BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

MDL No. 2767

In re: Mirena IUS Levonorgestrel-Related Products Liability Litigation (No. II)

Oral Argument Requested

RESPONSE TO PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407

Nearly two and a half years ago, the Panel denied Plaintiffs' motion to centralize Mirena cases involving idiopathic intracranial hypertension, correctly recognizing that the limited number of plaintiffs' counsel and the predominance of individualized factual issues made centralization unnecessary and inappropriate. Since the Panel's decision, there have been no significant changes in circumstances that would justify a different outcome. To the contrary, the case against centralization is even stronger today: nearly a dozen cases have already been resolved; the remaining cases are now in widely varying procedural postures; the parties have demonstrated an ability to coordinate discovery informally; and common discovery is effectively complete, leaving only individualized, case-specific facts to be discovered. Centralization now would only delay the resolution of cases that are already proceeding justly and efficiently. The Panel should reaffirm its prior decision and allow the existing cases to move forward expeditiously toward resolution.

BACKGROUND

A. Overview of Mirena and Idiopathic Intracranial Hypertension

Mirena is an intrauterine device ("IUD") manufactured by Bayer that is approved by the FDA for five years of contraceptive protection. OB/GYNs specifically recommend Mirena for patients who are overweight or obese, for whom it maximizes safety and efficacy while avoiding health risks associated with estrogen-containing contraceptives. *See, e.g.*, Ex. 1, Edelman 2016,

at 1. Indeed, one recent study found that 63% of Mirena users were overweight or obese, compared to 48% of the general population. Ex. 2, Saito-Tom 2015, at 369.

Idiopathic intracranial hypertension ("IIH") is a treatable disorder marked by increased pressure in the skull with no evident cause (*e.g.*, tumor, blood clot, infection). IIH's most common symptoms are headaches and vision problems. With early treatment, permanent vision loss is rare. To date, scientists have identified just four risk factors for IIH: female sex, reproductive age, excess weight, and recent weight gain.[1] Because Mirena is used exclusively by women of reproductive age and disproportionately by overweight and obese women, one would naturally expect to see cases of IIH among Mirena users, regardless of whether Mirena played any causal role.

Plaintiffs in these cases nonetheless assert that Mirena's hormone causes IIH. Over the past two years, significant common fact and expert discovery has taken place concerning that claim. Notably, Plaintiffs' lead causation expert, Dr. Etminan, who conducted the sole published study purporting to link Mirena with IIH, has withdrawn from all Mirena litigation and renounced his published analysis.[2] During the first of two anticipated days of deposition testimony, Dr. Mahyar Etminan acknowledged fundamental errors in his article's methodology. In a remarkable development, he then promptly withdrew from all IIH litigation and has since

[1] *See* Ex. 3, Wall 2010, at 596 ("Other than obesity and recent weight gain, many conditions believed to be associated with IIH are just common disorders of women in childbearing years and are likely chance associations."); Ex. 4, Ball 2006, at 434 ("Apart from female sex and obesity there are no proven associations in idiopathic intracranial hypertension."); Ex. 5, Dhungana 2010, at 75 ("Over the years, case reports have linked various medications and systemic diseases with IIH. However, a number of studies which sought to evaluate the existence of these proposed associations have found no convincing evidence.").

[2] Jones Ward PLC, which represents nearly two-thirds of all IIH Plaintiffs and which prosecuted the first motion before this Panel, retained Dr. Etminan in 2014. Dr. Etminan failed to disclose this retention in his 2015 article, falsely declaring "no conflict of interest." Ex. 6, Etminan 2015.

confirmed in a sworn affidavit that nothing in his article "***provide[s] evidence that Mirena use increases the risk for intracranial hypertension***" and, further, that a proper analysis "suggests[s] that intracranial hypertension and Mirena use are '***likely not related***.'" Ex 7, Etminan Notices of Withdrawal; Ex. 8, Dec. 12, 2016 Etminan Affidavit ¶ 11 (emphasis added).

B. The First Group of Mirena IIH Cases (January 2014 – March 2014) and the First Motion for Centralization

The firm of Jones Ward PLC filed the first IIH case against Bayer on January 6, 2014 in the Western District of Kentucky. Over the next three months, the same firm filed eight additional cases in six different district courts. The complaints alleged that Plaintiffs developed IIH as a result of using Mirena and asserted nearly identical legal claims.

On May 27, 2014, Jones Ward filed a motion to centralize all Mirena IIH cases for pretrial proceedings in the Middle District of Tennessee, representing that "hundreds" of tag-along cases would subsequently be filed by Jones Ward and other firms in "approximately 40 different jurisdictions." Ex. 9, First Motion for Centralization 2. During the pendency of its motion, Jones Ward filed six additional cases, raising the total number of filed cases to fifteen. And at oral argument, counsel represented that three additional plaintiffs' firms had filed IIH cases against Bayer. Ex. 19, Oral Argument Transcript, at 20:2–12.

The Panel denied Plaintiffs' centralization motion on August 12, 2014, holding that "informal cooperation among the involved attorneys is both practical and preferable to centralization" in light of the "few involved counsel." *In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (Mirena I)*, 38 F. Supp. 3d 1380, 1381 (J.P.M.L. 2014). The Panel noted that even assuming "the number of actions is likely to expand substantially," Bayer was represented by national coordinating counsel who stood "ready and willing to share any overlapping discovery." *Id.* The Panel further reasoned that "individualized causation disputes [were] likely

to predominate" because (a) Plaintiffs' nonspecific symptoms (headaches and vision problems) would necessitate "a fact-intensive inquiry over whether each plaintiff was properly diagnosed" with IIH, and (b) the occurrence of IIH in non-Mirena users would necessitate individualized determinations regarding the cause of each plaintiff's IIH. *Id.* at 1381 & n.3.

Finally, the Panel rejected Plaintiffs' reliance on its prior decision centralizing Mirena actions alleging a different injury, perforation of the uterus, emphasizing that the perforation MDL involved "a far greater number of actions" and "numerous different plaintiffs' counsel." *Id.* at 1381. The perforation MDL, centralized before the Honorable Cathy Seibel in the Southern District of New York, is largely complete, with Judge Seibel having granted summary judgment to Bayer on all member cases in July 2016. *See In re Mirena IUD Prod. Liab. Litig.*, No. 13-MC-2434 (CS), 2016 WL 4059224 (S.D.N.Y. July 28, 2016) (appeal pending).

C. The Second Group of Mirena IIH Cases (August 2014 – Present)

Events over the past two and a half years confirm the soundness of the Panel's decision. Critically, the number of involved plaintiffs' counsel remains limited: nearly every Mirena IIH Plaintiff today is represented by Jones Ward (70 cases) or Miller DellaFera PLC (32 cases).[3] And although the number of cases has grown, the influx is far less than Plaintiffs predicted. Today, there are 116 cases (not the "hundreds" threatened) pending in 17 jurisdictions (not the 40 threatened), with the vast majority of them in a single district. *See* Schedule of Actions.

[3] Jones Ward and Miller DellaFera have filed their District of New Jersey cases through local counsel — Parker Waichman LLP, The Orlando Firm, P.C., and The D'Onofrio Firm LLC — although Bayer has communicated directly with Jones Ward and Miller DellaFera, who are directing the course of the litigation. The remaining cases listed on the Schedule of Actions have been filed by Davis & Crump, P.C. (10 cases), McSweeney/Langevin (2 cases), and Arias Sanguinetti Stahle & Torrijos, LLP (1 case). Bayer does not know whether these additional counsel are collaborating with Jones Ward or Miller DellaFera, although Parker Waichman is serving as local counsel for both Jones Ward and Davis & Crump.

Moreover, since the Panel's 2014 decision, the parties have cooperatively and successfully coordinated discovery across cases. Indeed, even before the Panel's decision, Bayer agreed to provide Plaintiffs' counsel with the full document production in the perforation MDL in lieu of formal written discovery, in order to avoid inefficient and needless duplication. In addition, from the time the first IIH case was filed, Bayer cross-noticed all company depositions taking place in the perforation MDL in all pending IIH actions and made provisions for any interested counsel to participate. Plaintiffs' counsel in IIH cases, in fact, participated in sixteen such depositions and took an additional six company depositions focused exclusively on IIH.

Following the Panel's first decision, Bayer entered into a number of additional agreements with Plaintiffs' counsel to conduct extensive common discovery. For example, Bayer and Jones Ward agreed that general "discovery for all IIH . . . cases (both filed and unfiled)" would be concluded by December 4, 2015, and that depositions (including those taken in the perforation MDL) and discovery could be used in all current or future IIH cases. Ex. 10, E-mail chain between Brian O'Donoghue and Larry Jones.

Bayer subsequently reached similar agreements with the Miller DellaFera firm. *See* Ex. 11, E-mail chain between James Shepherd and Tom DellaFera (agreeing to use depositions taken by Jones Ward in lieu of re-deposing most Bayer company witnesses); Ex. 12, Joint Discovery Plan (*Lee*) ("Following the JPML's guidance, the parties have been working to coordinate discovery in this and all other IIH cases around the country. To date, certain depositions have been taken which the parties agree may be used in the present matter. . . . In addition, Bayer has produced discovery responses and documents in both the Mirena MDL and many of the pending non-consolidated IIH cases which may be pertinent. The parties anticipate using the discovery that has and will occur in the MDL and these other cases . . . .").

With these agreements in place, Bayer has provided Plaintiffs with more than ***11 million pages*** of documents, touching on every facet of Mirena's development, labeling, marketing, and safety surveillance, including:

- 483,067 pages from Mirena's Investigational New Drug Application and New Drug Application submissions, including (among other items) correspondence between Bayer and the FDA regarding Mirena, Mirena promotional materials, and safety reporting;
- 95,141 pages from Bayer's marketing database;
- 7,221 pages comprising standard operating procedures and policies governing Bayer's labeling, marketing, and safety practices;
- Documents from 41 custodians, including current and former Bayer employees with roles in Mirena's development, labeling, marketing, and safety surveillance;
- 5 depositions pursuant to Rule 30(b)(6) (consisting of 1,613 transcript pages) on multiple topics related to Bayer's regulatory, drug safety, sales, marketing, and medical affairs functions; and
- 29 fact depositions (consisting of 10,113 transcript pages) of current and former Bayer employees involved with the development, clinical trials, and post-marketing surveillance of Mirena.

While Plaintiffs have recently sought still more discovery, the overwhelming bulk of common discovery from Bayer has been complete for many months. Indeed, no current or former Bayer employee has been deposed since March 2016. Bayer will of course make all of this discovery available to additional plaintiffs in the same manner.

Against this discovery backdrop, cases are quickly advancing toward resolution. Eleven cases, including nearly half of those pending at the time of the Panel's first decision, have already been resolved:

- *Thurmond* (N.D. Ga.): Summary judgment granted for lack of expert testimony. *See Thurmond v. Bayer Healthcare Pharm., Inc.*, 649 F. App'x 1003 (11th Cir. 2016).
- *Hoover* (W.D. Mo.): Summary judgment granted for lack of expert testimony on specific causation. Ex. 13, *Hoover* Summary Judgment Order.
- *Kellington* (W.D. Va.): Voluntarily dismissed on the morning of *Daubert* and dispositive

motion hearing.

- *Creasy* (E.D. Tenn.): Voluntarily dismissed after the plaintiff failed to produce expert testimony on specific causation.
- *Houston* (N.D. Ala.): Voluntarily dismissed after the plaintiff's expert refused to give a causation opinion during her deposition.
- *Copley* (M.D. Tenn.): Voluntarily dismissed while summary judgment motion was pending.
- *Cutruzzulla* (W.D. Penn.): Dismissed upon the withdrawal of the plaintiffs' counsel and the *pro se* plaintiff's failure to appear.
- *Finn* (D.N.J.): Dismissed upon the withdrawal of the plaintiffs' counsel and the *pro se* plaintiff's failure to appear.
- *Adriana Miller* (C.D. Cal.): Dismissed upon the withdrawal of the plaintiffs' counsel and the *pro se* plaintiff's failure to appear.
- *Martin* (W.D. Ky.): Voluntarily dismissed.

In six additional cases before five different district courts (*Bridges*, *Cheek*, *Sellers*, *Miller*, *Zamudio-Soto*, and *Coning*), briefing on *Daubert* and summary judgment motions is complete and, in some instances, orders have been issued. *See* Ex. 14, *Sellers Daubert* Orders; Ex. 15, *Miller Daubert* Orders. Trial is scheduled to commence in *Zamudio-Soto* (N.D. Cal.) on April 10, 2017, and a trial in *Miller* and *Sellers* is scheduled for May 1, 2017 in the Western District of Missouri.

The fact that so many Mirena IIH cases have already been resolved or prepared for trial underscores that an MDL proceeding at this late stage is unnecessary.

D. The Present Motion

Conspicuously, in the two and a half years since this Panel's first order, neither Jones Ward nor Miller DellaFera — which together represent almost ninety percent of all Mirena IIH Plaintiffs — has sought centralization. The reason is simple: informal coordination has proved successful in mitigating any potential issues posed by the multiplicity of Plaintiffs.

Instead, the present motion is brought by Davis & Crump, P.C., which filed its first IIH case just six months ago and its remaining nine cases (including the single case pending in its preferred forum) less than three months before filing the present motion. Davis & Crump has taken no material steps to advance its cases. To the contrary, immediately after filing this motion, it sought to stay all proceedings.

Earlier today, Miller DellaFera filed an Interested Party Response stating that the litigation would benefit from formal coordination. Bayer has also inquired about the position that Jones Ward plans to take on Davis & Crump's motion. While the firm has not conveyed its final position, it has suggested that it too may reverse course and acquiesce in Davis & Crump's attempt to reboot the litigation. Given the extensive discovery and case-specific proceedings over the past two and a half years and the fact that there has been no meaningful change in the regulatory or scientific record, there is no principled basis to justify such an about face.

ARGUMENT

I. The Panel Should Not Centralize These Actions

A. The Principal Concerns Underlying the Panel's Earlier Denial of Centralization Apply with Even Greater Force Today

Reconsideration of a prior denial of centralization is appropriate "'only rarely, . . . where a significant change in circumstances has occurred.'" *In re Wells Fargo Bank, N.A., Mortg. Corp. Force-Placed Hazard Ins. Litig.*, 959 F. Supp. 2d 1363, 1364 (J.P.M.L. 2013). Here, there has been no such change. To the contrary, recent developments render centralization even less appropriate now than it was two and a half years ago.

First, it remains true that there are still "few involved counsel." *Mirena I*, 38 F. Supp. 3d at 1381. Of the 116 cases listed in the Schedule of Actions, only three cases involve law firms other than Jones Ward, Miller DellaFera, Davis & Crump, or their affiliated local counsel. And

Bayer continues to have "national counsel coordinating its response to this litigation." *Id.* As the Panel recently recognized, where plaintiffs are "represented by only three groups of plaintiffs' counsel," informal coordination remains "eminently feasible." *In re Xytex Corp. Sperm Donor Prod. Liab. Litig.*, No. MDL 2751, 2016 WL 7222067, at *1 (J.P.M.L. Dec. 7, 2016).[4]

Indeed, Bayer has closely coordinated discovery and pretrial matters with all three plaintiffs' firms. *See* Ex. 16, Joint Motion to Extend Deadlines (*Bridges*) (Jones Ward representing that "[t]he parties have agreed to informally coordinate the cases" and that "Plaintiffs' counsel has set depositions of [Bayer's] corporate representatives or former employees . . . for use in all cases"); Ex. 17, Joint Discovery Plan (*Anderson*) ¶ 5 (similar); Ex. 12, Joint Discovery Plan (*Lee*) ¶ 5 (Miller DellaFera representing that "the parties have been working to coordinate discovery in this and all other IIH cases" and that "[t]he parties anticipate using the discovery that has and will occur in the MDL and [other IIH] cases"); Ex. 18, Joint Discovery Plan (*Hopkins*) ¶ 5 (Davis & Crump representing that "plaintiffs across the country and defendant have worked to coordinate discovery in this and all other IIH cases" and that "[t]he parties here anticipate that they will be able to leverage this existing discovery to ensure an efficient litigation"). In short, the benefits of centralization are already being achieved informally. *See In re OxyElite Pro & Jack3d Prod. Liab. Litig. (No. II)*, 65 F. Supp. 3d 1412, 1413–14 (J.P.M.L. 2014) (re-denying centralization where the parties had "made substantial

[4] Davis & Crump's assertion that it "expects to file over one hundred lawsuits . . . and is currently aware of several hundred more unfiled cases" does not warrant centralization. Opening Br. 6. The Panel has repeatedly declined to "take into account the mere possibility of future filings in [its] centralization calculus," particularly where the additional "potential plaintiffs would be represented by movants' counsel" and the number of involved law firms would remain limited. *In re Qualitest Birth Control Prod. Liab. Litig.*, 38 F. Supp. 3d 1388, 1389 (J.P.M.L. 2014).

efforts to informally coordinate discovery in all actions" since the Panel's first denial).

Second, at this point in the litigation, further common discovery is both unnecessary and inappropriate. To date, Bayer has made available more than 11 million pages of documents in all matters where discovery has been served on Bayer and protective orders are in place. Bayer has also presented five company representatives for Rule 30(b)(6) depositions to address regulatory, drug-safety, sales, marketing, and medical-affairs issues. Plaintiffs' assertion that centralization is necessary to "ensure that all parties have access to the same essential documents" and to prevent duplicative depositions of Bayer's employees, Opening Br. 10, is belied by the fact that Bayer has already committed to produce the same documents and to use the same general depositions across all cases. To the extent that this discovery has not yet been provided to Davis & Crump, it is only because that firm has not yet sought information from Bayer in the few cases it has filed to date. Once it does, it will have access like all others. Where, as here, "plaintiffs in actions that are concluded or well advanced have conducted extensive discovery of defendant . . . in areas of common factual inquiry" and defense counsel is "willing[] to make this common discovery applicable in those actions that are not far advanced," centralization is unnecessary. *In re Eli Lilly & Co. Oraflex Prod. Liab. Litig.*, 578 F. Supp. 422, 423 (J.P.M.L. 1984).

In fact, the remaining discovery is largely case-specific. That discovery will consist primarily of collecting medical records and deposing Plaintiffs and their physicians. Centralization would not facilitate the efficient management of these efforts, which can be better overseen by district court judges in the relevant jurisdictions.

Third, the pending cases are in significantly different procedural postures, and many of them are procedurally advanced. Eleven cases have been already been resolved, three cases are set for trial in early 2017, and *Daubert* and summary judgment briefing is complete in three

others. By contrast, deadlines to complete case-specific discovery have yet to be set in many of the newer-filed cases. Centralizing the actions thus likely would delay the progress of the long-pending actions by yoking them to the newly filed cases, "with little corresponding efficiency or convenience benefits." *In re Time Warner Cable, Inc., Tel. Consumer Prot. Act (TCPA) Litig.*, No. MDL 2732, 2016 WL 5846036, at *1 (J.P.M.L. Oct. 3, 2016).[5]

Fourth, in the wake of this Panel's 2014 decision not to centralize these cases, Plaintiffs have chosen to file almost all new cases in the District of New Jersey. As a result, the vast majority of cases (89 of the 116 cases listed in the Schedule of Actions) are pending in a single district. There is no need to create a new apparatus to oversee the pretrial proceedings in cases that are already progressing in an orderly and efficient manner.

Finally, dispositive motions filed in further advanced cases confirm that "individualized causation disputes [are] likely to predominate." *Mirena I*, 38 F. Supp. 3d at 1381. Just as the Panel predicted in refusing centralization before, in every dispositive motion it has filed, Bayer has prominently featured arguments that the plaintiff did not suffer from IIH or that her IIH occurred for some reason unrelated to Mirena (*e.g.*, weight or recent weight gain). *See, e.g.*, Ex. 13, *Hoover* Summary Judgment Order; *Thurmond*, 649 F. App'x 1003. And while Bayer does not deny that the subject actions share some common issues, that has never been enough to

[5] *See also, e.g., In re CVS Caremark Corp. Wage & Hour Emp't Practices Litig.*, 684 F. Supp. 2d 1377, 1379 (J.P.M.L. 2010) (denying motion for centralization where "[a] significant amount of discovery had already taken place" in some cases, while "little, if any, pretrial activity" had occurred in others); *In re Table Saw Prods. Liab. Litig.*, 641 F.Supp.2d 1384, 1384–85 (J.P.M.L. 2009) (declining to create an MDL where "[a] significant number of the actions [were] substantially advanced" and "[o]ther actions were only recently commenced"); *In re G. D. Searle & Co. "Copper 7" IUD Prod. Liab. Litig.*, 483 F. Supp. 1343, 1345 (J.P.M.L. 1980) (holding that where "the parties have been expeditiously preparing the[] actions for trial or disposition by other means[,] . . . the inherent disadvantages of Section 1407 transfer outweigh the benefits of transfer for coordinated or consolidated pretrial proceedings" (citation omitted)).

justify centralization, *Qualitest*, 38 F. Supp. 3d at 1389, and here, the common issues require little discovery that has not already been conducted, *see In re Oxycontin Prod. Liab. Litig. (No. II)*, 395 F. Supp. 2d 1358, 1359 (J.P.M.L. 2005) ("Movants have failed to demonstrate that any common questions of fact and law are sufficiently complex, *unresolved* and/or numerous to justify Section 1407 transfer . . . ." (emphasis added)). Given the predominance of individualized factual inquiries, centralization is improper. *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 959 F. Supp. 2d 1375, 1376 (J.P.M.L. 2013) (noting that "whether any particular plaintiff developed [a disease] as a result of taking [a medicine]" is "a highly individualized inquiry").[6]

In short, Bayer submits that there has been no change in circumstances that would merit a reversal of the Panel's earlier decision. *Accord In re Ambulatory Pain Pump-Chondrolysis Prod. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010) (affirming earlier denial of centralization, even though the number of related actions had increased from 13 to 102, because "the issues that weighed against centralization in th[e] earlier docket remain").

There is recent Panel precedent close at hand. The Mirena IIH litigation is analogous to the Cymbalta litigation, which the Panel twice declined to centralize. In December 2014, the Panel denied the plaintiffs' motion for centralization of 25 Cymbalta cases, emphasizing that the procedural posture of the actions "varie[d] significantly," "most, if not all, of the common discovery ha[d] already taken place in . . . earlier-filed actions," and the litigation involved "only

[6] Although the Panel subsequently centralized the Lipitor litigation, the circumstances were far different than those presented here. There, 226 constituent and tag-along actions brought by 26 unique plaintiffs' counsel were pending before more than 40 district courts and 100 federal judges, making coordination "highly difficult, if not impossible," and common discovery was still in the very early stages. *In Re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Prods. Liab. Litig.* (*Lipitor II*), 997 F. Supp. 2d 1354, 1356 (J.P.M.L. 2014).

a limited number of plaintiffs' counsel." *In re Cymbalta (Duloxetine) Prods. Liab. Litig. (No. I)*, 65 F. Supp. 3d 1393, 1393–94 (J.P.M.L. 2014). In October 2015, the Panel again declined to centralize 41 cases, observing that "there ha[d] been no significant change in circumstances" — cases remained "at substantially different procedural stages," "[c]ommon discovery ha[d] advanced even further," and although the number of plaintiffs' firms had doubled to four, that increase was not "significant." *In re Cymbalta (Duloxetine) Prods. Liab. Litig. (No. II)*, 138 F. Supp. 3d 1375, 1376 (J.P.M.L. 2015). Less than nine months later, the parties reached a comprehensive framework for resolution — a remarkably rapid timeline for mass-tort litigation. Like the Cymbalta cases, the Mirena IIH cases are in substantially different procedural postures, have largely completed general discovery, and involve a small number of unique counsel. Centralization is not warranted here.[7]

B. Centralization Would Not Further the Goals of 28 U.S.C. § 1407(a)

Pursuant to § 1407(a), centralization is appropriate where (1) the cases involve "one or more common questions of fact," (2) centralization would serve "the convenience of parties and witnesses," and (3) transfer would "promote the just and efficient conduct of" the litigation.

Here, centralization would satisfy none of these criteria. Because general discovery is largely complete, transfer would not facilitate the litigation of any common factual questions. Nor would centralization serve "the convenience of parties and witnesses," as it would do little to minimize travel or other expenses associated with future case-specific discovery efforts.

Finally, centralization would not "promote the just and efficient conduct of" this

[7] The cases Plaintiffs cite are distinguishable. In *In re Pradaxa (dabigatran etexilate) Prod. Liab. Litig.*, 883 F. Supp. 2d 1355 (J.P.M.L. 2012), and *In re DePuy Orthopaedics, Inc., ASR Hip Implant Prod. Liab. Litig.*, 753 F. Supp. 2d 1378, 1379 (J.P.M.L. 2010), all of the parties supported centralization of the related actions. And *In re Nexium (Esomeprazole) Prod. Liab. Litig.*, 908 F. Supp. 2d 1362, 1364 (J.P.M.L. 2012), involved over one thousand plaintiffs.

litigation. Immediately after filing a handful of cases, and without taking any steps to advance its cases, Davis & Crump filed its petition for centralization, copying whole paragraphs nearly verbatim from Jones Ward's earlier unsuccessful brief. *Cf. In re Boehringer Ingelheim Pharm., Inc., Fair Labor Standards Act (FLSA) Litig.*, 763 F. Supp. 2d 1377, 1378 (J.P.M.L. 2011) (noting that counsel's filing of actions on the eve of its centralization motion "weigh[s] against centralization"). Counsel's petition proclaims that centralization "is necessary to avoid . . . inefficient litigation of these cases," Opening Br. 11, even though it represented in a filing just nine days earlier the exact opposite — that it would be able to leverage existing discovery from other IIH cases "to ensure an efficient litigation," Ex. 18, Joint Discovery Plan (*Hopkins*) ¶ 5. Immediately after filing its petition, counsel sought to avoid prosecuting the very cases it filed by moving to stay them during the petition's pendency, suggesting a plan to warehouse its lawsuits in an MDL while minimizing actual work that might advance resolution. *Cf. In re Mentor Corp. Obtape Transobturator Sling Prod. Liab. Litig.*, No. 4:08-MD-2004 (CDL), 2016 WL 4705827, at *1 (M.D. Ga. Sept. 7, 2016) (noting the practice of some plaintiffs' counsel to dump "non-meritorious cases" into MDLs with "little pre-filing preparation," in the hope of sharing in the proceeds of global settlements "without the individual merit of their case being scrutinized").[8] Indeed, the fact that the firm is waiting to see how the Panel resolves its petition before deciding whether to file over one hundred additional cases, *see* Opening Br. 6, confirms its "warehousing" strategy.

That tactic is anything but just or efficient. Section 1407 exists to allow the smooth coordination of existing actions, not "to further the interests of particular counsel" by providing a

[8] As the Panel has already recognized, IIH claims are uniquely susceptible to getting lost in an MDL, where the "fact-intensive inquiry over whether each plaintiff was properly diagnosed" would be substantially delayed and perhaps even avoided. *Mirena I*, 38 F. Supp. 3d at 1381.

mechanism to avoid diligently prosecuting filed cases. *CVS Caremark Corp.*, 684 F. Supp. 2d at 1379; *see also In re Truck Acc. Near Alamagordo, N.M., on June 18, 1969*, 387 F. Supp. 732, 734 (J.P.M.L. 1975) (holding that plaintiffs' "ulterior motive for seeking transfer amount[ed] to an attempted misuse of the statute"); *Jones v. Eli Lilly & Co.*, No. 1:15-CV-00701-JMS, 2015 WL 6132937, at *10 (S.D. Ind. Oct. 19, 2015) (in the wake of the Panel's denial of a Cymbalta MDL, declining to create a quasi-MDL for the "convenience [of] counsel," and admonishing that "Plaintiffs' counsel must be prepared to devote the resources needed to effectively litigate each client's claim, and should not file numerous lawsuits on behalf of dozens of clients if unable to do so").

II. If the Panel Determines That an MDL Is Warranted, the Cases Should Be Transferred to Judge Seibel in the Southern District of New York

Should the Panel conclude that centralization is warranted, any proceeding should be centralized before Judge Seibel, who ably managed the perforation MDL, in the Southern District of New York. In considering the proper forum for an MDL transfer, the Panel regularly considers whether a particular judge "already has relevant experience with some issues likely involved in th[e] litigation." *In re Wireless Tel. Radio Frequency Emissions Prod. Liab. Litig.*, 170 F. Supp. 2d 1356, 1358 (J.P.M.L. 2001); *see also In re Sony Corp. SXRD Rear Projection Television Mktg., Sales Practices & Prod. Liab. Litig.*, 655 F. Supp. 2d 1367 (J.P.M.L. 2009) (emphasizing that the transferee judge was "already familiar with the contours of th[e] litigation by virtue of presiding over similar litigation" in the past); *In re "Factor VIII or IX Concentrate Blood Products" Prod. Liab. Litig.*, 853 F. Supp. 454, 455 (J.P.M.L. 1993) (highlighting that the transferee judge had gained "familiarity with the issues . . . by presiding at [a] recent trial" involving the product at issue); *In re Cutter Labs., Inc. "Braunwald-Cutter" Aortic Heart Valve Prod. Liab. Litig.*, 465 F. Supp. 1295, 1298 (J.P.M.L. 1979) (transferring the litigation to a judge

who had presided over trials that shared many of the same "complex technical and medical questions"). For instance, in transferring the *In re Effexor (Venlafaxine Hydrochloride) Product Liability Litigation* to Judge Rufe, the Panel emphasized that she was already presiding over an MDL that involved another of the defendant's products, presented potentially overlapping discovery issues, and involved some of the same counsel. 959 F. Supp. 2d 1359, 1360 (J.P.M.L. 2013). Similarly, the Panel recently transferred the *In re Fluoroquinolone Product Liability Litigation* to Judge Tunheim because his "familiar[ity] with the scientific and regulatory background of Levaquin in his capacity as transferee judge for a separate Levaquin MDL" involving a different injury would "benefit the parties and facilitate the just and efficient conduct of th[e] litigation." 122 F. Supp. 3d 1378, 1381 (J.P.M.L. 2015).

Judge Seibel is deeply familiar with many of the general issues presented by the IIH cases, given her experience presiding over the Mirena perforation MDL. *See Lipitor II*, 997 F. Supp. 2d at 1356 (noting that an MDL judge "of necessity[] acquires an unusually high degree of familiarity with . . . the litigation's underlying subject matter"). Not only is Judge Seibel knowledgeable about the scientific and regulatory background of Mirena, but she and Magistrate Judge Smith are also well versed in Bayer's document production and 30(b)(6) and fact-witness depositions, which the parties are using in the IIH cases. Judge Seibel and Magistrate Judge Smith are therefore best positioned to adjudicate disputes regarding any future discovery requests that Plaintiffs might propound.

Moreover, Judge Seibel has proven herself to be a capable transferee judge in complex pharmaceutical product liability MDLs, having fairly and efficiently resolved all 1,755 actions in

the perforation MDL in a span of approximately three years.[9] Indeed, Judge Seibel initially terminated the MDL on August 9, 2016, but subsequently reopened it for administrative convenience to account for any newly filed cases during the pendency of an appeal of her *Daubert* and summary judgment orders. Given that Judge Seibel is not presently presiding over any other MDL proceeding, she has ample bandwidth to steer the Mirena IIH litigation to a just and efficient resolution.

Transferring the litigation to Judge Seibel would also satisfy many of the other criteria that the Panel regularly considers in selecting an appropriate transferee district: the Southern District of New York is near Bayer's corporate headquarters, and it is a geographically-central metropolitan forum that is easily accessible to the parties, witnesses, and counsel by several major international airports.[10] *See In re Mirena IUD Prod. Liab. Litig.*, 938 F. Supp. 2d 1355, 1358 (J.P.M.L. 2013) (transferring the Mirena perforation MDL to the Southern District of New York in part because it was near Bayer's corporate headquarters and the district would be "easily accessible for th[e] nationwide litigation"); *In re Propecia (Finasteride) Prod. Liab. Litig.*, 856 F. Supp. 2d 1334, 1335 (J.P.M.L. 2012) (transferring the litigation to the Eastern District of New York to be close to the defendant's New Jersey headquarters); *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, 398 F. Supp. 2d 1371, 1372 (J.P.M.L. 2005) (emphasizing that the transferee forum is "a geographically central, metropolitan district equipped with the

[9] *See* U.S. Judicial Panel on Multidistrict Litigation, *MDL Statistics Report* (Sept. 15, 2016), http://www.jpml.uscourts.gov/sites/jpml/files/Recently_Terminated%20MDLs-1-1-2016_to_9-15-2016.pdf (noting that fewer than 25% of the MDLs terminated in 2016 did so within three years of transfer).

[10] Bayer's national counsel are located in Chicago, Washington, D.C., and Houston, and Plaintiffs' counsel are located in Louisville, Charlottesville, and Gulfport, Mississippi. The Bayer Defendants are headquartered in New Jersey, Germany, and Finland. Plaintiffs are scattered throughout 32 different states.

resources that this complex products liability litigation is likely to require"). Nor is the absence of IIH actions pending in the Southern District of New York dispositive, given Judge Seibel's unique experience. *See In re Pella Corp. Architect & Designer Series Windows Mktg., Sales Practices & Prod. Liab. Litig.*, 996 F. Supp. 2d 1380, 1382–83 (J.P.M.L. 2014) (transferring litigation to a district where no constituent actions were pending, because the transferee judge's experience overseeing another MDL with similar allegations was "likely to benefit the parties . . . and to otherwise facilitate the just and efficient conduct of th[e] litigation").

Other potential districts do not offer the same advantages:

Southern District of Mississippi: Bayer would have no substantive objection to centralization in the Southern District of Mississippi before Chief Judge Guirola, who is an experienced and able jurist, but the forum would be considerably less convenient to the parties and all of the counsel except (notably) Davis & Crump, which is based there.

District of New Jersey: Miller DellaFera now seeks centralization in the District of New Jersey. Although Judge Wigenton currently presides over the largest number of IIH cases, neither Judge Wigenton nor the District of New Jersey has favorable docket conditions. Judge Wigenton is already presiding over the *In re Zimmer Durom Hip Cup Products Liability Litigation* (MDL No. 2158) and its 464 pending constituent actions. *See* U.S. Judicial Panel on Multidistrict Litigation, *MDL Statistics Report* (Jan. 17, 2017), http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-January-17-2017.pdf. And the District of New Jersey has 18 pending MDL dockets (the third most of any judicial district in the country) — including two nationwide products liability MDLs that were transferred in the last four months, *id.* — and a median time of 42 months from filing to trial (which ranks 60th among U.S. district courts), U.S. Courts, *United States District Courts — National Judicial Caseload Profile*

(Sept. 30, 2016), http://www.uscourts.gov/sites/default/files/data_tables/fcms_na_distprofile0930.2016.pdf. Moreover, the District of New Jersey cases are not far advanced: the vast majority of cases were filed in the past twelve months, and case-specific fact and expert discovery is complete in just four cases. And because the parties have relied principally on the discovery record generated before Judge Seibel and have agreed on additional IIH-specific discovery in a cooperative fashion, Judge Wigenton has not had to become involved in any discovery matters, and her substantive involvement to date has been limited to addressing motions on the pleadings. Therefore, although the majority of cases are being informally coordinated in New Jersey (which is reason enough to reject the creation of an MDL proceeding), foisting the remainder of the nationwide litigation on Judge Wigenton would be far less preferable than transferring all cases to Judge Seibel, whose MDL docket is currently empty and who has already overseen the extensive company discovery and familiarized herself with the scientific issues surrounding Mirena.

Western District of Missouri: Jones Ward has suggested that it may offer the Western District of Missouri as its preferred transferee district. This newfound interest in that locale apparently springs from the district judge's recent denial of Bayer's *Daubert* motions in the two cases currently pending in that district. *See* Ex. 14, *Sellers Daubert* Orders; Ex. 15, *Miller Daubert* Orders.[11] Such a naked tactic should be rejected. First, the Panel should be especially skeptical of attempts to steer an MDL based on some perceived merits advantage; if an MDL is created, the parties should begin on an even playing field devoid of any suggestion that a key legal issue underlying the litigation has already been resolved. Second, the Western District of

[11] The court dismissed an additional case because the plaintiff failed to offer case-specific expert testimony connecting her IIH to Mirena. *See* Ex. 13, *Hoover* Summary Judgment Order.

Missouri offers none of the convenience advantages of the Southern District of New York. And third, the only two actions pending there are set to be tried on May 1, ending that district's involvement in the litigation before an MDL would even take shape. In short, there is no principled justification for such a result, and the Panel should decline any such invitation to the transfer these matters to Western District of Missouri.

CONCLUSION

For the foregoing reasons, Plaintiffs' second motion for centralization should be denied in its entirety. In the alternative, the Panel should centralize the cases before Judge Seibel in the Southern District of New York.

Respectfully submitted,

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