

**PUBLISHED**

UNITED STATES COURT OF APPEALS  
FOR THE FOURTH CIRCUIT

---

**No. 20-1846**

---

CLAUDIO DE SIMONE; EXEGI PHARMA, LLC,

Plaintiffs – Appellees,

v.

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

Defendants – Appellants,

and

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

Defendant.

---

**No. 20-1869**

---

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.

---

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

---

Argued: January 27, 2022

Decided: June 7, 2022

---

Before NIEMEYER, DIAZ, and QUATTLEBAUM, Circuit Judges.

---

Affirmed by published opinion. Judge Diaz wrote the opinion, in which Judge Niemeyer and Judge Quattlebaum joined.

---

**ARGUED:** Robert Scott Brennen, MILES & STOCKBRIDGE P.C., Baltimore, Maryland; Turner Anderson Broughton, WILLIAMS MULLEN, Richmond, Virginia, for Appellants. Jeremy Wyeth Schulman, SCHULMAN BHATTACHARYA, LLC, North Bethesda, Maryland, for Appellee. **ON BRIEF:** Brian L. Schwalb, Calvin R. Nelson, Washington, D.C., Mitchell Y. Mirviss, Elizabeth C. Rinehart, VENABLE LLP, Baltimore, Maryland, for Appellant VSL Pharmaceuticals, Inc. Erinn M. Maguire, MILES & STOCKBRIDGE P.C., Baltimore, Maryland, for Appellant Alfasigma USA, Inc. Jeffrey S. Gavenman, SCHULMAN BHATTACHARYA, LLC, Bethesda, Maryland, for Appellees.

DIAZ, Circuit Judge:

VSL Pharmaceuticals, Inc. and Alfasigma USA, Inc. appeal the district court's order finding them in contempt of the court's permanent injunction. The injunction prohibited VSL and Alfasigma from suggesting in promotional materials that their probiotic contained the same formulation as one marketed by Claudio De Simone and ExeGi Pharma, LLC.

VSL and Alfasigma argue (1) their statements weren't contemptuous, (2) their statements didn't harm De Simone or ExeGi, (3) the district court improperly awarded De Simone and ExeGi attorneys' fees, and (4) VSL and Alfasigma shouldn't be jointly liable for the fee award. We affirm.

## I.

Claudio De Simone, an Italian professor and inventor, helped develop an eight-strain probiotic, which he patented in 1998. De Simone's probiotic helps treat conditions such as irritable bowel syndrome and ulcerative colitis. He licensed the probiotic's formulation to VSL, which partnered with Leadiant Biosciences, Inc., to market it under the name VSL#3. Leadiant later assigned its rights under the contract to Alfasigma.

In 2015, De Simone cut ties with VSL, Leadiant, and Alfasigma. He began licensing his formulation to ExeGi, which marketed it under the name Visbiome. Meanwhile, VSL developed a new probiotic in Italy and began selling it under the name VSL#3.

In May 2015, De Simone and ExeGi sued VSL, Leadiant, and Alfasigma in the District of Maryland. The amended complaint alleged that (1) Alfasigma and Leadiant violated the Lanham Act by falsely advertising the new VSL#3 as clinically equivalent to

its prior version and (2) VSL breached its license agreement with De Simone. A jury found Leadiant and Alfasigma liable for false advertising, awarding ExeGi \$15 million, and VSL liable for violating the agreement, awarding De Simone \$967,435.

Based on that verdict, the district court issued a permanent injunction, which enjoined Alfasigma and Leadiant 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 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. 451.

Less than four months after the district court issued the injunction, ExeGi moved for a civil contempt order against VSL and Alfasigma. ExeGi identified four violations of the injunction, three of which are relevant here<sup>1</sup>—(1) a letter Alfasigma sent to healthcare providers (the Healthcare Providers Letter), (2) comments on Facebook (the Facebook Commentary), and (3) an Actial Farmaceutica S.r.l.<sup>2</sup> press release (the Actial Press Release).

---

<sup>1</sup> ExeGi also alleged that VSL#3’s product information sheets violated the injunction. The district court rejected the claim, so that issue is not before us.

<sup>2</sup> Actial is VSL’s parent company. It’s not a party to this appeal.

A.

The Healthcare Providers Letter was on Alfasigma's website before the court issued the permanent injunction. The Letter says:

Evidence introduced at trial [in the District of Maryland] . . . showed that the current Italian-made VSL#3® contains bacteria that is equivalent to the [original] VSL#3® . . . Experts and Scientists who worked on VSL#3 when it was originally made in Italy in the 1990s and early 2000s confirmed that:

- I. Italian-made VSL#3® contains the same 8 strains of bacteria as the [original] product . . . ;
- II. Italian-made VSL#3® is equivalent to the [original] product; and
- III. Studies previously performed on the [original] product can be relied on to show the efficacy and safety of the Italian-made product.

J.A. 520 (emphasis omitted).

Once the court issued the injunction, Alfasigma removed links to the Healthcare Providers Letter from its website. But Alfasigma didn't remove the Letter itself. ExeGi later discovered that consumers could still access the Letter by searching "vsl3 litigation" on Google.<sup>3</sup> It so informed Alfasigma, who then broke the link to the letter.

B.

Alfasigma also rendered VSL#3's Facebook page inaccessible once the injunction issued. When Alfasigma brought the page back online, its caption under the heading "Our Story" read: "VSL#3® is a high-potency probiotic medical food that is clinically proven in the dietary management of IBS, ulcerative colitis[,] and ileal pouch and must be used

---

<sup>3</sup> The link to the Letter was the second result in the Google search.

under medical supervision.” J.A. 560. In response to consumers’ questions, Alfasigma repeatedly responded:

VSL#3® was temporarily not available for sale while a packaging update was being made to comply with the court’s final order. The court did not prohibit the sale of VSL#3®. VSL#3® was not recalled or discontinued, there are no safety or efficacy concerns[,] and the formula has not changed.

J.A. 561–68.

C.

ExeGi alleged that Actial’s Press Release, which discussed separate litigation in Italy about who owned VSL#3’s bacterial strains, unfairly compared VSL#3 and Visbiome.

The Release quoted Luca Guarna, the CEO of VSL and Actial:

VSL#3® is available for purchase in the U.S. and many markets globally, and we remain committed to making the VSL#3® probiotic available to our dedicated customers and healthcare providers notwithstanding De Simone and ExeGi’s aggressive efforts to sell their competing, generic probiotic product[.]

J.A. 523. At least a dozen media outlets—including the Citizen Tribune, the Manchester Times, and Yahoo Finance—circulated the Release.

D.

In the district court, VSL and Alfasigma argued that they had substantially complied with the injunction. They claimed that they took down the Healthcare Providers Letter and Facebook Commentary as soon as they learned about them. As for the Actial Press Release, they contended that their use of the term “generic” didn’t violate the permanent injunction because De Simone and ExeGi hadn’t patented Visbiome and ExeGi had once

called Visbiome “generic.” VSL and Alfasigma also said that none of the statements harmed ExeGi.

In its reply, ExeGi raised another alleged violation of the permanent injunction in Alfasigma’s YouTube Materials. Between 2012 and 2017, VSL#3’s account posted a series of YouTube videos promoting the probiotic. These videos had accompanying captions describing VSL#3, some of which were functionally identical to the description in the Facebook Commentary. Other captions boasted that VSL#3 had “more than a decade of patient support and use,” calling it “one of the most studied and sought-after high-potency probiotic medical foods.” J.A. 664.

E.

The district court found that VSL and Alfasigma violated the permanent injunction. Starting with the Healthcare Providers Letter, the court saw no dispute that its contents violated the injunction. Instead, VSL and Alfasigma urged merely that the violation wasn’t willful and that they tried to render the Letter inaccessible. But the court determined that willfulness wasn’t an element of contempt. So even if the violation were inadvertent, said the court, Alfasigma was still in contempt.

In discussing the Facebook Commentary, the court found that VSL and Alfasigma “effectively conceded that the statements [to consumers] violated the Permanent Injunction.” *De Simone v. VSL Pharms., Inc.*, No. 15-cv-1356, 2020 WL 4368103, at \*4 (D. Md. July 30, 2020). The court also found “that [the commenters] clearly had a script from which they were working.” *Id.* at \*4. And as with the Healthcare Providers Letter, that Alfasigma took down the comments once De Simone and ExeGi complained about

them was of no moment. Because there were a “number of different violations,” some of which “persisted over an extended period of time,” the court found that VSL and Alfasigma’s efforts to comply with the injunction “were notably deficient.” *Id.* at \*6.

The court then addressed the YouTube Materials. It noted that the Materials contained similar statements about VSL#3—i.e., that it was “clinically proven” to alleviate certain gastrointestinal symptoms. *Id.* at \*4. Although the court recognized that those statements may have been true when the videos were first posted (when VSL#3 used the De Simone Formulation), it still found they violated the permanent injunction.

Likewise, the district court found VSL’s arguments about the Actual Press Release unconvincing. The court said that VSL hadn’t shown that Luca Guarna used the term “generic” in a technical sense—i.e., referring to the lack of a patent—because the Release was “widely circulated to diverse media outlets.” *Id.* at \*5. It then rejected VSL’s argument that ExeGi had described Visbiome as generic to VSL#3. The court acknowledged that ExeGi described Visbiome as generic in 2015, before Visbiome used the De Simone Formulation. But by 2019 (when the Release issued), the circumstances had “materially changed,” making the Release’s use of “generic” contemptuous. *Id.*

Next, the district court found that the violations of the injunction harmed De Simone and ExeGi.<sup>4</sup> It explained that the statements “were designed to create a false continuity

---

<sup>4</sup> De Simone didn’t move for sanctions. Nonetheless, the district court treated ExeGi’s motion as though De Simone signed on to it. Since VSL and Alfasigma don’t challenge the court’s authority to include De Simone in the order, we delve no deeper into the question.

between Italian VSL#3 and the De Simone Formulation so that VSL#3 could keep its prior customers and potentially poach new ones.” *Id.* at \*6.

And although ExeGi didn’t “identify[] a direct link between the violations of the Permanent Injunction and” its lost sales, it “establish[ed] that customer confusion over whether VSL#3 still contains the De Simone Formulation . . . caused ExeGi to lose business.” *Id.* Specifically, two consumers said that they continued to take VSL#3 after it stopped using the De Simone Formulation because none of the product’s marketing disclosed the formula change.

But the court declined to award lost profits because De Simone and ExeGi didn’t show “quantifiable damages.” *Id.* Instead, the court ordered VSL and Alfasigma to pay De Simone and ExeGi’s attorneys’ fees.<sup>5</sup>

This appeal followed.

## II.

We begin with a procedural contention. De Simone and ExeGi claim that, by not raising them before the district court, VSL and Alfasigma waived four arguments: (1) Alfasigma didn’t know the Healthcare Providers Letter was accessible on its website after removing its internal links; (2) Alfasigma was unaware of the Facebook Commentary; (3) the Press Release wasn’t promotional material; and (4) VSL and Alfasigma shouldn’t be

---

<sup>5</sup> To date, the district court hasn’t fixed the fee award. But “the pendency of a ruling on an award for fees and costs does not prevent, as a general rule, the merits judgment from becoming final for the purposes of appeal.” *Ray Haluch Gravel Co. v. Cent. Pension Fund of Int’l Union of Operating Eng’rs & Participating Emps.*, 571 U.S. 177, 179 (2014).

jointly liable for the fee award. We conclude that VSL and Alfasigma sufficiently raised the first three arguments but waived the fourth.

“It is well established that this court does not consider issues raised for the first time on appeal absent exceptional circumstances.” *Hicks v. Ferreyra*, 965 F.3d 302, 310 (4th Cir. 2020) (cleaned up). “In assessing whether an issue was properly raised in the district court, we are obliged on appeal to consider any theory plainly encompassed by the submissions in the underlying litigation.” *Volvo Constr. Equip. N. Am., Inc. v. CLM Equip. Co.*, 386 F.3d 581, 604 (4th Cir. 2004). “[V]ariations on arguments made below may be pursued, so long as the appealing party asked both courts to evaluate the same fundamental question.” *United States v. Boyd*, 5 F.4th 550, 556 (4th Cir. 2021) (cleaned up). But a party may not leave the district court without “any signal” that it contests a fact or point of law. *See In re Under Seal*, 749 F.3d 276, 288 (4th Cir. 2014).

We are satisfied that VSL and Alfasigma sufficiently raised the first three arguments before the district court. First, Alfasigma contended that it “was not aware that there was old content still available to users who could locate a pathway from other sources, such as Google.” J.A. 592. That statement expressly raises whether Alfasigma knew that the Healthcare Providers Letter was accessible on its website.

Similarly, Alfasigma argued that it was unaware of the Facebook Commentary. Alfasigma said it “first learned of ExeGi’s challenges to the Facebook [C]ommentary on or about October 1, 2019.” J.A. 583. That statement again contests Alfasigma’s knowledge.

As for the Actual Press Release, VSL claimed in the district court that ExeGi “provide[d] no argument or explanation for why [it] violate[d] the injunction.” J.A. 595–96. Specifically, VSL argued that the use of the term “generic” was “accurate.” J.A. 595. Read narrowly, that argument challenges whether it’s permissible to *call* Visbiome generic, not *where* one may do so. Before us, however, VSL focuses on the latter argument—claiming that the Release wasn’t promotional material. But we choose to read VSL’s argument in district court as broad enough to preserve this challenge.<sup>6</sup>

On the other hand, VSL and Alfasigma never raised their fourth argument—that they aren’t jointly liable for each other’s statements. To start, the injunction binds both parties. Federal Rule of Civil Procedure 65 binds “other persons who are in active concert or participation with” the parties to the injunction so long as they “receive actual notice” of said injunction. *See* Fed. R. Civ. P. 65(d)(2). VSL received notice of the injunction and conceded that the injunction applied to it. J.A. 476–77 (“[T]o the extent that VSL engages in any [marketing] activity, yes, we stand shoulder to shoulder with Alfasigma[,] and we would be subject to the injunction.”).

Further, VSL and Alfasigma knew De Simone and ExeGi sought joint liability. ExeGi grouped the companies together in its civil contempt motion. And the district court did the same in its opinion issuing the permanent injunction. Since VSL and Alfasigma didn’t contest below the district court’s ability to impose joint and several liability, we may consider “the newly raised argument [only if it] establishes a fundamental error or a denial

---

<sup>6</sup> As we explain later, the first three arguments fail on the merits.

of fundamental justice.” *United States v. Turner Constr. Co.*, 946 F.3d 201, 208 (4th Cir. 2019). No one makes that claim here. Thus, VSL and Alfasigma have waived this argument.

### III.

Turning to the merits, a party moving for civil contempt must establish four elements by clear and convincing evidence:

(1) the existence of a valid decree of which the alleged contemnor had actual or constructive knowledge; (2) that the decree was in the movant’s favor; (3) that the alleged contemnor by its conduct violated the terms of the decree, and had knowledge (at least constructive knowledge) of such violations; and (4) that the movant suffered harm as a result.

*Ashcraft v. Conoco, Inc.*, 218 F.3d 288, 301 (4th Cir. 2000) (cleaned up). “Once the [movant] establishes that the [alleged contemnor] violated the [decree], the burden shifts to the [alleged contemnor] . . . to demonstrate that she made in good faith all reasonable efforts to comply with the [decree].” *United States v. Ali*, 874 F.3d 825, 831 (4th Cir. 2017) (cleaned up). “We review a district court’s civil contempt order for abuse of discretion.” *Id.* at 829.

The parties agree that the first two elements—a valid decree in De Simone and ExeGi’s favor—are present. But VSL and Alfasigma assert a variety of arguments to contest the remaining two elements. We reject them all.

A.

VSL and Alfasigma argue the Healthcare Providers Letter wasn't contemptuous because they didn't know of the violation and made reasonable efforts to comply with the injunction.

1.

We have held in the civil contempt context that parties have constructive knowledge of their websites. *See Rainbow Sch., Inc. v. Rainbow Early Educ. Holding LLC*, 887 F.3d 610, 618–19 (4th Cir. 2018). “[C]onstructive knowledge” is “[k]nowledge that one using reasonable care or diligence should have, and therefore that is attributed by law to a given person.” *Knowledge*, Black’s Law Dictionary (11th ed. 2019). Here, the Healthcare Providers Letter was on Alfasigma’s website. So Alfasigma constructively knew about the violation.

VSL and Alfasigma concede that a party needn't have actual knowledge of a violation to warrant civil contempt. *See Appellants' Br.* at 21 (“Without proof by clear and convincing evidence of such knowledge (actual *or constructive*), contempt cannot be found.” (emphasis added)). Because Alfasigma had constructive knowledge of the Healthcare Providers Letter, its actual knowledge is irrelevant.

VSL and Alfasigma emphasize that consumers couldn't access the Letter from Alfasigma's home page. That's true, as De Simone and ExeGi showed only that consumers could access the Letter by searching “vsl3 litigation” on Google. But the way in which consumers could access the Letter is irrelevant to Alfasigma's constructive knowledge that it remained on the website.

2.

VSL and Alfasigma next argue that Alfasigma took reasonable steps to comply with the injunction. They call the Healthcare Providers Letter a “technical violation.” Appellants’ Br. at 24. And they reiterate that Alfasigma removed its website’s links to the Letter after the district court issued the injunction.

Substantial compliance with a decree is a defense to civil contempt. *United States v. Darwin Constr. Co.*, 873 F.2d 750, 754 (4th Cir. 1989). “Substantial compliance is found where all reasonable steps have been taken to ensure compliance: inadvertent omissions are excused only if such steps were taken.” *Id.* at 755 (cleaned up).

The district court acknowledged that Alfasigma tried to remove the Letter from its website. Alfasigma disabled direct links to the Healthcare Providers Letter and redirected other links to a different portion of the website. No doubt, those are steps to ensure compliance.

But Alfasigma needed to take “*all* reasonable steps” to ensure compliance. *Id.* (emphasis added). We think verifying that the Letter wasn’t readily accessible via external links is a reasonable step.

After Alfasigma prevented its website’s visitors from accessing the Letter, the next logical step was to prevent others from doing the same. And the search terms that yielded the Letter (“vsl3 litigation”) were basic—the product’s name and a major event surrounding it. So there’s a good chance Alfasigma would have discovered the link had it tried to do so. And there’s no dispute that once discovered, the link was easily broken.

Thus, the district court didn't abuse its discretion by finding that VSL and Alfasigma failed to take all reasonable steps to ensure compliance with the injunction.

B.

VSL and Alfasigma parrot these same arguments for the Facebook Commentary, claiming they were unaware of the Commentary and that they made a good-faith effort to comply with the injunction.

As with the Healthcare Providers Letter, Alfasigma had constructive knowledge of the Facebook Commentary. *See Rainbow*, 887 F.3d at 618–19. The only difference is that the statements appeared on a Facebook page, not Alfasigma's website. But that distinction is immaterial. As we've explained, the constructive knowledge doctrine charges individuals with "[k]nowledge that one using reasonable care or diligence should have." *Knowledge*, Black's Law Dictionary (11th ed. 2019).

Alfasigma maintained its Facebook page, just like its website. And had Alfasigma exercised reasonable diligence in managing the page, it would have known about the Commentary.

More fundamentally, it's undisputed that Alfasigma's agents (in responding to consumers' questions about VSL#3) authored the Facebook Commentary in the course of their employment. Federal Rule of Civil Procedure 65 provides that an injunction against a party binds "the parties' officers, agents, servants, employees, and attorneys." Fed. R. Civ. P. 65(d)(2)(B). And we impute knowledge to a principal when an agent is acting within the scope of their employment. *See Helton v. AT & T, Inc.*, 709 F.3d 343, 356 (4th Cir. 2013).

The district court found that VSL#3 representatives made the relevant statements. And it determined that they “had a script from which they were working.” *De Simone*, 2020 WL 4368103, at \*4. Given that they were responding to consumers, the representatives were acting within the scope of their employment. Thus, Alfasigma had constructive (if not actual) knowledge of the Facebook Commentary.

VSL and Alfasigma point to one curative step Alfasigma took for the Facebook Commentary—removing the comments immediately after De Simone and ExeGi complained about them. But that alone doesn’t absolve Alfasigma of liability for contempt.

Here, the district court found that Alfasigma’s employees were working off a script. If Alfasigma gave its employees that script before the court issued its injunction, Alfasigma should have instructed its employees to stop using it. And if Alfasigma issued the script after the court ruled, then it actively sought to violate the injunction. So Alfasigma didn’t make a good-faith effort to comply with the injunction.

### C.

VSL and Alfasigma don’t challenge the district court’s conclusion that the YouTube Materials were contemptuous. They assert only that De Simone and ExeGi waived this argument by raising it for the first time in their reply before the district court. De Simone and ExeGi respond that their contentions about the Facebook Commentary and YouTube Materials are one and the same—they’re simply different factual applications.

We assume, without deciding, that De Simone and ExeGi’s arguments on the Facebook Commentary and YouTube Materials were different. For even if they were, the

district court didn't err in considering the YouTube Materials as a source of contemptuous statements.

Generally, “new arguments cannot be raised in a reply brief” before the district court. *United States v. Smalls*, 720 F.3d 193, 197 (4th Cir. 2013). A contrary rule runs the risk of depriving a nonmovant an opportunity to respond. *See Mt. Hebron Dist. Missionary Baptist Ass'n. of AL v. Sentinel Ins. Co.*, No. 16-cv-658, 2018 WL 6822621, at \*1 (M.D. Ala. Oct. 24, 2018) (“[T]his rule is designed to prevent any prejudice that might result when a party is deprived of the opportunity to respond to new arguments.”).

But just as we may overlook waiver, a district court may consider an argument raised for the first time on reply under appropriate circumstances. *Clawson v. FedEx Ground Package Sys., Inc.*, 451 F. Supp. 2d 731, 734 (D. Md. 2006) (“However, the power to decline consideration of [waived] arguments is discretionary, and courts are not precluded from considering such issues in appropriate circumstances.”). We review a district court's decision to consider a waived argument for abuse of discretion. *See Cray Commc'ns, Inc. v. Novatel Comput. Sys., Inc.*, 33 F.3d 390, 395 (4th Cir. 1994).

In exercising such discretion, district courts may rely on a variety of circumstances, two of which are relevant here. First, the untimely argument may be “intimately related” to the original grounds for the motion, in which case a district court can overlook waiver. *Powell v. United States*, No. 16-cv-2960, 2017 WL 3172831, at \*3 (D. Md. July 26, 2017). Second, a non-movant's opportunity to contest an untimely argument in a sur-reply supports a district court's decision to consider the untimely argument. *Clawson*, 451 F. Supp. 2d at 735.

The Facebook Commentary and YouTube Materials contain identical offending statements. Both say VSL#3 was “clinically proven” to alleviate gastrointestinal symptoms. J.A. 560, 659. The district court acknowledged the similarity, stating the YouTube Materials and Facebook Commentary were “accompanied by the same representation.” *De Simone*, 2020 WL 4368103, at \*4. Thus, even assuming the arguments are different, they’re “intimately related.” *Powell*, 2017 WL 3172831, at \*3.

Additionally, VSL and Alfasigma could have sought leave to file a sur-reply. To be clear, “there is no requirement that a party file a sur-reply to address an argument believed to be improperly addressed” in a reply brief. *Hardrick v. City of Bolingbrook*, 522 F.3d 758, 763 n.1 (7th Cir. 2008). But the lack of a requirement doesn’t mandate that we (or the district court for that matter) ignore a non-movant’s strategic decision. Ten months elapsed between *De Simone* and ExeGi’s reply brief and the court’s order, which gave VSL and Alfasigma ample opportunity to seek leave to file a sur-reply.

Because ExeGi’s arguments about the Facebook Commentary and YouTube Materials are intimately related and VSL and Alfasigma didn’t pursue a sur-reply, we find that the district court acted within its discretion to consider the YouTube Materials.

#### D.

VSL and Alfasigma next assert that the Actual Press Release doesn’t fall within the permanent injunction’s scope and their use of the term “generic” wasn’t prohibited. We disagree.

1.

The district court enjoined VSL and Alfasigma from making certain misleading statements in “promotional materials directed at or readily accessible to United States consumers.” J.A. 451. The Actial Press Release violated this admonition.

First, the Press Release is promotional material.<sup>7</sup> The injunction doesn’t define “promotional materials.” But the Lanham Act, which the jury found that Leadiant and Alfasigma violated by falsely advertising VSL#3, prohibits misleading statements in “commercial advertising or promotion.” 15 U.S.C. § 1125(a)(1)(B). Since the phrase “commercial advertising or promotion” provided the basis for Alfasigma’s liability in the first place, it serves as a guidepost for our inquiry.

Under the Lanham Act, “commercial advertising or promotion” is “commercial speech . . . for the purpose of influencing consumers to buy goods or services.” *Handsome Brook Farm, LLC v. Humane Farm Animal Care, Inc.*, 700 F. App’x 251, 256 (4th Cir. 2017). Speech is more likely commercial when the declarant “hoped to realize an economic gain when disseminating its message.” *Id.* at 258. “When a message communicates both commercial and noncommercial speech, it is treated like commercial

---

<sup>7</sup> VSL and Alfasigma complain that the district court never found that the Actial Press Release was promotional material. While the court didn’t say so directly, it acknowledged that the permanent injunction only applied to promotional materials. *De Simone*, 2020 WL 4368103, at \*3. And it again referenced this restriction in discussing the Actial Press Release. *Id.* at \*5. Because the district court knew that materials could only be contemptuous if they were promotional, it implicitly found that the Press Release fit the bill.

speech unless the commercial and noncommercial messages are inextricably intertwined.”  
*Id.* at 261 (cleaned up).

The Press Release details the factual and procedural background for this dispute. But the Press Release’s final sentence emphasizes VSL#3’s commercial availability: “VSL#3® is available for purchase in the U.S. and many markets globally.” J.A. 523. So the district court reasonably viewed the message as an attempt to realize economic gain.

And the offending statements aren’t intertwined with the rest of the Release. Rather, they’re set aside in their own paragraph. Thus, the Actial Press Release is commercial speech.

The statements also cast De Simone and ExeGi in a negative light, calling their “efforts to sell” Visbiome “aggressive.” J.A. 523. And they diminish Visbiome, labeling it “competing” and “generic.” J.A. 523. The statements also evince an intent to steer consumers away from Visbiome and toward VSL#3.

Because the Actial Press Release meets both requirements for “commercial advertising or promotion,” the district court properly classified it as promotional material.

Second, the Actial Press Release was “directed at or readily accessible to United States consumers.” “[D]iverse media outlets” “widely circulated” the Press Release. *De Simone*, 2020 WL 4368103, at \*5. At least a dozen publications ran the story on their websites.

In sum, the injunction applied to the Actial Press Release.

2.

VSL and Alfasigma argue that they shouldn't be liable for the Actial Press Release because they believed they could describe Visbiome as "generic." "[C]ivil contempt may be appropriate if there is no objectively reasonable basis for concluding that the [offender's] conduct might be lawful." *Taggart v. Lorenzen*, 139 S. Ct. 1795, 1799 (2019). To show their belief was reasonable, VSL and Alfasigma make three points. First, the permanent injunction didn't explicitly prohibit use of the term "generic." Second, "generic" has multiple meanings. And third, ExeGi described Visbiome as "generic" in the past. We aren't persuaded.

To start, the permanent injunction doesn't enumerate all prohibited phrases. True, it lists "original proprietary blend" and "same mix in the same proportions" as impermissible comparisons between VSL#3 and Visbiome. J.A. 451. But the injunction isn't limited to those examples. So VSL and Alfasigma's argument that the injunction doesn't explicitly bar use of the term "generic" is meritless.

Similarly, VSL and Alfasigma argue that "generic" has multiple meanings. They claim that Actial intended to use generic's patent-specific meaning. According to VSL and Alfasigma, Actial said merely that Visbiome isn't patented. And if the Press Release stated that Visbiome isn't patented, it wouldn't violate the injunction because it wouldn't reference VSL#3 or Visbiome's formula.

The problem for VSL and Alfasigma is that the permanent injunction prohibits the bound parties from "stating *or suggesting* . . . that the present version of VSL#3 . . . continues to contain the same formulation found in [earlier] versions of VSL#3." J.A. 451

(emphasis added). So even if the Actual Press Release intended a certain meaning for “generic,” the injunction’s restraint on avoiding a different suggestion applies.

The word “generic” can intimate a nondistinct quality. *See Generic*, Merriam-Webster Dictionary (1st ed. 2019) (“having no particularly distinctive quality”); *Generic*, American Heritage Dictionary of the English Language (5th ed. 2018) (“Relating to or descriptive of an entire group or class”); *Generic*, Webster’s New World College Dictionary (5th ed. 2014) (“without individual character or distinctive characteristics”); *Generic*, Merriam-Webster’s Collegiate Dictionary (11th ed. 2011) (“having no particularly distinctive quality or application”). Suggesting that VSL#3 and Visbiome aren’t distinct is a stone’s throw from saying they have the same formulation. So the district court didn’t abuse its discretion in finding that the Actual Press Release’s use of “generic” implied that VSL#3 and Visbiome used the same formulation.

Last, VSL and Alfasigma say that ExeGi marketed Visbiome as a “generic” version of VSL#3 in the past. Since ExeGi used the term to describe its own product, VSL and Alfasigma say they could do the same.

VSL and Alfasigma, however, can’t hide behind ExeGi’s prior use of “generic.” ExeGi called Visbiome generic in 2015. But that was when VSL#3 used the De Simone Formulation. In other words, ExeGi marketed an old formulation as the generic version of the De Simone Formulation. ExeGi has never referred to a product using the De Simone Formulation (as Visbiome now does) as generic. So ExeGi’s prior references to Visbiome as “generic” don’t entitle VSL and Alfasigma to do so now.

\* \* \*

Because the Healthcare Providers Letter, Facebook Commentary, YouTube Materials, and Actial Press Release were all contemptuous, we discern no error in the district court's decision to find all of them sanctionable.

#### IV.

As we've mentioned, a party moving for civil contempt must establish that it suffered harm by clear and convincing evidence. *Ashcraft*, 218 F.3d at 301. VSL and Alfasigma argue there's no evidence that De Simone and ExeGi suffered harm because they didn't show (1) a direct connection between each violation and the harm it caused, and (2) that any consumers had seen the Healthcare Providers Letter or Actial Press Release. We reject these arguments.

#### A.

Where, "a prior judgment includes a finding that [the contemnor's] conduct . . . harmed the [movant]," that finding continues to bind the contemnor. *Rainbow*, 887 F.3d at 619. In *Rainbow*, the parties "consented to judgment being entered as though the allegations of trademark infringement had been proven at trial." *Id.* (cleaned up). And the judgment included a finding that the contemnor's conduct harmed the movant.

Here, the jury awarded ExeGi \$15 million in damages after Alfasigma falsely advertised VSL#3 by referencing studies done on the De Simone Formulation. The district court found that Alfasigma intended to cause confusion in the marketplace as to the

competing probiotic formulations. So, just as in *Rainbow*, there's a binding judgment establishing that the contemnor's conduct harms the movant.

In any event, De Simone and ExeGi didn't need to prove a direct connection between each violation and the harm they suffered. For civil contempt, we recognize "informational harms not connected to any specific monetary loss." *Consumer Fin. Prot. Bureau v. Klopp*, 957 F.3d 454, 465 (4th Cir. 2020). When a movant alleges "informational harms disconnected from exact monetary damages," the movant needn't prove a specific amount. *Id.* Customer "confusion" is one example of an informational harm. *Id.*

VSL and Alfasigma distinguish *Klopp* in two ways. First, they claim the harm in that case—failure to upload into a nationwide registry a consent order prohibiting the contemnor from engaging in the mortgage industry—was apparent because it created an information asymmetry between regulators based on their jurisdiction. Second, they argue that we have only recognized informational harms in the trademark context.

VSL and Alfasigma's first distinction misses the mark. We've never held that informational harm need be apparent for civil contempt. In any event, the harm is apparent here. As the district court noted, the violations created "a false continuity between Italian VSL#3 and the De Simone Formulation so that VSL#3 could keep its prior customers and potentially poach new ones." *De Simone*, 2020 WL 4368103, at \*6. The court also cited its prior findings that "the false statements caused customers to continue to purchase VSL#3 and thus to withhold their trade from ExeGi." *De Simone*, 2020 WL 4368103, at \*6 (citing *De Simone v. VSL Pharms., Inc.*, 395 F. Supp. 3d 617, 628–30 (D. Md. 2019)).

So even if informational harms must be apparent, the misleading information VSL and Alfasigma spread meets that requirement.

VSL and Alfasigma's other distinction—that *Klopp* was a trademark case—fares no better. True, we have recognized informational harms in the trademark context. *Klopp*, 957 F.3d at 465; *Rainbow*, 887 F.3d at 619. But we haven't so limited the doctrine, and we decline to do so here.

## B.

Next, VSL and Alfasigma say there's no evidence consumers saw the Healthcare Providers Letter or Actial Press Release. Not so.

Two consumers said that VSL#3's marketing failed to disclose a change in formula when it transitioned away from the De Simone Formulation. They continued using VSL#3, but their symptoms worsened. They both researched VSL#3 online and learned of this litigation. While neither consumer explicitly referenced the Healthcare Providers Letter or Actial Press Release, their statements show that consumers took to the internet for answers. And a Google search for "vsl3 litigation" yielded the Letter as the second result. So the declarations are some evidence that consumers saw the contemptuous statements.

More to the point, VSL and Alfasigma cite no authority requiring De Simone and ExeGi to prove that consumers saw the statements. In fact, the Lanham Act holds liable "any person who . . . uses in commerce any . . . false or misleading representation of fact, which . . . is *likely to cause* confusion." 15 U.S.C. § 1125(a)(1)–(a)(1)(A) (emphasis added). Because the Lanham Act doesn't require proof that consumers saw the statements, the injunction needn't have required such proof either. *See Howard Johnson Co., Inc. v.*

*Khimani*, 892 F.2d 1512, 1519 (11th Cir. 1990) (“The district court’s use of the Lanham Act to guide its structuring of the civil contempt sanction was reasonable and within its discretion.”)

Thus, De Simone and ExeGi demonstrated harm.

## V.

VSL and Alfasigma next contend that the district court lacked authority to award attorneys’ fees because they didn’t willfully disobey the injunction and the fees were punitive.<sup>8</sup> We disagree.

### A.

“The appropriate remedy for civil contempt is within the court’s broad discretion.” *In re Gen. Motors Corp.*, 61 F.3d 256, 259 (4th Cir. 1995). “[A] court may assess attorneys’ fees for the willful disobedience of a court order as part of the fine to be levied on the defendant.” *Alyeska Pipeline Serv. Co. v. Wilderness Soc’y*, 421 U.S. 240, 258 (1975) (cleaned up). But the power to award fees for willful disobedience doesn’t “take away the inherent authority of a court to award attorneys’ fees in a civil contempt

---

<sup>8</sup> The district court ordered that VSL and Alfasigma pay De Simone and ExeGi’s “reasonable attorney’s fees.” *De Simone*, 2020 WL 4368103, at \*6. Because the court hasn’t fixed the fee award, the only question before us is whether an award of reasonable attorneys’ fees for civil contempt is inherently punitive without a finding of willful disobedience.

proceeding.” *Cook v. Ochsner Found. Hosp.*, 559 F.2d 270, 273 (5th Cir. 1977).<sup>9</sup> We have affirmed an award of attorneys’ fees without finding willful disobedience. *In re Gen. Motors*, 61 F.3d at 258–59.

VSL and Alfasigma rely on *Omega World Travel, Inc. v. Omega Travel & Shipping Agencies, Inc.*, 905 F.2d 1530, 1990 WL 74305 (4th Cir. 1990) (per curiam) and *Wright v. Jackson*, 522 F.2d 955 (4th Cir. 1975) to show that willfulness is a prerequisite to awarding attorneys’ fees for civil contempt. Neither case supports such a requirement.

In *Wright*, we found “three general grounds” which showed the contemnor was disobedient. 522 F.2d at 958. But our holding was narrower: the contemnor’s “refusal of performance, which led . . . to a finding of contempt . . . could not justify an assessment for a previous part of the case in which no obstinacy occurred.” *Id.* In other words, when an award of attorneys’ fees depends solely on the contemnor’s disobedient conduct, the award can only include expenses related to that conduct. This rule doesn’t prohibit awarding attorneys’ fees absent willful disobedience.

---

<sup>9</sup> Every circuit to address the question has reached the same conclusion. *PlayNation Play Sys., Inc. v. Vexlex Corp.*, 939 F.3d 1205, 1215 (11th Cir. 2019); *John Zink Co. v. Zink*, 241 F.3d 1256, 1261–62 (10th Cir. 2001); *Food Lion, Inc. v. United Food & Com. Workers Int’l Union, AFL-CIO-CLC*, 103 F.3d 1007, 1017 n.14 (D.C. Cir. 1997); *Weitzman v. Stein*, 98 F.3d 717, 719 (2d Cir. 1996); *Robin Woods, Inc. v. Woods*, 28 F.3d 396, 400 (3d Cir. 1994); *Perry v. O’Donnell*, 759 F.2d 702, 705 (9th Cir. 1985); *TWM Mfg. Co., Inc. v. Dura Corp.*, 722 F.2d 1261, 1273 (6th Cir. 1983); *CFTC v. Premex, Inc.*, 655 F.2d 779, 784 n.9 (7th Cir. 1981); see also *United States v. Dinwiddie*, 885 F. Supp. 1299, 1306 & n.8 (W.D. Mo. 1995).

*Omega* also misses the mark. There, we said that courts “*may* assess attorneys’ fees” when a party willfully disobeys an order. 1990 WL 74305, at \*4 (emphasis added). But we didn’t say that willful disobedience is the only basis for awarding attorneys’ fees.

We’ve never required district courts to find a party’s willful disobedience before awarding attorneys’ fees. And we decline to impose that requirement here.

B.

Nor was the district court’s award of attorneys’ fees punitive. “Judicial sanctions in civil contempt proceedings may, in a proper case, be employed for either or both of two purposes[:] to coerce the defendant into compliance with the court’s order, and to compensate the complainant for losses sustained.” *United States v. United Mine Workers of Am.*, 330 U.S. 258, 303–04 (1947). An award of “attorney’s fees incurred because of the misconduct at issue” is compensatory. *Goodyear Tire & Rubber Co. v. Haeger*, 137 S. Ct. 1178, 1186 (2017).

The district court awarded attorneys’ fees to compensate De Simone and ExeGi. To that end, it awarded only De Simone and ExeGi’s “reasonable attorney’s fees expended in advancing the [contempt m]otion.”<sup>10</sup> *De Simone*, 2020 WL 4368103, at \*6. At no point did the court suggest that the fee award should exceed the actual cost to De Simone and ExeGi. Thus, the decision to award fees wasn’t punitive.

---

<sup>10</sup> A “court can shift only those attorney’s fees incurred because of the misconduct at issue.” *Goodyear*, 137 S. Ct. at 1186. And the district court found that the product information sheets weren’t contemptuous. We think it sufficiently clear that the district court’s award doesn’t include fees related to the argument that the product information sheets violated the injunction.

VI.

For the above reasons, the district court's judgment is

*AFFIRMED.*