United States District Court
for the
Southern District of Florida

Vanessa Lombardo, Plaintiff	)	
	)	
v.	)	
	)	Civil Action No. 13-60536-Civ-Scola
Johnson & Johnson Consumer Companies, Inc., and others, Defendants	)	

Order on Motion To Dismiss Amended Complaint

Plaintiff Vanessa Lombardo brought this putative class action alleging that Defendants Johnson & Johnson Consumer Companies, Inc. ("Johnson & Johnson") and Neutrogena Corporation ("Neutrogena") have violated the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") in connection with the marketing and labeling of certain sunscreen products. Presently before the Court is Defendants' Motion to Dismiss Plaintiff's Amended Complaint. (ECF No. 55). For the reasons set forth below, the motion is **granted in part** and **denied in part**.

A. Background*

This case concerns the advertising and labeling of certain sunscreens manufactured by the Defendants with sun protection factor ("SPF") designations greater than 50. Johnson & Johnson distributes, markets, and sells Aveeno Active Naturals Continuous Protection Waterproof Sunblock Lotion SPF 70 and SPF 85 (the "Aveeno Sunscreens"). Neutrogena distributes, markets, and sells Ultra Sheer Dry-Touch Waterproof Sunblock SPF 55 and SPF 85, Pure & Free Baby Waterproof Sunblock Lotion SPF 60+, and Sensitive Skin Waterproof Sunblock Lotion SPF 60+ (the "Neutrogena Sunscreens").

SPF values—included on sunscreen products for more than 30 years—are determined by a test that compares the amount of ultraviolet radiation exposure it takes to cause sunburn when wearing the sunscreen, to the amount of exposure it takes to cause sunburn without the sunscreen. Although sunscreens with higher SPF values filter out more ultraviolet rays

* This introductory section is comprised of Plaintiff's allegations, which the Court accepts as true and construes in the light most favorable to her under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

than those with lower SPF values, after a certain point, the scale of clinical benefit provided by higher SPF values is not directly proportional. For example, there is significant clinical benefit for consumers switching from a SPF 10 sunscreen to a SPF 40 sunscreen, while there is allegedly little to no additional clinical benefit from switching from a SPF 55 sunscreen to a SPF 85 sunscreen. Lombardo alleges that despite this, the Defendants represented that their products provided additional clinical benefit over comparable products with an SPF of only 50, and charged premium prices accordingly.

Lombardo also alleges that the advertising and labeling of both the Aveeno Sunscreens and Neutrogena Sunscreens contained false and misleading language. Both sunscreens claimed to provide "waterproof" and "sunblock" protection. The Aveeno Sunscreens also claimed to provide "continuous" protection and the Neutrogena Sunscreens claimed to provide "sweatproof" protection.

Lombardo argues that because sunscreen does not "block" all ultraviolet radiation, the term "sunblock" is false and misleading. And similarly, because sunscreen protection diminishes after exposure to or immersion in water and exposure to sweat, claims that sunscreens are "waterproof" or "sweatproof" are false and misleading. Lastly, because sunscreen must be reapplied every two hours even without exposure to water or sweat, claims that sunscreens provided "continuous" protection were also false and misleading.

The United States Food and Drug Administration ("FDA") classifies sunscreens as over-the-counter drugs regulated by the Food, Drug, and Cosmetic Act ("FDCA"). The FDA recently promulgated labeling and testing requirements for manufacturers, who were given until December 17, 2012 to comply with the requirements. Labeling and Effective Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates, 77 Fed. Reg. 27591 (May 11, 2012). The Final Rule prohibits labels from claiming that a sunscreen is "sunblock," "sweatproof," or "waterproof," or that a sunscreen provides "continuous" protection. Labeling and Effective Testing; Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35628 (Jun. 17, 2011). The Final Rule provides manufacturers with guidance on appropriate language for labeling and marketing.

Lombardo relied on the representations and higher price when she purchased the products, which she claims did not perform as represented. Johnson & Johnson and Neutrogena moved to dismiss Lombardo's original complaint based primarily on theories of preemption. (*See* ECF No. 7). That motion was granted in part, and the Court ruled that Lombardo's claims are preempted with respect to Aveeno and Neutrogena Sunscreens that 1) were

sold on or after June 17, 2011 (the date the Final Rule was enacted) and 2) were labeled before December 17, 2012 (the deadline for compliance). As such, in her Amended Complaint, Lombardo seeks to represent a class of Florida residents who purchased Johnson & Johnson and Neutrogena products between 2009 and June 16, 2011. She also excludes Sunscreens that are regulated by the Final Rule. (*See* Am. Compl. ¶76, ECF No. 48.) Lombardo's allegations are therefore limited to products purchased by putative class members on or before June 16, 2011.

B. Legal Standard

When considering a motion to dismiss under Rule 12(b)(6), the Court must accept all of the complaint's well-pled factual allegations as true, construing them in the light most favorable to the plaintiff. *Pielage v. McConnell*, 516 F.3d 1282, 1284 (11th Cir. 2008). A Rule 12(b)(1) facial challenge applies the same standard. *Carmichael v. Kellogg, Brown & Root Servs., Inc.*, 572 F.3d 1271, 1279 (11th Cir. 2009).

Federal Rule of Civil Procedure 8(a)(2) requires only that a pleading contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Though Rule 8(a)(2) does not require detailed factual allegations, it does require "sufficient" facts, such that, if accepted as true, support "a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (brackets, internal citation, and internal quotation marks omitted). Facial plausibility exists "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* Thus a pleading that offers mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" will be dismissed. *Id.*

C. Analysis

Johnson & Johnson and Neutrogena argue that Lombardo's amended claims are preempted by federal laws that govern the labeling of sunscreens, that Lombardo fails to state a claim under FDUTPA, and that Lombardo lacks standing to pursue injunctive relief.

1. Federal Law Does Not Preempt Lombardo's Claims

Johnson & Johnson and Neutrogena argue that Lombardo's claims are barred by both express and implied preemption. "Federal law may preempt

state law in three ways:" (1) "Congress may withdraw specified powers from the states by enacting a statute containing an express preemption provision;" (2) where Congress has determined that a certain field "must be regulated by [Congress's] exclusive guidance," states are precluded from regulating conduct; and (3) state laws "are preempted when they conflict with federal law." *Arizona v. United States*, 567 U.S. ---, 132 S. Ct. 2492, 2500–01 (2012). No matter the type of preemption, "the purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (internal quotations omitted). The plain wording of an express preemption clause contains the best evidence of Congress's preemptive intent. *Id.* But implied preemption may take either of two more-nuanced forms. First, implied "conflict" preemption requires identification of an "actual conflict" between state and federal law, *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 884 (2000), or a determination that state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 698–99 (1984). Second, federal law may "so thoroughly occupy a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." *Cipollone*, 505 U.S. at 516 (internal quotations omitted).

a. Express Preemption

Johnson & Johnson and Neutrogena contend that § 379r of the FDCA expressly preempts Lombardo's state-law claim. (Mot. to Dismiss 17, 23, ECF No. 55.) Section 379r prohibits states from establishing any "requirement" that relates to the regulation of a nonprescription drug and "is different from or in addition to, or [] is otherwise not identical with, a requirement" under the FDCA. 21 U.S.C. § 379r(a). The Supreme Court has found that certain state law claims classify as "requirements" subject to express preemption in the context of several statutory preemption clauses. *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1280 (C.D. Ca. 2008) (citing *Cipollone*, 505 U.S. at 521; *Medtronic v. Lohr*, 518 U.S. 470, 503–505 (1996) and *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005)). But where an express preemption provision does not foreclose additional obligations under state law, there is no express preemption of claims that seek relief outside the scope of the federal preemption clause. *See Cipollone*, 505 U.S. at 518–19. For the reasons stated below, the Court finds that Lombardo's claim is outside the scope of the Final Rule, and thus is not subject to express preemption under § 379r.

1. *"Waterproof," "Sweatproof," "Sunblock," and "Continuous Protection" Claims*

Lombardo's allegations challenge the same language that the Final Rule issued by the FDA on June 17, 2011 prohibits—specifically claims that a sunscreen provides "sunblock," "sweatproof," or "waterproof" protection. Labeling and Effective Testing; Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35628 (Jun. 17, 2011). The Court already ruled that Lombardo's claims after the Final Rule was issued are expressly preempted, but Johnson & Johnson's and Neutrogena's brief did not address whether a state-law claim is preempted when that claim involves conduct that occurred before the enactment of a federal law regulating that same conduct. As such, they have not met their burden of demonstrating that Lombardo's claims for products sold *before* June 17, 2011 are preempted. (*See* Order Granting Mot. to Dismiss 5, ECF No. 47.) Therefore, the Court will not dismiss Lombardo's claims under the preemption doctrine to the extent they allege misleading conduct that occurred before June 17, 2011.

2. *SPF Claims*

Every sunscreen must contain an SPF value that is derived from FDA-approved testing. 21 C.F.R. § 201.327(a)(1); *see also* Sunscreen Drug Products For Over-The-Counter Human Use; Final Monograph, 64 Fed. Reg. 27688 (May 21, 1999). Currently, there is no minimum or ceiling for SPF values, but all SPF values included on sunscreen labels must accurately reflect the results of FDA-approved testing. *See* 21 C.F.R. § 201.327(a)(1); see also Sunscreen Drug Products For Over-The-Counter Human Use; Final Monograph, 64 Fed. Reg. 27688 (May 21, 1999).

Lombardo is not attempting to enforce any sort of state labeling requirement in addition to the Final Rule—her complaint is not that the SPF values were inaccurate, but rather, the SPF values were misleading. She argues that the way Johnson & Johnson and Neutrogena marketed their products—combining the SPF value with claims of greater protection and a higher price—were false and misleading. In *Corra v. Energizer Holdings, Inc.*, 962 F. Supp. 2d 1207 (E.D. Cal. 2013), a consumer sought damages against a sunscreen distributor based on violations of the California Unfair Competition Law. Like Lombardo, Corra argued that the combination of the higher SPF designations with price differentials and claims of proportionally greater protection "misled consumers into purchasing more expensive, higher SPF-rated products even though" the products did not provide "proportionally greater protection than less expensive, lower SPF-rated products." *Id.* at 1214–

15. The sunscreen distributor sought to dismiss the claims based on theories of express and implied preemption under the Final Rule. *Id.* at 1214. The court reasoned that Corra's claims were not preempted because the SPF labeling duties would remain unchanged even if Corra prevailed. *Id.* Corra's grievance—like Lombardo's—was with the combination of the higher SPF rates with misleading claims and higher prices. *Id.*

The court held that Corra's state law claim was not expressly preempted because 21 C.F.R. § 201.327 includes a brief list of claims that may be "false or misleading," but the list is prefaced with a caveat that "[t]hese claims include but are not limited to . . . ." 21 C.F.R. § 201.327(g). The court interpreted the inclusion of that phrase to mean that the list of false or misleading language was "not exclusive to other claims, and in the [c]ourt's view, clearly evinces no intent to preempt state consumer fraud claims." *Corra*, 962 F. Supp.2d at 1215. This Court finds that Lombardo's claim, like Corra's, is not expressly preempted because the SPF labeling requirements would remain unchanged even if Lombardo were to prevail. Johnson & Johnson and Neutrogena would be liable for falsely misleading customers into believing that a higher SPF provided significantly greater clinical protection than sunscreens with SPF 50.

b. Implied Preemption

Johnson & Johnson and Neutrogena argue that implied preemption exists in this case because Lombardo seeks to prohibit what federal regulation permits, the inclusion of SPF values over 50 on labels. Lombardo counters that the FDA has not established requirements relating to the labeling of SPF values above 50. The Court finds that Lombardo's claims do not seek to enforce a state law requirement that is different from or in addition to the Final Rule.

Lombardo's claims—that high SPF values combined with statements of increased effectiveness and higher price—are not impliedly preempted. Implied, or conflict, preemption arises where "(1) compliance with both federal and state regulations is a physical impossibility, or (2) the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Fresenius Med. Care Holdings, Inc. v. Tucker*, 704 F.3d 935, 936 (11th Cir. 2013) (internal quotation marks omitted). If Lombardo were successful, manufacturers could still comply with FDA requirements and a finding of liability on Lombardo's claims would not result in "an obstacle to the accomplishment and execution of the full purposes" of the FDCA. *Fresenius*, 704 F.3d at 936. For example, manufacturers could display specific values on product labels based on testing results but

manufacturers would not be allowed to couple those SPF values with claims that an SPF value greater than 50 provides significantly greater protection than sunscreens with an SPF value of only 50.

Moreover, Lombardo's claims only require the Court to determine whether the advertising claims made by Defendants between 2009 and June 16, 2011 were false or misleading FDUTPA violations; they do not require the Court to interpret the Final Rule. *Corra*, 962 F. Supp. 2d at 1215 (holding no implied preemption where plaintiff's claims were not based on and did not require interpretation of the Final Rule and only required determination of whether advertising claims were false or misleading.).

2. Lombardo Fails to Adequately Allege Standing to Pursue Injunctive Relief

Johnson & Johnson and Neutrogena argue that Lombardo's Amended Complaint also fails to properly plead standing to pursue injunctive relief because she fails to allege that she is threatened by repetition of the injury. The Court dismissed Lombardo's claims for injunctive relief in her original complaint but her amended request for injunctive relief does not fare any better—she failed to plead future harm.

Lombardo argues that there is no requirement under "FDUTPA that a 'plaintiff show an ongoing practice or irreparable harm, and declaratory relief is available regardless of whether an adequate remedy at law exists.'" (Resp. in Opp. to Mot. to Dismiss 11, ECF No. 64 (citing *Gastaldi v. Sunvest Communities USA, LLC*, 637 F. Supp. 2d 1045, 1057–58 (S.D. Fla. 2009) (Altonaga, J.)). But Lombardo's argument is assailable—declaratory relief and injunctive relief are separate legal doctrines. Declaratory judgments are neither legal nor equitable and do not provide for any enforcement. *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 310 (1988); 28 U.S.C. § 2201. Declaratory relief is a "unilateral request to determine the legal status or ownership of a thing." *Black's Law Dictionary* 1482 (10th ed. 2014).

In contrast, injunctive relief is an order by the Court "commanding or preventing an action." *Black's Law Dictionary* 904 (10th ed. 2014). Injunctive relief "should issue only where the intervention of a court of equity is essential in order effectually to protect property rights against injuries otherwise irremediable." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982) (citation omitted). Simply put, injunctive relief requires a command for action by the Court, declaratory relief only requires a determination.

Although FDUTPA allows plaintiffs to pursue injunctive relief even where the individual plaintiff will not benefit from an injunction, it does not displace

Constitutional standing requirements. *Davis v. Powertel, Inc.*, 776 So.2d 971, 974 (Fla. 1st DCA 2000). Article III requires that a plaintiff seeking injunctive relief allege threat of future harm. "The Supreme Court has long held that to seek prospective or injunctive relief, plaintiffs (including individually named plaintiffs representing a class) must be able to demonstrate more than mere injury from past wrongs." *Veal v. Citrus World, Inc.*, Case No. 12-801, 2013 WL 120761, at *6 (N.D. Ala. Jan. 8, 2013); *see also O'Shea v. Littleton*, 414 U.S. 488, 495–96 (1974) ("Past exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief . . . if unaccompanied by any continuing, present adverse effects.").

Although Lombardo sufficiently alleges her past injury, she again fails to sufficiently allege a threat of future harm. Lombardo argues that adding paragraph 73 to her Amended Complaint saves her claim for injunctive relief. In paragraph 73, she alleges that she "continues to be misled by deceptive representations that higher SPF values provides greater sunburn protection," but this is not enough. (Am. Compl. ¶73, ECF No. 48.) She fails to allege any facts or details to support this threadbare conclusion. Accordingly, she fails to allege sufficiently Article III standing to pursue injunctive relief, and her injunctive relief claims are therefore dismissed.

3. Lombardo is able to state a claim under FDUTPA

Johnson & Johnson and Neutrogena's litany of other reasons to dismiss the Amended Complaint are unavailing. Johnson & Johnson and Neutrogena argue that Lombardo's claim fails because plaintiffs must plead "sufficient facts to show that [they have] been actually aggrieved by the unfair or deceptive act committed by the seller in the course of trade or commerce." *Shibata v. Lim*, 133 F. Supp. 2d 1311, 1317 (M.D. Fla. 2000); *Macias v. HBC of Fla., Inc.*, 694 So. 2d 88, 90 (Fla. 3d DCA 1997). Accordingly, plaintiffs must plead that they were "exposed to the Defendants' advertising and marketing materials alleged to constitute a deceptive trade practice" and that they "suffered actual damages as a result of the misrepresentations" in those materials. *Macias*, 694 So. 2d at 90; *Himes v. Brown & Co.*, 518 So. 2d 937, 938 (Fla. 3d DCA 1987).

The Amended Complaint adequately alleges the misleading marketing. It includes allegations that Johnson & Johnson's products provided labels of "better, longer-lasting sun protection," contained higher SPF values, and were sold at higher prices than products with lower SPF values. It also includes allegations that these products claimed to provide "sunblock," "waterproof," and "continuous" protection and that those claims were misleading and deceptive. The Amended Complaint also includes allegations that Neutrogena's

products misleadingly claimed to be "supported by science," contain higher SPF values, and were sold at higher prices than products with lower SPF values. Neutrogena's products also claimed to provide "sunblock," "waterproof," and "sweatproof" protection. The Amended Complaint alleges that the misleading marketing occurred while the products were sold by various retailers, including Target, Walgreen, and CVS. Lombardo also alleges how she was misled—that the combination of these claims led her to believe that the products provided greater clinical protection than sunscreen with an SPF value of 50. She also alleges that Johnson & Johnson and Neutrogena obtained higher revenue for these products as a consequence of the misrepresentations.

To the extent that Johnson & Johnson and Neutrogena argue that Lombardo cannot state a claim for FDUTPA because the FDA has since held the challenged language—"higher SPF gives more sunburn protection"—to be "truthful and nonmisleading," Lombardo takes issue with the phrases and marketing that Defendants' employed *before* the FDA promulgated a final rule permitting the language. (*See* Mot. to Dismiss 19, ECF No. 55.) She seeks damages for Defendants' practices before the rule. The Court has already found that claims after the enactment of the Final Rule are preempted, but Defendants provide no support that the Final Rule is applied retroactively or pertains to marketing practices before June 17, 2011. *See Selman v. CitiMortgage, Inc.*, Case No. 12-0441, 2013 WL 838193, at *4 (S.D. Ala. Mar. 5, 2013) (Where no indication that a federal law applies retroactively, it does not preempt a state law claim predating the federal law); *W.R. Huff Asset Mgemt. Co. LLC v. BT Securities Corp.*, 190 F. Supp. 2d 1273, 1276 (N.D. Ala. 2001).

To the extent that Defendants again argue that Lombardo's claims are barred by FDUTPA's safe harbor provision, their argument fails. The "safe harbor" provision of FDUTPA states that the Act "does not apply to an act or practice required or specifically permitted by federal or state law." Fla. Stat. § 501.212(1). This provision does not bar Lombardo's remaining claims, which predate the Final Rule specifically addressing the challenged language. Defendants provide no authority to apply the safe harbor provision to claims that predate the law. Moreover, the FDA has not approved Johnson & Johnson and Neutrogena's marketing. That the FDA allows high SPF values does not establish FDA approval of representations made alongside those higher SPF values. Because the FDA did not specifically approve or authorize Johnson & Johnson and Neutrogena to make these representations, the "safe harbor" provision does not apply.

D. Conclusion

For the reasons explained above, Defendants' Motion to Dismiss Plaintiff's Amended Complaint (ECF No. 55) is **granted in part**—the injunctive relief claims are dismissed. Defendants' motion for judicial notice (ECF No. 56) is **denied** as moot, and Defendants' motion for a hearing on the motion to dismiss (ECF No. 58) is **denied** as moot.

Done and ordered in chambers, at Miami, Florida, on September 9, 2014.

Robert N. Scola, Jr.
United States District Judge