In re Bard IVC Filters Prods. Liab. Litig.

Decided Feb 11, 2016

MDL No. 2641

02-11-2016

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION This Order Relates to: All Actions

---

David G. Campbell United States District Judge

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular Services, Inc. ("Bard") seek a protective order to prevent Plaintiffs from using the December 15, 2004 report of Dr. John Lehmann. Doc. 306. The issues are fully briefed (Docs. 379, 412), and the Court heard oral argument on January 29, 2016 (Doc. 507). The Court concludes that no additional discovery or evidentiary hearing is necessary to resolve this issue. For the following reasons, the Court will grant Bard's motion.

I. Background.

The facts in this section are taken largely from testimony given in an evidentiary hearing in *Alexander v. Bard*, No. 3:12-CV-05187-O-BK (N.D. Tex. June 11, 2014). *See* Doc. 319-2 at 7-137. The Court will explain later in this order why it finds the testimony credible.

Dr. Lehmann is a consultant who has provided different services to Bard at different times. Beginning in late 2003, Dr. Lehmann was retained to serve as Bard's acting director of medical services. Doc. 319-2 at 93, 107-08. Dr. Lehmann served in this capacity until Bard hired Dr. David Ciavarella to replace him in May 2004.
2 Docs. 319-2 at 93-94; 412-1 at 6. As acting medical director, Dr. Lehmann reviewed and *2 approved documents, prepared health hazard evaluations ("HHE") and remedial action plans ("RAP"), responded to queries from various medical divisions, and assisted in Bard's hiring of Dr. Ciavarella. Doc. 319-2 at 93-96. In this role, Dr. Lehmann drafted two HHEs that are particularly relevant to this dispute: the March 10, 2004 HHE (Doc. 445-1 at 4-15), and the April 27, 2004 HHE (Doc. 414 at 3-15), both of which address Recovery Filter migration events. The Law Department occasionally asked Dr. Lehmann in his capacity as acting medical director to review medical records for particular cases. Doc. 319-2 at 30. Once Bard hired Dr. Ciavarella, Dr. Lehmann did not work on anything related to the Recovery Filter until the Law Department retained his services in November 2004. *Id*. at 102.

In early 2004, Bard began receiving notices of adverse events associated with the Recovery Filter. For example, in February 2004 Bard learned of a patient death related to the migration of a Recovery Filter. Docs. 319-2 at 40-41; 445-1 at 5. In April, Bard learned of a second migration death associated with the filter. Doc. 414 at 4. Bard's assistant general counsel, Donna Passero, began to receive letters demanding compensation from lawyers and patients who had experienced such adverse events. Doc. 319-2 at 25. In June, Passero responded to a letter that raised possible product liability and medical malpractice claims. Doc. 319-2 at 28-29. In July, Bard

notified its insurance carrier of potential claims involving the Recovery Filter. Docs. 319 at 27-29; 319-2 at 29, 91. These potential claims led the Law Department to retain Dr. Lehmann to conduct a broad risk assessment of the Recovery Filter. Doc. 319-2 at 38-39.

The Law Department retained Dr. Lehmann as a consultant in November 2004. *Id*. at 2-3, ¶ 6, 93. On November 15, 2004, Dr. Lehmann and Judith Reinsdorf, Bard's General Counsel, executed a consulting agreement. Docs. 319-2 at 3, ¶ 8, 36, 94; 335 at 3-9. The agreement said that Dr. Lehmann's services would be provided in "anticipation of litigation." Doc. 335 at 3, ¶ 1. Dr. Lehmann's work for the Law Department was unlike the work he had performed as acting medical director; he was retained to provide a broad assessment of
3 the risks associated with Bard's Recovery Filter to assist the Law *3 Department in advising Bard on the extent of its legal exposure. Doc. 319-2 at 31-32, 96. Dr. Lehmann reviewed relevant medical literature, examined the Recovery Filter complaints Bard had received up to that point, analyzed data from the FDA's adverse event reporting database (known as "MAUDE"), reviewed bench testing data for the Recovery Filter and its competitors, and prepared a written report of his findings. Docs. 319-2 at 97-98; 335 at 9. During this investigation, and at Passero's direction, Dr. Lehmann communicated with "a small and limited number of Bard employees for the purpose of obtaining and providing information in order to" complete his work. Doc. 319-2 at 3, ¶ 10.

On December 15, 2004, Dr. Lehmann submitted his report ("Report") to Passero. Docs. 319-2 at 3, ¶ 11, 98, 104-05; 335 at 3, ¶ 2, 11. The Report contained a header on every page stating that it was "[p]rivileged and confidential," "[a]ttorney work product," and "[p]ursuant to contract." *See*, *e.g*., Doc. 335 at 13. Passero distributed the Report to five Bard employees, including Bard's general counsel. Doc. 319-2 at 3, ¶ 11, 36, 83. Eventually, the Report was distributed to approximately 12 Bard employees.[1] *See id*. at 140-41, ¶¶ 3-4. Passero testified that she distributed the Report internally because it recommended that Bard immediately and urgently address several issues. *Id*. at 37; *see also id*. at 3, ¶ 11. Passero instructed the recipients "that the report and associated materials were confidential and that any further distribution of the report should be limited to only those employees or consultants who need the report to perform their proper job functions." *Id*. at 3, ¶ 11, 83. There is no evidence that the Report was distributed to anyone other than Bard employees.

[1] The record does not clearly establish how the remaining Bard employees received the Report. Presumably, the individuals to whom Passero gave the Report passed it along to others. *See* Doc. 319-2 at 3, ¶ 11. The record is similarly unclear as to the identities of the 12 Bard employees who received the Report, although Bard's briefing suggests that it is the 12 individuals named in Robert Carr's February 3, 2014 affidavit. *See* Doc. 306 at 9, 16; *see also* Doc. 319-2 at 140-41, ¶¶ 3-4.

II. Legal Standard.

4 "A party or any person from whom discovery is sought may move for a protective *4 order in the court where the action is pending." Fed. R. Civ. P. 26(c)(1). Rule 26(c) authorizes a district court to grant a protective order where "good cause" is shown. *See San Jose Mercury News*, *Inc*. *v*. *U.S*. *Dist*. *Ct*., 187 F.3d 1096, 1103 (9th Cir. 1999). "[T]he party seeking protection bears the burden of showing specific prejudice or harm will result if no protective order is granted." *Phillips v*. *G.M*. *Corp*., 307 F.3d 1206, 1210-11 (9th Cir. 2002) (quotation marks and citations omitted).

III. Analysis.

Bard argues that (1) the Report is protected from disclosure by the work product doctrine; (2) Plaintiffs have not shown a substantial need for the Report, or that they will experience an undue hardship in obtaining substantially equivalent information; and (3) Bard did not waive the Report's work-product protection. The

Court will explain why it agrees with these three assertions.

A. The Report is protected work product.

"Ordinarily, a party may not discover documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's attorney, *consultant*, surety, indemnitor, insurer, or *agent*)." Fed. R. Civ. P. 26(b)(3)(A) (emphasis added). Courts in the Ninth Circuit use the "because of" test to determine whether dual purpose documents were prepared in anticipation of litigation:

> In circumstances where a document serves a dual purpose, that is, where it was not prepared exclusively for litigation, then the "because of" test is used. Dual purpose documents are deemed prepared because of litigation if in light of the nature of the document and the factual situation in the particular case, the document can be fairly said to have been prepared or obtained because of the prospect of litigation. In applying the "because of" standard, courts must consider the totality of the circumstances and determine whether the document was created because of anticipated litigation, and would not have been created in substantially similar form but for the prospect of litigation.

5 *United States v. Richey*, 632 F.3d 559, 567-68 (9th Cir. 2011) (quotation marks and citations omitted). *5

Before the start of this MDL, Passero and Lehmann testified in an evidentiary hearing in the *Alexander* case cited above. *See* Doc. 319-2 at 7-137. Attorneys who are part of the Plaintiffs' Steering Committee in this MDL participated in the hearing and cross-examined Passero and Lehmann. *Id*. at 9. Bard relies on affidavits, documentary evidence, and testimony from the *Alexander* hearing to show that the Report was created because of anticipated litigation. *See* Doc. 306 at 9-13.

Documents confirm that, beginning in early 2004, Bard and its legal counsel began receiving notices that the Recovery Filter was associated with adverse events, including several deaths. *See* Docs. 319 at 14-25 (letters and emails involving lawyers and patients who had experienced adverse events associated with the Recovery Filter); *id*. at 31-80 (Bard complaint files for patients who had experienced adverse events associated with the Recovery Filter); 319-1 at 1-230 (same). Bard received several threats of litigation. Doc. 319 at 14-16 (February 3, 2004); *id*. at 20-21 (June 7, 2004); *id*. at 23 (June 15, 2004). In July 2004, Bard notified its insurance carrier of potential claims relating to the Recovery Filter. Docs. 319 at 27-29; 319-2 at 29, 91. Plaintiffs do not dispute this documentation.

Ms. Passero stated in an affidavit and during her testimony in *Alexander* that these events caused the Law Department to retain Dr. Lehmann as a consultant to conduct a broad risk assessment. Doc. 319-2 at 2 (¶¶ 6-7), 32. Dr. Lehmann confirmed this fact in his testimony. *Id*. at 93-95.

The consulting agreement was executed by Dr. Lehmann and Bard's general counsel, and provided that Dr. Lehmann would report directly to, and take directions from, attorney Passero and the Law Department. Docs. 319-2 at 3, ¶ 9, 36, 94; 335 at 3-9. The agreement stated that Dr. Lehmann's services were being retained in "anticipation of litigation." Doc. 335 at 3, ¶ 1. Dr. Lehmann's Report was submitted directly to Passero. Docs. 319-2 at 3, ¶ 11, 98, 104-05; 335 at 3, ¶ 2, 11. The Report contained a header stating that it was "[p]rivileged and confidential," "[a]ttorney work product," and "[p]ursuant to contract." *See*, *e.g.*, Doc. 335 at 13. *6

Plaintiffs argue that the Report was prepared in the ordinary course of business. *See* Doc. 379 at 12-19. They assert that Bard's regular business includes remedial actions and "significant obligations to investigate and to report product failures, including conducting comparisons to competitor products." *Id*. at 13. Plaintiffs point to

Bard's Regulatory Affairs Manual (Doc. 445-2 at 11-26, 35-53) and various statutes and administrative regulations as proof of these obligations. *See* Doc. 379 at 5-6, 13-14. Plaintiffs contend that Bard's Regulatory Affairs Manual establishes that Dr. Lehmann was a member of Bard's Product Assessment Team when he was serving as acting medical director. *Id*. at 13-14. Even if this is true, Plaintiffs fail to link this fact to Dr. Lehmann's work in preparing the Report - work that was conducted months later and in his capacity as a consultant for the Law Department.

It is true that the statutes and regulations impose on Bard certain obligations: to maintain complaint and adverse event files (*see* 21 C.F.R. §§ 820.198, 803.1), investigate and report to the FDA certain product failures (*see* 21 C.F.R. § 820.198), undertake certain duties with respect to misbranded or adulterated devices (*see* 21 U.S.C. §§ 321, 331, 351, 352, 360), and perform quality audits (*see* 21 C.F.R. § 820.22). But these laws do not impose an obligation to conduct the extensive and comparative statistical and bench testing data analyses undertaken by Dr. Lehmann and memorialized in the Report. Both Passero and Dr. Lehmann testified that the Report was an unusual undertaking, prepared in anticipation of litigation and unrelated to Bard's regulatory obligations. *See* Doc. 319-2 at 33-34, 38, 93-98, 108-10, 113-17. Even considering and crediting Plaintiffs' evidence, the Court finds these assertions largely unrebutted. The Report was a more extensive and detailed analysis than Bard normally created. The evidence does not support Plaintiffs' assertion that the Report was prepared in the ordinary course of Bard's business. It supports a finding that the Report "would not have been created in substantially similar form but for the prospect of litigation," *Richey*, 632 F.3d at 568, which satisfies the Ninth
7 Circuit's work product test.[2] *7

[2] At oral argument, the Court asked Plaintiffs to cite the specific statute or regulation that they claim required Bard to produce the Report. Plaintiffs cited 21 C.F.R. § 820.22. The Court has closely reviewed this regulation, as well as related regulations, and concludes that § 820.22 did not require Bard to create the Report. First, § 820.22 focuses on quality systems. *Id*. ("Each manufacturer shall *establish procedures for quality audits* and conduct such audits to assure that the *quality system is in compliance* with the established quality system requirements and to *determine the effectiveness of the quality system*.") (emphasis added). Quality system" is defined as "the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.' *Id*. § 820.3(v). This suggests that the quality audits mentioned in § 820.22 are focused on ensuring that manufacturers have proper quality assurance procedures in place and are, in fact, following those procedures. Second, the FDA's comments in the preamble to the regulation confirm that this is the purpose of § 820.22. *See* 61 Fed. Reg. 52602, 52614 (Oct. 7, 1996) ("Quality audit[s] are for an internal audit and review of the quality system to verify compliance with the quality system regulation. The review and evaluations under § 820.22 are very focused. During the internal quality audit, the manufacturer should review all procedures to ensure adequacy and compliance with the regulation, and determine whether the procedures are being effectively implemented at all times."). Third, the regulatory structure indicates that § 820.22 is focused on procedures and processes, rather than on a particular product's safety. The regulation is located in Subpart B "Quality System Requirements," and not in other subparts that more directly address the subject matter of the Report, such as Subpart G "Production and Process Controls," Subpart I "Nonconforming Product," or Subpart J "Corrective and Preventative Action."

Plaintiffs also argue that the Report was used for Bard's business purposes, and that there is no evidence it was used for litigation purposes. Doc. 379 at 14-15. Plaintiffs identify three internal Bard documents that contain information from the Report: the December 12, 2004 HHE, the January 4, 2005 RAP, and a December 9, 2004 draft of the January RAP. *Id*. at 14. A review of these documents confirms that the Report was used in creating them. Bard also admitted this fact during oral argument and in its reply brief. Doc. 412 at 7. But use of the Report to create internal HHEs and RAPs does not deprive the Report of work product protection. To the contrary, the "because of" test is directed at documents that serve both litigation and business purposes. *See*

Richey, 632 F.3d at 567-68 ("In circumstances where a document serves a dual purpose, that is, where it was not prepared exclusively for litigation, then the 'because of test is used."). The Court must determine whether "the document was created because of anticipated litigation, and would not have been created in substantially similar form but for the prospect of litigation." *Id*. at 568. As discussed in this order, the evidence supports such a finding.

Plaintiffs also cite no authority for their argument that Bard must show the Report was actually used in litigation. The test is whether the Report was "*prepared* in *8 anticipation of litigation," not whether it was used in litigation. Fed. R. Civ. P. 26(b)(3) (emphasis added). Requiring parties to show that a document was used in litigation would likely invade both the work product protection and the attorney-client privilege.

Plaintiffs similarly argue that the Report does not mention litigation, legal analysis, or litigation strategy. But work product protection is not limited to legal analysis or litigation strategy - it includes "documents and tangible things that are prepared in anticipation of litigation . . . for another party or its representative," including by its "consultant" or "agent." *Id*.; *see Richey*, 632 F.3d at 567 ("The work-product doctrine covers documents or the compilation of materials prepared by agents of the attorney in preparation for litigation."). Thus, a purely technical analysis of a Bard filter prepared by one of Plaintiffs' consulting experts in anticipation of litigation would be work product regardless of whether it included litigation strategy or legal analysis. Indeed, when work product must be disclosed under Rule 26 for substantial need, courts are directed to withhold "mental impressions, conclusions, opinions, or legal theories of a party's attorney or other representative concerning the litigation," making clear that work product includes more than this kind of legal analysis. Fed. R. Civ. P. 26(b)(3)(B).

Plaintiffs contend that the Report is not work product because litigation was not "imminent." Doc. 379 at 16-17. But Plaintiffs cite no authority for the proposition that work product protection applies only when litigation is imminent. The test is whether litigation was reasonably anticipated, and the adverse events and litigation threats of 2004 clearly satisfied this requirement.

Plaintiffs also argue that Bard did not reasonably anticipate litigation when it retained Dr. Lehmann because Bard had not yet implemented a litigation hold on documents and electronically stored information. *Id*. at 16. But even if Bard failed to implement a timely litigation hold as Plaintiffs contend - an issue the Court does not decide at this time - that fact would not prove that litigation was not reasonably anticipated. Parties can fail to comply with preservation obligations in the face of reasonably anticipated litigation. Plaintiffs do not dispute that deaths and injuries from *9 the Recovery Filter had been reported in 2004, that Bard had received demands for compensation, or that Bard had put its insurance carrier on notice of possible claims. The totality of the circumstances clearly shows that litigation was reasonably anticipated.

Plaintiffs argue that the Report was prepared in the ordinary course of business because "Dr. Lehmann's work was well underway long before he was given a contract with the Law Department." Doc. 379 at 17. While there is no dispute that Dr. Lehmann worked as Bard's acting medical director in late 2003 and early 2004, Dr. Lehmann testified in the *Alexander* hearing that this role terminated on the hiring of Dr. Ciavarella in May 2004 and that, other than occasional communications with Dr. Ciavarella, he performed no work for Bard until November 2004. Doc. 319-2 at 93-98. Dr. Lehmann also testified that the work he performed as acting medical director was substantially different from the work done to produce the Report. *Id*. Plaintiffs present no direct evidence to contradict this testimony. Plaintiffs instead identify several documents as indirect evidence that Dr.

Lehmann's work as acting medical director was related to his Law Department work that culminated in the Report: the March 10, 2004 HHE (Doc. 445-1 at 4-15); an April 15, 2004 email (Doc. 443-1 at 5-8); and the April 27, 2004 HHE (Doc. 414 at 3-15).

Dr. Lehmann's testimony directly addressed the differences between these HHEs and the Report. Dr. Lehmann testified that: HHEs were prepared pursuant to Bard's regulatory obligations, while the Report was not; the purpose of HHEs was to "guide potential market actions or corrections," while the purpose of the Report was to provide guidance on Bard's risk and overall exposure from adverse events associated with the Recovery Filter; HHEs considered a product's risks and benefits, while the Report considered only the Recovery Filter's risks; HHEs each focused on a single adverse event involving migration, while the Report dealt with all adverse events associated with the Recovery Filter; and the Report involved detailed statistical analysis personally performed by Dr. Lehmann, while HHEs did not. *See* Doc. 319-2 at 96-98. The Court's close review of the
10 HHEs and the Report confirms these distinctions. *10

The four-page HHE dated March 10, 2004 was prepared by Dr. Lehmann after the February 2004 death of a patient due to the migration of a massive blood clot and a Recovery Filter to the patient's heart.[3] Doc. 445-1 at 5. The HHE focused on this single adverse event and discussed the placement of the filter, the patient's risk factors, the autopsy report, and other medical evidence. *Id*. at 5-6. The HHE included a short review of other Recovery Filter migration complaints. *Id*. at 6. The HHE then addressed the following subjects: human exposure to the problem, general consequences, population exposed to risk, mitigating or predisposing factors, nature and seriousness of the risk, likelihood of occurrence, likelihood of harm, whether the product is essential to health, whether there are available alternatives, whether the problem must be corrected surgically, whether the problem is expected and within an acceptable statistical range, whether the problem can be field corrected, whether the problem is obvious to the user, whether the product can continue to be used with proper warnings, and whether the device is used only by specially-trained health care professionals. *See id*. at 6-8. The HHE concluded that "[t]here have been 3 migrations of the Recovery VC Filter in which the device ended up in or near the heart, with one fatality, in an estimated 6,402 sales through March 2, 2004, for a rate of 0.05%." *Id*. This is the only statistical calculation in the HHE, and includes a warning that comparative assessments using data from "the MAUDE database do not yield reliable quantitative estimates." *Id*. With respect to whether the problem is expected and within an acceptable statistical range, the HHE stated that "[e]stimates based on MAUDE and sales data suggest that there is no significant difference in the rates of these complications between devices, including the Recovery" Filter. *Id*. at 8.

3 The April 27, 2004 HHE is similar to the March HHE in all relevant respects.

The Report has a broader focus. It contains statistical analyses relating to selected types of adverse events associated with the Recovery Filter and other filters on the market, including rates of reported filter fractures, caval perforation, filter movement, filter embolization, and filter embolization deaths. Doc. 335 at 13. Using
11 MAUDE data, *11 actual sales data for the Recovery Filter, and estimated sales data for other filters, the Report calculates and compares adverse event reporting rates for the Recovery Filter and seven other types of filters. *Id*. at 19-20. The Report then uses the reporting rates to calculate relative risks for each of the eight filters for different types of adverse events. *Id*. at 21-27. The Report also reviews Bard's bench testing data that was used to determine migration resistance for each of the eight filters, and compares the bench data to the frequency of adverse events reported in the MAUDE data base. *Id*. at 31-33. The Report concludes that "[t]his data and analysis provides two significant signals (MAUDE rates and bench test data) that further investigation of the Recovery VCF filter performance in relation to migration and fracture is urgently warranted." *Id*. at 16. This is

a different focus than the HHEs. True, there are some similarities between the HHEs and the Report, but the documents clearly serve different purposes and their substantial differences corroborate Dr. Lehmann's testimony that the Report was a different undertaking than the work he did as acting medical director.

In the April 15, 2004 email relied on by Plaintiffs, Dr. Lehmann stated that "[c]omparison with other filters is problematic in many ways, and we should avoid / downplay this as much as possible." Doc. 443-1 at 5. Plaintiffs argue that this statement shows that Dr. Lehmann performed the same work as acting medical director that he did in preparing the Report. But the fact that Dr. Lehmann - or others within Bard - did some comparisons with other filters while he was acting as Bard's medical director does not prove that the detailed statistical analysis and evaluation of bench-testing results contained in the Report were done before his contract with the Law Department or for another reason. Nor have Plaintiffs cited any authority for the proposition that work product is not entitled to protection if it is similar in some way to work the person has done before. Rather, the test is whether the Report "would not have been created in substantially similar form but for the prospect of litigation." *Richey*, 632 F.3d at 568. After examining the HHEs and the April 2004 email, and comparing them with the Report, the Court finds that they do not undercut the testimony of Dr. Lehmann that
12 the *12 Report was prepared at the behest of the Law Department and would not have been created in substantially similar form otherwise.

Finally, Plaintiffs cite language from the December 2004 draft RAP which states that Dr. Lehmann "was commissioned by *Corporate Senior Management* to provide an independent study of the risk/benefit of the [Recovery Filter] in bariatric patients." Doc. 379 at 9 (emphasis added by Plaintiffs). Plaintiffs argue that this proves Dr. Lehmann was hired by the business, not by the legal department, to prepare the Report. But Dr. Lehmann's consulting contract was signed by Judith Reinsdorf, Bard's Vice President, General Counsel, and Secretary. Doc. 335 at 8. She clearly qualified as "Corporate Senior Management," as stated in the draft RAP. She also was Bard's lead in-house lawyer. The Court cannot conclude that the statement in the draft RAP is somehow inconsistent with the fact that the Report was prepared at the request of the Law Department and in anticipation of litigation.[4]

> 4 What is more, this language did not appear in the January 4, 2005 final version of the RAP. *See* Doc. 306-1 at 43-44 ("As part of the ongoing evaluation of [the Recovery Filter], Bard requested an independent study of the risks and benefits of the [Recovery Filter], with an emphasis on its use in bariatric surgery and trauma patients.").

In summary, the Court finds that the clear threat of litigation in 2004, Dr. Lehmann's retention by the Law Department in November of that year, the contract he signed with Bard's general counsel, the scope of work be performed under the contract, and the clear labeling of the Report as work product all support a finding that the Report was prepared because of anticipated litigation. Dr. Lehmann testified that his work in late 2003 and early 2004 as acting medical director was different than the work he did under the contract, and the documents cited by Plaintiffs do not undercut that testimony. To be sure, there are some general similarities between the HHEs and the Report, and the Report was used for some business purposes, but these facts do not contradict the clear evidence that the Report "would not have been created in substantially similar form but for the prospect of litigation." *Richey*, 632 F.3d at 568. The Court finds no evidence to support Plaintiffs' suggestion
13 that the work product label for the Report was some kind of *13 grand ruse, implemented to hide unfavorable information. Based on the totality of the circumstances, the Court concludes that the Report was prepared "because of" anticipated litigation and is protected by the work-product doctrine. Fed. R. Civ. P. 26(b)(3)(A); *Richey*, 632 F.3d at 567-68.

B. Plaintiffs have not shown substantial need or undue hardship.

Work product protection is not absolute. A protected but otherwise discoverable document may be obtained in discovery if "the party shows that it has substantial need for the materials to prepare its case and cannot, without undue hardship, obtain their substantial equivalent by other means." Fed. R. Civ. P. 26(b)(3)(A). The Advisory Committee has made clear that a "special showing" is required. *See Bickler v. Senior Lifestyle Corp.*, 266 F.R.D. 379, 384 (D. Ariz. 2010) (citing Fed. R. Civ. P. 26(b)(3) advisory committee's note (1970)).

Bard argues that Plaintiffs have full access to all of the data analyzed in Dr. Lehmann's Report and that their experts can - and already have in some of the consolidated cases - perform the same analysis. Plaintiffs do not disagree, but instead attempt to show their substantial need by arguing this:

> Yes, Plaintiffs can analyze the same data Dr. Lehmann did. Plaintiffs in other cases have even hired experts to do the same work. But Plaintiffs should not be required to present the evidence in this cumbersome fashion and incur the expense and delay associated with hiring an independent expert simply to show what Bard knew as of December 2004 and communicated to several high-ranking officials in its corporation. The Report does all of that. Why waste days of trial (in every MDL case remanded for trial) with the concomitant strain on judicial and party resources to employ, prepare, present, and depose experts, along with the inevitable *Daubert* hearing exercise, when all that same information is in one report provided to several Bard employees primarily used to comply with Bard's reporting requirements to the FDA?

Doc. 379 at 28.

The Court finds this argument wholly unpersuasive. Plaintiffs essentially concede that they can create the substantial equivalent of the Report through their own experts, but argue - in this substantial and well-funded
14 MDL proceeding - that they should not be *14 put to the time and expense of retaining their own experts. If this were a sufficient "special showing" to overcome work product protection, *Bickler*, 266 F.R.D. at 384, the protection would be lost in every case where the opposing side would have to expend meaningful resources to obtain the substantial equivalent of the work product. This is not the law. *See*, *e.g.*, *Fletcher v. Union Pac. R.R. Co.*, 194 F.R.D. 666, 671 (S.D. Cal. 2000) (citing 8 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2025, at 374, n.15 (3d ed. 2015)) (finding "mere[] expense or inconvenience" insufficient to constitute undue hardship).

Plaintiffs asserted during oral argument that there is a fact they cannot prove through their own experts: that Bard *knew* of Dr. Lehmann's unfavorable conclusions. But Plaintiffs' briefing on this issue suggestions otherwise: "Plaintiffs should not be required to . . . incur the expense and delay associated with hiring an independent expert simply to show what Bard *knew* as of December 2004." Doc. 379 at 28 (emphasis added). What is more, Plaintiffs' briefing includes many cites to evidence they claim shows that Bard knew about the problems arising from its filters, including a statement in which Dr. Lehmann, in his role as acting medical director, allegedly was urging Bard to downplay the problem. *See* Doc. 443-1 at 5 ("Bottom line: good filter, severe case, bad outcome, deep regret. This is the simple story we should repeat again and again. Comparison with other filters is problematic in many ways, and we should avoid / downplay this as much as possible."). Plaintiffs asserted in oral argument that Dr. Lehmann's report would make this point even more credibly, but the Court cannot conclude that enhanced credibility satisfies the special showing required to overcome work product protection. *See Baker v. Gen. Motors Corp.*, 209 F.3d 1051, 1054 (8th Cir. 2000) ("A party also does not demonstrate substantial need when it merely seeks corroborative evidence.").

It is undisputed that Plaintiffs have access to the same data that Dr. Lehmann relied on in creating the Report. Docs. 306 at 14; 379 at 28. Further, "Plaintiffs in other cases have even hired experts to do the same work." Doc. 379 at 28; *see* Doc. 319-2 at *15 143-64 (expert report of Dr. Michael Freeman). Plaintiffs have not made the showing of substantial need or undue hardship required to overcome the Report's work product protection.

C. Bard did not waive the Report's work product protection.

Plaintiffs argue that Bard waived any claim to work product protection by (1) internal distribution of the report to 12 Bard employees, (2) disclosure of the report in the *Phillips* trial in the District of Nevada, (3) attempting to use work product protection as both a sword and a shield, and (4) using the Report in furtherance of a crime or fraud. *See* Doc. 379 at 20-27. The Court will address each argument separately.

1. Internal distribution of the Report.

"Courts have recognized that work product protection may be lost when the disclosure substantially increases the opportunity for potential adversaries to obtain the information." *Bickler*, 266 F.R.D. at 384 (quotation marks and citation omitted). Bard contends that its distribution of the Report to 12 internal employees did not substantially increase the opportunity for Plaintiffs to obtain the Report. The Court agrees.

Passero distributed the Report to five people, including Bard's general counsel, with instructions that it was confidential and distribution "should be limited." Doc. 319-2 at 3, ¶ 11, 36-37. Passero testified that she distributed the report internally because the Report recommended that Bard promptly take certain steps and she thought it important to give it "to people who would know what to do with that information." *Id*. at 37. Eventually, the Report was distributed to a total of 12 Bard employees. *See* Doc. 319-2 at 140-41, ¶¶ 3-4.

Plaintiffs argue that the Report was circulated without restrictions. They cite deposition testimony of Dr. Ciavarella that "he received the Report 'without restriction' as to its use," and that he was "*never instructed that the Report was secret or prepared in anticipation of litigation*." Doc. 379 at 10 (emphasis by Plaintiffs). Plaintiffs' Exhibit 5 contains several pages of Dr. Ciavarella's deposition transcript, but none of them contains this testimony. *See* Doc. 445-2 at 1-9. The Court therefore cannot consider Ciavarella's *16 statement in context. But even if it was made as quoted by Plaintiffs and is accepted as true, the Court cannot conclude that one high-level employee's receipt of the Report without Passero's restrictions substantially increased the risk that the Report would be distributed outside of Bard. Every page of the Report was labeled "[p]rivileged and confidential" and "[a]ttorney work product." Doc. 335 at 13-46. In addition, Bard's internal policies state that communications between Bard's legal counsel and its employees are to be kept confidential, as are documents created in anticipation of litigation. Doc. 319-2 at 2, ¶ 5.

The Court concludes that Bard's internal distribution of the Report to 12 employees did not substantially increase the opportunity for Plaintiffs or others outside of Bard to obtain the Report. *Bickler*, 266 F.R.D. at 384.

2. Disclosures of the Report in the *Phillips* trial.

Courts have been willing to preserve a document's work product protection where an earlier disclosure of the document was compelled. *Bickler*, 266 F.R.D. at 384 (citation omitted); *see also Shields v. Sturm, Ruger & Co.*, 864 F.2d 379, 382 (5th Cir. 1989) ("When a party is compelled to disclose privileged work product and does so only after objecting and taking other reasonable steps to protect the privilege, one court's disregard of the privileged character of the material does not waive the privilege before another court."). In *Phillips v. Bard*, No.

3:12-CV-344-RCJ-WGC (D. Nev. Feb. 2, 2015), the Report was admitted into evidence during trial over Bard's work product objection. *See* Doc. 306-1 at 150-55; 159-60. Bard argues that this compelled disclosure did not amount to waiver. The Court agrees.

Bard took reasonable steps to protect the Report's confidential nature during the *Phillips* trial. Bard objected to the Report's use at trial, argued against its admission during a hearing in the middle of trial, and objected again when the Report was actually introduced in evidence. *See* Doc. 306-1 at 150-55, 159-60. The Court is not persuaded by Plaintiffs' argument that "Bard failed to timely request that [the] Report (and other trial exhibits) be sealed." Doc. 379 at 27. Bard actively opposed the use of the Report *17 during trial and moved to seal the Report at the conclusion of the trial. Doc. 412 at 15. Bard's compelled disclosure was not a waiver of its work product protection. *Bickler*, 266 F.R.D. at 384; *Shields*, 864 F.2d at 382.

3. Sword and shield argument.

The attorney-client privilege and work product protection may not be used as both a sword and a shield. "Where a party raises a claim which in fairness requires disclosure of the protected communication, the privilege may be implicitly waived." *Columbia Pictures Television*, *Inc*. *v*. *Krypton Broad*. *of Birmingham*, *Inc*., 259 F.3d 1186, 1196 (9th Cir. 2001) (quotation marks and citations omitted).

Plaintiffs assert that Bard has selectively quoted the Report in several documents, including the December 17, 2004 HHE (Doc. 306-1 at 52-56) and the January 4, 2005 RAP (*id*. at 39-50). Both the HHE and the RAP do repeat the Report's findings that the Recovery Filter was experiencing significantly higher reporting rates of adverse events than comparable filters. *See id*. at 44, 53. The documents also convey some of the Report's limitations, such as the lack of reliable data and the need to conduct follow-up research. *See id*. But Plaintiffs do not show how this use of the Report constitutes a sword. The sword-shield rulings stand for basic fairness - a party should not be allowed to use work product affirmatively to gain some advantage in litigation, and at the same time withhold the work product from scrutiny by asserting the work product protection. The use of data and conclusions from the Report in internal Bard documents, such as the RAPs and the HHEs, does not amount to such affirmative use, and fairness therefore does not demand disclosure of the full document.

Plaintiffs also point to representations that Bard made to "the FDA and the medical community that the Recovery [Filter] failed at the same rate as competition models while knowing from the Report that this was not true." Doc. 379 at 21-22 (citing Doc. 443-1 at 5-8). For support, Plaintiffs cite an April 15, 2004 email from Dr. Lehmann. Doc. 443-1 at 5-8. But this email does not support Plaintiffs' position. At the time, Dr. Lehmann could not have known from the Report that the Recovery Filter was *18 failing at higher rates than its competitors because the Report had not been created - it was not issued for another eight months. What is more, making a public statement contrary to what is contained in work product does not constitute use of the work product as a sword. The work product is not used at all in such a communication. The work product may contradict the public statement, but the sword-shield basis for waiver does not turn on impeachment value; it turns on the unfairness of using a document to make an affirmative assertion for one's advantage while simultaneously withholding the document from scrutiny. Dr. Lehmann's email did not do that.

4. Crime-fraud exception.

The attorney-client privilege and work product protection do not apply to communications made or work done in furtherance of a crime or fraud. *In re Grand Jury Proceedings*, 87 F.3d 377, 381 (9th Cir. 1996); *United States v*. *Zolin*, 491 U.S. 554, 562-63 (1989); *In re Richard Roe*, *Inc*., 68 F.3d 38, 40 n.2 (2d Cir. 1995) (work product). A party that invokes the crime-fraud exception must show that: (1) "the client was engaged in or

planning a criminal or fraudulent scheme when it sought the advice of counsel to further the scheme," and (2) the work product was sufficiently related to and was made in furtherance of the intended, or present, continuing illegality. *In re Napster*, *Inc. Copyright Litig.*, 479 F.3d 1078, 1090 (9th Cir. 2007) (quotation marks and citations omitted), *abrogated on other grounds by Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100 (2009).

Plaintiffs argue that the crime-fraud exception can be established merely by showing "reasonable cause" to believe that the legal services were used to promote an unlawful scheme. Doc. 379 at 22. But the case law cited by Plaintiffs concerns grand jury proceedings, and the Ninth Circuit has noted that there is reason to apply a lower standard in such proceedings - which require speed and simplicity - than in civil cases. *In re Napster*, 479 F.3d at 1094. The Ninth Circuit has held that a party in a civil case must establish the crime-fraud exception by a preponderance of the evidence when challenging attorney-client communications. *Id*. at 1094-95 ("For
19 several reasons, we *19 conclude that in a civil case the burden of proof that must be carried by a party seeking outright disclosure of attorney-client communications under the crime-fraud exception should be preponderance of the evidence."). Plaintiffs do not address this holding, nor do they provide reason for the Court to conclude that a different standard should apply to work product protection. The Court concludes that the preponderance of the evidence standard should be applied to this work product challenge.[5]

> 5 The Court finds that the four reasons given by the Ninth Circuit for adopting the preponderance standard for challenges to attorney-client communications apply as well to work product: (1) the importance of the work product protection has been recognized since *Hickman v. Taylor*, 329 U.S. 495 (1947); (2) the *prima facie* standard is not inconsistent with a preponderance standard; (3) Federal Rule of Evidence 104(a) applies to admissibility questions regarding work product and calls for a preponderance standard; and (4) the problem of limited access to proof is mitigated by the possibility of *in camera* review as well as the substantial need exception to work product protection. *See In re Napster*, 479 F.3d at 1095-96.

In an opening footnote on this issue, Plaintiffs cite a recall of another Bard product in 1990, criminal charges brought in 1993 against Bard related to other products, two MDL proceedings against Bard, and Bard's settlement of a qui tam lawsuit. Doc. 379 at 23-24 n.15. Plaintiffs provide no evidence linking these events to this case. Moreover, the crime-fraud exception does not apply to past conduct. *Zolin*, 491 U.S. at 562-63.

Plaintiffs assert that Bard committed a "cover up of adverse testing, injuries, and deaths associated with its filters," which they contend is both fraudulent and criminal. Doc. 379 at 24. Plaintiffs produce the following evidence: Bard learned of the first reported death associated with the Recovery Filter in February 2004; in response, Bard formed a Crisis Communication Team; in April 2004, a Bard executive emailed Dr. Lehmann expressing concern about the Recovery Filter's mortality rate; in July 2004, Bard issued an HHE that showed the Recovery Filter had a failure rate 28 times higher than other filters; the Report showed high rates of adverse events associated with the Recovery Filter; and witnesses have testified about the Recovery Filter's high rate of adverse events. *Id*. at 24-25. Plaintiffs assert that Bard committed fraud by not reporting this information to the FDA, doctors, and patients, and by failing to issue a product recall.

20 Bard presents contrary evidence and arguments. Doc. 412 at 13. Bard notes that *20 the two deaths, which led to creation of the Crisis Communications Team, were both reported to the FDA. Doc. 319 at 32, 44. In addition, the adverse outcome rates set forth in the Report were based on adverse events in the MAUDE database, which is maintained by the FDA. Doc. 335 at 14. Bard thus asserts that FDA was fully aware of the deaths and adverse events Plaintiffs rely on for their fraud allegations. Bard also cites evidence of additional adverse-event-rate disclosures to the FDA in October 2004. Doc. 412 at 13. Bard further cites evidence that migration rates for the Recovery Filter were well below rates reported in medical literature for all IVC filters (Doc. 412 at

12), and that the overall adverse event rates for the Recovery Filter were small (*id*.). Finally, Bard notes that the FDA, which is aware of Recovery Filter adverse event rates, has never suggested that the Recovery Filter be recalled. *Id*. at 13.

Given the parties' conflicting evidence and allegations, the Court cannot find by a preponderance of the evidence that Bard engaged in fraudulent or criminal conduct. Plaintiffs have failed to carry their burden of proving the crime-fraud exception.

IV. Additional discovery or evidentiary hearing.

If the Court is inclined to reject their arguments, Plaintiffs ask for additional discovery and an evidentiary hearing. The Court declines this request for two reasons.

First, this issue has already been litigated in many state and federal courts that preceded this MDL. Thirteen court decisions have found the Report to be protected work product.[6] Four have found the Report subject to
21 discovery.[7] The Court does not find *21 these four decisions persuasive. In one, *Giordano v. Bard*, the California Superior Court denied Bard's attempt to clawback the inadvertently produced Report without providing any comment or analysis. Doc. 306 at 4-5 n.2. In two others - *Tillman v. Bard* and *Payne v. Bard* - Magistrate Judge Toomey of the Middle District of Florida applied the more rigorous "primary purpose" work product standard, which protects "documents prepared principally or exclusively to assist in anticipated or ongoing litigation." *See* Doc. 443-1 at 110-132. The fourth case, *Phillips v. Bard*, actually involved two conflicting decisions in Nevada Federal District Court. After briefing and a hearing, Magistrate Judge Cobb held that the Report was protected work product. *See* Doc. 306-1 at 120-24, 133, 139-141. During trial, the plaintiff in *Phillips* sought to place the Report in evidence, Bard objected, and District Judge Jones - without the benefit of briefing - overruled the objection. *Id*. at 152-54. Thus, the four decisions which found the Report discoverable either were made without explanation, applied a different legal standard than the Ninth Circuit's "because of" test, or were made without briefing.

6 *Alexander v. Bard*, No. 3:12-CV-05187-O-BK (N.D. Tex.); *Barkley v. Bard*, No. CV2011-021250 (Ariz. Super. Ct.); *Carr v. Bard*, 297 F.R.D. 328 (N.D. Ohio 2014); *Cason v. Bard*, No. 1:12-CV-01288-MHS (N.D. Ga.); *Ebert v. Bard*, No. 5:12-CV-01253-LS, 2014 WL 1632155 (E.D. Pa. Apr. 24, 2014); *Jones v. Bard*, No. 3:13-CV-00599-K (N.D. Tex); *Kilver v. Bard*, No. 1:13-CV-01219-MMM-JEH (C.D. Ill.); *Leus v. Bard*, No. 13-CV-00585-W-GAF (W.D. Mo.); *Peterson v. Bard*, No. 3:13-CV-00528-JJR-RLB (M.D. La.); *Phillips v. Bard*, 290 F.R.D. 615 (D. Nev. 2013) (Cobb, M.J.); *Rackliff v. Bard*, No. CV2011-021206 (Ariz. Super. Ct.); *Stesney v. Bard*, No. CV2012-006103 (Ariz. Super. Ct.); *Towlson v. Bard*, No. CV2011-022334 (Ariz. Super Ct.).

7 *Giordano v. Bard*, No. 37-2011-00069363-CU-PO-EC (Cal. Super. Ct.); *Payne v. Bard*, No. 6:11-CV-01582-ORL-37GJK (M.D. Fla.); *Phillips v. Bard*, No. 3:12-CV-00344-RCJ-WGC (D. Nev.) (Jones, J.); *Tillman v. Bard*, No. 3:13-CV-00222-J-34JBT (M.D. Fla.). --------

Moreover, the fact that the Report has been litigated more than 15 times in a wide range of courts shows that it has been the subject to ample discovery and argument. And as noted above, it was the subject of an evidentiary hearing in *Alexander v. Bard*, in the Northern District of Texas. The plaintiff's lawyers in that hearing are members of the Plaintiffs' Steering Committee in this MDL. *See* Doc. 319-2 at 7. Bard was represented by the same lawyers who are representing it in this MDL. *See id*. at 8.

Given this prior litigation history, the Court cannot conclude that Plaintiffs have been disadvantaged in any way by a lack of discovery or opportunity to develop their arguments. *See* Fed. R. Civ. P. 26(b)(2)(C)(ii).

Second, the evidence the Court has considered in making this decision does not suggest that an evidentiary hearing is needed. The testimony of Passero and Lehmann is consistent with the documentary evidence. Plaintiffs have presented no evidence that causes the Court to think this is a difficult evidentiary issue requiring
22 in-person credibility determinations. In short, this is not a close question. The Court therefore will *22 deny Plaintiffs' request for additional discovery and an evidentiary hearing. There are more relevant and productive tasks to be completed in this MDL.

V. Effect of this ruling on prior rulings in other cases.

The parties agree that this Court's ruling should not affect any prior rulings on this issue in other cases. *See* Docs. 306 at 21-23; 379 at 29-30. The Court agrees. This ruling shall operate prospectively only, and shall apply in all MDL cases where the issue has not previously been decided.

VI. Conclusion.

The Court finds that Bard will suffer specific prejudice or harm if Plaintiffs are permitted to use a Report entitled to work product protection in discovery or at trial. Bard has shown good cause for a protective order. *San Jose Mercury News*, 187 F.3d at 1103; *Phillips*, 307 F.3d at 1210-11.

IT IS ORDERED:

1. Defendants' motion for a protective order (Doc. 306) is **granted.** Dr. John Lehmann's December 15, 2004, report is protected work product pursuant to Federal Rule of Civil Procedure 26(b)(3). Plaintiffs may not use or rely on the report in any pending or future case in this MDL. This order shall not affect any transferor courts' previous orders regarding the discoverability or use of Dr. Lehmann's report.

2. Defendants' unopposed motion to seal (Doc. 413) is **granted.** The Clerk is directed to accept for filing under seal the document lodged on the Court's docket as Doc. 414.

Dated this 11th day of February, 2016.

/s/_____

David G. Campbell

United States District Judge