UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 19-1731

CLAUDIO DE SIMONE; EXEGI PHARMA, LLC,

Plaintiffs − Appellees,

v.

ALFASIGMA USA, INC., a Delaware corporation,

Defendant – Appellant,

and

VSL PHARMACEUTICALS, INC.; LEADIANT BIOSCIENCES, INC., formerly known as Sigma-Tau Pharmaceuticals, Inc.,

Defendants.

REBECCA TUSHNET,

Intervenor,

LAW PROFESSORS,

Amicus Supporting Appellee.

No. 19-1761

CLAUDIO DE SIMONE; EXEGI PHARMA, LLC,

Plaintiffs − Appellees,

v.

VSL PHARMACEUTICALS, INC.,

Defendant – Appellant,

and

ALFASIGMA USA, INC., a Delaware corporation; LEADIANT BIOSCIENCES, INC., formerly known as Sigma-Tau Pharmaceuticals, Inc.,

Defendants.

REBECCA TUSHNET,

Intervenor,

LAW PROFESSORS,

Amicus Supporting Appellee.

No. 19-1762

CLAUDIO DE SIMONE; EXEGI PHARMA, LLC,

Plaintiffs − Appellees,

v.

LEADIANT BIOSCIENCES, INC., formerly known as Sigma-Tau Pharmaceuticals, Inc.,

Defendant – Appellant,

and

ALFASIGMA USA, INC., a Delaware corporation; VSL PHARMACEUTICALS, INC.,

Defendants.

REBECCA TUSHNET,

Intervenor,

LAW PROFESSORS,

Amicus Supporting Appellee.

Appeal from the United States District Court for the of Maryland, at Greenbelt. Theodore D. Chuang, District Court Judge. (8:15-cv-01356-TDC)

Argued: October 29, 2020 Decided: February 17, 2021

Before NIEMEYER, DIAZ, and QUATTLEBAUM, Circuit Judges.

Affirmed in part and vacated in part by unpublished per curiam opinion.

ARGUED: Robert Scott Brennen, MILES & STOCKBRIDGE, PC, Baltimore, Maryland; Brian Lawrence Schwalb, VENABLE LLP, Washington, D.C.; Liesel Johanna Schopler, RIFKIN WEINER LIVINGSTON, LLC, Bethesda, Maryland, for Appellants. Jeremy Wyeth Schulman, SCHULMAN BATTACHARYA, LLC, Bethesda, Maryland, for Appellee. **ON BRIEF:** Charles S. Fax, RIFKIN WEINER LIVINGSTON, LLC, Bethesda, Maryland, for Appellant Leadiant Biosciences, Inc. Mitchell Y. Mirviss, Calvin R. Nelson, Elizabeth C. Rinehart, VENABLE LLP, Washington, D.C., for Appellant VSL Pharmaceuticals, Inc. Erinn Maureen Maguire, Annie Meredith McGuire, MILES & STOCKBRIDGE, PC, Baltimore, Maryland, for Appellant Alfasigma USA, Inc. Jeffrey S. Gavenman, SCHULMAN BHATTACHARYA, LLC, Bethesda, Maryland, for Appellees. Brian Wolfman, Washington, D.C., for Amici Law Professors.

Unpublished opinions are not binding precedent in this circuit.

PER CURIAM:

In this consolidated appeal, VSL Pharmaceuticals, Inc., Leadiant Biosciences, Inc., and Alfasigma USA, Inc. (collectively, the "VSL Parties") challenge two district court orders, in relevant parts: (1) denying Leadiant's and Alfasigma's motions for judgment as a matter of law on ExeGi Pharma, LLC's claim for false advertising in violation of the Lanham Act; (2) denying VSL's and Leadiant's motions for judgment as a matter of law on Claudio De Simone's claim for unjust enrichment; (3) denying VSL's motion for a new trial on VSL's counterclaim against De Simone for breach of fiduciary duty; and (4) issuing a permanent injunction against Leadiant and Alfasigma in relation to ExeGi's false advertising claim.[1] A jury found in ExeGi's and De Simone's favor on all claims and awarded a total of $17,046,606 in damages for false advertising and unjust enrichment.

We affirm the district court in upholding the jury's verdicts and damages awards. We likewise affirm the district court in issuing a permanent injunction to prevent additional

[1] Though the VSL Parties' opening brief purports to seek broader review, including that of the district court's summary judgment order, their arguments—and the relief their conclusion requests—are narrower in scope. The VSL Parties argue that the district court inappropriately "expanded" its summary judgment ruling in a jury instruction, but they don't challenge the ruling itself. And the VSL Parties didn't object to the jury instruction that they now take issue with. Thus, we deem this issue waived. *See Grayson O Co. v. Agadir Int'l LLC*, 856 F.3d 307, 316 (4th Cir. 2017) ("A party waives an argument by failing to present it in its opening brief or by failing to develop its argument—even if its brief takes a passing shot at the issue.") (cleaned up); *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 154 n.6 (4th Cir. 2012), *as amended* (May 9, 2012) (holding that appellant waived its challenge to jury instructions when it "fail[ed] to provide a record citation to where it objected to any given or omitted jury instruction" below).

false advertising by the VSL Parties. But because we hold that the injunction is overbroad as written, we also vacate in part.

I.

A.

The claims at issue relate to an eight-strain probiotic formulation that De Simone invented in the 1990s in collaboration with two other scientists. De Simone obtained a patent for his probiotic formulation in 1998.[2] De Simone also developed certain "know-how" consisting of a unique biochemical profile, formulae, processes, data, and other technical and non-technical information (the "Know-How").

In 1999, De Simone began talks with brothers Claudio and Paolo Cavazza, who owned Sigma-Tau Group, a large Italian pharmaceutical conglomerate. De Simone and Sigma-Tau Group entered into an agreement recognizing De Simone's ownership rights in both the probiotic patent and the Know-How and granting Sigma-Tau Group "an exclusive option for an exclusive license related to" those rights for the purpose of commercializing the patent in the U.S. as a drug. J.A. 291.

In 2000, De Simone and the Cavazza brothers shifted course, intending to bring products based on various patents that De Simone owned to the U.S. market as nutritional supplements instead. The three incorporated VSL for that purpose. De Simone and the

[2] De Simone originally co-owned the patent but later gained full ownership rights. The patent was reissued in 2008 to list De Simone as the sole inventor and owner.

two Cavazzas each owned one-third of VSL through various holding companies. De Simone was named VSL's CEO and was also appointed to its board of directors.

De Simone transferred the trademark "VSL#3" to VSL on September 18, 2000.[3] De Simone and VSL subsequently executed a patent license agreement granting VSL an exclusive license to De Simone's rights in the probiotic patent "for the production and for the commercialization" in the U.S. of any product "marketed as dietary supplement or functional food" containing the bacteria described in the patent. J.A. 662, 663. The agreement required VSL to pay a percentage of the product's net sales to De Simone as royalties and was effective until the patent expired on February 9, 2015.

In August 2001, VSL partnered with a company that later became Danisco USA, Inc. to manufacture a probiotic based on De Simone's patent. That probiotic, branded as VSL#3, was first offered for sale in the U.S. in mid-2002. In 2003, VSL entered into an agreement with Sigma-Tau, an American subsidiary of the Cavazzas' Sigma-Tau Group, to market, distribute, and sell VSL#3 in the U.S. That company eventually became Leadiant (and is still owned by the Cavazzas).[4] Leadiant eventually assigned all rights and interests in its agreement with VSL to another company, which later merged into Alfasigma (which is partially owned by the Cavazzas). VSL#3 was a successful product, in large part

[3] De Simone previously owned the trademark through a different company.

[4] Claudio Cavazza died in 2011 and his children inherited his interests in Sigma-Tau Group. References to "the Cavazzas" after 2011 refer to Paolo Cavazza and Claudio's heirs.

due to clinical studies that supported its safety and efficacy in helping individuals manage certain gastrointestinal disorders.

De Simone's relationship with the Cavazzas began to fray in 2005. The strain eventually led to the execution of three agreements: (1) a 2006 confidential disclosure agreement between De Simone, Danisco, VSL, and various VSL affiliates in which the parties "recognized and agreed that De Simone is the owner of" VSL#3's product formulation, recognized De Simone's right to discontinue a company's license to make VSL#3, and instructed Danisco "to discontinue the use and/or manufacture of VSL #3" upon notice of such discontinuation, J.A. 296; (2) a 2007 agreement between De Simone and VSL in which De Simone granted VSL a license to use the Know-How to distribute VSL#3 in Canada; and (3) a 2008 supply agreement between De Simone and Danisco that required Danisco to keep De Simone's Know-How confidential and echoed De Simone's right to dictate whom Danisco could supply with VSL#3.

In 2010, De Simone and VSL executed an agreement in which De Simone granted VSL an exclusive license to use the Know-How for the manufacture, production, marketing, and sale of VSL#3 in the U.S. That license was to become effective upon expiration of the probiotic patent and related license agreement in February 2015 and would remain in effect until January 31, 2016. The agreement contained various termination provisions, one of which gave De Simone the right to immediately terminate the license if there was a change of control at VSL.

The tension between De Simone and the Cavazzas worsened in 2013, and their working relationship had completely broken down by mid-2014. During this time, the

holding company that was VSL's majority shareholder (and was controlled by the Cavazzas) began making requests for corporate records that De Simone refused. These events sparked a Delaware lawsuit that the parties eventually settled.

Meanwhile, in June of 2014, De Simone and VSL entered into an amended supply agreement with Danisco. This agreement provided that De Simone in his individual capacity would replace VSL as the buyer of the probiotic "in the event that the [2010] Know How License Agreement is terminated or expires before the expiration or termination of this Agreement for any reason." J.A. 300.

De Simone resigned as CEO and from VSL's board of directors on November 14, 2014. That same day, he terminated the 2010 Know-How agreement based on its change of control provision (another member of VSL's three-member board had resigned in October). In a letter, De Simone told VSL that it "no longer retained" the necessary expertise to manufacture VSL#3 and proposed that VSL license the VSL#3 trademark to him under a new arrangement that would "bring basically the same net earnings to the Company." J.A. 301 (cleaned up). VSL ultimately rejected this proposal.

De Simone later informed Sigma-Tau (Leadiant's predecessor) that, when the probiotic patent expired on February 9, 2015, VSL would no longer have the right to purchase VSL#3 from Danisco (or to continue licensing that right to Sigma-Tau). On May 18, 2015, De Simone informed Danisco that VSL and Sigma-Tau were "no longer

authorized purchasers" of VSL#3 and that Danisco could not fill any orders placed by VSL or Sigma-Tau after that date.[5] J.A. 302.

De Simone subsequently went into business with ExeGi. After the probiotic patent (and related patent license agreement) expired, ExeGi informed VSL that it would be launching a generic version of VSL#3 made with De Simone's Know-How (which De Simone licensed to ExeGi). ExeGi began to promote this product, Visbiome, in May 2015.

B.

De Simone filed his original complaint against VSL and Sigma-Tau (which later became Leadiant) on May 11, 2015 seeking (1) a declaratory judgment that he owned the Know-How used to manufacture VSL#3, and alleging (2) breach of contract against VSL for failure to pay royalties, (3) unjust enrichment against VSL and Sigma-Tau for continuing to sell and market VSL#3 in the United States after the patent license agreement expired, (4) misappropriation of trade secrets against both defendants, and (5) civil conspiracy against both defendants. VSL filed an answer, a counterclaim, and a third-party complaint joining three defendants and alleging over 20 causes of action including breach of fiduciary duty, trademark infringement, numerous business torts, and a request for a declaratory judgment that VSL, not De Simone, owned the Know-How. Sigma-Tau also filed an answer, a counterclaim, and a third-party complaint seeking declaratory relief and alleging various business torts.

[5] De Simone later delayed this date until September 23, 2015 pursuant to an agreement with the VSL Parties.

The parties amended the pleadings numerous times over the next three years. Notably, De Simone added a Lanham Act false advertising claim against Leadiant and Alfasigma based on allegations that, in marketing VSL's new VSL#3 product manufactured in Italy without De Simone's Know-How, the companies falsely advertised that the new product was "the same as" the former version of VSL#3 that Danisco manufactured with De Simone's Know-How. J.A. 520.

The parties also sought various preliminary injunctions. Relevant here, on September 25, 2015, the district court enjoined De Simone from interfering with VSL's supply of VSL#3 from Danisco until January 31, 2016 (when the 2014 supply agreement would have expired). This was based on the court's finding that VSL was likely to succeed on its claim for breach of fiduciary duty because De Simone was still VSL's CEO (and thus owed VSL fiduciary duties) when, among other actions, he amended the supply agreement with Danisco to add the provision that allowed him to step into VSL's shoes as VSL#3's buyer upon termination of the 2010 Know-How agreement. The court reasoned that allowing De Simone to cut off VSL's supply of VSL#3 in 2015 would cause irreparable harm to VSL and would unjustly allow De Simone to profit from self-dealing because VSL's new manufacturer couldn't start production until January 2016 and, in the meantime, ExeGi planned to bring Visbiome to market as early as October 2015.

When the case reached summary judgment, the remaining claims generally consisted of (1) claims relating to the Know-How's ownership; (2) claims relating to De Simone's alleged breaches of fiduciary duty vis-à-vis VSL; (3) claims relating to the VSL

Parties' sales of VSL#3 after De Simone resigned from VSL; and (4) Lanham Act trademark infringement and false advertising claims.

Faced with competing requests to declare either De Simone or VSL the owner of the Know-How—which both parties claimed was a protectable and valuable trade secret—the district court found that De Simone owned the Know-How and, after a detailed analysis of the relevant agreements, rejected VSL's argument that De Simone had transferred ownership to VSL. This finding either partially or wholly resolved many of the parties' claims.

The district court also (1) granted partial summary judgment to De Simone on VSL's breach of fiduciary duty claims to the extent that they were based on events that occurred prior to 2012 (on statute of limitations grounds); (2) granted summary judgment as to liability on De Simone's breach of contract claim based on VSL's failure to pay royalties it owed De Simone under the patent license agreement; (3) granted summary judgment to the VSL Parties on De Simone's trade secrets claims; (4) granted partial summary judgment to the VSL Parties on their trademark infringement claims; and (5) denied summary judgment on all other claims.

Four claims made it to trial: (1) De Simone's breach of contract claim related to the unpaid patent royalties (on damages only); (2) De Simone's unjust enrichment claim against VSL and Leadiant; (3) ExeGi's false advertising claim against Leadiant and Alfasigma; and (4) VSL's breach of fiduciary duty counterclaim against De Simone.

After a three-week trial, a jury returned verdicts in De Simone's and ExeGi's favor on all claims. The jury awarded ExeGi $15 million in damages against Alfasigma for false

advertising and De Simone $2,046,606 in total damages for unjust enrichment ($1,874,602 against VSL and $172,004 against Leadiant).[6]

The parties filed numerous post-trial motions. The district court denied the VSL Parties' Rule 50 motions for judgment as a matter of law on the false advertising and unjust enrichment claims.[7] The district court also denied VSL's Rule 59 motion for a new trial on its breach of fiduciary duty counterclaim.[8] The district court granted De Simone's post-trial motion in part and issued a permanent injunction against Alfasigma and Leadiant.

The VSL Parties timely appealed.

II.

We review a district court's denial of a Rule 50 motion for judgment as a matter of law de novo. *Legacy Data Access, Inc. v. Cadrillion, LLC*, 889 F.3d 158, 164 (4th Cir. 2018). We won't overturn a jury's verdict unless "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*, 93 F.3d 1241, 1249 (4th Cir. 1996) (cleaned up). In making this determination, "we may not substitute our judgment for that of the jury or

[6] The VSL Parties don't appeal the jury's award for the breach of contract claim.

[7] The district court also denied the VSL Parties' joint Rule 59 motion for a new trial on the unjust enrichment and false advertising claims, but the VSL Parties make no argument relevant to that motion in their briefing.

[8] This motion also asked for a new trial on VSL's declaratory relief claim, but the VSL Parties' briefing neither requests nor argues for a new trial on that claim.

make credibility determinations." *Id.* Instead, we view the evidence in the light most favorable to the prevailing party in the trial court. *Legacy Data Access*, 889 F.3d at 164.

Whether to grant or deny a motion for a new trial is "within the sound discretion of the district court and will not be disturbed absent a clear showing of abuse of discretion." *Chesapeake Paper Prods. Co. v. Stone & Webster Eng'g Corp.*, 51 F.3d 1229, 1237 (4th Cir. 1995). A district court may grant a new trial if 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." *Id.*

Finally, "[w]e review an order granting an injunction for abuse of discretion, reviewing factual findings for clear error and legal conclusions *de novo*." *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 125 (4th Cir. 2011).

A.

We hold that the evidence presented at trial supports the jury's verdicts and damages awards. Regarding false advertising, ExeGi alleged that Alfasigma and Leadiant violated the Lanham Act by falsely advertising that VSL's new Italian-made version of VSL#3, which was manufactured by a reverse-engineering process without De Simone's Know-How, was essentially the same probiotic as the prior version of VSL#3 manufactured by Danisco. ExeGi sought approximately $27.8 million in damages from Alfasigma, which was the amount Alfasigma made in profits from selling Italian-made VSL#3 from July 1, 2016 through the end of trial.[9]

[9] ExeGi didn't seek damages from Leadiant for false advertising.

The elements of a Lanham Act false advertising claim are:

> (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product; (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 products.

Scotts Co. v. United Indus. Corp., 315 F.3d 264, 272 (4th Cir. 2002). When a statement made in an advertisement is literally false (as was alleged here), a party need not present evidence of consumer deception in order to succeed. [10] *See id.* at 273. However, when a

[10] A statement is "literally false" when it's false on its face. *Id.* (cleaned up). The parties here presented conflicting expert testimony regarding whether the Italian-made version of VSL#3 was essentially the same as the Danisco-made version. The VSL Parties argued that, under *In re GNC Corp.*, 789 F.3d 505 (4th Cir. 2015), their expert's testimony that the two products were genetically and functionally equivalent precluded a finding of literal falsity as a matter of law. The district court rejected this argument.

Nonetheless, amici urge us to declare that our literal falsity analysis in *GNC* is erroneous dicta. But we see no reason to do so. *GNC* addressed—and rejected—an argument very similar to the one that the VSL Parties made (and that amici fear): "Plaintiffs [] object that our holding today would 'permit a manufacturer of the most dubious product to engage an "expert" and then contend it was immune from a consumer fraud action.' However, plaintiffs who believe that no *reasonable* scientist would agree with the challenged representations remain free to make that allegation. . . . A manufacturer may not hold out the opinion of a minority of scientists as if it reflected broad scientific consensus." *GNC*, 789 F.3d at 515–16 (citation omitted). And the district court applied *GNC* accordingly here. *See* J.A. 846 ("*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.").

claim involves multiple false statements (as was also alleged here), a plaintiff "may not mix and match statements, with some satisfying one Lanham Act element and some satisfying others." *Verisign, Inc. v. XYZ.COM LLC*, 848 F.3d 292, 299 (4th Cir. 2017). Rather, at least one statement must satisfy all five elements to constitute a Lanham Act violation. *Id.* The jury found Alfasigma and Leadiant liable for false advertising and awarded ExeGi $15 million in damages against Alfasigma.

Regarding unjust enrichment, De Simone sought $2,585,297 in damages against VSL and $6,192,159 in damages against Leadiant based on the companies' continued sale of VSL#3 made with De Simone's Know-How from September 15, 2015 to January 31, 2016.[11] De Simone argued that after the probiotic patent and its related licensing agreement expired, VSL and Leadiant had no right to continue selling the probiotic made from his Know-How because he terminated the 2010 Know-How agreement that would have given them that right.

In Maryland, the elements of unjust enrichment are: (1) "[a] benefit conferred upon the defendant by the plaintiff"; (2) "[a]n appreciation or knowledge by the defendant of the benefit"; and (3) "[t]he 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.

[11] September 15, 2015 was the date after which De Simone refrained from preventing Danisco from selling the probiotic to the VSL Parties only because the district court enjoined him from doing so.

2007). The jury found Leadiant and VSL liable for unjust enrichment and awarded De Simone a total of $2,046,606 in damages.

The district court upheld the jury's verdicts and damages awards. Regarding false advertising, the court reasoned that the evidence at trial supported a finding that at least one statement made by each of the two companies satisfied the requisite elements under the Lanham Act. The district court also upheld the jury's $15 million award against Alfasigma, denying competing requests by the parties to either increase or decrease the award. Regarding unjust enrichment, the court reasoned that the evidence also supported a finding that VSL and Leadiant were unjustly enriched as a result of their continued sales of Danisco-manufactured VSL#3 from September 15, 2015 to January 31, 2016.

After carefully reviewing the record and considering the parties' briefs and arguments, we affirm the jury's verdicts and damages awards on the district court's well-reasoned opinions.

B.

We also hold that the district court acted within its discretion in denying VSL's motion for a new trial on its breach of fiduciary duty claim. As the district court observed, VSL's motion was filed "out of an abundance of caution" and was based almost entirely on the premise that the district court erroneously declared De Simone to be the owner of the Know-How at summary judgment and that the summary judgment order might be vacated or reversed on appeal. J.A. 872 (cleaned up). VSL didn't offer any argument on

this point in its motion, and it hasn't developed the argument on appeal.[12] Therefore, we decline to disturb the district court's summary judgment ruling.

C.

Finally, we hold that the district court acted within its discretion in issuing a permanent injunction to prevent the VSL Parties from continuing their false advertising, but we also hold that the injunction is overbroad as written. The Lanham Act gives a district court the "power to grant injunctions, according to the principles of equity and upon such terms as the court may deem reasonable" to prevent a violation of the Act. 15 U.S.C. § 1116(a). "[T]he party seeking the injunction must demonstrate that (1) it has suffered an irreparable injury; (2) remedies available at law are inadequate; (3) the balance of the hardships favors the party seeking the injunction; and (4) the public interest would not be disserved by the injunction." *PBM*, 639 F.3d at 126 (citing *eBay, Inc. v. MercExchange*, 547 U.S. 388, 391 (2006)). If issued, an injunction "should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs" and "should be carefully addressed to the circumstances of the case." *Id.* at 128.

Here, the district court issued the following injunction:

> Alfasigma USA, Inc. ("Alfasigma") and Leadiant Biosciences, Inc. ("Leadiant") are hereby PERMANENTLY ENJOINED from (1) stating or suggesting in VSL#3 promotional materials directed at or readily accessible to United States consumers that the present version of VSL#3 produced in Italy ("Italian VSL#3") continues to contain the same formulation found in the versions of VSL#3 produced before January 31, 2016 ("the De Simone

[12] To the extent that VSL's motion can be read to separately take issue with the jury instruction at trial regarding De Simone's ownership of the Know-How, VSL failed to timely object to that instruction and thus waived its right to challenge it.

> Formulation"), including but not limited to making statements that VSL#3 contains the "original proprietary blend" or the "same mix in the same proportions" as earlier version[s] 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.

J.A. 895. The court reasoned that "the essential injury to ExeGi . . . is the VSL Parties' repeated false assertions in their advertising that Italian VSL#3 continues to be composed of [De Simone's probiotic formulation]." J.A. 882. Thus, the court concluded, "an injunctive remedy carefully addressed to the circumstances of this case is one focused on curtailing such claims of continuity between Italian VSL#3 and the De Simone formulation." *Id.* We agree, and thus we affirm the injunction to the extent that it prohibits claims of continuity between the Danisco-made VSL#3 and VSL's new reverse-engineered version.[13]

But we hold that the language prohibiting the VSL Parties from "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" is too broad. To the extent that this language is intended to prohibit the VSL Parties from citing or referring to the clinical studies *as though* they were performed on Italian VSL#3 (rather than on the Danisco-made version), it's superfluous to prohibiting claims of continuity between the products. But prohibiting the VSL Parties from citing or referring to the clinical studies as

[13] We also affirm the district court in including Leadiant in its injunction, because we agree that Leadiant's "voluntary discontinuance of challenged activities" doesn't satisfy its "heavy burden" to show that "there is *no* reasonable expectation that the wrong will be repeated." *Lyons P'ship, L.P. v. Morris Costumes, Inc.*, 243 F.3d 789, 800 (4th Cir. 2001).

even *relevant* to Italian VSL#3 goes too far, as they could feasibly do so without claiming continuity between their old product and their new one.

* * *

Accordingly, we vacate the portion of the district court's permanent injunction purporting to bar the VSL Parties from "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." In all other respects, we affirm the district court's orders.

AFFIRMED IN PART AND VACATED IN PART