BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

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

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

Bayer's unusually vitriolic opposition brief would have this Panel believe that Plaintiffs' counsel is the legal amalgamation of such diabolical villains as Professor Moriarty or Dr. Evil. According to Bayer, counsel has masterminded a nefarious scheme in which he has a) ginned up meritless cases across the country (Br. at p. 1), b) "manufacture[d] an MDL" (Br. at p. 2), and c) "transparently" manipulated federal court dockets to advance the *Copley* case ahead of the other filed cases (Br. at p. 7) –all in hopes of having this Panel centralize the cases with a transferee judge before whom Plaintiffs' counsel has never previously had a case. In the words of Shakespeare, Bayer "doth protest too much, methinks." *See* William Shakespeare, *Hamlet*, Act III, Scene II. Rather than focusing on the elements of 28 U.S.C. § 1407, which provides the guideposts for this Panel's inquiry, Bayer attempts to smear counsel with *ad hominem* attacks intended distract this Panel from the relevant factual and legal inquiry, which support centralization of these cases.

1. **Bayer's Foreign Labels Warn of Papilledema –"The Most Important Neurological Manifestation of Intracranial Hypertension."**

Bayer endeavors to taint this Panel's view of the "merits" of the underlying cases by claiming that there is no "scientific" evidence to support Plaintiffs' claims. (Br. at p. 4). While

the strength of the scientific evidence has no relevance to the Panel's section 1407 inquiry, Plaintiffs' will briefly address some of Bayer's assertions.

Bayer cleverly suggests that there is no causal relationship between levonorgestrel and Pseudotumor Cerebri/*Idiopathic* Intracranial Hypertension. (Br. at p. 3). Bayer is correct that "idiopathic" means of "unknown" origin or cause. However, when a cause of intracranial hypertension is immediately discernable by the physician, he/she denotes it as "secondary intracranial hypertension," meaning it is caused by some secondary factor.[1] Many of the women injured by Mirena were diagnosed with the "idiopathic" form of the condition (which is why it is referenced as such in their complaints) because ***Bayer*** did not alert the doctors that levenorgestrel could cause intracranial hypertension. *See* Exhibit A, *Causes of Secondary IH,* published by the Intracranial Hypertension Research Foundation (noting "other causes" of secondary intracranial hypertension include "Levonorgestrel (Norplant)"); *see also* Exhibit B, *Levonorgestrel Drug Information*, published by CIMS/MIMS India, (listing "[b]enign intracranial hypertension" as an "adverse drug reaction" for several levonorgestrel-based products, including the 52 mg Mirena product at issue in these cases).

In terms of providing immediate care for the patient, the doctor cares less about the cause of the patient's condition and more about the symptoms to be treated. Had Bayer warned the physicians about the connection between levonorgestrel and intracranial hypertension, as it was legally required to do, not only would the physicians have diagnosed the IH as "secondary" to Mirena usage, the physicians could have mitigated the permanent harm these women suffered by actually removing the device.

[1] Bayer minimizes the serious nature of intracranial hypertension, almost suggesting that it is a phantom disease, like some believe about fibromyalgia. Bayer's brief characterizes it as a "diagnosis of exclusion –there is no blood test or imaging that can positively identify a patient with PTC/IIH." (Br. at 3). However, what Bayer neglects to mention is that there *is* a test that can positively identify a patient with intracranial hypertension –it is a spinal tap that measures the cerebrospinal fluid ("CSF") pressure, which provides ample objective evidence of the condition.

Bayer continues its scientific sleight of hand by ignoring that "the most important neurological manifestation [of intracranial hypertension] is papilledema." *See* Exhibit C, Gans, M.S., *Idiopathic Intracranial Hypertension*, Medscape (Oct. 2012) (the article also notes that "exogenous substances associated with IIH include … levonorgestrel implants … .") Indeed, in practice, papilledema (swelling of the optic nerves) is the chief presenting diagnosis that precedes a PTC/IIH diagnosis.

Does Bayer know about the connection between levonorgestrel and papilledema? Bayer's foreign labels certainly suggest that it does. *See e.g.,* Exhibit D (South African labeling information) (warning of papilledema); Exhibit E (Israeli labeling information) (warning of papilledema); Exhibit F (Hong Kong labeling information) (warning of papilledema). For example, Bayer's July 29, 2002 South African version of the Mirena label specifically warns of papilledema. *See* Exhibit D. Further, Bayer warns of papilledema in its lower-dosed Canadian levonorgestrel-releasing IUS, but not in its United States equivalent. *Compare* Exhibit G, Jaydess labeling information (Bayer Canada's lower 13.5 mg dose levonorgestrel-releasing intrauterine system, which contains a papilledema warning) *with* Exhibit H, Skyla labeling information (Bayer US's lower 13.5 mg dose levonorgestrel-releasing intrauterine system, which contains no such warning).[2] If Bayer's argument that the scientific evidence will not support Plaintiffs' claims is ultimately proven correct, it would seem to behoove Bayer to have the cases centralized for a single *Daubert* determination of what might be a globally dispositive issue. Indeed, such a global determination achieves exactly the kinds of efficiencies envisioned by section 1407. Accordingly, Plaintiffs' motion for centralization should be granted.

[2] Bayer asserts that Mirena works by "releasing a small daily dose of the hormone levonorgestrel directly into the uterus." (Br. at p. 2). But Bayer neglects to mention that this "small daily dose" produces local endometrial concentrations of levonorgestrel that are over 100 times higher than in users of an oral contraceptive containing 0.25 mg of Levonorgestrel. Nonetheless, Bayer seeks to compare its Mirena label to the labels of oral contraceptive pills, including pills that contain a combination of levonorgestrel and ethinyl estradiol. (Br. at p. 4-6).

2. Individual Causation Issues Do Not Preclude Centralization.

Bayer argues that case specific causation issues will predominate over the common questions. (Br. at p. 8). But this Panel rejected Bayer's similar response to the creation of MDL 2434 on April 8, 2013: "Almost all injury litigation involves questions of causation that are case- and plaintiff-specific. Such differences are not an impediment to centralization where common questions of fact predominate." *In re Mirena IUD Prods. Liab. Litig.*, 938 F. Supp. 2d 1355, 1357 (J.P.M.L. 2013) ("Mirena MDL 2434") (citations omitted). Here, like MDL 2434, common questions of fact predominate. Accordingly, Plaintiffs' motion for centralization should be granted.

3. Bayer's Lack of Cooperation in the Various Jurisdictions Has Caused Undue Delay and Inefficiencies.

Bayer argues that centralization is not necessary because the parties can "cooperate" in discovery to achieve the same results. In theory, that would be true. In practice, however, Bayer has not been agreeable to coordinating the discovery schedule in any of the filed cases. For instance, after a hearing in the *Copley* case in April 2014, the Magistrate Judge considered the parties' competing discovery proposals and entered a Scheduling Order that incorporated some of the Plaintiffs' suggestions and some of Bayer's suggestions.

As the other cases progressed, Bayer refused to agree to a discovery schedule that would essentially mirror the *Copley* schedule, which was entered on April 8, 2014; instead, Bayer continued to push its very aggressive discovery schedule –in hopes that a judge would finally enter it. Bayer's plan came to fruition when Judge Orinda Evans entered Bayer's proposed scheduling order on June 11, 2014 in the *Thurmond* case, without changes. And without scheduling a case management conference to discuss the competing schedules and other discovery issues, as proposed by *both* parties. As a result, the fact discovery cutoff in the

Thurmond case is November 28, 2014 (almost one year before the *Copley* cutoff date). Yet, even having achieved its aggressive schedule in the *Thurmond* case, Bayer has refused to provide any documents (confidential or not) in the *Thurmond* case, or any other case for that matter, until Plaintiffs agree to sign the protective order negotiated by the parties in MDL 2434, which did not include Plaintiffs' counsel in this case. Clearly, a single judge is needed to effectively manage this case.

Moreover, rather than voluntarily coordinate the cases, Bayer has engaged local counsel who each act independently, but allegedly at the direction of "national counsel." Plaintiffs' counsel has engaged in the same conversations about protective orders and other case management issues with *each* of the local counsel, without the "national counsel" ever making an appearance. This has resulted in numerous duplicative calls with each counsel in an attempt to negotiate things such as the protective order, only to be informed that "Bayer's national counsel" insists that Plaintiffs' execute a protective order that Plaintiffs had no hand in negotiating. Section 1407 centralization would indeed "centralize" all activities into the hands of one "national counsel" with the power to make decisions for Bayer and one judge who can manage disputes without conflicting rulings. Accordingly, the motion for centralization should be granted.

4. The Number of Actions Is Sufficient to Justify Centralization.

Eleven similar cases have been filed to date. Bayer argues that too few cases exist to justify centralization. (Br. at p. 6-7). But Bayer overlooks that "about one-half of all open MDLs are comprised of ten of fewer actions." Hon. John G. Heyburn II, *A View from the Panel: Part of the Solution*, 82 Tul. L. Rev. 2225, 2241 (2008) (internal citations omitted). *See also In re TJX Cos., FACTA Litig.*, 505 F.Supp 2d 1379 (J.P.M.L. 2007) (Coordinating six actions); *In re*

Wellnx Mktg. & Sales Practices Litig., 505 F.Supp 2d 1380 (J.P.M.L. 2007) (Coordinating nine actions); *In re Paxil Prods. Liab. Litig.*, 296 F.Supp 2d 1374 (J.P.M.L 2003) (Coordinating eleven pharmaceutical cases); *In re Air West, Inc. Sec. Litigation*, 384 F Supp 609 (J.P.M.L 1974) (When 2 or more complaints assert comparable allegations against identical defendants based upon similar transactions and events, common factual questions are presumed, and mere fact that divergent legal theories are asserted arising out of same substantive claims and allegations presents no bar to 28 USC § 1407 transfer). Therefore, the Panel should grant Plaintiffs' motion for centralization.

5. Centralization in the Southern District of New York Would Prove to be Unworkable for All Interested Parties.

a. MDL 2434 Is Limited In Scope to Migration and Perforation Cases.

MDL 2434 was established on April 8, 2013 for the sole purpose of centralizing "migration and perforation" cases. Both the Defendants and the transferee judge have steadfastly opposed the inclusion of any non-migration and perforation cases in MDL 2434:

> As this Court's Order No. 1 recognizes, the Judicial Panel on Multidistrict Litigation's Transfer Order ***limited the scope of this MDL to cases 'alleging migration or perforation injuries caused by [Mirena].'*** For this reason, Bayer proposes that the Court establish a procedure for the efficient transfer of cases that ***do not allege perforation or migration injuries*** out of MDL 2434 to the proper venue. The concern that cases ***outside the scope*** of the MDL will be filed is not theoretical as Bayer has already had to file oppositions to conditional MDL transfer orders of cases that ***do not allege perforation or migration.***

See Exhibit I, Corresp. from Shayna S. Cook, Lead Counsel for Bayer Healthcare Pharmaceuticals, Inc. to Hon. Cathy Seibel, MDL 2434, DN 79 (May 10, 2013) (emphasis added).

Since the formation of MDL 2434, all parties and the Court have focused their litigation efforts within the limited scope of the MDL. Now, apparently, Bayer has a change of heart as it

relates to *these* cases. (Br. 11-12). Just as Bayer argued before this Panel in 2013, and as the Panel then held:

> One case-specific matter requires our attention. The action listed on Schedule B does not allege that the product poses a risk of perforation or migration. This action alleges that the product causes autoimmune disorders and that the product's label fails to provide adequate warnings with respect to such disorders. Based on the Panel's review of the complaint, no common factual issues are readily apparent. Therefore, we decline to centralize this action.

In re Mirena IUD Prods. Liab. Litig., 938 F. Supp. 2d at 1357-58.

Like the auto-immune cases (and the many other types of cases that Bayer has fought to keep out of the MDL), the similarities between the cases begin and end with the name of the product. Plaintiffs' cases are even more dissimilar than others denied entry into MDL 2434 because Plaintiffs' cases stem not from the *device*, but from the *drug* released by the device. The mechanism of action is different, the failure mechanism is different, and the injuries are different. Accordingly, the cases should not be transferred to the Southern District of New York.

b. Discovery Has Been Limited in MDL 2434 and is Almost Complete.

By the time the Panel resolves the underlying motion for centralization, MDL 2434 will be approaching its 16-month birthday. According to co-lead counsel for MDL 2434, Bayer has painstakingly scrutinized every case designated for transfer to insure that it is a migration and perforation/embedment claim. If it varied in any way from the "limited scope" of the initial MDL transfer order, Bayer has consistently contested transfer of any such cases. Moreover, Bayer has adamantly opposed any discovery in MDL 2434 that has not been focused on migration and perforation/embedment causation and injuries. The discovery from MDL 2434 will be of marginal value to Plaintiffs.

Indeed, discovery is not nearly as overlapping as Bayer represents. Proof of general causation (and specific causation) requires an entirely different stable of experts, with specialties

that are much different than those necessary for MDL 2434. Plaintiffs in this case are interested in entirely different aspects of the testing, approval, labeling and marketing of Mirena. While there may be some limited overlap, the differences are far greater than the similarities.

Moreover, fact discovery is nearly finished in MDL 2434. Any efficiencies to have been gained by conducting joint depositions have long passed. While Bayer has recently begun cross-noticing MDL 2434 depositions in the Plaintiffs' cases (without consulting Plaintiffs about the scheduling), Plaintiffs are unable to ask any questions until a) they receive documents; and b) they review the documents. Other than having a judge that is familiar with the Mirena product and who is familiar with Bayer's national counsel, there are no appreciable efficiencies to be gained from transferring these cases to the Southern District of New York.

c. The Southern District of New York Clerk's Office is Understaffed and Overwhelmed With its Current Caseload.

On August 14, 2013, in an early case management conference for MDL 2434, Judge Seibel stated the following in response to inquiries about an electronic "direct-filing" procedure:

> The main issue I have, and this is because even though we're a big court in a metropolitan area, we are in the Dark Ages in some aspects of our clerk's office operation, and although I am told that at some point in the foreseeable future we will no longer be manually opening cases, people still do that both here and in Manhattan. That's the problem. A flood of hundreds of cases is just going to bring everybody to a halt. If we were doing it like more of our technologically advanced sister courts where the lawyers upload everything it would be very different. But our court has been rather conservative in terms of doing things electronically and we're catching up to other people. And given the personnel shortages in our clerk's office, where we've had to get rid of people, which is awful, we just don't have the bodies, literally.

See Exhibit J at p. 58-59. Judge Seibel made this statement in the earliest stages of MDL 2434. Since that time hundreds of additional cases have been filed in MDL 2434. According to MDL 2434 PSC sources, the clerk's office is no more equipped today as it was in August 2013. The clerk's office employees are good people, who work very hard, but they are simply overworked

and understaffed, according to Judge Seibel While there may be just eleven cases on file today for purposes of the underlying motion, there will be at least seventy-five cases, even if not a single additional lawyer begins filing cases. But there will be additional cases, filed by additional lawyers. Lawyers who will benefit, along with Bayer, from the substantial cost savings associated with having these cases venued in a judicial district that is equipped for direct filing, which has become a staple for pharmaceutical MDLs. But, perhaps more importantly, it would be unfair to the clerk's office to transfer these cases to the Southern District of New York.

6. Counsel Denies Manipulating the Docket.

Bayer's personal attacks are admittedly hurtful. But rather than respond with an equally vitriolic response, Plaintiffs will merely answer with the facts.

Smith was filed on December 13, 2013. Bayer filed a motion to dismiss.

Houston was filed on January 8, 2014. Bayer filed a motion to dismiss.

Bridges was filed on January 8, 2014. Bayer filed a motion to dismiss.

Hardwick was filed on January 17, 2014. Bayer filed a motion to dismiss.

Kellington was filed on February 6, 2014. Bayer answered on May 5, 2014. The first case management conference is scheduled for June 26, 2014.

Copley was filed on February 11, 2014. Bayer answered on March 12, 2014. At the time of filing, the court *sua sponte* ordered a case management conference to be held on April 7, 2014. The conference was held, the court entered a scheduling order, and set a trial date.

Creasy was filed on February 20, 2014. Bayer answered on May 5, 2014.

Thurmond was filed March 20, 2014. Bayer answered on April 28, 2014. The court entered Bayer's scheduling order on June 11, 2014, without holding a case management conference. This occurred after the underlying motion for centralization was filed.

Babich-Zacharias was filed on May 15, 2014. Bayer has not answered.

Martin was filed on May 30, 2014. Bayer has not answered.

Hausner was filed on or about June 17, 2014. Bayer has not answered.

The *Copley* case advanced the quickest simply because *Copley* was the first case in which Bayer actually filed an answer. *Copley* was the first case in which Bayer's counsel and Plaintiff's counsel conferred, it was the first case in which a court-ordered case management conference occurred, it was the first case in which a scheduling order was entered, it was the first case in which Rule 26 disclosures were made, and it was the first case in which a trial date was set. The reason why Plaintiffs served discovery in *Copley* is because 1) it was the only case in which discovery had commenced at the time of the MDL petition; and 2) Bayer refused to informally turn over documents (even those disclosed in its Rule 26 disclosures) without an agreement to relent to Bayer's unilaterally proposed protective order. Therefore, Bayer's nefarious "docket manipulation" theory is simply unfounded.

CONCLUSION

For the foregoing reasons, Plaintiffs request that the Panel grant the motion to centralize the cases in the Middle District of Tennessee.

Respectfully submitted,

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