

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

DAVID STARR, et al.,
Plaintiffs,
v.
VSL PHARMACEUTICALS, INC., et
al.,
Defendants.
Civil Action No. 19-02173-LKG
Dated: May 31, 2023

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

In this putative class action lawsuit, Plaintiffs allege that Defendants, VSL Pharmaceuticals, Inc. ("VSL"), Ladiant Biosciences, Inc. ("Ladiant"), Alfasigma USA, Inc. ("Alfasigma") (collectively, the "VSL Defendants"), Nutrilinea S.R.L. ("Nutrilinea") and Centro Sperimentale del Latte S.R.L. ("Centro"), violated the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-68 (2018); the Uniform Commercial Code ("UCC"); and state law, by engaging in a scheme to deceive consumers by, among other things, misrepresenting the chemical formulation of a probiotic known as VSL#3. ECF No. 93. Nutrilinea has moved to dismiss the claims brought against it for lack of personal jurisdiction, failure to state a claim, and as time-barred, pursuant to Fed. R. Civ. P. 9(b), 12 (b)(2) and 12(b)(6), and Centro joins this motion.1 ECF Nos. 252; 253-1; and 255. Nutrilinea has also

1 Nutrilinea and Centro previously filed motions to dismiss on January 7, 2022. ECF Nos. 136; 140; and 141-1. After Plaintiffs were permitted to take jurisdictional discovery, Nutrilinea filed an amended motion to dismiss. ECF Nos. 252; 253-1. In addition, on May 31, 2023, Nutrilinea filed a motion to seal (ECF No. 277) and a reply brief in support of its amended motion to dismiss (ECF No. 279). Pursuant to the Court's January 24, 2023, Scheduling Order, Nutrilinea's reply brief was due on April 13, 2023, and the reply brief is thus, untimely. ECF No. 250.

moved to file the memorandum in support of its motion and the related exhibits and attachments thereto under seal. ECF No. 254.

In addition, Plaintiffs have moved to file certain exhibits to their response in opposition to Nutrilinea's motion under seal. ECF No. 267-1. Lastly, the VSL Defendants have moved for reconsideration of the Court's September 23, 2022, memorandum opinion and order sustaining Magistrate Judge Simms' June 6, 2022, Decision granting non-party Professor Claudio De Simone's motion to modify a subpoena served on Danisco USA, Inc. ECF Nos. 239; 239-1.

These motions are fully briefed. ECF Nos. 252; 235-1; 239-1; 243; 248; 254; 255; and 265. No hearing is necessary to resolve the motions. L.R. 105.6 (D. Md. 2021). For the reasons that follow, the Court: (1) **GRANTS** Nutrilinea's motion to dismiss; (2) **GRANTS** Nutrilinea's motion to seal; (3) **GRANTS** Plaintiffs' motion to seal; (4) **DENIES** the VSL Defendants' motion for reconsideration; (5) **DENIES-as-MOOT** Centro's motion to dismiss (ECF No. 136); (6) **DENIES-as-MOOT** Nutrilinea's motion dismiss (ECF No. 140); and (7) **DISMISSES** Plaintiffs' RICO claim against Nutrilinea.

II. FACTUAL AND PROCEDURAL BACKGROUND²

A. Factual Background

The Plaintiffs in this putative class action matter are purchasers of a probiotic medical product, VSL#3, who allege that Defendants engaged in a scheme to deceive consumers by, among other things, misrepresenting the chemical formulation of VSL#3, from June 2016 to the present, through "false and misleading advertising and marketing." ECF No. 93. Plaintiffs bring RICO, breach of express warranty, unjust enrichment and various state law consumer protection claims related to the Defendants' sale, advertising and manufacturing of VSL#3. *Id.* at ¶¶ 160-299.

As this Court has previously observed, this case is the latest in a long-running intellectual property dispute between former business partners Professor Claudio De Simone and VSL regarding who has rightful ownership of a proprietary probiotic formulation ("the De Simone Formulation") used in a product sold for many years under the name "VSL#3," a trademark

² The facts recited in this memorandum opinion and order are taken from the second amended complaint and Nutrilinea's amended motion to dismiss, and the memorandum in support thereof and the exhibits attached thereto.

owned by VSL. ECF No. 205. In November 2018, a jury returned a verdict in favor of Professor De Simone and his new business venture, ExeGi Pharma, LLC. ECF No. 93 at 6. And so, on June 20, 2019, this Court issued a permanent injunction against Leadiant and Alfasigma, the companies that have marketed and distributed VSL#3 on behalf of VSL, enjoining them from: (1) stating or suggesting in VSL#3 promotional materials directed at United States consumers that the present version of VSL#3 produced in Italy continues to contain the De Simone Formulation, including by stating that VSL#3 contains the “original proprietary blend” or the “same mix in the same proportions” as the earlier version of VSL#3 and (2) “citing to or referring to any clinical studies performed on the De Simone Formulation or earlier versions of VSL #3 as relevant or applicable to Italian VSL#3.” Prelim. Inj. Order at 2, ECF No. 930, *De Simone v. VSL Pharm., Inc.*, No. TDC-15-1356 (D. Md. June 20, 2019).

In this case, Plaintiffs assert RICO and other claims against Defendants related to the marketing and sale of VSL#3 in the United States. ECF No. 93 at ¶¶ 2–5. VSL owns the VSL#3 trademark and, during the period of 2002 to 2016, VSL marketed and sold a version of VSL#3 that used a proprietary formulation created by Professor Claudio De Simone. *Id.* at ¶ 2.

Plaintiffs allege that VSL lost the right to sell the De Simone Formulation in 2016 and that Professor De Simone granted an exclusive license to ExeGi Pharma, LLC to market and sell the De Simone Formulation in the United States at that time. *Id.* at 3. Plaintiffs also allege that VSL continued to use the VSL #3 mark to market and sell a different formulation (“Current Formulation”). *Id.*

Plaintiffs contend that the marketing of VSL#3 and the Current Formulation misled consumers to believe that VSL#3 continued to contain the De Simone Formulation. *Id.* And so, Plaintiffs allege in this action that the marketing of the Current Formulation fails to disclose material differences from the De Simone Formulation, including the number and proportion of bacteria strains (the active ingredients in VSL#3). *Id.* at 3-4.

Plaintiffs’ RICO Claim Against Nutrilinea

Relevant to the pending motion to dismiss, on July 28, 2021, Plaintiffs filed a second amended complaint, which added Nutrilinea and Centro as Defendants in this action with regards to their RICO claim. *See generally id.* In the second amended complaint, Plaintiffs allege that Nutrilinea and Centro worked in “concert and in coordination” with the VSL Defendants to advance the VSL Defendants’ alleged false advertising scheme. *Id.* at ¶ 1.

Nutrilinea is a limited liability company, organized and incorporated under the laws of Italy, with its principal place of business in Gallarate, Italy. *Id.* at ¶ 34. Nutrilinea manufactures and packages food supplements, medical foods and medical device products at its plants located in Gallarate (VA), Cusano Milanino (MI), and Monselice (PD), Italy. *Id.* at ¶¶ 2, 12.

It is undisputed that Nutrilinea does not have any employees, offices, or operations in the United States. *Id.* at ¶¶ 5–6; ECF No. 253-1 at 13. It is also undisputed that Nutrilinea does not have a registered agent for service of process in the State of Maryland, or anywhere in the United States. ECF No. 253-1 at ¶ 6.

Nutrilinea also does not own any real property in the United States; nor has it ever acquired, disposed of, owned, or leased any real property in the United States. *Id.* at ¶¶ 7–8. In addition, Nutrilinea does not pay taxes to Maryland, or the United States, and it is not registered to do business in Maryland, or in any other State in the United States. *Id.* at ¶¶ 9–10. As required by federal law, Nutrilinea is registered with the United States Food and Drug Administration (“FDA”) as a foreign food facility. ECF No. 253-2 at ¶ 31.

Nutrilinea’s Supply Agreement

In November 2016, Nutrilinea entered into an agreement with Centro, Sacco S.R.L., and Alfasigma to partially manufacture and package VSL#3 (the “Supply Agreement”). *Id.* at ¶ 16; Ex. 1 (J.R.0001). The Supply Agreement is governed by Italian law and contains a forum selection clause providing for exclusive jurisdiction in Rome, Italy. *Id.* at 18.

Nutrilinea manufactures and packages VSL#3 under the Supply Agreement at its plant located in Gallarate, Italy. ECF No. 253-2 at ¶ 13; SAC ¶¶ 35, 164. In this regard, Nutrilinea receives instructions and the active ingredients for manufacturing VSL#3 in Italy. ECF No. 253-2 at ¶ 21; SAC ¶ 6. Alfasigma determines the contents of the packaging and labeling, including the product information sheet, for VSL#3 and also instructs Nutrilinea regarding the packaging and labeling of VSL#3 as part of the manufacturing process in Italy. ECF No. 253-2 at ¶ 22; SAC ¶¶ 30, 82, 90–92 (alleging that VSL Defendants provide information to Nutrilinea for use in the manufacture, packaging, marketing, and sale of VSL#3).

After Nutrilinea manufactures and packages VSL#3 at its facility in Gallarate, Italy, it delivers and transfers ownership and title of the VSL#3 to Alfasigma at that same facility in accordance with the Supply Agreement. ECF No. 253-2 at ¶¶ 23–25. In this regard, the Supply Agreement provides, in relevant part that: “the Seller [Nutrilinea] shall deliver Products EX-

WORKS Incoterms 2012 from the Seller’s facility in Gallarate (VA), Italy, to the delivery address requested by Alphasigma.” *Id.* at ¶ 23. The Supply Agreement also specifies that the delivery address is “Nutrilinea srl Via Gran Bretagna 1 21013 Gallarate (VA)” and requires Nutrilinea to deliver and transfer ownership and title to VSL#3 to Alfasigma at Nutrilinea’s facility in Gallarate, Italy. *Id.* at ¶ 24; ECF No. 253-3 at 9.

Nutrilinea maintains that: (1) its sole responsibility under the Supply Agreement is to deliver VSL#3 to Alfasigma at its facility in Gallarate, Italy; (2) ownership and title to VSL#3 (and all related risk of loss or damage) are transferred to Alfasigma upon delivery; and (3) Alfasigma bears full and exclusive responsibility for any subsequent use of VSL#3, including the probiotics transportation from Italy to the United States. ECF No. 253-2 at ¶¶ 23–25. Nutrilinea also maintains that it does not market, sell, promote, or advertise VSL#3 in Maryland, or anywhere in the United States. *Id.* at ¶ 28. And so, Nutrilinea contends that it is not responsible for the marketing, advertising and sale of VSL#3 in the United States. SAC ¶¶ 2, 5, 30–33, 67–68, 79–80, 116.

B. Relevant Procedural History

Plaintiffs commenced this putative class action matter on July 23, 2019. ECF No. 1. Plaintiffs amended the complaint by leave of the Court on January 8, 2020, and July 28, 2021, respectively. ECF Nos. 40; 93.

On February 17, 2023, Nutrilinea filed an amended motion to dismiss, pursuant to Fed. R. Civ. P. 9, 12(b)(2) and 12(b)(6), and a memorandum in support thereof. ECF Nos. 252; 253 and 253-1. On April 14, 2023, Plaintiffs filed a response in opposition to Nutrilinea’s motion to dismiss. ECF Nos. 265; 266. On February 23, 2023, Centro filed a notice stating that it joins Nutrilinea’s motion to dismiss. ECF No. 255.

On February 17, 2023, Nutrilinea filed a motion to file the memorandum in support of its motion to dismiss and the related exhibits and attachments thereto under seal. ECF No. 254. On April 14, 2023, Plaintiffs filed a motion to file the unredacted version of their response in opposition to Nutrilinea’s motion to dismiss under seal. ECF No. 267.

On November 29, 2022, the VSL Defendants filed a motion for reconsideration of the Court’s September 23, 2022, memorandum opinion and order. ECF Nos. 205; 239. On December 13, 2022, Claudio De Simone filed a response in opposition to the VSL Defendants’

motion for reconsideration. ECF No. 243. On December 27, 2022, the VSL Defendants filed a reply brief. ECF No. 248.

These motions having been fully briefed, the Court resolves the pending motions.

III. LEGAL STANDARDS

A. Fed. R. Civ. P. 12(b)(2)

A motion to dismiss for lack of personal jurisdiction brought pursuant to Fed. R. Civ. P. 12(b)(2) “raises an issue for the [C]ourt to resolve, generally as a preliminary matter.” *Grayson v. Anderson*, 816 F.3d 262, 267 (4th Cir. 2016). The burden is “on the plaintiff ultimately to prove the existence of a ground for jurisdiction by a preponderance of the evidence.” *Combs v. Bakker*, 886 F.2d 673, 676 (4th Cir. 1989). To do so, a plaintiff need only make “a *prima facie* showing of personal jurisdiction to survive the jurisdictional challenge.” *Grayson*, 816 F.3d at 268. When deciding a motion brought pursuant to Fed. R. Civ. P. 12(b)(2), the Court may “rule solely on the basis of motion papers, supporting legal memoranda, affidavits, and the allegations in the complaint.” *State v. Exxon Mobil Corp.*, 406 F. Supp. 3d 420, 437 (D. Md. 2019) (citations omitted). And so, the Court must consider all disputed facts and make reasonable inferences in favor of the plaintiff in determining whether the plaintiff has made the requisite showing that the Court possesses personal jurisdiction over a defendant. *See Carefirst of Md., Inc. v. Carefirst Pregnancy Ctrs., Inc.*, 334 F.3d 390, 396 (4th Cir. 2003).

B. Personal Jurisdiction And Fed. R. Civ. P. 4(k)(2)

When a federal court sits in diversity, it “has personal jurisdiction over a non-resident defendant if (1) an applicable state long-arm statute confers jurisdiction and (2) the assertion of that jurisdiction is consistent with constitutional due process.” *Nichols v. G.D. Searle & Co.*, 991 F.2d 1195, 1199 (4th Cir.1993) (citing *Blue Ridge Bank v. Veribank, Inc.*, 755 F.2d 371, 373 (4th Cir. 1985)). The reach of Maryland’s long-arm statute is coextensive with the reach of the Due Process Clause of the United States Constitution, and so the “statutory inquiry merges with [the] constitutional examination.” *Beyond Sys., Inc. v. Realtime Gaming Holding Co., LLC*, 878 A.2d 567, 580 (Md. 2005).

This Court may exercise general or specific personal jurisdiction. *Perdue Foods, LLC v. BRF S.A.*, 814 F.3d 185, 188 (4th Cir. 2016). General personal jurisdiction requires “continuous

and systemic” contacts with the forum state. *See Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414–16 (1984) (quoting *Perkins v. Benguet Consolidated Mining Co.*, 342 U.S. 437 (1952)). The Supreme Court has held that a court has specific personal jurisdiction over a defendant if the defendant “purposefully established minimum contacts in the forum State” such “that [it] should reasonably anticipate being haled into court there.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474 (1985) (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 295 (1980)) (internal quotation marks and citations omitted).

To determine whether specific jurisdiction lies in the forum State, the Court considers: “(1) the extent to which the defendant purposefully availed itself of the privilege of conducting activities in the State; (2) whether the plaintiffs’ claims arise out of those activities directed at the State; and (3) whether the exercise of personal jurisdiction would be constitutionally reasonable.” *Perdue Foods*, 814 F.3d at 189 (quoting *ALS Scan, Inc. v. Digital Serv. Consultants, Inc.*, 293 F.3d 707, 712 (4th Cir. 2002)) (internal quotation marks omitted). To determine whether a defendant purposefully availed itself of the privilege of conducting activities in the forum State, the Court considers numerous nonexclusive factors including, in the business context, whether the defendant: (1) “maintains offices or agents in the forum state;” (2) “owns property in the forum state;” (3) “reached into the forum state to solicit or initiate business;” (4) “deliberately engaged in significant or long-term business activities in the forum state;” or (5) “made in-person contact with the resident of the forum in the forum state regarding the business relationship.” *Id.* (quoting *Consulting Eng’rs Corp. v. Geometric Ltd.*, 561 F.3d 278 (4th Cir. 2009)). The Court also considers: (1) “whether the parties contractually agreed that the law of the forum State would govern disputes;” (2) “whether the performance of contractual duties was to occur within the forum;” and (3) “the nature, quality and extent of the parties’ communications about the business being transacted.” *Id.*

The Court may also consider whether personal jurisdiction over a defendant might lie, because the defendant entered into a contract that requires it to perform significant contractual duties in the forum State. *Id.* at 190 (citing *Peanut Corp. of Am. v. Hollywood Brands, Inc.*, 696 F.2d 311, 314 (4th Cir. 1982)). For example, a plaintiff may be able to establish specific personal jurisdiction through a single contract, because often a contract is “but an intermediate step serving to tie up prior business negotiations with future consequences which themselves are the real object of the business transaction.” *Burger King*, 471 U.S. at 479 (internal quotation marks

omitted). And so, specific personal jurisdiction can arise from one contract, “where the defendant deliberately has engaged in significant activities within a State or has created continuing obligations between [it]self and residents of the forum.” *Id.* at 475–76 (internal quotation marks and citations omitted).

Lastly, Federal Rule of Civil Procedure Rule 4(k)(2) addresses personal jurisdiction over a defendant and provides that:

For a claim that arises under federal law, serving a summons or filing a waiver of service establishes personal jurisdiction over a Defendant if:

- (A) the Defendant is not subject to jurisdiction in any state’s courts of general jurisdiction; and
- (B) exercising jurisdiction is consistent with the United States Constitution and laws.

Fed. R. Civ. P 4(k)(2). The Court’s due process analysis under Rule 4(k)(2) is nearly identical to traditional personal jurisdiction analysis discussed above with one significant difference—rather than considering contacts between the defendant and the forum State, the Court considers contacts with the nation as a whole. *Resolute Forest Prods., Inc. v. Greenpeace Int’l*, No. 17-cv-02824-JST, 2019 WL 281370, at *5 (N.D. Cal. Jan. 22, 2019); *Receiver for Rex Venture Grp., LLC v. Banca Commerciale Victoriabank SA*, 843 F. App’x 485, 492 (4th Cir. 2021). And so, to establish personal jurisdiction under Rule 4(k)(2), a plaintiff must show, among other things, that: (1) the Defendant “purposefully directed” its activities towards the United States; (2) the plaintiff’s claim “results from alleged injuries that arise out of or relate to those activities;” and (3) “the assertion of personal jurisdiction would comport with fair play and substantial justice.” *Syngenta Crop Protection, LLC v. Willowood, LLC*, 139 F. Supp. 3d 722, 732-33 (M.D.N.C. 2015) (citation omitted); *De Simone v. VSL Pharms, Inc.*, No. TDC-15-1356, 2017 WL 66323, at *22 (D. Md. Feb. 16, 2017).

IV. LEGAL ANALYSIS

Nutrilinea has moved to dismiss the RICO claim brought against it in this putative class action pursuant to Fed. R. Civ. P. 9(b), 12 (b)(2) and 12(b)(6). ECF Nos. 252; 253-1; and 255. Specifically, Nutrilinea argues that the Court should dismiss this claim because: (1) the Court lacks personal jurisdiction over Nutrilinea; (2) Plaintiffs lack standing to bring their RICO claim

against Nutrilinea; (3) Plaintiffs fail to state a plausible RICO claim; and (4) Plaintiffs' RICO claim is time-barred under RICO's four-year statute of limitations. *See generally* ECF No. 252.

Plaintiffs counter that: (1) Nutrilinea maintains sufficient contacts with the United States to assert personal jurisdiction; (2) they have standing to bring their RICO claim; (3) they state a plausible RICO claim against Nutrilinea in the second amended complaint; and (4) their RICO claim is not time-barred. *See generally* ECF No. 265. And so, Plaintiffs request that the Court deny Nutrilinea's motion to dismiss.

Nutrilinea and Plaintiffs have also moved to file certain filings and exhibits related to the briefing of Nutrilinea's motion to dismiss under seal. ECF Nos. 254; 267-1. Lastly, the VSL Defendants have moved for reconsideration of the Court's September 23, 2022, memorandum opinion and order sustaining Magistrate Judge Simms' June 6, 2022, Decision granting non-party Professor Claudio De Simone's motion to modify a subpoena served on Danisco USA, Inc. ECF Nos. 239; 239-1. Professor De Simone opposes this motion. *See generally* ECF No. 243.

For the reasons that follow, the undisputed facts before the Court show that Nutrilinea lacks sufficient contacts with the United States to assert personal jurisdiction over Nutrilinea in this civil action. In addition, Nutrilinea and Plaintiffs have shown that it is appropriate to maintain certain filings and exhibits related to Nutrilinea's motion to dismiss under seal. Lastly, the VSL Defendants have not shown that reconsideration of the Court's September 23, 2022, memorandum opinion and order is warranted. And so, the Court (1) **GRANTS** Nutrilinea's motion to dismiss; (2) **GRANTS** Nutrilinea's motion to seal; (3) **GRANTS** Plaintiffs' motion to seal; (4) **DENIES** the VSL Defendants' motion for reconsideration; (5) **DENIES-as-MOOT** Centro's motion to dismiss (ECF No. 136); (6) **DENIES-as-MOOT** Nutrilinea's motion to dismiss (ECF No. 140); and (7) **DISMISSES** Plaintiffs' RICO claim against Nutrilinea.

A. The Court Does Not Possesses Personal Jurisdiction Over Nutrilinea

As an initial matter, the Court must resolve the threshold issue of whether it is appropriate to assert personal jurisdiction over Nutrilinea in this civil action. Generally, this Court has personal jurisdiction over Nutrilinea if Nutrilinea "purposefully established minimum contacts in the forum State" such "that [it] should reasonably anticipate being haled into court there." *Burger King Corp.*, 471 U.S. at 474 (internal quotation marks and citations omitted). To determine whether specific personal jurisdiction lies here, the Court considers: "(1) the extent to which Nutrilinea purposefully availed itself of the privilege of conducting activities in the State;

(2) whether the Plaintiffs' RICO claim arises out of those activities directed at the State; and (3) whether the exercise of personal jurisdiction would be constitutionally reasonable." *Perdue Foods*, 814 F.3d at 189 (internal quotation marks omitted).

The Court also considers numerous nonexclusive factors to determine whether Nutrilinea purposefully availed itself of the privileges of conducting activities in the forum State, including in the business context, whether Nutrilinea: (1) "maintains offices or agents in the forum state;" (2) "owns property in the forum state;" (3) "reached into the forum state to solicit or initiate business;" (4) "deliberately engaged in significant or long-term business activities in the forum state;" or (5) "made in-person contact with the resident of the forum in the forum state regarding the business relationship." *Id.* The Court may also consider: (1) "whether the parties contractually agreed that the law of the forum state would govern disputes;" (2) "whether the performance of contractual duties was to occur within the forum;" and (3) "the nature, quality and extent of the parties' communications about the business being transacted." *Id.*

In this case, Plaintiffs rely upon Fed R. Civ. P. 4(k)(2) to establish personal jurisdiction. ECF No. 265 at 14-26. Under Rule 4(k)(2), the Court may assert personal jurisdiction over Nutrilinea if: (1) the suit arises under federal law; (2) Nutrilinea is not subject to personal jurisdiction in any state; and (3) Nutrilinea has contacts with the United States consistent with the United States Constitution and federal law. *Grayson*, 816 F.3d at 271; *see also* Fed R. Civ. P. 4(k)(2). The parties do not dispute that this lawsuit arises under federal law and that Nutrilinea is not subject to personal jurisdiction in any State, including Maryland. ECF Nos. 266-1 at 15; 253-1 at 18-19. And so, the Court focuses its analysis here on whether Nutrilinea has contacts with the United States consistent with the United States Constitution and federal law. *Grayson*, 816 F.3d at 271.

To demonstrate that Nutrilinea has sufficient contacts with the United States, Plaintiffs must show three things, namely, that: (1) Nutrilinea "purposefully directed" its activities towards the United States; (2) their RICO claim "results from alleged injuries that arise out of or relate to those activities;" and (3) "the assertion of personal jurisdiction would comport with fair play and substantial justice." *Syngenta Crop Protection*, 139 F. Supp. 3d at 732-33 (citation omitted); *De Simone*, 2017 WL 66323, at *22. For the reasons that follow, Nutrilinea persuasively argues that Plaintiffs cannot make such a showing in this case.

First, the factual record before the Court does not show that Nutrilinea “purposefully directed” its manufacturing activities towards the United States. *See generally* ECF Nos. 93; 253-1. It is undisputed that Nutrilinea is a limited liability company organized and incorporated under the laws of Italy, and that its principal place of business is located in Gallarate, Italy. ECF Nos. 93 at ¶ 34; 253-1 at 24-25. It is also undisputed that Nutrilinea does not have any employees, offices, or operations in the United States. ECF Nos. 93 at ¶¶ 5–6; 253-1 at 13.

The parties also agree that Nutrilinea does not own, or lease, any real property located in the United States. ECF No. 93 at ¶¶ 7–8; *see generally* ECF No. 266. Nutrilinea also represents to the Court, and Plaintiffs do not dispute, that Nutrilinea does not advertise, market, or sell any of the products that it manufactures within the United States, including VSL#3. *Id.* And so, the undisputed facts show that Nutrilinea has not “purposefully directed” its manufacturing activities towards the United States.

Plaintiffs’ reliance upon Nutrilinea’s Supply Agreement with, among others, Alfasigma to show that Nutrilinea purposefully directed its activities towards the United States is also misplaced. As the Supreme Court and the Fourth Circuit have recognized, personal jurisdiction over a defendant company might lie, because the defendant entered into a contract that requires it to perform significant contractual duties in the forum State. *Perdue Foods*, 814 F.3d at 190; *see also Peanut Corp.*, 696 F.2d at 314. And so, specific personal jurisdiction over Nutrilinea might lie here, if the Supply Agreement involves significant activities within the United States, or creates continuing obligations between Nutrilinea and residents of the United States. *Burger King*, at 475-76; 479, 105 S.Ct. 2174 (internal quotation marks omitted).

But the undisputed facts show that the Supply Agreement at issue here does not involve such significant activities or continuing obligations within the United States. As discussed above, the parties agree that Nutrilinea manufactures and packages VSL#3 at its plant located in Gallarate, Italy pursuant to the Supply Agreement. ECF No. 253-2 at ¶¶ 13-17; SAC ¶¶ 35, 164; ECF No. 253-3 at 2-4. The evidence before the Court also shows that Nutrilinea does not perform its contractual duties under the Supply Agreement within the United States. *See generally* ECF Nos. 93; 253-2; 253-3. Notably, the affidavit of Maurizio Castorina makes clear that Nutrilinea delivers and transfers ownership and title of the VSL#3 to Alfasigma in Italy, in accordance with the terms of the Supply Agreement. ECF No. 253-2 at ¶¶ 23–25; *see also* ECF No. 253-1 at 9 (providing that “[Nutrilinea] shall deliver Products EX-WORKS Incoterms 2012

from the Seller's facility in Gallarate (VA), Italy, to the delivery address requested by Alphasigma- "Nutrilinea srl Via Gran Bretagna 1 21013 Gallarate (VA)."). ECF Nos. 253-2 at ¶ 24; 253-3 at 9; 253-3 at 42. The Supply Agreement also states that the agreement is governed by Italian law and requires that all of Nutrilinea's relevant contractual duties occur in Italy. ECF No. 93 at 13-14. Given this, the terms of the Supply Agreement make clear that this agreement does not involve significant activities in the United States.

The evidence before the Court also shows that the Supply Agreement also does not create any continuing obligations between Nutrilinea and residents of the United States. There is no dispute that Nutrilinea does not market or sell VSL#3 to residents of the United States. ECF No. 93 at ¶¶ 7-8; *see generally* ECF No. 266. As discussed above, there is also no dispute that Nutrilinea is not registered to do business in Maryland, or in any other State in the United States. ECF No. 253-1 at ¶¶ 6-10. While it is true that the VSL#3 probiotic manufactured by Nutrilinea is sold in the United States, there is no dispute that Nutrilinea has no role in marketing or selling VSL#3 in the United States. And so, the Supply Agreement simply fails to establish a series of continuing contacts in the United States to establish personal jurisdiction over Nutrilinea in this civil action.

Plaintiffs' argument that Nutrilinea purposefully directed its activities towards the United States, because the company is registered as a foreign food facility with the FDA, is equally unavailing. Nutrilinea acknowledges that it is registered with the FDA as a foreign food facility. ECF No. 253-1 at 29. And so, Nutrilinea certainly has *some* contacts with the United States. But Nutrilinea's FDA registration, without more, is not sufficient to show that the company *purposefully directed* its manufacturing activities towards the United States. As the United States District Court for the Eastern District of Virginia has held, FDA registration, alone, is not sufficient to establish personal jurisdiction, where the defendant company has not sent any representatives to the selected forum or held any meetings or activities in the forum State. *See Baker v. Patterson Med. Supply, Inc.*, No. 4:11cv37, 2011 WL 2731259, at *4, 9-25 (E.D. Va. Nov. 17, 2011) (holding that the Court did not have personal jurisdiction over FDA-registered and third-party defendants because the third-party defendants did not have any representatives or events in the forum to demonstrate sufficient minimum contacts). Similarly here, the undisputed facts show that Nutrilinea has not sent any representatives to the United States, or held any

activities in the United States. And so, again, the undisputed facts do not show sufficient minimum contacts with the United States to establish personal jurisdiction.

Because the undisputed facts show that Nutrilinea's manufacturing activities are limited to Italy, and that the company does not market or sell VSL#3 to residents of the United States, the evidence before the Court fails to establish that Nutrilinea "purposefully directed" its manufacturing activities towards the United States. And so, the Court does not have personal jurisdiction over Nutrilinea under Rule 4(k)(2).

The Court also observes that, even if Plaintiffs could show that Nutrilinea purposefully directed its manufacturing activities towards the United States, they can neither show that their RICO claim against Nutrilinea results from alleged injuries that arise out of or relate to Nutrilinea's manufacturing activities, nor that the assertion of personal jurisdiction would comport with fair play and substantial justice. *See Syngenta Crop Protection*, 139 F. Supp. 3d at 732-33 (citation omitted); *De Simone*, 2017 WL 66323, at *22. While the second amended complaint broadly alleges a RICO scheme that involves the manufacturing, sale and marketing of VSL#3, a close reading of the second amended complaint makes clear that the specific conduct complained of with regards to Plaintiffs' RICO claim against Nutrilinea involves the *marketing and sale* of VSL#3 within the United States, rather than the manufacturing of VSL#3. *See* ECF No. 93 at 58-59, 61 (alleging that "Defendants VSL Inc. and Alfasigma are continuing to market and sell the Fraudulent Formulation of VSL#3 as if it were the De Simone Formulation, using the same or similar means of false pretenses, misrepresentations, promises and/or omissions, in particular by continuing to sell VSL#3 to consumers using false advertising messages and without disclosing to them that the current version of VSL#3 uses a different formulation than the prior version, and the current version has not been proven to be clinically effective" and that Plaintiffs "relied, to their detriment, on Defendants' fraudulent misrepresentations and omissions, which were made by means of websites, mass mailings, newspaper advertisements, product packaging and inserts, telephone calls, marketing materials and virtually uniform representations or omissions.") The Court also agrees with Nutrilinea that asserting personal jurisdiction over Nutrilinea in this civil action would not comport with fair play and substantial justice, given the company's limited contacts with the United States.

Because the evidence before the Court, when construed in the light most favorable to Plaintiffs, shows that Nutrilinea lacks sufficient contacts with the United States to establish personal jurisdiction under Fed. R. Civ. P. 4(k)(2), the Court DISMISSES Plaintiffs' RICO claim against Nutrilinea for lack of personal jurisdiction. Fed. R. Civ. P. 12(b)(2).³

B. The Court Grants The Parties' Motions To Seal

Nutrilinea and Plaintiffs have filed motions to seal certain documents filed in connection with the briefing of Nutrilinea's motion to dismiss. Specifically, on February 17, 2023, Nutrilinea filed a motion to file its memorandum in support of its motion to dismiss and the related exhibits and attachments under seal. ECF No. 254. On April 14, 2023, Plaintiffs also filed a motion to seal the unredacted version of their response in opposition to Nutrilinea's motion to dismiss. ECF No. 267. No objections to these motions have been filed. The Court finds that: (1) the proposed sealed documents contain sensitive, personal, and confidential information about the parties and (2) there are no less restrictive alternatives to sealing that would sufficiently protect this sensitive information. And so, for good cause shown, the Court GRANTS the motions to seal filed by Nutrilinea and Plaintiffs.

C. Reconsideration Of The Court's Discovery Order Is Unwarranted

As a final matter, the VSL Defendants have moved for reconsideration of the Court's September 23, 2022, memorandum opinion and order (the "September 23, 2022, Decision") sustaining Magistrate Judge Simms' June 6, 2022, decision granting non-party Professor De Simone's motion to modify a subpoena served on Danisco USA, Inc. ECF No. 239; 239-1. The subpoena at issue seeks information and documents that VSL requested *via* a third-party subpoena served on Danisco on November 30, 2021 (the "Challenged Requests").⁴

³ Because the Court determines that it cannot assert personal jurisdiction over Nutrilinea, the Court does not reach the other issues raised in Nutrilinea's motion to dismiss.

⁴ VSL's subpoena seeks, among other things, the following documents and information

1. All documents produced by Danisco in the De Simone Litigation.
2. All documents reflecting any change in the bacteria used in the manufacture of VSL#3.
3. All documents reflecting any change in the bacteria used in the manufacture of Visbiome.

In their motion, the VSL Defendants argue that the Court should reconsider the “September 23, 2022, Decision, because: (1) Plaintiffs are challenging the safety and efficiency of VSL #3 in this action and (2) Defendants need the information at issue in this discovery dispute to test and challenge Plaintiffs’ theory regarding value of VSL #3 and the alleged injury in this action.” ECF No. 239-1 at 1. Professor De Simone counters that reconsideration of the Court’s September 23, 2022, Decision is unwarranted, because: (1) the information that the VSL Defendants seek does not pertain to the value, safety, or efficacy of VSL#3; (2) the VSL

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4. All documents reflecting any change in the cryoprotectants used in VSL #3 from July 1, 2000, through the final date of its production by Danisco.
 5. All documents reflecting any change in the excipients used in the manufacture of VSL #3 from July 1, 2000, through the final date of its production by Danisco.
 6. All documents reflecting the cryoprotectants used in the manufacture of Visbiome from the date of its initial production by Danisco to present.
 7. All documents reflecting the excipients used in the manufacture of Visbiome from the date of its initial production by Danisco to present.
 8. All documents reflecting any change in the cryoprotectants used in the manufacture of Visbiome from the date of Visbiome's initial production by Danisco to present.
 9. All documents reflecting any change in the excipients used in the manufacture of Visbiome from the date of Visbiome's initial production by Danisco to present.
 10. All documents reflecting the relative ratio of bacteria used in the production of Visbiome from the date of Visbiome's initial production by Danisco to present.
 11. All documents reflecting the half-life of each of the bacterial ingredients present in Visbiome from the date of Visbiome's initial production by Danisco to present.
 12. All documents reflecting any efforts to remove lactose from Visbiome from the date of Visbiome's initial production by Danisco to present.
 13. All documents reflecting the pre-manufacturing ratio of bacterial strains in Visbiome from the date of Visbiome's initial production by Danisco to present.
 14. All documents reflecting the post-manufacturing ratio of bacterial strains in Visbiome from the date of Visbiome's initial production by Danisco to present.
 15. All documents reflecting any change in the manufacturing process for Visbome from the date of Visbiome's initial production by Danisco to present.
 16. All documents reflecting the half-life of the bacterial strains present in Visbiome from the date of Visbiome's initial production by Danisco to present.
 19. All documents that present, discuss, or analyze in any way the prices at which Visbiome is sold.

See ECF No. 205 at 2-3.

Defendants put forward no legally cognizable grounds for reconsideration; and (3) the Court's Decision does not restrict the VSL Defendants' ability to obtain information about the safety and efficacy of VSL#3. ECF No. 243 at 2-3.

For the reasons that follow, the Court agrees and DENIES the VSL Defendants' motion for reconsideration.

The gravamen of the VSL Defendants' motion for reconsideration is that the September 23, 2022, Decision is clearly erroneous and would work manifest injustice, because the Court erred in finding that "there are no claims about VSL#3's safety, value, or efficacy in his case." ECF No. 239-1 at 1. Reconsideration of an interlocutory order is generally appropriate when: (1) there has been an intervening change in controlling law; (2) there is additional evidence that was not previously available; or (3) the prior decision was based on a clear error of law or fact or would work "manifest injustice." *Am. Canoe Ass'n*, 326 F.3d at 514-15. In this regard, prior decisions of the Court become law of the case and must be followed unless, "(1) a subsequent trial produces substantially different evidence; (2) controlling authority has since made a contrary decision of law applicable to the issue; or (3) the prior decision was clearly erroneous and would work manifest injustice." *Id.* at 515 (citing *Sejman v. Warner-Lambert Co., Inc.*, 845 F.2d 66, 69 (4th Cir. 1988)).⁵ But parties "should not be permitted to use a motion to reconsider as a vehicle to introduce additional evidence which could have been adduced during the pendency of the prior motion. . . Dispositive motions serve judicial economy by encouraging parties to winnow out extraneous issues." *Fayetteville Inv'rs v. Commercial Builders, Inc.*, 936 F.2d 1462, 1470 (4th Cir. 1991). And so, "reconsideration of a judgment after its entry is an extraordinary remedy which should be used sparingly." *Pac. Ins. Co. v. Am. Nat. Fire Ins. Co.*, 148 F.3d 396, 403 (4th Cir. 1998) (citation omitted).

⁵ This Court has held that "[c]lear error or manifest injustice occurs where a court 'has patently misunderstood a party, or has made a decision outside the adversarial issues presented to the Court by the parties, or has made an error not of reasoning but of apprehension. . .'" *Wagner v. Warden*, No. ELH-14-791, 2016 WL 1169937, at *3 (D. Md. Mar. 24, 2016) (quoting *King v. McFadden*, 2015 WL 4937292, at *2 (D.S.C. August 18, 2015)). But "mere disagreement" with the Court's ruling does not support a motion to reconsider. *Hutchinson v. Staton*, 994 F.2d 1076, 1082 (4th Cir. 1993); *see also Lynn v. Monarch Recovery Mgmt., Inc.*, 953 F. Supp. 2d 612, 620 (D. Md. 2013).

The VSL Defendants have not met their burden to show that reconsideration of the Court's September 23, 2022, Decision is warranted for several reasons.

First, to the extent that the VSL Defendants are correct in arguing that the Court erred by finding that "[t]here are no claims about VSL#3's safety, value, or efficacy in this case," such an error does not warrant the relief that the VSL Defendants seek. Notably, the VSL Defendants have not shown that the Challenged Requests seek information or documents about the value, safety, or efficacy of VSL#3. As Professor De Simone correctly observes in his response in opposition to the VSL Defendants' motion for reconsideration, the words "safety," "value," and "efficacy" do not appear in the Challenged Requests. ECF No. 8-9; *see also* ECF No. 205 at 2-3. The parties also appear to agree that the Challenged Requests do not seek any information concerning the Italian version of VSL#3 (the Current Formulation), which is the probiotic at issue in this case. ECF Nos. 239-1; 243; 248 at 4. Given this, the VSL Defendants have not shown that the information and documents sought in the Challenged Requests are relevant to the claims and affirmative defenses in this case.

The VSL Defendants' argument that the September 23, 2022, Decision precludes them from obtaining information about the value, safety, or efficacy of the Italian version of VSL#3 is also unsubstantiated and unpersuasive. The VSL Defendants argue that they are entitled to this discovery to test and challenge Plaintiffs' theory of injury, by demonstrating that their probiotic product is safe. But the VSL Defendants fail to explain how the Court's decision to grant Professor DeSimone's motion to modify subpoena would prevent them from obtaining information and documents about the safety of the Italian version of VSL#3 through discovery. ECF Nos. 239-1; 248.

The remainder of the VSL Defendants' arguments improperly seek to revisit issues that the parties, and this Court, have already addressed during the course of this litigation. *See generally*, ECF Nos. 239-1; 248. The Court observes that the VSL Defendants have had multiple opportunities to present their views on Professor DeSimone's motion to modify, and that the Court has carefully considered their arguments on several occasions. The VSL Defendants' motion for reconsideration "may not be used merely to reiterate arguments previously rejected by the court." *Quigley v. United States*, 865 F. Supp. 2d 685, 700 (D. Md. 2012) (denying motion for reconsideration on these grounds). And so, to the extent that the VSL Defendants seek to do so here, their motion for reconsideration must be denied.

Because the VSL Defendants have not shown that reconsideration of the Court's September 23, 2022, Decision is warranted, the Court must DENY this motion.

V. CONCLUSION

In sum, the undisputed facts and evidence before the Court shows that: (1) Nutrilinea lacks sufficient contacts with the United States for the Court to assert personal jurisdiction over Nutrilinea in this case; (2) the parties have shown that it is appropriate to maintain certain filings and related exhibits in this matter under seal; and (3) the VSL Defendants have not shown that reconsideration of the Court's September 23, 2022, Decision is warranted.

And so, for the foregoing reasons, the Court:

- (1) **GRANTS** Nutrilinea's motion to dismiss;
- (2) **GRANTS** Nutrilinea's motion to seal;
- (3) **GRANTS** Plaintiffs' motion to seal;
- (4) **DENIES** the VSL Defendants' motion for reconsideration;
- (5) **DENIES-as-MOOT** Centro's motion to dismiss (ECF No. 136);
- (6) **DENIES-as-MOOT** Nutrilinea's motion dismiss (ECF No. 140); and
- (7) **DISMISSES** Plaintiffs' RICO claim against Nutrilinea.

The Court **DIRECTS** the Clerk of the Court to keep and maintain (1) Nutrilinea's memorandum in support of its motion to dismiss, and the related exhibits and attachments thereto (ECF No. 254) and (2) Plaintiffs' unredacted response in opposition to Nutrilinea's motion to dismiss (ECF No. 267) **UNDER SEAL**.

In addition, the Court **DIRECTS** the Clerk of the Court to **STRIKE** Nutrilinea's reply brief in support of its motion to dismiss (ECF No. 279) and its motion to seal (ECF No. 277), as untimely under the Court's January 24, 2023, Scheduling Order.

The Clerk is directed to enter judgment accordingly.

Each party to bear its own costs.

IT IS SO ORDERED.

s/Lydia Kay Griggsby
LYDIA KAY GRIGGSBY
United States District Judge