UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ELI DAYAN, *individually on behalf of himself and others similarly situated,*	:	
Plaintiff,	:	**MEMORANDUM & ORDER ADOPTING REPORT & RECOMMENDATION**
SWISS-AMERICAN PRODUCTS, INC.,	:	15-cv-6895 (DLI)(VMS)
Defendant.	:	

DORA L. IRIZARRY, Chief Judge:

Before the Court are Swiss-American Products, Inc.'s ("Defendant") Objections to the Report and Recommendation issued by United States Magistrate Judge Vera M. Scanlon on January 3, 2017 (the "Objections" to the "R&R"), recommending that Defendant's motion to dismiss the complaint (the "Motion") be granted, in part, as to Eli Dayan's ("Plaintiff") claim alleging violations of the Magnuson-Moss Warranty Act ("MMWA"), 15 U.S.C. § 2301 *et seq.*, and otherwise be denied. For the reasons set forth below, the R&R is adopted in its entirety.

BACKGROUND[1]

On December 4, 2015, Plaintiff initiated this action alleging that Defendant violated the MMWA and various state laws by selling its EltaMD UV Aero sunscreen (the "Sunscreen") with a label indicating it had a sunburn protection factor ("SPF") value of 45, when in fact, the actual SPF value was less than half that amount. (Compl., Dkt. Entry No 1, at 3-4; R&R, Dkt. Entry No. 23, at 2-3.) Plaintiff supports his assertions by attaching test results purporting to show the SPF value of the Sunscreen was 18 and 22, respectively. (R&R at 3; Compl. Ex. A.) The Complaint purports to state claims for violations of: (i) the MMWA; (ii) New York General Business Law

[1] The Court assumes familiarity with the facts of this case, which are set forth in greater detail in the R&R. (R&R at 2-3; *see* Compl., Dkt. Entry No. 1.)

Sections 349 (deceptive acts or practices), 350 and 350-a (false advertising), (iii) the consumer-protection and breach of express warranty laws of various states and the District of Columbia, and (iv) common law claims for breach of implied warranty, unjust enrichment and negligent misrepresentation. (Compl. at 11-32.)

On January 22, 2016, Defendant moved to dismiss the Complaint for failure to state a claim, arguing: (i) Plaintiff's claims are expressly and impliedly pre-empted by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "FDCA"); (ii) Plaintiff fails to state a claim under the MMWA; and (iii) Plaintiff fails to state a claim for misbranding given that he has failed to account for four FDA-compliant tests validating the SPF 45 value stated on the Sunscreen's label. (Mot., Dkt. Entry No. 12; *see* Pl. Mem. in Opp. to Mot., Dkt. Entry No. 17; Reply in Further Support of Mot. ("Reply), Dkt. Entry No. 20.) On June 16, 2016, this Court referred the Motion to Magistrate Judge Scanlon for the preparation of the R&R.

On January 3, 2017, the magistrate judge issued the R&R recommending that the Motion be granted, in part, as to Plaintiff's claim alleging violations of the MMWA, and otherwise be denied. (R&R.) With respect to pre-emption, the magistrate judge ruled that neither express nor implied pre-emption prevented Plaintiff from bringing his claims. The magistrate judge found that express pre-emption did not apply because, "[u]nder even the strictest of the[] standards" used by courts applying the express pre-emption doctrine, Plaintiff's claims seek to hold Defendant "liable for failing to label properly the product's SPF value, a standard identical to the standard established by the FDCA." (*Id.* at 8.) The magistrate judge, thus, interpreted the "savings clause" of the FDCA to apply to Plaintiff's claims. (*Id.*) The magistrate judge then provided an extensive analysis of the doctrine of implied pre-emption involving the FDCA, assessing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) and the ensuring decisions by the Second Circuit

Court of Appeals. (R&R 10-17.) Through these precedents, the magistrate judge determined, as an initial matter, that the claims at issue here are distinct from those at issue in *Buckman* in that they "represent the states regulating the health and safety of their citizens, fields which the states traditionally occupy and in which there is a strong presumption against federal pre-emption." (R&R at 15.) The magistrate judge then determined that, "[a]lthough Plaintiff's allegations touch on areas regulated by the FDCA and require reference to the FDCA's rules regarding measurement of SPF, Plaintiff's state law claims sit next to federal regulations and are not premised on Defendant's alleged failure to comply with FDCA requirements." (R&R at 16.) Stated differently, the state law claims are based on the alleged failure of Defendant's product to measure up to the quality of the product as marketed.

Turning to Plaintiff's MMWA claim, the magistrate judge recommended that the claim could be dismissed on either of two grounds: (i) Plaintiff failed to plead that the product contained a warranty as to a specified level of performance over a specified time period, which is required to sustain an MMWA claim (R&R at 23-25); or (ii) the claim is barred in any event by 15 U.S.C. § 2311(d) because the label is governed by the FDCA (R&R at 25-26).

Finally, the magistrate judge found that Plaintiff had stated a plausible claim for relief, ruling that while "Defendant's tests may ultimately prove more persuasive than Plaintiff's . . . 'issues of fact, credibility and the weight of the evidence' when it comes to scientific studies is not the role of the Court on a motion to dismiss." (R&R at 28 (quoting *Stitt v. Nature's Bounty, Inc.*, 2016 WL 5372794, at *10 (E.D.N.Y. Sept. 26, 2016)).)

On January 24, 2017, Defendant filed the Objections. Through the Objections, Defendant largely reiterates the same arguments raised in its motion to dismiss: "[p]laintiff's claims are expressly and impliedly pre-empted by federal law, and each fails independently to state a

plausible claim for relief." (Objections at 1.) Defendant urges the Court to reject the R&R, "except for that portion recommending dismissal [Plaintiff's MMWA claim], which should be accepted. (*Id.*)

February 14, 2017, Plaintiff timely opposed Defendant's Objections, arguing that they "are nothing more than reiterations of the tenuous arguments it advanced in its motion to dismiss." (Opp. to the Objections at 1, Dkt. Entry No. 25.)[2]

DISCUSSION

When a party objects to an R&R, a district judge must make a *de novo* determination as to those portions of the R & R to which a party objects. *See* FED. R. CIV. P. 72(b)(3); *United States v. Male Juvenile*, 121 F.3d 34, 38 (2d Cir. 1997). Pursuant to the standard often articulated by the district courts of this Circuit, "[i]f a party simply relitigates his original arguments, the Court reviews the Report and Recommendation only for clear error." *Antrobus v. New York City Dep't of Sanitation*, 2016 WL 5390120, at * 1 (E.D.N.Y. Sept. 26, 2016) (citations and quotation marks omitted); *see also Rolle v. Educ. Bus Transp., Inc.*, 2014 WL 4662267, at *1 (E.D.N.Y. Sept. 17, 2014) ("[A] rehashing of the same arguments set forth in the original papers . . . would reduce the magistrate's work to something akin to a meaningless dress rehearsal.") (citations and internal quotation marks omitted). On the other hand, the Second Circuit Court of Appeals has suggested that a clear error review may not be appropriate "where arguably 'the only way for a party to raise . . . arguments is to reiterate them.'" *Moss v. Colvin*, 845 F.3d 516, 520 n.2 (2d Cir. 2017) (quoting *Watson v. Geithner*, 2013 WL 5441748, at *2 (S.D.N.Y. Sept. 27, 2013) (alteration added in *Moss*; other alterations from *Moss* omitted). Nonetheless, a court will not "ordinarily . . . consider

[2] The Court notes that both parties requested oral argument on Defendant's Objections. Because Court found that the analysis of the R&R was clear its and rationale sound, it did not believe oral argument would be useful in this instance.

arguments, case law and/or evidentiary material which could have been, but [were] not, presented to the magistrate judge in the first instance." *Santiago v. City of New York*, 2016 WL 5395837, at *1 (E.D.N.Y. Sept. 26, 2016) (internal citation and quotation marks omitted). After its review, the district court may then "accept, reject, or modify the recommended disposition; receive further evidence; or return the matter to the magistrate judge with instructions." FED. R. CIV. P. 72(b)(3); *see also* 28 U.S.C. § 636(b)(1).

I. Plaintiff's Claims Are Not Expressly Pre-Empted.

With respect to the magistrate judge's conclusion that Plaintiff's claims were not expressly pre-empted, Defendant contends that the magistrate judge: (i) "apparently accorded little weight to" decisions from the California Court of Appeal, *Eckler v. Neutrogena Corp.*, 238 Cal. App. 4th 433 (Cal. Ct. App. 2015), and the United States District Court for the Southern District of California, *Gisvold v. Merck & Co.*, 62 F. Supp. 3d 1198 (S.D. Cal. 2014), upon which Defendant relies heavily; and (ii) "erroneously rejected" the rationale set forth in cases "[c]loser to home." (Objections at 9-12 & n.6.) Defendant is in error on both grounds.

As to the California cases, the magistrate judge squarely addressed both cases, ultimately concluding that each one (as well as the other "non-binding cases" cited by Defendant in its Motion) "involves a plaintiff attempting to hold a defendant liable for conduct not proscribed by the FDCA." (R&R at 8-9.) Regarding *Gisvold*, in particular, the magistrate judge set forth in detail the facts of that case and explained why the claims at issue there, unlike those here, would have added to the FDCA's requirements. (*Id.* at 9 (quoting *Gisvold*, 62 F. Supp.3d at 1200-03).) The magistrate judge also distinguished the other cases cited by Defendant, including a case from a district court in the Second Circuit which found, similar to the ruling in *Gisvold*, that the plaintiffs' claims "would impose a requirement that is in addition to or not identical with federal

law, and it would do so on a subject matter that clearly could be regulated by the FDA." (*Id.* (quoting *Bimont v. Unilever U.S., Inc.*, 2015 WL 5256988, at *6 (S.D.N.Y. Sept. 9, 2015).)

This Court independently has reviewed each of the cases cited by Defendant in support of its argument that Plaintiff's claims are expressly pre-empted, including those that it complains the magistrate judge did not address explicitly.[3] The Court's review has revealed no compelling precedent that would disturb the magistrate judge's conclusion that Plaintiff's claims here are sufficiently narrow so as not to interfere with the FDCA's requirements.

II. Plaintiff's Claims Are Not Impliedly Pre-Empted.

Defendant's regurgitated arguments with respect to implied pre-emption also fall flat. Defendant contends that the magistrate judge "concluded erroneously that [the United States Supreme Court's decision in *Buckman*] does not control this case," and takes issue with the magistrate judge's conclusion that the Second Circuit's decision in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), "somehow takes Plaintiff's claims outside the purview of *Buckman*'s holding." (Objections at 14) As noted above, the magistrate judge set forth a comprehensive analysis of the limited controlling case law in this area, explaining, in sum, that, "to avoid implied pre-emption, a claim must be one that sounds in traditional state tort law and would exist even if the FDCA had not been enacted, *i.e.* the claim must be parallel to the FDCA and not depend on it." (R&R at 14; *see* Objections at 17.) According to Defendant's interpretation of Plaintiff's claims, they would be pre-empted under the very standard articulated by the magistrate judge because the claims "are predicated solely upon an alleged violation of the FDA's

[3] Contrary to Defendant's argument, *Lombardo v. Johnson & Johnson Consumer Companies, Inc.*, 2014 WL 10044838 (S.D. Fla. Sept. 10, 2014) and *Corra v. Energizer Holdings, Inc.*, 962 F. Supp.2d 1207 (E.D. Cal. 2013) support the magistrate judge's conclusion because, in each case, the court found plaintiffs' claims were not expressly pre-empted where, as here, the "the SPF labeling requirements would remain unchanged even if [the plaintiffs] were to prevail." *Lombardo*, 2014 WL 10044838 at *5 (citing *Corra*, 962 F. Supp.2d at 1215).

SPF regulations, which mandate that sellers of sunscreen test their products according to the detailed testing protocol in 21 C.F.R. § 201.327(a)(l), and then accurately report the result on the sunscreen product label."[4] (Objections at 17.)

The problem with Defendant's arguments is that they attempt to broaden both the scope of Plaintiff's claims and the doctrine of implied pre-emption. The magistrate judge summarized the crux of Plaintiff's allegations as follows: "the [Sunscreen] was advertised as having a SPF value of 45 when it has in fact a lower, less protective number, thus deceiving Plaintiff." (R&R at 8.) Using this articulation of Plaintiff's claims (with which this Court agrees) as a starting point, Plaintiff's claims can, in fact, sit side-by-side with the FDA's SPF labeling regime.

As Defendant itself notes, "[a] state claim survives if it incorporates but is not entirely dependent upon a violation of the FDCA and 'is premised on conduct that would give rise to liability under traditional common law principles.'" (Objections at 19 (quoting *In re Bayer Corp. Combination Aspirin Prod. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 369 (E.D.N.Y. 2010)).) Though admittedly a tricky distinction, the magistrate judge concluded correctly that the allegations Plaintiff articulates are not entirely dependent on the FDCA because they would exist as traditional common law tort claims even if the FDCA had never been enacted. Indeed, Defendant's argument that Plaintiff's claims are "premised exclusively on the FDA's SPF labeling and testing regulations" (Objections at 18), drastically overstates Plaintiff's allegations. In actuality, the Complaint does not articulate a *per se* challenge to Defendant's testing or labeling; instead, the allegation that the SPF value is not correct is used only to substantiate Plaintiff's claim that Plaintiff was deceived because the Sunscreen did not protect him to the degree that was

[4] Defendant makes three other objections to specific portions of the R&R, all of which concern the "basis and nature of Plaintiff's claims." (Objections at 18.)

expected. In this way, Plaintiff's claims sound in traditional state tort law. *See Bayer*, 701 F. Supp. 2d at 375 ("Although these statements touch on areas regulated by the FDA, and may even require reference to FDA definitions as to what the requirements are for adequate sources of calcium and phytosterols and what the dangers of larger doses of aspirin are, they are not preempted. The misleading nature of the statement can be verified without relying on any special expertise of the FDA and is therefore properly before this Court.") (internal citations omitted). The Court, therefore, concurs with the magistrate judge that Plaintiff's claims are not subject to implied pre-emption.

III. Plaintiff Articulates a Plausible Claim for Relief.

Finally, Defendant contends that the "Magistrate Judge's mischaracterization of Swiss-American's [plausibility] argument, failure to consider Swiss-American's actual argument based on *Iqbal* and her recommendation that the Court deny Swiss-American's motion to dismiss, constitute legal error." (R&R at 23; *see Ashcroft v. Igbal*, 556 U.S. 662 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).) Defendant is mistaken as to all three.

Defendant argues that the magistrate judge "mischaracterized Swiss-American's plausibility argument,"[5] stating that, in actuality:

> Swiss-American asked her to consider [its four validating SPF tests] with regard to its argument that Plaintiff has not plausibly alleged false labeling under the FDCA because he has possession of Swiss-American's four tests validating the SPF 45 rating, yet fails to allege that (and how) any of these tests deviate from the FDA-mandated testing methodology (or even refer to any of the tests in his Complaint).

[5] The Court notes that Defendant did not state its "failure to state a claim" argument in terms of an *Iqbal/Twombly* "plausibility" challenge until the Reply. In the initial memorandum of law in support of the Motion, Defendant argued that Plaintiff had failed to state a claim for misbranding under 21 U.S.C. § 352(a) because he failed to account for test results that contradicted his claims, without reference to "plausibility" or *Iqbal/Twombly*. Nevertheless, the magistrate judge construed Defendant's overall argument to be "that Plaintiff does not state a plausible claim for relief." (R&R at 26.)

(Objections at 22-23.) However, Defendant misapprehends the magistrate judge's holding on this point as the magistrate judge squarely considered, and rejected, Defendant's argument that Plaintiff's claims were not plausible because of Plaintiff's receipt of, and failure to account for, Defendant's test results. Indeed, only after rejecting that argument, did the magistrate judge rule alternatively, "*[e]ven if the Court were to determine that it may consider the tests that Defendant submitted*, Defendant's argument is not persuasive." (R&R at 27 (emphasis added).) Moreover, with respect to the additional authority cited by Defendant for the proposition that Plaintiff "must allege how, if at all, Swiss-American's tests deviate from the FDA-mandated testing protocol" (Objections at 22), the Court is not convinced that such a requirement exists at this stage as the cases Defendant has cited are inapposite. For example, in *Morrison v. Hoffmann-La Roche, Inc.*, 2016 WL 5678546 (E.D.N.Y. Sept. 29, 2016), this Court held that the plaintiff must plead "the existence of an alternative design that would make [the drug] safer," *only where* such allegations were "required to establish a design defect under New York law." *Id.* at *5; *see Reed v. Pfizer, Inc.*, 839 F. Supp.2d 571, 579 (E.D.N.Y. 2012) (finding plaintiffs "fail to state an express warranty claim" because, among other reasons, their conclusions "lack the required factual content identifying [the difference from what was promised] and making its existence plausible"); Objections at 23. The Court is aware of no such pleading requirement with respect to Plaintiff's state law claims here, and Defendant has not pointed any authority suggesting as much.

Ultimately, the magistrate judge concluded that, for Plaintiff's claims to survive at this stage, it was sufficient for him to: (i) "allege[] that the product falsely advertised itself as SPF-45 when its SPF is lower than that;" and (ii) "submit[] tests that he alleges were conducted in compliance with FDA regulations that he claims substantiate his allegations." (R&R at 27.) For the reasons articulated by the magistrate judge (R&R at 26-28), the Court agrees.

CONCLUSION

Upon due consideration and review, the objections are overruled, and the R&R is adopted in its entirety. Accordingly, Plaintiff's MMWA claim is dismissed and the Motion is otherwise denied.

SO ORDERED.

Dated: Brooklyn, New York
March 31, 2017

/s/
DORA L. IRIZARRY
Chief Judge