BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: MIRENA® IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION	MDL Docket No. 2559

BAYER HEALTHCARE PHARMACEUTICALS INC.'S OPPOSITION TO PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407

Defendant Bayer HealthCare Pharmaceuticals Inc. ("Bayer") respectfully submits this Opposition to Plaintiffs' Motion for Transfer of Actions to the United States District Court for the Middle District of Tennessee, Nashville Division, and for Coordination or Consolidation of All Pre-Trial Proceedings Pursuant to 28 U.S.C. Section 1407.

A total of ten lawsuits have been filed by a single plaintiff's attorney, Lawrence L. Jones II, alleging injuries related to the Mirena intrauterine system's active ingredient, levonorgestrel. Mr. Jones claims that levonorgestrel causes a disorder called idiopathic intracranial hypertension ("IIH"). Although Mr. Jones claims in his Motion that he has many more potential plaintiffs and further claims that other plaintiff firms are ready to file similar actions, Mr. Jones' current inventory of just 10 cases is the sum total of all the cases claiming IIH from use of Mirena.

The reason that so few IIH cases have been filed is because there is not a single study published anywhere in the medical literature suggesting that Mirena is even associated with IIH, let alone causes IIH. Instead, Plaintiffs' entire theory of causation is that Norplant – an entirely different form of hormonal contraception that was on the market 20 years ago – might have caused IIH. Plaintiffs reason that because Mirena contains the same active ingredient as Norplant, it too may somehow cause IIH. Plaintiffs' causation-by-analogy theory is belied by

the fact that the FDA has approved at least 40 other drugs containing this same active ingredient that do not carry FDA-approved warnings for IIH.

As set forth below, transfer is at best premature and based on the current record is not appropriate. Mr. Jones' attempt to manufacture an MDL by filing a handful of cases in a few district courts at least should be predicated on a recognized scientific theory rather than the guesswork underlying plaintiffs' causation theory. Given plaintiffs' tenuous causation argument, individual issues of fact unique to each Plaintiff will predominate in these actions. Further, because Mr. Jones is the lead plaintiffs' counsel behind these actions, suitable alternatives to Section 1407 transfer are available to all parties to avoid the risk of duplicative discovery.

In the event the Panel concludes consolidation is appropriate, Bayer requests in the alternative that these actions be transferred to Judge Cathy Seibel in the United States District Court for the Southern District of New York. Judge Seibel currently presides over 800 plaintiffs' suits in *In re Mirena IUD Products Liability Litigation*, MDL 2434. She is familiar with the overlapping issues and discovery between these actions and that MDL. As a result, Judge Seibel is in the best position to efficiently manage the transferred cases.

I. PROCEDURAL AND FACTUAL BACKGROUND

A. Mirena

First approved as safe and effective by the FDA in 2000 for contraception and still on the market today, Mirena is an intrauterine device that is small (1.26 inches long), T-shaped, and made of soft, flexible plastic. Mirena requires a doctor's prescription and is inserted into a patient's uterus during an office visit. Mirena works by releasing a small daily dose of the hormone levonorgestrel directly into the uterus.

Between 2005 and 2012, approximately 6.2 million Mirenas were sold in the United States (Ex. 1, Bayer Response to FDA Information Request, at 18).

B. Idiopathic Intracranial Hypertension/Pseudotumor Cerebri

Idiopathic intracranial hypertension, also known as psuedotumor cerebri ("PTC/IIH") is not a known side effect of Mirena. Indeed, PTC/IIH is a disease of unknown etiology.[1] It is characterized by raised cerebrospinal fluid pressure in the absence of any other pathology or secondary causes of intracranial hypertension. *See* S. Dhungana et al., *Idiopathic intracranial hypertension*, 121 Acta Neurol. Scand. 71, 71 (2010) (attached as Ex. 2). The most common symptom of PTC/IIH is headache, but PTC/IIH can also result in more serious complications, including papilledema (optic disc swelling).

The diagnosis of PTC/IIH is one of exclusion – there is no blood or imaging test that can positively identify a patient with PTC/IIH; a diagnosis is only made after various other conditions are ruled out. *Id.* at 74-75. "IIH has become a 'disease of theories' because of the many postulated hypotheses that have been put forward to explain its pathogenesis." *Id.* at 72. "Over the years, case reports have linked various medications and systemic diseases with IIH. However, a number of studies which have sought to evaluate the existence of these proposed associations have found no convincing evidence." *Id.* at 75 (citations omitted).

According to Plaintiffs, a study has shown that in females between the ages of 15 to 44, PTC/IIH occurs at a rate of approximately 3.3 per 100,000 persons per year (Br. at 5-6). Assuming *arguendo* the accuracy of that background rate, and considering Mirena's 2005-2012 sales of 6.2 million units, then just by pure coincidence one would expect to see many women diagnosed with PTC/IIH during Mirena use. Of course, Mirena has been on the market longer than just those eight years, so the actual expected number of Mirena users who happen to be diagnosed with PTC/IIH could be very high.

[1] The term "idiopathic" refers to a disease that arises from an unknown cause.

C. These Actions Allege No Plausible Scientific Basis To Connect Plaintiffs' Injuries to Mirena

Plaintiffs' brief is scientific hypothesis presented as scientific fact. According to Plaintiffs, there is believed to be an association between PTC/IIH and Norplant – an entirely different contraceptive system delivered in the form of arm implants, not an intrauterine device, and developed and marketed by a company other than Bayer. From that presumption, Plaintiffs jump to the conclusion that because Norplant contained the drug levonorgestrel, and Mirena also contains the drug levonorgestrel, that Mirena causes PTC/IIH. Plaintiffs' "fact" section is replete with misstatements and unsubstantiated claims about Mirena and its alleged causal relationship with PTC/IIH, usually accompanied by no source or citation. Plaintiffs cite no scientific or regulatory evidence of a causal link between Mirena and PTC/IIH. And the few sources that Plaintiffs do cite for their Norplant theory contradict Plaintiffs' assertions.

1. There is No Scientific Evidence that Establishes a Causal Relationship Between Levonorgestrel and PTC/IIH

The cornerstone of Plaintiffs' argument against Mirena is that other contraceptive systems containing levonorgestrel have been shown to cause PTC/IIH (*see, e.g.*, Br. at 4 ("a known link between levonorgestrel and PTC/IIH"); *id.* at 6-8). However, every single source Plaintiffs cite for this proposition establishes that, in fact, no causal connection between levonorgestrel and PTC/IIH is scientifically accepted. *See, e.g.*, Norplant Package Insert (Br. at 7) ("a causal relationship" between Norplant and PTC/IIH "is unclear"). In addition, although Plaintiffs do not mention them, there are many levonorgestrel-containing birth control pills

marketed in the United States; none of their FDA-approved labels include any statement about PTC/IIH (*see, e.g.*, Ex. 3, 2010 Seasonique Label).[2]

The primary "scientific article" cited by Plaintiffs (which, in actuality, is just a four-paragraph, non-peer-reviewed letter to the editor of the New England Journal of Medicine) bluntly states, "Levonorgestrel may have contributed to the onset of intracranial hypertension, or it may have had nothing to do with it." John B. Alder & F.T. Fraunfelder, *Letter to the Editor: Levonorgestrel Implants and Intracranial Hypertension*, 332 New Eng. J. Med. 1720, 1721 (1995) (Br. at 7 & n.4) (Ex. 5). Every single other piece of literature Plaintiffs cite concurs that there is no known causal connection between Norplant and PTC/IIH. *See* Allan J. Coukell & Julia A. Balfour, *Levonorgestrel Subdermal Implants: A Review of Contraceptive Efficacy and Acceptability*, 55 Drugs 861, 877 (1998) ("causality is uncertain"); Karen R. Meckstroth & Philip D. Darney, *Implantable Contraception*, 27 Obstet. Gynecol. Clin. North Am. 781, 796 (2000) ("Causality is uncertain"); Wysowski DK, Green L., *Serious adverse events in Norplant users reported to the Food and Drug Administration's MedWatch Spontaneous Reporting System.*, 85 Obstet. Gynecol. 538, 541 (1995) ("it is not possible to determine whether Norplant, obesity or weight gain, or both factors are related to the occurrence of pseudo-tumor cerebri") (all found at Br. at 7 n.5).

2. Mirena and Norplant Are Very Different Contraceptive Systems

Mirena and Norplant are very different forms of contraception, delivering vastly different doses of levonorgestrel by vastly different methods. Even if studies had confirmed a causal link between Norplant and PTC/IIH – which they have not – that evidence, without more, is insufficient to suggest a link between Mirena and PTC/IIH.

[2] The Drugs@FDA database on the FDA's website contains information on most FDA-approved drugs. A search of that database conducted on June 12, 2014 for drugs that contain the active ingredient levonorgestrel returned over 40 results (*see* Ex. 4, 6/12/14 Printout of Search Results).

Mirena is inserted into a woman's uterus, whereas Norplant is implanted beneath the skin of a woman's upper arm. This is an important distinction. Because Norplant is inserted in the arm, it necessarily relies on systemic spread of the levonorgestrel to exert its intended effects. In contrast, Mirena, implanted directly into the uterus, does not rely on systemic spread of the levonorgestrel to exert its intended effects. As a result, Norplant must deliver significantly higher levels of levonorgestrel than Mirena.

Mirena contains a cylindrical reservoir containing 52 milligrams of levonorgestrel (Ex. 6, 2013 Mirena Label at 2). Norplant consists of 6 silicone capsules containing a total of 216 milligrams of levonorgestrel – more than four times as much as Mirena (Ex. 7, Norplant Label, printed in Physician's Desk Reference, at 3407). Mirena releases levonorgestrel at an approximate rate of 20 micrograms per day directly into the uterus just after insertion, eventually decreasing to about 10 micrograms/day (Ex. 6 at 2). Norplant releases approximately 85 micrograms of levonorgestrel into the arm per day just after insertion, eventually decreasing to about 30 micrograms/day (Ex. 7 at 3407). Thus, the daily dose of levonorgestrel is 3-4 times higher for Norplant than for Mirena at any given time.[3]

D. Procedural History

As of May 27, 2014, when the instant Motion was filed, only nine total actions were pending in the entire country alleging that the Mirena intrauterine device causes PTC/IIH (*see* Pls' Br. ISO Transfer ("Br."), at 9-11). All nine cases were filed by Lawrence L. Jones II of Jones Ward PLC, and the Plaintiffs in those cases constitute all of the Plaintiffs bringing the instant Motion. One additional PTC/IIH case has now been filed – also by Mr. Jones. *See*

[3] Compare these values to the oral contraceptive Seasonique, a levonorgestrel-containing pill that administers a dose of approximately 150 micrograms/day – 7.5-15 times the daily dose from Mirena – and contains no warnings related to PTC/IIH (Ex. 3, 2010 Seasonique Label at §§ 3, 12).

Decora Martin v. Bayer HealthCare Pharmaceuticals Inc., Case No. 3:14-cv-00398-TBR (W.D. Ky.) (filed May 30, 2014). The ten actions filed by Mr. Jones are the only cases pending in the country (state or federal) alleging a causal connection between Mirena and PTC/IIH injuries.

Plaintiffs make much of the fact that at the time of their Motion, the "most advanced case" was located in their preferred MDL destination – the Middle District of Tennessee.[4] Senior Judge John T. Nixon, Plaintiffs argued, "presides over the only case in which discovery has commenced, a trial date has been assigned and briefing deadlines have been set" (Br. at 15-16).

Plaintiffs' argument heralding the pace of discovery in *Copley* is completely disingenuous. The only reason discovery had "commenced" in *Copley* is because two days before filing this Motion, in an apparent effort to influence this Panel, Mr. Jones served an omnibus 189-part document request in *Copley* and only *Copley*, despite discovery being open in several other cases also filed by Mr. Jones. Such a transparent manipulation of the docket should not be credited by the Panel.

In any event, Mr. Jones' attempted manipulation of the docket has not even been successful. On June 11, 2014, a Scheduling Order was entered and target trial date set in *Jenna Thurmond v. Bayer Healthcare Pharmaceuticals, Inc.*, Case. No. 1:14-cv-822 (N.D. Ga.) (Ex. 8, 6/11/14 Order), and discovery has now been served in that case. The Scheduling Order in *Thurmond* set the close of fact discovery for November 28, 2014 – approximately 11 months ***before*** the deadline in *Copley*. And the trial date in *Thurmond* is tentatively scheduled for December 2015, approximately 9 months ***before*** the *Copley* trial date. Moreover, Judge Orinda D. Evans in *Thurmond* ordered immediate production of executed medical authorizations. If this

[4] *Katrina Dawn Copley v. Bayer Healthcare Pharmaceuticals, Inc.*, Case No. 3:14-cv-406 (M.D. Tenn.).

Panel goes by Plaintiffs' definition of "most advanced case," then *Thurmond* is now the most advanced of Mr. Jones' ten cases. As of the filing of this brief, *Thurmond* is also the ***only*** case in which Mr. Jones has moved for a stay pending this Panel's decision.

II. ARGUMENT

A. Transfer of These Actions is Inappropriate Under 28 U.S.C. § 1407

This Panel is empowered to transfer actions for coordinated or consolidated pre-trial proceedings if transfer "will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a). Although the preliminary inquiry in any Section 1407 transfer analysis looks to common questions of fact, this Panel has identified a variety of factors that counsel against transfer even when common questions of fact exist. In these actions, individual questions of fact unique to each action predominate over any common issues, and suitable alternatives to Section 1407 transfer are available to all parties in these actions to avoid the risk of duplicative discovery. In addition, the limited number of counsel involved weighs against centralization.

A denial of transfer will therefore promote the just and efficient conduct of these actions.

1. Questions of Fact Unique to Each Individual Action Predominate

The primary questions of fact presented by these actions are uniquely individual, and the few common questions between them are in no way complex.

Due to the idiopathic nature of PTC/IIH and the non-specific symptoms associated with that disorder (e.g., headache), discovery into the specific cause of each Plaintiff's condition will be an extraordinarily fact-intensive and individualized process. The individualized inquiry into the proper diagnosis of these 10 plaintiffs and their specific causation facts would swallow the common questions about whether Mirena can cause IIH generally.

2. Suitable Alternatives Exist to Avoid Duplicative Discovery with Respect to the Few Common Issues

Plaintiffs suggest their ten cases present common issues related to the testing, labeling, and marketing of Mirena. However, adequate measures already exist to prevent duplication of discovery efforts. Each of these are also issues in *In re Mirena IUD Products Liability Litigation*, MDL 2434, currently pending in front of Judge Cathy Seibel in the Southern District of New York. Approximately 10 million pages of documents have been produced in that MDL. Mr. Jones, who represents multiple plaintiffs in MDL 2434, has access to every single one of those documents, and Bayer has agreed to make a full production of those documents in these actions upon entry of an appropriate protective order. In addition, Bayer has cross-noticed every single company fact witness deposition with Mr. Jones' PTC/IIH cases since they were filed. In fact, Mr. Jones' law firm has appeared on behalf of its MDL 2434 plaintiffs for each of those depositions.

Since "suitable alternatives to transfer under Section 1407 exist in order to minimize the possibility of duplicative discovery," transfer will not promote the just and efficient conduct of these actions. *In re G. D. Searle & Co. "Copper 7" IUD Products Liab. Litig.*, 483 F. Supp. 1343, 1345 (J.P.M.L. 1980); *see also In re Texas Instruments Inc. Employment Practices Litig.*, 441 F. Supp. 928, 929 (J.P.M.L. 1977). Just as Bayer has offered since the inception of these actions, upon the entry of a protective order, Bayer stands ready and willing to share any overlapping discovery and to cross-notice any overlapping generic witness depositions. Transfer to form a second Mirena MDL in a second court, in which Plaintiffs will surely claim the right to duplicate much of the effort that Bayer has already undertaken in MDL 2434, does not serve the purposes of Section 1407.

3. The Limited Number of Counsel Involved Weighs Against Centralization

In considering transfer under Section 1407, the fact that most or all of the Plaintiffs share the same counsel is a factor weighing against transfer. Here, only ten lawsuits have been brought in the entire country alleging that Mirena caused a Plaintiff's PTC/IIH, and all ten of those Plaintiffs are represented by Jones Ward PLC.

When most or all Plaintiffs are represented by a single law firm, and another firm represents Defendant in all actions, the Panel presumes that the "parties therefore have every ability to cooperate and minimize the possibilities of duplicative discovery and inconsistent pretrial rulings." *In re: Quaker Oats Trans-Fat Mktg. & Sales Practices Litig.*, 777 F. Supp. 2d 1344, 1344 (J.P.M.L. 2011). "In these circumstances, informal cooperation among the involved attorneys is both practicable and preferable." *In re: Chilean Nitrate Products Liab. Litig.*, 787 F. Supp. 2d 1347, 1347 (J.P.M.L. 2011); *see also In re: Boehringer Ingelheim Pharm., Inc., Fair Labor Standards Act (FLSA) Litig.*, 763 F. Supp. 2d 1377, 1378 (J.P.M.L. 2011). "The limited number of actions and relatively few involved counsel" therefore "weigh against centralization." *In re: Plavix Products Liab. Litig.*, 829 F. Supp. 2d 1378, 1378 (J.P.M.L. 2011).

Mr. Jones apparently recognizes that his motion for consolidation is seriously undermined by the fact that only his firm has filed PTC/IIH cases or requested consolidation. Seemingly that is why he states without any actual evidence that he is "aware of other attorneys in other jurisdictions who are preparing their respective cases for filing" (Br. at 2). This promised wave of additional PTC/IIH cases has not materialized, perhaps because of the total absence of any credible scientific evidence linking Mirena to PTC/IIH.

In any event, Mr. Jones' suggestion that additional firms soon will file cases only establishes that his motion for consolidation is premature, not that it is meritorious. If additional claims are filed by other attorneys, then at that time this Panel and the parties can address

whether informal means of coordination short of MDL consolidation remain the most efficient way to handle such cases. Specifically, in light of the few simple common questions of fact amongst these actions, if the number of different counsel remains small, the parties should be able to minimize duplicative discovery and inconsistent pretrial rulings through informal cooperation. But in the absence of actual plaintiffs and actual lawyers filing on their behalf, unsubstantiated representations of future claimants should not be the basis for transfer.

B. In the Alternative, Transfer to Judge Cathy Seibel of the Southern District of New York Will Promote the Just and Efficient Conduct of These Actions

If the Panel believes that transfer pursuant to Section 1407 will promote the just and efficient conduct of these actions, then the ideal forum for a PTC/IIH MDL is the Southern District of New York, where Judge Cathy Seibel has been presiding over *In re Mirena IUD Products Liability Litigation*, MDL 2434 for over a year.

As this Panel explained in its Transfer Order for MDL 2434:

> Bayer Healthcare LLC is located in New York and other Bayer corporate affiliates are located nearby in New Jersey, Connecticut, and Pennsylvania. Thus, the primary witnesses and documentary evidence on the common factual issues likely will be located in New York and the surrounding area. This district also will be easily accessible for this nationwide litigation. Judge Cathy Seibel . . . is an experienced transferee judge who we are confident will steer this litigation on a prudent course.

In re Mirena IUD Products Liab. Litig., 938 F. Supp. 2d 1355, 1358 (J.P.M.L. 2013). Bayer believes that if consolidation of these PTC/IIH actions is necessary, Judge Seibel is in the best position to efficiently oversee them.

In addition to her fair and effective oversight of MDL 2434, Judge Seibel has a familiarity with Bayer and Mirena that will help facilitate a second MDL. In just over a year of its existence, MDL 2434 has grown to over 800 plaintiffs. Judge Seibel and Magistrate Judge Lisa Smith have presided over extensive discovery, including multiple Bayer 30(b)(6) and fact

witness depositions and voluminous document discovery. Judge Seibel agreed to hear an early dispositive motion, which is currently pending, and both Plaintiffs and Defendants have selected their candidates for an Initial Disposition Pool of twelve cases that will be scheduled for intensive fact and expert discovery, dispositive motions, and, if necessary, trial.

Furthermore, Judge Seibel has actively coordinated MDL 2434 with a consolidated Mirena proceeding in New Jersey state court, which currently involves over 700 plaintiffs. Together, MDL 2434 and the New Jersey consolidated litigation comprise over 75% of all Mirena plaintiffs in the country. Judge Seibel and Judge Brian Martinotti, who oversees the New Jersey litigation, have coordinated their schedules such that all conferences occur on consecutive days and can be easily attended by all counsel while reducing the costs to the parties. Consolidation of the PTC/IIH actions in front of Judge Seibel, if consolidation is deemed necessary, will promote judicial economy by ensuring that any additional MDL can be effectively coordinated with the already-pending consolidated litigations.

Finally, as described in more detail above, discovery is certain to overlap between these actions and MDL 2434. Judge Seibel is in the best position to coordinate the entry of a protective order consistent with that entered in MDL 2434, which will ensure a seamless sharing of discovery between actions. Judge Seibel and Magistrate Judge Smith are already familiar with the discovery issues in the litigation and Magistrate Judge Smith has heard and resolved discovery disputes.[5]

[5] One of Plaintiffs' alternative choices as a transferee judge – Judge William M. Acker, Jr. of the Northern District of Alabama – requested that the parties inform this Panel of his preference against receiving this MDL.

III. CONCLUSION

Bayer respectfully asks the Panel to deny Plaintiffs' Motion for Transfer of Actions to the Middle District of Tennessee, Nashville Division, and for Coordination or Consolidation of all Pretrial Proceedings Pursuant to 28 U.S.C. § 1407. In the alternative, Bayer asks that this Court transfer these actions to Judge Cathy Seibel in the Southern District of New York, for coordinated or consolidated proceedings.

Dated: June 17, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the forgoing document was served this 17th day of June 2014 via the Court's electronic filing system and/or U.S. Mail upon the following:

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