UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

CLAUDIO DE SIMONE, Plaintiff/Counterclaim Defendant, EXEGI PHARMA, LLC, Plaintiff, v. VSL PHARMACEUTICALS, INC., Defendant/Counterclaim Plaintiff, LEADIANT BIOSCIENCES, INC., and ALFASIGMA USA, INC. Defendants, v. DANISCO USA, INC., Counterclaim Defendant.	Civil Action No. TDC-15-1356

MEMORANDUM OPINION

On November 20, 2018, after a 14-day trial, the jury returned a verdict (1) in favor of Plaintiff Claudio De Simone against Defendant VSL Pharmaceuticals, Inc. ("VSL") on Count II of his Complaint, a claim for breach of contract, and awarded damages in the amount of $967,435; (2) in favor of De Simone against VSL and Defendant Leadiant Biosciences, Inc. ("Leadiant") on Count III of his Complaint, a claim for unjust enrichment, and awarded damages in the amount of $1,874,602 against VSL and $172,004 against Leadiant; (3) in favor of Plaintiff ExeGi Pharma, LLC ("ExeGi") against Leadiant and Defendant Alfasigma USA, Inc. ("Alfasigma") on Count VI

of its Complaint, a claim for false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a) (2012), and awarded damages in the amount of $15,000,000 against Alfasigma; and (4) in favor of Counterclaim Defendant De Simone against Counterclaim Plaintiff VSL on Count IV of VSL's Counterclaim, alleging breach of fiduciary duty.

Before the case was submitted to the jury, VSL, Leadiant, and Alfasigma (collectively, "the VSL Parties") each made Motions for Judgment as a Matter of Law under Federal Rule of Civil Procedure 50(a). The Court reserved its decision on these motions. *See* Fed. R. Civ. P. 50(b). The VSL Parties have now each renewed their Rule 50 motions and have also filed Motions for a New Trial under Rule 59. *See* Fed. R. Civ. P. 50(b), 59. De Simone and ExeGi (collectively, "the De Simone Parties") have opposed the Motions. Having reviewed the submitted materials, the Court finds no hearing necessary. *See* D. Md. Local R. 105.6. For the reasons set forth below, the Motions are DENIED.

DISCUSSION

I. Motions for Judgment as a Matter of Law

A. Legal Standard

A district court may overturn a jury verdict by rendering judgment as a matter of law only if there is no "legally sufficient evidentiary basis to find for the [prevailing] party on that issue." Fed R. Civ. P. 50(a). Thus, a party is entitled to judgment as a matter of law under Rule 50 only "if the nonmoving party failed to make a showing on an essential element of his case with respect to which he had the burden of proof." *Price v. City of Charlotte, N.C.*, 93 F. 3d 1241, 1249 (4th Cir. 1996) (citations omitted). In determining whether the non-moving party has carried its burden as a matter of law, the district court "may not substitute [its] judgment for that of the jury or make credibility determinations." *Id., see generally* U.S. Const. amend VII (guaranteeing the right to a

civil trial by jury and requiring that "no fact tried by a jury ... shall be otherwise reexamined in any Court of the United States"). The court must instead "view the evidence in the light most favorable to the non-moving party and draw legitimate inferences in its favor." *Anheuser-Busch, Inc. v. L & L Wings, Inc.*, 962 F. 2d 316, 318 (4th Cir. 1992). Thus, if there is any evidence on which a reasonable jury could return verdicts in favor of the non-moving party, the court must deny a Rule 50 motion. *Price*, 93 F.3d at 1249–50. However, courts must not merely "rubber stamp" a jury verdict, as they "have a duty to reverse the jury verdict[] if the evidence cannot support it." *Id.* at 1250.

B. False Advertising

The jury found both Alfasigma and Leadiant liable to ExeGi for false advertising, in violation of the Lanham Act, 15 U.S.C. § 1125(a). Although ExeGi did not seek damages from Leadiant on this claim, it sought monetary relief from Alfasigma in the amount of $27,843,149, representing Alfasigma's profits from sales of VSL#3 from July 1, 2016 through the end of trial, as calculated by ExeGi's damages expert, Bryan Callahan. The jury awarded ExeGi $15,000,000 on its false advertising claim against Alfasigma.

Alfasigma and Leadiant seek judgment as a matter of law on the false advertising claim on the grounds that ExeGi failed to establish each of the elements of the claim. To prevail on a Lanham Act claim of false advertising, a plaintiff must establish that:

> (1) The defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about its product or the product of another;
> (2) The misrepresentation is material, in that it is likely to influence the purchasing decision;
> (3) The misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience;
> (4) The defendant placed the false or misleading statement in interstate commerce; and

> (5) The plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its product.

Scotts Co. v. United Indus. Corp., 315 F.3d 264, 272 (4th Cir. 2002). The contested statement may either be "false on its face" or "although literally true, likely to mislead and to confuse consumers given the merchandising context." *Id.* (quoting *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare L.P.*, 131 F.3d 430, 434 (4th Cir. 1997)). If an advertisement is literally false, a party can succeed on a false advertising claim without evidence of any consumer deception. *Id.* at 273. However, "if a plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged advertisements tend to mislead or confuse consumers." *Id.* When a false advertising claim involves multiple statements, a plaintiff "may not mix and match statements, with some satisfying one Lanham Act element and some satisfying other"; rather, at least one challenged statement must satisfy all five elements. *Verisign, Inc. v. XYZ.Com, LLC*, 848 F.3d 292, 299 (4th Cir. 2017).

In arguing that ExeGi's evidence was legally insufficient to support the verdict on false advertising, Alfasigma broadly asserts that none of the challenged advertisements meets all of the requirements of a Lanham Act false advertising claim. At trial, ExeGi's false advertising claim against Alfasigma was based largely on three challenged items: a page of the VSL#3 website entitled "VSL#3: new formula dairy-free" ("the VSL#3 Webpage"), Trial Exhibit ("Tr. Ex.") 412; an August 31, 2016 press release that was then posted, in whole or in part, on the VSL#3 website entitled "VSL#3, A Leader in Probiotic Medical Foods, is Now Dairy Free," ("the VSL#3 Press Release"), Tr. Ex. 341; and statements made on the VSL#3 Facebook page ("the VSL#3 Facebook Page"), Tr. Ex. 375. The false advertising claim against Leadiant centered on the following two items: a frequently asked questions ("FAQ") training document entitled, "Potential Future HCP

Objections, Misconceptions, Questions, or Concerns . . . and Answers," Tr. Ex. 1203; and a May 17, 2016 letter from Mary Ocnean, Vice President of Sigma-Tau Pharmaceuticals, Inc. ("Sigma-Tau"), Leadiant's predecessor company, with the salutation, "Dear Healthcare Provider" ("the Healthcare Provider Letter"), Tr. Ex. 297. In arguing that no single item satisfied all five elements of a false advertising claim, Alfasigma asserts several evidentiary deficiencies, specifically, that (1) the contested statements are not literally false; (2) the contested statements are not actionable under the Lanham Act because they are a matter of scientific debate; (3) some of the contested statements do not constitute commercial advertising; and (4) the trial evidence was legally insufficient to establish proximate causation of injury.

Viewing the evidence in the light most favorable to ExeGi, as the Court is required to do, the Court finds that, as discussed below, the evidence was sufficient to establish that at a minimum, the VSL#3 Webpage, Tr. Ex. 412, satisfies all of the elements of false advertising as to Alfasigma. The VSL#3 Webpage included a statement by Ocnean that "[m]oving VSL#3 back to the original manufacturing facility in Italy allowed the brand to revert back to an established process that removes all dairy while maintaining the original proprietary mix of eight strains of live bacteria." Tr. Ex. 412. As for the false advertising claim against Leadiant, as discussed below, the Court finds that the Healthcare Provider Letter, Tr. Ex. 297, which was sent to hundreds of doctors around the United States, satisfies all five elements of false advertising. That letter stated, as relevant here, that "VSL#3 is the same quality product, containing the same genus and species of bacteria, in the same proportions that you have come to expect." Tr. Ex. 297.

1. Commercial Advertising in Interstate Commerce

On the first element, whether the defendant made a false or misleading statement in a commercial advertisement about its product or the product of another, Alfasigma concedes that

the VSL#3 Webpage was posted on the VSL#3 website during the time period when Alfasigma was the distributor of VSL#3 in the United States, but it generally claims that ExeGi failed to establish that Alfasigma was responsible for the statements made on that webpage. In her testimony, however, Ocnean specifically stated that the VSL#3 Webpage was an excerpt from the VSL#3 Press Release that had been issued by Alfasigma. Because the Alfasigma Licensing Agreement, Tr. Ex. 1366, established that Alfasigma had an exclusive license to "promote, distribute, offer for sale and sell" VSL#3 in the United States, the jury could reasonably infer that Alfasigma was responsible for the posting of the VSL#3 Webpage. The Court thus rejects Alfasigma's nonspecific contention that Alfasigma did not make the statements contained in the VSL#3 Webpage for purposes of liability for false advertising. As for the Healthcare Provider Letter, issued by Sigma-Tau, Leadiant makes no claim that it is not responsible for the statements contained in it. Although the VSL Parties argue that certain alleged items of false advertising did not constitute commercial advertising within the meaning of the Lanham Act, there is no dispute that both the VSL#3 Webpage and the Healthcare Provider Letter were disseminated in a manner sufficient to constitute commercial advertising placed in interstate commerce, so the evidence was sufficient to establish the first element of a false advertising claim.

2. Literal Falsity

As to falsity, the Court finds that the evidence was sufficient to support the conclusion that both the VSL#3 Webpage and the Healthcare Provider Letter contained literally false statements. At a minimum, the Court finds that the evidence supports a finding that the statement in the VSL#3 Webpage that VSL#3 "maintain[s] the original proprietary mix of eight strains of live bacteria," Tr. Ex. 412, and the statement in the Healthcare Provider Letter that "VSL#3 is the same quality product, containing, the same genus and species of bacteria, in the same proportions that you have

come to expect," Tr. Ex. 297, were false. *See Scotts Co.*, 315 F.3d at 274 ("In analyzing whether an advertisement is literally false, a court must determine, first, the unambiguous claims made by the advertisement, and second, whether those claims are false.").

ExeGi introduced evidence, in the form of testimony from Dr. Patrick Gillevet, an expert on human gastrointestinal microflora, that the new version of VSL#3 produced in Italy ("Italian VSL#3") had only seven strains of live bacteria, not eight, and was thus genetically different from the version of VSL#3 produced by Danisco USA under De Simone's guidance ("the De Simone Formulation"). Dr. Gillevet was "100%" certain of this conclusion. 11/7/18 AM Tr. at 96. Dr. Gillevet also testified that based on a fermentation analysis, the two products would degrade compounds differently and thus function differently. Dr. Gillevet's testimony thus directly contradicted the claim that Italian VSL#3 has eight strains of bacteria. This testimony provided a sufficient basis for the jury to conclude that the claims in the VSL#3 Webpage and the Healthcare Provider Letter to the effect that Italian VSL#3 has "the original proprietary mix of eight strains of live bacteria" was a literally false description of fact. *See C.B. Fleet Co., Inc. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F. 3d 430, 434 (4th Cir. 1997) ("Whether an advertisement is literally false is an issue of fact.").

Moreover, Luca Guarna, the President and Chief Executive Officer of VSL, acknowledged in his testimony that after De Simone left VSL, because VSL did not have access to the specific formulation of, and the proportions of each bacteria contained in, the De Simone Formulation, VSL arranged for scientists to reverse engineer the product in an attempt to "understand[] what was in the product" by "isolat[ing] the strains" so VSL could then re-create the De Simone Formulation and produce its own version of VSL#3. 11/7/18 PM Tr. 60, 63. Guarna acknowledged that in doing so, "you can determine a certain range of the presence of the strains

but you cannot precisely assess the exact quantity of the strains," so their scientists were "not able to give a precise indication of the percentage of each strain[] contained" in VSL#3, or a "formal" range for such proportions, but instead could only measure the amount of each strain with a margin of error of 30 percent. 11/7/18 PM Tr. 61–65. Viewed in the light most favorable to the verdict, this testimony supports a conclusion that the claim that Italian VSL#3 had the "originally proprietary mix" or the "same proportions" of bacterial strains as in original VSL#3 was false. This conclusion is reinforced by Dr. Gillevet's testimony that fermentation analysis revealed that Italian VSL#3 would degrade compounds differently and thus function differently.

In the face of such evidence, Alfasigma asserts, citing *In re GNC Corp.*, 789 F.3d 505 (4th Cir. 2015), that when the statement underlying a Lanham Act false advertising claim is based on scientific representations, the statement cannot be found to be literally false unless "all reasonable experts in the field agree that the representations are false." *Id.* at 516. Alfasigma argues that it is entitled to judgment as a matter of law because the testimony of Dr. Rodolphe Barrangou, the VSL Parties' designated expert on the issue of the genetic and functional equivalence of VSL#3 and Visbiome, precludes a finding of literal falsity. Barrangou testified that Italian VSL#3 had eight strains of bacteria, and that the relative ratios of strains was "[i]ndistinguishable within one percent," 11/13/18 PM Tr. 77, but he did not testify that the ratio of the strains in Italian VSL#3 were the same as the "original proprietary mix" of the De Simone Formulation. Although Barrangou referenced variability in the composition of VSL#3 over the years, the testimony of Scott Bush, a Danisco food scientist who was involved in the manufacture of the De Simone Formulation when it was sold as VSL#3, established that this variability arose not from any imprecision in the ratios of strains in the De Simone Formulation, but from the need to add more bacteria to the product than actually set forth in the original proprietary mix—an overage—to

account for bacteria die-off, and the changing estimates of the amounts necessary to include to ensure that when the probiotic gets to the consumer, it has the correct ratio of bacteria called for in the De Simone Formulation.

In *GNC*, the plaintiffs advanced a Lanham Act false advertising claim by alleging the literal falsity of promotional statements asserting the effectiveness of vitamin supplements containing glucosamine and chondroitin in relieving joint pain, but also acknowledged in their complaint that "the scientific evidence regarding the efficacy of glucosamine and chondroitin is equivocal." *Id.* at 515. In affirming the district court's grant of a motion to dismiss, the United States Court of Appeals for the Fourth Circuit stated that "[w]hen litigants concede that some reasonable and duly qualified scientific experts agree with a scientific proposition, they cannot also argue that the proposition is 'literally false.'" *Id.* *GNC* thus does not broadly hold that a false advertising claim based on a statement grounded in science must fail if the defendant presents an expert witness supporting its position. In the absence of a concession that the statement is the subject of reasonable scientific debate, that question is properly decided by the jury.

Here, the Court specifically instructed the jury that:

> If an alleged false statement states a scientific proposition, and you find that there is a reasonable difference of scientific opinion about that proposition, that is, duly qualified experts in the field have a reasonable disagreement about the accuracy or validity of the proposition, the challenged statement is not "literally false."

Jury Instruction No. 22. With this guidance, the jury could reasonably conclude that to the extent there was a disagreement about the number of strains in Italian VSL#3, or whether Italian VSL#3 contained the same original proprietary mix as the De Simone Formulation, it was not a reasonable disagreement. Beyond Dr. Gillevet's testimony that Italian VSL#3 had a different number of bacterial strains and functioned differently, the De Simone Parties presented other evidence and expert witnesses who referenced various studies in support of their position. For example, Dr.

Christian Loch, an expert in the field of proteomics, the study of how genes produce proteins and what proteins they produce, stated that based on his comparative proteomic testing of VSL#3 and Visbiome, "the two products were very different." 11/6/18 PM Tr. 76. In particular, Dr. Loch concluded that there was a 25 percent difference in the protein expression of Italian VSL#3 and Visbiome, meaning that of the approximately 4,000 proteins identified in the two products, about 1,000 of them were different. Dr. Loch concluded that this difference in protein expression would "result in different performance." *Id.* at 77. Similarly, Dr. Alessio Fasano, a Professor of Gut Physiology and Pediatric Gastroenterology at Harvard Medical School who testified as an expert in the use of probiotics for the management of gastroenterological and immunological disorders, stated that based on his review of various scientific studies comparing the De Simone Formulation with Italian VSL#3 that "the new formulation from Italy is not ... comparable to the formulation that is from the United States." 11/6/18 AM Tr. 136. These expert witnesses' conclusions that Visbiome and Italian VSL#3 exhibit different protein profiles and are functionally different, though not directly focused on the genetic makeup and proportions of Italian VSL#3, bolster Dr. Gillevet's testimony and provide support for the conclusion that Dr. Barrangou's opinion was not reasonable.

Significantly, apart from any purported scientific debate, the jury could reasonably conclude that the number of strains or the proportion of those strains were different based on non-scientific evidence. ExeGi presented evidence of regulatory filings made by VSL to Health Canada in 2013 and 2018 describing the composition of VSL#3. The 2013 filing, describing the De Simone Formulation, listed eight strains of bacteria, while the 2018 filing, describing Italian VSL#3, listed only seven. These regulatory filings thus acknowledge that Italian VSL#3 has only seven strains of bacteria. When coupled with Guarna's concession that VSL did not actually know

the composition of the De Simone Formulation and could not and did not precisely recreate it, the jury could reasonably have discounted the opinion of Dr. Barrangou as unreasonable or not credible and concluded that either the number of strains, the proportions of the strains, or both, were different.

Even if the statements on the number and proportions of strains could not be deemed literally false, the evidence also supported a finding that the VSL#3 Webpage and the Healthcare Provider Letter contained false statements on VSL#3's original manufacturing facility. Although the VSL#3 Webpage stated that the manufacturing of VSL#3 would be "moving back to "the original manufacturing facility in Italy," Tr. Ex. 412, and the Healthcare Provider Letter similarly stated that Italian VSL#3 would be produced "in the same facility that [VSL#3] was originally produced," Tr. Ex. 297, De Simone testified unequivocally that CSL had never manufactured VSL#3 for commercial sale, and that, instead, VSL#3 had "always" been produced for commercial sale in manufacturing facilities in the United States. 10/31/18 AM Tr. 45. Thus, the evidence was sufficient to support a finding of literal falsity on this point as well.

3. Materiality and Consumer Deception

A Lanham Act false statement is material if it is "likely to influence the purchasing decision." *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F. 3d 302, 311 (1st Cir. 2002) The false statements on the number and proportions of strains are plainly material because they related to an "inherent quality or characteristic" of VSL#3. *Id.* at 311–12 (stating that "[o]ne method of establishing materiality involves showing that the false or misleading statement relates to an 'inherent quality or characteristic' of the product") (quoting *Nat'l Basketball Ass'n v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997)). As noted above, Dr. Fasano testified that Italian VSL#3 was not comparable to the De Simone Formulation; that, based on those differences it was

"not appropriate" to conclude that Italian VSL#3 is the same product studied in prior clinical trials; and that no doctor would prescribe a product that was not itself the subject of clinical tests. 11/6/18 AM Tr. 122. As for the statement that Italian VSL#3 would be produced at the original manufacturing facility, where Dr. Fasano testified that the claims in the VSL#3 Webpage relating to the manufacturing facility and number and proportion of strains were "not appropriate" and that "the new formulation from Italy" was not comparable to "the formulation that is from [the] United States," *id.* at 120–21, 135, the jury could reasonably infer that the false claim that Italian VSL#3 was being made in the "original manufacturing facility" of VSL#3 could influence purchasing decisions by causing purchasers to mistakenly believe that Italian VSL#3 and the De Simone Formulation were actually the same and that Italian VSL#3 was thus supported by the history of clinical trials relating to the De Simone Formulation, a history that, according to Dr. Fasano, was necessary to convince doctors to prescribe the product.

Because the evidence supports a finding that the statements in the VSL#3 Webpage and the Healthcare Provider Letter were literally false, there was no need for evidence of consumer deception because deception of the purchasing audience is presumed. *Scotts Co.*, 315 F.3d at 273. ("Where the advertisement is literally false, a violation may be established without evidence of consumer deception.") (citation omitted).

4. Injury and Proximate Causation

On the element of whether the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill, *Scotts Co.*, 315 F.3d at 272, Alfasigma asserts that ExeGi failed to offer sufficient evidence to establish that any of the alleged false advertising was the proximate cause of an injury to ExeGi. As a threshold issue, this element does not require proof of actual damages such as lost sales to ExeGi. The

Lanham Act specifically provides that a party engaged in false advertising "shall be liable in a civil action by a person who believes that he or she is *or is likely to be* damaged by such act." 15 U.S.C. § 1125(a)(1) (emphasis added). On its face, therefore, the statute permits false advertising actions based on the threat of injury alone. In *Verisign, Inc. v. XYZ.com LLC*, 848 F.3d 292 (4th Cir. 2017), the Fourth Circuit, even while stating that "[t]o recover damages under the Lanham Act," the plaintiff had to show that the false statements "caused Verisign actual damages" and analyzing whether such damages were proven, specifically reaffirmed that the "fifth element of a Lanham Act claim" is that "the plaintiff has been *or is likely to be* injured as a result of the alleged misrepresentation." *Verisign*, 848 F. 3d at 299–300 (quoting *Design Resources, Inc. v. Leather Indus. of Am.*, 789 F.3d 495, 501 (4th Cir. 2015)) (holding that the plaintiff has "failed to establish . . . that it suffered an injury flowing directly from the challenged statements"). Indeed, other courts have clarified that in Lanham Act cases, proof of injury or likelihood of injury does not require proof of actual damages. In *Web Printing Controls Co., Inc. v. Oxy-Dry Corp.*, 906 F.2d 1202 (7th Cir. 1990), for example, the United States Court of Appeals for the Seventh Circuit reversed the district court's entry of judgment on a Lanham Act false advertising claim because that court had "confused the elements necessary to prove a breach of the law with elements necessary to justify a certain remedy for that breach. It mixed two stages of inquiry—violation of the law; remedies for the violation—that should be kept separate." *Id.* at 1204. *Accord Logan v. Burgers Ozark Country Cured Hams, Inc.*, 263 F.3d 447, 462–63 (5th Cir. 2001); *Balance Dynamics Corp. v. Schmitt Indus.*, 204 F.3d 683, 689 (6th Cir. 2000). The *Web Printing* court noted that the inquiry into violation and the inquiry into remedies had to be kept conceptually separate because the Lanham Act provides for multiple types of remedies. *Id.* at 1205 (stating that only a "plaintiff wishing to recover damages for a violation of the Lanham Act must prove … that

the plaintiff suffered actual injury, *i.e.* a loss of sales, profits, or present value"). Based on this reasoning, coupled with the explicit statement in *Verisign* that liability under the Lanham Act requires proof only of a likelihood of injury, *Verisign*, 848 F. 3d at 299–300, the Court concludes that the reference in *Verisign* to the need for proof of actual damages should be read to apply to instances in which, as there, the plaintiff in a Lanham Act false advertising action seeks damages. *Id.* at 299.

Here, there was evidence from which a jury could infer that ExeGi was injured or likely to be injured by Alfasigma's false advertising. The United States Supreme Court has stated that a Lanham Act injury can occur "when deception of consumers causes them to withhold trade from the plaintiff." *Lexmark Intern. v. Static Control*, 134 S. Ct. 1377, 1391 (2014) (addressing the issue of standing for a Lanham Act claim). ExeGi's evidence supports an inference that the false statements caused consumers to continue to purchase VSL#3 and thus to withhold their trade from ExeGi. In particular, ExeGi Chief Executive Officer Marc Tewey testified that Alfasigma's advertising about the composition of VSL#3 effectively "makes it appear as though the product they are currently selling is the same formula as what was studied" in a broad of range of clinical studies on the original VSL#3, even though ExeGi has the "real" De Simone Formulation. 11/5/18 PM Tr. 72. As a result, ExeGi has been unable fully "to leverage the benefits of the brand." *Id.*

In further support of this point, Dr. Fasano provided expert testimony that the change in manufacturing locations for VSL#3 and the move to a dairy-free formulation meant it was neither appropriate nor accurate to claim that VSL#3 continued to be the "same quality product containing the same genus and species of bacteria in the same proportions that you have come to expect," and that to make such a claim would require VSL#3 to be subjected to efficacy testing to ensure continuity of outcomes. Dr. Fasano further testified that physicians generally rely on clinical data

in choosing which particular probiotic to prescribe for a patient's specific condition and that no doctor would prescribe a product without such clinical data. Coupled with the testimony of Dr. Gillevet and other evidence establishing that Italian VSL#3 does not have the same strains in the same proportions as the original VSL#3, Dr. Fasano's testimony supports the reasonable inference that this advertising about the false continuity between original VSL#3 and Italian VSL#3 was leading physicians to continue to prescribe VSL#3, and thereby fail to prescribe ExeGi's product containing the De Simone Formulation, Visbiome, where they would not have done so had they instead received truthful statements about the changes in the product.

Such a theory of causation, that Alfasigma injured ExeGi by improperly claiming to sell the actual De Simone Formulation when Italian VSL#3 was different, has been applied in similar circumstances by various courts. In *Logan*, the court found that the plaintiff, who had invented a "spiral slicing" method for cutting meat, had presented sufficient evidence of likely injury caused by false advertising where a honey-baked ham company had falsely depicted its use of the spiral slicing method, because the inventor's ability to license his spiral slicing method to others may have been adversely affected by the ham company's false claims that they used his method. *Logan*, 263 F.3d at 461. The court reached this conclusion on the grounds that a Lanham Act injury can be established where a defendant's "literally false advertising about its own goods influenced its customers to buy its product instead of [the plaintiff's]." *Id. See also Famous Horse Ind. v. 5th Ave. Photo, Inc.*, 624 F.3d 106, 114–15 (2d Cir. 2010) (finding that a plaintiff had stated a Lanham Act claim based on the assertion that it was injured when a competitor falsely passed off counterfeit jeans as genuine brand-name jeans also sold by the plaintiff), *abrogated on other grounds*, *Lexmark Intern. v. Static Control*, 134 S. Ct. 1377, 1391 (2014). The evidence here is therefore

sufficient to support a finding that ExeGi was injured, or likely to be injured, by the false advertising.

Alfasigma further asserts that even if injury or likelihood of injury could be established, ExeGi's evidence at most demonstrated correlation, not causation, between any false advertising and an injury to ExeGi. *See Verisign*, 848 F.3d at 300–01 (distinguishing between correlation and causation relating to the defendant's false advertising and the plaintiff's lost sales and finding a lack of evidence to support the inference that every new sale to the defendant was caused by the false statements). Alfasigma relies on *Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379 (5th Cir. 1996), in which the court found a lack of evidence sufficient to show causation between a Coca-Cola presentation containing false statements that was made to distributors to convince them to switch from Seven-Up to Coca-Cola's Sprite and Seven-Up's subsequent loss of contracts with several distributors. *Id.* at 1388. Notably, no distributor cited the presentation as a reason for the termination decision; rather, two distributors testified that other factors led to the their decision to switch products. *Seven-Up*, 86 F. 3d. at 1382, 1389. Alfasigma also cites *A.L.S. Enterprises Inc. v. Robinson Outdoor Prods., LLC*, No. 14-cv-500, 2017 WL 393307 (W.D. Mich. Jan. 30, 2017), in which a manufacturer of carbon-based, scent-control hunting clothing sued its former licensee, Robinson, for false advertising when Robinson launched a new product using synthetic polymers and made false claims about its effectiveness. *Id.* at *1–2. The court found insufficient evidence of causation between the false claims and reduced sales of A.L.S.'s product where no witnesses testified to the reasons for the changes in retailer's purchasing decisions and where another company, Under Armour, began to market its own scent-control hunting clothing in the same time frame. *A.L.S.*, 2017 WL 393307 at *6–7.

Although ExeGi elicited no direct testimony from prescribing physicians or consumers establishing that they decided to purchase or prescribe VSL#3 instead of Visbiome as a result of Alfasigma's false advertisements for VSL#3, they did, as noted above, elicit expert testimony from Dr. Fasano that doctors would not prescribe a product if it had not been the subject of clinical trials. ExeGi also offered the testimony of Susan Linke, a dietician who mentored approximately 2,000 dieticians and actively posted on several listservs for dieticians with a combined membership of over 10,000 members. Linke testified that it was important to her as a dietician to know what strains of bacteria were in VSL#3 and whether those strains matched up with the product that was the subject of clinical tests so that she could make informed recommendations to her clients. This evidence was sufficient for the jury reasonably to conclude that the false statements caused injury or were likely to cause injury to ExeGi. Unlike in *Seven-Up*, there was no evidence from purchasers that they chose VSL#3 over Visbiome for other reasons, *Seven-Up*, 86 F. 3d. at 1382, 1389, and unlike in *A.L.S.*, there was no evidence of another competitor whose presence may have impacted purchasing decisions, *A.L.S.*, 2017 WL 393307 at *6–7.

More fundamentally, the present case involves a markedly different and more compelling scenario that in *Verisign, Seven-Up*, and *A.L.S.* Unlike in those cases, the false statements here do not merely present one reason among many potential reasons for purchasers to choose one product over another. Rather, the heart of ExeGi's claim is that the falsity of Alfasigma's advertising is the representation that, in essence, its product is the exact same product, with the exact same formulation, as ExeGi's product, where it is undisputed that the De Simone Formulation is otherwise available only through ExeGi in the form of Visbiome. Where the falsity promulgated is that Italian VSL#3 is the exact same product offered by ExeGi, the violation is akin to the form of trademark infringement known as "passing off" or "palming off" a product as the same as

another product. *Ely-Norris Safe Co. v. Mosler Safe Co.*, 7 F.2d 603, 604 (2d Cir. 1925), *rev'd on other grounds*, *Mosler v. Ely-Norris*, 273 U.S. 132 (1927). Under these circumstances, the path from the false advertising to the plaintiff's injury is shorter and more direct. In such an instance, where "the plaintiff has a monopoly of the kind of wares concerned, and if to secure a customer the defendant must represent his own as of that kind, it is a fair inference that the customer wants those and those only. Had he not supposed that the defendant could supply him, presumably he would have gone to the plaintiff who alone could." *Id.* This case therefore is comparable to *Logan*, where the defendant engaged in false advertising that it was using the plaintiff's unique "spiral slicing method" and the court concluded that sufficient evidence existed to infer that the false advertising caused injury to the plaintiff because the defendant's "literally false advertising about its own goods" drew customers to buy its product, rather than the plaintiff's. *Logan*, 263 F.3d at 461, 463. Thus, ExeGi's evidence that only Visbiome contained the De Simone Formulation but that Alfasigma falsely marketed Italian VSL#3 as containing that original proprietary mix, viewed in the light most favorable to the verdict, was sufficient to establish proximate causation of injury or likely injury.

The Court also finds no cause to disturb the jury's award of Alfasigma's profits. Where a Lanham Act plaintiff seeks not damages but the defendant's profits, it need not show actual injury or harm but instead must show that the defendant benefited from the false advertising. *See Logan*, 263 F.3d at 465 (holding that where disgorgement is sought, the plaintiff must "present evidence that the defendant benefitted from the alleged false advertising"); *Tao of Sys. Integration, Inc. v. Analytical Svcs. & Materials, Inc.*, 330 F. Supp. 2d 668, 672–73 (E.D. Va. 2004) (finding that a plaintiff seeking disgorgement on a false advertising claim under the Lanham Act must "come forward with evidence of a causal connection between" the alleged false advertising and a benefit

to the defendant). The same evidence discussed above, particularly Dr. Fasano's and Linke's testimony, which supports the conclusion that if medical professionals knew that Italian VSL#3 no longer contained the De Simone Formulation, they would not prescribe or recommend it without additional clinical studies, was sufficient to show that the false statements unfairly benefited Alfasigma by allowing it to maintain or expand sales that otherwise would have been lost to ExeGi had the true facts been known.

Where the evidence was sufficient to support the jury's verdicts on the false advertising claims, Alfasigma's and Leadiant's Rule 50 motions will be denied as to those claims.

C. Unjust Enrichment

The jury found VSL and Leadiant liable to De Simone for unjust enrichment for their continued sale of Danisco-manufactured VSL#3 from September 15, 2015 to January 31, 2016. De Simone sought $2,585,297 in damages from VSL and $6,192,159 in damages from Leadiant. The jury awarded De Simone $1,874,602 in damages from VSL and $172,004 in damages from Leadiant.

A claim of unjust enrichment has three elements:

1. A benefit conferred upon the defendant by the plaintiff;
2. An appreciation or knowledge by the defendant of the benefit; and
3. The acceptance or retention by the defendant of the benefit under such circumstances as to make it inequitable for the defendant to retain the benefit without the payment of its value.

Hill v. Cross Country Settlements, LLC, 936 A.2d 343, 351 (Md. 2007).

1. Leadiant

Leadiant asserts that De Simone's claim of unjust enrichment fails as a matter of law because De Simone did not prove that he conferred any benefit on Leadiant. Leadiant's theory is that its ability to purchase and sell VSL#3 came from its exclusive licensing agreement with VSL,

not from any contract it had with De Simone, such that it did not receive any benefit from De Simone.

Leadiant's insistence that De Simone's claim fails without evidence that De Simone "directly bestowed" that benefit, Leadiant Mot. at 5, ECF No. 861, finds no persuasive support in the case law. In *Plitt v. Greenberg*, 219 A.2d 237 (Md. 1966), the Court of Appeals of Maryland held that "[i]t is immaterial" how a defendant obtained the alleged benefit, "and the fact that it was received from a third person will not affect his liability" on an otherwise viable claim for unjust enrichment. *Id.* at 241. In *Plitt*, the court reversed a grant of judgment of acquittal and found that the jury could reasonably have found that the defendant was liable for unjust enrichment when the plaintiff wrote a check in the amount of $38,333.34 based on misrepresentations by his later-disbarred attorney, and those funds were then wired to the defendant, even though the defendant had no knowledge of the original source of the funds. *Id.* at 239–40.

Although Leadiant correctly notes that *Plitt* further provides that a claim for unjust enrichment cannot succeed if "a transferee came into possession of a plaintiff's money in good faith after paying a good and valuable consideration for it," *id.* at 241, the jury could reasonably conclude that Leadiant did not act in good faith because it is beyond dispute that its predecessor, Sigma Tau, was not an independent third party but was instead deeply entrenched in these business relationships. The evidence established that the Cavazza family had a controlling interest in VSL, owned Sigma Tau, and had representatives in the management of both companies. The jury could therefore reasonably infer that Sigma Tau was fully aware of De Simone's claim to the know-how associated with VSL#3 ("the Know-How") and of De Simone's November 2014 decision to terminate the 2010 Know-How Agreement, the agreement by which De Simone granted VSL an exclusive license to use the Know-How from the expiration of the 2001 Patent License Agreement

in February 2015 through January 31, 2016, in an effort to prevent further sales of VSL#3 by Sigma Tau. Leadiant claims that the disagreement as to whether Sigma Tau could continue to sell the Danisco-produced VSL#3 was grounded in a bona fide dispute relating to the ownership of the Know-How, but even if such a dispute could establish good faith, the jury could have reasonably concluded that Leadiant's position was unjustified. Thus, under *Plitt*, the evidence was sufficient to establish Leadiant's liability for unjust enrichment.

The case law cited by Leadiant provides no basis to alter this conclusion. In *Bennett Heating & Air Conditioning, Inc. v. NationsBank of Maryland*, 674 A.2d 534 (Md. 1996), the court's dismissal of an unjust enrichment claim by subcontractors who had not been paid for work on a home against the purchasers of the property in foreclosure was based on a specific doctrine relating to claims by subcontractors where "an owner ... has paid the general contractor" that is inapplicable here. *Id.* at 539. Moreover, *Bennett Heating*'s guidance that "a third party is not unjustly enriched when it receives a benefit from a contract between two other parties where the party benefitted has not requested the benefit or misled the other parties" is inapplicable where, as here, there was no binding contract between De Simone and VSL relating to the relevant time period. *Id.* at 540.

The unreported cases cited by Leadiant are likewise unpersuasive. In *Tower Oaks Blvd, LLC v. Virginia Commerce Bank*, 223 Md. App. 781 (Md. Ct. Spec. App. 2015) (unreported), the landlord of an office building, Tower Oaks, agreed to forgive $3 million in unpaid rent owed by a tenant, Sun Control, then later sued a bank which had received loan payments from Sun Control for unjust enrichment. *Id.* at *1–2. Although the court dismissed the claim "because the benefit conferred on the defendant (the Bank) was not conferred by the plaintiff (Tower Oaks), but by a third party (Sun Control)," *id.* at *7, under the specific facts of the case, the benefit provided by

Sun Control, loan repayment, was a different benefit than the one provided by Tower Oaks to Sun Control, which was debt forgiveness. Here, the benefit provided by De Simone, a license to sell Danisco-produced VSL#3, was the same benefit provided to VSL and then in turn to Leadiant. Similarly, in *Martin Marietta Materials, Inc. v. Redland Genstar, Inc. (In re BACX Corp.)*, No. JFM-99-42, 1999 WL 33955337 (D. Md. Sept. 8, 1999), the court dismissed an unjust enrichment claim by an unsecured creditor based on the theory that a purchaser of the debtor's assets was unjustly enriched by an indemnification agreement with the debtor's surety, finding that the alleged benefit, the indemnification agreement, was not directly or indirectly provided by the plaintiff. *Id.* at *3. Here, by contrast, a clear line can be traced from De Simone to Leadiant.

Leadiant also asserts that the evidence was insufficient to establish that Leadiant accepted a benefit from De Simone under circumstances that would make it inequitable for Leadiant to "retain the benefit without the payment of its value." *Hill*, 936 A.2d at 351. Leadiant claims that where it paid VSL for the right to sell VSL#3, a requirement that it disgorge its profits would be inequitable because it would have effectively paid twice for selling VSL#3. Again, where the evidence established that VSL and Leadiant were both controlled in part by the same owners, such that Leadiant was aware that De Simone had asserted claims over the Know-How that would prevent the sale of VSL#3 by either company, the jury could reasonably conclude that it would be unjust to allow Leadiant, the company which actually received revenue from the sales of VSL#3, to keep its profits without compensation to De Simone, particularly where De Simone sought only Leadiant's net profits. *See Price*, 93 F.3d at 1249.

Finally, Leadiant asserts that the evidence was insufficient to establish the value of any benefit bestowed by De Simone on Leadiant, because De Simone's damages expert, Bryan Callahan, testified only to an overall computation of damages, without distinguishing between

VSL and Leadiant. Whatever the deficiencies in Callahan's testimony, there is no dispute that Leadiant's profit and loss statement from the relevant period provided a month-by-month breakdown of Leadiant's net profits from sales of VSL#3. *See* Tr. Ex. 1202. Although Leadiant argues that its profits are not the same as "the value of the benefit," Leadiant Reply at 15, ECF No. 912, under Maryland law, the measure of recovery for unjust enrichment is "the gain to the defendant, not the loss by the plaintiff." *Mass Transit Admin. v. Granite Const. Co.*, 471 A. 2d 1121, 1126 (Md. Ct. Spec App. 1984) (citation omitted). Under this standard, the evidence of Leadiant's profits from the sale of VSL#3 was sufficient to support the jury's verdict on the unjust enrichment claim against Leadiant.

2. VSL

VSL asserts that De Simone's unjust enrichment claims necessarily fail under *Kimble v. Marvel Entertainment, LLC*, 135 S. Ct. 2401, 2415 (2015), in which the Supreme Court revisited and reaffirmed its holding in *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), that license provisions requiring payment of patent royalties after the expiration of the patent are unenforceable. *Brulotte*, 379 U.S. at 34. In *Brulotte*, the Court concluded that royalty provisions that extended beyond the life of a patent were contrary to "the free market visualized [in patent law] for the post-expiration period," and that, if available, they would subject the market "to monopoly influences that have no proper place there." *Id.* at 32–33. Thus, in general, the life of a patent licensing agreement must be coterminous with the life of the patent. *See id.* at 33–34. *Kimble* affirmed that basic principle while offering further articulation on its limits. As relevant here, *Kimble* holds that licensing provisions providing for "post-expiration royalties are allowable so long as tied to a non-patent right—even when closely related to a patent." *Kimble*, 135 S. Ct. at 2408. To provide a permissible example, *Kimble* offered a license agreement as to a patent and a trade secret that set

"a 5% royalty during the patent period (as compensation for the two combined) and a 4% royalty afterward (as payment for the trade secret alone)." *Id.*

That example maps onto the facts here. In 2001, De Simone entered into a Patent License Agreement with VSL under which he was to receive a three percent royalty on net sales of VSL#3 until those sales totaled $50 million, after which his royalty was increased to five percent. The Patent License Agreement, by its own terms, was to remain in effect until the expiration of the VSL#3 patent, which occurred in February 2015. In 2010, De Simone and VSL entered into the Know-How Agreement, designed to ensure that VSL could continue to supply the U.S. market after the expiration of the patent. The Know-How Agreement licensed to VSL "the exclusive right to [De Simone's] Know How" for the manufacture, production, marketing, and sale of VSL#3 in the U.S. market in exchange for a five percent royalty on sales. Tr. Ex. 4 ¶ 2.1 "Know-How" was defined as "relevant information related to the Product including but not limited to discoveries, processes, composition, technical and scientific data which are in possession or in control of [De Simone] and are needed in order" to manufacture VSL#3. *Id.* ¶ 1.8. By the terms of the Know-How Agreement, it would become effective upon the expiration of the 2001 Patent License Agreement and would remain in effect until January 31, 2016.

Although the Patent License Agreement and the Know-How Agreement are two separate documents, they are the equivalent of the hybrid license discussed in *Kimble* in that they provide for post-patent expiration royalties for intellectual property rights other than the patent. *Kimble*, 135 S. Ct. at 2408. The royalties provided for in the Know-How Agreement were expressly based on the use of the Know-How only. Under *Kimble*, an agreement to provide royalties for intellectual property other than the patent is enforceable. *Kimble*, 135 S. Ct. at 2408.

Even if the Court were to conclude that the lack of a reduction in the amount of royalties after the expiration of the Patent License Agreement was problematic, in that it could be interpreted as effectively extending the requirement to pay royalties for the patent, at most that would render the Know-How Agreement's royalty provision unenforceable. *Brulotte*, 379 U.S. at 34. But De Simone terminated the Know-How Agreement in November 2014, so its enforceability is not at issue. The jury found VSL and Leadiant liable not for breach of contract, but for unjust enrichment, because they were able to continue to sell VSL#3 without paying royalties to De Simone for the Know-How which he owned and controlled. *Brulotte* and *Kimble* not only do not foreclose De Simone's claims for unjust enrichment, but they expressly acknowledge that rights to royalties for "closely related" forms of intellectual property other than a patent may survive beyond the expiration of the patent. *Kimble*, 135 S. Ct. at 2408. *Brulotte* and *Kimble* therefore do not hold that it is inequitable to receive such royalties. *See St. Regis Paper Co. v. Royal Indus.*, 552 F.2d 309, 315 (9th Cir. 1977) (holding that a hybrid license provision that did not distinguish between patent rights and know-how rights was unenforceable but noting that the plaintiff was nevertheless "entitled to compensation for its know-how" and affirming the award of $53,088.90 for the know-how); *Pitney-Bowes, Inc. v. Maestre*, 517 F. Supp. 52, 65 (S.D. Fla. 1981) (finding in a case involving hybrid patent and trade-secrets licenses that, after the expiration of the patent, there remained "material factual questions" whether the licensee's continued use of the trade secret without royalty payments would cause it to be unjustly enriched). Accordingly, the jury could reasonably conclude that it was unjust for VSL and Leadiant, even after the expiration of the patent, to continue to sell VSL#3 without compensating De Simone for the use of his Know-How.

VSL's remaining arguments against the verdict on unjust enrichment also fail. For the reasons discussed above, VSL's claims that De Simone did not confer a benefit on VSL and that

VSL in turn had no appreciation of a benefit because De Simone did not have the right to charge royalties for the Know-How are unpersuasive. VSL cites no authority to support its claims that, as a matter of law, De Simone was required to make a demand for royalties at any particular time, or that his claim is foreclosed by the preliminary injunction issued by this Court. To the extent that these issues arguably could support VSL's claim that they either did not appreciate the benefit of the right to continue to use the Know-How or that it was not unjust to do so, they in no way foreclose the jury's conclusions to the contrary. *See Price*, 93 F.3d at 1249.

For the foregoing reasons, Leadiant's and VSL's Rule 50 Motions will be denied as to De Simone's unjust enrichment claims.

II. Motions for a New Trial

A. Legal Standard

A district court may set aside a jury verdict and order a new trial when it finds that the verdict is against the clear weight of the evidence, is based upon false evidence, or will result in a miscarriage of justice. *Chesapeake Paper Prods. Co. v. Stone & Webster Eng'g Corp.*, 51 F.3d 1229, 1237 (4th Cir. 1995) (citations omitted). In making this determination, "a trial judge may weigh the evidence and consider the credibility of the witnesses," and may set aside the verdict "even if supported by substantial evidence." *Poynter By Poynter v. Ratcliff*, 874 F.2d 219, 223 (4th Cir. 1989). The decision to grant or deny a Rule 59 motion is a matter committed to this Court's sound discretion. *Chesapeake Paper*, 51 F.3d at 1237. However, "a motion for a new trial should not be granted ... where the moving party has failed to timely object to the alleged impropriety giving rise to the motion." *Dennis v. Gen. Elec. Corp.*, 762 F.2d 365, 367 (4th Cir. 1985).

B. Alfasigma

Alfasigma asserts four grounds for a new trial on the false advertising claim against it: (1) the jury's verdict was against the weight of the evidence and was based on evidence that is false; (2) the Court did not balance the equities before awarding damages; (3) because disgorgement is an equitable remedy, damages should not have been submitted to the jury; and (4) the verdict form was defective because it was a general verdict form, rather than a special one.

Alfasigma provides no detail on his first assertion that the jury's verdict on false advertising was against the weight of the evidence, so the Court notes only that, based on the evidence described in the analysis of Alfasigma's Rule 50 motion, the Court finds no reason to set aside the jury's verdict.

Alfasigma also asserts that it was error for ExeGi's false advertising claim to be submitted to the jury because, as ExeGi sought disgorgement, the claim was equitable in nature. In *Dairy Queen, Inc. v. Wood*, 369 U.S. 469 (1962), the Supreme Court, in deciding that the plaintiff in a trademark infringement claim who sought the remedy of an "equitable accounting" of the defendant's profits was entitled to a jury trial, stated that determining whether a remedy was equitable or legal—and thus whether or not the constitutional jury trial right adhered—did not depend on word choice but on the substantive question whether there was "the absence of an adequate remedy at law." *Id.* at 478. The Court explained that, when the remedy sought was "a money claim," it was a "rare case" where no remedy at law would be available, limited to those instances where "the accounts between the parties are of such a complicated nature that only a court of equity can satisfactorily unravel them." *Id.* at 477–78. *Dairy Queen* directs the outcome here. Although disgorgement may have some history in equity, ExeGi's claim required nothing more than the adding up of unjustly earned profits, a task well within the ken of the jury. *See Ver*

Brycke v. Ver Brycke, 843 A.2d 758, 773 (Md. 2004) ("Although the Ver Bryckes relied on unjust enrichment and promissory estoppel, two 'traditionally equitable' doctrines, and requested the remedy of restitution, an equitable remedy, their claims sound in law because they seek the repayment of money."). The Court finds no error in having the jury decide that ExeGi was entitled to Alfasigma's profits and to calculate them.

Next, Alfasigma asserts that under *Synergistic International, LLC v. Korman*, 470 F.3d 162 (4th Cir. 2006), it was reversible error for this Court to rely solely on the jury's verdict in entering money judgment against Alfasigma without itself weighing the equities. In *Synergistic*, the Fourth Circuit affirmed the district court's grant of summary judgment to the plaintiff on its Lanham Act claim, but reversed and remanded on the issue of damages because, in awarding damages, that court merely "summarily stated ... that the equities had been balanced." *Id.* at 174–75. Because *Synergistic* involves a case that was resolved at summary judgment, it sets forth no requirement that, in a Lanham Act case, a court must supplement a jury verdict with its own findings of fact, nor is such a requirement evident in the statute, which states only that "[t]he court shall assess such profits and damages or cause the same to be assessed under its direction." 15 U.S.C. § 1117(a). Here, the Court directed the jury to consider, applying the relevant factors identified in *Synergistic* as stated in Jury Instruction No. 37, whether to award Alfasigma's profits and in what amount. As discussed above, such a task was a proper one for a jury to undertake.

To the extent that the Lanham Act may require the Court, in such a circumstance, to make findings to address the equities apart from the jury's verdict, the Court's failure to date to make explicit findings on the record in no way necessitates a new trial. Rather, the Court could consider the facts presented at trial and render findings without a new trial. These equitable considerations are relevant to the De Simone Parties' separate pending post-trial motion, in which they ask this

Court to enhance the jury's profits award. In an abundance of caution, then, the Court incorporates the equitable analysis in that opinion and concludes that the jury's award was just and was neither inadequate nor excessive. *See Synergistic*, 470 F.3d at 175; *De Simone v. VSL*, De Simone Parties' Post-Trial Motions Mem. Op. § I.

Finally, Alfasigma challenges the verdict form, arguing that it was error for the Court to submit a general verdict form, rather than a special verdict form, to the jury. Alfasigma has offered no persuasive basis to conclude that there was any error in using a general verdict form. Crucially, Alfasigma voiced no objection to the verdict form at trial, so this basis for the Rule 59 Motion fails. *See* Fed. R. Civ. P. 51(c)(2)(A) (stating that an objection to jury instructions is timely if made when provided an opportunity for objections prior to the delivery of the instructions); *N.O. by Orwig v. Alembik*, 694 F. App'x 895, 900 (4th Cir. 2017) (per curiam) (applying this rule to verdict forms). The verdict form therefore cannot provide a basis for a new trial. *See Dennis*, 762 F.2d at 367.

Where Alfasigma has not offered a persuasive argument for a new trial, its Rule 59 Motion will be denied.

C. Omnibus Motion

The VSL Parties have collectively filed an omnibus Rule 59 Motion asserting several bases for a new trial on De Simone's unjust enrichment claim and ExeGi's false advertising claim: (1) the trial and resulting verdict were tainted by repeated inflammatory rhetoric by the De Simone Parties suggesting that Italian VSL#3 was a dangerous product; (2) evidence that confused "species" and "strains" was erroneously admitted; (3) the VSL Parties were prejudiced by the reliance by the De Simone Parties' expert witnesses on previously undisclosed testing data; and

(4) the use of a general verdict form was erroneous. As to the verdict form, the Court rejects this allegation for error for the reasons stated above. *See supra* part II.B.

On the issue of the De Simone Parties' alleged inflammatory rhetoric, the VSL Parties assert that the De Simone Parties made improper remarks about the alleged safety risks of Italian VSL#3, falsely asserted that the VSL Parties could be liable for punitive damages, and improperly shifted the burden of proof to the VSL Parties. Of these asserted errors, only one is arguably preserved: the VSL Parties' objection to the De Simone Parties' remarks about product safety. Where the VSL Parties failed to object to the other asserted errors, they provide no basis for granting a new trial. *See Dennis*, 762 F.2d at 367. In any event, the Court notes that at the outset of the trial, both the VSL Parties and the De Simone Parties sought punitive damages, and the parties, in fact, submitted proposed jury instructions and a proposed verdict form referring to punitive damages.

On the issue of product safety, during the De Simone Parties' opening statement and closing argument, the VSL Parties objected only to the De Simone Parties' counsel's description of the case as one involving "fraud on an enormously serious scale" asserting, for example, that the VSL Parties "have placed ... patients at grave risk" by "peddling a medical product that has not been tested." 11/16/18 Tr. 54–55. In both instances, the Court, at the request of the VSL Parties, gave a curative instruction to the jury clarifying that there was no fraud claim before the jury. To the extent that the reference to a fraud could be deemed unduly prejudicial, the Court's instruction resolved any arguable prejudice, because there is an "almost invariable assumption of the law that jurors follow their instructions." *Nichols v. Ashland Hosp. Corp.*, 251 F.3d 496, 501 (4th Cir. 2001) (quoting *Richardson v. Marsh,* 481 U.S. 200, 206–07 (1987)).

The VSL Parties now claim that a new trial is warranted by other statements during the De Simone Parties' opening statement and closing argument relating to the potential health risk of marketing Italian VSL#3 without having subjected it to clinical trials, and by questions to witnesses relating to Vioxx and other issues regarding safety. However, the Court, having heard the identified statements in the context of the entire trial, perceives no basis on which to conclude that the trial was tainted by the De Simone Parties' rhetoric. First, De Simone's explanation for his decision to start a new company to market the De Simone Formulation, which the VSL Parties claimed to be a breach of fiduciary duty, included his concern that the VSL Parties sought to alter the formulation in a manner that would make the product less effective or potentially unsafe. Thus, some discussion of whether Italian VSL#3 might be less effective or safe was relevant. Second, where the VSL Parties have cited 10 allegedly inflammatory statements over the course of a three-week trial, the Court finds that such scattered statements, not all of which were the subject of an objection, were insufficient to constitute a critical mass that tainted the trial. *See Prichard v. Kurucz*, 22 F. App'x 122, 126 (4th Cir. 2001) (per curiam) ("[T]he district court is in the best position to gauge the effects of an attorney's improper remarks and of its own remedial efforts."). The jury's verdict supports this conclusion. Although the De Simone Parties prevailed on their unjust enrichment and false advertising claims, the jury awarded them far less in damages than they sought. On the unjust enrichment claim, the jury awarded De Simone just over $2 million in damages, only a fraction of the nearly $9 million he sought. The jury likewise cut ExeGi's requested $27 million on the false advertising claim down to $15 million. Under these circumstances, the Court rejects the claim that the jury acted based on inflamed passions rather than reasoned deliberation. *See Nichols*, 251 F.3d at 501 ("We can infer from the partial verdict in favor of Ashland that the jury was *not* swayed by passion or prejudice in the wake of the

outburst, but rather conscientiously followed instructions to disregard the improper statements and conduct.") (citation omitted).

Accordingly, the VSL Parties' reliance on *Warner v. Rossignol*, 538 F.2d 910 (1st Cir. 1976), and *Shamblin's Ready Mix, Inc. v. Eaton Corp.*, 873 F.2d 736 (4th Cir. 1989), is misplaced. In *Warner*, repeated references to a brain injury that were unsupported by the evidence, despite repeated warnings by the trial judge to refrain from such references, had "a profound effect on the jury's fact-finding." *Warner*, 538 F.2d at 911, 913. In *Shamblin's*, counsel based "a large part" of his closing argument on testimony by a witness that was not based on personal knowledge and that proved to be inaccurate, and the prejudicial effect of the testimony and argument was "most forcefully manifested in the jury's punitive damages award, which exceeded the compensatory damages by a ratio of over 184 to 1." *Shamblin's*, 873 F.2d at 739. No such evidentiary errors or manifest impact on the jury's verdict was present here.

The VSL Parties next assert that a new trial is warranted because the De Simone Parties introduced evidence, in particular, the filings with Health Canada, that confused "species" and "strains." As the VSL Parties acknowledge, this issue was addressed and resolved in this Court's denial of VSL's Motion in Limine to Preclude Evidence or Argument Regarding Health Canada, ECF No. 685. The Court finds no basis to revisit its earlier determination and thus rejects this ground for a new trial.

Lastly, the VSL Parties assert that they were prejudiced by the reliance of the De Simone Parties' expert witness, Dr. Gillevet, on allegedly previously undisclosed testing of Italian VSL#3 undertaken at Daegu University in South Korea ("the Korea Testing"). Dr. Gillevet testified that the Korean Testing was conducted on actual Italian VSL#3 purchased from a store and that it demonstrated that the product differed from the De Simone Formulation. Dr. Gillevet used as a

demonstrative aid a slide containing a summary of the results from the Korea Testing. VSL objected to the testimony regarding the Korea Testing because it was not previously disclosed in Dr. Gillevet's expert report and because the slide was not previously disclosed. According to the VSL Parties, Dr. Gillevet's expert report referenced testing of isolates, which refers to bacteria as catalogued in a genome bank, rather than sachets, which refers to actual product purchased on the open market.

The VSL Parties' claim of unfair surprise is not persuasive. First, the Korea Testing was referenced in Dr. Gillevet's supplemental expert reports of October 12 and October 18, 2018. Although these reports were disclosed within a month of trial, the parties had agreed to the admission of expert testimony derived from more recent analysis disclosed in supplemental expert reports. Before trial, the De Simone Parties filed a Motion in Limine to Limit the Testimony of Rodolphe Barrangou, the VSL Parties' designated expert on genetic and functional equivalence. *See* ECF No. 698. Among other arguments asserted, the De Simone Parties sought to limit Dr. Barrangou's testimony to exclude any discussion of his third supplemental expert report, which had been disclosed in August 2018, long after the close of discovery and only three months before trial. *See* Fed. R. Civ. P. 37(c)(1). However, in resolving the motion, the Court learned that in response to Dr. Barrangou's August supplemental expert report, Dr. Gillevet had submitted two additional supplemental expert reports on October 13 and 18, and that Dr. Barrangou had filed another supplemental expert report after reviewing Dr. Gillevet's October 13 supplement. In light of these developments, the VSL Parties took the position that "Dr. Gillevet and Dr. Barrangou should both be permitted to testify to their October opinions, or neither should be able to do so," and informed the Court that they were "comfortable" with "letting all of this come into the jury" because "the issue of equivalence should be decided on a full scientific record." 10/25/18 Pre-Tr.

Conf. 5; 10/25/18 Ltr. at 2, ECF No. 766. Accordingly, the Court denied the De Simone Parties' Motion in Limine seeking to exclude Dr. Barrangou's testimony and noted more broadly that where the numerous supplements "do not appear to offer brand new opinions," and the parties were already on notice of the subject of the expert testimony to be elicited, the various supplements would not be excluded under Rule 37. 10/25/18 Pre-Tr. Conf. 8. The Court therefore informed the parties that "we should just work under the assumption that all of those reports or the contents of the reports are available for the experts to discuss." *Id.* 8–9. Where the VSL Parties explicitly agreed to allow expert testimony from both sides based on recently exchanged supplemental expert reports, in order to ensure that their own expert's recent analysis would be admitted, there was nothing unfair or prejudicial about permitting testimony grounded in Dr. Gillevet's October 2018 supplemental expert reports even if, as the VSL Parties argue, it left little time for follow up discovery or investigation.

The VSL Parties claim that the supplemental expert report did not disclose that the Korean Testing was performed on commercially available products is likewise unpersuasive. Dr. Gillevet's October 12, 2018 supplemental expert report describes the subjects of "API 50 CHL kit" testing as "[t]he original De Simone formulation (capsule), Visbiome (capsule) and Actial VSL#3 products (capsules)." First Gillevet Supp. at 6, ECF No. 766-1. Dr. Gillevet's second supplement states that "the Actial VSL#3 product and the De Simone/Visbiome products cannot be considered functionally equivalent. Furthermore, the fermentation capacity of the combined 8 strains in the De Simone product (sachets) was shown in my previous opinion to be different from the combined 7 strains of the Actial VSL#3 product (sachets) based on the results of the API analysis." Second Gillevet Supp. at 4, ECF No. 766-2. By referring to sachets rather than isolates, the supplemental report reveals that the Korean Testing was performed on a commercial product.

Because the information about which the VSL Parties complain was, in fact, disclosed to them prior to trial in a report that they agreed was sufficiently timely that it could form the basis of expert testimony, Dr. Gillevet's testimony relating to the Korean Testing does not provide a basis for a new trial.

Because the Court is not persuaded by any of the VSL Parties' arguments in the Omnibus Motion that a new trial is warranted, that Motion will be denied.

D. VSL

Lastly, VSL moves for a new trial under Rule 59 based on its contention that this Court's grant of summary judgment to De Simone on the issue of his ownership of the Know-How was erroneous. VSL offers no legal argument on this point, instead stating that it intends to appeal this Court's grant of summary judgment on this issue, and that its Rule 59 motion is filed "[o]ut of an abundance of caution." VSL Rule 59 Mot. at 3, ECF No. 864. The Court finds no basis on which to revisit its summary judgment determination and thus finds no basis to grant a new trial based on that ruling. The Motion will be denied.

CONCLUSION

For the reasons set forth above, Alfasigma's Motions for Judgment as a Matter of Law and a New Trial will be DENIED; Leadiant's Motion for Judgment as a Matter of Law will be DENIED; VSL's Motions for Judgment as a Matter of Law and a New Trial will be DENIED; and the VSL Parties' Omnibus Motion for a New Trial will be DENIED. A separate Order shall issue.

Date: June 20, 2019

THEODORE D. CHUANG
United States District Judge