# UNITED STATES JUDICIAL PANEL on MULTIDISTRICT LITIGATION

# IN RE: MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO. II)

MDL No. 2767

### TRANSFER ORDER

**Before the Panel:**<sup>\*</sup> Plaintiffs in 10 actions move under 28 U.S.C. § 1407 to centralize pretrial proceedings in this litigation in the Southern District of Mississippi or, alternatively, the Western District of Missouri or the District of New Jersey. This litigation currently consists of 113 actions pending in 17 districts, as listed on Schedules A and B.<sup>1</sup> Since the filing of the motion, the Panel has been notified of 37 related federal actions.<sup>2</sup> This litigation involves alleged intracranial hypertension injuries caused by the hormonal component of the Mirena IUD contraceptive system. Defendants are Bayer HealthCare Pharmaceuticals Inc. (BHCP), Bayer Oy, and Bayer Pharma AG (together, Bayer), which allegedly are responsible for the development, manufacture, and distribution of Mirena.

All responding plaintiffs support centralization, but differ on the transferee district. They variously propose the Western District of Missouri, the District of New Jersey, the Eastern District of Pennsylvania, and the Southern District of Mississippi. Defendants oppose centralization, but propose the Southern District of New York as the transferee district in the event we create an MDL over their objections.

## I.

This litigation is before us a second time. In July 2014, we denied a motion for centralization filed by a different group of plaintiffs alleging that Mirena's hormonal component causes or substantially contributes to the development of intracranial hypertension. *See In re: Mirena Levonorgestrel-Related Prods. Liab. Litig.*, 38 F. Supp. 3d 1380 (J.P.M.L. 2014). The motion sought centralization of nine actions pending in six districts, all brought by the same counsel against a single defendant, BHCP. At that time, there were six potential tag-along actions. In denying centralization, we observed that the actions involved common factual issues, but determined that informal coordination was preferable to centralization in light of the limited number of actions, the

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<sup>\*</sup> Judge Ellen Segal Huvelle took no part in the decision of this matter.

<sup>&</sup>lt;sup>1</sup> The motion for centralization lists three other actions that have been closed.

<sup>&</sup>lt;sup>2</sup> These and any other related actions are potential tag-along actions. *See* Panel Rules 1.1(h), 7.1 and 7.2.

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few involved plaintiffs' counsel, and defendant BHCP's commitment to coordinating common discovery through its national coordinating counsel. *See id.* at 1381. We also expressed concern that individualized causation disputes were likely to predominate considering the non-specific nature of the symptoms of intracranial hypertension – principally, headaches and vision problems – which defendant asserted would give rise to case-specific inquiries over whether each plaintiff was diagnosed properly. *See id.* We acknowledged that an MDL had been created in 2013 to centralize pretrial proceedings for Mirena actions alleging uterine perforation and migration injuries (MDL No. 2434, often referred to as the Perforation MDL), but observed that MDL No. 2434 involved a far greater number of actions, districts, and counsel, which precluded effective voluntary coordination. *See id.* 

II.

In this second motion for centralization, plaintiffs argue that the litigation has expanded dramatically over the past two years in terms of the number of actions, districts, and distinct plaintiffs' firms independently litigating the actions, and informal coordination of discovery and pretrial motions has become impracticable.<sup>3</sup> In opposing centralization, Bayer principally argues that informal coordination has been successful and remains preferable because (1) the number of actions and involved counsel remains relatively limited, and Bayer continues to have national counsel coordinating its response to the litigation; (2) plaintiff-specific causation issues remain central to each action and are more efficiently managed outside of an MDL; (3) common discovery is, from Bayer's perspective, nearly complete; and (4) the actions are in substantially different procedural postures, including four with trial dates this year.

As an initial matter, we note that an earlier denial of centralization does not preclude us from reaching a different result on a second motion. But we will do so only rarely, where a significant change in circumstances has occurred. *See, e.g., In re: Lipitor (Atorvastatin Calcium) Mktg., Sales Practices and Prods. Liab. Litig. (No. II),* 997 F. Supp. 2d 1354, 1356 n.3 (J.P.M.L. 2014). Upon careful review of the record, we have determined that there has been such a change.

First, the number of actions, districts, and counsel have grown substantially. The motion for centralization encompasses 113 pending actions in 17 districts, and there are at least 37 potential tagalong actions bringing the total number of involved districts to 20. The number of distinct plaintiffs' counsel involved in this litigation also has expanded. There now are at least 12 unaffiliated plaintiffs' firms in widely dispersed geographic locations. And although Bayer continues to have national coordinating counsel, at least 20 firms are litigating the underlying actions on the motion on its behalf. In our judgment, the number of actions, districts, and plaintiffs' and defense counsel make effective coordination on an informal basis impracticable.

 $<sup>^3</sup>$  The second motion for centralization includes 8 of the 15 actions before the Panel in 2014. The other actions then before the Panel were terminated over the past two years – two on summary judgment, and five through voluntary dismissals.

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Second, the plaintiff-specific causation issues identified by Bayer presently do not appear to be an obstacle to centralization, considering the development of the litigation over the past two years. While we previously expressed concern that individualized causation issues might predominate in this litigation, the records in the many actions filed since then demonstrate that discovery and pretrial motions concerning the issue of general causation have been, or will be, at the center of all actions – that is, whether the hormonal component in Mirena is capable of causing intracranial hypertension. Thus, we believe that the existence of individualized causation issues will not negate the efficiencies gained by centralization. *See In re: Fluoroquinolone Prods. Liab. Litig.*, 122 F. Supp. 3d 1378, 1379 (J.P.M.L. 2015) ("Almost all personal injury litigation involves questions of causation that are plaintiff-specific. Those differences are not an impediment to centralization when common questions of fact are multiple and complex."). Once discovery and other pretrial proceedings related to the common issues have been completed, the transferee judge may suggest Section 1407 remand of actions to their transferor courts for more individual discovery and trial, if necessary. *Id*.

Third, the record demonstrates that centralization is necessary to facilitate the efficient conduct of common discovery. Although fact and expert discovery has closed in the ten longest pending actions, discovery remains open in nearly all other actions, with most actions at a relatively early stage of discovery or still at the pleading stage.<sup>4</sup> While Bayer asserts that the longer pending proceedings have resulted in the completion of all common discovery, plaintiffs vigorously disagree. The record indicates that the vast majority of plaintiffs intend to seek full discovery without being limited by prior discovery, which they assert was inadequate. Plaintiffs identify a number of significant common discovery from the Perforation MDL limits plaintiffs' discovery rights in the intracranial hypertension litigation, whether certain Bayer custodial files are subject to discovery, and whether additional depositions from Bayer witnesses may be taken. The discovery in this litigation also is likely to be complex, involving anticipated requests for discovery concerning allegedly related Bayer contraceptive implants and international discovery from the foreign Bayer defendants.

Fourth, although a handful of actions are in an advanced procedural posture, the transferee judge possesses broad discretion to formulate a pretrial program that accounts for any significant differences among the actions and ensures that duplicative activity is minimized or eliminated.<sup>5</sup> *See In re: Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, 148 F. Supp. 3d 1383, 1386 (J.P.M.L. 2015). Thus, we believe that the differing procedural postures can be efficiently managed within an MDL, except as to two actions that appear to be trial-ready. These two actions – the *Miller* 

<sup>&</sup>lt;sup>4</sup> The record before the Panel indicates that fact discovery is complete or nearly complete in about 30 actions, but with expert discovery still to be taken. In another 70 actions, fact discovery appears to be at a relatively early stage or has not commenced.

<sup>&</sup>lt;sup>5</sup> Bayer also cites 11 actions involving intracranial hypertension that have been terminated. But all except three actions were terminated as a result of lack of prosecution by plaintiffs, and thus those dispositions do not indicate that the overall litigation is mature, as Bayer asserts.

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and *Sellers* actions in the Western District of Missouri, listed on Schedule B – have completed nearly all pretrial proceedings, including resolution of *Daubert* and summary judgment motions, and thus are not appropriate for centralization under Section 1407.<sup>6</sup>

On the basis of the papers filed and the hearing session held, we find that the actions listed on Schedule A involve common questions of fact, and that centralization will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. These actions share factual questions arising out of allegations that the synthetic hormone released by Mirena (levonorgestrel) causes abnormal elevation of cerebrospinal fluid in the skull, resulting in a neurological condition referred to as intracranial hypertension or pseudotumor cerebri, and that defendants did not adequately warn prescribing physicians or consumers of the alleged risk. Issues concerning general causation, the background science, and Mirena's labeling and regulatory history with respect to the alleged injury will be common to all actions. Centralization will eliminate duplicative discovery, prevent inconsistent pretrial rulings on *Daubert* and other issues, and conserve the resources of the parties, their counsel, and the judiciary.

III.

After weighing all factors, we conclude that the Southern District of New York is an appropriate transferee district for this litigation. This district is near Bayer's corporate headquarters in New Jersey, where many of the common documents and witnesses are likely to be located. Centralization in this district also will provide a geographically convenient forum for this nationwide litigation, and ensure that any potential overlap with the Mirena litigation involving perforation and migration injuries in MDL No. 2434 is coordinated efficiently. Judge Paul A. Engelmayer is an experienced transferee judge with the willingness and ability to manage this litigation. We are confident he will steer this litigation on a prudent course.

<sup>&</sup>lt;sup>6</sup> Two other actions also have trial dates in 2017 - Coning in the Eastern District of Tennessee and *Thompson* in the Central District of Illinois – but *Daubert* and summary judgment motions remain pending. Thus, the Panel has determined that the just and efficient conduct of the litigation would be served by their inclusion in the MDL.

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IT IS THEREFORE ORDERED that the actions listed on Schedule A and pending outside the Southern District of New York are transferred to the Southern District of New York and, with the consent of that court, assigned to the Honorable Paul A. Engelmayer for coordinated or consolidated pretrial proceedings.

IT IS FURTHER ORDERED that transfer of the actions listed on Schedule B is denied.

PANEL ON MULTIDISTRICT LITIGATION

Jarak Vance

Sarah S. Vance Chair

Marjorie O. Rendell Lewis A. Kaplan Catherine D. Perry Charles R. Breyer R. David Proctor Case MDL No. 2767 Document 58 Filed 04/06/17 Page 6 of 13

## IN RE: MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO. II)

MDL No. 2767

## **SCHEDULE A**

Northern District of Alabama

BRIDGES, ET AL. v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:14-00036

Eastern District of California

PATTERSON v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 1:14-01087

Northern District of California

JACKSON v. BAYER CORPORATION, ET AL., C.A. No. 3:16-06091

Central District of Illinois

THOMPSON v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 1:15-01117

Northern District of Indiana

CHEEK, ET AL. v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:15-00020

Western District of Kentucky

SMITH v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 3:14-00006
HARDWICK v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 3:14-00082
WASHINGTON v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 3:16-00827
VINCENT v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 4:16-00126
BABICH-ZACHARIAS v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 5:14-00101 - A2 -

Middle District of Louisiana

MITCHELL v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 3:16-00816

District of Minnesota

MITLYNG v. BAYER PHARMA AG, ET AL., C.A. No. 0:16-03492 BOURGOIN, ET AL. v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 0:16-03494

Northern District of Mississippi

HOSKIN v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 3:16-00231 HOLMES v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 4:16-00203

Southern District of Mississippi

TALLEY v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 1:16-00447

District of New Jersey

HAUSNER, ET AL. v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:14-03834 COOPER v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:14-04651 ROSELAND, ET AL. v. BAYER PHARMA AG, ET AL., C.A. No. 2:15-02480 SIMPSON v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:15-06072 MILES, ET AL. V. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:15-07944 GUGLIELMO v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:15-07999 ROBINSON v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:15-08576 BLACK v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:16-00054 DUDLEY v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:16-00056

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RIEGEL-GREEN v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,
C.A. No. 2:16-00057
GOYENA v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:16-00301
HOFFMAN v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,
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ET AL., C.A. No. 2:16-01774
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C.A. No. 2:16-02594
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C.A. No. 2:16-03051
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MCGEE v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,
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BURNS, ET AL. v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,
C.A. No. 2:16-03477
WALKED V BAVED HEALTHCAPE PHAPMACEUTICALS INC. ET AL

WALKER v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:16-03478 - A4 -

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C.A. No. 2:16-04245
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C.A. No. 2:16-04376
HAMILTON V. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,
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ANDERSON v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,
C.A. No. 2:16-05921
VON LANE v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,
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SANDERLIN v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,	
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REESE v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,	
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C.A. No. 2:16-08908
VEGA v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,
C.A. No. 2:16-08910
EVANS v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,
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WILLIAMS v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,
C.A. No. 2:16-09339
KIRK v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.,
C.A. No. 2:16-09340
HANKINS v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:16-09440
FACKRELL v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:16-09443
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District of Oregon

BOOTH, ET AL. v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 3:15-00598

DIEHL v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 3:15-01687

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Eastern District of Tennessee

CONING v. BAYER PHARMA AG, ET AL., C.A. No. 3:15-00137

Middle District of Tennessee

SCHALL v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 3:15-01138

Western District of Tennessee

HAMILL v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 2:15-02645

District of Vermont

TOLBERT v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 5:15-00065

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# IN RE: MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO. II)

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## **SCHEDULE B**

Western District of Missouri

MILLER v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 4:14-00652

SELLERS v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., C.A. No. 4:14-00954