DLA PIPER LLP (US)
Stephen C. Matthews (#055801994)
Amanda Laufer Camelotto (#902142012)
51 John F. Kennedy Parkway, Suite 120
Short Hills, New Jersey 07078-2704
stephen.matthews@dlapiper.com
amanda.camelotto@dlapiper.com
Tel.: (973) 520-2541

Attorneys for Defendants Sanofi U.S. Services, Inc. and sanofi-aventis U.S. LLC

PARTIALLY GRANTED

IN RE TAXOTERE LITIGATION

SUPERIOR COURT OF NEW JERSEY LAW DIVISION – MIDDLESEX COUNTY

CASE TYPE: MCL NO. 628

MASTER DOCKET NO.: MID-L-4998-18-CM

CIVIL ACTION
IN RE TAXOTERE LITIGATION

ORDER

THIS MATTER having been brought before the Court upon the motion of Defendants Sanofi U.S. Services Inc., f/k/a Sanofi Aventis U.S. Inc., sanofi-aventis U.S. LLC (together, "Sanofi Defendants") and Defendants Sandoz, Inc., Sun Pharmaceutical Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories, Ltd., Actavis Pharma, Inc., and Actavis LLC f/k/a Actavis Inc. (together, the "505(b)(2) Defendants," and collectively with Sanofi Defendants, "Defendants"), for an Order dismissing the Master Long Form Complaint for failure to state a claim upon which relief can be granted pursuant to *Rule* 4:6-2(e); and the Court having considered the supporting papers, opposition and reply papers, if any; and oral argument, if any; and the Court having determined that, based upon same, and for good cause shown;

IT IS on this 28th day of August 2019:

ORDERED that Count I (strict product liability under common law, statute, and the New Jersey Product Liability Act) of the Master Long Form Complaint is hereby partially dismissed as to the common law and other statutory grounds but is hereby upheld under the statutory provisions of the New Jersey Product Liability Act; and

ORDERED that Counts II (negligence), Count III (negligence per se), Count IV (negligent misrepresentation), Count V (fraudulent misrepresentation), Count VI (fraudulent concealment), Count VII (fraud and deceit), Count VIII (violation of the New Jersey Consumer Fraud Act), Count IX (violation of consumer protection laws), Count X (breach of express warranty), Count IX (violation of consumer protection laws), Count IIX (punitive damages), Count XIII (negligent infliction of emotional distress), and Count XIV (loss of consortium) are upheld as properly plead and are to remain viable claims.

ORDERD that Count XI (breach of implied warranty) of the Master Long Form Complaint are hereby dismissed without prejudice, pursuant to R. 4:6-2(e); and

ORDERED that Plaintiffs may file a motion to amend their Complaint pursuant to R. 4:9-1 within sixty (60) days of the date hereof; and

IT IS FURTHER ORDERED a copy of this Order shall be served on all parties within seven (7) days of the date of this Order.

* See Attached.

James F. Hyland, J.S.C.

In re Taxotere Litigation

Master Docket No. Mid. L-4998-18-CM

Superior Court of New Jersey, Law Division, Middlesex County

January 23, 2019, Argued; August 19, 2019, Decided August 28, 2019

I. Introduction

Sanofi U.S. Services Inc. f/k/a Sanofi Aventis U.S. Inc., Sanofi-Aventis U.S. LLC, Sandoz Inc., Sun Pharmaceuticals Industries, Inc. f/k/a Caraco Pharmaceutical Laboratories, Ltd., Actavis Pharma, Inc., and Actavis LLC f/k/a/Actavis Inc. (collectively "Defendants") have jointly filed the instant motion to dismiss, with prejudice, Plaintiffs' Master Complaint for failure to state a claim pursuant to *New Jersey Court Rule* 4:6-2(e). This motion requires the Court to interpret the applicability of the New Jersey Supreme Court's opinion in *In re Accutance Litig.*, 235 N.J. 299 (2018), to Plaintiffs' Master Complaint, which claims common law and statutory causes of action based on: 1) strict product liability under common law, statute, and the New Jersey Product Liability Act ("PLA"); 2) negligence; 3) negligence per se; 4) negligent misrepresentation; 5) fraudulent misrepresentation; 6) fraudulent concealment; 7) fraud and deceit; 8) violation of the New Jersey Consumer Fraud Act ("CFA"); 9) violation of consumer protection laws; 10) breach of express warranty; 11) breach of implied warranty; 12) punitive damages; 13) negligent infliction of emotional distress; and 14) loss of consortium.

II. Facts

This case arises out of alleged personal injuries suffered by multiple Plaintiffs after being prescribed the drug docetaxel, an active ingredient in Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate. Docetaxel is a chemotherapy drug administered to both men and women for the treatment of breast cancer. Docetaxel is approved by the FDA for the

treatment of breast cancer. Plaintiffs allege that Defendants are all involved with the sponsoring, manufacturing, labeling, and/or distribution of these drugs. Specifically, Plaintiffs allege to have suffered from permanent alopecia (hair loss) six months after the completion of chemotherapy with docetaxel. Moreover, Plaintiffs maintain that the Defendants had knowledge of this side effect but chose to not provide any warning to patients, healthcare providers, or the Food and Drug Administration ("FDA"). On July 17, 2018, the New Jersey Supreme Court designated all pending and future suits arising out alleged injuries resulting from the consumption of docetaxel as consolidated into the instant multicounty litigation ("MCl").

III. Choice of Law

As a preliminary matter, Defendants argue that New Jersey law should be applied to all claims filed in this MCL, even those claims brought by foreign plaintiffs relating to injuries which occurred outside of New Jersey. *See In re Accutane Litig.*, 235 N.J. 229, 235-36 (2018). Plaintiffs join in Defendants' position. Therefore, since the parties are in agreement on the applicability of New Jersey law, New Jersey law shall apply and no further analysis is needed at this time.

IV. Application of the Product Liability Act to Plaintiff's Master Complaint

The main dispute in the instant motion is to what extent New Jersey law preempts the common law and statutory claims presented in the Master Complaint. Defendants argue that because New Jersey law applies to all claims in this MCL, Plaintiffs' claims based on common law principles and other statutory causes of action are subsumed by the PLA. *See Sinclair v. Merck & Co.*, 195 N.J. 51, 54 (2008). Plaintiffs maintain that the PLA does not subsume all common law and statutory claims as the PLA states that "This act is not intended to codify all issues relating to product liability, but only to deal with matters that require clarification." *N.J.S.A.* 2A:58C-1. As

such, it is necessary to examine each of the claims asserted in the Master Complaint and make individual assessments for each one concerning the application of the PLA.

i. Count One:

Concerning count one (strict product liability), under the common law, statute, and the PLA, Defendants assert that the common law and the statutory basis of this count should be dismissed leaving only the PLA. Count one alleges that Defendants' docetaxel products contained a manufacturing defect which caused Plaintiffs' injuries. The Appellate Division has held that "Under the PLA, the causes of action for negligence, strict liability and implied warranty have been consolidated into a single product liability cause of action, the essence of which is strict liability." *Green v. Gen. Motors Corp.*, 310 N.J. Super. 507, 517 (App. Div. 1998). Specifically, manufacturing defect claims under the PLA must establish that the product was defective in design, manufacturing, or warnings, the defect existed at the time the product left the manufacturer's control, the defect was the proximate cause of plaintiff's injuries, and the plaintiffs were reasonably foreseeable users of the product. *Myrlak v. Port Auth.*, 157 N.J. 84, 97 (1999). Here, Defendants argue that the Master Complaint only makes vague assertions that docetaxel products were not fit for their reasonably intended purpose. There is no indication as to how the manufacturing process of these drugs was defective or made in derivation of industry standards and Plaintiffs have not presented evidence that the docetaxel products they consumed were defective when compared to identical products. Therefore, this claim must be dismissed. *See e.g. Miltz v. Borroughs-Shelving, Div. of Lear Siegler, Inc.*, 203 N.J. Super. 451, 467-68 (App. Div. 1985) (dismissing manufacturing defect claim where the plaintiff could not present evidence that his product was received in a defective condition when it left the manufacturer's control).

Plaintiffs, do not contest the Defendants' assertion that the PLA is applicable to this MCL, but rather asserts that certain common law and statutory claims are not subsumed by the PLA. *See* N.J.S.A. 2A:58C-1. Concerning the manufacturing defect claim specifically, Plaintiffs argue that this cause of action may be established through the same principles of strict liability as a design defect, even though the nature of proof may differ. *See* *Suter v. San Angelo Foundry & Machine Co.*, 81 N.J. 150, 170 (1979). Because Plaintiffs have properly plead a claim based on defective design in the Master Complaint, the manufacturing defect claim is therefore also properly plead.

ii. Counts Two, Three, Four, and Thirteen:

Concerning Plaintiff's negligence claims, Defendants asserts that counts two (negligence), three (negligence per se), four (negligent misrepresentation) and thirteen (negligent infliction of emotional distress) must be dismissed as the PLA subsumes common law and statutory law based negligence claims arising out of product liability suits. *Green, supra* at 517. Count two is based on the allegation that Defendants were negligent based on the acts and omissions of the Defendants relating to docetaxel which were the proximate cause of Plaintiffs injures. Count three is based on the theory that Defendants violated *21 U.S.C. § 331* and *21 U.S.C.* § 352 by misbranding docetaxel and not complying with federal regulations established by the FDA. Count four concerns alleged misrepresentations made by Defendants concerning the side effects of docetaxel which caused Plaintiffs to suffer permanent injury. Count thirteen alleges that Plaintiffs have suffered emotional injuries due to sever emotional distress from the side effects of docetaxel. Defendants note that in *Tirrell*, the Appellate Division upheld the trial court's decision

to dismiss all of the plaintiff's negligence claims as being subsumed under the PLA. *See* Tirrell v. Navistar Int'l, Inc., 248 N.J. Super. 390 (App. Div. 1991).

Plaintiffs assert that the negligence counts are permissible under the PLA as these claims involve harm arising from the alleged wrongful conduct of the Defendants, separate from the harmful effects of the docetaxel products themselves. *See* Dreier, Keefe & Katz, N.J. Products Liability & Toxic Torts Law, Cmt. 1:2-2 (2017). To determine if the PLA subsumes a particular claim, a court must examine the essential nature of the claim presented and decide whether the claim would traditionally be considered a products claim. Worrell v. Elliot & Frantz, 799 F. Supp. 2d 343, 351 (D.N.J. 2011). Negligence claims asserting a breach of duty independent of a manufactures' duty to provide non-defective products would not be subject to the PLA. *Id*. Here, the Defendants are alleged to have provided false or misleading information about the safety of consuming docetaxel, which is a claim unrelated to the alleged defective production of docetaxel, so Plaintiffs' negligence claims are not subsumed by the PLA.

iii. Counts Five, Six, Seven, Eight and Nine:

Next, Defendants assert that counts five (fraudulent misrepresentation), six (fraudulent concealment), seven (fraud and deceit), eight (violation of the CFA) and nine (violation of consumer protection laws) must all be dismissed as they are also subsumed by the PLA. Specifically, it is alleged under count five that Defendants made misleading representations as to the safety of docetaxel. Count six claims that Defendants fraudulently concealed and intentionally omitted material information concerning the safety and risks of docetaxel. Count seven alleges that Defendants committed various types of fraud relating to docetaxel with the

intent of deceiving Plaintiffs. Count eight asserts that Defendants knew or should have known that docetaxel causes permanent hair loss such that the promotion and release of the drug into commerce, which Plaintiffs ultimately purchased, amounts to a violation if the CFA. Lastly, count nine reiterates the claims in count eight but applies the consumer protection laws of fifty different jurisdictions instead of the CFA. In *Sinclair* the court found that a claim brought under the CFA would be subsumed by the PLA where "The heart of plaintiff's case is the potential harm caused by [the manufacturer's] drug". *Sinclair, supra* at 66. Moreover, claims couched in common law fraud are subsumed under the PLA where the injury was caused by the product. *See Brown v. Philip Morris, Inc.*, 228 F. Supp. 2d 506, 517 (D.N.J. 2002).

In opposition, Plaintiffs reiterate their arguments concerning counts two, three, four, and thirteen. Defendants rely on case law which supports the position that the PLA subsumes common law fraud and claims based on the FCA. However, the supremacy of the PLA is only applicable where the alleged injury arises from the defendant's product alone. *Sinclair, supra* at 66; *Brown, supra* at 517. Where the Defendants' actions themselves are alleged as part of the underlying injury on top of the product that was produced, then common law claims can be maintained along with claims under the PLA. *Worrell, supra* at 351.

iv. Count Fourteen

Count fourteen (loss of consortium) is based on the assertion that the family members of Plaintiffs have suffered as a result of Plaintiffs consuming docetaxel. Defendants claim that the plain language of the PLA does not afford recovery for this type of injury. See *N.J.S.A.* 2A:58C-1. Plaintiffs contends that contrary to Defendants position, a loss of consortium claim is recognized

as a specifically enumerated harm under the statute. Moreover, the PLA does not subsume this claim because it is distinct from the Plaintiffs' personal injury claims such as to qualify as a separate recognizable harm. *See* Patusco v. Prince Macaroni Inc., 50 N.J. 365, 366 (1967).

v. Count Ten and Eleven

Count ten (breach of express warranty) is based on violations of several states breach of express warranty statutes. The allegation is that Defendants expressly warranted that docetaxel was safe and fit for consumption, was of merchantable quality, and possessed side effects which were comparable to other breast cancer treatment drugs. Defendants argue that because the instant MCL is based in New Jersey, it would be improper for Plaintiffs to claim a breach of express warranty under the statutes of several different states as the court in *In re Accutane* has found that to apply the laws of numerous states in a single MCL is a "wholly unworkable scheme." *In re Accutane Litig., supra* at 264. Moreover, Plaintiffs have not presented any evidence as to the contents of the warranty or who made it, both of which are necessary elements of this claim. Clements v Sanofi-Aventis, U.S., Inc., 111 F. Supp. 3d 586, 602 (D.N.J. 2015). Concerning count eleven (breach of implied warranty), this is based on the position that Defendants breached various implied warranties by making representations that docetaxel was safe and more efficacious that other medications while fraudulently withholding information concerning the risks of consuming docetaxel. As noted in *Green*, common law claims based on breach of implied warranty are preempted by the PLA. *Green, supra* at 517.

Plaintiffs contend that the PLA is not applicable to count ten so Plaintiffs are permitted to present the breach of express warranty claim under various different state's statutes. *See* N.J.S.A.

2A:58C-1(b)(3). Plaintiffs do not present any position that the implied warranty claims are not subsumed under the PLA as noted in *Green, supra* at 517.

vi. Count Twelve

Count twelve alleges punitive damages based on the Defendants intentional, willful, knowing, fraudulent malicious acts, omissions, and reckless disregard for public safety and welfare. Defendants claim that the pursuant to *N.J.S.A.* 2A:58C-5(c), punitive damages under the PLA are expressly prohibited where the drug which is alleged to have caused the injury was approved by the FDA. While the statute does provide for punitive damages against a drug manufacturer where the manufacturer withheld information from the FDA, this provision has been found to be preempted by federal law. *See McDarby v. Merck & Co.*, 401 N.J. Super. 10, 93-94 (App. Div. 2008)(citing *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 349 (2001)).

Plaintiffs argue that their punitive damages claim is not preempted by the PLA or federal law under *McDarby* and *Buckman*. Concerning the preemption under the PLA, the plain meaning of *N.J.S.A.* 2A:58C-5(c) permits a party to seek punitive damages when claiming that the defendant manufacturer of an FDA approved drug withheld or misrepresented information to the FDA concerning the drug. Plaintiffs, in their Master Complaint, allege that Defendants never updated consumers, their labeling, or the FDA about the risk of permanent hair loss caused by docetaxel, so Plaintiffs have properly plead a claim for punitive damages under the PLA. Moreover, the preemption under federal law alluded to in *McDarby* and *Buckman* is to be used sparingly. There is a strong presumption against preempting state health and safety laws. *See Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 770-71 (3rd Cir. 2018)(*citing Medtronic, Inc. v.*

Lohr, 518 U.S. 470, 485 (1996). Additionally, the U.S. Supreme Court has held that federal law does not preempt a state-law tort action against a manufacturer of a prescription drug for its failure to give adequate warnings about the significant risks of administering that drug. *See Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

V. Standard of Review

In considering a motion to dismiss under *R.* 4:6-2(e), courts must accept the facts asserted in the pleadings as true, and give the pleader the benefit of all inferences that may be drawn in its favor. *Printing Mart v. Sharp Electronics Corp.*, 116 N.J. 739, 746 (1989). Nevertheless, "if the complaint states no basis for relief and discovery would not provide one, dismissal is the appropriate remedy." *Banco Popular North America v. Gandi*, 184 N.J. 161, 166 (2005). "The inquiry is confined to a consideration of the legal sufficiency of the alleged facts apparent on the face of the challenged claim." *Matter of Prudential Ins. Co. Derivative Litigation*, 282 N.J. Super. 256 (App. Div. 1995). "[A] dismissal is mandated where the factual allegations are palpably insufficient to support a claim upon which relief can be granted." *Id.* Ultimately, a "pleading must allege sufficient facts to give rise to a cause of action; mere conclusions and an intention to rely on discovery are inadequate." *Glass v. Suburban Restoration Co.*, 317 N.J. Super. 574, 582 (App. Div. 1998).

VI. Analysis

Here, Defendants' motion is partially granted. Both Plaintiff and Defendant agree that *In re Accutane* establishes the supremacy of the PLA in this MCL. Concerning count one, the court's opinion in *Green* supports Defendants' position that count one of the Master Complaint should

be partially dismissed so as to reflect a claim based solely on strict product liability under the PLA. Next, regarding the vitality of the manufacturing defect portion of count one under the PLA, as noted in *Myrlak*, a plaintiff must establish that the product was defective in design, manufacturing or warnings, the defect existed at the time the product left the manufacturer's control, the defect was the proximate cause of plaintiff's injuries and the plaintiffs were reasonably foreseeable users of the product. However, the court in *Suter* held that the elements for a design defect claim are the same as a defective manufacturing claim. Because this Court must give all deference to Plaintiffs' Master Complaint under *Printing Mart*, the Court is convinced that Plaintiffs have properly presented adequate facts to present a claim for strict product liability under a design defect theory. Therefore, under *Suter* the Plaintiffs have also plead a proper claim for strict liability under the manufacturing defect theory. Thus, concerning count one of the Master Complaint, the strict product liability claim is upheld under the PLA, but the common law and statutory grounds for this count are dismissed.

Next, concerning Plaintiffs' negligence claims under counts two, three, four, and thirteen, the Court is persuaded by Plaintiffs' position that the tort claims are properly plead in the Master Complaint. While *Green* indicates that common law and statutory negligence claims are subsumed by the PLA, the District of New Jersey noted in *Worrell* that negligence claims asserting a breach of duty independent of a manufacturer's duty to provide non-defective products would not be subject to the PLA. Plaintiffs are claiming that Defendants provided false or misleading information about the efficacy of docetaxel, which is a harm unrelated to the alleged defective production of Defendants' docetaxel products. As noted in *Printing Mart*, this Court must accept the facts asserted as true, and give all inferences to the pleader. Additionally, *Banco Popular* held

that dismissal is only proper where there is no basis for relief and discovery would not provide one. Because the Plaintiffs claim negligence against the Defendants based on their actions, separate from the production of docetaxel products in general, the negligence claims cannot be dismissed at this time.

Moreover, the Court is convinced that Plaintiffs' fraud claims under counts five, six, seven, eight, and nine are viable for the same reasons the Plaintiffs' negligence claims are not subsumed under the PLA. Defendants direct the Court to *Sinclair*, in which the court held, in part, that a fraud claim brought under the CFA would be subsumed by the PLA where the crux of the claim was based on harm done to the plaintiff due to the drug manufacturer's product. Similarly, the court in *Brown* held that common law fraud claims were subsumed by the PLA when the injury was caused by a product. However, as noted, Plaintiffs' claims are based not solely on injures incurred by the Defendants docetaxel products, but also by the actions of the Defendants themselves in advertising and promoting their docetaxel products. Therefore, under *Worrell*, like Plaintiffs' negligence claims, the fraud claims must are properly plead.

Concerning counts ten and eleven, breach of express and implied warranty, the *Green* court indicated that the PLA subsumes common law and statutory claims based on implied warranty. Plaintiffs have not presented any case law that contradicts Defendants' position. Therefore, this Court finds the Defendants' arguments to be persuasive so count eleven is hereby dismissed.

However, concerning count ten, the plain language of the PLA defines 'product liability action' as "...any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, expect actions for harm caused by breach of express

warranty." N.J.S.A. 2A:58C-1 (b)(3). The plain language of the statute indicates that the PLA is not applicable to breach of express warranty claims. While the court in *Clements* poses that a claim for breach of express warranty requires the plaintiff to provide evidence of who made the warranty, this opinion has to be reconciled with *Printing Mart*, in which, this Court must give deference to the allegations in Plaintiffs' Master Complaint. The Master Complaint while not identifying specific individuals who made express warranties, does plead that the Defendants made express warranties concerning the efficacy and side effects of their docetaxel drugs. The Court is satisfied that Plaintiffs' pleadings sufficiently overcome the requirements enumerated in *Clements*. Therefore, count ten of the Master Complaint should not be dismissed at this time.

For the loss of consortium claim under count fourteen, the plain language of N.J.S.A. 2A:58C-1 only make one reference to loss of consortium claims. Specifically, the PLA states that "The Legislature finds that there is an urgent need for remedial legislation to establish clear rules with respect to certain matters relating to actions for damages for harm caused by products..." N.J.S.A. 2A:58C-1 (a). The law goes on to explain that "Harm means....any loss of consortium..." *Id.* at (b)(2)(internal citations omitted). The Court is convinced that the plain language of the statute does not subsume a loss of consortium claim and therefore, count fourteen should not be dismissed.

Lastly, for count twelve, Plaintiffs' punitive damages claim is permissible. The PLA states that while punitive damages are not permitted against an FDA approved drug, where the drug manufacturer knowingly withheld or misrepresented information which had to be divulged to the FDA, punitive damages are permissible. *See* N.J.S.A. 2A:58C-5(c). Also, *McDarby* and *Buckman* stand for the position that a punitive damages claim against the manufacturer of an

FDA approved drug will be preempted by federal law. Plaintiffs' assertion is that the Defendants knowingly withheld or misrepresented information to the FDA and consuming public about the possible side effects of consuming docetaxel and as such, the prohibition against punitive damages under the PLA is circumvented. The Court agrees with Plaintiffs' position since the Court must give deference to the allegations in the Master Complaint so the alleged failure of Defendants to divulge the possible hair loss side effect of docetaxel to the FDA must be taken as true.

As for preemption of punitive damages under federal law as illustrated in *McDarby* and *Buckman*, the U.S. Supreme Court's opinion in *Wyeth*, which was decided after *McDarby* and *Buckman*, stands for the position that federal law should not preempt state law tort actions against a drug manufacturer who allegedly failed to provide adequate warning about the risks associated with a drug. Moreover in *Shuker* and *Medtronic*, the courts advocated for a strong presumption against federal law preempting state health and safety laws. Therefore, the Court believes that Plaintiffs have properly plead a claim for punitive damages.

VII. Conclusion

Pursuant to R. 4:6-2(e) the Court has discretion to dismiss a claim with or without prejudice and permit the claimant to amend the complaint. The instant motion asks that the Plaintiffs' first Master Complaint be dismissed with prejudice as to all counts. Given the early stage of this MCL, it is appropriate that Plaintiffs' dismissed counts be dismissed without prejudice and that Plaintiff's be permitted to file an Amended Master Complaint to comport with this Court's decision.

Therefore, Defendants' motion is hereby PARTIALLY GRANTED.