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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

The Court held a fifth case management conference with the parties on August 23, 2016. In preparation for the conference, the parties provided a joint status report that identified a number of issues for discussion. Doc. 3102. The report noted that the parties disagree on the discoverability of certain electronically stored information ("ESI") generated by foreign entities (subsidiaries or divisions of Defendant C.R. Bard) that sell IVC filters abroad. Plaintiffs seek discovery of communications between the foreign entities and foreign regulatory bodies regarding the IVC filters at issue in this case. Doc. 3264 at 2. The Court discussed this topic at some length during the status conference on August 23, 2016, and directed the parties to provide focused briefing. Each side has now filed a memorandum addressing this issue. Docs. 3309, 3326. For the reasons set forth below, the Court will deny Plaintiffs' request for this discovery.

I. New Legal Standards Governing the Scope of Discovery.

Rule 26(b)(1) of the Federal Rules of Civil Procedure was amended on December 1, 2015. The new rule defines the scope of permissible discovery as follows:

> Parties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the party's access to relevant information, the

> party's resources, the importance of the discovery in resolving the issues, and whether the burden and expense of the proposed discovery outweighs its likely benefit.

Fed. R. Civ. P. 26(b)(1).

A. Relevancy.

To be discoverable under the first part of this test, information must be "relevant to any party's claim or defense." *Id*. This language has not changed from the previous version of Rule 26(b)(1).

Before the 2015 amendments, Rule 26(b)(1) also provided that inadmissible evidence was discoverable if it "appears reasonably calculated to lead to the discovery of admissible evidence." Some courts – and many lawyers – used this language to define the scope of discovery. *See, e.g., Surfvivor Media, Inc. v. Survivor Prods.*, 406 F.3d 625, 635 (9th Cir. 2005) ("Relevant information for purposes of discovery is information 'reasonably calculated to lead to the discovery of admissible evidence.'") (quoting *Brown Bag Software v. Symantec Corp.*, 960 F.2d 1465, 1470 (9th Cir. 1992)).

This phrase was eliminated by the 2015 amendments and replaced with a more direct declaration of the phrase's original intent: "Information within this scope of discovery need not be admissible in evidence to be discoverable." Fed. R. Civ. P. 26(b)(1). The Advisory Committee on the Federal Rules of Civil Procedure provided this explanation for the deletion:

> The former provision for discovery of relevant but inadmissible information that appears "reasonably calculated to lead to the discovery of admissible evidence" is also deleted. The phrase has been used by some, incorrectly, to define the scope of discovery. As the Committee Note to the 2000 amendments observed, use of the "reasonably calculated" phrase to define the scope of discovery "might swallow any other limitation on the scope of discovery." The 2000 amendments sought to prevent such misuse by adding the word "relevant" at the beginning of the sentence, making clear that "relevant" means within the scope of discovery as defined in this subdivision . . . ." The "reasonably calculated" phrase has continued to create problems, however, and is removed by these amendments.

Rule 26, Advis. Comm. Notes for 2015 Amends.

The 2015 amendments thus eliminated the "reasonably calculated" phrase as a definition for the scope of permissible discovery. Despite this clear change, many courts

continue to use the phrase. Old habits die hard.[1] In this circuit, courts cite two Ninth Circuit cases – *Surfvivor Media, Inc. v. Survivor Prods.*, 406 F.3d 625, 635 (9th Cir. 2005), and *Brown Bag Software v. Symantec Corp.*, 960 F.2d 1465, 1470 (9th Cir. 1992) – for the proposition that information is relevant for purposes of Rule 26(b)(1) if it is "reasonably calculated to lead to the discovery of admissible evidence."[2] But these cases, and others like them, simply applied the earlier version of Rule 26(b)(1).

Amended Rule 26(b)(1) was adopted pursuant to the Rules Enabling Act, 28 U.S.C. § 2072, et. seq. That statute provides that "[a]ll laws in conflict with such rules shall be of no further force or effect after such rules have taken effect." *Id.*, § 2072(b). Thus, just as a statute could effectively overrule cases applying a former legal standard, the 2015 amendment effectively abrogated cases applying a prior version of Rule 26(b)(1). The test going forward is whether evidence is "relevant to any party's claim or defense," not whether it is "reasonably calculated to lead to admissible evidence."

B. Proportionality.

The 2015 amendments also added proportionality as a requirement for permissible discovery. Relevancy alone is no longer sufficient – discovery must also be proportional to the needs of the case. The Advisory Committee Note makes clear, however, that the amendment does not place the burden of proving proportionality on the party seeking

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[1] Last month alone, seven cases relied on the "reasonably calculated" language to define the scope of permissible discovery. *See Fastvdo LLC v. AT&T Mobility LLC*, No. 16-CV-385-H (WVG), 2016 WL 4542747, at *2 (S.D. Cal. Aug. 31, 2016); *Sierra Club v. BNSF Ry. Co.*, No. C13-0967-JCC, 2016 WL 4528452, at *1 (W.D. Wash. Aug. 30, 2016); *Shell v. Ohio Family Rights*, No. 1:15-CV-1757, 2016 WL 4523830, at *2 (N.D. Ohio Aug. 29, 2016); *Arrow Enter. Computing Sols., Inc. v. BlueAlly, LLC*, No. 5:15-CV-00037-FL, 2016 WL 4287929, at *1 (E.D.N.C. Aug. 15, 2016); *Ecomission Sols., LLC v. CTS Holdings, Inc.*, No. MISC. 16-1793 (EGS), 2016 WL 4506974, at *1 (D.D.C. Aug. 26, 2016); *Clouser v. Golden Gate Nat'l Senior Care, LLC*, No. CV 3:15-33, 2016 WL 4223755, at *4 (W.D. Pa. Aug. 9, 2016); *Scott Hutchinson Enters., Inc. v. Cranberry Pipeline Corp.*, No. 3:15-CV-13415, 2016 WL 4203555, at *2 (S.D.W. Va. Aug. 9, 2016). Several other cases cited the language as though it were still part of Rule 26(b)(1). *See Fairley v. Wal-Mart Stores, Inc.*, No. CV 15-462, 2016 WL 4418799, at *2 (E.D. La. Aug. 19, 2016); *Kuczak v. City of Trotwood, Ohio*, No. 3:13-CV-101, 2016 WL 4500715, at *1 (S.D. Ohio Aug. 26, 2016); *Kubik v. Cent. Michigan Univ. Bd. of Trustees*, No. 15-CV-12055, 2016 WL 4425174, at *2 (E.D. Mich. Aug. 22, 2016).

[2] *See Fastvdo*, 2016 WL 4542747, at *2 (quoting *Surfvivor Media*, 406 F.3d at 635); *Sierra Club*, 2016 WL 4528452, at *1 (quoting *Brown Bag*, 960 F.2d at 1470).

discovery. The amendment "does not change the existing responsibilities of the court and the parties to consider proportionality, and the change does not place on the party seeking discovery the burden addressing all proportionality considerations." Rule 26, Advis. Comm. Notes for 2015 Amends. Rather, "[t]he parties and the court have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes." *Id.*

The inquiry to be conducted under the proportionality requirement, therefore, requires input from both sides. As the Advisory Committee explained:

> A party claiming undue burden or expense ordinarily has far better information – perhaps the only information – with respect to that part of the determination. A party claiming that a request is important to resolve the issues should be able to explain the ways in which the underlying information bears on the issues as that party understands them. The court's responsibility, using all the information provided by the parties, is to consider these and all the other factors in reaching a case-specific determination of the appropriate scope of discovery.

Id. The Court therefore will look to evidence and arguments from both sides in deciding whether discovery from the Bard foreign entities is permitted under Rule 26.

II. Analysis.

A. Relevancy.

From the information provided by the parties, it appears that most of Defendants' regulatory communications, including communications with foreign regulators, are generated by Defendants' United States operations, which have been and continue to be subject to extensive discovery. Robert Carr, the key Bard witness on this issue, explained that the relevant Bard division within the United States "handles the regulatory burden" for a particular product. Doc. 3311-1 at 4. The division supplies "all the required documentation" to foreign Bard entities, and the foreign entities then share that information with foreign regulators. *Id.* Some foreign entities have their own regulatory staff, but Bard's United States operations "supply all the pertinent information, answer all the questions. They provide the documentation and translations back and forth." *Id.* at 11.

Carr further explained that there are regulatory persons on every Bard product development team, and that "they determine the potential regulatory pathway for a product being developed early on." *Id*. at 13. "[T]hroughout the project, they identify the required standards that need to be met in countries that we know we're going to go to, because testing requirements are different in different countries." *Id.* at 14. "And then at the end of the project they would put together the supporting documentation to allow themselves to file in America and . . . the other international regulatory groups to file in their particular countries using our data. And they would liaise with them throughout that approval process globally." *Id*. at 14.

Documents submitted by the parties support Bard's assertion that regulatory communications are largely controlled from within the United States. For example, Exhibit F to Defendants' memorandum is an email chain showing Bard employees within the United States compiling information to respond to inquiries made by a regulator in Great Britain. Doc. 3313-7.

It also appears, however, that employees in foreign entities sometimes engage in their own communications with foreign regulators. Mr. Carr provided this testimony about when Bard's foreign personnel could have communications with foreign regulators that are different from the communications prepared in the United States:

> Q. There's not a single place where they would be different?
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> A. If the indication for use, which is a regulatory term, defines how and where a product can be used, how a filter can be used, if it happens to have a different indication for use in a different country, then that's possible. And so they would be able to change that information. Japan is a common example of that.
>
> Q. Okay.
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> A. They will change wording and things like that, that's based on the Japanese regulatory approval, not necessarily marketing effort.
>
> Q. Sure. They have to get a change in an IFU approved by BPV or C.R. Bard before they can do it?
>
> A. No, they approve it at their level.

Doc. 3266 at 10-11.

This exchange suggests that employees in foreign Bard entities at least sometimes communicate with foreign regulators on their own. This fact is confirmed by Exhibit 4 to Plaintiffs' memorandum. It is a communication from David Marshall, an employee of Bard in Great Britain, recounting communications he had with British regulators regarding Bard filters. Doc. 3266 at 13.

For purposes of this discovery dispute, the Court concludes that most of the communications with foreign regulators originate in the United States and thus will be captured by the ESI searches currently underway. There do appear, however, to be some communications that originate abroad and may not be captured in the current searches.

The Court also finds, however, that the relevancy of these communications is uncertain for at least two reasons. First, there are no Plaintiffs in this MDL from foreign countries. All plaintiffs received their Bard filters and allegedly were injured in the United States. Second, Plaintiffs seek communications with foreign regulators for a narrow purpose – to determine if any of those communications have been inconsistent with Defendants' communications with American regulators. It is inconsistency that Plaintiff's seek to discover.

Courts generally recognize that relevancy for purposes of discovery is broader than relevancy for purposes of trial. Even still, the Court concludes that the discovery sought by Plaintiffs is only marginally relevant. With no foreign-based Plaintiffs, and mere conjecture that communications between foreign entities and foreign regulators might be inconsistent with Defendants' communications with American regulators, the discovery appears to be only potentially relevant – more hope than likelihood.

B. Proportionality.

Rule 26(b)(1) identifies several factors to be considered in addressing proportionality. Plaintiffs have addressed some of those factors in the evidence cited above. The "importance of the discovery in resolving the issues," as the Court has explained, appears marginal. The parties "relative access to relevant information" favors Plaintiffs, but only in Defendants' possession of possibly relevant information.

Defendants argue that the burden or expense of the proposed discovery outweighs its likely benefit, and they provide some specifics. They note that Bard has entities in Canada, Korea, Australia, India, Singapore, Malaysia, Italy, Ireland, the United Kingdom, Denmark, the Netherlands, Sweden, Norway, Finland, Mexico, Chile, Brazil, and China. Doc. 3309 at 6 n.6. Plaintiffs seek discovery of all communications these entities have had with foreign regulatory authorities involving all Bard IVC filters since 2003. *Id*. To comply with Plaintiffs' requests, Defendants assert that they would be required to identify the applicable custodians from these foreign entities for the last 13 years, collect ESI from these custodians, and search for and identify communications with foreign regulators. The Court is persuaded by these specifics that the burden of this foreign discovery would be substantial.

Plaintiffs are engaging in substantial discovery with respect to Defendants' communications with American regulators, including extensive ESI searches and depositions of relevant witnesses. This discovery should capture communications with foreign regulators that originate in the United States, as most appear to. The Court concludes that the burden and expense of searching ESI from 18 foreign entities over a 13-year period outweighs the benefit of the proposed discovery – a mere possibility of finding a foreign communications inconsistent with United States communication.

Because the proposed discovery is not proportional to the needs of the case considering the factors set forth in Rule 26(b)(1), the Court concludes that Defendants need not search the ESI of foreign Bard entities for communications with foreign regulators.

Dated this 16th day of September, 2016.

David G. Campbell
United States District Judge