IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

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| KENNETH CHRISTISON, *individually and as surviving spouse of Annalee Christison, deceased, and as personal representative of the estate of Annalee Christison, deceased,*<br><br>Plaintiff,<br><br>v.<br><br>BIOGEN IDEC,<br><br>ELAN PHARMACEUTICALS, LLC,<br><br>Defendants. | MEMORANDUM DECISION<br><br>Case No. 2:11-cv-01140-DN-DBP<br><br>District Judge David Nuffer<br><br>Magistrate Judge Dustin B. Pead |

## I. INTRODUCTION

This matter was referred to the Court under 28 U.S.C. § 636(b)(1)(A). (ECF No. 117.) On December 15, 2015, Plaintiff Kenneth Christison ("Plaintiff") filed his motion for leave to amend his First Amended Complaint ("Complaint"). (ECF No. 169.) For the reasons set forth below, the Court **DENIES** Plaintiff's motion to amend.

## II. MOTION TO AMEND

### a. Parties' arguments

Plaintiff claims that a Public Health Service Biological Materials Licensing Agreement ("Licensing Agreement") between Defendant Biogen Idec Inc. and the National Institute of Health ("NIH"), which Defendants produced on September 28, 2015, supports a new claim for negligent undertaking. (ECF No. 169.) Plaintiff's proposed amended complaint alleges that

Defendants failed to adequately develop a test, called a JC Virus antibody assay, which could help determine whether patients taking Defendants' drug Tysabri® were at risk of developing progressive multifocal leukoencephalopathy ("PML"). Plaintiff asserts that the Licensing Agreement demonstrates that Defendants had access to a JC Virus antibody assay in October 2006. Defendants did not make a JC Virus antibody assay commercially available until January 2012. Plaintiff asserts that the delay in commercializing the JC Virus antibody assay was the result of actionable negligence on Defendants' part.

Defendants argue that Plaintiff must meet the good cause standard set forth in Federal Rule of Civil Procedure 16 because Plaintiff's motion to amend was filed after the deadline for filing amended pleadings. Defendants argue that Plaintiff cannot show good cause here because he knew by at least January 2015 that Defendants received the JC Virus antibody assay from the NIH. (ECF No. 171.) Notwithstanding that knowledge, Plaintiff did not seek his amendment until December 2015. Further, Defendants argue that the negligent undertaking claim is futile for a number of reasons.

**b. Legal standard**

"After a scheduling order deadline, a party seeking leave to amend must demonstrate (1) good cause for seeking modification under Fed.R.Civ.P. 16(b)(4) and (2) satisfaction of the Rule 15(a) standard." *Birch v. Polaris Indus., Inc.*, 812 F.3d 1238, 1247 (10th Cir. 2015) (quoting *Gorsuch, Ltd., B.C. v. Wells Fargo Nat. Bank Ass'n*, 771 F.3d 1230 (10th Cir. 2014)). Once the deadline for an amendment has passed, a party may amend its pleading under Rule 15 only with his opponent's written consent or with the court's leave, which should be "freely" given when justice so requires. *Birch* at 1247 (quoting Fed. R. Civ. P. 15(a)(2)). "Under Rule 16(b)(4), a scheduling order 'may be modified only for good cause and with the judge's consent.'" *Id.*

> In practice, the Rule 16(b)(4) standard requires the movant to show the scheduling deadlines cannot be met despite the movant's diligent efforts. Rule 16's good cause requirement may be satisfied, for example, if a plaintiff learns new information through discovery or if the underlying law has changed. If the plaintiff knew of the underlying conduct but simply failed to raise tort claims, however, the claims are barred.

*Id.* (alterations omitted).

**c. Plaintiff has not demonstrated good cause to amend the scheduling order**

Plaintiff's motion to amend is untimely. Plaintiff does not address Rule 16's good cause requirement. Instead, Plaintiff argues the motion is "[t]imely [g]iven [t]he [c]ircumstances." (ECF No. 174 at 3.) This statement is incorrect. The deadline for amending pleadings in this case was May 29, 2014. (ECF No. 121.) Plaintiff did not file this motion until December 15, 2015. Thus, the motion is untimely and Plaintiff must establish good cause under Rule 16.

While Plaintiff does not explicitly address the good cause requirement, Plaintiff does argue that the amendment was influenced by newly-discovery information, specifically the Licensing Agreement. (ECF No. 169.) Newly-discovered information can provide good cause in certain circumstances. *See Pumpco, Inc. v. Schenker Int'l, Inc.*, 204 F.R.D. 667, 668 (D. Colo. 2001) (cited with approval in *Gorsuch*, 771 F.3d 1230). The court concludes the present case does not present such circumstances.

Plaintiff does not identify any new information in the Licensing Agreement that was necessary for him to bring the negligent undertaking claim. The Proposed Second Amended Complaint only mentions the Licensing Agreement in passing: "Then in October 2006, Biogen acquired a JC virus antibody assay from NIH through a material licensing agreement for the purpose of developing this assay for commercial use." (ECF No. 169, Ex. 1.) Plaintiff elsewhere asserts that there is little new factual information at play: "The only new factual issue is . . . that Defendants had possession of a JC Virus antibody assay as early as 2006 . . . ." (ECF No. 169 at

11.) Yet, even this was not a new factual issue. Plaintiff's own expert's report, issued in January 2015, indicated that the JC Virus Antibody assay was licensed to Defendants from the NIH in "approximately 2007." (ECF No. 171, Ex. 18 ("I am also aware of Material License Agreements involving the ELISA assay . . . licensed by the Office of Tech Transfer, NIH to . . . BiogenIdec, Boston, MA 2007.").) At best, the only information the Licensing Agreement can be said to have provided was clarification of the date of transfer from sometime in 2007, to October 2006.

Even in his reply, Plaintiff never identifies any specific information he lacked prior to disclosure of the Licensing Agreement. Plaintiff concludes that he "simply did not have enough information on which to base an earlier motion for leave to amend." (ECF No. 174 at 3.) Yet, Plaintiff never identifies any information in the Licensing Agreement that provided the basis for his amendment. He vaguely references the "terms or rights of the parties contained" in the Licensing Agreement, but Plaintiff knew the only terms he mentions in his proposed amended claim: Defendants obtained a license to the JC Virus Antibody assay. It is clear that Plaintiff knew this information by January 2015 because his own expert discussed the assignment in his expert report. (*See* ECF No. 171, Ex. 18.) The only information that could in any way be considered new is that Defendants obtained the assay in October 2006, rather than "approximately 2007." (*Id.*) Plaintiff does not suggest he was unable to bring the claim before he knew the particular month Defendants obtained the assay. While Plaintiff apparently believes that the Licensing Agreement will strengthen the negligent undertaking claim, he has not shown that this information provides good cause to justify his tardy motion to amend. Rather, "plaintiff knew of the underlying conduct but simply failed to raise [his] tort claim[], [thus] the claim[ is] barred." *Birch*, 812 F.3d at 1247.

**d. Plaintiff's proposed negligent undertaking claim is futile**

Additionally, Plaintiff's claim is futile because he does not allege reliance or that his risk of harm was increased by the undertaking. As Defendants point out, to state a claim for negligent undertaking, Plaintiff must allege that Defendants' undertaking increased Plaintiff's risk of harm, or that the harm resulted from Plaintiff's reliance on the undertaking. *See MacGregor v. Walker*, 322 P.3d 706, 710 (Utah 2014) ("A mere failure 'to facilitate the prevention of harm that occurred through other causes' is insufficient."). Plaintiff alleges neither.

Plaintiff does not address this portion of Defendants' argument in his reply. The court is unable to independently identify any way in which Defendants' attempts to develop a JC antibody assay increased Plaintiff's risk of harm. Successful development of the assay very well may have helped Plaintiff, but that is not sufficient to impose a duty on Defendants. Plaintiff must plead, and ultimately prove, that Defendants' efforts to develop the assay (their undertaking) increased Plaintiff's risk of harm. Plaintiff has not alleged any increased risk of harm as a result of Defendants' allegedly negligent undertaking, nor described it in his briefing. Additionally, Plaintiff does not appear to claim that he relied on the undertaking. Instead, his briefing suggests he was not aware of the undertaking prior to this litigation. (ECF Nos. 169, 174.) Accordingly, Plaintiff's proposed negligent undertaking claim is futile.

## III. ORDER

For the reasons analyzed above, the Court **DENIES** Plaintiff's motion for leave to amend his complaint. (ECF No. 169.)

Dated this 11th day of May, 2016.

By the Court:

Dustin B. Pead
United States Magistrate Judge