IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

KENNETH CHRISTISON, Individually and as Surviving Spouse of ANNALEE CHRISTISON, Deceased, and as Personal Representative of the Estate of ANNALEE CHRISTISON, Deceased,

Plaintiff,

v.

BIOGEN IDEC INC. and ELAN PHARMACEUTICALS, INC.,

Defendants.

MEMORANDUM DECISION AND ORDER REGARDING DEFENDANTS' MOTIONS TO DISMISS

Case No.: 2:11-cv-01140

District Judge David Nuffer

Defendants Biogen Idec Inc. ("Biogen") and Elan Pharmaceuticals, Inc. ("Elan") each filed motions to dismiss Plaintiff Kenneth Christison's ("Christison") complaint (collectively, the "Motions").[1] On October 31, 2013, argument from counsel was heard related to the Motions. Defendants were represented by Joseph G. Blute of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. and John A. Anderson of Stoel Rives, LLP; Plaintiff was represented by Allen Till of Blizzard & Nabers, LLP and Karthik Nadesan of Nadesan Beck, P.C. Supplemental memoranda of points and authorities on the choice of law issue were later submitted by both Defendants and Plaintiff.

I. FACTUAL BACKGROUND

The Complaint alleges that in May 2004, Defendants sought approval from the Food & Drug Administration ("FDA") of an immunomodulator, Tysabri®, for the treatment of a

[1] Docket nos. 17 and 21, filed by Biogen, and docket nos. 15 and 30 filed by Elan, respectively.

degenerative neurological disease known as multiple sclerosis ("MS").[2] The FDA approved Tysabri to treat MS in November of that year.[3] Shortly thereafter, Defendants began to market and distribute Tysabri in the United States.[4]

In February 2005, Defendants removed Tysabri from the market and from use in clinical trials after Defendants received notice of two adverse event reports relating to patients diagnosed with Progressive Multifocal Leukoencephalopathy ("PML").[5] After a safety review was conducted, the FDA approved the reintroduction of Tysabri monotherapy in treating MS subject to a prescribing program called Tysabri Outreach: Unified Commitment to Health ("TOUCH").[6] The TOUCH program requires every Tysabri prescriber, infusion site and MS patient receiving Tysabri in the United States to enroll in a risk management program that monitors patients for early indications of PML.[7] The FDA also required Defendants to include a black box warning in the drug labeling concerning the PML risk.

In 1991, Plaintiff's spouse, Annalee Christison ("Ms. Christison"), was diagnosed with MS and she was prescribed Tysabri by her treating neurologist in 2007.[8] Ms. Christison commenced Tysabri infusions pursuant to the TOUCH prescribing program in February 2007.[9] Ms. Christison was treated with Tysabri infusions administered monthly over two years,

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[2] Compl., at ¶¶ 15, 22, docket no. 33-1.

[3] *Id*. at ¶ 14.

[4] *Id.*

[5] *Id.* at ¶ 23.

[6] *Id.* at ¶ 24.

[7] *Id*.

[8] *Id.* at ¶¶ 36-37.

[9] *Id.* at ¶ 37.

terminating in July 2009 when Ms. Christison was diagnosed with PML.[10] Ms. Christison died as result of PML one week after her diagnosis.[11]

II. PROCEDURAL BACKGROUND

The Plaintiff, a Utah resident, filed his Complaint in California state court on his own behalf and on behalf of the decedent. Biogen Idec removed the case to the United States District Court for the Northern District of California. Thereafter, the court granted Defendant's Motion to Transfer pursuant to 28 U.S.C. § 1404(a) and transferred the case to this Court.

The Plaintiff's Complaint alleges design defect, failure to warn, strict liability in tort, negligence, breach of implied warranty, wrongful death, and violation of California Civil Code § 1750. The Plaintiff seeks damages, including punitive damages, of an unspecified amount. The stated grounds for the claim asserted are (1) that the Defendants acted negligently in their design and failure to warn of the risks associated with Tysabri, and (2) that Ms. Christison died from PML as result of the Defendants' negligence and sale of a defective product. With respect to the warnings claims, Plaintiff alleges that Defendants failed to adequately warn that the PML risk associated with Tysabri use increases with longer treatment duration.

The Defendants move to dismiss the Complaint on grounds that the Complaint fails to state a claim under Fed. R. Civ. P. 12(b)(6) as interpreted by *Bell Atlantic Corp. v. Twombly*[12] and *Ashcroft v. Iqbal*.[13] Specifically, Defendants argue that Plaintiff's claims based on a design defect theory and under California Civil Code § 1750 are expressly barred under Utah law. Similarly, Defendants also argue that punitive damages are expressly barred under Utah law in cases involving prescription drugs approved by the FDA pursuant to Utah Code Ann. § 78B-8-

[10] *Id.* at ¶¶ 38-39.

[11] *Id.* at ¶ 41.

[12] 550 U.S. 544 (2007).

[13] 556 U.S. 662 (2009).

203(1). The only exception to this limitation is if the Plaintiff can prove "by clear and convincing evidence that the drug manufacturer knowingly withheld or misrepresented information required to be submitted to the Federal Food and Drug Administration under its regulations, which information was material and relevant to the claimant's harm."[14] Defendants argue Plaintiff cannot offer any plausible basis for such an argument and that this exception cannot apply in this case because the application of the exception is preempted by federal law under *Buckman Co. v. Plaintiff's Legal Comm.*[15] Lastly, Defendants argue that the Plaintiff's remaining claims for failure to warn, negligence, and breach of warranty are all based on boilerplate, conclusory assertions that do not meet the minimum federal pleading standards under *Twombly* and *Iqbal*. In particular, Defendants argue (1) that the Plaintiff fails to allege the specific deficiency in the adequacy of the labeling and the information reasonably scientifically available to the Defendants at the time the drug was prescribed to Ms. Christison that would mandate a different warning, and (2) that the Plaintiff fails to allege any facts in support of the claim that a different warning would have changed the prescribing physician's medical judgment as to whether to prescribe Tysabri for the treatment of Ms. Christison's multiple sclerosis.

III. ORDER

In order to withstand a motion to dismiss under *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal*, a plaintiff must allege enough facts, "taken as true, to state a claim to relief that is plausible on its face."[16] A plaintiff must "offer specific factual allegations to support each claim" and while the Court must "accept as true all of the allegations contained in the complaint"

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[14] Utah Code Ann. § 78B-8-203(2).

[15] 531 U.S. 341 (2001).

[16] *Kansas Penn Gaming, LLC v. Collins*, 656 F.3d 1210, 1214 (10th Cir. 2011) (internal quotation marks omitted) (quoting *Twombly*, 550 U.S. at 570)

this requirement is "inapplicable to legal conclusions."[17] A plaintiff's "obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do."[18] Therefore, "in ruling on a motion to dismiss, a court should disregard all conclusory statements of law and consider whether the remaining specific factual allegations, if assumed to be true, plausibly suggest the defendant is liable."[19]

Having reviewed the memoranda in support of and opposition to the motions to dismiss, including the supplemental memoranda on punitive damages and separate supplemental memoranda on the choice of law issue, and having considered the oral arguments of counsel, Plaintiff having stipulated to the dismissal of certain causes of action, and good cause appearing,

IT IS HEREBY ORDERED as follows:

1. Because this matter was transferred from the United States District Court for the District of Northern California to this district, pursuant to 28 U.S.C. §1404(a), this Court must apply California's choice of law rules.[20] California courts apply a "governmental interest" analysis to resolve choice of law questions.[21] This analysis looks at the competing interests of the states whose laws are potentially applicable to the claim. The court applies the law of the state whose interests would be most significantly impaired if not chosen to apply to the dispute.[22]

Utah law governs the substantive issues in the case. Accordingly, Utah's substantive law rules shall governs any and all state law claims asserted in the complaint or any subsequently

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[17] *Id.* at 1214.

[18] *Twombly*, 550 U.S. at 555.

[19] *Kansas Penn Gaming*, 656 F.3d at 1214.

[20] *Van Dusen v. Barrack*, 376 U.S. 612, 635-37 (1964); *Trierweiler v. Croxton & Trench Holding Corp.*, 90 F.3d 1523, 1532 (10th Cir. 1996).

[21] *McCann v. Foster Wheeler, LLC*, 48 Cal. 4th 68, 83 (Cal. Feb. 18, 2010).

[22] *Id.*

filed amended complaint. Utah's substantive law has been applied in reaching the rulings set forth herein except to the extent Plaintiff's counsel has stipulated to the dismissal of any cause of action under any state's laws or where federal pleadings standards apply.

2. For purposes of this motion only, Elan's motion to dismiss is denied to the extent it seeks to have Elan treated separately from Biogen. All rulings contained herein apply equally to Elan and Biogen.

3. Plaintiff's first cause of action for "Design Defect" is dismissed with prejudice based on the Utah Supreme Court's holding in *Grundberg v. Upjohn*[23] and based on the stipulation of Plaintiff's counsel.[24]

4. Plaintiff's second cause of action for "Strict Liability - Failure to Warn" is dismissed with prejudice based on the stipulation of Plaintiff's counsel.[25]

5. Plaintiff's third cause of action for "Strict Liability In Tort" is dismissed with prejudice based upon the stipulation of Plaintiff's counsel to dismiss.[26]

6. Plaintiff's fourth cause of action for "Negligence" is dismissed without prejudice. Plaintiff is granted leave to amend to restate this cause of action by asserting specific facts about the existence of information that made the labeling of Tysabri® inadequate at times material to Plaintiff's decedent's ingestion of the drug, together with specific facts alleging that a change in warnings would have had an impact on the prescribing physician's decision to prescribe Tysabri® to Plaintiff's decedent.

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[23] 813 P.2d 89 (Utah 1991).

[24] Plaintiff's Opposition to Defendant Biogen Idec, Inc.'s Motion to Dismiss at 13, docket no. 33, filed January 30, 2012.

[25] Reporter's Transcript of Proceedings at 7:25-8:3, docket no. 76, filed November 4. 2013.

[26] *Id.* at 8:6-15

7. Plaintiff's fifth cause of action for "Breach of Implied Warranty" is dismissed with prejudice based on the stipulation of Plaintiff's counsel.[27]

8. Plaintiff's sixth cause of action for "Wrongful Death" is dismissed as an independent cause of action. Plaintiff may restate the fact of Plaintiff's decedent's alleged wrongful death as a predicate to Plaintiff's re-pleaded claim for negligence.

9. Plaintiff's seventh cause of action for "Violation of Civil Code §1750" is dismissed with prejudice based on the stipulation of Plaintiff's counsel.[28]

10. Plaintiff's prayer for "Punitive Damages" under any cause of action is dismissed without prejudice based on Plaintiff's failure to plead that FDA itself has found that Defendants knowingly withheld or misrepresented information required to be submitted to FDA under its regulations in connection with Tysabri®. Plaintiff is not in this order granted leave to amend to pray for punitive damages under his remaining theory of negligence. However, Plaintiff may file a motion to amend to pray for an award of punitive damages if Plaintiff can allege that FDA itself has found that Defendants knowingly withheld or misrepresented information required to be submitted to FDA under its regulations in connection with Tysabri®.

Dated December 26, 2013.

BY THE COURT:

David Nuffer
United States District Judge

[27] *Id*. at 25:25-26:15.

[28] *Id*. at 8:21-9:5.