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MEMO ENDORSED

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January 2, 2014

Pre-motion conference to be held on:
1/15/14 at 9:30 AM
Opposing counsel to state position (by letter not
to exceed 3 pages) in writing one week in advance.

BY EMAIL AND FACSIMILE

Honorable Cathy Seibel
United States District Judge
Southern District of New York
Hon. Charles L. Bricant Jr. Federal
Building and United States Courthouse
300 Quarropas Street
White Plains, NY 10601-4150

So ordered.

Cathy Seibel
Cathy Seibel, U.S.D.J.

Dated: 1/2/14

*In re Mirena IUD Products Liability Litigation, 13-MD-2434, 13-MC-2434;
Dorena Borders v. Bayer HealthCare Pharmaceuticals Inc., 7:13-cv-06818-CS*

*Re Clerk shall
docket this
letter in all
time of these
dockets.*

Dear Judge Seibel:

Defendants respectfully request a pre-motion conference with Your Honor in order to discuss an exemplar Motion to Dismiss on statute of limitations grounds. Given the large number of actions currently pending in the MDL that are time-barred on their face, Defendants believe that a ruling on a dispositive motion on this narrow issue will greatly serve judicial economy and conserve the resources of both parties. A Memorandum of Law in support of Defendants' proposed Motion to Dismiss is attached as Exhibit 1.

The injuries alleged in this MDL are well suited to resolution on statute of limitations grounds. The JPML closely circumscribed these proceedings to include only plaintiffs that allege injuries from perforation, embedment, or migration of Mirena coupled with surgical removal. All the lawsuits before this Court necessarily allege that the plaintiff's Mirena caused an injury by perforating through or embedding into the wall of the uterus or migrating outside of the uterus. These injuries are marked in all instances by definitive diagnoses by medical professionals linking Mirena to the alleged injury. Mirena is unlike other cases claiming a pharmaceutical product caused a latent injury or a generic injury (e.g., a heart attack) with no immediately apparent connection to the product at issue. Because of the unique nature of the alleged perforation, embedment, and migration injuries – injuries where the involvement of the Mirena is clear from the very diagnosis of the injury – no further discovery is needed before ruling on the proposed Motion to Dismiss.

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consequent running of the statute of limitations prior to August 2013: (1) her suspicion that Mirena was the cause of her injury on or before October 12, 2010, which under Ohio and New Jersey law, among other states, qualifies as constructive or inquiry notice of her claims; (2) diagnosis of embedment on October 12, 2010, which establishes actual knowledge that her injury relates to Mirena; and (3) surgical removal of her embedded Mirena on April 20, 2011, which also establishes actual knowledge that her injury relates to Mirena.

In cases alleging perforation, embedment, and migration injuries, each of these events constitutes a bright-line marker that triggers accrual of personal injury causes of action. And as described above, approximately 70 plaintiffs plead some combination of these events falling outside of their respective states' statute of limitations periods. Construing New Jersey law in the context of a remand motion, a court in the Eastern District of Missouri recently held in a Mirena action that the discovery rule could not toll the statute of limitations beyond the date a plaintiff was diagnosed with a perforated uterus. *Witherspoon v. Bayer HealthCare Pharms. Inc.*, 4:13CV01912 ERW, 2013 WL 6069009 (E.D. Mo. Nov. 18, 2013). That Court held that upon diagnosis of perforation, the plaintiff "possessed 'reasonable medical information' connecting Mirena to her injury," and that the plaintiff had "not met her burden of demonstrating she qualifies for application of the discovery rule." *Id.* at *4-*5. Indeed, Plaintiffs can point to no state's discovery rule or other equitable tolling doctrine that would permit tolling the statute of limitations beyond actual discovery of the alleged injury and the injury's relation to Mirena. The bright-line markers exemplified by Ms. Borders' Complaint would be bright-line markers under any state's statute of limitations analysis.

For these reasons, we respectfully request a pre-motion conference with the Court to discuss Defendants' proposed Motion to Dismiss. Defendants suggest that this pre-motion conference be held in conjunction with the parties' next scheduled conference on January 15, 2014.

Respectfully submitted,

/s/ Shayna S. Cook

Shayna S. Cook

Lead Counsel for Defendants

*Bayer HealthCare Pharmaceuticals Inc., Bayer OY, and
Bayer Pharma AG*

CC (via email):

Counsel for Plaintiffs Diogenes P. Kekatos, Fred Thompson, James R. Ronca, Matthew McCauley;
Counsel for Bayer James Shepherd and William Harrington

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Preservation of Judicial and Party Resources

As of December 17, 2013, there were approximately 450 female-user plaintiffs in this MDL, all pleading injuries due to perforation, embedment, or migration. Approximately 70 of those plaintiffs (~15% of the total) plead, on the face of their complaints, dates of removal of their Mirena that fall outside their respective states' statute of limitations periods.

An early ruling on narrow statute of limitations issues – whether removal of plaintiff's Mirena, or diagnosis of the alleged perforation, embedment, or migration injury, trigger accrual of plaintiffs' causes of action – would have an immediate and significant impact on more than just the 70 plaintiffs known to fall into this category. Approximately 100 plaintiffs do not allege a removal date at all, and many more allege no date of diagnosis. An early statute of limitations ruling would streamline discovery in many of those cases and would likely lead to voluntary dismissal by many plaintiffs and deter future filing of similarly time-barred cases.

An early ruling would also avoid wasting resources on unnecessary discovery in cases with straightforward statute of limitations issues. Given the significant percentage of cases that are potentially time-barred, if they are not disposed of early, their sheer volume will necessitate that Defendants select certain of them for the Initial Disposition Pool in April 2014. Early clarification of this issue will permit Your Honor and the parties to use the Initial Disposition Pool process to focus on cases that require fact and expert discovery before filing dispositive motions.

Basis for Anticipated Motion to Dismiss

Defendants have chosen a representative plaintiff, Dorena Borders, whose complaint exemplifies the statute of limitations issues found in dozens of other complaints. (See Borders Complaint, attached as Exhibit 2.) Ms. Borders, an Ohio resident, alleges that her Mirena was inserted on December 12, 2008 in Columbus, Ohio. (*Id.* at ¶¶ 3, 42.) On October 12, 2010, Ms. Borders presented to her healthcare provider requesting removal of her Mirena because she felt it to be the cause of her painful intercourse. (*Id.* at ¶ 44.) Upon requesting removal of Mirena, Ms. Borders "was informed by her medical providers that the MIRENA® IUD had embedded in her uterus." (*Id.*) On April 20, 2011, Ms. Borders underwent surgery to remove her embedded Mirena. (*Id.* at ¶ 45.) Ms. Borders waited to file her complaint until August 26, 2013 in the United States District Court for the District of New Jersey.

Ms. Borders' claims are time-barred under both New Jersey and Ohio law – the only two states whose law might apply to her claims.¹ Both New Jersey and Ohio have two-year statutes of limitations for product liability actions. See N.J. STAT. ANN. § 2A:14-2(a); OHIO REV. CODE ANN. § 2305.10(B)(1). Even under each state's discovery rule, Ms. Borders' August 26, 2013 filing was untimely. Ms. Borders' complaint alleges three separate events that triggered the accrual of her causes of action and the

¹ As is set forth in the Memorandum of Law in support of Defendants' proposed Motion to Dismiss, Exhibit 1 at 3-8, there is no conflict between New Jersey and Ohio law as applied to the timeliness of Plaintiff's lawsuit.