23-710

In the
United States Court of Appeals
For the Second Circuit

MASHON BAINES, on behalf of herself and all others similarly situated and NANCY FRONING, on behalf of themselves and all others similarly situated,

Plaintiffs-Appellants,

v.

NATURE'S BOUNTY (NY), INC. and THE BOUNTIFUL COMPANY (NY),

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK (CENTRAL ISLIP)

BRIEF AND SPECIAL APPENDIX FOR PLAINTIFFS-APPELLANTS

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I. STATEMENT OF JURISDICTION

The Eastern District of New York had diversity jurisdiction over this matter pursuant to 28 U.S.C. § 1332(d)(2). Plaintiff Baines is a resident of Rome, New York. Plaintiff Froning is a resident of San Diego, California. Defendant Nature's Bounty Inc. is a New York corporation with its principal place of business in Ronkonkoma, New York. The Bountiful Company is a Delaware Corporation, with its principal place of business in Ronkonkoma, New York. The amount in controversy exceeds $5,000,000 for the Plaintiffs and members of the Class collectively, exclusive of interest and costs, by virtue of the combined purchase prices paid by Plaintiffs and members of the putative Class, and the profits reaped by Defendants from their transactions with Plaintiffs and the Class, as a direct and proximate result of the wrongful conduct alleged herein, and by virtue of the injunctive and equitable relief sought.

This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1291. Pursuant to FRAP Rule 4, Plaintiffs' Notice of Appeal was timely filed on April 27, 2023, within 30 days of the final order and judgment entered in the Eastern District of New York on March 28, 2023, disposing all of Plaintiffs' claims in this case.

II. STATEMENT OF ISSUES PRESENTED FOR REVIEW

A. DID THE DISTRICT COURT ERR IN FINDING PLAINTIFFS' CLAIMS PREEMPTED BY THE FEDERAL FOOD DRUG & COSMETIC ACT?

B. DID THE DISTRICT COURT ERR IN FINDING THAT NO REASONABLE CONSUMER WOULD BE DECEIVED BY THE LABELING OF DEFENDANTS' PRODUCT?

C. DID THE DISTRICT COURT ERR BY NOT AFFORDING PLAINTIFFS LEAVE TO AMEND?

III. STATEMENT OF THE CASE

Defendants/Appellees Nature's Bounty Inc. and The Bountiful Company (collectively "Defendants" or "NBI") market and sell a Product which they claim to be, and label as, 1400 mg of Fish Oil ("Product").[A-11].[1] They reinforce this label claim stating the contents of the Product are verified by the U.S. Pharmacopeia ("USP"), assuring consumers that the Product "contains the ingredients listed on the label." *Id.*

Contrary to what is represented on its label, however, this Product is not fish oil and labeling it as such is false, deceptive and misleading. *Id.*

Fish oil is derived through a basic mechanical process whereby small oily fish are caught, cooked, pressed, bleached and deodorized before being encapsulated and bottled. [A-19]. The process begins with raw material, i.e, fish, and ends with crude fish oil. [A-20]. This is a physical process where the fundamental nature of the substance is not altered, (i.e., oil is effectively squeezed from a fish, cleaned and bottled). *Id.*

In stark contrast, NBI's Product is the result of an intense chemical process known as trans-esterification, whereby an industrial solvent is used to transform crude fish oil by breaking all its molecular bonds, i.e., the fundamental building

[1] Appendix (hereinafter "A-"); Special Appendix (hereinafter "SPA-").

blocks that make it fish oil, into free fatty acids and then re-bonding them to ethanol to create an entirely new synthetic substance called a fatty acid ethyl ester, which neither exists in fish, nor anywhere in nature. [A-22].

Critically, trans-esterification is not a physical processing step in rendering fish into crude fish oil, but rather a chemically transformative processing step changing crude fish oil into an entirely new synthetic product. [A-22-25].

Unlike the processing of fish oil, which begins with fish and ends with crude fish oil, the trans-esterification process begins with crude fish oil, and ends in the formation of: Ethyl Esters, Fatty Acids, Mixed Glycerides, Omega-3 Concentrates and Purified Esters, each of which are distinct products bearing their own common or usual names. [A-23].

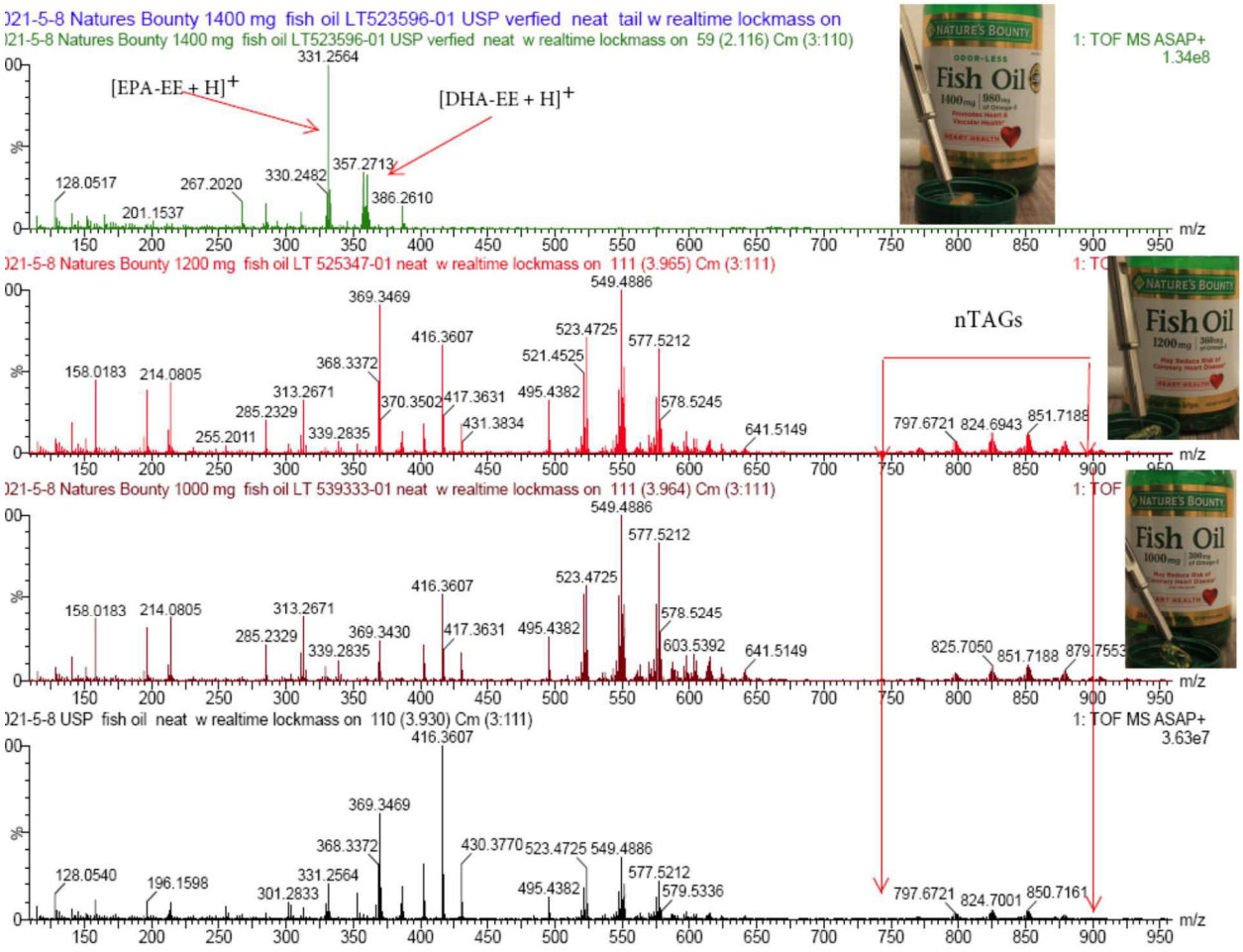
NBI not only labels its Product "Fish Oil," on both its principal display panel ("PDP") and in the Supplement Fact section, but it emblazons the USP logo on the PDP purposefully conveying to consumers that the ingredients of this Product have been independently tested and verified. [A-65].

The USP is one of the most comprehensive sources for dietary supplement standards in the world. [A-27]. The USP provides a series of monographs which articulate the quality expectations for "identity, strength, purity, and performance" of dietary supplements. [A-28]. The monograph (i.e., molecular definition) for

"Fish Oil" is among its standards and ostensibly used by NBI to verify the contents of its Product. [A-28].

Plaintiff acquired the official USP monograph for Fish Oil and compared it to NBI's product, unequivocally confirming that Defendants' Product is an Omega-3 ethyl ester, and not fish oil. [A-29].

Taking the analysis one step further, Plaintiff juxtaposed two other NBI products, both of which similarly claim to be fish oil, differing from the Product at issue only in strength (i.e., 1000 and 1200 mg). Despite also being labeled "Fish Oil," their mass spectra did **not** match the Product at issue here, but did match the USP monograph because they actually do contain fish oil. [A-29].



The comparative mass spectra demonstrate that these are materially different products, i.e., natural fish oil as opposed to a synthetic Omega-3 concentrate. Such molecular distinctions are not insignificant or trivial, but rather the fundamental building blocks of every product and, with respect to dietary supplements, often the only way to distinguish one from another. Indeed, a reasonable consumer looking at the three NBI products next to one another on a retail shelf would have no way of meaningfully differentiating them, and given the fact they are labeled the same, no cause to do so. [A-28-29].

NBI's Product differs from fish oil in two material respects. First, it is principally an Omega-3 concentrate formed by breaking down the component parts of crude fish oil with an industrial solvent in order to isolate and magnify the Omega-3 content. Second, it is entirely synthetic. [A-22, 28, 35]. The resulting solution of fatty acid ethyl esters and its constituent ingredients (Omega-3s in the form of EPA-EE and DHA-EE) are independently recognized by governmental entities (e.g., National Institute of Health and U.S. Customs and Border Protection [A-25-27, 32-33]) and compendial authorities as unique ingredients with their own chemical structures, monographs and corresponding names, all of which are distinct from "Fish Oil." [A-27-32].

Plaintiffs reasonably believed the representations on the Product's label that, among other things, it was actual fish oil, not a synthetic Omega-3. [A-14-15]. Plaintiffs relied on Defendants' labeling and were misled thereby. *Id.* Plaintiffs would not have purchased the Product, or would have purchased the Product on different terms, had they known the truth. *Id.*

Consumers wishing to ingest Omega-3s have numerous choices. Principal among them, whether to take an Omega-3 supplement or consume a marine oil (e.g., fish, krill, algae). Each product is molecularly different and has an array of qualities that differ from one another. These qualities differentiate the products in the marketplace and are material to consumers' purchasing decisions. NBI's failure

to identify their Products by their common and usual name, obfuscated the most important information that is conveyed about a product—its name and contents. By failing to properly name its Products, NBI has deceived Plaintiffs and members of the class, depriving them of a consumer's most basic right—to make an informed purchasing decision. [A-36].

Plaintiff Baines filed her original complaint on September 24, 2021. [A-3]. Defendants filed a Letter Motion requesting a pre-motion conference on November 22, 2021 indicating their intention to move to dismiss the Complaint. [A-5]. Although there was no basis for an amendment which would have resolved the issues raised in Defendants' Letter Motion, Plaintiffs were provided leave to amend the Complaint, principally to add an additional plaintiff. The Amended Complaint ("Complaint") was filed on January 6, 2022. *Id.* Defendants moved to dismiss on February 7, 2022. [A-6]. The matter was fully briefed and taken under submission without oral argument. *Id.* On October 31, 2022, the District Court referred the Motion to the Magistrate for a Report and Recommendation, which was subsequently issued on January 3, 2023. [A-6, 7]. The Magistrate recommended granting Defendants' motion to dismiss, finding Plaintiffs' claims were preempted and that no reasonable consumer would be misled by the labeling of Defendants' product. Plaintiffs timely filed objections to the Report & Recommendation. [A-7]. On March 28, 2023, the District Court issued an order overruling Plaintiffs'

objections, adopting the Report & Recommendation in its entirety and granting judicial notice of certain documents proffered by the Defendants. *Id.* A judgement was entered the same day and this appeal timely ensued. [A-8].

IV. SUMMARY OF THE ARGUMENT

Plaintiffs/Appellants have taken this appeal to seek reversal of three findings by the Lower Court which resulted in the dismissal of this case.

First, despite Plaintiffs' detailed allegations, the Lower Court concluded that the common or usual name of Defendants' Product is "Fish Oil," and therefore Plaintiffs' contention that it is not, is preempted under the Food Drug & Cosmetic Act. The Court's conclusion is erroneous for several reasons.

As a predicate matter, the Court fails to recognize that the trans-esterification process used to create Defendants' Omega-3 ethyl ester is not a common processing step in the rendering of crude fish oil, but a transformative one that **converts** crude fish oil into an entirely new substance with a different molecular fingerprint and a different common or usual name. The distinction between these substances is unequivocally demonstrated through comparative mass spectra as well as compendial sources referenced in the Complaint.

Second, the Court erred in finding that Plaintiffs' references contradict the allegations of their Complaint. In contrast to the Lower Court's finding, however, Plaintiffs' references are not contradictory, but universally affirm that Fish Oil and Omega-3 ethyl esters are distinct substances which are not otherwise interchangeable.

Third, the Court erred in finding that Plaintiffs failed to provide an alternative common or usual name for Defendants' Product. The Complaint, however, is replete with references to the appropriate common or usual name of Defendants' Product. It identifies it generically as a fatty acid ethyl ester, specifically as an Omega-3 ethyl ester and its sub ingredients as EPA and DHA ethyl esters. Moreover, the record also includes an exemplar label of a competitor product confirming the same.

Based on the same reasoning, the Lower Court also concluded that no reasonable consumer would be misled by Defendants' Product label, because, in the Court's estimation, it is properly named fish oil. Defendants' Product, however, is unquestionably an Omega-3 ethyl ester and so should be named. Although Defendants claim that the contents of their Products are verified by the USP, Plaintiffs' testing reveals that Defendants' Product does not comport with the USP monograph for fish oil and therefore naming it as such is false, deceptive and misleading.

Finally, the Lower Court denied Plaintiffs' request for leave to amend despite having identified a number of issues that could have been addressed on amendment. Plaintiffs have not substantively amended their Complaint before. To the extent not futile, leave to amend should have been granted.

V. ARGUMENT

A. STANDARD OF REVIEW

Appellate Courts "review a district court's grant of a motion to dismiss *de novo*, "accepting as true all factual claims in the complaint and drawing all reasonable inferences in the plaintiff's favor." *Evergreen E. Coop. v. Whole Foods Mkt., Inc.*, 2023 U.S. App. LEXIS 2155, at *3-4 (2d Cir. Jan. 27, 2023), quoting *Henry v. County of Nassau*, 6 F.4th 324, 328 (2d Cir. 2021) and *Fink v. Time Warner Cable*, 714 F.3d 739, 740-41 (2d Cir. 2013).

When considering a motion to dismiss a complaint for failure to state a claim upon which relief may be granted, the court "is required to accept as true the facts alleged in the complaint, consider those facts in the light most favorable to the plaintiff, and determine whether the complaint sets forth a plausible basis for relief." *Galper v. JP Morgan Chase Bank, N.A.*, 802 F.3d 437, 443 (2d Cir. 2015). The Court should "draw[ ] all reasonable inferences in [the plaintiff's] favor," *Rich v. Fox News Network, LLC*, 939 F.3d 112, 117 n.2 (2d Cir. 2019), and "construe[] any ambiguities 'in the light most favorable to upholding the plaintiff's claim.'" *Sung Cho v. City of New York*, 910 F.3d 639, 642 n.1 (2d Cir. 2018). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). "Rule 12(b)(6) does not

countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). *Marino v. Coach, Inc*., 264 F. Supp. 3d 558, 570 *quoting Williams v. Gerber Prods. Co*., 552 F.3d 934, 939 (9th Cir.2008).

"At the pleading stage, we consider only whether the complaint includes factual allegations sufficient to raise a right to relief above the speculative level." *Alexander v. Bd. of Educ.*, 648 F. App'x 118, 120 (2d Cir. 2016) quoting *Twombly*, 550 U.S. 544, 570. The determination whether a plaintiff has alleged a plausible claim is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. 662, 679.

B. THE LOWER COURT ERRED IN FINDING THAT THE COMMON OR USUAL NAME OF DEFENDANTS' PRODUCT IS FISH OIL, AND THEREFORE PREEMEPTED UNDER THE FOOD DRUG & COSMETIC ACT

Purportedly considering "all the materials [] referenced in the Amended Complaint's first forty-eight footnotes" and "..careful to read all of these materials in the light most favorable to Plaintiffs, without acting as an expert in scientific fields such as chemistry…," the Lower Court found that "the name "fish oil" is, as required by the Food Drug and Cosmetic Act, the Product's common name." [SPA-4, 5, 2]. "The Court's holding is that the common name of the Product, and all OM3 supplements – however derived from fish oil – are required to bear the common name fish oil." [SPA-29][2]. "Plaintiffs' proposition that it be labeled differently seeks to impose state law requirements that are preempted." [SPA-2].

The Court's conclusion is erroneous due to three fatal errors in its reasoning. First, the Court fails to recognize that the trans-esterification process used to create Defendants' Omega-3 ethyl ester is not a common processing step in the rendering of crude fish oil, but a transformative one that **converts** crude fish oil into an entirely new substance, (i.e., converting natural fish oil into a synthetic Omega-3 concentrate). Second, the Court errs in finding that Plaintiffs' references contradict

[2] Omega-3 ("OM3").

the allegations of their Complaint. Indeed, all of Plaintiffs' references universally affirm that Fish Oil and Omega-3 ethyl esters are distinct substances and are not otherwise interchangeable. The references presented do not contradict, but rather support Plaintiffs' allegations. Finally, the Court erred in finding that Plaintiff failed to provide an alternative common or usual name for Defendants' Product. Indeed, the Complaint is not only replete with references to the appropriate common or usual name of Defendants' Product, but the record also includes an exemplar label of a competitor product confirming the same.

For these reasons, and those articulated below, the Court's finding that Plaintiffs' claims are preempted should be reversed.

1. Legal Standard on Preemption

The parties agree on the predicate legal principles underlying the standard for preemption.

The Federal Food Drug and Cosmetic Act (the "FDCA"), as amended by The Nutrition Labeling and Education Action of 1990 ("NLEA") forbids the misbranding of foods and supplements by way of false or misleading labeling. 21 U.S.C. § 343. Section 403A of the NLEA provides, in pertinent part, that states may not establish "any requirement for the labeling of food of the type required by section . . . 343(i)(1) . . . that is not identical to the requirement of such section . . ."

21 U.S.C. § 343-1(a)(3). NLEA preemption does not foreclose any and all state law claims alleging false advertising or labeling. Thus, a plaintiff may pursue claims "to impose state-law requirements that are identical to those imposed by the FDCA. 21 C.F.R. §101.3(a) requires that a "statement of identity" appear on a packaging's principal display panel. That "statement of identity" must be set forth in terms of:

> (1) The name . . . specified in or required by any applicable Federal law or regulation; or, in the absence thereof;
> (2) The common or usual name of the food; or, in the absence thereof;
> (3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food. 21 C.F.R. §101.3(b)(1)-(3).

Here, the parties agree that there is no name for the Product that is specified by Federal law or regulation, which would trigger application of 21 C.F.R. §101.3(b)(1), therefore the Product must bear its "common or usual name" pursuant to 21 C.F.R. §101.3(b)(2).

The FDCA provides additional guidance as how to determine such a "common or usual" name.

> (a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, *the basic nature of the food or its characterizing properties or ingredients*. The name shall be *uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name*.

21 C.F.R. §102.5(a) (emphasis added).

2. Molecular Differences Matter; Trans-Esterification is not a Processing Step in the Creation of Fish Oil, but a Transformative Step by Which Crude Fish Oil is Converted Into an Omega-3 Ethyl Ester

The Lower Court held in relevant part, Plaintiffs' claims "are based upon molecular differences observable in products derived from different methods for the processing of fish oil." [SPA-17]. "All of Plaintiffs' claims turn on acceptance of this molecular distinction." [SPA-18]. "…. [T]here is no claim that molecular differences matter…," therefore "[a]cceptance of Plaintiffs' argument – even beyond the pleading stage – would require this Court to order the opposite of what the NLEA requires – substitution of a product's common name by a confusing description of its molecular structure." [SPA-27].

In so holding, the Lower Court failed to recognize a very basic and common sense proposition -- that the import of processing is its purpose and intended outcome, that molecular differences are not trivial but material and are often the only way to distinguish one substance from another.

Everything is "processed." It is axiomatic therefore that the relevance of a process is not merely the fact that it is "a process," but rather its purpose and intended outcome. Common sense dictates that the process of washing an apple is materially different than the process of converting an apple into an extract. Just as

cleaning (i.e., deodorizing and bleaching) fish oil is very different than molecularly transforming into an Omega-3 ethyl ester.

Contrary to the Court's conclusion, trans-esterification is **not** merely another processing step in the rendering of fish oil, but a completely separate transformative step designed to convert fish oil into one of several esterified products. [A-23; SPA-12]. Critically, rendering fish oil begins with "Raw Material" (i.e. fish) and ends with fishmeal and "Crude Fish Oil." *Id.*. In contrast, trans- esterification **begins** with Crude Fish Oil and ends with one of several ethyl ester products (i.e. Ethyl Esters, Fatty Acids, Mixed Glycerides, Omega-3 Concentrates, Purified Esters). *Id.*

There is no question that Defendants' Product was transformed from crude fish oil into an Omega-3 ethyl ester. The mass spectra comparing the molecular fingerprint of Defendants' Product to the USP standard for fish oil unequivocally confirms that Defendants' Product: (a) is not Fish Oil and (b) it is an ethyl ester. *Id.*

Although the Court properly recognized that there are molecular distinctions between Defendants' Product and Fish Oil, it dismisses them as trivial. [SPA-13], finding "[i]t is implausible to believe that any consumer shopping for a fish oil supplement seeks only DHA/EPA with an intact glycerol backbone molecule." [SPA-31]. While a consumer would not necessarily know the molecular makeup of fish oil, nor would this knowledge be reasonably imputed upon them in making a

purchasing decision, they most assuredly would want to know whether they are purchasing fish oil – a natural product – or a synthetic Omega-3.

Molecular differences should not be dismissed as trivial or insignificant because of their size, but acknowledged as the unique fingerprints by which substances are differentiated. While molecular distinctions are less critical to consumers when differences between products are visible (e.g., apple versus a pear), they are highly critical when it is impossible to differentiate between products devoid of organoleptic differences. Indeed, visible differences among types of fish oil (e.g., Salmon, Tuna, Menhaden), or as between fish oil and Omega-3, or as between forms of Omega-3s (i.e., triglycerides, ethyl esters, re-esterified triglycerides) can only be determined on a molecular level. It is only because of these molecular differences, that manufacturers can properly label products and consumers make informed purchasing decisions.

3. Plaintiffs' Evidence Does Not Contradict Their Allegations

According to the Magistrate, "a close review of each of Plaintiffs' references also demonstrates that, with the exception of references that refer only generally to DHA and EPA, everyone refers to all OM3 DHA/EPA products – however derived – as "fish oil" or fish oil supplements. While some of these scientific reference materials speak to molecular-level differences, none rely on these differences to

describe a "common name" for an Omega 3 supplement as anything other than fish oil." [SPA-26].

The Lower Court's conclusion is flawed. Defendant's Product is unquestionably an Omega-3 ethyl ester. According to the Lower Court, the mere fact that the transformation began with crude fish oil, is sufficient basis to call this product "Fish Oil." This conclusion is based on the Lower Court's finding that "none [of Plaintiffs' sources] rely on [molecular][] differences to describe a "common name" for an Omega 3 supplement as anything other than Fish Oil." Indeed, they all do. Plaintiffs provided three compendial sources, each of which: (a) identify the molecular fingerprint for fish oil; (b) identify the molecular fingerprints for synthetic and natural omega-3 concentrates; and (c) provide unique nomenclature for each. [3] [A-27-32]. That some compendial sources incorporate the words fish oil to modify the origins of the Omega-3 ethyl esters does not support the Court's leap of logic that Plaintiffs sources do not differentiate between the two types of substances, nor does it support its further erroneous conclusion that Defendants can simply use the name "Fish Oil" to describe their Product. Indeed, the Court's ultimate conclusion, "*that all DHA/EPA supplements – however derived*

[3] Each compendial source defines "Fish Oil" and then separately defines Omega-3 Ethyl Esters. E.g. GOED: "EPA and/or DHA Omega-3 Oil Ethyl Ester Concentrates" [66], Codex --"Concentrated fish oils ethyl esters, USP – "Omega-3-Acid Ethyl Esters," "Fish Oil Omega-3 Acid Ethyl Esters Concentrate."

from the original crude fish oil – are properly referred to as fish oil" [SPA-26] turns the mandate of 21 C.F.R. §102.5(a) on its head. Naming every single Omega supplement in the marketplace, however derived from crude fish oil, as "Fish Oil" would effectively eliminate the material distinctions between hundreds of unique Omega products and irreparably confuse and mislead consumers.

In addition to the compendial sources proffered by Plaintiffs for the purpose of differentiating Defendants' Product from Fish Oil, Plaintiffs provided numerous citations to other sources designed to substantiate other claims made in the Complaint, (e.g., the chemical make up of EPA-EE, the underpinnings of the trans-esterification process, the impact of Omega-3s on the human body, etc). The complete documents from which the citations were drawn, were requested by the Lower Court, and consist of nearly a thousand pages of material, many of which are not relevant to Plaintiffs' allegations. From these, which the Lower Court claims to have carefully reviewed, it concluded that "everyone refers to all OM3 DHA/EPA products – however derived – as "fish oil." This is simply untrue. A sampling of the references demonstrates that Omega-3s and Fish Oil are not referred to interchangeably but routinely distinguished for their different properties.

- There are several rationales for producing concentrates of omega-3 fatty acids…. For functional food applications, concentrates of omega-3 fatty acids will be more suitable for 'low-fat' applications than the starting fish oils. [A-244]

- Depending on the degree of fractionation, and the nature of the fractionation tools which have been utilized in the process, the fatty acid distribution of omega-3 concentrates will have changed significantly from that of their marine origin. Minor fatty acids which occur naturally in fish oils may show an increase or decrease in concentration [A-262] (emphasis added)

- If an oil has been 'restructured', 'concentrated' or 'esterified', or if individual fatty acids have been esterified and evidence cannot be produced to show pre-1997 human food use in one or more EU member states, then there is a high probability that the oil could be considered to be a novel ingredient, particularly if there has been any change to the molecular structure of the oil. [A-378]

- The European Pharmacopoeia (Ph.Eur.) contains a number of different monographs covering fish oils and omega-3 fatty acids. Those with direct relevance to omega-3 oils are: Fish oil, rich in omega-3 acids; Omega-3 acid ethyl esters 60; Omega-3 acid ethyl esters 90; Omega-3 marine triglycerides. These monographs are intended to be used for the identification of the oil **or** fatty acid. (emphasis added) [A-383]

- There also seems to be some confusion among EU member countries as to which form of the omega-3 long-chain fatty acids should be preferred. In some EU countries, such as Finland and Denmark, the ethyl ester form of the omega- 3 fatty acids is not allowed to be sold in dietary supplements. If one wants to sell omega-3 fatty acids as ethyl esters in these countries, then one must register them as pharmaceuticals. [A-410]

- Dietary supplements can contain several different forms of omega-3s, including natural triglycerides, free fatty acids, ethyl esters, re-esterified triglycerides, and phospholipids [32-341. Natural triglycerides are the form that occur naturally in fish oil, whereas ethyl esters are synthesized from natural triglycerides by replacement of the glycerol molecule of the triglyceride with ethanol. Re-esterified triglycerides are formed by the conversion of ethyl esters back to triglycerides. Omega-3s as re-esterified triglycerides, natural triglycerides and free fatty acids have somewhat higher bioavailability than ethyl esters….. [A-435-36, 563]

- There are additional processing steps that can be used to convert the refined marine oils to concentrates and relatively purified esters or fatty acids. The processing steps are designed to separate the fatty acids from the glycerin backbone of the triglyceride and then to fractionate the fatty acids or esters into concentrates or relatively pure individual fatty acids. [A-529] (emphasis added)

- The two marine omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), prevalent in fish and fish oils, have been investigated as a strategy towards prophylaxis of atherosclerosis. While the results with fish and fish oils have been not as clear cut, the data generated with the purified ethyl ester forms of these two fatty acids are consistent. [A-611]

- "Consumers appear to be much more aware than before of the connections between components of healthy foods and their beneficial effects on the body, according to a new study conducted by the International Food Information Council (IFIC, 2006). In an on-line poll of 1060 US adults, 70% rated fish oil as "somewhat or extremely healthful" and 58% believed the same of omega-3 fatty acids. [A-400-401] (emphasis added)

Second, context is key. Omega-3s in various forms are discussed in Plaintiffs' reference materials for many reasons, most not directly relevant to the allegations in Plaintiffs' Complaint, and none of which directly opine as to the common or usual name of such products, or how they should be properly referenced on a product label. Finally, even if there are differences between how these sources refer to

Omega-3s, they must be read in context, evaluated and weighed in relation to the other sources cited by Plaintiffs (including their compendial sources).[4]

Ultimately, if there is any question as to whether "*all DHA/EPA supplements – however derived from the original crude fish oil – are properly referred to as fish oil,*" the matter should not be decided on a motion to dismiss as a matter of law. Determining a products' common or usual name is often a factual dispute, one subject to further discovery and ultimate determination by the trier of fact. *See, e.g. Reynolds v. Wal-Mart Stores, Inc.*, 2015 U.S. Dist. LEXIS 53405, at *15 (N.D. Fla. Apr. 23, 2015)(Finding facts alleged sufficient to state a claim that the product fails to bear the "common or usual name of the food" and is misbranded under 21 U.S.C. § 343(i). A jury could conclude that the "common or usual name" of this product does not "accurately describe" the characterizing ingredients); *Gustavson v. Wrigley*

[4] "If a document relied on in the complaint contradicts allegations in the complaint, the document, not the allegations, control, and the court need not accept the allegations in the complaint as true." *Poindexter v. EMI Record Grp. Inc.*, 2012 WL 1027639, at *2 (S.D.N.Y. Mar. 27, 2012). This rule is predicated on the premise that the referenced documents *clearly contradict* the allegations in the complaint. Employing this rule, Courts typically will have documents that unequivocally contradict a representation in the complaint. *Peter F. Gaito Architecture, LLC v. Simone Dev. Corp.*, 602 F.3d 57, 64 (2d Cir. 2010)("In copyright infringement actions, 'the works themselves supersede and control contrary descriptions of them); *Alexander v. Bd. of Educ. Of City of N.Y.*, 648 F. App'x 118, 120 n.2 (2d Cir. 2016) ("termination letter"); *Axon v. Florida's Nat. Growers, Inc.*, 813 F. App'x 701, 704-05 (2d Cir. 2020)("survey"); *In re Chembio Diagnostics, Inc.*, 586 F. Supp. 3d 199, 215 (E.D.N.Y. 2022)(SEC filings). Here, no such documents exist. None of the sources opine directly on the common or usual name of Omega-3, nor how they should be formally referred to.

Sales Co., 961 F. Supp. 2d 1100, 1123 (N.D. Cal. 2013)(Absent on-point authority concerning the term, the Court refused to preempt Plaintiffs' allegation that use of the acronym "PGPR" to identify polyglycerol poyricinoleic acid was not the common or usual name); *Allred v. Frito-Lay N. Am., Inc., 2018 U.S. Dist. LEXIS 37617, at *1 (S.D. Cal. Mar. 7, 2018)*(declining to preempt plaintiff's claim finding the absence regulations leaves a question of fact whether all forms of malic acid can be designated by the generic name malic acid); *Young v. Neurobrands, LLC*, 2019 U.S. Dist. LEXIS 67905 (N.D. Cal. Feb. 19, 2019)(same); *United States v. Crescent-Kelvan Co.*, 164 F.2d 582, 587-88 (3d Cir. 1948)(finding the USP National Formulary definitions evidence to be weighed by the jury, in addition to all the other evidence presented, as to the common or usual name of the drug). The same should hold true here.

4. Plaintiffs Have Proffered a Common or Usual Name for Defendants' Product

The Court further notes that while Plaintiffs argue against the use of "fish oil" to describe the Product, they do not really offer a more "common or usual" alternative. Thus, they fail to show the common usage of any name other than fish oil, as set forth in 21 C.F.R. §102.5(a). [SPA-26].

As an initial matter, it is not Plaintiffs' burden to re-label Defendants' Product. It is enough to allege that Fish Oil is not an acceptable standard of identity

or common or usual name. Notwithstanding, Plaintiffs identified the nature of Defendants' product as a fatty acid ethyl ester and its constituent components as EPA-EE and DHA-EE. Since Omega-3 makes up the majority of the Product (980 mg out of 1400mg) [A-65], it can also be properly identified as an Omega-3 Ethyl Ester. All these names are proffered throughout the Complaint.

Despite providing compendial sources and a number of alternatives to "Fish Oil," (e.g., "It seems that Plaintiffs would have the product labeled as "DHA-EE and EPA-EE" or as "omega-3 fatty acid ethyl ester" or as "Omega-3 FAEE," or as "Omega-3 EPA-EE and DHA-EE" or perhaps just as "FAEE."), the Court instead found compelling that Plaintiffs "cite to no product on the market bearing such names, and there are no less common names imaginable for the Product. Acceptance of Plaintiffs' argument – even beyond the pleading stage – would require this Court to order the opposite of what the NLEA requires – substitution of a product's common name by a confusing description of its molecular structure." [SPA-27].

Although citation to market competitors is not necessary, especially in light of compendial sources, Plaintiffs could have provided them, should the Court have given leave to amend. Fortunately, however, the answer to the Court's rhetorical inquiry is neither dependent upon its imagination, nor on Plaintiffs' ability to amend their Complaint, but has been provided by the Defendants. Defendants sought

judicial notice of a competitor's product label, which Defendants described as an ethyl ester "1400 mg Fish Oil dietary supplement with DHA and EPA." [A-67]. It was submitted in conjunction with their Motion to Dismiss ostensibly to demonstrate that competitor products consisting of ethyl esters also name their products "Fish Oil." The Magistrate recommended Defendants' Request be granted and the District Court granted the request in its Adoption Order. [SPA 21-22, 46].

As cautionary tale on reading labels too quickly, a careful examination of the principal display panel Nature Made's product label itself, reveals that this product is not fish oil, as Defendants here claim, but rather an *"Omega-3" derived "from fish oil."* Despite the emphasis on the term "Fish Oil," the product is clearly labeled as an "Omega-3," one simply derived from fish oil. After the word "Omega-3," the label bears a "††," signaling to the consumer that more is revealed elsewhere. Turning to the Supplement Facts section on the back of the label, the product again is **not** described as "Fish Oil", but rather as an "Omega-3 Concentrate from fish oil." The same is repeated in the Ingredient list. Every Omega-3 reference, (including sub ingredients EPA and DHA) on the product's principal display panel and on the back carry a "††" which ultimately informs the consumers that indeed this Omega-3 is in ethyl ester form.

NBI's near identical Product should have been similarly labeled.[5] Moreover, it demonstrates, to the Court's point, how an Omega-3 product "derived from fish oil" may be properly labeled in compliance with 21 C.F.R. §102.5(a).

At the pleading stage, this Court "does not operate as a fact-finder," but instead must "presume all facts plead as true." *Branca v. Bai Brands, Ltd. Liab. Co.*, 2019 U.S. Dist. LEXIS 37105, at *8 (S.D. Cal. Mar. 7, 2019); *Valcarcel v. Ahold U.S.A., Inc.*, 2021 U.S. Dist. LEXIS 244968, at *9 (S.D.N.Y. Dec. 22, 2021)(declining to ascertain how a term is commonly used on a motion to dismiss); *Augustine v. Talking Rain Bev. Co.*, 386 F. Supp. 3d 1317, 1327 (S.D. Cal. 2019)("At this stage of the proceedings, the Court cannot say that Plaintiffs' argument is preempted"); *Allred v. Frito-Lay*, 2018 U.S. Dist. LEXIS 37617 at *3 ("it is clear that there are two forms of malic acid ... [t]hus, the Court cannot say at this stage that Plaintiffs' argument is preempted.").

The Magistrate relies heavily on *Branca v. Bai Brands, Ltd*. Liab. Co., 2019 U.S. Dist. LEXIS 37105, at *3 (S.D. Cal. Mar. 7, 2019), in support of its holding on preemption. *Branca* is, however, inapposite because malic acid, unlike fish oil, has standard of identity under the FDCA. 21 C.F.R. §184.1069 defines "malic acid [as]

[5] Despite being labeled as an Omega-3 ethyl ester, Nature Made's over emphasis of the term "Fish Oil" only further demonstrates that the name and the commodity are material to, and highly desired by consumers. [A-67].

the common name for 1-hydroxy-1, 2-ethanedicarboxylic acid. L (+) malic acid, referred to as L-malic acid, occurs naturally in various foods. Racemic DL-malic acid does not occur naturally. As acknowledged by the Lower Court and all parties, no such regulation exists for fish oil. Further distinguishing *Branca*, an OM3 is not a variety of fish oil such as "Salmon Oil" or "Tuna Oil," but all together a different product. Finally, even among Courts analyzing the distinction between d-malic and l-malic acids, many have reached the opposite conclusion reached by *Branca*. See - *e.g., Allred v. Frito-Lay N. Am., Inc*., 2018 U.S. Dist. LEXIS 37617, at *10 (S.D. Cal. Mar. 7, 2018)(Refusing to preempt plaintiff's claim, noting that the regulation identifies two forms of malic acid --DL-malic and L-malic acid – which are specific names of the collective, common name malic acid).[6] *See also, Hilsley v. Ocean*

[6] The holdings of *Regan v. Sioux Honey Ass'n Coop*., 921 F. Supp. 2d 938 (E.D. Wis. 2013) and *Brod v. Sioux Honey Ass'n Coop.*, 895 F. Supp. 2d 972 (N.D. Cal. 2012) are similarly distinguishable. There, plaintiffs claimed that defendant's labeling of a product as honey was false and misleading because they failed to disclose the honey was stripped of bee pollen in violation of Wisconsin and California honey laws, respectively. The Court's preempted both claims finding the state laws inconsistent with federal law – specifically that the common or usual name of these products were honey. In reaching this conclusion, the Court found the following: (a) the honey products met the typical definition of honey found in dictionaries; a meta analysis of state honey statutes have similarly defined honey, none of which requiring it to be non-filtered pollen; (c) regulations establishing grades of honey promulgated by the U.S. Department of Agriculture defined honey without requiring it to be non-filtered pollen and (d) no party was able to provide an alternative common or usual name. None of these factors are at issue in the case at bar. As demonstrated above, there are no state or federal regulations that define Fish Oil or Omega-3. In lieu, Plaintiff has provided all relevant compendial sources and monographs which distinguish between Fish Oil and Omega-3 ethyl esters and

Spray Cranberries, Inc., 2018 WL 5617701, at *7 (S.D. Cal. Oct. 30, 2018); *Young v. Neurobrands*, Inc., 2019 U.S. Dist. LEXIS 67905, at *11; *Augustine v. Talking Rain Bev. Co.*, 386 F. Supp. 3d 1317, 1327 (S.D. Cal. 2019).

Significantly, whether these allegations are sufficient to withstand a motion to dismiss is precisely the question addressed by Judge Schofield of the Southern District of New York, who reached the opposite conclusion to the Magistrate and the District Court in a matter nearly identical to the case at bar. *Rodriguez v. Target Corp*., 2022 U.S. Dist. LEXIS 23376 (S.D.N.Y. Dec. 30 2022). In relevant part the Court stated:

> Defendants rely on 21 U.S.C. § 343-1(a)(1) and § 343(g) for its express preemption argument. Both of those provisions apply only if a food "is the subject of a standard of identity established under" § 341. The parties agree that "there is no standard of identity for fish oil." Instead, the parties rely on regulations requiring that, in the absence of a standard of identity, products must bear their "common or usual name." 21 C.F.R. §§ 101.3(a), (b)(1)-(2); 102.5(a), (d). It is not clear that 21 U.S.C. § 343-1(a)(1) preempts state laws that are inconsistent with the "common or usual name" regulations absent a "standard of identity." However, even assuming express preemption is in play, it does not apply here.

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provide acceptable nomenclature as to common name. Additionally, Plaintiff has provided customary names for the product (i.e., Omega-3 ethyl ester), its sub ingredients EPA-EE, DHA-EE and Defendant has provided a competitor product that provides a label exemplar of the common or usual name of an Omega-3 ethyl ester and how to properly label it. Should the Lower Court have additionally required a dictionary definition in support of Plaintiffs' claims, with leave, Plaintiff would have provided one.

> *. *. *
>
> Plaintiffs allege that using the name "fish oil" for an FAEE product is misleading in part because it is inconsistent with "common usage," and fails to "accurately identify or describe . . . the basic nature of the food or its characterizing properties or ingredients," and is "confusingly similar to the name of any other food that is not reasonably encompassed within the same name" and "fails to distinguish[] it from different foods" -- i.e., "natural" fish oil. 21 C.F.R. § 102.5(a), (d). Plaintiffs' allegations about the Product's "common or usual name" are plausible. The Complaint alleges that several recognized authorities distinguish between "fish oil" and FAEE.

Id. at 13-14.

As in the case at bar, the parties argued about the whether common or usual name of the Defendant's product was fish oil but the Court in *Rodriguez* properly opined that it could neither "weigh the evidence," nor "choose between competing inferences at the motion to dismiss stage," finding that "[i]t is reasonable to infer from the Complaint that the common or usual name of the Product should distinguish it from "fish oil" with materially different properties. Plaintiffs' claims therefore are not expressly preempted by the FDCA. *Id*. at 15. Respectfully, the same result should inure here and the Lower Court's decision finding this matter preempted be overturned.[7]

[7] The Lower Court opines at several points in its decision that there is no difference with respect to the efficacy of natural DHA/EPA versus a synthetic ethyl ester (DHA-EE/EPA-EE). [SPA-12-13]. "Indeed, the Court has reviewed all of the scientific materials referenced in the Amended Complaint and states confidently that neither the Amended Complaint nor any document referenced therein makes any claim that one form of fish oil (triglyceride or ethyl ester) is superior to the

C. THE LOWER COURT ERRED IN FINDING THAT A REASONABLE CONSUMER WOULD NOT BE MISLED BY DEFENDANTS' PRODUCT LABEL

In addition to, and based upon, its finding that Plaintiffs' claims are preempted, the Court opined that no reasonable consumer would be mislead by Defendants' Product label because "there is nothing false about calling the Product fish oil." [SPA-33] "Even if Plaintiffs' claims were not preempted, they are all implausible and should be dismissed." [SPA-29]. "To suggest that molecular differences between such products make a difference to a reasonable consumer is plainly implausible. Thus, all claims alleging that a reasonable consumer would think otherwise are implausible and lacking completely in merit." [SPA-33].

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other as to an association with health benefits." [SPA-15]. Although comparative efficacy is not the focus of Plaintiffs' Complaint, a careful reading of Plaintiffs' citations demonstrates that substantively the Court is incorrect. E.g., "[I]t has been established that several distinct differences exist with regard to how the body handles ethyl ester versus triglyceride EPA and DHA." [A-476]. Ethyl esters do not occur naturally in the human diet, are hydrolyzed by the pancreas 10-50 times slower than triglycerides, may not mimic the physiologic activity of triglycerides and are less molecularly stable [A-478]. Indeed, of the six clinical studies available as of the date of the MacKay article (2007), four had concluded that the natural triglyceride form absorbs better than ethyl esters. [A-476]. This contradiction again highlights the danger and impropriety of weighing evidence on a motion to dismiss, especially on matters that may require scientific expertise. Moreover, 22 years have passed since the writing of the MacKay article, undoubtedly more studies have been undertaken regarding the distinction between forms of Omega-3, along with the materiality of such distinctions to consumers.

Under the "reasonable consumer" test, Plaintiffs must prove only that an ordinary consumer acting reasonably would attach importance to defendant's label statements, or, alternatively, that defendant knows or has reason to know that consumers are likely to regard the label statements as important in making purchasing decisions. *Swearingen v. Late July Snacks LLC*, 2017 U.S. Dist. LEXIS 69280, at *10-11 (N.D. Cal. May 5, 2017). Plaintiffs have done so.

The same arguments as to why Plaintiffs' claims should not have been preempted, animate the reasons a reasonable consumer would be mislead by Defendants' Product label and therefore why the Lower Court's ruling is in err and should be reversed.

As a predicate matter, there is nothing ambiguous about the term "Fish Oil." Labeling a product by something else other than its common or usual name is *de-facto* false, misleading and deceptive to the reasonable consumer.

Second, even if the term "Fish Oil" were ambiguous, which it is not, the remainder of Defendants' Product label does not serve to resolve any perceived ambiguity, but rather, exacerbates it. The Product's principal display panel simply says "Fish Oil." [A-65]. It carries no marking suggesting there is a disclaimer or any ambiguity to which the consumer should be alerted. Rather, it boldly claims it has been verified by the USP. On the reverse side of the label at the top, the label

explains that "the USP has tested and verified ingredients." The Supplement Fact section re-affirms the false statement, that the Product is "Fish Oil." On the third line down in the middle of line, blended into, and after the word Acids, there is a barely recognizable single "†." The marking appears once after the word Fatty Acids, but not after "EPA", "DHA", or "Other Omega-3 Fatty Acids." At the very bottom of the panel, outside the Supplement Fact section, the † states "As Ethyl Esters." Even assuming a consumer could find and read this without a magnifying glass, the disclosure, at most indicates fatty acids are ethyl esters. This supposed qualifier stands in contrast to a label that boldly claims the product is "Fish Oil", a natural product, as verified by the USP.[8] Under these circumstances, whether a reasonable consumer would see and understand the qualifier can only, be resolved with further evidence, and not on a motion to dismiss. *Stoltz v. Fage Dairy Processing Indus., S.A.*, 2015 WL 5579872, at *20 (E.D.N.Y. Sept. 22, 2015) quoting *Verizon Directories Corp. v. Yellow Book USA, Inc.*, 309 F.Supp.2d 401, 407 (E.D.N.Y. 2004) (noting that resolution of the issue may require "surveys, expert testimony, and other evidence of what is happening in the real world").

[8] Notably, Defendants' qualifier stands in stark contrast with Nature Made's. Notwithstanding the fact that Nature Made is labeled as an Omega-3, it uses a more significant †† qualifier which appears on both its principal display panel and the back label and every reference to an Omega-3, no less than six times on the label. Compare [A-65] to [A-67].

The Lower Court cites *Nguyen v. Algenist LLC*, 2022 WL 17251733 (S.D.N.Y. Nov. 28, 2022) for the proposition that in instances where there is an ambiguity, and a consumer could be misled, the existence of clarifying information elsewhere on the package could serve to resolve the ambiguity.

This Court has addressed circumstances in which a court could consider non-challenged statements and representations on packaging concluding that, "reasonable consumers should not be expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box. Instead, reasonable consumers expect that the ingredient list contains more detailed information about the product that confirms other representations on the packaging." *Mantikas v. Kellogg Co*., 910 F.3d 633, 637 (2d Cir. 2018) *citing Williams v. Gerber Prods. Co*., 552 F.3d 934, 939 (9th Cir. 2008). Even considering purportedly clarifying information on the ingredient list, the *Mantikas* Court still held the label misleading, finding that certain entries on the list "contradict, rather than confirm, Defendant's 'whole grain' representations on the front of the box." *Id.*

Under the reasonable consumer test, a plaintiff must show that acts are materially deceptive or misleading "to a reasonable consumer acting reasonably under the circumstances." *Goldemberg v. Johnson & Johnson Consumer Cos*., 8 F. Supp. 3d 467, 478 (S.D.N.Y. 2014) (quoting *Oswego Laborers' Local 214 Pension*

Fund v. Marine Midland Bank, N.A., 647 N.E.2d 741, 745 (N.Y. 1995)). The issue, however, is not what a consumer might ascertain by reading all the fine print on a label or investigating facts by other means, but "what a person of ordinary intelligence would imply." *Lavie v. Procter & Gamble Co.*, 105 Cal. App. 4th 496, 505 (2003). Put another way, a consumer is not required to ferret out the truth within misleading claims. *Williams*, 552 F.3d at 939. Even assuming arguendo, that the Product's purported statement of identity was confusing, the label must be looked at holistically, and "disclaimers do not *ipso facto* sanitize misleading marketing practices." *Kommer v. Bayer Consumer Health*, 252 F. Supp. 3d 304, 312. Here, even if one were to notice the reference to ethyl esters buried on back, it modifies the term "fatty acids" and not EPA, DHA, other Omegas or Fish Oil, thereby rendering its "qualification" far more confusing than clarifying. *Engram v. GSK Consumer Healthcare Holdings (US) Inc.*, 2021 WL 4502439, at *3 (E.D.N.Y. Sept. 30, 2021) ("Where the front of a package makes a bold and blatant misstatement about a key element of a product, there is little chance that clarification or context on the reverse of the package will suffice to overcome a deception claim . . . .).

The Lower Court's citations to *Kennedy v. Mondelez Global LLC*, 2020 WL 4006197, at *9 (E.D.N.Y. July 10, 2020), *Nguyen v. Algenist LLC*, 2022 WL 17251733, at * 5 (S.D.N.Y. Nov. 28, 2022); *Devane v. L'Oréal USA, Inc.*, 2020 WL

5518484, at *1, 4-5 (S.D.N.Y. Sept.14, 2020); and *Kommer v. Bayer Consumer Health*, 252 F. Supp. 3d 304, 306, 311 (S.D.N.Y. 2017) are of no consequence as the reasonable consumer inquiry is fact intensive and each of these cases is factually inapposite. This is perhaps most illustrated by the Court's conclusion that cases which "border on fantasy," should be dismissed out of hand. While true in those instances, Plaintiffs' allegations here are readily distinguishable. Indeed, the Lower Court did not attempt to analogize this matter to those cases because of the obvious and stark differences. *In re Frito Lay N. Am., Inc*., 2013 U.S. Dist. LEXIS 123824, at *50-52 (E.D.N.Y. Aug. 29, 2013) (i.e., allegations that sugary cereals named Crunch Berries and Froot Loops actually contained real fruit)(internal citations omitted). Indeed, the Court in *In re Frito-Lay N. Am., Inc*, overruled the motion to dismiss on the facts before it, finding possible that the "all natural" label statement did not preclude a finding that a reasonable consumer could be deceived into believing the product is GMO-free," and that "the reasonable consumer inquiry is, in most instances, a factual one. Only in cases outside the heartland have courts rejected these kinds of claims on a motion to dismiss. This case is not one of those cases." *Id.* at 51-52. Neither is this.

As articulated by the Seventh Circuit Court of Appeals, agreeing with its sister 1st, 2nd and 9th Circuits, "[w]hat matters here is how consumers actually behave—how they perceive advertising and how they make decisions. These are

matters of fact, subject to proof that can be tested at trial, even if as judges we might be tempted to debate and speculate further about them. We doubt it would surprise retailers and marketers if evidence showed that many grocery shoppers make quick decisions that do not involve careful consideration of all information available to them. *See, e.g.*, U.S. Food & Drug Admin., *Guidance for Industry: Letter Regarding Point of Purchase Food Labeling* (Oct. 2009)("FDA's research has found that with [Front of Package] labeling, people are less likely to check the Nutrition Facts label on the information panel of foods (usually, the back or side of the package). *Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 481 (7th Cir. 2020).[9] "It is important to remember that "at least in some cases, 'a federal trial judge, with a background and experience unlike that of most consumers, is hardly in a position

[9] The Lower Court surmised that Plaintiffs "clams rise and fall on the notion that consumers would be misled by a difference observable only on a molecular level" and that "[i]t is implausible to believe that any consumer shopping for a fish oil supplement seeks only DHA/EPA with an intact glycerol backbone molecule." [SPA-31]. This characterization and conclusion is erroneous in several respects. First, consumers do differentiate among dietary supplement offerings that provide Omega-3s such as DHA and EPA. As a predicate, they must choose between Fish Oil or another Omega-3 product. If the latter, then consumers must also choose the origin and form of the Omega-3 (e.g., triglyceride, ethyl ester, re-esterified triglyceride, phospholipid, etc). While a consumer may not say they are seeking "DHA/EPA with an intact glycerol backbone molecule," they certainly do find material the differences between fish oil and other Omeg-3 offerings. [A-400-401]. "Consumers wishing to ingest Omega-3s have numerous choices. Principal among them, whether to take an Omega-3 supplement or consume a marine oil (e.g., fish, krill, algae). Each product is molecularly different and has an array of qualities that differ from one another. These qualities differentiate the products in the marketplace and are material to consumers' purchasing decisions." [A-36].

to declare' that reasonable consumers would not be misled." *Campbell v. Whole Foods Mkt. Grp., Inc.*, 516 F. Supp. 3d 370, 384 (S.D.N.Y. 2021)(internal citations omitted). In short, "[i]t is not implausible that consumers would understand the words on the box to say what they mean. Evidence… not merely judicial introspection, is needed to determine what consumers understand the phrase to mean in the context of this particular product and its packaging. *Id. at 385.* "Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations." *Lynch v. City of New York*, 952 F.3d 67, 75 (quoting *Twombly*, 550 U.S. at 556).

Respectfully, the Lower Court's decision finding that no reasonable consumer would be deceived by Defendants' Product label should be reversed.[10]

D. THE LOWER COURT ERRED IN NOT GRANTING PLAINTIFFS' REQUEST FOR LEAVE TO AMEND

The Second Circuit reviews the denial of leave to amend a complaint under an abuse of discretion standard. *Jin v. Metropolitan Life Ins. Co.*, 310 F.3d 84, 101

[10] The Court addressed Plaintiffs remaining claims derivatively, finding "[d]ismissal of Plaintiffs' claims on the grounds set forth above disposes of any and all of Plaintiffs' claims, whether arising under statutory or common law" [SPA-33]. "Indeed, Plaintiffs concur that this is the law, i.e., if their false labeling claims fail, so too do their state law claims for breach of warranty." [SPA-34]. The converse is also true. Accordingly, if the Lower Court's rulings on preemption and the reasonable consumer standard are reversed as to Plaintiffs consumer law claims, then Plaintiffs remaining claims so to should be reinstated.

(2d Cir. 2002). “Leave to amend should be freely granted, but the district court has the discretion to deny leave if there is good reason for it, such as futility, bad faith, undue delay, or undue prejudice to the opposing party." *Id.* Ultimately, “it is within the sound discretion of the district court to grant or deny leave to amend." *Kim v. Kimm*, 884 F.3d 98, 105 (2d Cir. 2018).

The Lower Court denied Plaintiffs’ request for leave to amend finding it deficient as they “sought leave to amend only in the final sentence of their opposition to the motion to dismiss and at no point offered any new factual allegations that they would make if granted leave to amend.” [SPA-53].

Plaintiffs amended their Complaint once, and only then to principally add an additional Plaintiff. The Magistrates’ Report and Recommendation was the initial instance any curable deficiencies were pointed out by the Court. By way of example, the Magistrate, and the District Court by adoption, highlighted the absence of competitor products using the name Omega-3 ethyl esters and an analysis of the comparative qualities of triglycerides versus ethyl esters (e.g., efficacy, bioavailability, healthfulness) as issues in their Orders. Had the Magistrate or the District Court requested, Plaintiffs could have provided exemplars and/or evidence regarding both.

Barring futility, under such circumstance, failure to provide Plaintiffs leave to amend was an abuse of discretion and reversable error.

VI. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request this Court reverse the Lower Court's finding that the matter is preempted as well its finding that no reasonable consumer would be mislead by Defendants' Product label and thereby reinstate this matter.

Respectfully Submitted,

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Dated: June 26, 2023

SPECIAL APPENDIX

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------X
MASHON BAINES and NANCIE FRONING, on behalf of themselves and all others similarly situated,

Plaintiffs,

-against-

NATURE'S BOUNTY (NY) INC., and THE BOUNTIFUL COMPANY (NY),

Defendants.
----------X

REPORT AND RECOMMENDATION
CV 21-5330 (JS)(AYS)

SHIELDS, Magistrate Judge:

This is an action commenced by Plaintiffs, Mashon Baines ("Baines") and Nancie Froning ("Froning") (collectively "Plaintiffs"), against Defendants, Nature's Bounty (NY) Inc. and The Bountiful Company (NY) (collectively "Defendants"). (Am. Compl., Docket Entry ("DE") [21].) Plaintiffs allege New York and California State law claims sounding in false advertising. (Id.) Federal jurisdiction is alleged pursuant to 28 U.S.C. §1332(d)(2).

Plaintiffs seek to represent New York and California sub-classes of individuals who state they have been harmed by the allegedly false labeling on Defendants' product, a dietary supplement marketed under the name "Nature's Bounty 1400 mg Fish Oil" (the "Supplement" or the "Product"). Plaintiffs argue that the way in which the Product is processed makes the use of the name "fish oil" false. Their causes of action are as follows: (1) New York and California state law claims for breach of warranty (First Cause of Action); (2) claims alleged pursuant to Sections 349 and 350 of the General Business Law of the State of New York, N.Y. Gen. Bus. L. §§349-350 ("Section 349" and "Section 350") (Second and Third Causes of Action alleged on behalf of a New York State sub-class); (3) claims alleging violation of the unfair competition and

false advertising laws of the State of California (Fourth, Fifth, Sixth, Seventh and Eighth Causes of Action alleged on behalf of a California State sub-class); and, (4) claims pursuant to theories of quasi-contract/unjust enrichment (Ninth Cause of Action). While all claims arise under state laws, federal jurisdiction is properly alleged pursuant to 28 U.S.C. §1332(d)(2).

Presently before the Court, upon referral by the Honorable Joanna Seybert, is Defendants' motion to dismiss the Amended Complaint, pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. Also before the Court is Defendants' motion requesting that the Court take judicial notice of certain documents in connection with the motion to dismiss. The latter motion is granted to the extent that the Court has elected to consider the full label of the Product and a publication of the Food and Drug Administration (the "FDA") setting forth agency guidance as to labeling.

As to the motion to dismiss, this Court finds that the name "fish oil" is, as required by the Food Drug and Cosmetic Act, the Product's common name. Plaintiffs' proposition that it be labeled differently seeks to impose state law requirements that are preempted. All claims should therefore be properly dismissed. Additionally, Defendants' use of the fish oil name is in no way false or misleading, which further forecloses any state law claims on the merits. The motion to dismiss should be granted without leave to re-plead.

BACKGROUND

I. Procedural Background

Plaintiffs commenced this action on September 24, 2021. (DE [1].) On January 26, 2022, Plaintiffs filed an Amended Complaint. (DE [21].) On February 7, 2022, Defendants moved to dismiss the Amended Complaint. (DE [25].) The motion was fully briefed on March 23, 2022.

(DE [28].) On October 31, 2022, the District Court referred that motion to this Court for Report and Recommendation. (Electronic Order of Seybert, J., dated Oct. 31, 2022.)[1]

II. Factual Background

A. The Parties

Plaintiff Baines is a resident of Rome, New York. She states that she has purchased the Product on numerous occasions over the three-year period preceding the filing of this lawsuit. (Am. Compl. ¶¶15-16.) Baines alleges that she believed that the Product "was actual fish oil containing DHA and EPA," which, according to Baines, it is not. (Id. ¶17.) She states that she would not have purchased the Product, or would have purchased it on different terms, had she known the truth. (Am. Compl. ¶20.) Baines also states that if she knew that the marketing and sale of the Product was lawful and not misleading, and/or that she could rely on the labeling, she would consider purchasing the Product again. (Id. ¶21.)

Plaintiff Froning is a resident of San Diego, California. Like Baines, Froning alleges that she has purchased the Product over the past three years. (Id. ¶25.) Froning also believed that the Product "was actual fish oil containing DHA and EPA," was misled by the labeling of the Product, and would consider purchasing the Product in the future if the labeling was not misleading. (Id. ¶¶26-32.)

Defendant Nature's Bounty, Inc. is a New York corporation with its principal place of business in this District. (Id. ¶33.) "Nature's Bounty" is alleged to be the "flagship brand" of the Defendant Bountiful Company, a family of wellness brands "committed to providing people with high quality products to complement their lifestyles and physical health." (Id.) The Bountiful

[1] Defendants' motion for judicial notice was administratively closed by the District Court on September 30, 2022. It was thereafter referred, along with the motion to dismiss, by the Order of October 31, 2022.

Company is a Delaware corporation with its principal place of business in this District. It is a "manufacturer, marketer and seller of vitamins, minerals, herbal and other specialty supplements." (Id. ¶34.)

B. Scientific Material Discussed in the Amended Complaint

The Amended Complaint contains detailed factual information regarding the processing of fish oils for packaging in capsules that are marketed as dietary supplements. Terms used in the Amended Complaint include, inter alia, fish oil, omega-3 fatty acids, and omega-3 fatty acid ethyl esters. It explains different processing methods used to transform crude fish oil into products marketed as supplements that bear the name "fish oil." Whenever the Amended Complaint refers to a scientific fact forming the basis of Plaintiffs' claims, it references (mostly in footnotes) a variety of materials.

Some of the materials referenced in the Amended Complaint are articles published in scientific journals, and some are public documents disseminated by groups including the Food and Drug Administration (the "FDA"), the United States National Institutes of Health (the "NIH"), the World Trade Organization (the "WTO"), the United States Pharmacopeia (the "USP"), the Codex Alimentarius Commission ("Codex"), the Global Organization for EPA and DHA omega ("GOED") and the United States Customs And Border Protection Agency ("CBP"). CBP is mentioned in the Amended Complaint because it is the agency responsible for interpreting the Harmonized Tariff Schedule of the United States ("HTS"). Plaintiffs also rely on what appear to be chapters or excerpts from scientific textbooks. Other references are websites for products that compete with the Product. Together, these materials are referenced in the Amended Complaint's first forty-eight footnotes, which appear in the first twenty-four pages of the fifty-page Amended Complaint, which pleading consists of 187 paragraphs.

Pursuant to an Order dated November 2, 2022, all documents cited in the footnotes to the Amended Complaint were separately provided. As discussed below, each such document is properly considered in the context of this motion. While not every reference material is discussed in this Report and Recommendation, the Court has been careful to read all of these materials in the light most favorable to Plaintiffs, without acting as an expert in scientific fields such as chemistry, or as to the business and taxation of the commercial fishing industry. Where any such expertise is necessary, the Court has refrained from interpretation and applied only its own plain-language reading of each document in the light most favorable to the text of the Amended Complaint. The Court states the facts therein – not its own interpretation thereof.

It is important to note that where the text of a document relied upon does not support factual allegations of the Amended Complaint, or where the pleading selectively quotes from the reference, the Court properly considers the full text of the reference material when determining the plausibility of Plaintiffs' claims. See BYD Co., Ltd. v. VICE Media, LLC, 531 F. Supp. 3d 810, 817 (S.D.N.Y. 2021) (stating that where a document relied upon in a pleading contradicts allegations in the pleading, the court need not accept pleading allegations but may properly rely on the referenced document).

The Amended Complaint includes information organized into subject headings entitled: Omega-3 Fatty Acids, Fish Oil, Omega-3 Fatty Acid Ethyl Esters and the Trans-esterification Process. The basic facts necessary to understand the links between these terms and Plaintiffs' claims, while supported by hundreds of pages of scientific articles are, when considered through the lens of common-sense, not difficult to understand and can be readily applied to evaluate the pending motion. The Court's explanation of those facts follows.

1. Omega-3 Fatty Acids and Health Claims Related Thereto

Omega-3 fatty acids ("Omega-3's" or "OM3's") are polyunsaturated carboxylic Acids. (Am. Compl. ¶ 36.) Among the eleven types of OM3's, the three most important to human physiology are alpha-linolenic acid ("ALA"), docosahexaenoic acid ("DHA") and eicosapentaenoic acid ("EPA"). (Id. ¶ 37.) To be used for something other than energy, ALA must first be converted into EPA or DHA. (Id. ¶ 38.) Thus, it is important for humans to ingest adequate amounts of the OM3's known as DHA and EPA. The primary source of DHA and EPA are marine oils present in certain fatty fish, such as salmon and other seafood. (Id. ¶ 39.) Other foods containing these OM3's are nuts, seeds, plant oils and certain fortified foods. (Id. ¶ 40 n.6 (referencing "2022 NIH Fact Sheet for Consumers" (hereinafter "NIH Consumer Fact Sheet").)

Scientific studies support (although not conclusively) various health benefits attributable to ingestion of fish oil and fish oil supplements. (Id. ¶ 40; see generally NIH Consumer Fact Sheet.) Despite these findings, neither the NIH nor any United States governmental authority has declared any minimum daily requirement for DHA or EPA. (NIH Consumer Fact Sheet.) Nonetheless, it is clear that between 2017 and 2019, medical experts noted the benefit of eating one to two servings of fatty fish each week. (Am. Compl. ¶ 42.)

Relying on a scientific article entitled "A Comparison of Synthetic Ethyl Ester From Fish Oil vs. Natural Triglyceride Form" by Douglas Mackay, MD, (Id. ¶ 40 n.9 (hereinafter the "MacKay Article"), the Amended Complaint states the "unfortunate fact" that Americans do not consume a sufficient amount of fatty fish necessary to maintain adequate levels of EPA and DHA. In response to this deficiency, health care professionals began recommending that Americans supplement their diets with fish oil. (Id. ¶ 43 n.9.) The MacKay Article notes that

contamination of oceans creates a potential health hazard associated with eating fish. Therefore, MacKay concludes that "fish oil supplements may well be the healthier choice." (Id.)

In 2019, the FDA lent its limited support to health claims associated with the ingestion of fish oil and fish oil supplements. In an official agency statement, it announced that it would not object to the making of certain "qualified" health claims that consumption of the OM3's EPA and DHA "in food or dietary supplements may reduce the risk of hypertension and coronary heart disease." (Id. ¶ 42 and n.8 (hereinafter "FDA 2019 Heart Claim Announcement").) The 2019 FDA Heart Claim Announcement states that while the overall evidence before the agency did not meet the "significant scientific agreement" standard required for an authorized health claim, it did meet the "credible evidence" standard for a qualified health claim in the labeling of conventional foods and dietary supplements. Thus, by June of 2019, the FDA made clear that it would take no enforcement action against labeling stating that:

- consuming EPA and DHA combined may help lower blood pressure in the general population and reduce the risk of hypertension. However, FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [ ] gram(s) of EPA and DHA;

- consuming EPA and DHA combined may reduce blood pressure and reduce the risk of hypertension, a risk factor for CHD (coronary heart disease). However, FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [ ] gram(s) of EPA and DHA;

- consuming EPA and DHA combined may reduce the risk of CHD (coronary heart disease) by lowering blood pressure. However, FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [ ] gram(s) of EPA and DHA;

- consuming EPA and DHA combined may reduce the risk of CHD (coronary heart disease) by reducing the risk of hypertension. However, FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [ ] gram(s) of EPA and DHA, and

- Research shows that consuming EPA and DHA combined may be beneficial for moderating blood pressure, a risk factor for CHD (coronary heart disease). However, FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [ ] gram(s) of EPA and DHA.

2019 FDA Health Announcement (Id. n.8).

In addition to allowing the above-referenced language, the FDA had, since 2004, exercised its enforcement discretion to allow for the making of the qualified health claim that "'supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease under certain circumstances.'" (Id.) Against the backdrop of these scientific findings, and the FDA's announcement allowing certain health claims to be made in connection with the marketing of DHA and EPA via food and supplements, it is not surprising that many companies have entered the fish oil supplement market.

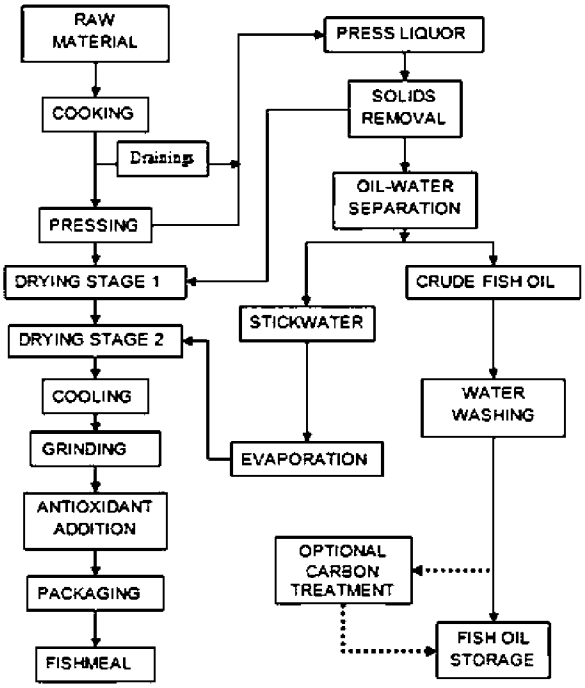
Plaintiffs' claims do not (and, in light of the materials set forth in their pleading, could not) attack any health-related claim made by Defendants. Instead, they argue that the Product may not be called "fish oil" because of the molecular difference between the form of DHA and EPA contained in the Product. While it is not alleged that the Product is the only fish oil supplement containing this form of EPA/DHA, Plaintiffs draw a molecular distinction between the form contained in the Product and that found in other DHA/EPA fish oil supplements on the market. This molecular difference is attributable to the different methods used to extract and process fish oil. The Court turns to discuss those differences.

2. Fish Oil Extraction: Early Methods and the Current "Wet Reduction Process"

OM3's (and more specifically to this matter, the OM3's EPA and DHA) are found in a variety of foods, including the oil of fatty fish. (Am. Compl. ¶45.) The Amended

Complaint describes two different processes for extracting oil from such fish. These are processes for converting raw fish into fish oil that can be placed in capsules that are marketed as dietary supplements. First, the Amended Complaint describes a process that has been used, in one way or another, since the 1800's. Pursuant to that early process, caught fish were cooked "and a rock weighted process was used to press oil from the fish." (Id.) Later on – but still more than 100 years ago – "the rock weighted process was replaced with a hydraulic press." (Id. ¶ 45 and n.13 (referencing H. Breivik, Long-chain Omega-3 Specialty Oils, Woodhead Publishing in Food Science, Technology and Nutrition, at 11).)

The Amended Complaint goes on to state that, today, a process to extract fish oil from fish, known as the "wet reduction process," "remains relatively the same." (Id. ¶ 46.) Thus, after being caught, fish are "on-boarded to a fishing vessel and quickly boiled." (Id. ¶ 46.) The fish are then "cooked and pressed, separating the water and oil from proteins and solids." (Id.) Today, in addition to the mechanical pressing of fish, the wet reduction process requires the additional steps of separating water from the oil and "a polishing process," which includes "de-acidifying, degumming, and washing the oil several times." (Id. ¶ 46.) The Amended Complaint also describes the next parts of the wet reduction process. These additional steps involving further processing and purification. (Id. n. 21 (hereinafter "Science-based Health").) These steps require that after pressing, fish oil must be bleached and deodorized. (Id. ¶ 46 and n.17.) The washing and bleaching processes do not remove cholesterol, saturated fatty acids or contaminants like heavy metal, dioxins or pesticides. The wet reduction process is described in graphic form in the following flow chart appearing in the Amended Complaint:



(Id. n.14.) The original flowchart appears in Bimbo, A. (2011) Marine oils; edible oil processing, AOCS Lipid Library, December 2016 ("Bimbo Article"). The Bimbo Article also describes in detail the "cooling and stabilization" phases of fish oil processing. This involves the use of an anti-oxidant. While tocopherols may be used for this process, Bimbo also refers to "ethoxyquin" (a synthetic chemical food preservative) as the oxidant of choice. Bimbo also states that if contaminants such as dioxins are noted to be present, a carbon treatment may be added as an additional optional processing step. In addition to the wet reduction process, the Bimbo Article describes several other methods used to extract fish oil, but a description of these other processes is not necessary to consider in the context of the present motion.

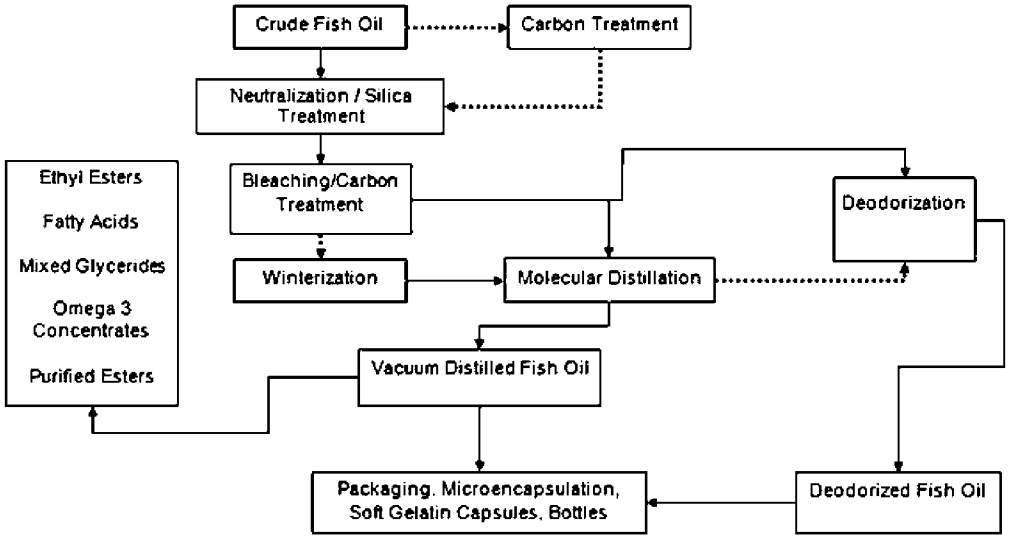
The Amended Complaint stresses that the wet reduction process described above is critical to understand, because it is a physical extraction method that differs from another method used to extract fish oil, which Plaintiffs characterize as a chemical process. This distinction is

central to Plaintiffs' case, because it is the molecular differences that result from the latter process for fish oil extraction that forms the basis for their claims that the Product may not bear the name "fish oil." Before evaluating this claim for plausibility, the Court turns to a discussion of the information the Amended Complaint addresses under sections entitled "OM3 Fatty Acids Ethyl Esters" and "The Trans-Esterification Process." The latter is the name for the alleged chemical process that forms the basis of Plaintiffs' claims that DHA and EPA extracted via the trans-esterification process may not be called "fish oil."

3. Ethyl Esters and Trans-Esterification

Triglycerides are formed by fatty acids (such as DHA and EPA) that, as a matter of chemistry, are bound to a glycerol "backbone." This is a molecular "backbone," not the backbone of any fish. Unrefined fish oil contains triglycerides with varying amounts of DHA and EPA. In or around the 1980's, scientists developed a process known as "trans-esterification" as a method of freeing DHA and EPA from glycerol. Use of this process increases the concentration of DHA and EPA in fish oil. (Am. Compl. ¶ 50.) It also allows for manipulation of amounts of these OM3's. Specifically, trans-esterification involves removing the glycerol molecular "backbone" from DHA and EPA. The glycerol is removed by introduction of ethanol, which frees the EPA and DHA from the glycerol. In a subsequent process known as "molecular distillation," the mixture is heat distilled resulting in a "condensate omega-3 ethyl ester solution." (Id. ¶ 52; Science-based Health; McKay Article.)

Like its description of the wet reduction process, the Amended Complaint contains a flow chart describing the trans-esterification process:



While this process includes additional steps, it also starts with crude fish oil. Both the wet reduction process and the trans-esterification process include the steps of bleaching and deodorization. (Id. ¶ 52.) The trans-esterification process, however, adds the additional molecular step of separating fatty acids from glycerol. As noted, this process can yield a product with higher levels of EPA and DHA, and levels of these OM3's that can be separately manipulated. This allows for manufacture of a product containing more DHA and EPA, at a cheaper cost of production. (Id. ¶ 53.) It can also result in the production of an OM3 product with levels of DHA and EPA that may only be available via prescription. (MacKay Article.) Additionally, the trans-esterification process results in DHA and EPA free from mercury, which may remain present in DHA and EPA that were present in OM3's derived via the process used in the 1800's and today, via the wet reduction and other methods that leave the glycerol molecule intact.

4. Alleged Differences in the Forms of DHA/EPA Derived From Different Processes

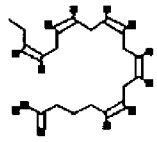
The Amended Complaint describes the DHA and EPA that are freed from the glycerol backbone through the trans-esterification process as "ethyl ester" DHA and EPA –

or, as described by Plaintiffs, as "DHA-EE" and "EPA-EE." The literature notes that there are, indeed, different molecular level forms of DHA and EPA that are derived by the different methods used to process and purify raw crude fish oil into supplements. Plaintiffs argue that the only forms of DHA and EPA that may lawfully bear the "fish oil" name are those derived by a process that does not involve removal of the glycerol backbone of the molecule, which they refer to as DHA/EPA "triglycerides" or DHA/EPA-"G."

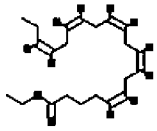
The Court's review of the reference material contained in the Amended Complaint reveals the limited scientific use of the addition of the "EE" to the terms DHA and EPA to identify ethyl esters. However, these distinctions appear either as background information (noting that most fish oil products on the market use the ethyl ester form), in connection with the claim that DHA/EPA derived via trans-esterification allows for products with higher levels of these OM3's, or in a study evaluating whether one offers more health benefits than the other (no conclusive study shows, by the way, any such difference). (Id. n.17 (NIH Omega-3 Fatty Acids Fact Sheet for Health Professionals (hereinafter "NIH Professional Fact Sheet") (discussing dietary supplements and stating that there is no scientific question but that "consumption of all forms [of DHA/EPA] significantly increase plasma" EPA and DHA)) (emphasis added).

Despite the fact that the scientific literature relied upon in the Amended Complaint makes no distinctions between the forms of DHA/EPA as to efficacy, Plaintiffs properly plead that there are, indeed, molecular differences between these forms. Thus, the MacKay Article notes that while there were hundreds of fish oil supplements available, these supplements were made up of "two distinctly different molecular forms of fish oil supplements; one containing "synthetic" ethyl esters and one containing "natural" triglycerides." (MacKay Article) (emphasis added).

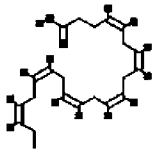
Plaintiffs' claims regarding molecular differences is also supported by an image of side by side molecular structures of DHA and EPA, which concludes that the molecules are "distinct in every regard," noting that "they have different molecular weights, chemical structures, physical properties and common/usual names." (Am. Compl. ¶ 57.)



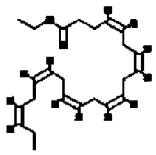
Chemical Structure of EPA



Chemical Structure of EPA-EE



Chemical Structure of DHA



Chemical Structure of DHA-EE

Discerning the differences among these chemical structures is challenging. However, given enough time, chemists and most observers would be able to see them.

After observing these molecular-level differences, the MacKay Article poses the question whether these two divergent "*delivery forms* of DHA and EPA produce a meaningful difference in the bioavailability of Omega-3's to the body." (MacKay Article) (emphasis added). MacKay concludes that it is "difficult to establish conclusively their relative bioavailability" and that early "small trials revealed that DHA and EPA from ethyl esters are well absorbed when compared to triglycerides." (Id.) McKay notes, after reviewing inconclusive studies, and considering the fact that most DHA/EPA products are synthesized using the ethyl ester process, that he finds no difference between the use of the two forms of OM3's as supplements. Indeed, McKay goes on to state that "most consumers and health care professionals are unaware that there are two different delivery forms of these valuable nutrients." (Id.) (emphasis added).

Ultimately, no scientific literature annexed to the Amended Complaint takes the position that one form of DHA/EPA is superior to the other from a health perspective (except for the possible presence of mercury in the triglyceride form). Indeed, the Court has reviewed all of the scientific materials referenced in the Amended Complaint and states confidently that neither the Amended Complaint nor any document referenced therein makes any claim that one form of fish oil (triglyceride or ethyl ester) is superior to the other as to an association with health benefits.

5. References to USP Mass Spectra Monograph

The Product is USP certified. Plaintiffs do not argue otherwise. However, in paragraphs 58-60 of the Amended Complaint, Plaintiffs refer to USP standards and to a USP monograph. Plaintiffs allege that the USP monograph lends further support to their molecular difference claims. Thus, they state that the monograph demonstrates that the different molecules (EPA/DHA (G and EE)) each have "a unique mass to charge ratio (m/z)." (Am. Compl. ¶ 60.) Plaintiffs support these claims with a "mass spectrograph" appearing at page twenty-one of their

Amended Complaint. Plaintiffs' graph of molecular mass spectra makes their previously discussed flow charts and chemical structure models look downright simple. However, for purposes of this motion, it is necessary only that the Court accept this material as further support for Plaintiffs' claims as to the molecular differences previously discussed.

6. CODEX and Tariff Documents

Plaintiffs refer and rely upon the Codex, GOED and CBP tariff documents in support of their factual allegations. Codex standards are voluntary and are used by the WTO as a benchmark for global trade disputes. (Id. ¶ 62.) Section 2.2 of the Codex standards defines "fish oils" as "those derived from one or more species of fish or shellfish." Section 2.6 of that document defines "concentrated fish oils ethyl esters" as those derived from fish oils composed primarily of fatty acids ethyl esters. (Id. ¶ 62 n.37.)

GOED is a trade group stated to be "the largest and most significant trade group" of the OM3 industry. A voluntary monograph of that industry is stated to refer to such OM3's by a series of different names, including "refined EPA and/or DHA Omega-3 Oils triglycerides, EPA and/or DHA Omega-3 Oils Ethyl-Ester Concentrates, EPA and/or DHA Omega-3 Triglycerides Concentrates, Tuna Oil, Salmon Oil and Anchovy Oil." Plaintiffs argue that these trade organization references are further confirmation that "fish oil is not synonymous with fatty acid ethyl esters and cannot be so named." (Id. ¶ 66.)

Finally, in support of Plaintiffs' claims as to the alleged clear differences between EPA/DHA as triglycerides and DHA/EPA as fatty acid ethyl esters, the Amended Complaint relies on a 2011 CBP tariff decision as to the proper duty rate to be applied to the importation of fish oil ethyl ester capsules. (Id. ¶ 70.)

III. Plaintiffs' Causes of Action: The Amended Complaint

The Amended Complaint sets forth nine state law claims under the common and statutory laws of the States of New York and California. Plaintiffs seek certification of sub-classes and relief in the forms of disgorgement of profits, compensatory, statutory and punitive damages. They also seek injunctive relief, costs and attorney's fees. (See generally id. ¶¶115-187; Prayer for Relief.)

Given the detailed scientific information discussed above, it comes as no surprise that all claims are based upon molecular differences observable in products derived from different methods for the processing of fish oil. It is equally unsurprising that Plaintiffs nowhere argue that Defendants make false claims about the health benefits of their Supplement. Any such claim is directly contradicted by Plaintiffs' many reference materials. Further, Plaintiffs have no quarrel with use of the name "fish oil" in connection with the marketing of omega-3 fatty acid DHA and EPA products derived using the wet reduction process (which OM3's they variously refer to as EPA and DHA with the addition of the letter "G" for triglyceride). It is just the OM3's derived via the trans-esterification process that Plaintiffs state may not lawfully bear the name "fish oil." Thus, Plaintiffs frame their argument for falsity as follows:

> Ultimately, once trans-esterified, fish oil is substantially and irrevocably transformed into an Omega-3 fatty acid ethyl ester – a [ ] that cannot be found in any part of a fish. Calling it "fish oil," therefore, is fraudulent, deceptive and misleading.

(Id. ¶ 55.)

The blank space above does not appear in the Amended Complaint – it is supplied by the Court because the sentence, as it appears in Paragraph 55 of the Amended Complaint, is not a full sentence. (Id. ¶ 55.) It is possible the existence of a partial sentence appears intentionally for dramatic effect, but that is not at all clear. The Court reasonably presumes that the blank space is

a typographical error, and given the opportunity to fill the blank, Plaintiffs would insert a word such as "substance" or "molecule." The Court will construe the sentence as such and presume that, given the overall gist of the Amended Complaint, Plaintiffs are alleging that once trans-esterified fish oil is transformed into fatty acid ethyl esters, which are not natural and/or the same as the molecules derived from a different process. Thus, Plaintiffs' case turns on the argument that the freeing of fatty acids from the glycerol backbone of the OM3 molecule transforms the Product away from "fish oil" into "omega-3 fatty acid ethyl esters," which they define as "fish oil and omega-3 fatty acid ethyl esters." (Id. ¶ 56.) The Product is stated to have been transformed from something that can commonly be called "fish oil" into a substance with a different "common or usual name," presumably an "omega-3 fatty acid ethyl ester." (Id.) All of Plaintiffs' claims turn on acceptance of this molecular distinction.[2]

IV. The Motion to Dismiss

Defendants move, pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), to dismiss the Amended Complaint in its entirety. First, Defendants argue that Plaintiffs' claims are completely preempted by Federal Law, which forecloses application of any state labeling requirement that is "not identical" to federal labeling requirements. They argue that since Federal law requires that dietary supplements be labeled according to their "common" or "usual" name,

[2] This case is not the only one commenced by Plaintiffs' counsel alleging that the use of the term "fish oil" is false and misleading. A case alleging the same theory was commenced by Plaintiffs' counsel in the United States District Court for the Central District of California. See Gatto v. Int'l Vitamin Corp., No. 21-889 (JLS-DFM). That case, recently dismissed without prejudice on grounds not applicable here, was also styled as a class action brought on behalf of members of putative New York and California sub-classes. The New York plaintiff in that case resided in Massapequa, New York, which is in the Eastern District of New York, while the New York Plaintiff here also resides in New York, but in a different District.

which in this case is unquestionably "fish oil," any application of state law requiring something different is preempted.

Defendants also argue that their labeling of the Product is not misleading as a matter of law. According to Defendants, no reasonable consumer could make a distinction between fish oil derived from a mechanical or chemical process. Moreover, to the extent any consumer was aware of any such difference, the label for the Product does in fact disclose that the OM3's contained therein are derived as ethyl esters. Plaintiffs oppose the motion in its entirety.

Having explained Plaintiffs' claims and the motion, the Court turns to the merits of the present motion to dismiss.

DISCUSSION

I. Legal Principles

A. Standards on Defendants' Rule 12 Motions to Dismiss

Defendants move to dismiss, pursuant to Rules 12(b)(1) and 12(b)(6), the Amended Complaint in its entirety. The standards that apply to their Rule 12(b)(1) motion are not distinguishable in this case from their Rule 12(b)(6) motion. No party argues otherwise.

To survive a Rule 12(b)(6) motion to dismiss, a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678-79 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)); see also Arista Records, LLC v. Doe 3, 604 F.3d 110, 119-20 (2d Cir. 2010). Facial plausibility is established by pleading factual content sufficient to allow a court to reasonably infer the defendant's liability. Twombly, 550 U.S. at 556. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. at 555. Nor is a pleading that offers nothing more than "labels and conclusions" or "a formulaic recitation of the

elements of a cause of action," sufficient. Iqbal, 556 U.S. at 678 (2009) (quoting Twombly, 550 U.S. at 555). As required in the context of this motion to dismiss, the factual allegations in the Complaint, though disputed by Defendants, are accepted to be true for purposes of this motion, and all reasonable inferences are drawn therefrom in favor of the Plaintiff.

B. Materials Considered

1. Footnote References

While facts to consider in the context of a Rule 12 motion are generally limited to those set forth in the pleadings, a court may consider matters outside of the pleadings under certain circumstances. Specifically, in the context of a Rule 12(b)(6) motion, a court may consider: (1) documents attached to the complaint as exhibits or incorporated by reference therein; (2) matters of which judicial notice may be taken; or (3) documents upon the terms and effect of which the complaint "relies heavily" and which are, thus, rendered "integral" to the complaint. Chambers v. Time Warner, Inc., 282 F.3d 147, 152-53 (2d Cir. 2002); see also International Audiotext Network, Inc. v. American Tel. and Tel. Co., 62 F.3d 69, 72 (2d Cir. 1995).

Here, the Amended Complaint references numerous documents in the footnotes therein. These materials are integral to the facts pled in support of Plaintiffs' claims and are, therefore, properly considered. See Daniel v. Mondelez Int'l. Inc., 287 F. Supp. 3d 177, 183 (E.D.N.Y. 2018). While the footnotes contained in the Amended Complaint refer to hundreds of pages of materials, these materials are not separately filed on the docket. Nor are they filed so that they can be accessed by direct link to the Amended Complaint. While the reader can (sometimes) access the entirety of each reference by separately searching the internet, this access is insufficient to provide the ease of access required of Court documents. Nor does such access

ensure that the reader is evaluating the precise document upon which Plaintiffs rely – or what the document looked like on the date it was viewed. Therefore, to evaluate the merits of the present motion, this Court has required Plaintiffs to provide courtesy copies of all such documents. See Order of Shields, M.J., dated Nov. 2, 2022. Each referenced document will be considered in its entirety in connection with the motion. In addition, to ensure ease of public access to each document referenced in the footnotes to the Amended Complaint, the Court hereby requires that Plaintiffs file each such document, in full, on the docket herein within one week of the date of this Report and Recommendation.

2. Materials as to Which Judicial Notice is Taken

Defendants have also moved, separately, to have this Court take judicial notice as to certain material for consideration in connection with this motion. (DE [26].) That motion seeks to have the Court consider images of product labeling appearing in the Amended Complaint, images of product labels from publicly available websites, and the FDA's Food Labeling Guide, available at the agency's website. Like the motion to dismiss, the motion for judicial notice, was made on February 7, 2022. It was administratively terminated by the District Court in an Order dated September 30, 2022. The District Court stated that it would rule upon that motion together with Defendants' motion to dismiss. See Order of Seybert, J., dated Sept. 30, 2022. The October 31, 2022 referral of the pending motion to dismiss also referred Defendants' motion requesting judicial notice. See Order of Seybert, J., dated Oct. 31, 2022.

Plaintiffs have not responded to the judicial notice motion at all – either in a separate Memorandum of Law addressed to the motion, or in their Memorandum of Law submitted in opposition to Defendants' motion to dismiss. As to the latter, a review of the table of contents therein reveals no reference to any case referred to in the motion for judicial notice. (DE [27] at

ii-vi.) In view of the foregoing, the Court recommends that the motion for judicial notice be granted to the extent that it refers to any such document herein, as both unopposed and on the merits. The Court's references to these materials is limited and not, standing alone, dispositive of the motion. Nonetheless, the Court recommends granting the motion for judicial notice as to the entirety of the label for the Product (Defendants' Request for Judicial Notice, Exh. A and C (DE [26-1], [26-3]) and to a publicly available statement on the FDA website providing labeling guidance regarding the use of scientific names to describe ingredients (Defendants' Request for Judicial Notice, Ex. D (DE [26-4]). The label appears as a website printout and is obviously proper to consider in light of the fact that its alleged falsity forms the basis of each and every claim. See Sola Franchise Corp. v. Solo Salon Studios, Inc., No. 14-CV-0946, 2015 WL 1299259, at *19 (E.D.N.Y. 2015) (taking judicial notice of material appearing on website). Judicial notice is also undoubtedly proper as to statements contained in FDA labeling guidance. See Richardson v. New York City Bd. of Educ., 711 F. App'x 11, 14 (2d Cir. 2017); In re Zyprexa Prods. Liab. Litig., 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008) (holding that public documents issued by government agencies such as the FDA may be judicially noticed). The Court has not referred to nor relied on the other document for which judicial notice is sought. (DE [26-2].) Therefore, it need not report and recommend as to whether that label is subject to judicial notice for the purpose of this motion to dismiss.

3. Alleged Violation of The District Court's Page Limitations

The Court makes clear that it has considered all pages of the parties' Memoranda of Law. Defendants seek to have the Court ignore the last three pages of Plaintiffs' opposition brief. Relying on the Individual Rules of the referring District Court (which limit opposition briefs "to 25 pages" "double spaced (no more than 23 lines/page")), they note that

Plaintiffs' opposition has "26 lines per page, netting an extra three pages (75 extra lines over 25 pages)." (DE [28] n.1.) While this appears to be true, Defendants should not be so quick to crow about their adherence to page limits. Their ten-page reply brief includes six single-spaced tiny-font footnotes containing significant legal argument. The inclusion of this material in the body of the Memorandum of Law would likely have doubled the size of the reply brief. This is equally true of Plaintiffs' opposition brief, which includes seventeen single-spaced footnotes which likewise contain significant legal argument. The parties' copious use of substantive footnotes clearly violates the spirit (if not always the letter) of Court-imposed page limitations.

Perhaps, if the parties had more time, they could have made their submissions shorter. In any event, this Court has considered all pages and all footnotes contained in all motion papers submitted in support of and in opposition to the referred motions.

DISCUSSION

I. Preemption

A. Legal Principles

The Federal Food Drug and Cosmetic Act (the "FDCA") forbids the misbranding of foods and supplements by way of false or misleading labeling. See POM Wonderful, LLC v. Coca-Cola Co., 573 U.S. 102, 106 (2014). The Nutrition Labeling and Education Action (the "NLEA") amends the FDCA to impose particular labeling requirements. It also contains a preemption clause that prohibits any state or political subdivision from imposing any labeling requirement "that is not identical to" those imposed by the NLEA. See 21 U.S.C. §343-1(a)(5). Preempted state-imposed labeling requirements include "any statute, standard, regulation, or other requirement that is issued by a State." 21 C.F.R. §100.1(b)(5). This preemption provision also broadly includes common law duties. See Ackerman v. Coca-Cola, CV 09-0935, 2010 WL

2925955, at * 6 (E.D.N.Y. 2010). In the context of the NLEA, "not identical" means any requirement that directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food that differ "from those specifically imposed by or contained in the applicable [federal regulation]." 21 C.F.R. §100.1(c)(4); see, e.g., Brod v. Sioux Honey Ass'n Co-op., 895 F. Supp. 2d 975, 981 (N.D. Ca. 2012).

NLEA preemption does not foreclose any and all state law claims alleging false advertising or labeling. Thus, a plaintiff may pursue claims "to impose state-law requirements that are identical to those imposed by the FDCA or state-law requirements that are not related to areas already covered by the FDCA or federal regulation." Chong v. Nestle Waters N. Am., Inc., CV 19-10901, 2020 WL 7690175, at * 3 (C.D. Ca. Nov. 30, 2020). Where, however, a plaintiff seeks to require labeling that is not identical to that required by federal law, any such claim is expressly and clearly preempted. See Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008).

The NLEA regulation relevant here requires that a "statement of identity" appear on a packaging's principal display panel. 21 CF.R. §101.3(a). That "statement of identity" must be set forth in terms of:

> (1) The name . . . specified . . . or required by any applicable Federal law or regulation; or, in the absence thereof,
>
> (2) The common or usual name of the food; or, in the absence thereof,
>
> (3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

21 CF.R. §101.3(a) (emphasis added).

Here, the parties agree that there is no name for the Product that is specified or required by Federal law or regulation, which would trigger application of 21 CF.R. §101.3(b)(1). Thus,

the Product must bear its "common or usual name," 21 CF.R. §101.3(b)(2), if such common or usual name exists.

As to such "common or usual" names, the relevant Federal regulation provides that:

> (a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name.

21 C.F.R. §102.5(a) (emphasis added). Additionally, a "common or usual" name "may be established by common usage." 21 C.F.R. §102.5(d).

B. Preemption Analysis

Turning to application of the preemption analysis, the first issue is whether the common name required by the NLEA is, as Defendants argue, "fish oil." If it is, and Plaintiffs seek to prohibit the use of this name, their claims, however denominated, would amount to a request for non-identical labeling and would be preempted. In making the latter determination, it is important for the Court to state exactly what Plaintiffs' claims are, and what they are not. This allows the Court to decide whether Plaintiffs seek to impose labeling that is "not identical" to the name required by the NLEA. But first, the Court must decide whether the Product's common name is fish oil. It undoubtedly is.

1. The Common Name of the Product is Fish Oil

The Product is a supplement processed from the oil of fish. As such, common sense dictates that it should be called fish oil. The Court's holding as to this common name is supported not only by a common sense reading of the facts set forth in the Amended Complaint, but also by the fact pleaded therein. Thus, "fish oil" is the name used in nearly every reference set forth therein. To be sure, many reference materials support Plaintiffs' scientific

explanation regarding molecular differences between different forms of DHA/EPA. All agree that such differences exist. Such differences are described as differences in "delivery forms" not as different end products. See MacKay Article at 1. A close review of each of Plaintiffs' references also demonstrates that, with the exception of references that refer only generally to DHA and EPA, everyone refers to all OM3 DHA/EPA products – however derived – as "fish oil" or fish oil supplements. The Court's reference to "everyone" includes the FDA, the NIH, MacKay, Bimbo, other scientists referred to in the Amended Complaint, trade organizations and taxing authorities – they all use the term fish oil. See McKay Article at 1; Science Based Health; Bimbo Article; Breivik Article. While some of these scientific reference materials speak to molecular-level differences, none rely on these differences to describe a "common name" for an Omega 3 supplement as anything other than fish oil. Indeed, the Court cannot locate a single reference that uses the term ethyl ester (or any of the possible name combinations discussed below) in connection with discussion of a supplement, without also using the common name "fish oil." Even the trade-related documents (which the Court holds are of limited relevance to the issue of a common name addressed to consumers), use the term "fish oil" when describing OM3 supplements. While some documents use the term ethyl ester, even those documents also use the term fish oil. In sum, all of the documents relied upon by Plaintiffs, and reviewed by the Court, uniformly support a holding that all DHA/EPA supplements – however derived from the original crude fish oil – are properly referred to as fish oil. No issue of fact is raised to the contrary.

The Court further notes that while Plaintiffs argue against the use of "fish oil" to describe the Product, they do not really offer a more "common or usual" alternative. Thus, they fail to show the common usage of any name other than fish oil, as set forth in 21 C.F.R. §102.5(a). It

seems that Plaintiffs would have the product labeled as "DHA-EE and EPA-EE" or as "omega-3 fatty acid ethyl ester" or as "Omega-3 FAEE," or as "Omega-3 EPA-EE and DHA-EE" or perhaps just as "FAEE." But they cite to no product on the market bearing such names, and there are no less common names imaginable for the Product. Acceptance of Plaintiffs' argument – even beyond the pleading stage – would require this Court to order the opposite of what the NLEA requires – substitution of a product's common name by a confusing description of its molecular structure.

Despite their detailed scientific pleading – complete with sophisticated articles, flow charts, chemical structure pictures and complicated graphs, Plaintiffs fail to raise an issue of fact as to the common or usual name for the Product. That name is, without question, fish oil. The minutiae of scientific articles discussing molecules does not change that. If it did, the FDA would not state, as it does, that marketers are to avoid the use of an ingredient's chemical name instead of its common name. Instead, it would advise that labels include information regarding molecular structure. Thus, for example, the FDA's food labeling guide advises the use of the common term "sugar" instead of the scientific name "sucrose." https://www.fda.gov/files/food/published/Food-Labeling-Guide-%28PDF%29.pdf (Defendants' Request for Judicial Notice, Ex. D, DE [26-4]). Where, as here, there is no claim that molecular differences matter, such information would not be helpful to consumers. It is therefore not surprising that no such information is required.

Finally, the Court recognizes that other courts have rejected similar "common name" arguments, holding that that that any such requirement is preempted. Thus, in Regan v. Sioux Honey, 921 F. Supp. 2d 938, 943-44 (E.D. Wisc. 2013), the Court held that preemption applied where state law would prohibit a product to be labeled by its common or usual name, which was

undoubtedly "honey." Accord Brod, 895 F. Supp. 2d at 981(finding that the product's common or usual name is simply "honey" even though it has been filtered to contain no pollen); Birmingham v. Walgreen Co., 12-60922-Civ, 2014 WL 12479929, at *2-3 (S.D. Fla. Jan. 3, 2014).

Similarly, in Branca v. Bai Brands, LLC, 3:18-cv-00757, 2019 WL 1082562, at *5 (S.D. Ca. Mar. 7, 2019), the court rejected plaintiff's attempt to draw a distinction in labeling based upon a difference observable only on a molecular level. Thus, it rejected the argument that the common name for "malic acid" must reflect a particular isomer thereof known as "d-1 malic acid." Instead, the court held that the "common and usual name" of the ingredient is "malic acid" rather than the "scientific name of 'd-1 malic acid.'" Id.

2. Plaintiffs Seek To Require Labeling That is Not Identical to NLEA Labeling

Plaintiffs' claims, however denominated, are clear. They seek to bar Defendants from the use of the term "fish oil" to describe the Product. This would require Defendants to call the Product something other than fish oil. To be clear, Plaintiffs single out DHA/EPA OM3's that are derived via the esterification process as those that may not lawfully bear the common name "fish oil." The narrow nature of Plaintiffs' claim is clear. They steer away from making the argument that one form of DHA/EPA is "healthier" than the other. Plaintiffs are also careful not to extend their argument to include the claim that no supplement on the market may use the common name "fish oil." The Amended Complaint states clearly that Plaintiffs believed the Product "was actual fish oil containing DHA and EPA." (Am. Compl. ¶ 17 (Baines), ¶ 26 (Froning).) Thus, they would not be confused as to the nature of such a product. Plaintiffs are comfortable with other supplements that contain EPA and DHA using "fish oil" as their common or usual name. Plaintiffs single out as falsely labeled only those

products (including Defendants') that derive their fish oil through a particular process. All of Plaintiffs' claims turn on the fact that there is a molecular difference between the DHA/EPA that are derived by freeing of the glycerol molecule, and the DHA/EPA that are derived via processes that do not free fatty acids from glycerol. The latter may bear the common name moniker "fish oil;" the former may not. Further, according to Plaintiffs, the former (including Defendants' Product) has no "common or usual name," and even if such name exists, it cannot be "fish oil."

The Court's holding is that the common name of the Product, and all OM3 supplements – however derived from fish oil – are required to bear the common name fish oil. This holding, taken together with the unquestionable nature of Plaintiffs' claim, i.e., they seek to prohibit the use of this name for certain OM3 supplements, leads to the conclusion that they seek to impose a labeling requirement that is "not identical" to Federal law. As such, their claims are preempted. Even if Plaintiffs' claims were not preempted, they are all implausible and should be dismissed.

II. Plaintiffs Also Fail to State a Plausible Claim Under Any State Law

A. Consumer Protection Laws of California and New York

Plaintiffs bring their claims under the state laws of California and New York. This Court's preemption analysis disposes of all such claims. Even if it did not, Plaintiffs would nonetheless fail to state any claim. This is true whether their claims arise under California or New York statutory or common laws.

Plaintiff's putative California sub-class seeks relief pursuant to three different California statutes. All are governed by a "reasonable consumer" test, requiring a showing that "members of the public are likely to be deceived." Branca, 2019 WL 1082562, at * 9. This standard requires a probability "that a significant portion of the general consuming public or of targeted consumers, acting reasonably under the circumstances, could be misled." Id. (citation omitted).

More specifically, Plaintiffs must plausibly allege "more than a mere possibility that the advertisement might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner." Id.

Plaintiffs' putative New York sub-class seeks statutory relief pursuant to Sections 349 and 350 of the General Business Law. The standards applicable to these claims are substantially similar to the California claims. Thus, Section 349 prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." N.Y. Gen. Bus. Law § 349. Section 350 similarly prohibits "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state." N.Y. Gen. Bus. Law § 350.

To assert a claim under either Section 349 or 350, "'a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) they suffered injury as a result of the allegedly deceptive act or practice.'" Nguyen v. Algenist LLC, 22 Civ. 13, 2022 WL 17251733, at * 5 (S.D.N.Y. Nov. 28, 2022) (quoting Orlander v. Staples, Inc., 802 F.3d 289, 300 (2d Cir. 2015)) (additional citation omitted). The alleged deceptive act be a representation or an omission. See Nguyen, 2022 WL 17251733, at *5. The deception alleged "need not reach the level of common-law fraud to be actionable," and therefore "deceptive business practice and false advertising claims are not subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b)." Id. (citations omitted); see also Cooper v. Anheuser-Busch, LLC, 663 F. Supp. 3d 83, 93-94 (S.D.N.Y. 2021).

While factual allegations need not be pleaded in accord with the requirements of Rule 9(b), a material misrepresentation actionable under Sections 349 and 350 must be plausibly alleged as one that is "likely to mislead a reasonable consumer acting reasonably under the

circumstances." Cohen v. JP Morgan Chase & Co., 498 F.3d 111, 126 (2d Cir. 2007) (quoting Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A., 85 N.Y.2d 20, 26 (1995)); see also Orlander, 802 F.3d at 300. When considering this issue, courts consider the allegedly misleading statement in light of the context and the entirety of the label and/or advertising. See Belfiore v. Procter & Gamble Co., 311 F.R.D. 29, 53 (E.D.N.Y. 2015); Koenig v. Boulder Brands, Inc., 995 F. Supp. 2d 274, 288 (S.D.N.Y. 2014); Ackerman v. Coca-Cola, 2010 WL 2925955, at *15. Ultimately, the question is whether "a reasonable consumer in like circumstances would consider the misrepresentation material." Daniel, 287 F. Supp. 3d at 189-90.

It is clear that whatever sub-class Plaintiffs seek to represent, their claims require a showing that reasonable consumers would be misled by labeling of the Product as fish oil. The Court holds, as a matter of law, that they would not. First, there is no falsity in calling the Product fish oil. Any such claim of falsity is implausible and therefore subject to disposition in connection with this motion to dismiss. As discussed above and in detail, in Plaintiffs' pleading, their clams rise and fall on the notion that consumers would be misled by a difference observable only on a molecular level. It is implausible to believe that any consumer shopping for a fish oil supplement seeks only DHA/EPA with an intact glycerol backbone molecule. Moreover, even if such a consumer did exist – and the Court is unconvinced that any such person does – that consumer would see that the Product bears the common name of fish oil, and also discloses that the OM3's therein are ethyl esters. Under these circumstances there can be no plausible claim that any reasonable consumer is misled. See Nguyen, 2022 WL 17251733, at *7 (noting that even if a consumer could be misled, clarifying information existed in packaging information as a whole).

Plaintiffs argue that the issue of reasonability presents a question of fact. However, this is not always the case, and a defendant should not be made to go to the expense of litigating patently implausible claims through discovery and the inevitable motion for summary judgment. "It is well settled that a court may determine as a matter of law that an allegedly deceptive advertisement [or label] would not have misled a reasonable consumer." Kennedy v. Mondelez Global LLC, 19-CV-302, 2020 WL 4006197, at *9 (E.D.N.Y. July 10, 2020) (quoting Fink v. TimeWarner Cable, 714 F.3d 739, 741 (2d Cir. 2013)). "The standard is an objective one: 'Plaintiffs must plausibly allege that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled.'" Kennedy, 2020 WL 4006197, at *11-12 (quoting Jessani v. Monini N. Am., Inc., 744 F. App'x 18, 19 (2d Cir. 2018) (quotations omitted).

Courts have not hesitated to dismiss patently implausible false advertising claims on motions to dismiss. See, e.g., Nguyen, 2022 WL 17251733, at * 5; Kennedy, 2020 WL 4006197, at *11-12 (finding that terms "made with real honey," "Honey Maid," and "no high fructose corn syrup" did not misleadingly suggest that honey was the "exclusive or predominant sweetener"); Devane v. L'Oréal USA, Inc., No. 19-CV-4362, 2020 WL 5518484, at *1, 4-5 (S.D.N.Y. Sept. 14, 2020) (holding that a label that described a hair-care product as "100% Vegan" and "Keratin Caring" did not misleadingly suggest that the product itself contained keratin); Kommer v. Bayer Consumer Health, 252 F. Supp. 3d 304, 306, 311 (S.D.N.Y. 2017) (dismissing a claim that a "Foot Mapping Kiosk" misleads consumers into believing they are having custom orthotics designed for their feet), aff'd, 710 F. App'x 43 (2d Cir. 2018) (summary order); In re Frito-Lay N. Am., Inc. All Nat. Litig., No. 12-MD-2413, 2013 WL 4647512, at *16 (E.D.N.Y. Aug. 29,

2013) (observing that dismissal as a matter of law is appropriate where a plaintiff's allegations regarding deceptive labeling "border on fantasy").

While some cases present issues of fact as to falsity and reasonable interpretation by the reasonable consumer, this case falls squarely in the camp of those that do not. Here, Plaintiffs' claims are even less plausible than those dismissed in the cases described above. If it has not already been made clear, the Court states clearly here that there is nothing false about labeling the Product as fish oil. Describing the Product this way denotes nothing more than a statement of fact that the OM3's therein are derived from fish oil. It says nothing about the process by which crude fish oil makes its way to the OM3's found in each capsule. Plaintiffs do not, and cannot, argue that other supplements containing OM3'S derived from fish oil are properly named only if they are derived via a different process. All such products get their OM3's from fish oil. To suggest that molecular differences between such products make a difference to a reasonable consumer is plainly implausible. Thus, all claims alleging that a reasonable consumer would think otherwise are implausible and lacking completely in merit.

All of Plaintiffs' alleged statutory consumer protection claims, whether alleged pursuant to the laws of the States of New York or California, should be dismissed.

B. All Other Claims

Dismissal of Plaintiffs' claims on the grounds set forth above disposes of any and all of Plaintiffs' claims, whether arising under statutory or common law. To the extent the Court has not discussed common law claims, it makes clear now that all such claims are implausible and should be dismissed. See Wallace v. Wise Foods, Inc., 20-CV-6831, 2021 WL 3163599, at *3 (S.D.N.Y. July 26, 2021) (holding that dismissal false labeling claims as implausible requires dismissal of express warranty and unjust enrichment claims); Forouzesh v. Starbucks Corp., CV

16-3830, 2016 WL 4443203, at *4 (C.D. Cal. Aug. 19, 2015), aff'd, 714 F. App'x 776 (9th Cir. 2018) (finding same result applying California law); see also Nelson v. MillerCoors, LLC, 246 F. Supp. 3d 666, 679 (E.D.N.Y. 2017) (dismissing quasi-contract claim as duplicative of other dismissed alleged consumer deception claims); Ebin v. Kangadis Foods, Inc., 13 Civ. 2311, 2013 WL 6504547, at * 7 (S.D.N.Y. Dec. 11, 2013) (same). Indeed, Plaintiffs concur that this is the law, i.e., if their false labeling claims fail, so too do their state law claims for breach of warranty. (DE [27] at 10.)

Finally, even if Plaintiffs' claims had merit, they lack Article III standing to bring any claim for injunctive relief. Past purchasers, such as Plaintiffs here, cannot plausibly allege any future harm that could be redressed by a grant of injunctive relief. Pleading a possible future purchase based upon new labeling does not change this result. See Berni v. Barilla S.p.A., 964 F.3d 141, 147 (2d Cir. 2020); Barreto v. Westbrae Natural, Inc., 518 F. Supp. 3d 795, 809 (S.D.N.Y. 2021); Ashour v. Ariz. Beverages USA LLC, 19 Civ. 7081, 2020 WL 5603382, at * 4 (S.D.N.Y. Sept. 18, 2020).

RECOMMENDATION

For the foregoing reasons, the Court respectfully recommends that Defendants' motion for judicial notice be granted to the extent set forth above. The Court further respectfully recommends that Defendants' motion to dismiss be granted. While Plaintiffs have not sought leave to amend, the Court additionally recommends that any such request be denied as futile.

Finally, as set forth above, to ensure ease of public access to each document referenced in the footnotes to the Amended Complaint, the Court hereby orders Plaintiffs to file each such document, in full, on the docket herein within one week of the date of this Report and Recommendation.

OBJECTIONS

A copy of this Report and Recommendation is being provided to all counsel via ECF. Any written objections to this Report and Recommendation must be filed with the Clerk of the Court within fourteen (14) days of filing of this report. 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 6(a), 72(b). Any requests for an extension of time for filing objections must be directed to the District Judge assigned to this action prior to the expiration of the fourteen (14) day period for filing objections. Failure to file objections within fourteen (14) days will preclude further review of this report and recommendation either by the District Court or Court of Appeals. Thomas v. Arn, 474 U.S. 140, 145 (1985) ("[A] party shall file objections with the district court or else waive right to appeal."); Caidor v. Onondaga Cnty., 517 F.3d 601, 604 (2d Cir. 2008) ("[F]ailure to object timely to a magistrate's report operates as a waiver of any further judicial review of the magistrate's decision").

SO ORDERED.

Dated: Central Islip, New York
January 3, 2023

/s/ Anne. Y. Shields
ANNE Y. SHIELDS
United States Magistrate Judge

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------X
MASHON BAINES and NANCIE FRONING
on behalf of themselves and all
others similarly situated,

Plaintiffs,

-against-

NATURE'S BOUNTY (NY) INC. and
THE BOUNTIFUL COMPANY (NY),

Defendants.
----------X

ADOPTION ORDER
21-CV-5330(JS)(AYS)

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SEYBERT, District Judge:

Mashon Baines and Nancie Froning (together, the "Plaintiffs"), on behalf of themselves and others similarly situated, commenced this action against Nature's Bounty (NY), Inc. and The Bountiful Company (NY) (together, the "Defendants")

asserting state-law-based claims of false advertising.[1] At its essence, Plaintiffs' contention is that Defendants' subject Product[2] -- a dietary supplement -- is not fish oil as Defendants claim and represent it to be. (See generally Am. Compl., ECF No. 21.)

Defendants moved to dismiss Plaintiffs' Amended Complaint (hereafter, the "Dismissal Motion") (see ECF No. 25), which Plaintiffs opposed (see ECF No. 27). The Dismissal Motion, and Defendants' related motion requesting the Court take judicial notice of certain documents (hereafter, the "Judicial Notice Motion") (see ECF No. 26), were referred to Magistrate Judge Anne Y. Shields for a report and recommendation. Currently before the Court is the Magistrate Judge's January 3, 2023 Report and Recommendation ("R&R") (ECF No. 30) recommending the granting of Defendants' Judicial Notice and Dismissal Motions, together with Plaintiff's objections thereto (ECF No. 32), as well as Defendants' response (ECF No. 33). For the reasons stated herein, the Court ADOPTS the R&R in its entirety, and grants Defendants' Judicial Notice and Dismissal Motions.

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[1] As Magistrate Judge Anne Y. Shields states in her January 3, 2023 Report and Recommendation ("R&R"): "While all claims arise under state laws, federal jurisdiction is properly alleged pursuant to 28 U.S.C. § 1332(d)(2)." (R&R, ECF No. 30, at 2.)

[2] The terms of art defined in the R&R are adopted herein, familiarity with which is assumed.

BACKGROUND

I. Factual Background

The Court presumes the parties' familiarity with the factual background as set forth in Judge Shields' R&R and incorporates her recitation herein by reference. (See R&R at 3-21.) The Court recites only those facts necessary to resolve the instant motions.

Defendants' subject Product is a dietary supplement labeled Fish Oil, which includes, inter alia, a "USP Verified" mark. (See Am. Compl. ¶¶ 5, 6.) Defendants claim the Product contains "Eicosapentaenoic Acid ('EPA')" and "Docosahexaenoic Acid ('DHA')--the essential omega-3 fatty acids that naturally occur in fish." (Id. ¶ 5.) However, Plaintiffs' allege this claim is false and misleading: "Contrary to what is represented on the label, . . . this Product is not fish oil, nor does it contain a single milligram of EPA or DHA." (Id. ¶ 7.) As Plaintiffs further allege, that is because Defendants employ a chemical process known as trans-esterification to convert "low-grade oil derived from fish offal", or waste, "into a synthesized product that does not otherwise exist in fish." (Id. ¶ 8.) According to Plaintiffs, by this process, "the Omega-3s [in the fish oil], which include DHA and EPA, are converted into ethyl esters" which "are different molecules than the Omega-3s which exist naturally in fish oil" and that "[t]hese new chemical by-products are universally recognized

by their common or usual name—Fatty Acid Ethyl Esters ("FAEE")." (Id.; see also, e.g., id. at ¶ 71 ("[A]n omega-3 acid ethyl ester cannot be called fish oil. [Defendants'] Product is a fatty acid ethyl ester. Labeling and selling it as fish oil is false, misleading, deceptive and unlawful); ¶ 79 ("Fish Oil and Omega-3 Acid Ethyl Esters are not the same. They are different on a molecular level and have different common and usual names.").)

II. Judge Shields' Report & Recommendation

In preparing her R&R recommending Defendants' Dismissal Motion be granted, Judge Shields exhaustively reviewed the scientific and trade literature cited in the Amended Complaint. (See R&R at 5 ("While not every reference material [cited in the Amended Complaint] is discussed in this [R&R], the Court has been careful to read all of these materials in the light most favorable to Plaintiffs, without acting as an expert in scientific fields such as chemistry, or as to the business and taxation of the commercial fishing industry.").) Based upon those authorities, Judge Shields concluded that the common or usual name of the Product is "fish oil" consistent with federal labelling requirements. (See id. at 25-28.) As a result, Plaintiffs' state-law claims are preempted. (See id. at 28-29.) Similarly, finding the Product's label is neither false nor misleading, the Magistrate Judge found Plaintiffs' claims fail. (See id. at 29-33.) More particularly, Judge Shields found the type of EPA and DHA -- i.e.,

ethyl-ester versus triglyceride -- present in the Product is immaterial to reasonable consumers, and, even if it were material, the Product expressly discloses EPA and DHA are present in ethyl-ester form. (See id. at 31-33.) Finally, Judge Shields found Plaintiffs lack standing to pursue injunctive relief. (See id. at 34.)

DISCUSSION

I. Legal Standard

A district court "may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge." 28 U.S.C. § 636(b)(1)(C); see also FED. R. CIV. P. 72(b)(3). The district judge must evaluate proper objections de novo; however, where a party "makes only conclusory or general objections, or simply reiterates [the] original arguments, the Court reviews the Report and Recommendation only for clear error." Pall Corp. v. Entegris, Inc., 249 F.R.D. 48, 51 (E.D.N.Y. 2008) (quoting Barratt v. Joie, No. 96-CV-0324, 2002 WL 335014, at *1 (S.D.N.Y. Mar. 4, 2002)); see also FED. R. CIV. P. 72(b)(3); Thomas v. City of N.Y., Nos. 14-CV-7513, 16-CV-4224, 2019 WL 3491486, at *4 (E.D.N.Y. July 31, 2019) ("Objections seeking to relitigate arguments rejected by the magistrate judge do not constitute proper objections, and, as a result, are subject to clear error review."). Further, "[i]n this district and circuit, it is established law that a district judge will not consider new arguments raised in

objections to a magistrate judge's report and recommendation that could have been raised before the magistrate but were not." Trustees of Metal Polishers Local 8A-28A Funds v. Nu Look Inc., No. 18-CV-3816, 2020 WL 5793204, at *3 (E.D.N.Y. Sept. 29, 2020) (quoting Illis v. Artus, No. 06-CV-3077, 2009 WL 2730870, at *1 (E.D.N.Y. Aug. 28, 2009) (cleaned up; collecting cases)).

II. Analysis

A. Plaintiffs' Objections

Plaintiffs contend the Magistrate Judge erred by "misconstru[ing] the facts as alleged, and/or improperly substitut[ing] at this juncture her judgment for that of the reasonable consumer, producing in each case an erroneous finding of fact or law," to wit, that:

> • All claims are preempted because fish oil is the common name of the Product -- including the claim that the totality of the label (and not just the name) is deceptive ([R&R] at 25-29);
> • Chemical trans-esterification of fish oil is a minor and insignificant processing step ([id.] at 8-10, 17);
> • The use of ethyl esters in lieu of DHA and EPA is without import ([id.] at 12-15);
> • The Product is USP certified ([id.] at 15); and, critically,
> • None of the above attributes, characteristics, processes, and/or qualities, or lack thereof, either singularly or collectively, are material to a reasonable consumer making a purchasing decision, and therefore cannot be deceptive as a matter of law ([id.] 29- 33).

(Obj. at 3.) More specifically, Plaintiffs advance six objections.

First, as to the Magistrate Judge's finding that trans-esterification is insignificant and immaterial to consumers, Plaintiffs contend that, contrary to their allegations, Magistrate Judge Shields found "trans-esterification is simply another method for creation of fish oil," which leads to her "erroneous[] conclu[sions] that the transesterification process has no bearing on the fundamental nature of the Product as fish oil" and, thus, "Plaintiffs' claims to the contrary are preempted." (Obj. at 4.) It appears that Plaintiffs object to the Magistrate Judge's dismissal-as-immaterial of the molecular difference between fish oil and the Product because that finding is not consistent with their allegations that transesterification "is a distinctive and highly unnatural process that is material and that they would not have purchased the Product, or would have paid less for it, had they understood the true nature of the Product." (Id. at 5 (clarifying that they allege "they were misled by the label in its entirety, as well as singularly by its name").)

Second, Plaintiffs would assign error to Magistrate Judge Shields' finding, after "review of the reference material contained in the Amended Complaint," the "limited scientific use of the addition of the 'EE' to the terms DHA and EPA to identify ethyl esters." (Obj. at 6 (citing R&R at 13).) They contend the Magistrate Judge reached this erroneous conclusion in the face of

vast "scientific authority detailed in the body of the Complaint." (Id. (citing Am. Compl., ¶¶ 56-57, 59, 66, 67-71) (emphasis added).)

Third, Plaintiffs maintain it was error for the Magistrate Judge to find the "Product is USP certified. Plaintiffs do not argue otherwise." (Obj. at 7 (quoting R&R at 15).) That is because, while Plaintiffs acknowledge Defendants' claim that their Product is USP certified, "the [Amended] Complaint clearly alleges that such a representation is false and misleading." (Obj. at 7 (citing Am. Compl. ¶ 92).) Thus, Plaintiffs argue the Magistrate Judge "failed to heed black letter law on assessing a motion to dismiss," by not accepting as true the facts they allege in the Amended Complaint and considering those facts in the light most favorable to them. (Id.; see also id. at 8 ("[I]t is axiomatic that 'Rule 12(b)(6) does not countenance dismissals based on a judge's disbelief of a complaint's factual allegations.'" (quoting Twombly, 550 U.S. at 556)).)

Fourth, Plaintiffs assert Magistrate Judge Shields erred in finding the common or usual name for the Product is fish oil and that their "allegations that the Product is deceptively named or labeled in its entirety, is preempted." (Obj. at 8 (citing R&R at 26 (emphasis in original)).) Plaintiffs present two bases for this objection: (1) the Magistrate Judge's finding clashes with their allegations in the Amended Complaint "and the fact that there

are a wide variety of marine-based Omega-3 offerings which are properly labeled as 'Omega,' not as fish oil" (id. (footnote omitted)); and (2) the assertion that the Magistrate Judge "ignores the monographs and respective naming conventions used by multiple authorities," which Plaintiffs relied upon to bolster their allegations (id. at 9-10). Plaintiffs further clarify they "do not seek to impose a specific name on Defendant's Product," but "allege only that the way the Product is currently labeled is deceptive and misleading." (Id. at 10.) Plaintiffs rely heavily upon Rodriguez v. Target Corporation, a 2022 case from the Southern District of New York that also involved the alleged mislabeling of a dietary supplement as fish oil, to support their objection. (See id. at 10-11 (discussing Rodriguez v. Target Corp., No. 22-CV-2982, 2022 WL 18027615 (S.D.N.Y. Dec. 30, 2022)).)

Fifth, Plaintiffs assert error with the Magistrate Judge's determination that no reasonable consumer would be misled by the Product label as a matter of law. (Obj. at 12.) Highlighting the Magistrate Judge's finding that "there is no falsity in calling the Product fish oil" because "[i]t is implausible to believe that any consumer shopping for a fish oil supplement seeks only DHA/EPA with an intact glycerol backbone molecule" (R&R at 31), Plaintiffs argue that their claim as alleged is "that when seeking to purchase 'fish oil,' with DHA and EPA no less, a reasonable plaintiff would generally expect the oil

squeezed from a fish, not a synthetic omega-3 that was created by chemically altering fish offal - waste - and thereby producing a Product containing new and distinct, artificial compounds." (Obj. at 12 (citing Am. Compl. ¶ 55).) Additionally, Plaintiffs alleged "they were misled by the entirety of the labeling claims, and not exclusively the Product name." (Id. (citing Am. Compl. ¶¶ 20, 29).) They maintain that "[r]ead holistically, the totality of [Defendants'] misrepresentations, in concert with each other or standing alone, misled Plaintiffs into believing that Defendants' Products had characteristics and traits that they do not have;" therefore, their "claim cannot possibly be preempted given FDCA's express prohibition against labeling that is misleading, regardless of whether the label has otherwise complied with a specific federal regulation." (Id. at 13.) Moreover, Plaintiffs believe the Magistrate Judge applied a probability standard and not the applicable plausibility standard in recommending the Dismissal Motion be granted. (See id. at 13-15.)

Sixth and finally, Plaintiffs object to the Magistrate Judge's recommendation that Plaintiffs not be granted leave to amend since (1) in their concluding sentence of their Opposition, Plaintiffs requested such leave, and (2) leave to amend should be freely given, especially in light of Judge Schofield's decision in Rodriguez, a purported analogous case. (Obj. at 16.)

B. Consideration of R&R and Plaintiffs' Objections Thereto

1. The Judicial Notice Motion

As an initial matter, Magistrate Judge Shields recommends that Defendants' related Judicial Motion Notice, to which Plaintiffs did not respond, "be granted to the extent that it refers to any . . . documents [referenced in the R&R], as both unopposed and on the merits." (R&R at 22.) In the absence of any objection by Plaintiffs to this recommendation, and finding said recommendation is not clearly erroneous, it is ADOPTED. Accordingly, the Judicial Notice Motion is granted as to the following two items only: the entirety of the label for the Product (see ECF Nos. 26-1 (Defs.' Ex. A), 26-3(Defs.' Ex. C)), and the publicly available statement on the FDA website providing labeling guidance regarding the use of scientific names to describe ingredients (see ECF No. 26-4 (Defs.' Ex. D)).

2. Plaintiffs' Referenced Documents

Magistrate Judge Shields also stated that the numerous documents Plaintiffs referenced in their Amended Complaint, which she directed the Plaintiffs to file (and which were filed (see ECF No. 31-1 through 31-42)), "are integral to the facts pled in support of Plaintiffs' claims and are, therefore, properly considered." (R&R at 20.) Indeed, at the outset, the Magistrate Judge stated:

> While not every reference material is discussed in this [R&R], the Court has been careful to read all of these materials in the light most favorable to Plaintiffs, without acting as an expert in scientific fields such as chemistry, or as to the business and taxation of the commercial fishing industry. Where any such expertise is necessary, the Court has refrained from interpretation and applied only its own plain language reading of each document in the light most favorable to the text of the Amended Complaint. The Court states the facts therein – not its own interpretation thereof.

(Id. at 5. (further recognizing that the basic facts alleged by Plaintiffs are "supported by hundreds of pages of scientific articles").) She further advised that she considered the full text of the references materials when determining the plausibility of Plaintiffs' claims. (See id.; see also id. at 21 (clarifying that "[e]ach referenced document will be considered in its entirety in connection with the [Dismissal M]otion").)

Plaintiffs have not objected to the Magistrate Judge's consideration of its referenced document. (See generally Obj.) Nor does this Court find clear error in Magistrate Judge Shields doing so. Moreover, as to the referenced documents, it is well-settled that "[w]hen such documents 'contradict allegations, the documents, not the allegations, control, and the court need not accept the allegations in the complaint as true.'" Catania v. NYU Langone Health System, No. 22-CV-4362, 2022 WL 17539121, at *1 (S.D.N.Y. Dec. 5, 2022) (quoting TufAmerica, Inc. v. Diamond, 968

F. Supp. 2d 588, 592 (S.D.N.Y. 2013)) (cleaned up); (see also R&R at 5 (citing BYD Co., Ltd. v. VICE Media, LLC, 531 F. Supp. 3d 810, 817 (S.D.N.Y. 2021) (stating that where a document relied upon in a pleading contradicts allegations in the pleading, the court need not accept pleading allegations but may properly rely upon the referenced document))). The Court will assess Plaintiffs' objections accordingly.

3. Lack of Objection re: Claim for Injunctive Relief

Among other relief, Plaintiffs sought injunctive relief. However, Magistrate Judge Shields found Plaintiffs lack Article III standing to bring such a claim since, as past purchasers, they "cannot plausibly allege any future harm that could be redressed by a grant of injunctive relief." (R&R at 34.) In the absence of Plaintiffs objecting or otherwise addressed this finding, it is subject to clear error review. Finding no such error, the recommendation is upheld and ADOPTED.

4. The Court's Rulings on Plaintiffs' Objections

While not articulated, at their essence, the crux of each of Plaintiffs first five general objections is the implication that Magistrate Judge Shields should not have carefully reviewed and relied upon the very referenced materials Plaintiffs' cited to and relied upon in crafting their Amended Complaint, but, rather, should have taken their allegations at face value. Indeed, each of these objections refer the Court to Plaintiffs' allegations.

(See Obj. at 5 (re: 1st Objection (relying upon Complaint in support of argument that trans-esterification process results in a new product that is not fish oil)); at 6 (re: 2nd Objection (asserting Magistrate Judge "ignores the wealth of scientific authority detailed in the body of the Complaint" (emphasis added))); at 8 (re: 3rd Objection (arguing Defendants' claims regarding USP certification are "refuted by detailed, well pled allegations in the Complaint")); at 9 (re: 4th Objection (as to finding Product's common name is "fish oil" thereby finding Plaintiff's claims preempted, relying upon "detailed allegations in the Complaint")); at 12 (re: 5th Objection (pointing to allegations in Amended Complaint to support position that reasonable consumers would be misled)).) Such general, conclusory objections are unavailing.[3]

But for their references to substantial documentation upon which they relied in alleging their claims, this argument may have been enough to sustain Plaintiffs objections. However, that is not the scenario here; Plaintiffs, having relied upon their cited reference documents in drafting their Amended Complaint, the Magistrate Judge was, likewise, permitted to rely upon them. And, to the extent such documents contradicted allegations in the

[3] Further, the Court notes that the arguments Plaintiffs present in support of their objections are largely reiterations of their arguments originally raised in opposition to the Dismissal Motion. As such, the Court engages in clear-error review.

pleadings, the Magistrate Judge was not constrained to accept Plaintiffs' pled allegations, but could properly rely upon the referenced documents. That is what Magistrate Judge Shields has done. Cf. Axon v. Florida's Natural Growers, Inc., 813 F. App'x 701, 704 (2d Cir. May 29, 2020) ("[W]here the allegations of a complaint are materially inconsistent with the evidence a plaintiff relies on to make those allegations, we may easily conclude that plaintiff's claims lack the facial plausibility necessary to survive a motion to dismiss." (quoting Fink v. Time Warner Cable, 714 F.3d 739, 742 (2d Cir. 2013); cleaned up)). As Defendants aptly state, "Plaintiffs do not (and cannot) object to the fact that their own authorities refer to trans-esterified fish oil as 'fish oil'."[4] (Resp., ECF No. 33, at 5; see also id. at 6-7 ("Plaintiffs [sic] own authorities establish the Product's common or usual name is 'undoubtedly' and 'without question' 'fish oil'." (citing R&R at 25, 27)); id. at 8 ("Plaintiffs selectively ignore their own authorities.").)

[4] And, as Defendants note, Plaintiffs' "attempt to backtrack from the Amended Complaint by contending 'Plaintiffs do not seek to impose a specific name on Defendants' Product . . . [since they] allege only that the way the Product is currently labeled is deceptive and misleading'" "is disingenuous [as t]he Amended Complaint plainly alleges the common name of the Product is 'Fatty Acid Ethyl Esters.'" (Id. at note 1 (first quoting Obj. at 10 and then quoting Am. Compl. ¶ 8 ("These new chemical by-products are universally recognized by their common or usual name—Fatty Acid Ethyl Esters ("FAEE").").)

As for Plaintiffs' objection to Magistrate Judge Shields' finding that the Product's label is not misleading, their arguments merely reiterate those originally made in opposition to the Dismissal Motion, thereby subjecting them to clear error review. (Cf., e.g., Opp'n, ECF No. 27, at 11-12, with Obj. at 4-5, 12-13.) Upon such review and finding none, the Court overrules Plaintiffs' objection to the Magistrate Judge's finding:

> It is clear that whatever sub-class Plaintiffs seek to represent, their claims require a showing that reasonable consumers would be misled by labeling of the Product as fish oil. The Court holds, as a matter of law, that they would not. First, there is no falsity in calling the Product fish oil. Any such claim of falsity is implausible and therefore subject to disposition in connection with this motion to dismiss. . . . [I]n Plaintiffs' pleading, their clams rise and fall on the notion that consumers would be misled by a difference observable only on a molecular level. It is implausible to believe that any consumer shopping for a fish oil supplement seeks only DHA/EPA with an intact glycerol backbone molecule. Moreover, even if such a consumer did exist – and the Court is unconvinced that any such person does – that consumer would see that the Product bears the common name of fish oil, and also discloses that the OM3's therein are ethyl esters. Under these circumstances there can be no plausible claim that any reasonable consumer is misled.

(R&R at 31 (citing Nguyen v. Algenist LLC, No. 22-CV-0013, 2022 WL 17251733, at *7 (S.D.N.Y. Nov. 28, 2022) (noting that even if a consumer could be misled, clarifying information existed in packaging information as a whole)); (cf. Resp. at 8 ("Plaintiffs

do not specifically object to this finding, and this finding is not clearly erroneous." (emphasis in original))).

In any event, it is well settled: (1) "that a court may determine as a matter of law that an allegedly deceptive advertisement would not have misled a reasonable consumer," Fink, 714 F.3d at 741; and (2) that the "reasonable consumer" test is an objective one, i.e., "that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled.'" Kennedy v. Mondelez Global LLC, No. 19-CV-0302, 2020 WL 4006197, at *11-12 (E.D.N.Y. July 10, 2020) (citation omitted). In rejecting Plaintiffs' argument that it was a question of fact whether reasonable consumers would be misled by labeling of the Product as fish oil, Magistrate Judge Shields observed that "[c]ourts have not hesitated to dismiss patently implausible false advertising claims on motions to dismiss." (R&R at 32.) Even upon de novo review, the Court finds Magistrate Judge properly applied the objective reasonable consumer standard when she "state[d] clearly" that, in this case:

> there is nothing false about labeling the Product as fish oil. Describing the Product this way denotes nothing more than a statement of fact that the OM3's therein are derived from fish oil. It says nothing about the process by which crude fish oil makes its way to the OM3's found in each capsule. Plaintiffs do not, and cannot, argue that other supplements containing OM3'S derived from fish oil are properly named only if they are derived via a different process. All such

> products get their OM3's from fish oil. To suggest that molecular differences between such products make a difference to a reasonable consumer is plainly implausible.

(R&R at 33.) Likewise, given the record and applicable case law,[5] and even under de novo review, the Court finds no error in Magistrate Judge Shields' subsequent conclusion that "all claims alleging that a reasonable consumer would think otherwise are implausible and lacking completely in merit." Hence, Plaintiffs' objections to said conclusion are OVERRULED.

Finally, there is no basis to reject the Magistrate Judge's recommendation that Plaintiffs not be granted leave to amend. Plaintiffs "sought leave to amend only in the final sentence of their opposition to the motion to dismiss and at no point offered any new factual allegations that they would make if granted leave to amend." Powell v. Ocwen Loan Servicing, LLC, 840 F. App'x 610, 613–14 (2d Cir. Dec. 28, 2020) (citing Metz v. U.S. Life Ins. Co. in City of N.Y., 662 F.3d 600, 601 (2d Cir. 2011)(per curiam)); (see also Opp'n, ECF No. 27, at 25). Under such a

[5] The Court finds Plaintiffs' reliance upon Rodriguez v. Target Corporation unpersuasive. First, the subject product and corresponding product label in Rodriguez is distinguishable from the instant Product and label. (Cf. Rodriguez v. Target Corp., No. 22-CV-2982, Second. Am. Compl. (ECF No. 39) at 2-5 (S.D.N.Y. Sept. 1, 2022); see also Rodriguez, No. 22-CV-2982, Endorsed Order re: Pl.'s Mot. Recons. (ECF No. 59) (S.D.N.Y. Jan. 18, 2023).) Second and significantly, unlike here, there is no indication that the Rodriguez Court considered the documents Rodriguez referenced in his Second Amended Complaint when ruling upon the defendant's motion to dismiss.

scenario, a court is well within its discretion to deny the requested leave to amend. See Metz, 662 F.3d at 601. Thus, there is no error in the Magistrate Judge's recommendation that Plaintiffs be denied leave to further amend their Amended Complaint.

To the extent not specifically addressed, the Court has considered Plaintiffs' remaining arguments in support of their objections, but finds them unpersuasive. Finding no error -- clear or otherwise -- in Magistrate Judge Shields' R&R, Plaintiffs' objections are OVERRULED in their entirety.

CONCLUSION

For the stated reasons, **IT IS HEREBY ORDERED** that:

I. Plaintiffs' objections are OVERRULED;

II. The R&R is ADOPTED IN ITS ENTIRETY;

III. Defendants':

A. Judicial Notice Motion (ECF No. 26) is GRANTED to the extent articulated herein; and

B. Dismissal Motion (ECF No. 25) is GRANTED; and

IV. The Clerk of Court enter judgment accordingly and, thereafter, mark this case CLOSED.

SO ORDERED.

/s/ JOANNA SEYBERT
Joanna Seybert, U.S.D.J.

Dated: March 28, 2023
Central Islip, New York

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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MASHON BAINES and NANCIE FRONING on behalf of themselves and all others similarly situated,

Plaintiffs,

- against -

NATURE'S BOUNTY (NY) INC., and THE BOUNTIFUL COMPANY (NY),

Defendants.

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JUDGMENT
CV 21-5330 (JS) (AYS)

An Adoption Order of Honorable Joanna Seybert, United States District Judge, having been filed on March 28, 2023; adopting the January 3, 2023 Report and Recommendation of United States Magistrate Judge Anne Y. Shields its entirety; granting Defendants' judicial notice motion to the extent articulated in the March 28, 2023 Adoption Order; granting Defendants' motion to dismiss; and directing the Clerk of Court to enter judgment accordingly and mark this case closed, it is

ORDERED AND ADJUDGED that Plaintiffs Mashon Baines and Nancie Froning take nothing of Defendants Nature's Bounty (NY) Inc., and The Bountiful Company (NY); that Defendants' judicial notice motion is granted to the extent articulated in the March 28, 2023 Adoption Order; that Defendants' motion to dismiss is granted; and that this case is closed.

Dated: March 28, 2023
Central Islip, New York

BRENNA B. MAHONEY
CLERK OF THE COURT
By: /s/ James J. Toritto
Deputy Clerk