

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ALABAMA  
SOUTHERN DIVISION**

<b>YVONNE A. HARVEY,</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>Case No.: 2:06-CV-1140-VEH</b>
	)	
<b>NOVARTIS PHARMACEUTICAL</b>	)	
<b>CORPORATION,</b>	)	
	)	
<b>Defendant.</b>	)	

---

**ORDER**

This matter is before the Court on Plaintiff’s Motion For Leave To Designate Case Specific Expert (the “Motion”) (doc. 18), which is opposed by the Defendant. Pursuant to the Court’s Order Setting Certain Deadlines (doc. 19), the Defendant filed its response (doc. 20) on October 14, 2011, and the Plaintiff filed her reply (doc.21) on October 24, 2011. The Motion is now under submission. For the reasons set out below, the Court finds the Motion is due to be **DENIED**.

**I. Background**

This case arises out of a series of lawsuits by hundreds of individual plaintiffs who developed osteonecrosis of the jaw, a severe bone disease, allegedly as a result of taking FDA-approved prescription medications Zometa and Aredia. Zometa and

Aredia are bisphosphonate drugs produced by Novartis Pharmaceuticals Corporation (“Novartis”) that are administered intravenously, most often to cancer patients. The drugs are effective at preventing pathological fractures, spinal cord compression, and other bone pains.

Plaintiff Yvonne Harvey<sup>1</sup> (“Ms. Harvey”) filed an individual lawsuit against Novartis alleging that she developed osteonecrosis of the jaw as a result of taking Zometa. Ms. Harvey was prescribed Zometa around September 2002 as a post-cancer treatment of bone loss or osteoporosis. (Complt., Doc. 1 ¶ 5). She used Zometa weekly, as prescribed. (*Id.*). On July 25, 2005, she was diagnosed with Avascular osteonecrosis of the jaw. (*Id.* ¶ 6).

Ms. Harvey filed her products liability action in this Court on June 9, 2006. (Doc. 1). Subsequently, the Judicial Panel on Multidistrict Litigation (“JPML”) decided to centralize the cases involving Zometa and Aredia and transferred them to the Middle District of Tennessee for consolidated pretrial proceedings. (Order Transferring Case, Doc. 9). The multidistrict litigation (“MDL”) cases were assigned to Chief District Judge Todd J. Campbell.

On July 28, 2006, Chief Judge Campbell entered a Case Management Order

---

<sup>1</sup> Unfortunately, Ms. Harvey passed away on October 21, 2006, because of complications from her metastatic colon cancer. This lawsuit, therefore, is carried forward by her son, Dan Harvey, who serves as the personal representative of his mother’s estate.

(“CMO”) setting out various procedures and obligations that applied to all of the MDL cases against Novartis. *In Re: Aredia and Zometa Products Liability Litigation*, No. 3:06-MD-1760, Doc. 89 (M.D. Tenn. July 28, 2006) (hereinafter “*MDL-1760*”). The CMO set out an initial schedule for resolution of the cases, which has since been amended during the course of pretrial litigation. The deadlines set out corresponded to three separate “waves” of litigation, based on the various classes of plaintiffs. The final deadline established for Ms. Harvey’s class of plaintiffs to disclose their expert witnesses was February 21, 2011. (*MDL-1760*, Docs. 3223 (setting February 7, 2011 deadline for service of plaintiffs’ expert disclosures) and 4248 (granting two-week extension)).<sup>2</sup>

Consistent with the February 21, 2011, deadline, Ms. Harvey designated Dr. Jason Miller, her treating oral surgeon, as the sole expert on the issue of specific causation, *i.e.*, whether Zometa caused her to develop osteonecrosis of the jaw. At that time, Ms. Harvey did not designate a specially retained expert on the issue of specific causation.

Pursuant to other deadlines set by the MDL court, Novartis filed its *Daubert* and summary judgment motions in that court. (See *MDL-1760*, Docs. 4499–4500

---

<sup>2</sup> The MDL scheduling orders clarified that “[d]iscovery related to case-specific damages will occur after remand.” (See, e.g., *MDL-1760*, Doc. 3223 at 3). All other discovery was to be conducted prior to remand. (*Id.*).

(*Daubert* filings), 4501–4507 (summary judgment filings)). Although the MDL court ruled on two “waves” of dispositive and *Daubert* motions, it suggested remand of certain cases, like the instant case, in which summary judgment motions were fully briefed but not decided. (See *MDL-1760*, Order Summarizing MDL 1760 Proceedings Upon Suggestion of Remand, Doc. 4695 at 3).

The consolidated pretrial proceedings before Chief Judge Campbell, including discovery, have been completed. Accordingly, JPML remanded Ms. Harvey’s case back to this Court on July 26, 2011, pursuant to 28 U.S.C. § 1407(a). (Doc. 10, Conditional Remand Order).

Plaintiff now asks this Court for leave to identify and designate another case-specific causation expert, which would require the Court to, in effect, re-open discovery and modify the pre-trial scheduling orders established by the MDL court.

## **II. Standards**

The parties agree that Plaintiff’s request to modify the expert designation schedule is governed by Federal Rule of Civil Procedure 16(b)(4). Rule 16(b)(4) provides that “[a] schedule may be modified only for good cause and with the judge’s consent.” The Eleventh Circuit<sup>3</sup> has determined that “[t]his good cause standard

---

<sup>3</sup> Plaintiff encourages the Court to adopt four additional factors propounded by the Fifth Circuit, but the Court is not persuaded to adopt the position of another circuit where the Eleventh Circuit has clearly spoken. *Accord New Hampshire Ins. Co. v. Blue Water Off Shore, LLC*, No.

precludes modification unless the schedule cannot be met despite the diligence of the party seeking the extension.” *Sosa v. Airprint Systems, Inc.*, 133 F.3d 1417, 1418 (11th Cir. 1998) (internal quotation marks omitted). Thus, the analysis of good cause turns on whether the party seeking modification was diligent in attempting to meet the scheduling deadlines.

A district court’s decision to grant or deny a motion to modify a scheduling order is reviewed for clear abuse of discretion. *See Oravec v. Sunny Isles Luxury Ventures, L.C.*, 527 F.3d 1218, 1231 (11th Cir. 2008) (applying clear abuse of discretion standard of review to the Rule 16 modification standard).

### **III. Analysis**

In this case, the deadline set by the MDL court for Plaintiff’s disclosure of her expert witnesses was February 21, 2011. Plaintiff timely designated Dr. Miller and Dr. Susan Ferguson, two of Ms. Harvey’s treating physicians, as non-retained expert witnesses, but declined to designate any specially retained expert witnesses at that time. (See Doc. 20-15).

Plaintiff submits that “good cause” exists for her to now identify and designate

---

07-0754-WS-M, 2008 WL 4809169, at \*2 (S.D. Ala. Oct. 28, 2008) (J. Steele) (“Unable to show good cause under the [Rule 16(b)] standard, the plaintiff proposes that the Court employ the four-factor test adopted by the Fifth Circuit, under which the movant’s diligence is at best one factor. . . . The Court, of course, is bound by the Eleventh Circuit’s test, which focuses entirely on the movant’s diligence.” (emphasis added)).

yet another case-specific causation expert in light of the Sixth Circuit's recently issued unpublished opinion styled *Thomas v. Novartis Pharmaceuticals Corp.*, Nos. 09-6147, 09-6272, 09-6274, 2011 WL 3701816 (6th Cir. Aug. 23, 2011). In *Thomas*, the Sixth Circuit affirmed Chief Judge Campbell's rulings in three of the MDL actions that Plaintiff characterizes as "extremely similar" to the instant action (doc. 21 at 5 (emphasis in original)). The three actions involved plaintiffs *Thomas* (Case No. 06-cv-00377), *Melau* (Case No. 08-cv-01156), and *Anderson* (Case No. 08-cv-1157).

In each underlying case, Chief Judge Campbell granted Novartis's *Daubert* motions to exclude treating physician's testimony as evidence of specific causation. Accordingly, Novartis's motions for summary judgment were granted because the plaintiffs could not prove specific causation. *See Thomas*, 2011 WL 3701816 at \*2 ("In each of these cases, the district court held that the treating physicians could not give expert opinion testimony on the issue of specific causation. In reaching these conclusions, the district court relied in part on the physicians' statements that they did not consider themselves to be experts about osteonecrosis of the jaw.").

In affirming Chief Judge Campbell, the Sixth Circuit recognized that general causation and specific causation are among the common issues contested in the products liability lawsuits involving Zometa and Aredia. First, the Court concluded

that Judge Campbell “did not abuse [his] discretion in concluding that Thomas, Melau, and Anderson each failed to establish that their treating physicians were qualified to give expert opinions on the cause of their osteonecrosis of the jaw.” *Thomas*, 2011 WL 3701816 at \*6. Next, because the Court concluded that “[s]pecific causation is an essential element of the tort pled,” it held that “without any admissible evidence to raise a question of fact as to whether Zometa caused each individual’s osteonecrosis of the jaw, the district court properly granted summary judgment in favor of Novartis in each case.” *Id.* at \*5.

Plaintiff’s counsel now argues:

At the time Plaintiff designated Dr. Miller to testify as to specific causation [February 22, 2011], there was no need to anticipate, nor was there a need, as Novartis suggests, for designating an additional expert to offer identical testimony. It was not until the August 23, 2011, [unpublished] opinion of the United States Court of Appeals for the Sixth Circuit relating to three cases similar to that currently before this Court, which at the appellate level, further clarified and further cemented this interpretation of how extremely similar arguments relating to the admissibility of a treating physician’s testimony may play-out before this Court.

(Doc. 21 at 5 (footnote omitted)). To measure its diligence in reacting to the February 21, 2011, expert designation deadline, therefore, Plaintiff asks this Court to consider the reasonableness of its decision not to designate a case-specific causation expert other than Dr. Miller at that time. (*Id.*).

The Court finds that Plaintiff's lack of action exhibits a lack of diligence. First, delaying action based on the future issuance of an out-of-circuit appellate decision that would serve, *at best*, as persuasive authority in this Court, is not reasonable. Plaintiff knew all long that this cause would ultimately be resolved according to Eleventh Circuit precedent. Further, Plaintiff's position that the non-binding *Thomas* decision "may" affect how litigation will "play-out before this Court" is too tenuous and speculative to constitute good cause for a schedule modification.

Second, as Defendant points out in its opposition, Plaintiff shares overlapping legal counsel with the *Thomas*, *Melau*, and *Anderson* cases. Chief Judge Campbell made his rulings in all three cases on the same day: August 13, 2009. (See Doc. 20, Exs. 4–10). Thus, at least eighteen months prior to the expiration of Plaintiff's expert designation deadline, her counsel had firsthand knowledge of potential obstacles pertaining to expert testimony on specific causation. Plaintiff even admits in her reply brief that "[p]rior to the Sixth Circuit opinion, the exclusion of treating physicians, such as Dr. Miller, exhibited a trend." (Doc. 21 at 7) (emphasis added). In light of such knowledge, Plaintiff cannot persuasively argue that "there was no need" to designate an additional expert witness on causation prior to the August 23, 2011, *Thomas* opinion. Moreover, unlike other MDL plaintiffs, this Plaintiff failed to act in response to her knowledge of the exclusion trend.

By contrast, numerous other plaintiffs in the same “wave” of MDL proceedings as this Plaintiff *did* timely take action to designate the appropriate case-specific experts, as evidenced by their motion for extension of time filed in the MDL court. (See *Harvey*, Doc. 20-18; *MDL-1760*, Doc. 4310). The motion, filed on February 18, 2011, and served upon Plaintiff’s counsel through the court’s case filing system, stated as part of its grounds for a two-week extension:

As the [MDL] Court knows, these cases are complex pharmaceutical product liability cases and each and every element of plaintiffs’ claims is contested by [Novartis], particularly the causation issues. Moreover, as several rulings by Judge Campbell in these cases have shown, plaintiffs cannot rely on the opinions and/or diagnoses of their treating physicians to meet their burden of proof on case-specific causation. (See Docket Entries DE 257, 258; 272, 273; and 304, 305.) Therefore, Plaintiffs have to retain outside experts who have greater experience with and more familiarity with bisphosphonate related osteonecrosis of the jaw.

(*Harvey*, Doc. 20-18 at 5; *MDL-1760*, Doc. 4310 at 4) (emphasis added). Plaintiff provides no plausible explanation for why she did not file a similar motion prior to the February 21, 2011, deadline.

Instead, Plaintiff’s sole grounds for arguing “good cause” for modification of the expert disclosure deadline rests on the *Thomas* decision. The reactive nature of Plaintiff’s Motion to *Thomas*, however, does not support a finding of due diligence in meeting pretrial deadlines. *Thomas* is an unpublished, out-of-circuit case that does

nothing more than confirm what Plaintiff admittedly knew long ago—that there is a “trend” for excluding treating physicians from being able to testify as expert witnesses on topics for which they do not qualify as experts. (Doc. 21 at 7). For whatever reason, Plaintiff made no timely attempt to preserve the opportunity to designate an additional expert witness prior to the expiration of the deadline to do so, although nothing prevented her from doing so.

Moreover, Plaintiff’s contention (doc. 18 at 4) that the case-specific expert testimony is vitally important to her claim does not satisfy Rule 16’s “good cause” modification standard. *See Barrett v. Atl. Richfield Co.*, 95 F.3d 375, 381 (5th Cir. 1996) (“[T]he claimed importance of Plaintiffs’ expert testimony merely underscores the need for Plaintiffs to have complied with the court’s deadlines or at least informed the trial judge in advance if good faith compliance was not possible. . . . Even granting that the expert testimony was significant the importance of such proposed testimony cannot singularly override the enforcement of local rules and scheduling orders.” (internal quotation marks omitted)).

Novartis suggests that Plaintiff’s delay in designating an expert can only be attributed to “a strategic decision to rely upon Dr. Miller in full view of the still applicable law or his own lack of diligence.” (Doc. 20 at 13). The Court agrees, and notes that any litigation tactic or strategy, such as waiting on an appellate decision,

should be made within the bounds of court-established deadlines.

In sum, Plaintiff has not shown good cause as to why she waited to designate “a case-specific expert” until *after* the deadline for designation of experts expired, *after* discovery closed, *after* the Defendant filed *Daubert* and summary judgment motions, *after* the consolidated pretrial proceedings were completed in MDL court, and *after* the case was remanded back to this Court for final resolution of the pending motions. The Court discerns no evidence of Plaintiff’s diligence in designating her case-specific expert. To the contrary, the Court recognizes that based on Plaintiff’s counsel’s overlapping position in numerous other MDL cases that presented the same challenges to expert testimony in relation to the specific causation issue, Plaintiff’s counsel had every reason to be diligent in securing a viable expert on this issue earlier. Moreover, the Plaintiff presents no persuasive reason as to why such an expert could not have been designated before the February 21, 2011, deadline.

For all these reasons, Plaintiff has not met her burden of demonstrating that the February 21, 2011, deadline for designating expert witnesses could not be met “despite the diligence of the party seeking the extension.” *Sosa*, 133 F.3d at 1418 (internal quotation marks omitted). Therefore, no good cause exists upon which to grant the extension. *See* Fed. R. Civ. P. 16(b)(4).

#### **IV. Conclusion**

Accordingly, the Plaintiff's Motion is due to be and is hereby **DENIED**. As required by the Order Setting Certain Deadlines (doc. 19), the parties shall file their revised Report of Parties' Planning Meeting no later than thirty days after the date of this Order.

**DONE** and **ORDERED** this the 12th day of January, 2012.



---

**VIRGINIA EMERSON HOPKINS**  
United States District Judge