IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

JUDY LEONARD,

Plaintiff,

10cv1341
ELECTRONICALLY FILED

v.

TARO PHARMACEUTICALS USA, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER

Before the Court is Defendant Taro Pharmaceuticals USA, Inc.'s ("TARO's") Motion to Dismiss Plaintiff's Amended Complaint (doc. no. 11) pursuant to Fed.R.Civ.P. 12(b)(6). Plaintiff Judy Leonard's Amended Complaint, sounding in Pennsylvania common law negligence and strict products liability, asserts that Plaintiff was injured after taking prescription products containing the drug carbamazepine, which, Plaintiff claims, TARO designed, manufactured, sold and distributed in Pennsylvania. Amended Complaint (doc. no. 10).

Defendant removed this case from the Court of Common Pleas of Allegheny County, Pennsylvania, to this Court under 28 U.S.C. §1332, claiming complete diversity of the parties and averring that the damages will exceed $75,000. Notice of Removal (doc. no. 1), ¶¶ 1-7. Subsequently, Defendant filed a Motion to Dismiss the initial complaint, but Plaintiff's Amended Complaint rendered that Motion to Dismiss moot. TARO'S Motion to Dismiss the seven-count Amended Complaint under F.R.Civ.P. 12(b)(6) argues that it fails to allege any claim upon which relief could be granted.

For the reasons that follow, this Court will grant in part and deny in part Defendant's Motion to Dismiss the Amended Complaint.

I. Background

The following facts are taken from the Amended Complaint and are accepted as true for purposes of deciding the Motion to Dismiss the Amended Complaint.

Plaintiff, a resident of Western Pennsylvania, was prescribed, purchased, and ingested the drug carbamazepine, which TARO allegedly manufactured, designed, distributed and sold in Pennsylvania. Amended Complaint (doc. no. 10), ¶¶ 2, 8-9, 15. As a result, Plaintiff developed severe adverse cutaneous reactions caused by her use of carbamazepine as prescribed, suffered permanent damage to her internal organs, and developed Stevens Johnson Syndrome, and/or Toxic Epidermal Necrolysis syndrome. Id. at ¶¶ 15-16.

Plaintiff alleges TARO failed to investigate the accuracy of its carbamazepine drug product labeling, specifically its warnings. Id. at ¶¶ 53-56. Plaintiff further alleges Defendant had a legal obligation to conduct such investigations and to ensure that its warnings were accurate, and claims Defendant breached that duty when it failed to inform the drug's prescribers and end users of the extent of the foreseeable side effects. Id. at ¶¶ 57-74.

Plaintiff's Amended Complaint states the following claims: negligence (Count I), negligence *per se* (Count II), misrepresentation by omission (Count III), negligent misrepresentation (Count IV), breach of express warranty (Count V), breach of implied warranties (Count VI), and negligence: violation of resident state duties of care (Count VII). Defendant seeks to dismiss Plaintiff's misresentation by omission (Count III), negligent misrepresentation (Count IV), breach of express warranty (Count V), and breach of implied warranties (Count VI) claims pursuant to F.R.Civ. P. 12(6) on the grounds that such claims are barred by Hahn v. Richter, 673 A.2d 888 (Pa. 1996), in which the Pennsylvania Supreme Court held that negligence was the *only* basis of liability on a complaint seeking damages for failure to

provide adequate warnings with regard to prescription drugs, and that strict liability is not a valid cause of action in such cases. Defendant also seeks to dismiss the negligence claims (negligence (Count I), negligence *per se* (Count II), and negligence: violation of resident state duties of care (Count VII)) for failure to state a claim, for various reasons.

II. Standard of Review

In considering a Rule 12(b)(6) motion, federal courts require notice pleading, as opposed to the heightened standard of fact pleading. Federal Rule of Civil Procedure 8(a)(2) requires only " 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the ... claim is and the grounds on which it rests.' " Bell Atlantic Corp. v. Twombly, 550 U.S. 554, 555 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)).

To survive a motion to dismiss, plaintiff must allege sufficient facts that, if accepted as true, state "a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) (quoting Twombly, 550 at 570). A claim has facial plausibility when a plaintiff pleads facts that allow the court to draw the reasonable inference that the defendant may be liable for the misconduct alleged. Id. at 1949. However, the court is "'not bound to accept as true a legal conclusion couched as a factual allegation.' " Iqbal, 129 S.Ct. at 1950 (quoting Twombly, 550 U.S. at 555). In deciding a motion to dismiss, a court must determine whether the complaint "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." PA Prison Soc. v. Cortes, 622 F.3d 215, 233 (3d Cir. 2010), citing Iqbal, 129 S.Ct. at 1949. "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." Id.; see also Fowler v. UPMC Shadyside, 578 F.3d 203, 210-211 (3d Cir. 2009).

As explained succinctly by the United States Courts of Appeals for the Third Circuit:

> Pursuant to Ashcroft v. Iqbal, [citation omitted], district courts must conduct a two-part analysis when presented with a motion to dismiss. Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir.2009). "First, the factual and legal elements of a claim should be separated." Id. "The District Court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." Id. at 210-11. "Second, a District Court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.' " Id. at 211 (quoting Iqbal, 129 S.Ct. at 1950).

Edwards v. A.H. Cornell and Son, Inc., 610 F.3d 217, 219 (3d Cir. 2010).

When determining whether a plaintiff has met the second part of the analysis and presented facts sufficient to show a "plausible claim for relief," the Court must consider the specific nature of the claim presented and the facts pled to substantiate that claim. For example, in Fowler, a case predicated upon a violation of the Rehabilitation Act, the Court of Appeals determined that "[t]he complaint pleads how, when, and where [the defendant] allegedly discriminated against Fowler." 578 F.3d at 212. The Court, while noting that the Complaint was "not as rich with detail as some might prefer," it the "how, when and where" provided by the plaintiff sufficient grounds to establish plausibility. Id. at 211-212.

The Court of Appeals for the Third Circuit in Guirguis v. Movers Specialty Services, Inc., 346 Fed.Appx. 774, 776 (3d Cir. 2009), a civil rights and Title VII case, affirmed a decision to dismiss a plaintiff's complaint because the plaintiff failed to plead facts explaining why he believed his national origin was the basis for the termination of his employment.

Therefore, when deciding a motion to dismiss under Rule 12(b)(6), we apply the following rules. The facts alleged in the complaint, but not the legal conclusions, must be taken as true and all reasonable inferences must be drawn in favor of plaintiff. Iqbal, 129 S.Ct. at 1949; Twombly, 550 U.S. at 555. A court may not dismiss a complaint merely because it appears unlikely or improbable that plaintiff can prove the facts alleged or will ultimately prevail

on the merits. Id. at 556, 563 n.8. Instead, the court must ask whether the facts alleged raise a reasonable expectation that discovery will reveal evidence of the necessary elements. Id. at 556. In short, the motion to dismiss should not be granted if plaintiff alleges facts which could, if established at trial, entitle him to relief. Id. at 563 n.8. Generally speaking, a complaint that provides adequate facts to establish "how, when, where, and why" will survive a motion to dismiss. See Fowler and Guirguis, supra.

It is on this standard that this Court has reviewed Defendant's Motion to Dismiss Plaintiff's Amended Complaint.

III. Discussion

A. Motion to Dismiss Non-Negligence Claims under Hahn v. Richter

TARO argues that Plaintiff's misrepresentation by omission (Count III), negligent misrepresentation (Count IV), breach of express warranty (Count V), and breach of implied warranties (Count VI) claims must be dismissed in light of the Pennsylvania Supreme Court's decision in Hahn v. Richter, 673 A.2d 888, 889-90 (Pa. 1996).

In evaluating products liability claims, Pennsylvania courts have adopted the Restatement (Second) of Torts' position that those who sell unreasonably dangerous products are subject to strict liability. Kline v. Pfizer, Inc., 2008 WL 4787577 *2 (E.D. Pa. 2008) (citing Restatement (Second) of Torts § 402(A)(1) (1965) and Hahn). However, comment k to section 402(A)(1) lists an exception to this general rule of strict liability for those who make "unavoidably unsafe products." Id. (quoting Restatement (Second) of Torts § 402(A)(1) cmt. k (1965)).

Pennsylvania courts have concluded that prescription drugs are "unavoidably unsafe products," and actions based upon injuries caused by prescription drugs fall within the

Restatement (Second)'s exception and are not subject to strict liability. In the Hahn case, the Pennsylvania Supreme Court stated as follows:

> Comment k [of the Restatement (Second) of Torts § 402(A)(1)], titled "Unavoidably unsafe products," denies application of strict liability to products such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings. As to what constitutes proper warnings, comment j, titled "Directions or warning," provides that a seller must warn of risks, not generally known and recognized, of which he has or reasonably should have knowledge, and, further, that it can be assumed that where warnings are given they will be read and heeded.
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> In Incollingo v. Ewing, 282 A.2d 206, 219-20 (1971), where the manufacturer of a prescription drug was alleged to have caused injury by providing inadequate warnings to physicians about dangers associated with use of the drug, the manufacturer's duty to exercise reasonable care in providing adequate and proper warnings was recognized by this court. Negligence, not strict liability, was alleged as the basis for recovery. We noted that under comments j and k strict liability was not applicable to the case. 282 A.2d at 219-20. We further stated:
>
> > Since the strict liability rule of § 402A is not applicable, the standard of care required is that set forth in § 388 of the Restatement dealing with the liability of a supplier of a chattel known to be dangerous for its intended use. Under this section, the *supplier has a duty to exercise reasonable care to inform* those for whose use the article is supplied of the facts which make it likely to be dangerous.
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> 282 A.2d at 220 n. 8 (emphasis added).
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> In Baldino v. Castagna, 478 A.2d 807 (1984), suit was brought against a drug manufacturer on the basis of allegedly inadequate product warnings. Reaffirming that the basis of liability in such a case is the failure to exercise reasonable care rather than strict liability, this court stated:
>
> > In Incollingo we held that, assuming proper preparation and warning, a manufacturer of drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk. Id., 282 A.2d at 221. Rather, such a *manufacturer is liable only if he fails to exercise reasonable care to inform* those for whose use the article is supplied of the facts which make it

> likely to be dangerous. Id., 282 A.2d at 220 n. 8 (citing Section 388 of the Restatement (Second) of Torts).
>
> 478 A.2d at 810 (emphasis added). Reliance was again placed on the principles set forth in comments j and k to deny application of strict liability.
>
> Incollingo and Baldino, as well as comments j and k, make it clear that where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability. Accord Mazur v. Merck & Co., Inc., 964 F.2d 1348, 1353-55 (3d Cir.1992) (interpreting Incollingo and Baldino as making a prescription drug manufacturer's liability for failure to warn rest on negligence, not strict liability), cert. denied, 506 U.S. 974 (1992).

673 A.2d at 889-91 (footnotes and parallel citations omitted).

Since manufacturers of prescription drugs are not subject to strict liability, only negligence, such manufacturers have "a duty to exercise reasonable care to inform those for whose use [the drug] is supplied of the facts which make [the drug] likely to be dangerous." Hahn, 673 A.2d at 890 (citing Restatement (Second) of Torts § 388). "Where the adequacy of warnings associated with prescription drugs is the issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis for liability." Id. at 891.

Pennsylvania state and federal courts have interpreted Hahn broadly to bar all non-negligence based claims asserted against a manufacturer of prescription drugs. See, e.g., Aaron v. Wyeth, 2010 WL 653984 *1, 3 (W.D. Pa. Feb. 19, 2010) (dismissing breach of express and implied warranty claims under Hahn); Lance v. Wyeth, 4 A.3d 160, 166 (Pa.Super. 2010) (while strict liability failure to warn claim is properly dismissed under Hahn, "negligent design defect claim is considered to be distinct from, and not subsumed within, a strict liability design defect claim. Consequently, Appellant's negligent design claim is not precluded by comment k, and is a

valid cause of action upon which relief may be granted."); Kline v. Pfizer, Inc., 2008 WL 4787577 *4 (E.D. Pa. 2008) (dismissing breach of express and implied warranty claims, fraudulent misrepresentation, fraudulent concealment, and unjust enrichment claims under Hahn), reconsideration denied, 2009 WL 32477 *3-4 (E.D. Pa. 2009); Colacicco v. Apotex, Inc., 432 F.Supp. 2d 514, 548 (E.D. Pa. 2006) (dismissing breach of implied warranty, fraud by intentional misrepresentation, intentional infliction of emotional distress, and strict liability claims under Hahn), rev'd on other grounds, 521 F.3d 253 (3d Cir. 2008).

In light of Hahn and its progeny, this Court will grant defendant's Motion to Dismiss Plaintiff's breach of express warranty (Count V) and breach of implied warranty (Count VI) claims. Additionally, under Pennsylvania law, intentional misrepresentation, or fraud, can be predicated upon "a positive assertion as well as a failure to disclose" material facts. Piezo Crystal Co., a Div. of PPA Indus., Inc. v. Uddeholm Corp., 870 F. Supp. 589, 594 (M.D. Pa. 1994) (citation omitted). Because plaintiff's misrepresentation by omission claim (Count III) asserts *intentional* misrepresentation by omission ("Defendant's intentional misrepresentations and omissions were made willfully, wantonly, or recklessly to the Plaintiff to induce purchase of carbamazepine drug products over other safer alternative drugs on the market"), Amended Complaint (doc. no. 10), ¶ 139), this Court will also grant Defendant's motion to dismiss Count III, misrepresentation by omission, as this claim is also a non-negligence based claim akin to strict liability for failure to warn, and is barred by Hahn and its progeny.

However, this Court declines to dismiss Count IV, negligent misrepresentation. As the District Court for the Eastern District of Pennsylvania concluded in the Colacicco case:

> . . . Hahn requires us to dismiss Count IX (strict liability), as well as all of Plaintiff's remaining claims except the four that sound in negligence: negligent misrepresentation (Count IV), negligent infliction of emotional distress (Count VI), negligence (Count VII), and negligence per

> se (Count VIII). Accordingly, Count II (breach of implied warranty), Count III (fraud by intentional misrepresentation and violation of New York consumer protection law), Count V (intentional infliction of emotional distress), and Count IX (strict products liability) must be dismissed.

432 F.Supp.2d at 548.

B. Motion to Dismiss Negligence Claims

Defendant argues Plaintiff's "negligent design" claims are not supported by the facts alleged in the Amended Complaint because defendant, a generic drug manufacturer, did not "design" carbamazepine, and that Plaintiff's negligent manufacturing claims must fail because the Amended Complaint does not allege the particular carbamazepine used by the plaintiff differed in any way from carbamazepine generally. Motion to Dismiss (doc. no. 12), ¶ ¶ 14-15. Defendant additionally argues that under Pennsylvania's learned intermediary doctrine, the duty to warn runs only to the prescribing physician, not the patient, that negligence *per se* and violation of resident state duties of care are not viable independent causes of action, and that res ipsa loquitur has no place in the lawsuit. Id. at ¶ 21, 25-27. TARO also argues that the Amended Complaint is replete with redundancies and irrelevant matters, which should be stricken from the Amended Complaint. Id. at ¶ 29. Plaintiff counters that her negligent design and manufacture claims are subsumed within her broader negligence-based claims, and that all of the negligence claims are cognizable under Pennsylvania law and adequately supported by the facts alleged in the Amended Complaint.

The Court agrees with Plaintiff that her Amended Complaint provides adequate facts, which could, if established at trial, entitle plaintiff to relief on her negligence-based claims. Those facts, accepted for purposes of the motion to dismiss as true, state plausible claims under Pennsylvania common law negligence principles. While some of TARO's arguments may have

merit further down the litigation road, at this stage of the proceedings they are premature and must await further development of Plaintiff's claims during discovery.

Accordingly,

AND NOW, this 2nd day of December, 2010, after due consideration of Defendant's Motion to Dismiss the Amended Complaint (doc. no. 11), and plaintiff's response thereto, **IT IS HEREBY ORDERED** that said Motion to Dismiss is **DENIED** without prejudice with regard to plaintiff's negligence claims (Counts I, II, IV and VII), and **GRANTED** in part with regard to plaintiff's non-negligence based claims (Counts III, V and VI).

SO ORDERED

s/ Arthur J. Schwab
Arthur J. Schwab
United States District Judge

Cc: All Registered ECF Counsel and Parties