seeks the production of materials that are irrelevant and unlikely to lead to the discovery of admissible evidence. Bard argues that the majority of information requested by Plaintiffs pertains to hernia mesh products, rather than pelvic mesh, and bears no relationship in time to the products at issue in this MDL. Bard also complains that the subpoena requires the production of trade secrets and confidential commercial information and is burdensome to Shakespeare.

According to the record, Bard’s pelvic meshes and some of its hernia mesh products were manufactured using a polypropylene resin, Marlex HGX-030-01, distributed by Phillips Sumika. For a period of time, Bard contracted with Shakespeare to process the polypropylene resin into a polypropylene monofilament for use in constructing Bard’s mesh products. In 2007, Shakespeare discovered Phillips Sumika’s Material Safety Data Sheet (MSDS) for Marlex HGX-030-01, which explicitly warned that the resin should not be used in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues. Upon learning this, Shakespeare notified Bard that it would no longer produce polypropylene monofilament for Bard’s surgical mesh products. Bard ultimately obtained the monofilament from other suppliers.

Bard contends that it has not purchased polypropylene monofilament for pelvic mesh products from Shakespeare since 1998. Since all of the products at issue in the MDL were manufactured after 2006, none of the Plaintiffs were implanted with a product containing Shakespeare’s polypropylene monofilament. Bard further points out

that several of the document requests served on Shakespeare seek information about Secant Medical Inc. and Genzyme Corporation, companies connected with Bard that were involved *only* with hernia mesh products. Bard argues that Plaintiffs are conducting a broad sweep of clearly irrelevant information in an effort to uncover inflammatory and extraneous evidence. Thus, Bard raises three grounds in support of an order quashing or modifying the subpoena and for a protective order: (1) lack of relevance; (2) lack of appropriate time limitations (i.e. subpoena is overly broad and burdensome); and (3) improper disclosure of confidential commercial information and trade secrets.

In response, Plaintiffs disagree that the requested information is irrelevant. They argue that the common denominator in the materials sought is Marlex HGX-030-01 polypropylene resin. Plaintiffs contend that evidence of Bard's knowledge of the potential risks associated with the resin, and its response to Shakespeare's refusal to continue producing the monofilament are highly relevant to establish Bard's willfulness and wantonness. Plaintiffs also emphasize that Shakespeare raises no objection to the subpoena and is prepared to produce the requested documents. Consequently, Bard lacks standing to assert claims of burdensomeness, relevance, and breach of confidentiality, which are personal claims belonging to Shakespeare. To the extent that the document production includes Bard's confidential commercial information, Plaintiffs argue that the information is already protected by the parties' Stipulated Protective Order.

II. Relevant Standards

A motion to quash or modify a subpoena is governed by Federal Rule of Civil Procedure 45(d). Specifically, Rule 45(d)(3) outlines when a court *must* quash or modify

a subpoena, when it *may* do so, and when the court may direct compliance under specified conditions.¹ Ordinarily “only the party or person to whom the subpoena is directed has standing to move to quash or otherwise object to a subpoena.” *Transcor, Inc. v. Furney Charters, Inc.*, 212 F.R.D. 588, 590 (D.Kan. 2003) (citation omitted). However, an exception exists when the person objecting to the subpoena has a personal right or privilege in the information sought by the requester. *United States v. Idema*, 118 Fed. App’x 740, 744 (4th Cir. 2005); *see also Singletary v. Sterling Transport Company, Inc.*, 289 F.R.D. 237, 239 (E.D.Va. 2012).

When a subpoena issues under Rule 45 for the purpose of discovery, “Rule 45 adopts the standard[s] codified in Rule 26.” *Schaaf v. SmithKline Beecham Corp.*, 233 F.R.D. 451, 453 (E.D.N.C. 2005). In other words, a subpoena used for discovery must comply with the scope and limits of discovery set forth in Rule 26, and may be quashed or modified for the same reasons that would support a protective order under Rule 26. *HDSherer LLC v. Natural Molecular Testing Corp*, 292 F.R.D. 305, 308 (D.S.C. 2013). In this context, a subpoena may be used to discover “any nonprivileged matter that is relevant to any party’s claim or defense ... if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.” Fed. R. Civ. P. 26(b). “The scope of relevancy under the discovery rules is broad, such that relevancy encompasses any matter that bears or may bear on any issue that is or may be in the case.” *Carr v. Double T Diner*, 272 F.R.D. 431, 433 (D.Md.). For purposes of discovery, information is

¹ Rule 45(d)(3) explicitly authorizes “the court for the district where compliance is required” to modify or quash a subpoena. The subpoena at issue in this case is directed to Shakespeare Monofilament, Inc. in Wichita, Kansas and requires compliance at Shakespeare’s office in Columbia, South Carolina. Accordingly, this court is not located in the district where compliance of the subpoena is required. Nonetheless, jurisdiction to resolve the motion to quash or modify exists in this court under 28 U.S.C. § 1407. *See In re Neurontin Marketing, Sales Practices, and Product Liability Litigation*, 245 F.R.D. 55, 58 (D.Mass. 2007) (quoting *U.S. ex rel. Pogue v. Diabetes Treatment Centers of America*, 444 F.3d 462, 468-69 (6th Cir. 2006)).

relevant, and thus discoverable, if it “bears on, or ... reasonably could lead to other matter[s] that could bear on, any issue that is or may be in the case. Although ‘the pleadings are the starting point from which relevancy and discovery are determined ... [r]elevancy is not limited by the exact issues identified in the pleadings, the merits of the case, or the admissibility of discovered information.’ Rather, the general subject matter of the litigation governs the scope of relevant information for discovery purposes.” *Kidwiler v. Progressive Paloverde Ins. Co.*, 192 F.R.D. 193, 199 (N.D.W.Va. 2000) (internal citations omitted).

Simply because information is discoverable under Rule 26, however, “does not mean that discovery must be had.” *Schaaf*, 233 F.R.D. at 453 (citing *Nicholas v. Wyndham Int’l, Inc.*, 373 F.3d 537, 543 (4th Cir. 2004)). Discovery that seeks relevant information may nevertheless be restricted or prohibited pursuant to a Rule 26(c) motion when necessary to protect a person or party from annoyance, embarrassment, oppression, or undue burden or expense. Fed. R. Civ. P. 26(c). Moreover, with or without a motion, the court may limit the frequency and extent of discovery when the “burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties’ resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.” Fed. R. Civ. P. 26(b)(2)(C)(iii). The protections conferred by Rule 26 are incorporated in Rule 45(d)(3), which sets forth additional grounds for quashing, modifying, or molding the terms of a subpoena. *HDSherer LLC*, 292 F.R.D. at 308 (“Rule 45 does not list irrelevance or overbreadth as reasons for quashing a subpoena. However, the scope of discovery allowed under a subpoena is the same as the scope of discovery allowed under Rule 26.”) (citing *Cook v. Howard*, 484 Fed.Appx. 805, 812

(4th Cir. Aug. 24, 2012) (“Although Rule 45(c) sets forth additional grounds on which a subpoena against a third party may be quashed[,] ... those factors are co-extensive with the general rules governing all discovery that are set forth in Rule 26.”)); *see also Firetrace USA, LLC v. Jesclard*, No. cv–07–2001, 2008 WL 5146691, at *2 (D.Ariz. Dec. 8, 2008) (“According to its 1991 Advisory Committee Notes, Rule 45 [(d)](3) ‘tracks the provisions of Rule 26(c).’ Fed. R. Civ. P. 45. In this way, Rules 45 and 26 are not mutually exclusive, but rather cover the same ground.”)

Regardless of whether a motion is made under Rule 26(c) or Rule 45(d), the party opposing discovery has the obligation to submit evidence supporting its claims that the discovery is unduly burdensome, oppressive, or irrelevant. To prevail on the grounds of burdensomeness or breadth, the objecting party must do more to carry its burden than make conclusory and unsubstantiated arguments. *Convertino v. United States Department of Justice*, 565 F. Supp.2d 10, 14 (D.D.C. 2008) (the court will only consider an unduly burdensome objection when the objecting party demonstrates how discovery is overly broad, burdensome, and oppressive by submitting affidavits or other evidence revealing the nature of the burden); *Cory v. Aztec Steel Building, Inc.*, 225 F.R.D. 667, 672 (D.Kan. 2005) (the party opposing discovery on the ground of burdensomeness must submit detailed facts regarding the anticipated time and expense involved in responding to the discovery which justifies the objection); *Bank of Mongolia v. M & P Global Financial Services, Inc.*, 258 F.R.D. 514, 519 (S.D. Fla.2009) (“A party objecting must explain the specific and particular way in which a request is vague, overly broad, or unduly burdensome. In addition, claims of undue burden should be supported by a statement (generally an affidavit) with specific information demonstrating how the request is overly burdensome”).

Both Rule 26 and Rule 45 contain provisions protecting confidential commercial information. Rule 26(c)(1)(G) allows the court, for good cause, to issue an order “requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way.” In order for the court to apply the rule, two criteria must exist. First, the material sought to be protected must be “a trade secret or other confidential research, development, or commercial information.” Second, there must be a “good cause” basis for granting the restriction. The party seeking protection bears the burden of establishing both the confidentiality of the material and the harm associated with its disclosure. *Deford v. Schmid Prods. Co.*, 120 F.R.D. 648, 653 (D.Md. 1987) (citing *Cipollone v. Liggett Group, Inc.*, 785 F.2d. 1108, 1121 (3rd Cir. 1986)). Once these elements are demonstrated, the burden shifts to the party seeking disclosure to show that the material is relevant and necessary to its case. *Empire of Carolina, Inc. v. Mackle*, 108 F.R.D. 323, 326 (D.C. Fla. 1985). The court “must balance the requesting party’s need for information against the injury that might result if uncontrolled disclosure is compelled.” *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 (3rd Cir. 1994) (quoting Arthur R. Miller, *Confidentiality, Protective Orders, and Public Access to the Courts*, 105 Harv.L.Rev. 427, 432–33 (1991)).

If the court determines that disclosure is required, the issue becomes whether the materials should be “revealed only in a specified way.” Fed. R. Civ. P. 26(c)(1)(G) “Whether this disclosure will be limited depends on a judicial balancing of the harm to the party seeking protection (or third persons) and the importance of disclosure to the public.” *Id.* Factors to consider when deciding if and how to limit disclosure include:

(1) whether disclosure will violate any privacy interests; (2) whether the information is being sought for a legitimate purpose or for an improper purpose; (3) whether disclosure of the information will cause a party embarrassment; (4) whether confidentiality is being sought over information important to public health and safety; (5) whether the sharing of information among litigants will promote fairness and efficiency; (6) whether a party benefiting from the order of confidentiality is a public entity or official; and (7) whether the case involves issues important to the public.

Pansy, 23 F.3d at 787-91. Although the court exercises broad discretion in deciding “when a protective order is appropriate and what degree of protection is required, *Furlow v. United States*, 55 F.Supp.2d 360, 366 (D.Md. 1999) (quoting *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36, 104 S.Ct. 2199, 81 L.Ed.2d 17 (1984)), protective orders “should be sparingly used and cautiously granted.” *Baron Fin. Corp. v. Natanzon*, 240 F.R.D. 200, 202 (D.Md. 2006) (quoting *Medlin v. Andrew*, 113 F.R.D. 650, 653 (M.D.N.C. 1987)).

Similarly, Rule 45(d)(3)(B)(i) allows the court to quash or modify a subpoena that requires the disclosure of “a trade secret or other confidential research, development, or commercial information.” As an alternative to quashing or modifying the subpoena, the court may order production of the information under specified conditions if the serving party shows “a substantial need” for the information “that cannot be otherwise met without undue hardship” and “ensures that the subpoenaed person will be reasonably compensated.” Fed. R. Civ. P. 45(d)(3)(C). Once again, the moving party has the initial burden of demonstrating the confidential and proprietary nature of the information, and the party’s historical efforts to protect it from disclosure. *Gonzales v. Google, Inc.*, 234 F.R.D. 674, 684 (N.D.Cal. 2006); *Compaq Computer Corp. v. Packard Bell Elec., Inc.*, 163 F.R.D. 329, 338 (N.D.Cal. 1995). Once that showing is made, the burden shifts to the party serving the subpoena to establish a

substantial need for the information that cannot be met without undue hardship. *Id.*

Confidential commercial information, within the meaning of these Rules, is more than routine business data; instead, it is important proprietary information that provides the business entity with a financial or competitive advantage when it is kept secret, and results in financial or competitive harm when it is released to the public. *Gonzales*, 234 F.R.D. at 684; *see also Diamond State Ins. Co. v. Rebel Oil Co., Inc.*, 157 F.R.D. 691, 697 (D.Nev. 1994) (“Confidential commercial information” is “information, which disclosed, would cause substantial economic harm to the competitive position of the entity from whom the information was obtained.”). Examples of confidential commercial information entitled to protection under Rules 26(c)(1)(G) and 45(d)(3)(B)(i) include customer lists and revenue information, *Nutratch, Inc. v. Syntech Intern, Inc.*, 242 F.R.D. 552, 555 (N.D.Cal. 2007); product design and development and marketing strategy, *Culinary Foods, Inc. v. Raychem Corp.*, 151 F.R.D. 297, 305 (D.Ill. 1994); labor costs, *Miles v. Boeing*, 154 F.R.D. 112, 114 (E.D.Pa. 1994); and commercial financial information, *Vollert v. Summa Corp.*, 389 F.Supp 1348, 1352 (D.Hawaii 1975). Moreover, “[p]ricing and marketing information are widely held to be confidential business information that may be subject to a protective order.” *Uniroyal Chem. Co. Inc. v. Syngenta Crop Prot.*, 224 F.R.D. 53, 57 (D.Conn. 2004) (citing *Vesta Corset Co. v. Carmen Foundations, Inc.*, 1999 WL 13257, at *2 (S.D.N.Y. 1999)).

III. Discussion

Initially, the undersigned addresses Plaintiffs’ contention that Bard lacks standing to move to quash or modify the subpoena. Although the subpoena is directed to Shakespeare, Bard certainly has a right or privilege in its confidential commercial

information, and to the extent that the subpoena requires release of that information, Bard has standing to challenge it. *In re C.R. Bard, Inc. Pelvic Repair Systems Products Liability Litigation*, 287 F.R.D. 377, 383 (S.D.W.Va. 2012). Plaintiffs request materials concerning indemnification agreements, communications within distribution chains of Bard and its divisions, communications involving high level Bard executives, and communications regarding business decisions made by Bard and its divisions and associates. Clearly, documents responsive to these requests are likely to contain some confidential commercial information. Therefore, the undersigned finds that Bard has standing to challenge the subpoena to Shakespeare.

Furthermore, even if Bard cannot claim standing under Rule 45 to object to all of the documents requested from Shakespeare, Bard may still move for a protective order under Rule 26(c). *HDSherer LLC*, 292 F.R.D. at 307-08. “Under Rule 26(c), ‘a party may move for a protective order to protect itself from annoyance, embarrassment, oppression, or undue burden or expense, regardless of whether the moving party is seeking to prevent disclosure of information by a nonparty, as long as the moving party can tie the protected information to an interest listed in the rule....’” *Id.* (quoting *Firetrace USA*, 2008 WL 5146691, at *2). Bard alleges that Plaintiffs are on an expedition to ferret out inflammatory and extraneous information to use against Bard at trial, which surely could be viewed as an annoying and oppressive discovery tactic. Therefore, the undersigned finds that Bard’s motion should be considered on the merits.

First, Bard argues that the subpoena is overly broad because it is not limited in time frame; it seeks materials regarding all polypropylenes; and it requests information about Bard’s hernia mesh, which is not at issue in this MDL. The undersigned is not persuaded by Bard’s contention that the subpoena should be restricted to a particular

time frame given that the relationship between Shakespeare and Bard is not ongoing; rather, it occurred during a distinct period of time in the past. Considering that the documents sought are largely focused on the use of Marlex HGX-030-01 polypropylene resin, and Shakespeare is not complaining about the burden of locating, collecting, or producing the documents, the undersigned finds the lack of time restrictions to be harmless.

The undersigned is likewise unimpressed with Bard's concerns regarding hernia mesh documents. It is widely accepted that discovery of different products may be proper when the products contain the same injury-producing component as the product at issue. *United Oil Co., Inc. v. Parts Associates, Inc.*, 227 F.R.D. 404, 410 (D.Md. 2005). "[C]ourts look to see whether ... '[d]ifferent models of a product ... share with the accident-causing model those characteristics pertinent to the legal issues raised in the litigation.'" *Desrosiers v. MAG Indus. Automation Systems, LLC*, 675 F.Supp.2d 598, 602 (D.Md. 2009) (citation omitted). Here, Plaintiffs are not so much interested in hernia products as they are in surgical mesh constructed with polypropylene monofilaments containing Marlex HGX-030-01, the polypropylene resin allegedly used to manufacture the pelvic mesh products at issue in this MDL. Consequently, Plaintiffs may **discover** Bard's experience with mesh containing Marlex HGX-030-01 polypropylene resin, regardless of whether the mesh was used for pelvic surgery or hernia repair.

On the other hand, the court does agree with Bard that Plaintiffs have provided no basis for discovering documents pertaining to polypropylene in general. Plaintiffs have not stated that Shakespeare supplied a monofilament to Bard using any other type of polypropylene, nor do they supply an alternate explanation for why other

polypropylene resins would be relevant to the claims or defenses in this MDL. For that reason, the court limits Shakespeare's production to materials concerning Marlex HGX-030-01.

Next, Bard claims that the subpoena requires the production of documents that will "be competitively harmful to Bard and Shakespeare," such as Shakespeare's extrusion process, the chemical make-up of the extruded polypropylene product that Shakespeare sold to Bard, and the specifications Bard provided for the polypropylene monofilament. Bard argues that this information is proprietary to Bard and Shakespeare, and public disclosure will have disastrous financial consequences for them. In addition, Bard objects to Plaintiffs' request for indemnification agreements and other documents reflecting the business decisions of Bard and Shakespeare, as these materials have commercial value and are entitled to protection.

To establish good cause for a protective order in the context of confidential business documents, the moving party must show that disclosure of its commercial information will give rise to an "identifiable harm." *Minter v. Wells Fargo Bank, N.A.*, 2010 WL 5418910, at *8 (quoting *Deford*, 120 F.R.D. at 652–53); *see also In re Terrorist Attacks on Sept. 11, 2001*, 454 F.Supp.2d 220, 222 (S.D.N.Y.2006) (Good cause exists "when a party shows that disclosure will result in a clearly defined, specific and serious injury.") (quoting *Shingara v. Skiles*, 420 F.3d 301, 306 (3d Cir.2005)). The party "may not rely upon 'stereotyped and conclusory statements,' but "must present a 'particular and specific demonstration of fact' as to why a protective order should issue." *Baron Fin. Corp.*, 240 F.R.D. at 202 (quoting 8A Charles Alan Wright et al., *Fed. Prac. & Proc. Civ.* § 2035 (2d ed.1994)). "Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning, do not support a good cause showing." *Id.*

(quoting *Merit Industries, Inc. v. Feuer*, 201 F.R.D. 382, 384-385 (E.D.Pa.2001)). “Where the party seeking protection under Rule 26 is a business, ‘it must show that disclosure would cause significant harm to its competitive and financial position.’” *Waterkeeper Alliance v. Alan & Kristin Hudson Farm*, 278 F.R.D. 136, 140 (D.Md. 2011) (quoting *Minogue v. Modell*, 2011 WL 1308553, at *4 (D.Md. Mar. 30, 2011)). This showing must be made through “specific demonstrations of fact, supported where possible by affidavits and concrete examples rather than broad, conclusory allegations of potential harm.” *Deford*, 120 F.R.D. at 653; see also *Andrew Corp. v. Rossi*, 180 F.R.D. 338, 341 (N.D. Ill. 1998) (Sufficient specificity standard requires a likely and significant injury); *Waelde*, 94 F.R.D. at 28 (E.D.Mich. 1981) (Harm must be clearly defined, rather than speculative competitive damage).

In this case, Bard provides no particularized showing of fact or concrete examples of how the documents held by Shakespeare, if disclosed, would cause significant harm to Bard’s competitive and financial position. Indeed, Bard repeatedly stresses that it has not purchased any polypropylene monofilament from Shakespeare since 1998.² Consequently, it seems unlikely that the documents held by Shakespeare would be particularly damaging to Bard’s current competitive position. “While staleness of the information sought to be protected is not an absolute bar to issuance of an order, it is a factor which must be overcome by a specific showing of present harm.” *Deford*, 120 F.R.D. at 654. Bard fails to make a specific showing of present harm.

Moreover, the parties have agreed to a Stipulated Protective Order, (ECF No. 54), which allows confidential commercial information to be designated “Confidential,” or

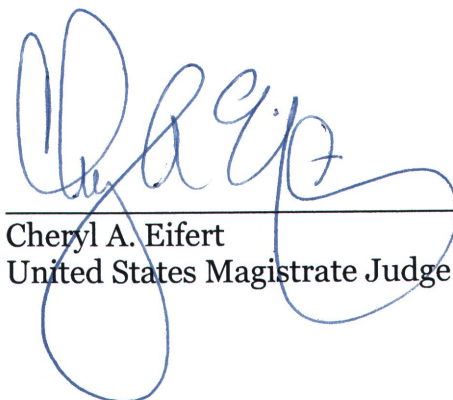
² The undersigned acknowledges an inconsistency in the facts supplied by the parties. Bard claims that it has not purchased **any** monofilament directly from Shakespeare since 1998. However, Plaintiffs contend that Shakespeare produced monofilament for Bard until 2007 when it learned of the MSDS warning related to Marlex HGX-030-01.

“Highly Confidential.” The parties concur in their memoranda that the documents produced by Shakespeare in response to Plaintiffs’ subpoena are subject to the Stipulated Protective Order. The undersigned finds that the Stipulated Protective Order provides sufficient protection for the documents and thus additional safeguards are unnecessary.

Therefore, Bard’s motion to quash the subpoena is **DENIED**. Bard’s motion to modify the subpoena and for protective order is **DENIED, in part**, and **GRANTED, in part**, as set forth herein.

The court **DIRECTS** the Clerk to file a copy of this order in 2:10-md-2187 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 2:14-cv-15109. 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: April 22, 2014



Cheryl A. Eifert
United States Magistrate Judge