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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In re Bard IVC Filters Products Liability Litigation	NO. MD-15-02641-PHX-DGC **THE PARTIES' JOINT REPORT PURSUANT TO CASE MANAGEMENT ORDER NO. 2**

In accordance with Paragraph D of Case Management Order No. 2 [Dkt. No. 249], the Parties hereby submit their Joint Report regarding their discussions concerning the "Second Phase" or "Phase II" of discovery.

I. DISCOVERY ACCOMPLISHED DURING THE FIRST PHASE

Pursuant to Paragraph C of Case Management Order No. 2 [Dkt. No. 249], the Parties have worked together and accomplished the following discovery during the "First-Phase" discovery period:

- On November 10, 2015, Bard produced communications between Bard and the FDA concerning the FDA's investigation, 483 Letters, and Warning Letter, as ordered by the Court;
- Between November 10, 2015, through January 15, 2016, Bard supplemented its production of communications between Bard and the

FDA concerning the FDA's investigation, 483 Letters, and Warning Letter, with all later communications subsequent to its initial production;

- On December 15, 2015, Plaintiffs took the 30(b)(6) deposition of Bard concerning the FDA's investigation, 483 Letters, and Warning Letter. Mr. Chad Modra appeared as Bard's 30(b)(6) witness, and he was deposed for seven hours;
- On January 20, 2016, Plaintiffs, with the agreement of Bard, continued the 30(b)(6) deposition of Bard concerning the FDA's investigation, 483 Letters, and Warning Letter. Mr. Modra again appeared as Bard's 30(b)(6) witness, and he was deposed for an additional three hours;
- On December 31, 2015, Bard voluntarily agreed to produce all of its available documentation concerning Ms. Kay Fuller. Bard supplemented this production on January 6, and January 7, 2016;
- On January 11, 2016, the parties deposed Ms. Fuller; and
- On January 15, 2016, Bard produced an updated production of its complaint files and adverse event tracking system relating to the Recovery®, G2®, G2®X, G2® Express, Eclipse®, Meridian®, and Denali® Filters.

II. THE PARTIES' PROPOSAL FOR PHASE II DISCOVERY

In preparation for the January 29, 2016, Case Management Conference, the parties discussed and ultimately agreed upon an organizational approach for the second phase of discovery in this MDL. The parties propose to divide the second phase into two separate tracks: one for those certain advanced cases previously identified in the parties' October 9, 2015, Joint Report to the Court that are near ready for trial (hereafter called the "First Track Cases"); and a separate track for the newer and to-be-filed cases (hereafter called the "Second Track Cases"). The parties propose for each track to have a separate set of deadlines to advance the First Track Cases toward trial and to accomplish

common-fact discovery for the Second Track Cases. The parties would have the two tracks run parallel so as to permit advancement of both sets of cases.

1. Proposed Schedule for First Track Cases

The First Track Cases sit in a different position relative to completion of discovery and their readiness for trial than the other more recently and to-be-filed cases in this MDL. For the former cases, the parties propose to (a) complete the remaining discovery for those cases, (b) permit any expert supplementation necessary as a result of that discovery, and then (c) get those matters to trial – either in front of this Court if the parties waive *Lexecon* or in their original Districts upon remand.

Phase II discovery in the First Track Cases will complete discovery regarding (a) the issues relating to and arising out of the FDA's July 13, 2015, Warning Letter to Bard and (b) issues relating to Kay Fuller. The parties have not agreed on the amount of discovery on these two issues. Their competing positions with respect to what discovery the Court should permit are addressed in Section III.3 and IV.1 of this Joint Report.

To accomplish this, the parties have agreed that it makes sense to have a schedule as follows for the First Track Cases:

- February 1, 2016 – Commencement of Phase II discovery
- July 1, 2016 – Close of Phase II discovery
- July 31, 2016 – Plaintiffs' supplemental expert reports due
- August 31, 2016 – Defendants' supplemental expert reports due
- September 16, 2016 – Plaintiffs' supplemental rebuttal expert reports due
- November 4, 2016 – Close of expert discovery
- November 11, 2016 – Joint submission regarding additional motions for Fast Track Cases

This proposed schedule will allow these cases to be ready for trial in early 2017.

2. Proposed Schedule for Second Track Cases/Common Discovery

The parties agree that the remaining current and future cases in this MDL (the Second Track Cases) sit in a different position due to their relative immaturity. For those cases, the parties will need to conduct common discovery, to disclose and to conduct discovery on common expert issues, to identify potential bellwether cases, and to have trial depositions of common witnesses for the non-bellwether cases.

Though the Second Track Cases require different discovery, the parties agree that it would be inefficient to delay discovery as to those cases until completion of the First Track Cases. Accordingly, the parties propose to commence common discovery on these cases and to run that discovery parallel to the above-proposed schedule for the First Track Cases. However, because of the different and broader needs in those cases, there should be a different schedule.

As to the Second Track Cases, the parties propose the following schedule:

- February 1, 2016 – Commencement of Phase II discovery
- October 28, 2016 – Close of Phase II discovery regarding general issues
- December 16, 2016 – Plaintiffs' common-issue expert reports due
- February 3, 2017 – Defendants' common-issue expert reports due
- March 3, 2017 – Plaintiffs' common-issue rebuttal expert reports due
- May 19, 2017 – Close of common-issue expert discovery

3. Bellwether Selection Process and Party Fact Sheets

The parties have had preliminary discussions regarding formulating a bellwether selection process. The parties propose to make a joint submission on March 1, 2016, that addresses the bellwether process and related subjects, including party fact sheets and any deadlines for case-specific discovery in any potential bellwether cases.

III. ISSUES IDENTIFIED BY THE COURT

1. Updated Collections and Productions of Previously Searched "Custodians" and ESI Sources:

a. Plaintiffs' Position:

Defendants contend that they have produced over time to Plaintiffs in individual cases substantial documents and ESI collected from their information systems over the years. In order to assess the sufficiency of what Defendants have previously produced and the manner in which they identified, collected, and reviewed it for production, Plaintiffs have requested that Defendants provide them with the following information:

> i) the architecture of Defendants' information systems, including the types of information Defendants maintain within that system, and where potentially relevant information is typically kept within it;
>
> ii) Defendants' collection of ESI, including dates of collection(s), locations from which Defendants collected ESI, and related information as to what was collected, from where, and what was not collected from locations where relevant information resides (or resided);
>
> iii) the steps Defendants have taken to preserve ESI that exists in locations where one would reasonably expect to find relevant information; and
>
> iv) the process(es) by which Defendants reviewed the collected ESI, resulting in the pool of documents that Defendants have produced.

To date, Plaintiffs have not received sufficient or complete information as to any of these subjects. Until Plaintiffs receive this information and can ascertain the adequacy of Defendants' prior productions, Plaintiffs cannot reasonably determine what is required to "update" the prior productions, if anything.

Additionally, based primarily on the prior productions, Defendants argue extensively for very restricted document and ESI discovery in this MDL. But, those productions were made years ago in individual cases on individual products and did not involve the Plaintiffs in this MDL (or most, if not all, of their attorneys). And Defendants have not demonstrated they performed reasonable searches to locate and to produce documents that are relevant and responsive in this MDL. Until they do so, it is premature to limit Defendants' future discovery obligations for ESI.

Plaintiffs address each of these issues in turn.

i. Information systems architecture – Where is Defendants' relevant ESI?

The first step in understanding whether Defendants have taken reasonable steps to produce relevant ESI first requires knowing what information they actually possess, how they organize and store it, the locations within their information systems that are reasonably likely to contain information regarding IVC filters and the other issues in this MDL, and where Defendants' personnel who are or were involved in with IVC filters would have created, maintained, accessed, or stored relevant information.

This type of information is relevant and discoverable by Plaintiffs. *See, e.g., Nissan N. Am., Inc. v. Johnson Elec. N. Am., Inc.*, 2011 WL 1002835, at *4 (E.D. Mich. Feb. 17, 2011) (permitting discovery of a "data map" because counsel should "have access to information from which it could readily discern what data is stored on each of Plaintiff's systems, who uses the systems, the retention of the data stored and where and how the data is backed up or archived"); *Heartland Surgical Specialty Hosp., LLC v. Midwest Div., Inc.*, 2007 WL 1054279, at *4 (D. Kan. Apr. 9, 2007) (allowing 30(b)(6) deposition covering, among other things, the location of computer servers, what was searched for responsive documents, and instructions provided to e-discovery vendor).

To that end, Plaintiffs requested that Defendants voluntarily disclose this information. In response, Defendants provided some policies and procedures and the transcript of a 2012 deposition of a Bard employee in the Avaulta Pelvic Support Systems Product Liability Litigation MDL (No. 2187) (the "Olenoski deposition"). But, neither the policies nor the testimony demonstrate the structure of Defendants' information systems or where relevant ESI is reasonably likely to exist within that structure.

For example, Mr. Olenoski testified (and Defendants have separately disclosed) that, among their systems, Defendants utilized a shared document management system, called QUMAS. According to Mr. Olenoski, QUMAS was organized as a tiered-folder system and that the folder-system structure was visible from within the system.

However, neither the Olenoski deposition nor any other information from Defendants disclose that tiered-folder organization or how different information was stored within it. Moreover, Defendants have disclosed that they, in fact, no longer utilize QUMAS and, in 2010, moved their "controlled documents" to Master Control. Master Control does not retain QUMAS's tiered-folder structure, and Defendants apparently did not retain information as to that structure. As a result, they claim not to be able provide information as to the organization of QUMAS or its tiered folders from which they collected ESI.

Similarly, Defendants have a number of "shared drives" on which Defendants' employees access and store information. Plaintiffs asked Defendants to identify those drives and the information maintained on them. Defendants identified four drives from which they collected ESI in 2005, but no others (or even how many they have) or how information is allocated across them. Nor have they identified whether they have done anything in the intervening ten years to collect from the drives they have identified.

Indeed Defendants' response to Plaintiffs' requests for this type of information has consistently been that Plaintiffs' questions are "too broad" because "Bard is a multi-national corporation with numerous subsidiaries and divisions." But, that response only obscures what should be relatively easy information to provide. Defendants should certainly be able to identify how they have organized their information systems so that Plaintiffs can ask more detailed questions as to those parts of that system that appear more likely to contain relevant ESI.

ii. Collections - Did Defendants collect the ESI from those locations where relevant ESI is likely to exist?

Once one identifies where relevant ESI is likely to exist in Defendants' information systems, the next step is to determine whether Defendants took reasonable steps to collect the ESI from those identified locations. Here, that means disclosure or discovery of Defendants' historic collection efforts; when they performed collections; and, for each collection, the locations(s) from which information was collected,

identification of what was collected (in terms of document types and volume), and identification of what ESI was not collected from the same location(s).

On this topic, Plaintiffs requested that Defendants identify and produce all reports or documentation prepared for each collection. To the extent Defendants claim to have made production for "custodians," Plaintiffs asked Defendants to explain how they attributed documents to particular "custodians" for collection. For each collection and custodian, Plaintiffs requested the date of collection(s), the location(s) of collection, the file/document types collected, the quantity of ESI collected, and whether there was additional ESI *not* collected from the location(s).

Defendants have taken the position that Plaintiffs' requests are "far beyond the scope of discovery." Defendants are wrong; information regarding what Defendants have done to collect relevant ESI is discoverable. *See, e.g., McNearney v. Washington Dep't of Corr.*, 2012 WL 3155099, at *6 (W.D. Wash. Aug. 2, 2012) (granting motion to compel response to interrogatory seeking "the identity of persons who performed the ESI searches, the ESI storage locations that were searched, and the search terms that were used"); *S2 Automation LLC v. Micron Tech., Inc.*, 2012 WL 3656454, at *32 (D.N.M. Aug. 9, 2012) (ordering party to provide "its search strategy for identifying pertinent documents, including the procedures it used and how it interacted with its counsel to facilitate the production process"). Simply put, it is impossible to know whether Defendants have taken reasonable steps to produce (and to preserve) relevant information without knowing what ESI they collected and whether they failed to collect ESI that could be relevant. *See, e.g., Small v. University Medical Ctr. of S. Nev.*, 2014 WL 4076507, at **1, 8, 11, 16 (D. Nev. Aug. 18, 2014) (noting party's failure to collect ESI from network share files, mobile devices, and other locations where it existed as part of basis for recommendation for sanctions).

Defendants have indicated to Plaintiffs that their collection efforts have primarily taken place by or at the direction of counsel. Presumably, there exists some form of

documentation at least as to what was collected each time, from what locations, and when. To date, Plaintiffs have received conflicting reports from Defendants as to whether such collection information exists.[1]

Plaintiffs contend that Defendants should have to make full disclosure of this information for all collections they have done.

iii. Preservation - What have Defendants done to preserve ESI?

Of considerable concern for Plaintiffs is Defendants' inconsistency in their position as to when they first began efforts to preserve potentially relevant information. In their representations to this Court at the initial case management conference and in correspondence to Plaintiffs' counsel in this MDL, Defendants have represented that they issued litigation hold notices for the first time in December 2004. *See* transcript of Oct. 29, 2015, case management conference at 150 ("my client issued its first legal hold in December 2004") and Section III.11. below. However, in its briefing on the Lehmann issues, Bard has claimed that litigation actually existed or was reasonably anticipated in February of that same year. *See* Dkt. No. 306, at 5. Obviously, if the latter claim is true, then there was significant potential for the destruction of documents and ESI during the ten months between which Defendants should have begun preservation efforts and when they actually did so.

Defendants have also disclosed that they "periodically updated" their litigation holds. In conjunction with their initial failure to institute a hold, these changes raise questions regarding the scope of the initial (late) hold as well as subsequent holds, what information was captured within them, and whether there has been actual compliance with the holds. Discovery is appropriate to resolve whether Defendants taken reasonable steps to preserve relevant information. *See Cannata v. Wyndham Worldwide Corp.*, 2011

[1] On the afternoon of January 19, 2016, Defendants delivered a "collection log" that contains information regarding certain custodians and quantity (in megabytes) of data collected from them. Though a starting point, the "log" does not contain information regarding the types of ESI collected, how Defendants attributed ESI to individual custodians for purposes of collection, from where within Defendants' information systems they collected the ESI, or what information Defendants did not collect from those locations.

WL 3495987, at *3 (D. Nev. Aug. 10, 2011) (permitting discovery of litigation hold and as to "when and to whom the litigation hold letter was given, what kinds and categories of ESI were included in defendants' litigation hold letter, and what specific actions defendants' employees were instructed to take to that end").

Because discussions to date have focused on Defendants' information system architecture and their collection efforts, the parties have not yet engaged in significant substantive discussion regarding preservation issues. Plaintiffs anticipate seeking additional information from Defendants on these issues in the second phase of discovery.

iv. How did Defendants determine what ESI to produce?

Defendants have disclosed that they utilized "key term" searches across the collected ESI to cull out files and documents for review. Defendants, however, have not disclosed the algorithm they used for such searches or whether they conducted any testing of the resulting "responsive" and "non-responsive" categories (and, if they did, the results of that testing) to determine whether the key terms and algorithm(s) were reasonable.

Though there was apparently some agreement by plaintiffs in pre-MDL individual cases on the key terms Defendants used for their electronic searches, access to the algorithm Defendants used for those searches is particularly important in understanding their effectiveness. As one judge has succinctly put it, key-term searching can be akin to playing a "game of Go Fish." *Da Silva Moore v. Publicis Groupe*, 287 F.R.D. 182, 191 (S.D.N.Y. 2012) ("Key words, certainly unless they are well done and tested, are not overly useful."). As a result, when used, testing should be done to ensure its reasonableness. *See In re Seroquel Products Liability Litig.*, 244 F.R.D. 650, 662 (M.D. Fla. 2007) (Baker, M.J.) ("[W]hile key word searching is a recognized method to winnow relevant documents from large repositories, use of this technique must be a cooperative and informed process. . . . Common sense dictates that sampling and other quality assurance techniques must be employed to meet requirements of completeness.").

Defendants have also disclosed information that gives rise to additional concerns about their search methodology; a report from their ESI experts suggests that a core criterion in the selection of key terms and custodians was the resulting number of documents, not the actual efficacy of the searches.

Plaintiffs need discovery to determine what Defendants did and whether it was reasonable. Courts routinely hold that information regarding such electronic searches is discoverable. *See, e.g., Burnett v. Ford Motor Co.*, 2015 WL 4137847, at *8 (S.D.W. Va. July 8, 2015) (stating that "common sense dictates that the party conducting the search must share information regarding the universe of potentially relevant documents being preserved, and those that no longer exist, as well as the search terms used in collecting relevant documents"); *Ruiz-Bueno v. Scott*, 2013 WL 6055402, at *4 (S.D. Ohio Nov. 15, 2013) (compelling disclosure of "procedures or methods [] used to search for responsive electronically stored information, or ESI"); *Victor Stanley, Inc. v. Creative Pipe, Inc.*, 250 F.R.D. 251, 260, 262 (D. Md. 2008) ("The implementation of the methodology selected should be tested for quality assurance; and the party selecting the methodology must be prepared to explain the rationale for the method chosen to the court, demonstrate that it is appropriate for the task, and show that it was properly implemented.").

As with preservation issues, Plaintiffs have received little information in this subject matter and would seek to take such discovery in Phase II.

v. Defendants have failed to prove the reasonableness of their prior searches and productions.

Defendants' argument as to future ESI discovery starts from what they did in the past, contending they spent millions of dollars and produced millions of pages of documents in prior Bard IVC filter litigation. But those first productions happened in cases that did not involve any plaintiffs or plaintiffs' counsel presently in this MDL. As Defendants state, they had spent that money and produced those documents "[b]y the time members of the PLC began filing Bard IVC filter lawsuits in 2011." Moreover,

even the searches and productions they did thereafter did not involve the vast majority of the attorneys on the PSC in this MDL.

Significantly, the cases in which Defendants made those prior productions each involved a single plaintiff and a single device (to Plaintiffs' knowledge no individual has had claims based on multiple devices). And, in each of those cases, Defendants took the position that discovery was limited due to proportionality considerations – particularly because they involved individual plaintiffs and single devices. But now, in a setting in which the proportionality argument is significantly different given the large number of cases and with all the devices at issue, Defendants rely on their past actions in other cases (and the costs they previously incurred to defend those cases) as the grounds to reduce the discovery that Plaintiffs should be permitted to take here. That could produce absurd results.

Indeed, Defendants' arguments to restrict discovery based on proportionality rely solely on raw numbers of documents produced and costs incurred. They ignore all of the other factors relevant to proportionality – "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). Here, those include not only what Defendants have done for their prior productions (including all the significant questions addressed in this Section relating to Defendants' collection, preservation, and searches), but the significant difference in the number of claims currently filed and to be filed in this MDL, the importance of the information to those claims (which involve the health and safety of Plaintiffs and the general public), an "amount in controversy" that is dozens, if not hundreds, of times greater than Defendants have faced in individual cases, and the benefit of the discovery that Plaintiffs would seek.

Proportionality does not alter Defendants' obligation to collect and to preserve relevant documents from locations where they are reasonably likely to exist; it does not alter Defendants' obligation to conduct reasonable searches of those documents to produce responsive records. For the reasons set forth herein, Plaintiffs cannot evaluate whether Defendants' prior productions have been reasonable and where the gaps exist for which additional document and ESI discovery should be taken.

vi. Plaintiffs need transparency and discovery on ESI.

At the last case management conference, the Court expressed an expectation of transparency regarding Defendants' prior ESI productions. To date, Plaintiffs have not received that transparency. Plaintiffs need sufficient disclosure to understand where Defendants were likely to keep relevant information within their information systems, whether their ESI collection efforts were reasonably designed to capture the potential ESI from those locations, Defendants' preservation of ESI, and their search-culling methods. As such, Plaintiffs are unable to determine what "updated" or additional discovery is necessary. Plaintiffs propose to take discovery in Phase II regarding the issues identified in this Section in order to gain the understanding of what has, in fact, been done and what additional updating and discovery is necessary to bring Defendants' productions current.

b. Defendants' Position:

As a threshold matter, Bard has been and remains committed to working with the plaintiffs on ESI issues. While the plaintiffs claim that Bard has not been transparent regarding ESI issues, the truth is that Bard has provided the plaintiffs with detailed information relating to its collection efforts over the last decade, custodians from whom it collected information, shared drives it collected from, and information relating to its document management systems (QUMAS/Master Control). Regarding collections, Bard has provided the plaintiffs with a chart of the following:

- Custodians from whom it collected data
- The timeframe of when it collected data

- The amount of data collected from each custodian
- Whether the custodians' data has been produced

Bard has also provided the plaintiffs information relating to shared drives it has collected from, when those collections occurred, how much data was collected, and whether it made any updated collections of those shared drives. Bard also provided the plaintiffs with information about the keywords used to search ESI, even though they already had this information (given that several members of the PLC were involved in selecting several of those keyword terms in previous litigation).

Bard has also provided the plaintiffs with another copy of a detailed report from its ESI vendor that outlines the history of Bard's ESI custodians and keyword terms used to search those custodians, and that was previously provided to the Lopez McHugh firm. *See* Exh. 3, November 20, 2015 Ltr. from Lerner to Stoller, attaching BIA's Proposed Discovery Protocol Analysis Report.

In addition, to help the plaintiffs further understand Bard's IT systems, Bard provided the plaintiffs with a 30(b)(6) deposition of Bard that was taken in other litigation relating to IT issues. Bard also provided the plaintiffs with dozens of policies and procedures relating to its IT systems which cover the period from the early 2000's to the present, and has responded to several questions raised by the plaintiffs.

Moreover, the parties have been meeting and conferring on these issues for the last several weeks. In fact, on December 16, 2015, in response to the plaintiffs counsel's December 2, 2015 letter, Bard's counsel wrote the plaintiffs' counsel a lengthy letter providing to the plaintiffs information they had requested and explaining why it was not only difficult -- but virtually impossible -- for Bard and its IT department to respond to some of the plaintiffs' broad requests. *See* Exh. 4, December 16, 2015 Ltr. from Lerner to Stoller. The plaintiffs take issue with Bard's stance that questions such as, "[w[hat types of information does Bard have?" and "where does [Bard] keep its various types of information?," are not so simple to answer and are, in fact, incredibly broad. As Bard

explained in its December 16, 2015 letter, Bard is a multinational corporation with numerous subsidiaries and divisions throughout the world and the United States. (The vast majority of those entities have no connection or involvement whatsoever with the company's IVC filter products.) So, how and where information is stored is necessarily dependent on the division, department, and employees involved. Even within the Bard division responsible for the development and marketing of Bard's IVC filter line -- Bard Peripheral Vascular, Inc. -- there are numerous employees and systems, many completely unrelated to filters. The plaintiffs, who are already familiar with the employees who have worked on Bard's IVC filter line (having deposed dozens of them over the course of multiple years of litigation), have declined to narrow their requests to any departments or individuals such that Bard can provide more specific responses.

While Bard's counsel raised these concerns and issues in its December 16, 2015 letter regarding the scope of the plaintiffs' requests, Bard's counsel also concluded the letter by requesting that the plaintiffs' counsel contact him after they had an opportunity to consider the issues addressed in the letter in an attempt to narrow the issues raised by the plaintiffs. Bard's counsel also reaffirmed its commitment to work with the plaintiffs to resolve any remaining ESI issues. Having not received any response from the plaintiffs' counsel to the December 16, 2015 letter, Bard's counsel proactively followed up with the plaintiffs' counsel again on January 7, 2016, and again suggested that counsel set up a time to talk regarding issues outlined in its December 16, 2015 letter. *See* Def. Exh. 4.

Thereafter, counsel for the parties had a brief conference on January 11, 2016, but the primary focus of that meeting was the ESI protocol that was due on January 15, 2016. During that brief meeting, counsel for both parties recognized that they still needed to further discuss ESI issues after the ESI protocol was finalized. The plaintiffs' counsel suggested that one way to move forward would be to provide them the opportunity to talk informally with an in-house IT person about Bard's general infrastructure. Bard has

considered that request and is willing to do so, as long as it is given sufficient advance notice of the specific topics and the scope of any inquiry and as long as the inquiry is focused on systems relevant to filters.

A summarized timeline of Bard's extensive responses to the plaintiffs' ESI questions and requests is as follows:

Plaintiffs' Requests	**Bard Provided**
11/05/15: General questions such as "How are Bard's information systems organized? What are the various servers, devices, and drives on which information is created or stored?" and "How does Bard's system determine where files and information are stored within its system? Are there shared drives accessible by the entire company, divisions, departments, teams, or projects?"	**11/13/15:** Bard provides 30(b)(6) deposition and exhibits from separate litigation relating to information systems and system architecture. **11/18/15:** Bard provides over 800 pages of document retention and IT policies previously produced to members of the PLC. **11/20/15:** Bard provides responses to the plaintiffs' questions, correspondence regarding shared drives and Master Control/QUMAS previously exchanged with members of the PLC and further responds to the plaintiffs' general questions. Bard provides chart of custodians for whom ESI was produced, and BIA's ESI Report from litigation with members of the PLC (including additional search terms, methodology, and analysis of the application of those terms to documents previously coded as non-responsive). Bard also requests information related to the plaintiffs' preservation of social media ESI.
12/02/15: The plaintiffs note two unanswered "fundamental" questions: "What types of information does Bard have? And, where does it keep its various types of information?" The plaintiffs also request 6 additional categories of information related to Bard's collection efforts to date:	**12/16/15:** Bard explains why it is having difficulty answering the plaintiffs' general questions, and asks follow-up questions to allow for more detailed responses. Bard provides further information regarding Master Control/QUMAS, and previous collection efforts. Bard responds to all 6 of the plaintiffs' requests:

1. "[A]ll reports or contemporaneous documentation…as to the collection of Bard's ESI for these matters." 2. The definition of Bard's use of the term "custodian." 3. "[H]ow Bard determined what documents, files, other ESI, and system locations belong to identified custodians for purposes of collection(s)." 4. "For each collection, please identify the date or dates of the collection and for which custodians and from which shared and non-shared drives or devices the collection was done." 5. For each custodian, identify the "dates for each collection", location of collection, "the file or document types", "quantity of ESI collected", and "whether there was additional ESI at the location that was not collected at the time." 6. For each "shared drive, individual drive, or device," the same information as number 5. Plaintiffs do not respond to Bard's request regarding preservation of the plaintiffs' social media.	1. Bard produces a collection log report compiled with BIA on January 19, 2016, which provides names of 181 custodians for whom data was collected, when it was collected, how much data was collected, and whether it was produced. 2. Bard explained that "In using the term 'custodian,' [Bard] is referring to individual employees of the company." 3. Bard "determined that information in 2005 based on our extensive interviews of over 80 employees. We have continued to talk with multiple employees over the years (often on a weekly basis) to assist us in identifying where documents and information responsive to various requests might be located." 4. Bard refers the plaintiffs to the list of custodians previously provided to the plaintiffs, and to the metadata containing file and email folder locations. This request is again answered by the collection log report. 5. Same as number 4 above. 6. Same as number 4 above. Bard further explained that "for the shared drives we collected in 2005 and 2006, we have not done a formal refresh collection of those shared drives since that time. We have, over the years, periodically collected documents that have been responsive to discovery requests from those drives and the other drives I referenced in my prior letters." Bard asks plaintiffs to call to discuss letter.

	01/7/16: Follow up letter after no response was received from the plaintiffs to Bard's 12/16/15 letter, and producing updated IT policies and diagrams. **01/11/16:** Telephone conference focused primarily on ESI protocol due 1/15/16.

In sum, while the parties may ultimately have ESI issues that need resolution by this Court, Bard has provided plaintiffs significant information relating to its collection history, timing of those collections, and numerous policies and procedures relating to its IT systems. Bard is further willing to facilitate an informal discussion between the plaintiffs and a Bard IT specialist. In short, Bard has attempted to be transparent in working with plaintiff on a number of ESI issues while taking issue with requests that are expansive and seek information far beyond that which is normally provided in litigation. Moreover, Bard has already provided the plaintiffs with much of the information they claim they are currently missing.

Although the foregoing provides a summary of Bard's position on ESI issues, Bard will also address each subcategory identified by plaintiffs.

i. Plaintiffs' Request for System Architecture Information is Unreasonable and Overly Broad

As noted above, the plaintiffs' request for system architecture is extraordinarily broad. If the plaintiffs will more narrowly focus their requests, Bard, as noted, will permit the plaintiffs to informally interview a Bard IT member to further help with discussions regarding general system architecture. However, the plaintiffs' request for detailed data maps and other information they claim to need in order to understand whether Bard has acted diligently and reasonably in their ESI preservation and production, is premature. The plaintiffs state that they simply seek to determine whether Bard has taken reasonable steps to produce relevant ESI in the years of litigation preceding the formation of this MDL, including those years involving litigation with

several members of the PLC, but have not yet demonstrated any need to engage in such "discovery about discovery," as required in the Ninth Circuit. *Watkins v. Hireright, Inc.*, 2013 WL 10448882, *2-3 (S.D. Cal. November 18, 2013); *see Nissan N. Am., Inc. v. Johnson Elec. N. Am., Inc.*, No. 09-CV-11783, 2011 WL 1002835, at *1 (E.D. Mich. Feb. 17, 2011) (informal request for mapping of entire information technology systems sought only after improprieties found with previous discovery responses). Moreover, it is questionable whether the plaintiffs are even entitled to the discovery they seek and that Bard has agreed to provide under the recent amended Rule 26(b)(1) of the Federal Rules of Civil procedures, which limits discovery to information that "is relevant to any party's claim or defense and proportional to the needs of the case." The plaintiffs' extensive requests for discovery about discovery, which would encompass the information technology structure employed by all of Bard's entities worldwide is not relevant to the plaintiffs' claims in this litigation.

ii. Bard Has Provided the Plaintiffs with Extensive Collection Information

Contrary to the plaintiffs' claims, and as illustrated earlier, Bard has provided the plaintiffs with substantial information regarding its collections efforts. On multiple occasions, Bard has provided to the plaintiffs a list of ESI custodians for whom they collected and produced data, as well as information about shared drives and data management systems from which they have collected data. Moreover, Bard has provided the plaintiffs with a collection log that it compiled, in consultation with its ESI vendor, which provides the name of individuals for whom it has collected data in the filter litigation, when the data was collected, whether the ESI was produced, and the data amounts for each of the 181 custodians. In addition, regarding the source of the ESI that has already been produced, the plaintiffs already have metadata for file and email folder path locations for each individual document produced. As to shared drives, Bard has been clear in correspondence with the plaintiffs' counsel that since it formally collected shared drives in 2005/2006, Bard has not done a formal refresh of those drives but "ha[s],

over the years, periodically collected documents that have been responsive to discovery requests from those." *See* Exh. 4, December 16, 2015 Ltr. from Lerner to Stoller. Considering that Bard has provided these materials, it is hard to imagine what additional information the plaintiffs need or how any further information would be relevant to any claim or defense. *See* Fed. R. Civ. P. 26(b)(1); *Advante Int'l Corp. v. Mintel Learning Tech.*, 2006 WL 3371576, at *4 (N.D. Cal. Nov. 21, 2006) ("Mintel is seeking "discovery about discovery," rather than information reasonably calculated to lead to the discovery of admissible evidence."); *see also Hanan v. Corso*, 1998 WL 429841, *7 (D. D.C. April 24, 1998) ("To the contrary, discovery is only permitted of information which is either relevant or likely to lead to admissible evidence. Fed.R.Civ.P. 26(b)(1)).

As in *Hanan*, the plaintiffs "never explain[] why discovery about discovery meets that standard, no matter how liberally it is construed, nor any legal authority for the proposition that the federal courts deem the discovery process itself a fit subject for additional discovery." *Id.* They attempt to shift the burden on Bard to show its discovery process was reasonable, when it is actually the plaintiffs who have the burden of showing evidence of inadequate discovery practices before being entitled to further discovery about discovery. *Watkins v. Hireright, Inc.*, No. 13CV1432-MMA BLM, 2013 WL 10448882, at *3 (S.D. Cal. Nov. 18, 2013) ("Plaintiff has failed to provide any evidence or support for the idea that Defendant has behaved improperly with respect to its efforts to preserve electronic data and Plaintiff has in fact already received a voluminous amount of discovery from Defendant."). Moreover, the case law cited by the plaintiffs for the proposition that "what Defendants have done to collect relevant ESI is discoverable" only emphasize this point, because in each of the three cases cited, the non-producing party identified specific and extreme shortcomings in the producing party's document production justifying the unusual remedy of permitting discovery regarding discovery, such as: failing to produce any ESI for individuals whom the producing party identified as key witnesses (*McNearney v. Washington Dep't of Corr.*, No. C11-5930 RBL/KLS,

2012 WL 3155099 (W.D. Wash. Aug. 2, 2012)), the producing party's counsel delegating the search methodology to his client and being "generally unaware of the manner in which [the producing party] had provided the documents…[and] unsure what protocol [the producing party] followed to locate responsive documents"(*S2 Automation LLC v. Micron Tech., Inc.*, No. CIV 11-0884 JB/WDS, 2012 WL 3656454 (D.N.M. Aug. 9, 2012)), and failing to preserve "work computers that were used by 24 of the 27 custodians" until "600 days after the filing of the complaint" (*Small v. Univ. Med. Ctr. of S. Nevada*, No. 2:13-CV-00298-APG, 2014 WL 4079507 (D. Nev. Aug. 18, 2014)). Finally, the plaintiffs request for information for "all" documentation relating to Bard's collection efforts implicates work product and attorney-client materials to the extent it seeks materials created by or at the request of counsel during Bard's collection efforts. *See, e.g., Gibson v. Ford Motor Co.*, 510 F.Supp.2d 1116, 1123 (N.D. Ga. 2007) (finding that defendants are not required to produce litigation hold letters because "[n]ot only is the document likely to constitute attorney work-product, but its compelled production could dissuade other businesses from issuing such instructions in the event of litigation").

iii. Plaintiffs' Attempt to Conduct Preservation Discovery Is Premature

As a basis for seeking discovery about Bard's preservation efforts, the plaintiffs have cited a seeming inconsistency in when Bard instituted a legal hold in December 2004 and the fact that Bard said that it anticipated litigation when it hired Dr. John Lehmann on November 15, 2004. The plaintiffs' argument is an attempt to impose needless additional expense on Bard when Bard's document productions have been more than sufficient throughout the IVC filter litigation.

As an initial matter, Bard has produced nearly 40,000 documents pre-dating December 2004. In fact, the plaintiffs have cited these documents extensively in opposition to Bard's Motion for Protective Order regarding Dr. Lehmann's work-product protected report. *See, e.g.*, Pl. Resp. to Mot. for Protective Or. (Doc. 379), at Exs. 1, 2, 3, 6, 9, 10, 11, 12, 18, 19. Similarly, in *Phillips v. C. R. Bard, Inc.*, the plaintiffs used many

documents that pre-dated December 2004 during trial. Moreover, the law regarding the timing of legal holds has been in a constant state of flux over the past decade, and Bard's legal hold in December 2004 is not inconsistent with law in the Ninth Circuit at the time. *See, e.g., National Association of Radiation Survivors v. Turnage*, 115 F.R.D. 543, 556 (N.D. Cal. 1987) (noting a duty to retain documents "once a complaint is filed"). Finally, even if Bard had slightly delayed in issuing a legal hold, Federal Rule of Civil Procedure 37(e) provides for replacing any lost discovery through other available discovery. The plaintiffs, however, have not identified any missing discovery nor have they shown irreplaceability of any missing discovery.

Moreover, courts routinely prohibit parties from conducting discovery about a party's preservation efforts without "any evidence or support for the idea that Defendant has behaved improperly with respect to its efforts to preserve electronic data." *Watkins v. Hireright, Inc.*, No. 13CV1432-MMA (BLM), 2013 WL 10448882, *2-3 (S.D. Cal. Nov. 18, 2013). In *Watkins*, a plaintiff sought to depose a defendant's corporate representative regarding that defendant's "efforts to date to preserve electronic data upon learning of the pendency of this lawsuit," well after over six hundred pages of discovery had been provided by the defendant. *Id.* at *2. The court refused to allow this "discovery about discovery," reasoning that the plaintiff was not entitled to "independently assess the adequacy of [Defendants'] preservation." *Id.* at *3. Here, as in *Watkins*, Bard has already provided voluminous discovery to the plaintiffs over the course of a decade of litigation—with over two and a half million pages of documents produced—and the plaintiffs can provide no evidence of impropriety in connection with Bard's preservation efforts. Because the plaintiffs fail to provide the evidence of improper conduct necessary to allow such discovery about discovery, the Court should not permit the plaintiffs to "independently assess the adequacy of [Defendants'] preservation" efforts.[2]

[2] Moreover, the wording of the plaintiffs' position is imprecise and could be construed to seek to discover the litigation hold documents themselves. Unless spoliation is at issue, however, a litigation hold letter generally is not discoverable. *Cannata v. Wyndham Worldwide Corp.*, No. 2:10-CV-00068-PMP, 2011 WL 3495987, at *2 (D. Nev. Aug. 10, 2011); *see Oleksy v. Gen. Elec. Co.*, No. 06 C 1245, 2011 WL 3471016, at *5 (N.D. Ill.

iv. Bard's Use of Keyword Terms Was and Is Reasonable

As noted earlier, Bard has used an extensive number of keyword terms that were negotiated with opposing counsel. The original 27 broad search terms were negotiated in 2010/2011. Although the plaintiffs claim these terms are insufficient because "those prior productions each involved a single plaintiff and a single device", that is not the case. Much like the members of the PLC previously involved in this litigation, the plaintiffs' attorneys who negotiated the 2010/2011 terms had a large inventory of cases, and as such, the keyword terms covered every generation of filter released at the time. Further, the original terms were generic and widely applicable: filter*, "Simon Nitinol," G1A, G1*, G2, G2X, G2 Express, Eclipse, RF, RNF, SNF, vena cava, IVC, fracture*, migrat*, tilt*, perforat*, detach* AND (limb or strut), electropolish, electro-polish, Everest, deep venous thrombosis, DVT, embol*, nitinol, Recovery, G-1*.

When members of the PLC became involved in the litigation, they proposed additional keyword terms (an additional 10 "anchor" terms, including "Meridian" and "Denali", with 171 connecting terms) and custodians.[3] The members of the PLC insisted that Bard apply the new search terms to the original custodian files, and apply both the original 2010/2011 terms and the new terms to the additional custodians that they identified. The plaintiffs now question the use of the keyword terms altogether, many of

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Aug. 8, 2011) objections overruled, No. 06 C 1245, 2013 WL 3944174 (N.D. Ill. July 31, 2013) (ordering litigation hold information to be produced because spoliation of evidence occurred); *Major Tours, Inc. v. Colorel*, No. CIV 05-3091(JBS/JS), 2009 WL 2413631, at *2 (D.N.J. Aug. 4, 2009); *Zubulake v. UBS Warburg LLC*, 229 F.R.D. 422, 425 nn. 15–16 (S.D.N.Y.2004) (disclosing the details of counsel's litigation hold communication after discovering that at least one e-mail had never been produced); Cache La Poudre Feeds, LLC v. Land O'Lakes, Inc., 244 F.R.D. 614, 634 (D.Colo. 2007) (permitting plaintiff to take a Rule 30(b)(6) deposition to explore the procedures defendants' counsel took "to identify, preserve and produce responsive documents" after finding that defendants expunged the hard drives of several former employees after the present litigation had begun). As the plaintiffs provide no evidence that Defendants spoliated any information, Bard respectfully requests that the Court deny the discovery of any litigation hold letters themselves.

[3] The members of the PLC originally demanded that Bard start its production from scratch (much like they are suggesting again here), with 28 additional keyword terms and 75 additional custodians, but after court intervention and a sampling report prepared by Bard's ESI vendor, these were narrowed to 10 anchor terms with connecting terms, and 20 additional custodians.

which were insisted on by members of the PLC, and claim that "Defendants [] have not yet disclosed the algorithm they used for such searches." But, not only are members of the PLC intimately familiar with the keyword term and search history since the parties extensively briefed the issue in 2012/2013, the members of the PLC themselves developed the additional keywords that were applied to every custodian's collection. Bard also again provided its e-discovery provider's analysis applying those 2012/2013 keywords developed by the PLC members to the new custodians' collections, as well as documents from the original custodians previously coded non-responsive. *See* Exh. 3, November 20, 2015 Ltr. from Lerner to Stoller, attaching BIA's Proposed Discovery Protocol Analysis Report. The plaintiffs cannot now claim ignorance of the methodologies that they, in part, developed, as justification for initiating discovery regarding discovery, or for Bard redoing its production.

Indeed, the vast majority of the plaintiffs' requests, including those which they believe seek "relatively easy information to provide," are based on current ESI and industry standards as if this litigation had just begun. Much of what the plaintiffs expect is impossible to apply retroactively since Bard cannot recreate history. The plaintiffs criticize Bard's efforts over the last decade, holding Bard to standards that did not exist at the time, in an attempt to require Bard to redo its production from scratch. Under the plaintiffs' logic, a new plaintiff in three years could require Bard to yet again redo its entire production based on future standards. The fact that alternative search methods exist today does not mean that the plaintiffs are entitled to impose the enormous burden of a new production, particularly since the plaintiffs have yet to identify any specific shortcoming in Bard's extensive document production.

v. History of ESI in Bard Filter Litigation and the Case for Limited "Refresh" Collections

Over the course of the filter litigation, Bard has produced over two and a half million pages of documents and ESI and has incurred over two millions dollars in related costs. Those past productions include documents relating to all generations of Bard's

filters, using keyword terms negotiated with opposing counsel, including members of the PLC, and they include ESI productions at least through 2013. Bard has continued to produce extensive other, hard copy documents in response to discovery requests both before and after 2013. While Bard recognizes that the plaintiffs may be entitled to ESI from "new" custodians regarding later-generation filters, as discussed in section III.2.b, below, Bard believes that any "refresh" collections for "previously searched" custodians should be significantly limited, particularly since Bard stopped distributing the earlier-generation filters (the Recovery®, G2®, G2® Express, and G2®X Filters) several years ago.[4] As a consequence, in addition to the 10 to 12 "new additional" ESI custodians Bard is proposing in section II.2., *infra*, Bard proposes that the plaintiffs should be limited to identifying no more than five additional custodians for whom they can request refresh collections.

The history of the Bard IVC filter litigation and ESI productions supports Bard's position. Bard's initial sweep of documents and ESI in 2005 and 2006 primarily included Bard's first two generations of retrievable IVC filters, the Recovery® and G2® Filters. That expansive sweep involved interviews of employees (over 80) thought to be involved with Bard's IVC filters. Through these interviews, the employees' custodial files were identified and collected. In addition, "shared drives" pertaining to IVC filters were identified and also swept for ESI, and Bard has produced voluminous materials from those drives.

Later, after negotiating with counsel representing several plaintiffs with actions pending in Arizona state court, Bard agreed to an ESI protocol for a "second sweep" of documents and ESI, which identified 24 potential custodians to search using 27 broad search terms.[5] By the time members of the PLC began filing Bard IVC filter lawsuits in

[4] In the United States, Bard stopped selling the Recovery® Filter in 2005, the G2® Filter in 2011, the G2® Express in 2009, and the G2®X in 2012.

[5] Those 27 terms included the following: filter*, recovery, "Simon Nitinol," G1A, G1*, G2, G2X, "G2 Express," Eclipse, RF, RNF, SNF, "vena cava," IVC, fracture*, migrat*, tilt*, perforat*, detach* AND (limb or strut), electropolish*, electro-polish*, EVEREST, "deep venous thrombosis," DVT, embol*, and Nitinol.

2011, Bard had already spent over $2 million collecting, reviewing, processing, and producing over 2 million pages of ESI and hard copy documents.

In subsequent litigation involving members of the PLC -- *Kevin Phillips v. C. R. Bard, Inc. et al.*, Case No. 3:12-cv-003344, United States District Court for the District of Nevada -- the parties and counsel (including members of the PLC Ramon Lopez and Troy Brenes) extensively briefed and argued ESI issues. In 2013, as part of *Phillips*, Bard searched ESI from an additional 20 custodians, using the original 27 search terms plus an additional 10 search anchor terms[6] with 171 connecting terms (negotiated with PLC members Mr. Lopez and Mr. Brenes). That work resulted in the production of over 500,000 more pages of ESI and an additional $600,000 in related costs. Further, while Bard has not done a formal refresh of any shared drives, from 2006 to the present, it has periodically collected and produced numerous documents from shared drives in response to specific discovery requests.

In 2015, the parties began trial in the *Phillips* case, which concerned the Recovery® Filter. The Lopez McHugh law firm was primary counsel for the plaintiff. After the plaintiff presented his case, relying on the documents and ESI produced by Bard, the parties settled the matter. Also in 2015, multiple cases involving the G2® and G2® Express/G2®X Filters were on the verge of trial (including, for example, *Tillman v. C. R. Bard, Inc.* and *Ocasio v. C. R. Bard, Inc.*[7]) before this MDL was created. Aside from the FDA investigation and warning letter and Kay Fuller's allegations made on national television (for which the parties have engaged in targeted discovery), nothing significant has occurred regarding Bard's earlier-generation filters that would warrant additional discovery regarding those devices. If the discovery conducted in the Bard IVC filter litigation up to 2015 was sufficient for the plaintiff to try the *Phillips* matter, and

[6] The 10 new anchor terms included the following: tetra, G3, platinum, Meridian, Denali, Saturn, silver, Vail, Venus, and Jupiter.

[7] Joe Johnson is counsel for the plaintiff in Tillman, and Ben Martin is counsel for the plaintiffs in Ocasio. Both Messrs. Johnson and Martin are members of the PLC.

was sufficient to have the *Tillman* and *Ocasio* matters on the cusp of trial, Bard believes it should be sufficient in this MDL, at least as to Bard's earlier-generation filters.

Considering the extensive ESI and document discovery that has already been conducted concerning earlier generations of Bard's IVC filters, the fact that most of the existing inventory of cases in the MDL involve those earlier-generation filters, and the fact that the most recent ESI production was conducted after Bard was no longer selling its earlier-generation filters, Bard believes that any further ESI in this MDL should be focused primarily on later-generation filters. Therefore, Bard proposes that the plaintiffs should be limited to identifying no more than five custodians for whom they can request updated or refresh collections, in addition to the 10 to 12 new ESI custodians Bard is proposing below. Regarding shared drives, given that Bard has extensively identified and produced voluminous relevant documents from those sources over time, Bard believes that the decision regarding any updated collection of shared drives, which could cost hundreds of thousands of dollars -- if not more -- cannot be made in a vacuum and should be reserved until such time as the plaintiffs identify specific categories of information they are requesting so the parties can better assess what additional shared drives, if any, should be collected or refreshed and produced.

2. Production of ESI From Custodians Involved With Later-Generation Filter Devices or Employed at Later Time Frames:

a. Plaintiffs' Position:

Defendants claim to have produced significant information for all devices with the exception of the Denali® IVC filter. For reasons discussed above in Section III.1.a, Plaintiffs have not yet been able to determine whether Defendants' production and search methodology for those other devices have been reasonable. Defendants' production methodology rests on the identification of custodians and the use of key-term searches. But they have not explained how they identified documents as belonging to particular custodians, let alone how their ESI systems are structured – information crucial to

determining whether Defendants conducted a reasonable search for relevant documents. And while Defendants note the number of "hits" based on their key-term searches, they provide no information as to the actual efficacy of those searches.

Defendants request that the Court limit new ESI reviews to "10 to 12 new custodians." But as with the other ESI issues, they have not provided adequate disclosure to allow Plaintiffs or this Court to determine whether their proposal is reasonable. Again, Plaintiffs do not know how Defendants determined what documents were associated with particular "custodians." Defendants have not identified how many people were involved with the Eclipse®, Meridian®, and Denali® filters and over what time periods. Nor have they identified the locations, including within Master Control or on shared drives, where this information should reasonably be located. Defendants' proposed numerical limits exist in a vacuum, and are therefore virtually useless in any reasonable analysis.

As with the other ESI issues, Plaintiffs believe these matters can only be determined once Defendants make full and transparent disclosure of their information systems and how their information is handled by the system's users.

b. Defendants' Position:

Please see section III.1.b, *supra*, for Bard's position concerning ESI and document discovery issues.

Bard has produced a significant number of documents and ESI from all generations of its IVC filters, including its later-generation filters, which Bard defines to include the Eclipse®, the Meridian®, and the Denali® Filters. While Bard recognizes that the plaintiffs are entitled to some additional discovery relating to these later-generation filters, Bard also believes that the number of additional custodians should be limited given the small number of cases involving those later-generation filters[8] and the fact that a substantial amount of discovery relating to those later-generation filters has

[8] In this litigation, there are currently 16 Eclipse® cases, seven Meridian® cases, and two cases involving the Denali® Filters. The remaining 59 or so cases involve the Recovery® or G2® line of filters.

already been completed. For reasons further explained below, Bard believes that the plaintiffs should be limited to identifying 10 to 12 "new" ESI custodians.

Notably, Bard has already used the words "Eclipse," "Meridian," and "Denali" as keyword search terms in past ESI collections and productions. In fact, Bard has already produced over 20,000 documents with the word "Eclipse," over 10,000 documents with the word "Meridian," and over 15,000 documents with the word "Denali."

Bard has also produced all complaint files for these later-generation filters through December 21, 2015.

In addition, as to the Eclipse® and Meridian® Filters, Bard has produced extensive "core" material, including the design history files, FDA regulatory files, post-market surveillance documents (e.g., dear customer letters, health hazard evaluations, remedial action plans, failure investigations, etc.), complaint trending material, and marketing materials.

Considering the foregoing, Bard believes that limiting further ESI to 10 to 12 new custodians -- whether requested independently or as part of a document request accompanying a deposition notice -- is appropriate. Bard would propose that a rolling production be conducted, and the parties meet and confer on a timetable for production if the court accepts the two-track discovery plan that the parties are proposing. Bard notes that none of the 13 trial-ready cases involve the Eclipse®, Meridian®, or Denali® Filters.

3. Further Discovery Related to the FDA Inspection and Warning Letter:

a. Plaintiffs' Position:

In accordance with this Court's Case Management Order No. 2, Plaintiffs took a Rule 30(b)(6) deposition of Defendants' designee regarding issues arising out of the FDA's July 13, 2015, Warning Letter. Defendants designated Chad Modra to testify at that deposition. There, Plaintiffs learned that Defendants' failures to accurately track, report, categorize, and analyze failures of their IVC filters were far greater and broader than those few identified on the face of the FDA's letter and were much more significant

than the "four or five" reporting problems dealing with "very technical disagreements" concerning such issues as Bard's failure to properly provide the birth date or weight of the victim, as suggested by Defendants' counsel at the October 29, 2015, hearing.

In fact, the Modra deposition revealed *hundreds* of failures to properly report serious injuries resulting from Bard's retrievable IVC filters. While the Warning Letter only referenced a handful of serious injuries that the FDA's audit identified where Bard had failed to properly identify an injurious event and to correctly report it, an internal audit Bard carried out in response to the Warning Letter unearthed failures to correctly track and to report serious injuries to the FDA in 300 of the 1,000 files Bard reviewed. And this was only for a recent two-year period that Bard self-selected. These injury-producing events necessarily reflected the failure of Bard's later-generation filters (which they argue are substantially safer and with lower defect rates). It is only fair to wonder whether true and accurate reporting of these failures to the FDA would have forced a recall by Bard.

Incredibly, Bard now argues "no harm, no foul" or that Plaintiffs' proposed discovery is a red herring because Bard is confident that its informal tracking was accurately identifying serious injuries and deaths caused by its devices. But the actual data that has been seen to date undermines this argument in its entirety. Indeed, Mr. Modra admits that the people who misreported this data in the first instance (requiring hours of retraining and re-certification) were the same employees that Bard now suggests accurately coded and trended the internal tracking data. Based on this assertion, Bard objects to Plaintiffs' discovery of such information as "irrelevant."

It is in this context that Plaintiffs have sought written discovery and depositions concerning Bard's actual injury and death data and for related issues such as Bard's internal tracking, the raw data and information available to Bard, and Bard's corporate knowledge and response to those problems. These questions are at the core of Plaintiffs' claims of defect, failure to warn, misrepresentation, fraud, and punitive damages.

Plaintiffs have submitted two document requests concerning the Warning Letter: (a) the documents subpoenaed to be produced with the witness – documents Bard refused to produce before the deposition, and (b) a request for production document based upon documents identified and discussed by Mr. Modra in his deposition.[9] All of this discovery is narrowly tailored to the critical information concerning the actual number of people being killed or injured by Bard filters, Bard's internal evaluation, trending, analysis, and response to that information, the truthfulness and accuracy of Bard's reporting of these injuries and deaths to the FDA, and more importantly how Bard represents the risk profile of its devices to physicians and patients.

In addition to written discovery, Plaintiffs seek to follow up on the deposition of Mr. Modra by examining those directly above or below Mr. Modra who were assigned the responsibility to clean up these problems:

1. Maureen Uebelocker – Bard's Director of Quality Assurance; she reported directly to Mr. Modra during the relevant time and was responsible for the individuals who performed the reporting, tracking, and trending of adverse events.

2. Judy Ludwig – A manager in the Quality Assurance department and one of the persons responsible for FDA reporting. She was a direct report to Ms. Uebelocker.

3. John Wheeler - A manager in the Quality Assurance department and one of the persons responsible for FDA reporting. According to Mr. Modra, Mr. Wheeler was responsible to investigate failures, complaint files, and MDR reporting. He was a direct report to Ms. Uebelocker.

4. Gin Schultz – Bard's Vice President of Quality and the direct report for Mr. Modra.

5. Mary Edwards – Ms. Edwards was in charge of Bard's submission of the 510(k) application for the Recovery® filter, which Bard contended included the Recovery® Cone retrieval device. The FDA Warning Letter states that Bard failed to

[9] Copies of these document requests are attached as Exhibits 1 and 2 to this Joint Report.

obtain appropriate clearance or approval for marketing of the Recovery® Cone; thus, its original decision not to seek separate clearance or approval of the separate device are at issue. As the primary person responsible for obtaining clearance of Bard's first retrievable devices, Ms. Edwards should have discoverable information regarding Bard's decision not to seek separate clearance or approval for the Recovery® Cone.

6. Robert Carr – Mr. Carr was the primary engineer on the Recovery® filter and Recovery® Cone. As such, he was significantly involved in the 510(k) application for the Recovery® filter. Like Ms. Edwards, he should possess information regarding Bard's original decision not to seek separate clearance or approval for the Recovery® Cone.

7. A 30(b)(6) deposition of Bard's internal characterization, counting, trending, and reporting of injuries and deaths.

Plaintiffs also requested that Defendants produce the files of Messrs. Ring, Williamson, and Gaede (who were addressed on the letters from the FDA) so that Plaintiffs can determine whether those individuals were sufficiently involved in the FDA matters to warrant their depositions for the First Track Cases. Plaintiffs have not asked for their depositions at this time and, contrary to Defendants' contention, have not yet determined whether these depositions are necessary.

b. Defendants' Position:

Bard does not believe that additional discovery concerning the FDA warning letter is appropriate or warranted under Fed. R. Civ. P. 26.

In accordance with Case Management Order No. 2, Bard produced to the plaintiffs all written communications to and from the FDA concerning the FDA's November 25, 2014 and January 5, 2015 483 Letters to Bard, and FDA's July 13, 2015 Warning Letter to Bard, totaling more than 13,000 pages of documents.[10] Following the initial

[10] Contained in that production was a memo discussing the results of the retrospective audit that Bard undertook, which was the fifth exhibit of thirteen exhibits total that the plaintiffs introduced at the December 15, 2015 deposition of Mr. Modra. Contrary to their characterizations, the plaintiffs did not "learn" of the existence of the audit or the

production, Bard has supplemented on several occasions, to furnish the plaintiffs with later communications with the FDA. Further, in response to the plaintiffs' Notice of Deposition served pursuant to Fed. R. Civ. P. 30(b)(6), on December 15, 2015, Bard produced for deposition Mr. Chad Modra, who is Bard Peripheral Vascular, Inc.'s Vice President of Quality. Mr. Modra was intimately involved with all aspects of FDA's inspections and the events leading up to the July 2015 warning letter, and he spearheaded the strategy and implementation of Bard's responses to FDA's communications, as well as the periodic reports following Bard's receipt of the warning letter. The December 15, 2015 deposition lasted an entire day and resulted in more than seven (7) hours of testimony, and, at the end of the day, the plaintiffs asked for additional time to depose Mr. Modra on the topics in the Notice. Bard agreed to produce Mr. Modra for an additional three hours of deposition, which took place on January 20, 2016.

As indicated in its prior submissions, Bard believes the issues raised by the FDA's July 2015 warning letter have little, if any, relevance to the issues present in this litigation. The plaintiffs' arguments as to why the letter somehow justifies extensive additional deposition and document discovery in fact highlight the minimal relevance of that letter.

For example, the plaintiffs' insistence that they need to launch significant discovery regarding the Recovery® Cone is a red herring: In ten years of litigation, Bard has never faced a single case alleging injury attributable to the Recovery® Cone. Indeed, at the conclusion of the July 30, 2015 JPML hearing, Judge Marjorie O. Rendell of the United States Court of Appeals for the Third Circuit compared the warning letter's assertion that the Recovery® Cone was misbranded to "like you getting a letter from the IRS saying you should have reported a certain bit of income that you reported on your return as wages rather than 1099 income." The plaintiffs also incorrectly claim that the

results thereof during Mr. Modra's deposition. They were well-informed about it in advance of the deposition, and their extensive questioning of him on that audit and related topics revealed that they had ample time to thoughtfully prepare their questions to him about it. The audit and its results were not "revelations" during Mr. Modra's depositions that now warrant additional exploration.

warning letter discussion of adverse event reporting justifies additional discovery. To justify that discovery, they erroneously characterize the documents and Mr. Modra's testimony regarding them to suggest that Bard subsequently discovered "*hundreds* of failures to properly report serious injuries" to the FDA.[11]

Additionally, Mr. Modra explained that while Bard conducted a retrospective review of complaint files in accordance with its then-understanding of the FDA's criteria, in later conversations with FDA officials Bard learned that the agency in fact did not deem certain of those events reportable. Further, Mr. Modra explained that Bard had verified the continuing accuracy of its trending, as the company was trending all filter complications regardless of whether the field assurance personnel had applied the decision tree in such a manner as to render it reportable to FDA or not.

As a result of the minimal relevancy the FDA warning letter has to any of the plaintiffs' claims in this litigation, Bard agreed from the outset that targeted and proportional discovery concerning the letter was warranted. Now, however, the plaintiffs appear intent on seizing upon the warning letter in an attempt to justify broad, sweeping discovery of many issues, including a flood of additional depositions and significant additional ESI. They make those demands despite the fact that Mr. Modra, the Bard

[11] During his deposition, Mr. Modra was asked many times about errors in complaint files and MDR reports filed with FDA where boxes were checked for "malfunction" as opposed to "serious injury." However, what the plaintiffs fail to appreciate, or fail to acknowledge, is that for various of these errors, the equivalent information was provided to FDA in another portion of the exact same report. For example, FDA's 483 letter included discussion of a complaint file involving a fracture of an Eclipse® Filter where a strut had embolized to the patient's heart. FDA's 483 letter criticized Bard for checking a box indicating "malfunction" instead of "serious injury." The plaintiffs seize upon such an error as evidence that Bard must have been hiding "critical information concerning the actual number of people being killed or injured by Bard filters" from FDA. However, the plaintiffs fail to acknowledge that in its MDR report to FDA, the same report where they mistakenly checked the box for "malfunction", Bard, in a separate section of the report, checked boxes for "Adverse Event" and, critically, "Life Threatening." As a result, although a field assurance employee at Bard may have mistakenly classified a filter fracture as a malfunction, practically speaking and for all intents and purposes relevant to this litigation, Bard did in fact inform FDA in the first instance that a potentially life threatening event had occurred.

executive who spearheaded Bard's responses to the warning letter, testified extensively for 10 hours on these issues.

Without even waiting for the conclusion of Mr. Modra's deposition, and without suggesting that Mr. Modra was not appropriately designated to address the topics in the Notice, the plaintiffs notified Bard that they wish to depose seven (7) additional fact witnesses regarding the FDA warning letter, also indicating their intent to serve another notice of deposition under Fed. R. Civ. P. 30(b)(6) with additional topics. In that initial demand, the plaintiffs included as one of the seven additional witnesses they seek to depose on issues related to the FDA warning letter C. R. Bard's Chairman and Chief Executive Officer, Tim Ring. Bard objected to that request, since Mr. Ring does not have "unique, first-hand, non-repetitive knowledge" regarding the circumstances giving rise to the issuance of the FDA warning letter, as is customarily considered when courts determine whether to allow the deposition of officials at the highest level, or "apex" of corporate management. *See, e.g., Groupion, LLC v. Groupon, Inc.*, No. 11-0870-MEJ, 2012 WL 359699, at *2 (N.D. Cal. Feb. 2, 2012). The plaintiffs also demanded the depositions of six other people at that time.

Now, in the present submission, the plaintiffs have submitted a new list of deponents. That list includes three people in Bard Peripheral's Quality Assurance department who reported directly to Mr. Modra (until his recent promotion). They also request the deposition of the Vice-President of Quality at the corporate level, to whom Mr. Modra reports, despite the fact that Mr. Modra's testimony emphatically demonstrated that he, and not his supervisor, coordinated Bard's response to the warning letter. The plaintiffs also demand the deposition of another Rule 30(b)(6) witness regarding trending, despite the fact that they spent considerable time asking Mr. Modra about those identical issues. Signaling their intent to expand the pool of deponents even wider, they also demand the ESI of a number of other employees to "determine whether those individuals were sufficiently involved in the FDA matters to warrant their

depositions." With that request, and the demand for other depositions, the plaintiffs signal their intent to use the warning letter to justify an even wider range of depositions in the future.

The plaintiffs' unreasonably expansive discovery demands regarding the FDA investigation, 483 letters, and warning letter is further evidenced by their recent request for additional documents. Indeed, before the conclusion of Mr. Modra's deposition, the plaintiffs served 27 supplemental requests for production, seeking documents related, some only tangentially, to the FDA warning letter and Mr. Modra's testimony regarding the letter. These supplemental requests demand production of a substantial amount of material, including, by way example, (a) all policies and procedures from 2003 to the present related to 12 different categories; (b) all of Bard's communications (regardless of privilege) with the law firms King & Spalding and Hogan Lovells regarding the FDA investigation, 483 letters, and warning letter; (c) all of Bard's complaint tracking and trending reports and analyses from 2003 to the present; (d) all internal and external audits relating to Bard's quality systems; (e) all documents relating to Bard's management board and the management review process; and (f) all of Bard's internal communications regarding the FDA investigation, 483 letters, and warning letter. Standing alone, those overly broad document requests would impose an extraordinary burden on the defendants.

In summary, Bard strongly believes that 10 hours of testimony and 13,000 pages of documents has provided an ample opportunity for the plaintiffs to explore issues surrounding the FDA warning letter. Bard believes that the parties' time and resources are better spent on discovery of matters truly relevant to the claims and defenses involved in this litigation, proportional to the needs of the case, and important in resolving their dispute, as is set forth in Fed. R. Civ. P. 26(b)(1).

4. ESI and Documents That Have Been Previously Withheld, if Any, as to Defendant's Later-Generation Devices, Such as the Eclipse®, Meridian®, and Denali® Filters:

a. Plaintiffs' Position:

Plaintiffs have addressed in response to question 2 above their general position as to the need for additional discovery on later-generation IVC devices. Coming out of the parties' meet-and-confer conference, Defendants provided Plaintiffs with a list of the categories of ESI and documents Defendants had produced for the Eclipse®, Meridian®, and Denali® filters. For the former two filters, Defendants contend to have produced most of the relevant documents. For reasons Plaintiffs discuss above, they cannot reasonably evaluate that claim. Nor can they determine what documents Defendants have previously withheld as to these filters. Plaintiffs propose to obtain disclosure and to take discovery from Defendants on the ESI issues in the Second Phase of discovery to be able to determine whether Defendants have taken reasonable steps to identify, locate, and produce documents relating to the Eclipse® and Meridian® filters.

With respect to the Denali® filter, Defendants have proposed to produce similar files to what they have produced for Eclipse® and Meridian®. As with Defendants' prior productions, Plaintiffs intend to evaluate that production based on the factors they discuss in response to question 1 above.

b. Defendants' Position:

Please see section III.2, *supra*, for Bard's position concerning ESI and document discovery regarding Bard's later-generation IVC filters.

Bard has not resisted production of documents relating to its later-generation filters, with the exception of the Denali® Filter. As noted, the first (and only) Denali® Filter lawsuit was filed in this MDL. While Bard has previously objected to discovery requests seeking extensive discovery relating to the Denali® Filter, Bard has nonetheless produced significant ESI and documents relating to the Denali® Filter, as "Denali" is

one of the keyword terms it has applied to its ESI. Moreover, Bard has produced all complaint files for of its later-generation filters (including Denali®) through December 17, 2015, and has produced "core" materials for the Eclipse® and Meridian® Filters.

Considering that a Denali® lawsuit has now been filed in this MDL, Bard is prepared to collect and produce "core" materials for the Denali® Filter, including design, regulatory, marketing, and post-market surveillance documents. In addition, as part of the "new" ESI custodians that they will be permitted to select, the plaintiffs can select custodians involved with the development and marketing of the Denali® Filter.

5. Discovery Related to the Simon Nitinol Filter:

a. Plaintiffs' Position:

Plaintiffs have requested discovery for the Simon Nitinol Filter ("SNF"). The SNF is the predicate device for all of the retrievable filters at issue in this MDL. As a practical matter, that means that every single filter at issue in this MDL is based off its design and dependent upon the FDA's clearance of it. In this MDL, Plaintiffs have challenged the efficacy of all of the retrievable filters based on, among other things, design and manufacturing defects and failures to warn. As the predicate device, the efficacy, design, and manufacture of the SNF are directly at issue. In particular, because all subsequent designs for the IVC filters at issue in this litigation are based on the SNF, its design, testing, failure modes, failure rates, adverse events, and complaints are all relevant to the efficacy of the later devices based on its design.

Additionally, as the predicate device, SNF's design, testing, efficacy, FDA approval or clearance, and failure rate are of critical importance in determining whether the subsequent retrievable filters were the "substantial equivalent" of the SNF as Defendants represented in order to obtain FDA clearance of the retrievable filters that are the subject of this MDL. The limited SNF discovery Plaintiffs have received suggests both significant design differences between it and the retrievable filters and that the retrievable filters' failure rates are tens to hundreds times greater than that of the SNF.

These strongly suggest that the SNF was not a predicate device for these filters and that Defendants improperly obtained clearance through a 510(k), which supports Plaintiffs' claims that Defendants were required to recall and/or cease marketing retrievable filters.

For this reason, Plaintiffs have requested Defendants produce documents relating to the design and testing of the SNF, those relating to Defendants' FDA submittals for clearance or approval of the SNF, and the complaint files for the SNF.

b. Defendants' Position:

The Simon Nitinol Filter ("SNF") is a permanent IVC filter developed by Nitinol Medical Technologies ("NMT") and later acquired by Bard in 2001. The SNF was cleared by the FDA in 1990, long before the Bard retrievable IVC filters, which are at issue in this MDL, were developed or introduced to the market. The SNF -- unlike all of the other filters in this litigation -- is indicated only for permanent placement. It has been on the market for approximately 26 years. Bard has not had a single personal injury lawsuit involving the SNF over the last ten years, and there is not a single SNF case pending in this MDL. Nevertheless, the plaintiffs seek expansive discovery relating to the SNF and have requested "all" documents regarding the SNF, merely because the device was listed as a predicate device for Bard's retrievable filters.

While Bard recognizes that some targeted discovery regarding the SNF may be justified, Bard believes that discovery regarding the SNF, if permitted at all, should be significantly limited. Bard notes it has already produced certain of the design documents pertaining to the SNF, including the SNF design history file, fact books, certain FDA submissions, and other materials obtained by Bard from NMT relating to the SNF. These documents were identified on the indices previously provided to the plaintiffs. Bard also notes that it has already produced over 33,000 documents that contain the words "SNF" or "Simon Nitinol." When Bard has inquired regarding what specific SNF materials the plaintiffs desire, the plaintiffs have simply stated that they want "everything." While Bard is willing to meet and confer with the plaintiffs to discuss production of a targeted

subset of SNF-related documents, it cannot do so until the plaintiffs identify the specific materials they are requesting.

6. Discovery Regarding the Recovery® Cone Removal System Design, Design Changes, Corrective Actions, Reasons Why Design Changes Were Made, Regulatory Communications, and Adverse Event Reports:

a. Plaintiffs' Position:

Plaintiffs continue to believe discovery concerning the Recovery® Cone Removal System is relevant for several reasons. Most importantly, the retrievable filters were marketed to doctors and patients as being retrievable (indeed, this was the cornerstone of their marketing). If the Recovery® Cone was or is not properly authorized, the filters may not be removed via simple retrieval through a patient's veins similar to how the filter was placed, as Defendants represented to doctors and ultimately to patients. Rather, if that is the case, every patient faces a significantly more complex removal procedure requiring actual surgery. Thus, although Defendants contend there is no case in this MDL based on a Recovery® Cone failure, Defendants' failure to obtain appropriate FDA approval and clearance affects literally every plaintiff with a lawsuit in the MDL. Such evidence goes to Plaintiffs' failure to warn, misrepresentation, fraud, and punitive damages claims.

Similarly, the FDA findings of violations in the July 2015 Warning Letter call into question Defendants' repeated assertions that they dealt openly and honestly with the FDA. Plaintiffs should be allowed to understand the representations made by Defendants to the FDA that resulted in it marketing a device for years that the FDA has now determined required clearance that was never obtained. At his deposition, Mr. Modra admitted the sole document that he had seen supporting Bard's (incorrect) contention that the Recovery® Cone was a Class One device was a single memo to file. He further admitted the FDA has concluded it is a Class Two device and that Bard has never has received proper clearance or approval to market the Recovery® Cone.

To the extent that Defendants claim to have produced "all" of the documents relating to the Recovery® Cone, the problems with Defendants' lack of transparency as to their document productions (as discussed above in response to question 1 above) pertain equally to these documents and files. In light of that, Plaintiffs simply are not in a position to determine what additional documents may exist in Defendants' possession.

b. Defendants' Position:

To justify their demand for broad discovery concerning the Recovery Cone, the plaintiffs claim the device is relevant in every individual case. In particular, they argue that the "misclassification" of the Recovery® Cone deprives patients of a method to remove the device. However, their position is not supported by the evidence. As the deposition of Mr. Modra established, the Recovery® Cone remains available for physicians to use. Immediately after receipt of the warning letter, Bard filed a 510(k) application to "cure" the claimed misclassification of the device. In addition, Bard immediately sought – and the FDA promptly granted – discretionary permission to continue selling the Recovery® Cone while the 510(k) application is pending. As a result, physicians have had uninterrupted access to the device, and the fact remains that there is not a single lawsuit (nor has there ever been) claiming an injury related to the Recovery Cone.

Nonetheless, the plaintiffs already have a vast amount of information regarding the device. In its numerous, past productions of hard copy documents and ESI, Bard has produced to the plaintiffs voluminous materials regarding the Recovery® Cone. With respect to its past ESI productions, the term "Recovery" has been a keyword term, and, thus, any document with the term "Recovery® Cone" would have been captured in the search for relevant documents. Bard has never withheld from production to the plaintiffs any ESI merely because it exclusively concerns the Recovery® Cone.

With respect to its past hard copy document productions, Bard has produced substantially all (if not all) of the core documentation regarding the Recovery® Cone, including the following:

- Design, testing, development, and specification files, including the five-volume "fact book" that spans over 3,400 pages (Bard notes that the design of the Recovery® Cone has not changed since Bard began selling it in 2003);
- Instructions for Use;
- Failure mode and effects analysis documents;
- Risk assessment documents;
- Representative marketing and training materials;
- Bard's 510(k) submission (K152136) and related FDA correspondence; and
- Health hazard evaluations/remedial action plans.

Finally, because the Recovery® Cone was discussed in detail in Bard's Recovery® Filter 510(k) submission for Recovery® Filter retrievability (K031328), numerous additional materials regarding the Recovery® Cone have been collected and produced, such as documents that reflect bench, animal, and clinical studies that utilized the Recovery® Cone to remove the Recovery® Filter. Similarly, Bard's subsequent 510(k) submissions for the G2®, G2®X, and G2® Express Filters (which have likewise been produced) include materials related to the Recovery® Cone and its use in bench, animal, and/or clinical testing to remove those filters.

In short, Bard has produced to the plaintiffs the core hard copy documents relating to the Recovery® Cone, as well as voluminous ESI relating to the Recovery® Cone. Based on Bard's keyword search of its vast document productions to the plaintiffs, Bard has determined that it has produced over 30,000 documents that include the term "Recovery Cone." Thus, Bard does not believe that the plaintiffs should need any additional documentation specifically related to that device.

7. Custodial Files and Other Discovery With Respect to Sales and Marketing Personnel:

a. Plaintiffs' Position:

Plaintiffs request discovery of Defendants' national and regional sales and marketing practices related to the IVC filters. Defendants have provided Plaintiffs an organizational structure for its marketing department that indicates three levels of employees: national corporate, regional supervisors, and local individual sales representatives. Plaintiffs do not believe that documents from or depositions of individual (local) sales representatives are necessary for general common fact discovery. However, both national and regional sales and marketing information are relevant to general common fact discovery for this MDL.

At the national level, Plaintiffs propose to take document and deposition discovery regarding Defendants' sales and marketing practices. At the regional level, Plaintiffs propose to take document discovery and to take the depositions of individuals who had supervisory responsibility within the different regions during the relevant times. Based on that discovery, Plaintiffs would determine whether any additional depositions are necessary at the regional level.

As to individual sales representatives, Plaintiffs propose that, absent exceptional circumstances, depositions only take place in the individual cases, including those selected for the bellwether process. With respect to documents at the local sales representative level, Plaintiffs believe that Defendants should produce information relevant to post-market surveillance but that other individual sales representative documents are likely best reserved for individual case discovery.

b. Defendants' Position:

Bard continues to believe that extensive discovery of the company's sales force is extremely burdensome, and premature as well. Although the plaintiffs previously announced their intent to collect ESI from all sales personnel employed over the past

decade (and even earlier), they now appear to agree that discovery of individual sales representatives (if it is to occur) should take place during case-specific discovery for individual cases.

The plaintiffs now state that they only desire to depose national and regional sales personnel during the general phase of discovery. Bard believes the plaintiffs objectives can be fully accomplished by deposing the employees who supervise sales on a national level, and that an extension of discovery to regional heads would unnecessarily expand the number of depositions being taken. At a minimum, Bard submits that any sales personnel deposed by the plaintiffs should count against the numerical limitation on additional depositions that Bard is requesting.

8. Pending Rule 30(b)(6) Deposition Notices in Cases Consolidated in This MDL or State-Court Cases:

a. Plaintiffs' Position:

There are four pending Rule 30(b)(6) deposition notices in cases transferred to this MDL on the following general subjects: (1) the FDA warning letter, (2) regulatory affairs and communication, (3) post-market surveillance and adverse events reporting, and (4) sales and marketing. As noted at the outset of this report, the first subject has been taken in this MDL. Defendants have agreed that a sales-and-marketing deposition is appropriate. As to the remaining two topics, Plaintiffs believe the subject matters are appropriate for discovery in this case. Defendants' sole objection to them is that similar depositions were taken in prior cases. Their argument rests entirely on the premise that depositions taken in prior pre-MDL cases somehow preclude Plaintiffs in this case from deposing Defendants on these subjects. The parties have separately briefed their competing positions on the binding effect of prior discovery. *See* Docs 375, 415. Plaintiffs also address prior depositions in response to the broader question regarding corporate representative depositions (question 9) below. As discussed at both those places, Plaintiffs believes the parties should approach the 30(b)(6) depositions in the

same manner – address prior depositions on a case-by-case and subject-by-subject basis to decide their use in this MDL and where supplemental depositions are necessary for facts, issues, claims, or subjects not adequately covered in the prior individual suits.

b. Defendants' Position:

The parties have conferred concerning the four Rule 30(b)(6) deposition notices previously served. At present, those notices are not pending in any state court action, but only in this MDL. One of those notices concerned the FDA warning letter, and that deposition has already taken place. The plaintiffs have agreed to withdraw another one of the notices (concerning regulatory affairs and communications). The defendants note that one of the two remaining notices (concerning post-market surveillance and adverse event reports) is identical to a notice served by the Lopez McHugh firm in 2012. A witness was produced in response to that notice, and the plaintiffs took a lengthy deposition of the employee designated to speak to those topics. The plaintiffs have articulated no justification for why they need to take this same deposition again.

The final deposition notice concerns sales and marketing issues. Bard does not object to the plaintiffs proceeding with that deposition, if they would like. However, Bard submits that any further Rule 30(b)(6) depositions taken by the plaintiffs should be counted toward any numerical limit placed on additional fact witness depositions.

9. Additional Deposition of Corporate and Third Party Witnesses:

a. Plaintiffs' Position:

As discussed above, the parties have agreed to parallel tracks for discovery for those cases that are near-ready for trial and the other later-filed and to-be-filed cases. As to the First Track Cases, Plaintiffs have identified the discovery they need for those cases to be ready for trial in the sections of this joint report regarding further FDA issue discovery (Section III.3) and Kay Fuller discovery (Section IV.1). As to the Second Track Cases, the parties are not in agreement on the scope of discovery for those cases.

The parties' competing positions are set out in their briefing as to the binding effect of prior discovery. Essentially, Defendants would like all prior discovery of Bard witnesses to be deemed taken in this MDL and binding on Plaintiffs such that they may not depose those witnesses again. Such a result is both unwarranted and contrary to the Rules of Civil Procedure. That being said, Plaintiffs believe that some of the prior depositions of Defendants' corporate witnesses (and potentially some of third party witnesses) could be used in this case with the consent of both sides.

Plaintiffs are committed to reviewing all such prior testimony before noticing depositions and to seek the agreement of Defendants for the use of such prior depositions in this MDL where appropriate. To that end, Plaintiffs do not intend to take wholesale discovery depositions of every (or even most) of Defendants' corporate witnesses or third parties who have previously been deposed. However, most of the prior depositions were somewhat limited in scope due to the particular device and issues in the individual cases in which they were taken. Consequently, many of the witnesses who have previously been deposed have never been examined as to certain of the IVC filters or relevant facts.

Plaintiffs believe that many of the prior depositions could be useful (and used) in this litigation to cut down on the discovery needed. But Plaintiffs must be permitted to approach the question on a case-by-case and witness-by-witness basis.

b. Defendants' Position:

The parties are in agreement that past depositions of corporate and third-party witnesses can be used in this MDL in order to further efficiency. As set forth in Bard's briefing regarding the effect of that already completed discovery, since those prior corporate witness and third-party witness depositions (of which there are approximately eighty-five) are being deemed taken in this MDL, the scope of additional discovery, and the proportionality of that discovery under Fed. R. Civ. P. 26, should be assessed against that background.

The plaintiffs, however, are insisting on the right, unilaterally, to take as many depositions as they deem "necessary," and to decide whether individuals already thoroughly deposed may be deposed again. As an initial request, they have asked for the depositions of roughly 25 people, including approximately 10 more people regarding the FDA warning letter and approximately 10 people that have never been deposed by the attorneys presently leading this litigation. Additionally, the plaintiffs have demanded that Bard re-produce five witnesses previously subjected to lengthy depositions taken by the Lopez McHugh firm.[12] In doing so, they have made it clear that they do not intend to limit those repetitive depositions to non-duplicative subjects. At the same time, the plaintiffs have made it clear that this initial request for 25 depositions is simply the beginning, and that they intend to take dozens more thereafter.

Bard recognizes that additional depositions will need to be taken in this MDL. However, the scope of additional discovery should build off of the discovery already accomplished in 10 years of litigation over these products. Bard believes there should be a numerical limit imposed on additional corporate depositions. In particular, Bard would propose that the plaintiffs be afforded the opportunity to take between 10 and 12 additional depositions of corporate employees and/or consultants (in addition to any further depositions permitted about the allegations made by Kay Fuller). That number would permit the plaintiffs to depose several people about each of the later generation devices, i.e. the Eclipse®, Meridian®, and Denali® Filters.[13] That number of additional depositions would also provide the plaintiffs the discretion to depose a few additional employees regarding the earlier generation filters. Bard believes that such an approach would be consistent with the overarching goals of the MDL process, while providing the

[12] The chart attached as Exh. 5 lists the prior depositions of these five witnesses taken by the Lopez McHugh firm.

[13] Bard notes, however, that as of January 29, 2015, there are only two cases in this MDL involving alleged injury arising from the implantation of a Denali® Filter. As such, and as is consistent with its previous statements regarding discovery related to the Denali® Filter, Bard questions the extent to which discovery related to the Denali® Filter is proportional to the needs of the case or furthers the over-arching MDL objective of efficiency.

plaintiffs ample opportunity to explore areas of inquiry which may not have been exhaustively covered during the prior eighty-five depositions of corporate and third-party witnesses taken in this litigation. Bard also believes that such an approach would be consistent with the dictates of the newly effective amendments to Rule 26.

Bard is also concerned about the fact that the plaintiffs appear intent on imposing an inordinate burden on the company with the selection of employees to be deposed. Specifically, a number of the depositions the plaintiffs have initially demanded amount to "apex depositions", i.e., depositions of high-level corporate officers and managers with limited, if any, direct personal knowledge of the specific facts at issue here. In determining whether to allow an apex deposition, courts consider (1) whether the deponent has unique first-hand, non-repetitive knowledge of the facts at issue in the case, and (2) whether the party seeking the deposition has exhausted other less intrusive discovery methods. *See e.g.*, *Groupion, LLC v. Groupon, Inc.*, 11-0870-MEJ, 2012 WL 359699 (N.D. Cal. Feb. 2, 2012). The plaintiffs' list of deponents they are requesting includes John McDermott, former President of Bard Peripheral Vascular, who has already been deposed twice and departed the company in 2007 (before the development of Eclipse®, Meridian®, and Denali® Filters); John Weiland, President and Chief Operating Officer of C. R. Bard, Inc., who was deposed in 2014 by the Lopez McHugh firm, which was limited to 5 hours of deposition time by the courts that permitted the deposition; and Tim Ring, Chairman and Chief Executive Officer of C. R. Bard, Inc. Bard strongly objects to any such depositions, and would request the opportunity to brief the issue if the plaintiffs continue to insist on taking these irrelevant and burdensome apex depositions.

Bard believes that, contrary to their prior representations, the plaintiffs are now attempting to essentially "start from scratch" with respect to depositions of corporate and third-party witnesses. Although Plaintiffs' Co-Lead Counsel indicated at the October 29, 2015, case management conference that the consensus among the plaintiffs' counsel was

that they were going agree to adopt prior discovery and were not going to "re-do" work except as necessary, Plaintiffs' Co-Lead Counsel's recent communications on the topic are inconsistent with that pledge. As stated above, Bard agrees that a limited number additional corporate and third-party witness depositions is appropriate. However, the sheer number of depositions demanded by the plaintiffs, with no attempt to limit their scope or breadth, would represent the very antithesis of the efficiency that multidistrict litigation was created to promote and the proportionality required by the Federal Rules.

10. Rule 26 Expert Disclosures and Expert Depositions:

Subject to the Court's approval, the parties have agreed to deadlines for expert disclosure and disclosure for each of the two parallel tracks as set forth in Section II above.

11. Discovery Related to ESI Preservation Issues:

a. Plaintiffs' Position:

Plaintiffs have addressed the need for this discovery above. Plaintiffs anticipate further meet and confers with Defendants regarding this information and discovery on the subject, as necessary, as part of the general discovery track for the Second Track Cases.

b. Defendants' Position:

Bard believes that it is premature for the parties to conduct discovery regarding ESI preservation issues at this early stage. As a threshold matter, courts routinely prohibit parties from conducting "discovery about discovery" because it is not relevant to any of the claims or defenses of the parties, especially without a predicate finding that there has been a failure to preserve evidence in the firs instance. Fed. R. Civ. P. 16(b)(1); *Hanan v. Corso*, No. CIV.A. 95-0292 TPJJMF, 1998 WL 429841, at *7 (D.D.C. April 24, 1998); *Orillaneda v. French Culinary Inst.*, No. 07Civ.3206(RJH)(HHBP), 2011 WL 4375365, at *6 (S.D.N.Y. Sept. 19, 2011); *Advante Int'l Corp. v. Mintel Learning Tech.*, No. 05-01022 JW (RS), 2006 WL 3371576, at *4 (N.D. Cal. Nov. 21, 2006). Here, there is no basis to conduct such discovery, given Bard's good-faith preservation efforts over

the years. Bard began issuing legal hold notices in December 2004. Since that time, Bard has periodically updated its legal hold notices and collected and preserved data and documents.

Even if discovery regarding discovery were somehow justified, under the recent amendments to Rule 37(e) of the Federal Rules of Civil procedure, before deciding what action should be imposed for any potential loss of ESI, a court is required to consider various things, including whether lost ESI cannot be "restored or replaced through additional discovery." Only if a party is able to show the predicate for imposition of sanctions under Rule 37(e) is a court then authorized to issue sanctions under the following scenarios: "(1) upon finding prejudice to another party from loss of the information, may order measures no greater than necessary to cure the prejudice; or (2) only upon finding that the party acted with the intent to deprive another party of the information's use in the litigation . . ." Considering the foregoing, from a practical standpoint, any "discovery about discovery" is premature at this early stage of this MDL. Whether any discovery relating to preservation efforts is later justified should be determined towards the end of discovery when the court is in a position to assess whether there is any lost ESI and whether any lost ESI could be "restored or replaced through additional discovery."

IV. OTHER ISSUES

1. Additional Discovery Regarding Kay Fuller's Allegations:

a. Plaintiffs' Position:

Plaintiffs took the deposition of Kay Fuller on January 11, 2016. In that deposition, Ms. Fuller testified regarding internal complaints she made regarding Defendants' Recovery® filter (the first of the retrievable filters that are the subject of this MDL) and Defendants' failure to take certain steps (including appropriate testing) prior to marketing the devices. She also testified that her signature was forged on certain documents submitted to the FDA regarding the Recovery® filter. She testified that Bard

failed to identify the true root cause of the fracture of a filter in Bard's only small clinical trial (conducted by Dr. Asch) and that this failure would lead (and, in fact, has led) to patients being injured or killed. This internal whistleblower testimony is significant to all the cases in the MDL. Defendants have indicated in Court and to Plaintiffs that they intend to call several witnesses who will contradict Ms. Fuller's testimony.

Accordingly, Plaintiffs proposed to take discovery from those persons who worked with Ms. Fuller, those to whom she reported, and those who were involved in the 510(k) application process for the Recovery® filter that was the subject of Ms. Fuller's internal complaints, and those that Defendants contend with contradict Ms. Fuller. In particular, Plaintiffs proposed to take the following depositions:

1. Mary Edwards – Ms. Edwards was Ms. Fuller's direct supervisor during the relevant time period; according to Ms. Fuller's testimony, Ms. Edwards instructed Ms. Fuller that she would be removed from the 510(k) application team if she continued to raise safety concerns;

2. Carol Vierling – Ms. Vierling worked directly with Ms. Fuller on the 510(k) application and was a signatory on the document for which Ms. Fuller testified her signature was forged;

3. Robert Carr – Mr. Carr was the primary engineer on the Recovery® filter and worked closely on the 510(k) submission issues, including with Ms. Fuller;

4. Dr. Murray Asch – Dr. Asch conducted the small clinical trial on which Bard relied in the 510(k) application for the Recovery® filter and about which Ms. Fuller raised questions as to the conclusions Bard reached regarding the results of the trial;

5. Dr. Jonathan Kaufman – Dr. Kaufman worked with Dr. Asch on the Recovery® filter clinical trial and has information regarding the trial's events and actual results and conclusions;

6. Sherry Allen – Ms. Allen took over regulatory responsibility for the 510(k) application after Ms. Fuller resigned from Bard and would have been responsible for addressing the same issues that Ms. Fuller raised; and

7. John McDermott – Mr. McDermott was the President of BPV at the time of Ms. Fuller's employment and presumably was involved with the decision to take the Recovery® to market despite the fracture in Dr. Asch's clinical trial.

b. Defendants' Position:

On January 11, 2016, the parties deposed Ms. Fuller for 8 hours concerning the allegations she had made on national television that a submission to the FDA regarding the Recovery Filter did not bear her original signature. As a threshold matter, Bard believes her deposition testimony was inconsistent with the media broadcast in several important respects, and the version of events she described in her deposition was inconsistent with numerous emails and other documents.

At the deposition, Ms. Fuller testified that she knew her signature line was affixed to a cover letter to the FDA, but she advised her supervisor Mary Edwards that she would not sign the letter because of her concerns about the filter. She testified that another employee, Carol Vierling, then signed the truth and accuracy statement for the regulatory submission, because she (Ms. Fuller) declined to sign that as well. At the same time, Ms. Fuller admitted that she knew about the entire contents of the submission, and she continued to work on the submission actively thereafter.

The plaintiffs' attorneys have suggested that they need to take multiple additional depositions concerning Ms. Fuller's allegations. As they have with regard to other issues, they insist on the right to depose anyone even tangentially referenced by Ms. Fuller, no matter how peripheral the individuals' involvement may have been with the pertinent events.

Bard agrees that two of the depositions demanded by the plaintiffs are justified, given Ms. Fuller's claim that she communicated her concerns directly to those two

individuals. Specifically, the plaintiffs have requested the deposition of Ms. Edwards, who was deposed for a full day in 2014 by the Lopez McHugh law firm, and a deposition of Ms. Vierling, who has not been deposed in this litigation. Bard believes that a second deposition of Ms. Edwards, limited to the issues related to Kay Fuller's allegations, and a deposition of Ms. Vierling should provide ample opportunity for the plaintiffs to investigate the issues related to Ms. Fuller's allegations.

The plaintiffs, however, once again try to launch a much more expansive discovery effort about this single issue. Beyond those two witnesses, the plaintiffs argue that Ms. Fuller's testimony somehow justifies deposing people who Ms. Fuller did not implicate at all. For example, they demand to depose John McDermott, the former president of BPV, even though he has previously been subjected to a lengthy deposition by the Lopez McHugh firm and even though Ms. Fuller never claimed to have had any discussions with him about her "concerns." Likewise, the plaintiffs insist on re-deposing Shari Allen (who has likewise given a lengthy deposition for the Lopez McHugh firm), even though Ms. Fuller did not implicate her at all. Perhaps best illustrating how the plaintiffs are using Ms. Fuller as a justification simply to expand discovery is the fact that Ms. Allen did not even begin work with Bard Peripheral Vascular until a number of months after Ms. Fuller left the company. Similarly, Ms. Fuller did not report any interactions whatsoever, with Drs. Kaufman and Asch, yet they claim that Ms. Fuller's testimony somehow justifies those depositions. Finally, they argue they should be able to re-depose Rob Carr, despite the fact that Mr. Carr has previously been deposed 10 times total, and 4 times by members of the Plaintiffs Steering Company.

The plaintiffs' ostensible justification for these multiple depositions appears to be the fact that a clinical study conducted by Dr. Asch reported a single incident of filter fracture, and Ms. Fuller testified that the report concerned her. The plaintiffs, however, have known about that report for years, and members of the steering committee have

asked dozens of witnesses about that event in previous depositions. Ms. Fuller's testimony does not justify rehashing that issue.

In sum, the plaintiffs appear intent on utilizing the Kay Fuller's testimony as still another justification to expand deposition discovery as broadly as they can. Bard submits they should be limited to deposing Ms. Edwards and Ms. Vierling on those issues, and then renew their request to depose others on the subject if they still think additional depositions are somehow necessary.

2. Early Consideration of the Plaintiffs' Equitable Tolling Argument:

a. Plaintiffs' position:

Defendants request early resolution of the equitable tolling of statute of limitations on individual claims. Plaintiffs do not believe "early consideration" of this issue is appropriate. First, the question of equitable tolling is a factual one based on the wrongful and fraudulent actions of Defendants. Those actions will be the subject of discovery in this MDL, and Plaintiffs need to conduct that discovery. Additionally, equitable tolling arises out of state law on the statute of limitations on individual claims and the applicable discovery rule for those claims. Resolution of such issues is necessarily individual and should be resolved in the individual suits based on the state-law applicable to the particular claims.

b. Defendants' position:

As raised by counsel for Bard at the initial case management conference, Bard believes that it may be appropriate to establish a procedure aimed at promoting economy and efficiency by facilitating early resolution of the applicability of the plaintiffs' allegations that fraudulent concealment tolls the running of the applicable statutes of limitations. The reference, "Managing Multidistrict Litigation in Products Liability Cases: A Pocket Guide for Transferee Judges" suggests that the issue of whether claims are barred by statutes of limitations or other legal bars is an issue that may be appropriately addressed early in the litigation. Bard believes such is the case here, where

an early ruling on this narrow issue -- i.e., whether an alleged fraudulent concealment should toll the applicable limitations period beyond actual discovery of a filter fracture, migration, perforation, or other complication -- would impact a substantial number of cases currently pending in this MDL, as well as streamlining discovery in additional cases and providing certainty with respect to the filing of future cases which may be similarly situated. Bard believes that a procedure similar to that employed by Judge Cathy Seibel in *In re: Mirena IUD Products Liability Litigation* pending in the United States District Court for the Southern District of New York would be appropriate in this MDL. There as here, the plaintiffs opposed such a procedure on the basis that "[s]tatute of limitations questions are typically case-specific and have to be resolved under the laws of the plaintiffs' respective affected states." Despite that argument, Judge Seibel determined that such a procedure was appropriate. Bard intends to submit a specific proposal to the court on or before March 1, 2016.

3. Proposed Agenda:

A proposed agenda for the Case Management Conference on January 29, 2016, is attached as Exh. 6.

4. List of Pending Motions:

The list of pending motions requested by the court in footnote No. 2 of Case Management Order No. 2 is attached as Exh. 7. The parties propose that they address a plan for those motions after the completion of Phase II discovery.

DATED this 21st day of January, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of January, 2016, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Nancy Jo Koenes
Nancy Jo Koenes

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