

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF KANSAS**

PAULA M. MARS	)	
<i>Executor of the estate of Mindy Knopf,</i>	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 11-2555-RDR
	)	
NOVARTIS PHARMACEUTICALS	)	
CORPORATION,	)	
	)	
Defendant.	)	

**MEMORANDUM AND ORDER**

This matter comes before the court upon Plaintiff’s Motion for Leave to File an Amended Complaint (ECF No. 87). Plaintiff Paula M. Mars seeks to amend her complaint to add a prayer for punitive damages. Defendant Novartis Pharmaceuticals Corporation opposes the motion. It argues Ms. Mars unduly delayed in attempting to amend, that Novartis would be unduly prejudiced by the amendment, and that the amendment is futile. Although this case was previously pending for a number of years, it was part of a multi-district litigation (MDL) action where pretrial activities and discovery typically involve a lengthier period of time. The delay in this case does not appear to be “undue.” The court also finds Novartis’ statements regarding undue prejudice are not sufficiently specific to warrant denying the motion on this basis; importantly, Novartis has been defending other cases remanded from the MDL proceedings that involve prayers for punitive damages. Finally, the arguments regarding futility largely involve a choice-of-law dispute and the weighing of evidence—issues more appropriately addressed at a later stage of this case. For these reasons, and those stated in more detail below, the court grants Ms. Mars’ motion.

## **I. Legal Standard**

Fed. R. Civ. P. 15 governs the procedure for amending the pleadings.<sup>1</sup> At this juncture of the case, the parties may amend only by consent of the opposing party or by leave of the court, which shall be freely given when justice requires.<sup>2</sup> When leave of the court is required for an amendment, the court may refuse leave “only [upon] a showing of undue delay, undue prejudice to the opposing party, bad faith or dilatory motive, failure to cure deficiencies by amendments previously allowed, or futility of the amendment.”<sup>3</sup>

## **II. Undue Delay**

When determining whether a movant has unduly delayed in bringing a motion to amend, the court “focuses primarily on the reasons for the delay.”<sup>4</sup> The court may refuse leave to amend when the movant has delayed in bringing the motion and has failed to provide an adequate explanation for the delay.<sup>5</sup>

Ms. Mars sought leave to amend by the deadline established by the Scheduling Order the court entered after this case was remanded from the MDL proceedings. The deadline contained in the Scheduling Order is the same deadline the parties proposed in their jointly prepared planning report.<sup>6</sup> Despite this, Novartis contends Ms. Mars unduly delayed in attempting to

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<sup>1</sup> Fed. R. Civ. P. 15(a)(2).

<sup>2</sup> See Fed. R. Civ. P. 15(a).

<sup>3</sup> *Wilkerson v. Shinseki*, 606 F.3d 1256, 1267 (10th Cir. 2010) (quoting *Duncan v. Manager, Dep’t Safety, City & Cnty. of Denv.*, 397 F.3d 1300, 1315 (10th Cir. 2005)).

<sup>4</sup> *Minter v. Prime Equip. Co.*, 451 F.3d 1196, 1206 (10th Cir. 2006)

<sup>5</sup> See *Panis v. Mission Hills Bank, N.A.*, 60 F.3d 1486, 1495 (10th Cir. 1995).

<sup>6</sup> Notably, the planning report noted numerous other disagreements between the parties, but it did not note a disagreement about the deadline for amendments to the pleadings.

amend because more than six years has passed since she filed her original complaint. Novartis also points out that one of Ms. Mars' attorneys also represents other plaintiffs in the MDL proceedings and that this same attorney had previously amended other litigants' complaints to seek punitive damages. Novartis cites several cases in which courts have found litigants unduly delayed in attempting to amend. None of these cases, however, involve the context of protracted MDL proceedings and a case only recently remanded from those proceedings. Here, Ms. Mars explains that the parties spent three years in discovery during the MDL proceedings. During discovery, Ms. Mars says she unearthed evidence she believes supports seeking punitive damages. Ms. Mars also notes that this action was remanded from the MDL proceedings with the direction that damages discovery is to take place following remand.

Having not presided over the MDL proceedings, this court is in the difficult position of evaluating whether Ms. Mars did indeed unduly delay in seeking to amend. While Ms. Mars may have arguably been able to amend earlier, the court finds any delay in this case was not "undue" given that the delay occurred in the context of a case consolidated with numerous others for MDL proceedings and given that Ms. Mars moved to amend by the deadline established in the Scheduling Order. Moreover, undue delay is closely related to undue prejudice.<sup>7</sup> And, as explained in the next section, Novartis has likely been aware for some time of the facts that give rise to plaintiff's prayer for punitive damages.

### **III. Undue Prejudice**

Undue prejudice means undue difficulty in prosecuting or defending a suit as a result of a

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<sup>7</sup> *United States v. Sturdevant*, No. 07-2233-KHV-DJW, 2008 WL 4198598, at \*3 (D. Kan. Sept. 11, 2008) (citing *Minter*, 451 F.3d at 1205).

change in tactics or theories.<sup>8</sup> Amendments generally cause some practical prejudice, but the court will not deny leave to amend “unless the amendment would work an injustice to [the opposing party].”<sup>9</sup> The Tenth Circuit has characterized undue prejudice as the most important factor to consider when deciding a motion to amend.<sup>10</sup>

Novartis argues it would be unduly prejudiced because the addition of the punitive damages claim would increase the universe of potentially admissible evidence—evidence that Novartis says it failed to inquire about in the depositions specific to this case. Novartis states another federal judge, presiding over a similar case brought by one of Ms. Mars’ attorneys, recognized that “corporate conduct” evidence lacked relevance in a case without a demand for punitive damages. Novartis therefore contends the proposed amendment would complicate this case with corporate conduct issues.

The court finds these general statements are insufficient to show undue prejudice. The Tenth Circuit has found that undue prejudice generally “occurs when the amended claims arise out of a subject matter different from what was set forth in the complaint and raise significant new factual issues.”<sup>11</sup> While the addition of a prayer for punitive damages may require additional evidence, Novartis has been defending against prayers for punitive damages in other civil cases that were a part of the same MDL proceedings. Neither party suggests the proposed prayer for punitive damages in this case is premised on facts wholly unknown to Novartis. It is difficult to

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<sup>8</sup> *Id.* (citing *Minter*, 451 F.3d at 1208 and *Jones v. Wildgen*, 349 F. Supp. 2d 1358, 1361 (D. Kan. 2004)).

<sup>9</sup> *Id.*

<sup>10</sup> *See Minter*, 451 F.3d at 1205.

<sup>11</sup> *Id.* at 1208.

see how allowing the amendment would raise any new factual issues. Therefore, the court finds that Novartis would not be unduly prejudiced.

#### **IV. Futility of the Amendment**

The court may deny a proposed amendment on the basis of futility “if the amendment would not withstand a motion to dismiss or otherwise fails to state a claim upon which relief may be granted.”<sup>12</sup> The party opposing the proposed amendment bears the burden of establishing its futility.<sup>13</sup> When determining whether an amendment is futile, the court analyzes the proposed amendment as if it were before the court on a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6).<sup>14</sup> Therefore, the court will only deny an amendment on the basis of futility when factual allegations fail to “state a claim to relief that is plausible on its face,”<sup>15</sup> or when an issue of law is dispositive.<sup>16</sup>

The parties disagree about whether New Jersey law or Kansas law governs punitive damages in this case. In any event, Novartis argues the choice-of-law dispute is irrelevant because Ms. Mars’ prayer for punitive damages fails under both bodies of law. N.J. Stat. Ann. § 2A:58C-5c pertains to punitive damages in products liability actions. The statute precludes punitive damages in actions involving drugs and devices approved by the Food and Drug Administration, except when a plaintiff can establish fraud on the FDA by proving the drug

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<sup>12</sup> *Wenner v. Bank of Am., NA*, 637 F. Supp. 2d 944, 950 (D. Kan. 2009) (internal quotations omitted) (quoting *Stewart v. Bd. of Comm’rs for Shawnee Cnty., Kan.*, 216 F.R.D. 662, 664 (D. Kan. 2003)).

<sup>13</sup> *Boykin v. CFS Enter., Inc.*, No. 08-2249, 2008 WL 4534400, at \*1 (D. Kan. Oct. 6, 2008).

<sup>14</sup> *Collins v. Wal-Mart, Inc.*, 245 F.R.D. 503, 507 (D. Kan. 2007) (citing *Sheldon v. Vermonty*, 204 F.R.D. 679, 682 (D. Kan. 2001)).

<sup>15</sup> *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

<sup>16</sup> *Collins*, 245 F.R.D. at 507 (citing *Neitzke v. Williams*, 490 U.S. 319, 326 (1989)).

company knowingly withheld or misrepresented certain information. Ms. Mars' proposed amended complaint alleges Novartis failed to report certain information to the FDA or provided information that was inaccurate.<sup>17</sup> Therefore, it does not seem that Ms. Mars' prayer for punitive damages is futile under the plain language of the New Jersey statute.

Novartis also argues, however, that New Jersey's statutory fraud-on-the-FDA exception is preempted by federal law and therefore null. Novartis made the same arguments about the New Jersey statute in a similar case, arguments that were rejected by Judge Arthur Spatt, sitting in the Eastern District of New York.<sup>18</sup> The court recognizes that judges have taken differing positions about federal preemption of New Jersey's statutory fraud-on-the-FDA exception.<sup>19</sup> But this does not mean it is established that Ms. Mars' prayer for punitive damages could not withstand a motion to dismiss. Novartis has not shown that the amendment would be futile under New Jersey law.

Novartis also argues Ms. Mars' claim for punitive damages fails under Kansas law because, according to Novartis, the proposed amended complaint "fails to allege any evidence remotely approaching [] 'clear and convincing evidence' that Novartis 'acted toward the plaintiff with willful or wanton conduct' required under Kansas law."<sup>20</sup> In *Ayers v. AG Processing, Inc.*, Magistrate Judge David J. Waxse rejected a similar argument. He noted that K.S.A. 60-3702(c),

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<sup>17</sup> See Proposed Am. Compl. and Jury Demand at ¶ 11-12, 21, ECF No. 87-1.

<sup>18</sup> See *Forman v. Novartis Pharm. Corp.*, 793 F. Supp. 2d 598 (E.D.N.Y. 2011).

<sup>19</sup> Compare *Forman*, 793 F. Supp. 2d 598 (holding the statutory fraud-on-the-FDA exception was not impliedly preempted by federal law) with *McDarby v. Merck & Co.*, 949 A.2d 223 (N.J. Supper. App. Div. 2008) (reaching the opposite conclusion).

<sup>20</sup> Def. Novartis Pharmaceuticals Corporation's Opp'n to Pl.'s Mot. for Leave to File Am. Compl. at 13, ECF No. 88.

which governs punitive damages, provides that a plaintiff must prove certain conduct “by clear and convincing evidence in the *initial phase of the trial* . . .”<sup>21</sup> As Judge Waxse stated, this language pertains to the burden of proof at trial. It does not require a litigant to come forward with a quantum of proof at the amendment stage. Novartis has not shown that the amendment would be futile under Kansas law. Because Novartis has not shown that the amendment would be futile under either body of law, and for the reasons previously stated, Ms. Mars’ motion to amend is granted.

Accordingly,

**IT IS THEREFORE ORDERED** that Plaintiff’s Motion for Leave to File an Amended Complaint (ECF No. 87) is granted. Within three (3) business days from the date of this order, plaintiff shall file her amended complaint (ECF No. 87-1) as a separate docket entry in this case.

**IT IS SO ORDERED.**

Dated this 16th day of April, 2012, at Topeka, Kansas.

s/ K. Gary Sebelius  
K. Gary Sebelius  
U.S. Magistrate Judge

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<sup>21</sup> *Ayres v. AG Processing, Inc.*, No. 04-2060-DJW, 2005 WL 1799261, at \*3 (D. Kan. July 22, 2005) (emphasis in original) (quoting K.S.A. 60-3702(c)).