UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: ZOFRAN (ONDANSETRON) PRODUCTS LIABILITY LITIGATION	**MDL No. 1:15-md-2657-FDS**
THIS DOCUMENT RELATES TO:	
ALL CASES	

MEMORANDUM IN SUPPORT OF PLAINTIFFS' POSITION ON DISPUTED ISSUES IN THE PARTIES' JOINT PROPOSED PROTECTIVE ORDER

I. INTRODUCTION

The Plaintiffs' Steering Committee and Defendant GlaxoSmithKline, LLC have submitted a joint proposed Protective Order Governing Confidential and Privileged Materials in this Multidistrict Litigation Proceeding (Doc. No. 178). After negotiation of the terms of the proposed order, two issues remain. The first concerns GSK's request for an advisory opinion that all costs of producing documents in response to future discovery requests shall be borne by the requesting party. The second issue similarly pertains to GSK's request for an advisory opinion that GSK may refuse to produce non-privileged information that it believes is a trade secret or otherwise "highly confidential," as well as information that GSK unilaterally decides it is not relevant.

As to each issue, this Memorandum sets forth Plaintiffs' reasons and legal authority supporting their positions that (1) GSK has failed to satisfy its burden to show that a requesting party should bear the costs of production; and (2) information that GSK believes is a trade secret or otherwise highly confidential or irrelevant should be produced in unredacted form and designated as Confidential Information in accordance with the proposed Protective Order, which expressly allows such qualifying material to be designated confidential.

II. ARGUMENT

A. GSK HAS FAILED TO SATISFY ITS BURDEN TO OVERCOME THE RULE THAT RESPONDING PARTIES BEAR THE COST OF RESPONDING TO DISCOVERY.

The Federal Rules of Civil Procedure permit "discovery regarding any non-privileged matter that is relevant to any party's claim or defense" or discovery of any information that "appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). *Rockstar Consortium US LP*, No. 14-91322-FDS, 2015 WL 5972422, at *4 (D. Mass. Oct. 14, 2015).[1] Because "discovery itself is designed to help define and clarify the issues," the discovery rules set forth in Rule 26 must be "construed broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case." *Rockstar Consortium US LP*, No. 14-91322-FDS, 2015 WL 5972422, at *4 (D. Mass. Oct. 14, 2015) (citation omitted). "[T]he court should and ordinarily does interpret 'relevant' very broadly to mean matter that is relevant to anything that is or may become an issue

[1]Effective December 1, 2015, Rule 26(b) was amended to include a proportionality consideration for the scope of discovery. This amended version "shall govern . . . in all proceedings in civil cases . . . and, insofar as just and practicable, all proceedings then pending." C.J. Robert's Order of Apr. 29, 2015 regarding Amendments to Fed. R. Civ. P. Because this MDL was formed before the amendment's effective date, the amendment does not apply without a finding that its application is just and practicable. Courts appear to have disagreed over the impact of the amendment on the scope of discovery. *Compare Gilead Scis., Inc. v. Merck & Co, Inc.*, No. 5:13-CV-04057-BLF, 2016 WL 146574, at *1 (N.D. Cal. Jan. 13, 2016) ("No longer is it good enough to hope that the information sought might lead to the discovery of admissible evidence. In fact, the old language to that effect is gone. Instead, a party seeking discovery of relevant, non-privileged information must show, before anything else, that the discovery sought is proportional to the needs of the case."); *and Eramo v. Rolling Stone LLC*, No. CV 3:15-MC-00011, 2016 WL 304319, at *2 (W.D. Va. Jan. 25, 2016) ("[G]iven the 2015 amendment, the court will put a greater emphasis on the need to achieve proportionality, in determining whether to grant the motion to compel."), *with Dao v. Liberty Life Assurance Co. of Boston*, No. 14-CV-04749-SI (EDL), 2016 WL 796095, at *3 (N.D. Cal. Feb. 23, 2016) ("Restoring the proportionality calculation to Rule 26(b)(1) does not change the existing responsibilities of the court and the parties to consider proportionality." Thus, while the language of the Rule has changed, the amended rule does not actually place a greater burden on the parties with respect to their discovery obligations, including the obligation to consider proportionality, than did the previous version of the Rule."). Here, application of the amendment to Rule 26 is practicable, as the MDL is in an early stage. However, inasmuch as amended Rule 26(b) is hereinafter construed to limit the injured parties' rights to discovery existing when this MDL was formed, plaintiffs object to application of the amended rule as unjust, particularly where the defendant had already been served with pre-amendment discovery requests.

in the litigation. *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978), 437 U.S. at 351 n. 12.

Federal courts have established a presumption "that the responding party must bear the expense of complying with discovery requests." *Id.* at 358. This presumption applies to all discovery. *See Dahl v. Bain Capital Partners, LLC*, 655 F. Supp. 2d 146, 146 (D. Mass. 2009); *see, also*, *e.g.*, *In re: Ethicon, Inc. Pelvic Repair Sys. Prods. Liability Litig.*, Pretrial Order No. 68 (S.D. W.Va. Sept. 18, 2013) (denying responding party's motion for protective order and cost-shifting), attached as Exhibit A. Moreover, after the 2015 amendments to Rule 26, "Courts and parties should continue to assume that a responding party ordinarily bears the costs of responding." Fed. R. Civ. P. 26, Advisory Comm. Note to 2015 amendments; *Ashmore v. Allied Energy, Inc.,* 2016 WL 301169 (D.S.C. Jan. 25, 2016) (assessing the reasonableness of a party's cost shifting request under amended Rule 26).

As a corollary to the rule requiring the responding party to pay its production costs, Rule 26(g) requires every discovery request to be signed by at least one attorney of record, certifying that to the best of the person's knowledge, information, and belief formed after a reasonable inquiry the discovery request is not (a) interposed for any improper purpose, such as to needlessly increase the cost of litigation or (b) unreasonable or unduly burdensome or expensive, considering the needs of the case, prior discovery in the case, the amount in controversy, and the importance of the issues at stake in the action. Fed. R. Civ. P. 26(g).

Given the presumption that the responding party is responsible for production costs and the safeguard established in Rule 26(g), courts have required a showing of exceptional circumstances before considering whether to shift production costs to a requesting party. *Dahl*, 655 F. Supp. 2d at 146. In the context of electronically stored information, for example, a "party

need not provide discovery of electronically stored information from sources that the party identifies as not reasonably accessible because of undue burden or cost." *W Holding Co. v. Chartis Ins. Co. of Puerto Rico*, 293 F.R.D. 68, 72 (D.P.R. 2013) (citing Rule 26(b)(2)(B)). "It is worth emphasizing again that cost-shifting is potentially appropriate only when inaccessible data is sought. When a discovery request seeks accessible data—for example, active on-line or near-line data—it is typically inappropriate to consider cost-shifting." *Zubulake v. UBS Warburg LLC*, 216 F.R.D. 280, 284 (S.D.N.Y. 2003). Put otherwise, as to "data that is kept in an accessible format, the usual rules of discovery apply: the responding party should pay the costs of producing responsive data." *Zubulake v. UBS Warburg LLC*, 217 F.R.D. 309, 324 (S.D.N.Y. 2003). A claimed burden or expense of discovery is deemed "undue" only when it "outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues." *Zubulake v. UBS Warburg LLC*, 217 F.R.D. 309, 318 (S.D.N.Y. 2003).

In determining whether to shift the costs of discovery to the requesting party, courts have considered whether the responding party has shown that "(i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;" or "(ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action;" or "(iii) the proposed discovery is outside the scope permitted by Rule 26(b)(1)." Fed. R. Civ. P. 26(b)(2)(C); *In re Ethicon*, Ex. 1, at p. 9 ("[A] fair cost-shifting analysis can be achieved by applying the factors found in Rule 26(b)(2)(C)."). Courts also have considered additional factors:

(1) the specificity of the discovery request;
(2) the quantity of information available from other and more easily accessed sources;
(3) the failure to produce relevant information that seems likely to have existed but is no longer available on more easily accessed sources;
(4) the likelihood of finding relevant, responsive information that cannot be obtained from other, more easily accessed sources;
(5) predictions as to the importance and usefulness of the further information;
(6) the importance of the issues at stake in the litigation; and
(7) the parties' resources.

W.E. Aubuchon Co. v. BeneFirst, LLC, 245 F.R.D. 38, 43 (D. Mass. 2007) (citing Fed. R. Civ. P. 26 Advisory Comm. note to 2006 Amendment).

Here, discovery in the MDL has not yet begun.[2] The parties have been addressing initial pleading and case management matters for the MDL. GSK has not made any of the showings required under Rule 26(b)(2)(C) – cumulativeness, undue delay, or irrelevance. In essence, GSK inappropriately seeks an advisory opinion on the issue of cost of production. Federal courts may not give opinions "advising what the law would be upon a hypothetical state of facts." *Chafin v. Chafin*, 133 S. Ct. 1017, 1023 (2013); *see also, e.g.*, *U.S. ex rel. Emanuele v. Medicor Assocs., Inc.*, No. CIV.A. 10-245, 2014 WL 3747666, at *2 (W.D. Pa. July 29, 2014) ("The bulk of the arguable costs identified by defendants are for discovery that relator has not requested. A ruling by the court on the proportionality of those costs at this time would be an advisory opinion and thus inappropriate.").

Looking ahead, Plaintiffs' counsel are mindful of Rule 26(g) and intend to tailor their discovery requests to discovery of relevant information, such as:

- GSK's pre-market investigation of Zofran's potential to cause birth defects;
- GSK's post-marketing surveillance of Zofran's potential to cause birth defects;
- GSK's knowledge of and responses to signals of the risk of Zofran-related birth defects;

[2] As to discovery requests served on GSK before creation of the MDL, CMO 1 (doc. no. 4, at p. 3) suspended the deadlines for responding.

- GSK's communications to healthcare providers and consumers concerning the risks of Zofran use during pregnancy;
- The nature and extent of the GSK's marketing of Zofran for use in pregnancy;
- The nature and extent of the GSK's offering of financial incentives to physicians to induce them to prescribe Zofran;
- GSK's communications with its sales and marketing personnel, consultants, and key opinion leaders engaged to promote Zofran; and
- GSK's knowledge of prescriptions of Zofran for treating pregnancy related nausea.
- GSK's communication with the FDA pre and post approval of Zofran
- GSK's communication with generic manufacturers of Ondansetron
- GSK's communications with Novartis, the current label holder of Zofran
- GSK's communications with third party entities that collaborated with GSK on Zofran

Forthcoming discovery must be viewed, however, in the context of the issues at stake in this litigation involving more than two hundred families alleging birth defects arising from false and misleading marketing of a drug for the treatment of pregnancy women and resulting in a multimillion dollar healthcare fraud settlement with the federal government. Much of the relevant information is in the exclusive control of the manufacturer. Moreover, GSK's counsel has indicated that GSK has already established measures to preserve documents made accessible for previous litigation involving Zofran: "I can attest having represented GSK and its predecessor companies for almost 25 years. They have very robust measures in place to preserve documents. They have done so in this litigation for a long time. There were previous litigations that also swept up Zofran documents from before, so this is many years in place. They are very best practice-oriented at GSK for preservation." No. 1:15-md-2657, Tr. of Status Conf. on Nov. 17, 2015, at p. 24, ln. 5-14 (doc. no. 103).

Finally, GSK affirmatively petitioned the Judicial Panel on Multidistrict Litigation for an MDL, asserting that centralizing the actions will "promote just and efficient resolution of the litigation by, inter alia, eliminating duplicative discovery, avoiding duplicative motions, . . . conserving judicial resources, and reducing litigation costs and effort for the parties." GSK Motion for Transfer, Doc. No. 1, at p. 2 (July 6, 2015). Having had its request based in part on

cost savings granted, GSK should not now be heard to argue that opposite – that its burden and cost in responding to discovery in a coordinated MDL, rather than numerous times to different counsel in various federal and state courts throughout the country, is undue. For all of these reasons, GSK's cost-shifting request should be rejected.

B. GSK SHOULD BE REQUIRED TO PRODUCE RESPONSIVE INFORMATION IN UNREDACTED FORM.

The jointly proposed Protective Order (doc. no. 178) affords GSK's internal documents confidentiality protection. But GSK also seeks the ability to unilaterally decide what non-privileged information is so "irrelevant" or "highly confidential" that GSK may withhold it from production to plaintiffs. GSK's position not only fails to comport with the rules of civil procedure but also frustrates the core purposes of the Protective Order – to expedite the flow of discovery, facilitate prompt resolution of disputes over confidentiality and adequately protect confidential information.

First, redacting information that GSK declares irrelevant is simply improper Rule 26:

> Redaction of documents that are responsive and contain some relevant information should be limited to redactions of privileged information when, as in this case, there is a protective order restricting the use and dissemination of other sensitive information.

Sexual Minorities of Uganda v. Lively, No. 3:12cv-30051, 2015 WL 4750931, *4 (D. Mass. Aug. 10, 2015); *ArcelorMittal Cleveland Inc. v. Jewell Coke Co.,* 2010 WL 5230862, at *2–3 (N.D. Ohio Dec. 16, 2010) (holding that redaction is not permitted under Fed. R. Civ. P. 34); *Medtronic Sofamor Danek, Inc. v. Michelson,* 2002 WL 33003691, at *4–5 (W.D. Term. Jan. 30, 2002) ("The Federal Rules of Civil Procedure do not recognize irrelevance as a privilege or an objection that warrants redaction, or that would involve the compilation of a privilege log, as with other redactions.").

Compelling practical reasons counsel against such a practice:

> The Court does not welcome unilateral editing of documents by the producing party. Even when implemented with restraint and in good faith, the practice frequently gives rise to suspicion that relevant material harmful to the producing party has been obscured. It also tends to make documents confusing and difficult to use. All too often, the practice results in litigation of collateral issues and in camera review of documents by the Court, with the result that the time of both counsel and the Court is wasted. These drawbacks ordinarily outweigh the minimal harm that may result from disclosure of some irrelevant material.

Michelson, 2002 WL 33003691, at *5. The rationale for disallowing such redactions was also articulated aptly in *Orion Power Midwest, L.P. v. American Coal Sales Co.*:

> Defendants' novel interpretation of their discovery obligations is not supported by the text of Fed. R. Civ. P. 34 and would open a fertile new field for discovery battles. Rule 34 talks about production of "documents," as opposed to the relevant information contained in those documents. It is at least implicit that the duty to "produce documents as they are kept in the usual course of business" includes the substantive contents of those documents. *See also* Fed. R. Civ. P. 34(b)(2)(E)(ii) (party must produce information "in a form or forms in which it is ordinarily maintained").
>
> Certainly, a party that seeks to "inspect" a document would anticipate being able to inspect the entire document. This interpretation of Rule 34 is consistent with the guidance in Fed. R. Civ. P. 1 that the Rules be construed to advance the just, speedy and inexpensive determination of cases. There is no express or implied support for the insertion of another step in the process (with its attendant expense and delay) in which a party would scrub responsive documents of non-responsive information. In sum, the Court cannot countenance Defendants' "redaction campaign."[9]

No. 2:05-cv-555, 2008 WL 4462301, at *2 (W.D. Pa. Sept. 30, 2008).

There have been decisions allowing certain limited redactions of irrelevant and confidential information, but those decisions are the minority view and were made following an *in camera* review of the documents at issue.[3] The better view is set forth in *Beverage*

[3]For example, in *Spano v. Boeing Co.,* 2008 WL 1774460 (S.D.Ill. April 16, 2008), the court addressed a situation in an employee benefits action where, despite the existence of a stipulated protective order, the defendant redacted information from the documents it produced in discovery. The court, after an *in camera* review, found that the redacted information was irrelevant, such that redaction was a proper way for the defendant to produce it. 2008 WL 1774460, at *2. The cases cited in *Spano* included *Beauchem v. Rockford Products Corp.,* 2002 WL 1870050

Distributors, Inc. v. Miller Brewing Co., in which judge reasoned that *in camera* review for relevance injects unnecessary burden and delay into the flow of discovery:

> These [redaction] decisions are not necessarily irreconcilable. The themes which pervade each of them are (1) that redaction of otherwise discoverable documents is the exception rather than the rule; (2) that ordinarily, the fact that the producing party is not harmed by producing irrelevant information or by producing sensitive information which is subject to a protective order restricting its dissemination and use renders redaction both unnecessary and potentially disruptive to the orderly resolution of the case; and (3) that the Court should not be burdened with an *in camera* inspection of redacted documents merely to confirm the relevance or irrelevance of redacted information, but *only when necessary to protect privileged material whose production might waive the privilege*.

No. 2:08-CV-1112, 2010 WL 1727640, at *4 (S.D. Ohio Apr. 28, 2010).[4]

Second, with respect to GSK's view that it should be permitted to redact portions of documents based upon what it deems as "highly confidential," that too is inappropriate. As the U.S. Supreme Court has observed, "there is no absolute privilege for trade secrets and similar confidential information." *Fed. Open Mkt. Comm. v. Merrill,* 443 U.S. 340, 362 (1979). "Trade secrets and other confidential commercial information enjoy no privilege from disclosure although courts may choose to protect such information." *Kleinerman v. U.S. Postal Serv.*, 100 F.R.D. 66, 69 (D. Mass. 1983). "Although a defendant may have a legitimate interest

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(N.D.Ill. Aug. 13, 2002), which was another employee benefits case permitting redaction only after an *in camera* inspection of the documents in question, found the redacted information to be irrelevant; and *Schiller v. City of New York,* 2006 WL 3592547 (S.D.N.Y. December 7, 2006), where, in a Section 1983 action arising from arrests at a public protests, the court also allowed both parties and non-parties to redact portions of documents that contained irrelevant information.

[4] Other Courts agree that "[r]edaction is, after all, an alteration of potential evidence" and "a party should not take it upon him, her or itself to decide unilaterally what context is necessary for the non-redacted part disclosed, and what might be useless to the case." *Evon v. Law Offices of Sidney Mickell,* No. S–09–0760, 2010 WL 455476, at *2 n. 1 (E.D. Cal.2 010). Furthermore, "[i]t is a rare document that contains only relevant information." *Bartholomew v. Avalon Capital Group, Inc.,* 278 F.R.D. 441, 451 (D.Minn.2011). Often times, "irrelevant information within a document that contains relevant information may be highly useful to providing context for the relevant information." *Id.; see also In re State Street Bank & Trust Co. Fixed Income Funds Inv. Litig.,* Nos. 08–1945, 08–333, 2009 WL 1026013, at *1 (S.D.N.Y.2009) ("[Unilateral] redactions are generally unwise. They breed suspicions, and they may deprive the reader of context."); *In re FedEx Ground Package Sys., Inc. Emp't Practices Litig.,* No. 3:05–MD–527, 2007 WL 79312, at *5 (N.D.Ind.2007) ("Generally, the Federal Rules provide no procedural device for unilateral redaction by a party and it is a procedure that is not favored.").

in protecting its trade secrets, 'that interest must yield to the right of the plaintiff to discover the full truth of the facts involved in the issues of the case . . . [where] the issues cannot be fairly adjudicated unless this information is available.'" *Id.* (citation omitted).

The most appropriate way to protect confidential or trade secret information is with a protective order. *See*, *e.g.*, *Jagex Ltd. v. Impulse Software*, 273 F.R.D. 357, 358 (D. Mass. 2011) (the Court may enter a protective order to prohibit or limit discovery from any person from whom discovery is sought, including requiring that a "trade secret" or other confidential information be revealed in a specified way). That is precisely what the parties have proposed here. Plaintiffs do not dispute that a protective order is appropriate and have agreed to appropriate measures for preserving the confidentiality in the proposed Protective Order.

Here, GSK has made no showing that the disclosure of "highly confidential" information (information that it has not even identified yet) would be harmful to its business. For example, the Protective Order allows for confidential treatment of proprietary design, development, research and testing regarding GSK products, including Zofran. On one hand, even if confidential, this information is relevant to GSK's knowledge of Zofran's health effects and risks over time and the adequacy of GSK's response to that knowledge. On the other hand, GSK claimed concern about competitive disadvantage is hypothetical for several reasons: (a) it has not identified any information that it seeks to withhold or redact due to a claimed highly confidential status; (b) Zofran's patents expired in 2006, and then generic ondansetron products having identical active ingredients, dosage form, strength and routes of administration entered the market; and (c) as of March 2015, GSK sold its Zofran product line. Under these circumstances, GSK has not identified good cause to withhold relevant, non-privileged information on confidentiality grounds.

Nor has GSK identified how the proposed Protective Order falls short of protecting its "highly confidential" information. The Protective Order allows GSK to designate trade secrets and other proprietary, non-public business information, among other things, as Confidential Information. Once designated, that information must be treated as confidential in accordance with the Protective Order. In short, GSK is not entitled to unilaterally withhold or redact relevant, non-privileged information on the basis of its unilateral belief that the information is confidential. The express purposes of the parties' proposed Protective Order are to expedite the flow of discovery; facilitate the prompt resolution of disputes over confidentiality; and adequately protect Confidential Information. (Doc. No. 178, at 1.) These purposes are adequately achieved in the current form of the Protective Order. They would only be frustrated by granting GSK an additional ability to unilaterally withhold information based on its unilateral view of irrelevance or confidentiality.

Dated: March 11, 2016

Respectfully submitted,

/s/ Robert K. Jenner

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CERTIFICATE OF SERVICE

I, Robert K. Jenner, hereby certify that on this 11th day of March, 2016, I electronically filed the foregoing with the Court using the CM/ECF system and thereby delivered by electronic means to all registered participants as identified on the Notice of Electronic Filing:

/*s*/ **Robert K. Jenner**
Robert K. Jenner

Exhibit A

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

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER #68
(Plaintiff's' Motion to Compel OUS Documents and
Ethicon's Motion for Protective Order)

This multidistrict litigation involves surgical mesh products designed, manufactured, marketed, and sold by Defendant, Ethicon, Inc., ("Ethicon") to treat pelvic organ prolapse and stress urinary incontinence. Two motions are pending regarding Ethicon's duty to produce documents located outside of the United States ("OUS" documents). (ECF No. 585, 699). Plaintiffs, all residents of the United States, seek an order compelling the production of documents prepared and maintained by Ethicon in the course of its overseas distribution of pelvic and abdominal mesh products. (ECF No. 585). Ethicon has produced some of the requested materials, but asks the court for a protective order limiting the extent of future productions or, in the alternative, requiring Plaintiffs to bear the costs of the discovery. (ECF No. 699). For the reasons that follow, the court **GRANTS** Plaintiffs' Motion to Compel, (ECF No. 585), and **DENIES** Ethicon's Motion for Protective Order. (ECF No. 699).

Positions of the Parties

According to Plaintiffs, they have had extensive discussions with Ethicon to resolve this discovery dispute and, as a result, have narrowed the subject matter of their requests to four areas of concern: testing, manufacturing, design, and foreign regulatory issues.[1] Plaintiffs argue that documents pertaining to these issues are highly relevant to their claims of design defect and failure to warn regardless of whether the information involves products distributed in the United States or overseas. They emphasize that certain products at issue in this litigation were originally designed and studied in countries other than the United States, and these studies form the basis of representations made by Ethicon in its global marketing of pelvic mesh products. Plaintiffs also argue that the knowledge Ethicon gained through distributing mesh products in foreign markets is particularly relevant to when Ethicon appreciated the nature and extent of complications associated with pelvic mesh. Plaintiffs contend that the federal rules do not limit relevant discovery to documents located within the United States, nor do the rules relieve Ethicon of its discovery obligations simply because production of OUS documents may be inconvenient.

Alternatively, Ethicon argues that it has already produced a substantial number of OUS documents, including millions of pages related to health, safety, and product marketing. Ethicon has supplied custodial files for 52 OUS custodians, marketing materials for 32 countries, and regulatory documents for three countries selected by Plaintiffs, including France, Australia, and Japan. In Ethicon's view, it should not be compelled to produce any additional regulatory documents for the simple reason that

[1] Ethicon concedes its obligation to produce OUS documents on the issues of testing, manufacturing, and design and, thereby, limits its motion for a protective order to the production of additional OUS regulatory documents.

the burden of gathering and producing such materials far outweighs any benefits to be derived by their production. Ethicon represents that it has regulatory submissions in 67 countries across the globe, and the materials are scattered among various custodians in each country. To fulfill Plaintiffs' requests, Ethicon will have to interview and collect documents from approximately 150 OUS employees, then translate and produce an estimated 150,000-250,000 pages at a cost of between $500,000 and $1,000,000. According to Ethicon, the regulatory documents have only a "tenuous connection" to the issues in dispute, given that courts generally do not admit evidence of foreign regulatory actions in cases governed by domestic law. Moreover, Ethicon argues that regulatory documents do not vary significantly from one country to another. Consequently, Plaintiffs are unlikely to discover more or different information from that which is already in their possession. The undersigned finds neither of these arguments to be persuasive.

Relevance of the Documents

Fed.R.Civ.P. 26(b) allows discovery "regarding any nonprivileged matter that is relevant to any party's claim or defense." It is well-established that "relevance" in the context of discovery is broader than relevance in the context of admissibility. *King v. Conde,* 121 F.R.D. 180, 194 (E.D.N.Y. 1988); *see, also, Caton v. Green Tree Services, LLC,* 2007 WL 2220281 (N.D.W.Va. 2007) (the "test for relevancy under the discovery rules is necessarily broader than the test for relevancy under Rule 402 of the Federal Rules of Evidence."); *Carr v. Double T Diner,* 272 F.R.D.431, 433 (D.Md. 2010) ("The scope of relevancy under 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"). Indeed, the Rule explicitly states that "[r]elevant information need not be admissible at trial if the

discovery appears reasonably calculated to lead to the discovery of admissible evidence. Thus, Ethicon's argument that discovery of foreign regulatory documents is proscribed by their inadmissibility at trial is flawed, and the cases cited by Ethicon are not especially germane to the issue before the court. Clearly, documents submitted by Ethicon to foreign regulatory bodies concerning pelvic mesh products identical or similar to mesh products distributed in the United States are relevant to the claims and defenses in this litigation. Moreover, these materials are likely to contain information bearing on the issues of "what [Ethicon] knew about the potential risks of the products at issue here, when [Ethicon] knew about those potential risks, what follow-up investigations [Ethicon] did to learn more about those potential risks, and other facts that are potentially relevant" to Plaintiffs' claims of failure to warn and product defects. *Hardy v. Pharmacia Corp.,* Case No. 4:09-cv-119 (CDL), 2011 WL 2118983, at *3 (M.D.Ga. May 27, 2011). Accordingly, Plaintiffs are entitled to collect all OUS regulatory documents.

Burdensomeness/Duplication

Having determined the relevancy of the OUS regulatory documents does not end the analysis, however. Under Fed.Rule.Civ.P. 26(c), a party may move the court for an order precluding or limiting proposed discovery if necessary to protect the party from annoyance, embarrassment, oppression, undue burden or expense. The person or party moving for the protective order bears the burden of demonstrating good cause, *Minter v. Wells Fargo Bank, N.A.,* 258 F.R.D. 118, 124 (D.Md.2009), and in doing so, "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. v. Natanzon,* 240 F.R.D. 200, 202 (D.Md.2006) (*quoting* 8A Charles Alan Wright

et al., *Fed. Prac. & Proc. Civ.* § 2035 (2d ed.1994)). The court has broad discretion under Fed.R.Civ.P. 26(c) "to decide when a protective order is appropriate and what degree of protection is required." *Seattle Times v. Rhinehart,* 467 U.S. 20, 36, 104 S.Ct. 2199, 81 L.Ed.2d 17 (1984). In crafting a protective order, the court "may be as inventive as the necessities of a particular case require in order to achieve the benign purposes of the rule." 8A Charles Alan Wright, Arthur R. Miller, & Richard L. Marcus, *Federal Practice and Procedure,* § 2036 (3d ed.).

Furthermore, under Fed.R.Civ.P 26(b)(2)(C), the court ***must***, on motion or on its own:

> limit the frequency or extent of discovery, otherwise allowed by these rules or by local rule if it determines that "(i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or (iii) 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.

This rule "cautions that all permissible discovery must be measured against the yardstick of proportionality." *Lynn v. Monarch Recovery Management, Inc.,* 285 F.R.D. 350, 355 (D. Md. 2012) (quoting *Victor Stanley, Inc. v. Creative Pipe, Inc.,* 269 F.R.D. 497, 523 (D. Md. 2010)). "The application of [Rule 26(b)(2)(C)] involves a highly discretionary determination based upon an assessment of a number of competing considerations." *Sommerfield v. City of Chicago,* 613 F.Supp.2d 1004, 1017 (N.D.Ill.2009).

Ethicon contends that the regulatory documents from the remaining 64 countries are largely duplicative of the materials already produced to Plaintiffs. However, Ethicon

apparently has not reviewed these documents and makes this representation based almost entirely upon an investigation conducted by its expert in electronic discovery, Ms. Pamela Downs. In support of Ethicon's motion, Ms. Downs supplies an affidavit detailing her investigation, which is somewhat confusing. She indicates that country–specific regulatory submissions are stored in the country of registration and not aggregated in a central repository. Notwithstanding this representation, she adds that records for the United States and the European Union are aggregated in a database and in network shares. She suggests that foreign countries "rely upon" previously produced documents for their submissions, but then identifies six countries that have unique regulatory requirements such as independent or government-approved in-country laboratory or clinical testing. She states that labels and instructions for use pertinent to the various countries "originate" from a previously produced US Global Label content management system, but concedes that the labels actually used may be slight modifications of the Global Label. Taken as a whole, the affidavit contains internal inconsistencies that are difficult to resolve. More importantly, Ms. Downs's investigation simply does not establish to the court's satisfaction that the unproduced regulatory materials are "largely" duplicative.

In contrast to Ms. Downs's affidavit, Plaintiffs contend that they have already found significant variations among the documents produced from Japan, Australia, and France. Moreover, approximately fifteen different mesh products were marketed by Ethicon, and these products were distributed at different times in different countries and over a period of years. Given these facts, and the additional fact that regulatory submissions have been produced for less than five percent of the countries comprising Ethicon's pelvic mesh market, Plaintiffs have presented valid reasons to doubt the

representation that regulatory materials are substantially the same in every country. Accordingly, after hearing from both parties, the undersigned concludes that while Ethicon has a good faith belief that the remaining OUS regulatory documents are duplicative of what has already been produced, Ethicon has not carried its burden to justify a protective order. Until submissions from a larger percentage of the OUS market have be examined, the extent of duplication is speculative, and Ethicon's motion for protective order is premature.

Therefore, the court **GRANTS** Plaintiffs' motion to compel. Nonetheless, the parties are **ORDERED** to agree on a process to produce OUS regulatory materials in a manner that is most likely to resolve the question of whether future productions will be unreasonably duplicative. If the parties cannot agree within **seven (7) days**, then plaintiffs shall start by choosing ten additional countries for immediate production and list the remaining countries in order of priority. In this way, the parties should be able to identify in short order the core regulatory documents, if any, that are substantially the same in every country and can forgo future duplicate productions. This order is not intended to modify the ESI protocol, however. Therefore, to the extent that documents located and reviewed by Ethicon are identical to those already produced, Ethicon is not required to produce them again. (ECF No. 235-1 at 4).

Cost-Shifting

Ethicon asks the court to shift to Plaintiffs the costs of additional discovery of OUS regulatory materials on the basis that the anticipated yield of noncumulative, nonduplicative information is low while the estimated expense involved in collecting, translating, reviewing, and producing the documents is high; thus, constituting an unfair burden on Ethicon. As a general rule, "the presumption is that the responding

party must bear the expense of complying with discovery requests." *Oppenheimer Fund, Inc. v. Sanders,* 437 U.S. 340, 358, 98 S.Ct. 2380, 57 L.Ed.2d 253 (1978). However, the practice of shifting discovery costs, in whole or in part, from the responding party to the requesting party has been recognized for decades, *see Boeynaems v. LA Fitness Intern, LLC,* 285 F.R.D. 331, 338 (E.D.Pa. 2012); most frequently in the context of electronically stored information ("ESI"). *See McPeek v. Ashcroft,* 202 F.R.D. 31, (D.D.C. 2001); *Rowe Entertainment v. The William Morris Agency, Inc.* 205 F.R.D. 421 (S.D.N.Y.2002); *Zubulake v. UBS Warburg LLC ("Zubulake I"),* 217 F.R.D. 309 (S.D.N.Y. 2003). The responding party "has the burden of proof on a motion for cost-shifting." *Zubulake v. UBS Warburg LLC ("Zubulake II"),* 216 F.R.D. 280, 283 (S.D.N.Y.2003).

In *McPeek v. Ashcroft,* the district court acknowledged the potentially enormous expense involved in searching, collecting, and producing relevant ESI. Consequently, to balance the requesting party's entitlement to broad discovery with the responding party's right to be protected from undue burden and expense, the court borrowed from the economic principle of "marginal utility" and adopted an analytic methodology to determine if cost-shifting was appropriate. *McPeek,* 202 F.R.D. at 34. Using this methodology, the court examined the likelihood that ESI would contain information relevant to a claim or defense. The more likely it was that ESI was relevant, the fairer it was to have the responding party incur the expense of searching, collecting and producing the ESI. The less likely it was that a search of ESI would bear fruit, the more unjust it was to make the responding party shoulder that burden alone. Other courts have developed their own tests for assessing the merits of cost-shifting. For example, the

district court in *Rowe* developed an eight-factor balancing test,[2] *Rowe,* 205 F.R.D. at 429, while the court in *Zubulake I,* favored a seven-factor test.[3] In *Thompson v. U.S. Dept. of Housing and Urban Development*, 219 F.R.D. 93 (D.Md. 2003), the District Court of Maryland suggested that the balancing factors contained in Rule 26(b)(2) might be "all that is needed to allow a court to reach a fair result when considering the scope of discovery of electronic records."[4] *Id.* at 98. The *Thompson* court noted that "[r]egardless of which test is used, the most important ingredient for the analytical process to produce a fair result is a particularization of the facts to support any challenge to discovery of electronic records." Here, the records at issue are a combination of ESI and hard-copy documents. Irrespective of the format of the documents, the undersigned agrees with the *Thompson* court that a fair cost-shifting analysis can be achieved by applying the factors found in Rule 26(b)(2)(C). After considering those factors, the undersigned finds that cost-shifting is not appropriate at this time.

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[2] The eight factors include: (1) the specificity of the discovery requests; (2) the likelihood of discovering critical information; (3) the availability of such information from other sources; (4) the purposes for which the responding party maintains the requested data; (5) the relative benefit to the parties of obtaining the information; (6) the total cost associated with production; (7) the relative ability of each party to control cost and its incentive to do so; and (8) the resources available to each party.

[3] The seven factors are: (1) The extent to which the request is specifically tailored to discover relevant information; (2)The availability of such information from other sources; (3) The total cost of production, compared to the amount in controversy; (4) The total cost of production, compared to the resources available to each party; (5) The relative ability of each party to control costs and its incentive to do so; (6)The importance of the issues at stake in the litigation; and (7)The relative benefits to the parties of obtaining the information.

[4] As previously stated, the factors in Rule 26(b)(2) include: [W]hether the discovery sought is unreasonably cumulative or duplicative; whether the information sought is obtainable from some other more convenient, less burdensome or inexpensive source; whether the party seeking the information already has had adequate opportunity to obtain the information; and whether the burden or expense of the proposed discovery outweighs its likely benefit, taking into consideration the following: the needs of the case, the amount in controversy, the resources of the parties, the importance of the issues at stake in the litigation and of the discovery sought to the resolution of the issues.

Looking at the first factor, Ethicon has not convinced the court that the remaining regulatory documents are ***unreasonably*** cumulative or duplicative of the documents produced to date. While there will no doubt be some duplication, the extent of the overlap is uncertain; therefore, this factor is neutral. The next two factors weigh in favor of the presumption that the responding party should bear the costs of discovery. There is nothing before the court to suggest a less burdensome, less expensive, and more convenient source from which Plaintiffs can obtain the regulatory documents. To the contrary, Plaintiffs would likely have to approach each individual regulatory body to gather the documents. Likewise, Plaintiffs have not had an adequate opportunity to obtain the information. They have only received complete regulatory submissions from three out of 67 countries.

When considering the needs of the case, the amount in controversy, the resources of the parties, the importance of the issues at stake and of the discovery sought, the undersigned finds that these factors weigh against cost-shifting. This multidistrict litigation includes over ten thousand plaintiffs, claiming to be permanently injured by Ethicon's mesh products. In cases involving Ethicon's pelvic mesh that have gone to trial, the Plaintiffs' verdicts have been in the millions of dollars. Accordingly, the amount in controversy far exceeds the projected costs of producing the regulatory documents, even when considering the costs already incurred by Ethicon in the course of discovery. Moreover, Ethicon is part of a multibillion dollar family of companies; therefore, absorbing these discovery costs should not financially cripple Ethicon. In addition, the issues at stake are not only important to the thousands of plaintiffs that have been treated with Ethicon's mesh, but may have broad public impact in the way that similar products are designed, manufactured, tested, marketed, sold, and

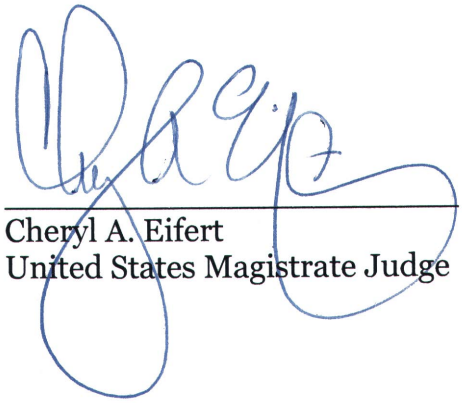
implanted. *See Zubulake I,* 217 F.R.D. at 321. The final factor, the importance of the discovery, carries no particular weight at this juncture because the documents have not been reviewed in their entirety by either party. Certainly, a substantial potential exists that the documents will play an important role in the litigation. Consequently, until Plaintiffs begin to collect regulatory materials that, with some repetition, are substantially the same as those already in their possession, the factors set forth in Rule 26(b)(2)(C) do not favor cost-shifting. It plainly is too early in the collection process to determine with any certainty the likelihood that future productions of regulatory documents will be cumulative and duplicative.

Therefore, the court **DENIES** Ethicon's request for cost-shifting of the expenses incurred to produce OUS regulatory materials. Having found thus, however, the court grants Ethicon leave to re-file a motion for cost-shifting if further production supports its position that the unproduced regulatory documents are substantially similar to the documents previously supplied, such that, the expense of continuing to collect, translate, review, and produce them truly outweighs the likelihood that new information will be obtained.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2327, 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-23147. 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: September 18, 2013.



Cheryl A. Eifert
United States Magistrate Judge