IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STEPHEN WENDELL AND LISA WENDELL, for themselves and as successors in interest to MAXX WENDELL, deceased,

Plaintiffs,

v.

JOHNSON & JOHNSON, et al.,

Defendants.
_____/

No. C 09-04124 CW

ORDER GRANTING IN PART AND DENYING IN PART ABBOTT LABORATORIES' MOTION TO DISMISS

This is a products liability action concerning three prescription drugs, Remicade, Humira and Purinethol. Defendant Abbott Laboratories (Abbott Labs), the manufacturer of Humira, moves to dismiss all claims alleged against it. Plaintiffs oppose the motion. The matter was taken under submission on the papers. Having considered all of the parties' papers, the Court grants Abbott Labs' motion in part and denies it in part .

BACKGROUND[1]

Plaintiffs allege that Defendants' products, used either alone or in combination, resulted in Maxx Wendell's development of hepatosplenic T-Cell lymphoma in 2007. Plaintiffs' claims against Abbott Labs concern the company's failure to warn adequately of lymphoma risks associated with an off-label use of Humira.

In 1998, at the age of twelve, Maxx Wendell was diagnosed with

[1]The following facts are alleged in the complaint.

inflammatory bowel disease and ulcerative colitis. Initially he was treated with a course of mercaptopurine (6-MP) and prednisone, a steroid. Compl. ¶ 59. Mercaptopurine, also sold under the brand name Purinethol,[2] is a "purine analog which interfered with nucleic acid biosynthesis and has been found to be active against human leukemias." Id. at ¶ 55. The only FDA-approved use of mercaptopurine is for the "remission induction and maintenance therapy of acute lymphatic leukemia." Id.

In May, 2002, Wendell's physicians recommended adding Remicade to his treatment regimen[3] with a course of steroid weaning. In June or July, 2002, Wendell received his first dose of Remicade. Remicade is a TNF-∝ inhibitor, which is designed to suppress the immune system in ways that can reduce the symptoms of autoimmune disorders, such as Crohn's disease and rheumatoid arthritis. Id. at ¶ 44. In November, 2006, Wendell's doctors replaced his intake of Remicade with Humira. Humira is also a TNF-∝ inhibitor with anti-inflammatory effects that provides relief for many symptoms affecting rheumatoid arthritis. Id. at ¶ 50. Humira is designed and manufactured by Abbott Labs. Id. at ¶ 21. He received at least five doses of Humira between November, 2006 and June, 2007. Id. at ¶ 63.

In July, 2007, doctors diagnosed Wendell with hepatosplenic T-cell lymphoma. Id. at ¶ 64. Despite aggressive chemotherapy and other treatments, Wendell died on December 19, 2007. Id. at ¶ 65.

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[2]Purinethol is manufactured by Defendants Smithkline Beecham, Teva Pharmaceuticals USA and Gate Pharmaceuticals. Compl. ¶¶ 22-24.

[3]Remicade is manufactured by Defendants Johnson & Johnson and Centocor, Inc. Compl. ¶ 19.

Plaintiffs allege that, following FDA approval of "Remicade in 1998 for treatment of rheumatoid arthritis and Crohn's disease in adults, it became common practice to prescribe mercaptopurine in combination concomitantly with TNF-blockers like Remicade or Humira in the treatment of autoimmune disorders." Id. at ¶ 57. Plaintiffs allege that such use, "which was not approved by the FDA -- was not only known to Defendants herein but encouraged and/or promoted and/or fostered and/or otherwise enabled by Defendants herein and each of them without adequate testing on the safety and/or efficacy of such combination use or in the pediatric or young adult populations." Id.

Plaintiffs assert ten causes of action against all Defendants: (1) fraud and deceit, (2) negligence, recklessness and gross negligence, (3) negligent misrepresentation, (4) negligence, (5) negligence per se, (6) strict liability, (7) breach of express warranty, (8) breach of implied warranty, (9) violation of Business and Professions Code Section 17200, et seq. and (10) wrongful death. Plaintiffs filed the complaint on June 2, 2009 in the Superior Court of California for San Francisco County. Plaintiffs served Abbott Labs on August 6, 2009 and on September 4, 2009, Abbott Labs removed the case to federal court. Plaintiffs have not challenged the removal. On September 27, 2009, Abbott Labs filed the instant motion to dismiss.

LEGAL STANDARD

A complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). When considering a motion to dismiss under Rule 12(b)(6) for failure to state a claim, dismissal is appropriate

only when the complaint does not give the defendant fair notice of a legally cognizable claim and the grounds on which it rests. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). In considering whether the complaint is sufficient to state a claim, the court will take all material allegations as true and construe them in the light most favorable to the plaintiff. NL Indus., Inc. v. Kaplan, 792 F.2d 896, 898 (9th Cir. 1986). However, this principle is inapplicable to legal conclusions; "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are not taken as true. Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949-50 (2009) (citing Twombly, 550 U.S. at 555).

When granting a motion to dismiss, the court is generally required to grant the plaintiff leave to amend, even if no request to amend the pleading was made, unless amendment would be futile. Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv. Inc., 911 F.2d 242, 246-47 (9th Cir. 1990). In determining whether amendment would be futile, the court examines whether the complaint could be amended to cure the defect requiring dismissal "without contradicting any of the allegations of [the] original complaint." Reddy v. Litton Indus., Inc., 912 F.2d 291, 296 (9th Cir. 1990). Leave to amend should be liberally granted, but an amended complaint cannot allege facts inconsistent with the challenged pleading. Id. at 296-97.

DISCUSSION

I. Pleading Standards

The parties disagree as to whether federal or state procedural law applies to this motion. Plaintiffs argue that, because the complaint was filed in state court, California's pleading rules

govern. This is not correct.

A Rule 12(b)(6) motion considers the substantive sufficiency of the pleadings as if the action had never been in state court. See Granny Goose Foods, Inc. v. Brotherhood of Teamsters & Auto Truck Drivers, Local No. 70 of Alameda County, 415 U.S. 423, 437 (1974) ("[O]nce a case has been removed to federal court, it is settled that federal rather than state law governs the future course of proceedings, notwithstanding state court orders issued prior to removal."). Further, Federal Rule of Civil Procedure 81(c) provides, "These rules apply to a civil action after it is removed from state court." This action has now been removed; therefore, federal law, not state law, governs the specificity that Plaintiffs must plead in order to survive a 12(b)(6) motion. Lopez v. GMAC Mortgage Corp., No. C 07-3911 CW, 2007 WL 3232448 at *4 (N.D. Cal.) ("In a case removed to federal court, the pleading requirements for a claim of fraud are analyzed under Federal Rule of Civil Procedure's 9(b).").

I. Off-Label Use of Humira Allegations

Abbott Labs argues that all causes of action against it should be dismissed because Plaintiffs did not allege that it promoted off-label use of Humera. Although the adequacy of Plaintiffs' allegations will be discussed below, the Court concludes that Plaintiffs have, at least in a general fashion, alleged that Abbott Labs promoted the off-label use of Humera. For instance, paragraph fifty-seven of Plaintiffs' complaint alleges that Humira's use in combination with Remicade and mercaptopurine in the treatment of autoimmune disorders, which "was not approved by the FDA," was

known to and promoted by Defendants.[4] Compl. ¶ 57. Therefore, this argument of Abbott Labs fails.

II. Learned Intermediary Doctrine

Abbott Labs also argues that all claims against it should be dismissed under the "learned intermediary" doctrine because "the FDA-approved labels for Humira specifically warned against the harm alleged here: the risk of lymphoma, particularly when Humira is used concomitantly with other immunosuppressive drugs." Motion at 12. The learned intermediary doctrine provides that a drug manufacturer's duty to warn "runs to the physician, not to the patient." Carlin v. Superior Court, 13 Cal. 4th 1104, 1116 (1996). However, this rule does not absolve manufacturers of a duty to provide physicians with adequate warnings about drugs such that physicians can adequately inform their patients. Id. at 1108. Although Abbott Labs claims that its warnings were adequate, the Court cannot make such a determination in this case on a motion to dismiss. Plaintiffs do not disagree that Abbott Labs provided a warning to physicians, but they dispute whether the warning adequately conveyed to physicians the known or knowable risks of Humira. At the pleading stage, Abbott Labs has not proved that the "learned intermediary" doctrine bars all of Plaintiffs' claims. Thus, the Court denies Abbott Labs' motion to dismiss Plaintiffs' complaint based on this defense.

III. Fraud, Negligent Misrepresentation and Business and Professions Code Section 17200

Plaintiffs' first, third and ninth causes of action are for

[4]Of course if it were later to appear that Plaintiffs had no good faith reason to believe that Abbott Labs promoted the off-label use of Humira, Rule 11 sanctions would apply.

fraud, negligent misrepresentation and violation of Business and Professions Code Section 17200 respectively. Because these causes of action are all grounded in allegations of fraud, the Court will discuss them together.

Under California law, "[t]he elements of fraud, which gives rise to the tort action for deceit, are (a) misrepresentation (false representation, concealment, or nondisclosure); (b) knowledge of falsity (or 'scienter'); (c) intent to defraud, i.e., to induce reliance; (d) justifiable reliance; and (e) resulting damage." Small v. Fritz Cos., Inc., 30 Cal. 4th 167, 173 (2003) (quoting Lazar v. Superior Court, 12 Cal. 4th 631, 638 (1996)). A claim for negligent misrepresentation does not require scienter or intent to defraud; rather, to establish fraud through non-disclosure or concealment of facts, it is necessary to show that the defendant "was under a legal duty to disclose them." Lingsch v. Savage, 213 Cal. App. 2d 729, 735 (1963); Buckland v. Threshold Enterprises, Ltd., 155 Cal. App. 4th 798 (2007).[5]

"In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. Proc. 9(b). The allegations must be "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything

[5]Most district courts within California have held that a negligent misrepresentation claim is subject to the heightened pleading requirements of Rule 9(b). Deitz v. Comcast Corp., 2006 WL 3782902 (N.D. Cal.); Neilson v. Union Bank of California, N.A., 290 F. Supp. 2d 1101, 1141 (C.D. Cal. 2003) (stating that the elements of a cause of action for negligent misrepresentation are the same as those of a claim for fraud, with the exception that the defendant need not actually know the representation is false).

wrong." Semegen v. Weidner, 780 F.2d 727, 731 (9th Cir. 1985). Statements of the time, place and nature of the alleged fraudulent activities are sufficient, id. at 735, provided the plaintiff sets forth "what is false or misleading about a statement, and why it is false." In re GlenFed, Inc., Sec. Litig., 42 F.3d 1541, 1548 (9th Cir. 1994). Scienter may be averred generally, simply by saying that it existed. Id. at 1547; see Fed. R. Civ. Proc. 9(b) ("Malice, intent, knowledge, and other condition of mind of a person may be averred generally"). Allegations of fraud based on information and belief usually do not satisfy the particularity requirements of Rule 9(b); however, as to matters peculiarly within the opposing party's knowledge, allegations based on information and belief may satisfy Rule 9(b) if they also state the facts upon which the belief is founded. Wool v. Tandem Computers, Inc., 818 F.2d 1433, 1439 (9th Cir. 1987).

Here, Plaintiffs' fraud claims do not meet Rule 9(b)'s requirements. Plaintiffs have not identified which Defendant is alleged to have made the misrepresentations or omissions, let alone the specific persons who made the fraudulent statements. Swartz v. KPMG LLP, 476 F.3d 756, 764-65 (9th Cir. 2007) ("Rule 9(b) does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to differentiate their allegations when suing more than one defendant . . . and inform each defendant separately of the allegations surrounding his alleged participation in fraud.") (internal quotations, brackets, and citation omitted).

Further, Plaintiffs have not plead facts describing what is false or misleading about any of Abbott Lab's statements. Plaintiffs generally allege that Defendants' "representations

regarding the safety and efficacy of their drug products when used either singly or in combination were in fact false and inaccurate" because "the use of their products either singly or in combination . . . was directly associated with and/or known to cause cancers, including and particularly hepatosplenic T-cell lymphoma." Compl. ¶ 73. Allegations such as these do not explain how any statement or omission was false. Therefore, the Court grants Abbott Labs' motion to dismiss these causes of action.

IV. Negligence, Strict Liability and Wrongful Death

Plaintiffs' claims for negligence, negligence per se, strict liability and wrongful death also fail to state a claim.[6] Although not governed by the same heightened pleading standards as fraud claims, these allegations fail to specify any tortious conduct by Abbott Labs. Plaintiffs simply recite the elements of each cause of action and repeat the same failure-to-warn allegations. Plaintiffs fail to allege how Abbott Labs' warnings about Humira were inadequate, how it was negligent in failing to satisfy any other duty of care alleged or how it violated any specific California consumer protection law that would serve as the basis of Plaintiffs' negligence per se claim. Plaintiffs' "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are insufficient to state a claim. Iqbal, 129 S. Ct. at 1949-50.

Further, Plaintiffs' opposition does not even address these causes of action, choosing instead to rely on the argument that Abbott Labs failed to "challenge the sufficiency of the pleadings

[6]These claims comprise counts two, four, five, six and ten.

under California law." Opposition at 27. As noted above, federal pleading standards control this motion and Plaintiffs' failure to respond to Abbott Labs' arguments regarding these causes of action leaves the Court with little option but to grant Abbott Labs' motion on these claims.

V. Breach of Express and Implied Warranties

Plaintiffs' seventh and eighth causes of action are for breach of express and implied warranty respectively. Abbott Labs argues that these claims fail because it is not in privity with Plaintiffs. However, California recognizes an exception to the privity requirement in breach of warranty claims pertaining to food or drug products. Gottsdanker v. Cutter Labs., 182 Cal. App. 2d 602 (1960). Abbott Labs asks the Court to ignore the rule in Gottsdanker because it has not been addressed by the California Supreme Court. The Court will not do so. Abbott Labs has not presented any California authority to suggest that this rule is no longer valid or that the California Supreme Court would rule as such.

However, for a different reason, the Court dismisses Plaintiffs' warranty claims. Simply stated, Plaintiffs' allegations fail to state a claim under Rule 8(a). Plaintiffs merely allege that Defendants expressly and impliedly "warranted" that the products were "safe, effective, fit and proper for their intended use," and that the products "were not safe and were unfit" for their intended uses." Compl. ¶¶ 120-21, 124, 126. Plaintiffs have not alleged the contents of any specific warranty or the breach thereof. Plaintiffs must allege more than just the elements of a warranty cause of action to survive a motion to dismiss.

CONCLUSION

For the foregoing reasons, the Court grants Abbott Labs' motion to dismiss. Docket No. 39. Plaintiffs may amend their complaint to cure the deficiencies outlined above. Plaintiffs may file an amended complaint within twenty-one days from the date of this order. If Plaintiffs do so, Abbott Labs may file a motion to dismiss three weeks thereafter, with Plaintiffs' opposition due two weeks following and Abbott Labs' reply due one week after that. Abbott Labs' motion, if one is filed, shall be taken under submission on the papers. Defendants who have already answered need not file another answer. A case management conference shall be held on April 20, 2010 at 2:00 p.m.

IT IS SO ORDERED.

Dated: 01/20/10

CLAUDIA WILKEN
United States District Judge