BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: Bard IVC Filters Products Liability Litigation

MDL No. 2641

BRIEF IN SUPPORT OF BARD'S MOTION TO EXPAND THE SCOPE OF MDL NO. 2641 TO INCLUDE CASES INVOLVING THE SIMON NITINOL FILTER

MDL No. 2641, pending before the Honorable David G. Campbell in the District of Arizona, currently involves product liability cases concerning six Bard retrievable inferior vena cava filters. The only other Bard inferior vena cava filter, the Simon Nitinol Filter ("SNF"), is a permanent inferior vena cava filter that is the subject of similar product liability cases. Although MDL No. 2641 is currently limited to "Bard's retrievable inferior vena cava filters," 86 SNF cases are currently pending in the MDL, and Judge Campbell has informed the parties that he is willing to oversee the SNF cases. All of the cases—permanent and retrievable filter alike—concern common and overlapping factual and legal issues with which Judge Campbell is intimately familiar. Discovery concerning the SNF has already occurred in MDL No. 2641: many documents that have been produced discuss the SNF, many witnesses have testified about the SNF, and many experts have offered opinions about the SNF. Thus, given the overlapping issues, the number of cases involved, and likelihood for inconsistent substantive and procedural determinations if the cases progress independently, coordination or consolidation of the SNF cases is warranted. Expanding MDL No. 2641 to include one additional filter would be the most convenient and efficient path forward, but creating a new MDL, pursuant to 28 U.S.C. section 1407, before Judge Campbell that concerns the SNF would be an alternative approach.

FACTS

An inferior vena cava filter is a prescription, implantable medical device that is placed into a patient's inferior vena cava (the largest vein in the body that returns blood to the heart) to prevent

large blood clots that develop in the lower extremities from moving through the heart and into the lungs where they can precipitate a life-threatening condition called a pulmonary embolism. Bard has designed, manufactured, and/or sold various inferior vena cava filters over the years. All of Bard's inferior vena cava filters except one (the SNF) are "retrievable" filters, meaning that they are designed to be placed into the patient's inferior vena cava for a period of time, and then later can be removed. At their discretion, physicians can also decide to leave these filters in the patient permanently. The SNF is a "permanent" filter, meaning that it is designed to be placed into the patient's inferior vena cava for the rest of the patient's life without the option to remove. Both retrievable and permanent filters are designed to protect the patient against pulmonary embolism.

On August 17, 2015, the Panel established *IN RE: Bard IVC Filters Products Liability Litigation*, MDL No. 2641, before the Honorable David G. Campbell in the District of Arizona. The Transfer Order directed centralization of cases involving "Bard's retrievable inferior vena cava filters . . . ." *In re: Bard IVC Filters Prod. Liab. Litig.*, 122 F. Supp. 3d 1375, 1376 (J.P.M.L. 2015). Bard's retrievable filters are the Recovery Filter, G2 Filter, G2X/G2 Express Filter, Eclipse Filter, Meridian Filter, and Denali Filter. Cases involving each of these filters are currently pending in MDL No. 2641.

In December 2015, Judge Campbell entered a case management order to allow the plaintiffs to file complaints directly in the MDL, rather than going through the transfer process from the venues in which the cases would otherwise be filed. The plaintiffs were permitted to file a "Short Form Complaint" that identified the District Court and Division in which venue would be proper absent direct filing. Upon completion of pretrial proceedings, the directly filed cases are expected to be transferred to the District Court identified in the Short Form Complaint. Case Management Or. No. 4, Dec. 17, 2015, at 3, attached as Exhibit A.

Since December 2015, more than 100 SNF cases have been directly filed in the MDL, and each Short Form Complaint identified the likely transferor court. Additionally, one SNF case was filed in California state court, removed to federal court, and then transferred to MDL No. 2641. All federal-court SNF cases are currently pending in MDL No. 2641, and a listing of all such cases is attached as Schedule of Actions, attached as Exhibit C. Although several of the SNF cases have been dismissed, and the plaintiffs in several other cases have announced their intent to dismiss their actions, 86 SNF cases are still pending in MDL No. 2641. Judge Campbell has informed the parties that he is willing to oversee the SNF cases if the Panel either expands MDL No. 2641 to include the SNF cases or forms a new MDL concerning the SNF cases. Case Management Order No. 38, Oct. 5, 2018, at 6, attached as Exhibit B.

As product liability cases involving the same product, the SNF cases will involve common questions of fact about the SNF's design, testing, risk profile, manufacturing, and labeling. The SNF cases also involve common questions of fact about Bard's interactions with the FDA, sales activity, marketing, employee training, interactions with physicians, warnings provided to the medical community, and post-market adverse event monitoring and analysis concerning the SNF. Nearly all of these issues concern information and activities that occurred in, or were directed from, Arizona. Most of the Bard current and former employees who are the likely corporate fact witnesses in the SNF cases are likewise located in Arizona, and many of them are the same witnesses who have been deposed or testified at bellwether trials in MDL No. 2641.

Fact and expert discovery in MDL No. 2641 have demonstrated that issues concerning the SNF and Bard's retrievable filters are intertwined and inextricable. For example, discovery concerning Bard's retrievable filters has resulted in the production of over 145,000 documents that discuss the SNF. These documents concern SNF-related submissions to the FDA, the sales and

marketing of the SNF, documents comparing filter performance and failure rates to the SNF, and internal and regulatory communications relating to the SNF. These documents have been used already in cases involving Bard's retrievable filters.

Additionally, in their depositions about Bard's retrievable filters, 88 Bard witnesses have been questioned about and/or testified about the SNF. Bard expects that when its witnesses are deposed about the SNF, the witnesses likewise will face questions about retrievable filters. Moreover, in the three MDL trials concerning Bard's retrievable filters, the jury considered extensive evidence, testimony, expert opinion, and arguments concerning the SNF. Bard expects that the trials involving the SNF will similarly concern evidence, testimony, expert opinion, and arguments concerning retrievable filters.

Finally, several major issues in the litigation are common to both the SNF and Bard's retrievable filters. Every case involves factual questions about whether inferior vena cava filters as a whole are effective in preventing pulmonary embolism. Every case involves factual questions about what the medical community has known for decades (stretching back to the 1970s and 1980s) about the risks associated with inferior vena cava filters as a whole. Every case involves factual questions about FDA's role in considering and overseeing pre-market and post-market issues concerning implantable medical devices and inferior vena cava filters. Every case involves the same metallurgical (all of the filters are made of the metal nitinol) issues about fracture resistance and use of electron microscopy to evaluate surface finishes. And every case involves evidence of different types of, and sufficiency of, bench testing of the filters, as well as types of, and sufficiency of, animal and clinical testing of the filters.

ARGUMENT

For the convenience of parties and witnesses and to promote the just and efficient conduct of the SNF cases, the Panel should expand the scope of MDL No. 2641 to include cases concerning Bard's SNF. Alternatively, pursuant to 28 U.S.C. section 1407, the Panel should establish a new MDL concerning the SNF before Judge Campbell in the District of Arizona.

A. The Panel should expand MDL No. 2641 to include SNF cases.

The Panel is empowered to expand the scope of an existing MDL where the cases proposed to be consolidated involve common questions of fact with the actions in the existing MDL. *See, e.g., In re Generic Digoxin & Doxycycline Antitrust Litig.*, 222 F. Supp. 3d 1341, 1343-44 (J.P.M.L. 2017) (expanding scope of MDL No. 2724 beyond generic digoxin and doxycycline to include additional generic drugs that shared common questions of fact with the actions in MDL No. 2724); *In re Viagra (Sildenafil Citrate) Prod. Liab. Litig.*, 224 F. Supp. 3d 1330, 1332 (J.P.M.L. 2016) (expanding scope of MDL No. 2691 from cases involving only Viagra to include Cialis cases where both types of cases involved common questions of fact).

Here, MDL No. 2641 already involves six types of Bard filters: Recovery Filter, G2 Filter, G2X/G2 Express Filter, Eclipse Filter, Meridian Filter, and Denali Filter. Just as the Panel found that cases involving each of the six "retrievable" Bard filters shared facts in common with one another, cases involving the SNF share facts in common with cases involving the retrievable filters. As noted above, over 140,000 documents discussing the SNF have already been produced in MDL No. 2641, 88 Bard witnesses have been questioned about and/or testified about SNF, and the three trials in MDL No. 2641 dealt with issues involving the SNF. Bard anticipates that SNF cases will likewise involve documents, deposition testimony, and trials that deal with issues regarding Bard retrievable filters. *In re Generic Digoxin & Doxycycline Antitrust Litig.*, 222 F. Supp. 3d at 1343

(J.P.M.L. 2017) (noting, as a factor in expanding the MDL, that "the same witnesses are likely [to be] subject to discovery across all actions"). Moreover, numerous global questions of fact concern all Bard filters, retrievable and SNF alike, including whether inferior vena cava filters as a whole are effective; the medical community's knowledge about risks associated with inferior vena cava filters as a whole; the nature of the scientific literature about inferior vena cava filters as a whole; the FDA's role in considering safety and efficacy of implantable medical devices and inferior vena cava filters; the metallurgical properties of nitinol, which comprise all of Bard's inferior vena cava filters; and the nature and sufficiency of bench testing, animal testing, and clinical studies about inferior vena cava filters as a whole. *In re Viagra (Sildenafil Citrate) Prod. Liab. Litig.*, 224 F. Supp. 3d at 1332 (noting, as a factor in expanding the MDL, that "[t]he actions likely will involve overlapping discovery concerning many of the same scientific studies, common expert witness issues, and duplicative pretrial motions.") Given these circumstances, "including an additional product in the MDL is warranted." *Id*.

Moreover, other practical considerations weigh in favor of expanding MDL No. 2641. Judge Campbell, having presided over MDL No. 2641 for over three years, is intimately familiar with the parties, counsel, the factual issues concerning Bard's retrievable filters and the SNF, as well as the recurring procedural and substantive legal issues. And Judge Campbell has informed the parties that he is willing to oversee the SNF cases if the Panel expands MDL No. 2641 to include the SNF cases. The SNF cases can proceed most expeditiously with several dozen case management orders already in place that govern nearly every aspect of discovery, and significant fact and expert discovery already having occurred concerning the SNF.

Expanding MDL No. 2641 to include the SNF cases also will avoid a host of inefficiencies, many of which likely will not be apparent until in the throes of discovery (should the MDL not be

expanded to include SNF cases). However, readily identifiable inefficiencies would include potentially changing the venue of 86 SNF cases, starting any coordinated or consolidated proceedings from scratch, re-litigating the scope and contents of a protective order, re-litigating the scope and contents of an ESI protocol, isolating and re-producing SNF-related documents, re-doing privilege logs, re-doing a deposition protocol, re-deposing witnesses about SNF-related issues, rehashing expert issues that involve common questions of fact with the retrievable filter cases (e.g., filter efficacy, metallurgical issues, and regulatory issues), reconfiguring and reproducing expert reports, and litigating potentially redundant *Daubert* challenges. All of these issues, and likely many more, can be avoided by expanding MDL No. 2641 to include SNF cases. Finally, any discovery conducted in SNF cases that is separate from MDL No. 2641 will need to be constantly re-produced and/or cross-noticed in MDL No. 2641 (and vice versa).

For all of these reasons, expanding the existing MDL No. 2641 to include SNF cases best promotes the just and efficient conduct of both the SNF cases and the retrievable filter cases.

B. Alternatively, the Panel should form a new MDL concerning the SNF in the District of Arizona before Judge Campbell.

Pursuant to 28 U.S.C. section 1407(c), a party to a civil action suitable for coordinated or consolidated pretrial proceedings may move to initiate such proceedings. Coordinated or consolidated proceedings are warranted when one or more common questions of fact are pending in different districts, and such proceedings will be for the convenience of the parties and witnesses and will promote the just and efficient conduct of such actions. 28 U.S.C. § 1407(a).

Here, C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. are named defendants in each of the 86 cases listed in Exhibit C. Pursuant to a case management order in MDL No. 2641, 85 of the 86 SNF cases were filed directly in MDL No. 2641, and the district courts that the plaintiffs identified as the proper venue absent direct filing reflect 40 different district courts (this

information is also included in Exhibit C). Thus, for purposes of this Motion, the SNF cases should be treated as venued across 40 different district courts.

The 86 SNF cases are product liability actions that will concern many common questions of fact related to the SNF's design, testing, risk profile, manufacturing, and labeling. The SNF cases also involve common questions of fact about Bard's interactions with the FDA, sales activity, marketing, employee training, interactions with physicians, warnings provided to the medical community, and post-market adverse event monitoring and analysis concerning the SNF.

Centralization of the cases will serve the convenience of the parties and witnesses and will promote the just and efficient conduct of the litigation. Without an MDL, the 86 SNF cases will be dispersed across more than 40 different district courts, thereby virtually assuring duplicative and inconsistent discovery, inconsistent pretrial rulings, inconsistent privilege rulings, and inconsistent *Daubert* rulings—centralization of the cases will eliminate these issues, and will conserve the resources of the parties, their counsel, and the judiciary. *In re: Bard IVC Filters Prod. Liab. Litig*., 122 F. Supp. 3d 1375, 1376 (J.P.M.L. 2015) (citing these issues as factors warranting centralization of cases involving Bard's retrievable filters).

Finally, the District of Arizona is the appropriate transferee district. Nearly all of the relevant SNF-related activity occurred in, or was directed from, Arizona. Most of the Bard current and former employees who are the likely fact witnesses in the SNF cases are likewise located in Arizona where Bard Peripheral Vascular is headquartered and have also been fact witnesses in the current MDL. Judge Campbell has informed the parties that he is willing to oversee the SNF cases if the Panel forms a new MDL. As discussed above, Judge Campbell is already familiar with the factual and legal issues involved in the cases, and he has worked with the parties' counsel for several years already. *In re Am. Investors Life Ins. Co. Annuity Mktg. and Sales Practices Litig.*,

398 F. Supp. 2d 1361, 1362 (establishing an MDL before a judge who "has already developed familiarity with the issues present in this docket as a result of presiding over motion practice and other pretrial proceedings in the actions pending before her for the past year"). As such, the District of Arizona has the capacity and resources to successfully manage an SNF-related MDL.

Accordingly, if the Panel determines that expanding MDL No. 2641 is not warranted, it should establish an MDL for the SNF cases before Judge Campbell in the District of Arizona.

CONCLUSION

For the foregoing reasons, Bard respectfully requests that the Panel expand the scope of MDL No. 2641, *IN RE: Bard IVC Filters Products Liability Litigation* to include cases concerning Bard's SNF; or, alternatively, pursuant to 28 U.S.C. section 1407, establish a new MDL concerning the SNF before Judge Campbell in the District of Arizona.

RESPECTFULLY SUBMITTED this 1st day of November, 2018.

s/ *Richard B. North, Jr.*
Richard B. North, Jr.
Georgia Bar No. 545599
Matthew B. Lerner
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com