Filed 11/17/21

CERTIFIED FOR PUBLICATION

COURT OF APPEAL, FOURTH APPELLATE DISTRICT

DIVISION ONE

STATE OF CALIFORNIA

NEURELIS, INC., Plaintiff and Respondent, v. AQUESTIVE THERAPEUTICS, INC., Defendant and Appellant.	D077984 (Super. Ct. No. 37-2019-00064665-CU-BT-CTL)
NEURELIS, INC., Plaintiff and Appellant, v. AQUESTIVE THERAPEUTICS, INC., Defendant and Respondent.	D078186 (Super. Ct. No. 37-2019-00064665-CU-BT-CTL)

APPEAL and cross-appeal from an order of the Superior Court of San Diego County, John S. Meyer, Judge. Affirmed in part, reversed in part, and remanded with directions.

Latham & Watkins, John T. Ryan, David F. Kowalski, and Nicole C. Valco, for Plaintiff and Appellant.

Steptoe & Johnson, Jason Levin, Melanie A. Ayerh, and Jamie L. Lucia, for Defendant and Respondent.

Steptoe & Johnson, Jason Levin, Melanie A. Ayerh, and Jamie L. Lucia, for Defendant and Appellant.

Latham & Watkins, John T. Ryan, David F. Kowalski, Nicole C. Valco, Amit Makker, Melissa Arbus Sherry, and Shannon Grammel, for Plaintiff and Respondent.

Neurelis, Inc. (Neurelis) and Aquestive Therapeutics, Inc. (Aquestive) are pharmaceutical companies developing their own respective means to administer diazepam, a drug used to treat acute repetitive seizures (ARS). Neurelis was further along in the development process than Aquestive. Thus, according to Neurelis, Aquestive engaged in a "multi-year, anticompetitive campaign to derail the Food and Drug Administration" (FDA) from approving Neurelis's new drug. Based on Aquestive's alleged conduct, Neurelis sued Aquestive for defamation, malicious prosecution, and violation of the unfair competition law (UCL; Bus. & Prof. Code, § 17200, et seq.). In response, Aquestive brought a special motion to strike the complaint under the anti-SLAPP (Strategic Lawsuit Against Public Participation) statute, Code of Civil Procedure section 425.16.[1]

The superior court granted in part and denied in part Aquestive's motion, finding that the defamation cause of action could not withstand the anti-SLAPP challenge. However, the court denied the motion as to Neurelis's other two causes of action.

---

1 Statutory references are to the Code of Civil Procedure unless otherwise specified.

Aquestive appeals, contending the court erred by failing to strike the malicious prosecution action as well as the claim for a violation of the UCL. Neurelis, in turn, cross-appeals from the order, maintaining that the conduct giving rise to its defamation cause of action was not protected under the anti-SLAPP statute.

We agree that at least some of the conduct giving rise to the defamation action is covered by the commercial speech exception (§ 425.17, subd. (c)) and not subject to the anti-SLAPP statute. Accordingly, we determine the superior court erred in granting the anti-SLAPP motion as to the defamation action. Some of this same conduct also gives rise to the UCL claim and is not subject to the anti-SLAPP statute as well. However, we note that Neurelis bases part of two of its causes of action on Aquestive's petitioning activity. That activity is protected conduct under the anti-SLAPP statute, and Neurelis has not shown a likelihood to prevail on the merits. Thus, allegations relating to this petitioning conduct must be struck. Finally, we determine that Neurelis has not shown a probability of success on the merits regarding its malicious prosecution claim. As such, that claim should be struck under the anti-SLAPP statute.

In summary, the superior court's order is affirmed in part and reversed in part. We will remand this matter back to the superior court with instructions to enter an order striking the allegations relating to Aquestive's petitioning activity, striking the malicious prosecution action, and denying the motion as to the UCL and defamation causes of action to the extent they are based on unprotected conduct.

FACTUAL AND PROCEDURAL BACKGROUND

The Operative Complaint

Neurelis is a Delaware corporation with its principal place of business in San Diego. Its focus is to develop pharmaceuticals to treat central nervous system disorders. Aquestive is a Delaware corporation with its principal place of business in New Jersey. Both Neurelis and Aquestive were working to develop a drug to treat patients with epilepsy who suffer from ARS. For over 20 years, Diastat® was the only approved drug on the market to treat ARS, but it requires rectal administration. Therefore, Neurelis and Aquestive were trying to develop a new method to administer the needed medicine.

To this end, Neurelis formed in 2007 with the aim of combining various technologies to find an effective way to create an intranasal delivery system for an ARS treating drug (diazepam). In 2008, Neurelis had developed a novel formation for nasal delivery of the drug diazepam, which would be named Valtoco®.

In 2011, after initial nonclinical studies, Neurelis began discussions with the FDA regarding Valtoco as an investigational new drug. That same year, Neurelis conducted the first human proof-of-concept study. It announced the completion of dosing on April 20, 2011. Two months later, Neurelis publicly announced the results from this phase 1 study that demonstrated a bioavailability[2] of 96 percent when comparing Valtoco with intravenous diazepam.

---

2 Bioavailability means "the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of drug action." (21 C.F.R. § 314.3 (2021).)

Based on these results, Neurelis scheduled a pre-investigational new drug application with the FDA, which was conducted in November 2011. On February 6, 2012, Neurelis publicly announced the FDA's acceptance of the NRL-1 (Valtoco) investigational new drug application. Per the direction of the FDA, Neurelis continued working toward the development of Valtoco throughout 2012, 2013, and 2014.

On December 22, 2015, Neurelis announced the receipt of orphan drug designation from the FDA for Valtoco for management of ARS. Such designation may be obtained when a rare disorder or condition meets criteria specified by the Orphan Drug Act of 1983 and the FDA's implementing regulations. This designation did not indicate that Valtoco was safe or effective for public use but, instead, operated to qualify Neurelis for various development incentives, like tax credits and potential exclusivity for seven years if the FDA ultimately approved Valtoco.

On January 5, 2017, Neurelis announced receipt of fast track designation from the FDA for Valtoco. That designation allows for the potential expedited or priority review from the FDA once the new drug application has been submitted. It also provides for prioritized interactions with the FDA during the clinical development program.

On September 24, 2018, Neurelis announced the filing of a new drug application for Valtoco as a treatment for ARS. At the time of filing the operative complaint (December 9, 2019), the FDA was still considering that application.

While Neurelis was in the process of developing Valtoco and seeking FDA approval, Aquestive also was working toward the development of its own drug to treat ARS, Libervant®. However, Aquestive was not as far along

in the process as Neurelis. Indeed, at various times, Aquestive approached Neurelis about partnering in the development process, but Neurelis declined.

Libervant has a different delivery system than Valtoco. Although Valtoco is administered nasally, Libervant utilizes "fast-melt strips" for a "buccal delivery of diazepam." So, the drug is delivered by placing a soluble strip in the patient's mouth against the cheek, which would quickly dissolve for oral administration. Libervant obtained orphan drug designation on November 10, 2016.

In June 2017, Aquestive's chief executive officer, Keith Kendall, and its chief operating officer, Dan Barber, met with Neurelis's chief executive officer, Craig Chambliss, to discuss "the two companies' diazepam programs and . . . to forge a potential strategic partnership between Aquestive and Neurelis." Chambliss explained Neurelis's historical efforts to bring Valtoco to market as well as his views of the importance of formulating a nasal administration of diazepam to treat ARS for the epilepsy community. Kendall interrupted Chambliss's explanation, stating, " 'Look, let's be honest here. We don't care about the patients, epilepsy, or any of this. We are not here for patients, we are here for our investors and need to show them a return.' " After these comments, Chambliss left the meeting.

Kendall and Barber requested another meeting with Chambliss in January 2018. Chambliss agreed in the hopes of discussing "some type of proposal about other products[ ] because the significant gap in progress between the two diazepam programs would not make a good partnership." However, at the meeting, Chambliss came to believe that Kendall and Barber were merely trying to obtain competitive intelligence on Neurelis and Valtoco. Kendall "attempted to insert Aquestive into a strategic partnering

process with Neurelis," but Chambliss explained that Aquestive was not an appropriate partner for Neurelis.

Aquestive completed its initial public offering on July 24, 2018. Before the offering, Aquestive filed a Form S-1 with the Securities and Exchange Commission (SEC). In that form, Libervant was featured prominently. Although development of Libervant was not as far along as Valtoco, Aquestive represented that it was "further along" than other companies who were developing "other routes of administration" of diazepam for the treatment of ARS, including companies developing intranasal and subcutaneous implementations. However, Aquestive admitted that if any of these other companies obtained FDA approval for their formulations of diazepam for the treatment of ARS before Aquestive, then Aquestive would be barred from marketing Libervant in the United States for seven years.[3]

In a subsequent filing with the SEC, Aquestive did not claim that it was further along in the development of Libervant than other companies developing their diazepam products, but it still admitted that if a company were to get its product approved by the FDA before Libervant then Aquestive would most likely not be able to market Libervant in the United States for seven years.

Because Aquestive encountered multiple obstacles in the development of Libervant and its stock value decreased significantly, Aquestive threatened

---

3 Neurelis alleges that, at the time of the filing of Aquestive's Form S-1, Aquestive had not yet completed any clinical trials for Libervant. Although Aquestive did not mention Neurelis or Valtoco by name, Neurelis avers Aquestive made its statements "with Neurelis in mind." Moreover, because Neurelis was further along in the development of Valtoco than Aquestive was with Libervant, Neurelis claims Aquestive's factual representations in the Form S-1 were false.

to file three inter partes review (IPR) petitions with the Patent Trial and Appeal Board (Board) of the United States Patent and Trademark Office (PTO) unless Neurelis signed a waiver of its orphan drug exclusivity. These petitions challenged the validity of claims from an issued United States patent belonging to Neurelis. Prompted by this threat, Chambliss agreed to meet with Kendall and Barber on January 9, 2019. Kendall would not consent to share the contents of the proposed petitions unless Neurelis agreed to "work together" with Aquestive. Chambliss had brought a Neurelis board member as well as an intellectual property attorney to the meeting. Yet, no agreement was reached.

Two days later, Aquestive's leadership and legal counsel had a phone call with Chambliss and Neurelis's legal counsel to discuss the threatened petitions. During the call, Aquestive stated that it would not share details of the petitions unless Neurelis signed a waiver of orphan drug exclusivity. Chambliss responded that the proposal was "ridiculous" and there was no need for further discussions.

At a follow up discussion the next week, Aquestive shared some details of the threatened petitions. Neurelis's legal counsel then determined the petitions were meritless. As such, Neurelis concluded that the petitions were proposed solely to extort it to sign an orphan drug exclusivity waiver. Chambliss therefore explained to Kendall on January 23, 2019, that Neurelis would not sign any waiver and given the frivolousness of the petitions, the money the parties would spend on litigation would be better served invested in the epilepsy community. To this end, Chambliss encouraged Kendall to " 'do the right thing here,' " but Kendall indicated Aquestive would move forward with the petitions.

On January 29, 2019, Aquestive filed the three IPR petitions with the Board, challenging the validity of all the claims of Neurelis's U.S. Patent No. 9,763,876 ('876 Patent). The Board denied institution of a review for one of the petitions because Aquestive's petition failed to demonstrate a reasonable likelihood of prevailing on showing invalidity of a claim. The Board also denied institution of a review for another one of the petitions, under 35 United States Code section 325(d), because that petition asserted the same or substantially the same prior art or arguments that had already been presented to the PTO during the original prosecution of the '876 Patent. As to the third petition, the Board instituted a review on August 13, 2019. At the time of the filing of the operative complaint, the petition remained pending.

In addition to filing the three petitions with the Board, Aquestive also filed a citizen petition with the FDA on November 1, 2019, requesting that the FDA stay approval of Neurelis's new drug application for Valtoco " 'until additional clinical studies have been conducted that would allow for adequate labeling as requested in this petition.' " Aquestive additionally requested that the FDA determine that Valtoco was neither clinically superior to other diazepam products nor offered a " 'major contribution to patient care.' " According to Neurelis, such a determination would be tantamount to the FDA not giving Valtoco orphan drug exclusivity. Neurelis argues that none of Aquestive's claims against Valtoco were accurate, but instead, they were "founded on misleading, inaccurate, and incomplete data."

Neurelis filed a responsive letter to the FDA on November 22, 2019, explaining why Aquestive's FDA petition was meritless. Aquestive then submitted a supplemental petition asking the FDA to require Neurelis to reformulate Valtoco because it contains Vitamin E. Again, Neurelis contends

the claims in Aquestive's supplemental filing were based on "inaccurate data and misinformation."

Moreover, on a November 6, 2019 quarterly investors call, Kendall stated, " 'Based on patient survey data, Libervant is preferred by 80-plus percent of patients when compared to nasal sprays. Once approved by the FDA, Libervant will be the only treatment option usable by and delivering a consistent, predictable dose to virtually all patients to whom it's prescribed.' "

Because of Aquestive's actions, Neurelis brought suit, alleging causes of action for violations of the UCL, defamation, and malicious prosecution.

The Anti-SLAPP Motion

In response to the operative complaint, Aquestive filed an anti-SLAPP motion. In that motion, Aquestive argued the three causes of action were based on speech protected under subdivisions (e)(1), (2), and (3) of section 425.16. Neurelis opposed the motion arguing that Aquestive's private threats were not protected under the anti-SLAPP statute and that any causes of action arising out of the statements to investors and the citizen petition were not protected because they fell under the commercial speech exemption. In addition, Neurelis contended that it had a probability of succeeding on the merits on each cause of action and Aquestive failed to carry its burden on any affirmative defense.

After considering the papers and evidence submitted in support of and in opposition to the motion as well as entertaining oral argument, the superior court asked the parties to submit supplemental briefing on two issues, whether: (1) the investor statements qualify for the commercial speech exemption and (2) the denial of the petitions filed with the Board could give rise to a malicious prosecution claim.

The court then considered the supplemental briefs and issued its ruling, denying in part and granting in part the anti-SLAPP motion. Specifically, the court struck the defamation cause of action, but allowed the UCL and malicious prosecution causes of action to stand. In doing so, the court found that the comments made to the investors did not fall under the commercial speech exception codified in section 425.17, subdivision (c)(2). In addition, the court determined that the denial of two of the petitions filed with the Board could serve as the basis for the malicious prosecution action. Regarding the probability of success on the merits, the court concluded that Neurelis did not satisfy its burden as to the defamation action but did so as to the UCL and malicious prosecution claims.

Appeals

Aquestive appeals the court's order as to its denial of the anti-SLAPP motion regarding the UCL and malicious prosecution causes of action. Neurelis appeals the order as to the granting of the motion concerning the defamation cause of action. On our own motion, we consolidated the two appeals.

DISCUSSION

I

THE ANTI-SLAPP MOTION

A. Legal Standards

"Enacted by the Legislature in 1992, the anti-SLAPP statute is designed to protect defendants from meritless lawsuits that might chill the exercise of their rights to speak and petition on matters of public concern. [Citations.] To that end, the statute authorizes a special motion to strike a claim 'arising from any act of that person in furtherance of the person's right of petition or free speech under the United States Constitution or the

California Constitution in connection with a public issue.' " (*Wilson v. Cable News Network, Inc.* (2019) 7 Cal.5th 871, 883-884 (*Wilson*).)

"A court evaluates an anti-SLAPP motion in two steps. 'Initially, the moving defendant bears the burden of establishing that the challenged allegations or claims "aris[e] from" protected activity in which the defendant has engaged. [Citations.] If the defendant carries its burden, the plaintiff must then demonstrate its claims have at least "minimal merit." ' [Citation.] If the plaintiff fails to meet that burden, the court will strike the claim." (*Wilson*, *supra*, 7 Cal.5th at p. 884.)

"The defendant's first-step burden is to identify the activity each challenged claim rests on and demonstrate that that activity is protected by the anti-SLAPP statute. A 'claim may be struck only if the speech or petitioning activity *itself* is the wrong complained of, and not just evidence of liability or a step leading to some different act for which liability is asserted.' [Citation.] To determine whether a claim arises from protected activity, courts must 'consider the elements of the challenged claim and what actions by the defendant supply those elements and consequently form the basis for liability.' [Citation.] Courts then must evaluate whether the defendant has shown any of these actions fall within one or more of the four categories of ' "act[s]" ' protected by the anti-SLAPP statute." (*Wilson*, *supra*, 7 Cal.5th at p. 884.)

The second step of the anti-SLAPP analysis has been described as a summary-judgment-like procedure. (*Sweetwater Union High School Dist. v. Gilbane Building Co.* (2019) 6 Cal.5th 931, 940 (*Sweetwater Union*).) The court determines whether " 'the plaintiff has stated a legally sufficient claim and made a prima facie factual showing sufficient to sustain a favorable judgment.' " (*Ibid.*) The plaintiff " 'may not rely solely on its complaint, even

if verified; instead, its proof must be made upon competent admissible evidence.' " (*Ibid*.) The defendant may submit evidence in support of its motion. (*1-800 Contacts, Inc. v. Steinberg* (2003) 107 Cal.App.4th 568, 585.) However, " '[t]he court does not weigh evidence or resolve conflicting factual claims.' " (*Sweetwater Union*, at p. 940.) Rather, the court " 'accepts the plaintiff's evidence as true, and evaluates the defendant's showing only to determine if it defeats the plaintiff's claim as a matter of law. [Citation.] "[C]laims with the requisite minimal merit may proceed." ' " (*Ibid*.)

We review an order granting an anti-SLAPP motion de novo. (*Sweetwater Union*, *supra*, 6 Cal.5th at p. 940.)

B. First Prong of the Anti-SLAPP Analysis

In the instant action, Neurelis alleges three causes of action against Aquestive—violation of the UCL, defamation, and malicious prosecution. As to the last cause of action, malicious prosecution arises from an underlying lawsuit and involves allegations that the defendant committed a tort by engaging in the underlying action. (See *Jarrow Formulas, Inc. v. LaMarche* (2003) 31 Cal.4th 728, 734-735, 740-741 (*Jarrow Formulas*) [concluding that malicious prosecution is not exempt from anti-SLAPP scrutiny and explaining that "every Court of Appeal that has addressed the question has concluded that malicious prosecution causes of action fall within the purview of the anti-SLAPP statute"].) Because the malicious prosecution claim meets the requirement of the first prong as it constitutes protected activity under section 425.16, we will address the parties' respective arguments as to that cause of action under the second prong of our anti-SLAPP analysis, *post*. In considering the first prong of the anti-SLAPP motion, we shall focus on the UCL and defamation claims.

As a threshold matter, we note that the UCL cause of action is a mixed claim; that is, it is based on protected and unprotected conduct. (See *Baral v. Schnitt* (2016) 1 Cal.5th 376, 396 (*Baral*).) Thus, the UCL claim relies on Aquestive's "extortionist behavior using litigation as leverage to force Neurelis into waiving [o]rphan [d]rug [e]xclusivity" as well statements Aquestive made in the citizen petition and representations it made to investors. Aquestive admits in its opening brief that the anti-SLAPP motion was not aimed at Aquestive's threats to Neurelis. As such, as to the UCL cause of action only, the anti-SLAPP motion could not have struck that entire cause of action. Therefore, at least the portion of the UCL claim based on the private threats is not part of this appeal and survives regardless of the outcome here. (*Ibid*.)

So, we are left with Aquestive's statements in the citizen petition and its representations to investors, both of which form the basis of Neurelis's causes of action for violation of the UCL and defamation. Aquestive maintains these statements and representations are protected conduct under the anti-SLAPP statute; thus, we must move on to the second prong of our analysis. Neurelis does not argue that the challenged statements do not concern an issue of public interest and, as such, are not covered under the anti-SLAPP statute for that reason. Instead, it counters that the conduct is not protected because it falls under the commercial speech exception found in section 425.17, subdivision (c). We accept the implicit concession by Neurelis that the statements concern an issue of public interest and turn to analyzing whether the commercial speech exception applies.

1. The Commercial Speech Exception

In 2003, the Legislature enacted section 425.17 to curb "a disturbing abuse of Section 425.16 . . . which has undermined the exercise of the

constitutional rights of freedom of speech and petition for the redress of grievances, contrary to the purpose and intent of Section 425.16." (§ 425.17, subd. (a).)[4] Section 425.17 seeks to accomplish that goal by expressly excluding several categories of claims from the scope of section 425.16.

Section 425.17, subdivision (c) establishes such an exclusion for claims concerning some commercial speech. As our high court explained, the exemption applies when: "(1) the cause of action is against a person primarily engaged in the business of selling or leasing goods or services; (2) the cause of action arises from a statement or conduct by that person consisting of representations of fact about that person's or a business competitor's business operations, goods, or services; (3) the statement or conduct was made either for the purpose of obtaining approval for, promoting, or securing sales or leases of, or commercial transactions in, the person's goods or services or in the course of delivering the person's goods or services; and (4) the intended audience for the statement or conduct meets the definition set forth in section 425.17(c)(2)." (*Simpson Strong-Tie Co., Inc. v. Gore* (2010) 49 Cal.4th 12, 30 (*Simpson*); see *Demetriades v. Yelp, Inc.* (2014) 228 Cal.App.4th 294, 308-309 (*Demetriades*).)

The burden of proof as to the applicability of section 425.17's commercial speech exemption falls on the party seeking the benefit of it, in

---

4 "[T]he legislative history of section 425.17 indicates it was drafted to track constitutional principles governing regulation of commercial speech based upon guidelines discussed in *Kasky v. Nike, Inc.* (2002) 27 Cal.4th 939 (*Kasky*). (See Assem. Com. on Judiciary, Analysis of Sen. Bill No. 515 (2003–2004 Reg. Sess.) as amended June 27, 2003, p. 8.)" (*JAMS, Inc. v. Superior Court* (2016) 1 Cal.App.5th 984, 994, fn. omitted (*JAMS*).) In *Kasky*, our high court observed that three elements distinguish commercial speech from noncommercial speech: the speaker, the audience, and the content of the message. (*Kasky*, at p. 960.)

this case, Neurelis. (*Simpson*, *supra*, 49 Cal.4th at p. 26.) As a statutory exception to section 425.16, section 425.17 must be narrowly construed. (*Simpson*, at p. 22; *JAMS*, *supra*, 1 Cal.App.5th at p. 992.) "Under the two-pronged test of section 425.16, whether a section 425.17 exemption applies is a first prong determination." (*Demetriades*, *supra*, 228 Cal.App.4th at p. 308.) We do not consider whether the plaintiff is likely to prevail on the merits. (*JAMS*, at p. 993.) We independently review the applicability of the commercial speech exemption. (*Simpson*, at p. 26.)

a. Aquestive's Comments to Investors

We first consider whether Aquestive's comments to investors fall under the commercial speech exception. Neurelis maintains that the first requirement of the exception is satisfied because Aquestive is "primarily engaged in the business of selling" "goods," including both pharmaceuticals and "securities." (See § 425.17, subd. (c).) Aquestive does not contest this point, nor could it effectively do so.

Neurelis also argues that section 425.17, subdivision (c)(1) is satisfied because the investor statements relate to Aquestive, Neurelis, and their respective ARS drugs. Therefore, the statements concern Aquestive's "or a business competitor's business operations, goods, or services." (See § 425.17, subd. (c)(1).) For example, in a 2018 Form S-1 filed with the SEC, Aquestive stated that Libervant was "further along in development than . . . other companies' versions of diazepam." Similarly, in a November 6, 2019, investor call, Aquestive stated that "[b]ased on patient survey data, Libervant is preferred by 80-plus percent of patients when compared to nasal sprays." These statements explicitly refer to Libervant and implicitly Valtoco, another "compan[y's] version[ ] of diazepam" and the only nasal spray then in development at that time.

Aquestive suggests that subdivision (c)(1) of section 425.17 may not be satisfied because the investor statements do not specifically mention Neurelis or Valtoco by name. However, mentioning a competitor or a competitor's product under the subdivision is not required. It is enough that the statements relate to Aquestive's own product. (See § 425.17, subd. (c)(1).) That said, the statements implicitly refer to Neurelis ("other companies") and its product ("nasal spray"). We thus reject Aquestive's argument that Neurelis has not carried its burden as to this factor of the commercial speech exception.

Additionally, Neurelis contends that the investor statements were made to an "intended audience" of "actual or potential buyer[s] or customer[s]" of Aquestive's pharmaceuticals and securities or to people "likely to repeat the statement to, or otherwise influence, . . . actual or potential buyer[s] or customer[s]" of Aquestive's pharmaceuticals and securities. (See § 425.17, subd. (c)(2).) To this end, Neurelis notes that Aquestive made statements at the H.C. Wainwright Conference to industry and business development executives, public and private companies, institutional investors, and private equity firms. Further, Aquestive has admitted that its investor calls were a "public forum." Finally, Neurelis points out that the investor statements were also made in "the context of a regulatory approval process, proceeding, or investigation." (§ 425.17, subd. (c)(2).)

Aquestive insists that Neurelis is incorrect that the intended target of the investor representations is sufficient to bring the investor statements under the auspice of the commercial speech exception because there is no evidence that the intended audience of the representations was " 'physicians, hospitals or others in the medical community, who may be interested in purchasing Libervant or Valtoco.' " Instead, the representations were made

to investors who buy Aquestive's stock not its products. As such, Aquestive contends the commercial speech exception cannot apply under the facts here.

Further, Aquestive contends that the commercial speech exception only applies to a certain subset of commercial speech, namely comparative advertising. (See *FilmOn.com Inc. v. DoubleVerify Inc.* (2019) 7 Cal.5th 133, 147-148 (*FilmOn.com*).)[5] Although we acknowledge that many of the reported cases addressing the commercial speech exception have involved false or misleading advertising (see, e.g., *JAMS*, *supra*, 1 Cal.App.5th at pp. 996-998*; L.A. Taxi Cooperative, Inc. v. The Independent Taxi Owners Assn. of Los Angeles* (2015) 239 Cal.App.4th 918, 930-932), none of these cases addressed a situation similar to what we have here—a defendant who makes allegedly false statements about itself and/or its product as well as that of a competitor to current and potential investors and the general public.

In the absence of any California cases on point, Aquestive relies on three federal district court cases to support its position: *Allergan, Inc. v. Merz Pharmaceuticals, LLC* (C.D.Cal. Nov. 14, 2011, No. SACV 11-446 AG

---

[5] The California Supreme Court noted that "certain commercially oriented statements will fall outside the scope of section 425.17, subdivision (c)." (*FilmOn.com*, *supra*, 7 Cal.5th at p. 148.) The court further observed that "the language of section 425.17, subdivision (c) and subsequent case law indicate that the provision exempts 'only a subset of commercial speech'—specifically, comparative advertising." (*Id.* at p. 147.) However, in that case, the court was not considering whether certain speech fell under subdivision(c). (*FilmOn.com*, at p. 147, fn. 4.) Instead, the court discussed section 425.17, subdivision (c) for the purpose of interpreting the "catchall" provision of section 425.16, subdivision (e)(4). (*FilmOn.com*, at pp. 142-143, 147-148.) We read nothing in *FilmOn.com* that precludes the applicability of the commercial speech exception under the facts before us. (See *Nolan v. City of Anaheim* (2004) 33 Cal.4th 335, 343 ["A decision, of course, does not stand for a proposition not considered by the court"].)

(Ex)) 2011 WL 13323246; *Tercica, Inc. v. Insmed Inc.* (N.D.Cal. June 9 2006, No. C 05-5027 SBA) 2006 WL 1626930; *RPost Holdings, Inc. v. Trustifi Corp.* (C.D.Cal May 11, 2012, No. CV 10-1416 PSG (SHx)) 2012 WL 12952728. Specifically, Aquestive maintains that these three cases stand for the proposition that statements to investors cannot be considered commercial speech. However, none of these cases addresses the commercial speech exception codified in section 425.17, subdivision (c). Instead, these cases concern what is actionable commercial speech under 15 United States Code section 1125(a)(1), the Lanham Act. The false advertising prohibition in the Lanham Act applies only to "commercial advertising or promotion" (15 U.S.C. § 1125(a)(1)(B)), a term not defined under the act. Federal courts have limited the term to "advertising" intended to influence "consumers." (*Rice v. Fox Broad Co.* (9th Cir. 2003) 330 F.3d 1170, 1181.) Section 425.17, subdivision (c) does not use the word "advertising," but instead, provides its own explanation regarding what the commercial speech exception covers. Indeed, subdivision (c) explicitly lists "securities" among the "goods or services" covered under the exception. (§ 425.17, subd (c).) Accordingly, these cases cited by Aquestive, construing claims under the Lanham Act, are not instructive here.

The only case cited by either party addressing the application of the commercial speech exception under the anti-SLAPP statute to representations made to investors is *Neuralstem, Inc. v. StemCells, Inc.* (D.Md. Aug. 4, 2009, No. Civil Action No. AW-08-CV-1173) 2009 WL 2412126 (*Neuralstem*). There, StemCells claimed that Neuralstem had "made false statements about the value or quality of StemCells' patents in order to devalue and injure the intellectual property of StemCells, to impugn the business honesty of StemCells, and to engage in unfair competition." (*Id.* at

p. *5.) Neuralstem argued that its statements were protected conduct under the anti-SLAPP statute; however, in applying California law, the court found the commercial speech exemption under subdivision (c) of section 425.17 applied. (*Neuralstem*, at p. *5.) The court determined that the public "statements were directed toward an audience of actual or potential buyers" because "Neuralstem is a publicly traded company and concedes these public statements were made to a specific target audience comprised of existing and potential investors." (*Id*. at p. *7.)

Neurelis relies on *Neuralstem*, maintaining it is analogous to the instant matter. Like StemCells and Neuralstem, Neurelis and Aquestive are business competitors. Similar to Neuralstem, Aquestive made statements of fact to its investors about its product as well as Neurelis's product (e.g., Libervant is further along in development than these other versions of diazepam and Libervant is preferred by 80-plus percent of patients when compared to nasal sprays). And both Neuralstem and Aquestive made their respective statements to investors and potential investors.

Despite Neurelis's reliance on *Neuralstem*, Aquestive does not discuss or even mention that case in its briefs. Instead, Aquestive argues that the commercial speech exception only applies if it had made the subject comments to customers or potential customers of its products (here, drugs) and not investors, who only buy its stock. Aquestive further points out that it is not in the busines of selling securities and securities are just the means by which it finds investment for its "true business" of "selling . . . pharmaceuticals for medical conditions." Therefore, Aquestive contends that if we adopt Neurelis's argument and find the commercial speech exception applicable here, then we will be improperly expanding the "narrowly construed commercial speech exemption." In other words,

Aquestive all but concedes that the investor statements at issue would be considered speech if they were made to an audience of potential buyers of their drugs. But as they are aimed at investors (i.e., those who would give Aquestive money to develop the drugs to sell), the statements are protected under the anti-SLAPP statute.

Here, we do not believe Aquestive's distinction between investors who buy stock and consumers who would purchase its drugs carries the day, at least under the facts of this case. Subdivision (c)(2) of section 425.17 identifies the "audience" to whom the defendant must make the statement for it to fall under the commercial speech exception. That subdivision provides, in relevant part:

> "The intended audience is an actual or potential buyer or customer, or a person likely to repeat the statement to, or otherwise influence, an actual or potential buyer or customer, or the statement or conduct arose out of or within the context of a regulatory approval process, proceeding, or investigation . . ." (§ 425.17, subd. (c)(2).)

Neurelis points out that some of the investor statements were made to industry and business development executives, public and private companies, institutional investors, and private equity firms. Then Neurelis claims, "[a]t the very least, this audience could have been expected to share what they learned with 'physicians, hospitals or others in the medical community, who may be interested in purchasing Libervant or Valtoco.' " Alternatively stated, Neurelis argues it can be inferred or assumed that the audience would repeat what they heard to potential consumers. Yet, under the plain language of the statute and the facts of this case, we do not need to make any such assumption or inference.

Here, the subject investor comments relate to Aquestive's development of Libervant. To this end, Aquestive emphasizes that Libervant is further

along in development than other competing drugs. Aquestive discusses patients' "response rate" to Libervant. Aquestive states that more than 80 percent of the patients prefer Libervant to nasal sprays. Moreover, the comments highlight the need to get FDA approval of Libervant before the competing drugs to ensure Aquestive is not barred from marketing Libervant for a seven-year period. And Aquestive admits that it made the subject statements to investors as a means to encourage investment in its business (by way of the purchase of securities) so it can fund its "true business" of "selling . . . pharmaceuticals for medical conditions." At the time these statements were made, Aquestive had not taken Libervant to market but was seeking additional funding to obtain FDA approval and begin offering Libervant as a treatment for ARS. Thus, there were no consumers that would have been able to purchase Libervant when the comments were made. However, clearly the audience of Aquestive's statements was in a position to "otherwise influence" a "potential buyer" of Libervant by investing in Aquestive to help ensure that company brought Libervant to market before other competing drugs, like Valtoco. Under these unique circumstances, we determine the subject investor statements are commercial speech and fall under the exception to the anti-SLAPP statute under section 425.17, subdivision (c).

Our conclusion is not inconsistent with the Second Appellate District's statement that "the legislative history of the commercial speech exemption to the anti-SLAPP statute confirms the Legislature's intent to except from anti-SLAPP coverage disputes that are purely commercial." (*Taheri Law Group v. Evans* (2008) 160 Cal.App.4th 482, 491 (*Taheri*); accord, *Brill Media Co., LLC v. TCW Group, Inc.* (2005) 132 Cal.App.4th 324, 342 (*Brill Media*) [section 425.17 "was intended to apply to commercial disputes"].) The instant

action does not involve a plaintiff attempting to limit a defendant's constitutionally protected free speech rights. (See *Rusheen v. Coheen* (2006) 37 Cal.4th 1048, 1055-1056.) To the contrary, here, we have two rival pharmaceutical companies competing for FDA approval of their respective drugs that treat the same condition. Neurelis has sued Aquestive, claiming that Aquestive has attempted to extort Neurelis and lied about Neurelis and Valtoco as well as its own drug (Libervant) while trying to bring its drug to market. This is not the type of case for which the anti-SLAPP statute was intended. (See *No Doubt v. Activision Publishing, Inc.* (2011) 192 Cal.App.4th 1018, 1026 ["The purpose of the statute is 'to provide a procedural remedy to dispose of lawsuits that are brought to chill the valid exercise of constitutional rights' "].) Instead, it is the type of case to be covered by the commercial speech exception of section 425.17, subdivision (c). (See *Taheri*, at p. 491; *Brill Media*, at p. 342.)

2. The Citizen Petition

In somewhat cursory fashion, Neurelis also contends that the citizen petition falls under the commercial speech exception. To this end, Neurelis observes: (1) Aquestive is primarily engaged in the business of selling goods; (2) the petition contained representations of fact; and (3) the petition was filed within the context of a regulatory approval process, proceeding, or investigation. In addition, Neurelis claims that section 425.17, subdivision (c) was specifically focused on overturning *DuPont Merck Pharmaceutical Co. v. Superior Court* (2000) 78 Cal.App.4th 562 (*DuPont*), which involved a pharmaceutical company's " 'false statements and conduct before a regulatory agency.' " Therefore, Neurelis argues the citizen petition here is analogous to the defendant in *DuPont* making "false statements

before regulatory bodies, the medical profession, and to the public in connection with one of its pharmaceutical products." (*Id.* at p. 564.)

Aquestive insists the commercial speech exception does not apply to the citizen petition because the petition does not concern its own drug but, instead, focuses on Neurelis's drug. Thus, the petition cannot constitute advertising subject to the commercial speech exception. Also, Aquestive maintains that it could not be considered to be submitting the petition as part of the regulatory approval process because that process only pertains to the approval of its own drug. As Aquestive did not discuss Libervant in the citizen petition but only Valtoco, it argues that the petition was not part of the regulatory approval process as required under subdivision (c)(2) of section 425.17.

Absent from either party's discussion of whether the commercial speech exception applies is any explanation of the citizen petition process. A citizen petition is "a means afforded by the FDA for raising concerns about products the FDA reviews; any individual may file such a petition concerning scientific or legal issues before or while the product is on the market." (*Apotex Inc. v. Acorda Therapeutics, Inc.* (2d Cir. 2016) 823 F.3d 51, 57 (*Apotex*).) Through this petition process, the FDA permits private entities to provide comments and opinions on draft guidance by filing these petitions. (21 C.F.R. § 10.30 (2021).) A petition can request that the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." (*Ibid.*) A citizen petition must describe the FDA action the petitioner requests and must include a certification by the petitioner that the petition "includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition." (*Ibid.*) As

such, a citizen petition is a means by which the FDA explicitly allows private entities to express safety, scientific, or legal concerns regarding a product. Alternatively stated, the citizen petition is a mechanism wherein a private entity, like Aquestive, can petition the government (here, a government agency) for redress.

Neurelis offers no argument that even suggests the commercial speech exception can trump a party exercising its First Amendment right to petition the government. It does claim that the proponents of the commercial speech exception "were specifically focused on overturning *DuPont*." Yet, even if we agree with this representation, there remains no basis on which to apply the commercial speech exception to a citizen petition based on *DuPont*. That case did concern allegations that the "defendant made false statements before regulatory bodies, the medical profession, and to the public in connection with one of its pharmaceutical products." (*DuPont*, *supra*, 78 Cal.App.4th at p. 564.) And the appellate court found those statements protected under the anti-SLAPP statute. (*Id*. at p. 567.) Further, the court summarized the alleged false statements falling into two categories: "(1) lobbying and other activities seeking to influence the decisions of regulatory and legislative bodies and (2) advertising, marketing, and public relations activities directed at the medical profession and the general public." (*Id*. at pp. 565-566.) However, there is no indication in *DuPont* that the plaintiffs were basing any of their claims against the defendant for filing a citizen petition.

Additionally, we are not persuaded that the commercial speech exception could apply to the citizen petition in any event. The citizen petition is classic protected activity under the anti-SLAPP statute. (See § 425.16, subd. (e)(2) ["any written or oral statement or writing made in connection with an issue under consideration or review by a legislative, executive, or

judicial body, or any other official proceeding authorized by law"].) And the right to petition has been called "an essential attribute of governing. . . . vital to a basic process in the state's constitutional scheme–direct initiation of change by the citizenry through initiative, referendum, and recall." (*Robins v. Pruneyard Shopping Center* (1979) 23 Cal.3d 899, 907-908, citations and fn. omitted, affd. sub nom., *PruneYard Shopping Ctr. v. Robins* (1980) 447 U.S. 74 [100 S.Ct. 2035, 64 L.Ed.2d 741]; accord, *United States v. Cruikshank* (1875) 92 U.S. 542, 552, [23 L.Ed. 588, 591] ["The very idea of a government, republican in form, implies a right on the part of its citizens to meet peaceably for consultation in respect to public affairs and to petition for a redress of grievances"].) Moreover, under the *Noerr-Pennington* doctrine, the statements made in the citizen petition are generally immune from civil liability. (See *California Motor Transport Co. v. Trucking Unlimited* (1972) 404 U.S. 508, 510-511, [92 S.Ct. 609, 30 L.Ed.2d 642] (*California Transport*); *Ludwig v. Superior Court* (1995) 37 Cal.App.4th 8, 21, fn. 17 (*Ludwig*) ["the principle applies to virtually any tort, including unfair competition and interference with contract"].)[6]

In short, the citizen petition is protected under the anti-SLAPP statute and the commercial speech exception does not apply. Therefore, to the extent any claim relies on the citizen petition, we must proceed with the second prong analysis of those claims.[7]

---

6 To the extent an exception applies to the *Noerr-Pennington* doctrine, we will consider it during our second prong analysis of the anti-SLAPP motion.

7 Here, we observe that two of Neurelis's causes of action are mixed, meaning that rely on both protected and unprotected conduct. The UCL claim is based on Aquestive's private threats, its investor statements, and the citizen petition. Similarly, the defamation claim is based on the investor statements and the citizen petition. As we discussed *ante*, only the citizen

C. Second Prong of the Anti-SLAPP Analysis

We turn to the second prong of the anti-SLAPP analysis to consider whether Neurelis has met its burden to establish a probability it would prevail on the merits. (*Baral*, *supra*, 1 Cal.5th at p. 384; § 425.16, subd. (b)(1).) "Only a cause of action that satisfies *both* prongs of the anti-SLAPP statute—i.e., that arises from protected speech or petitioning *and* lacks even minimal merit—is a SLAPP, subject to being stricken under the statute." (*Navellier v. Sletten* (2002) 29 Cal.4th 82, 88.)

In employing a summary-judgment-like procedure for the second prong, we determine whether Neurelis's prima facia showing is enough to win a favorable judgment. (*Sweetwater Union*, *supra*, 6 Cal.5th at p. 940.) This threshold is "not high." (*Greene v. Bank of America* (2013) 216 Cal.App.4th 454, 458.) Claims with minimal merit proceed. (*Sweetwater Union*, at p. 940.)

1. The Citizen Petition

Below, the superior court found that the statements in the citizen petition were protected under the litigation privilege, and Neurelis did not prove such statements were not privileged. (See Civ. Code, § 47, subd. (b).) Neurelis insists the superior court erred in reaching this conclusion because the court improperly placed the burden on Neurelis to establish the absence

---

petition is protected conduct under the anti-SLAPP statute. As such, Neurelis need only establish a probability of prevailing on its UCL and defamation claims based on the citizen petition. If it cannot do so, then the allegations concerning the citizen petition must be stricken. (See *Baral*, *supra*, 1 Cal.5th at p. 395.) However, we disregard the allegations concerning the unprotected conduct. (*Id*. at p. 396; *Sheley v. Harrop* (2017) 9 Cal.App.5th 1147, 1171.) As such, Neurelis does not have to prove a probability of success on the merits as to the UCL and defamation claims to the extent they are based on the private threats and/or investor statements.

of the privilege instead of requiring Aquestive to prove the privilege applies. Neurelis then argues that Aquestive "fell far short" of establishing the applicability of the litigation privilege to the citizen petition.

In response, Aquestive argues the only evidence it needed to provide to prove applicability of the litigation privilege was the citizen petition itself. To this end, Aquestive claims the petition was filed as part of an official proceeding pursuant to federal law. (Cf. *People ex. rel. Gallegos v. Pacific Lumber Co.* (2008) 158 Cal.App.4th 950, 958-959 (*Pacific Lumber*) ["allegedly fraudulent conduct in communicating information to government agencies . . . fall[s] squarely within the scope of the litigation privilege"].) In addition, Aquestive maintains, in any event, it was not its burden to prove the privilege but Neurelis's burden to disprove the privilege.

Neurelis has the better argument regarding who bears the burden in establishing the applicability of the litigation privilege. During the second prong of a court's anti-SLAPP analysis, a defendant bears the burden of proving a privilege's applicability. (*Hawran v. Hixson* (2012) 209 Cal.App.4th 256, 278; *Carver v. Bonds* (2005) 135 Cal.App.4th 328, 348-349.) Here, Aquestive insists it has done enough to prove the applicability of the privilege simply by pointing to the citizen petition. It has not.

Civil Code section 47, subdivision (b) renders absolutely privileged communications made as part of a "judicial or quasi-judicial proceeding." (*Silberg v. Anderson* (1990) 50 Cal.3d 205, 212 (*Silberg*); Civ. Code, § 47, subd. (b); *Action Apartment Assn., Inc. v. City of Santa Monica* (2007) 41 Cal.4th 1232, 1241 (*Action Apartment*).) "The usual formulation is that the privilege applies to any communication (1) made in judicial or quasi-judicial proceedings; (2) by litigants or other participants authorized by law; (3) to

achieve the objects of the litigation; and (4) that have some connection or logical relation to the action." (*Silberg*, at p. 212.)

" 'The principal purpose of [the litigation privilege] is to afford litigants and witnesses [citation] the utmost freedom of access to the courts without fear of being harassed subsequently by derivative tort actions. [Citations.]' " (*Action Apartment*, *supra*, 41 Cal.4th at p. 1241.) Stated differently, it "exists to protect citizens from the threat of litigation for communications to government agencies whose function it is to investigate and remedy wrongdoing. [Citation.]" (*Wise v. Thrifty Payless, Inc.* (2000) 83 Cal.App.4th 1296, 1303.)

Thus, the crux of the litigation privilege is that it covers communications made as part of a judicial or quasi-judicial proceeding. Here, Aquestive has not argued that the citizen petition is part of a judicial or quasi-judicial proceeding. Indeed, it does not describe the process whatsoever except to note that the citizen petition was "filed as part of an official proceeding pursuant to federal law." Further, Aquestive's reliance on *Pacific Lumber* is not helpful here. There, the appellate court concluded that communications made to government agencies during a California Environmental Quality Act (CEQA) administrative proceeding were covered by the litigation privilege. (*Pacific Lumber*, *supra*, 158 Cal.App.4th at pp. 958-959.) However, Aquestive has not explained why a CEQA proceeding is analogous to the citizen petition process with the FDA. And although some courts have defined "judicial or quasi-judicial" proceedings to include "all kinds of truth-seeking proceedings" (see *Silberg*, *supra*, 50 Cal.3d at p. 213), Aquestive makes no argument here why its statements in the citizen petition warrant protection under the litigation privilege codified in subdivision (b) of Civil Code section 47. Instead, it merely assumes it is privileged.

Consequently, Aquestive has not done enough to establish that the litigation privilege applies.[8]

Next, Aquestive maintains that even if the litigation privilege does not apply, Neurelis cannot overcome the *Noerr-Pennington* doctrine. "The *Noerr–Pennington* doctrine, which arose in the context of antitrust law, holds that '[t]hose who petition government for redress are generally immune from antitrust liability.' " (*Premier Medical Management Systems, Inc. v. California Ins. Guarantee Assn.* (2006) 136 Cal.App.4th 464, 478 (*Premier Medical*).) The doctrine has since been applied beyond the antitrust context and generally shields a defendant's petitioning activity before courts as well as administrative and other government agencies. (See *California Transport*, *supra*, 404 U.S. at pp. 510-511; *Ludwig*, *supra*, 37 Cal.App.4th at pp. 21-22).

However, "[a]n exception to the doctrine arises when efforts to influence government are merely a sham; such efforts are not protected by the *Noerr Pennington* doctrine . . . ." (*Hi-Top Steel Corp. v. Lehrer* (1994) 24 Cal.App.4th 570, 575.) There is a two part test for determining whether a defendant's petitioning activity falls outside the *Noerr-Pennington* doctrine. "[F]irst, it 'must be objectively baseless in the sense that no reasonable litigant could realistically expect success of the merits'; second, the litigant's subjective motivation must 'conceal an attempt to interfere *directly with the business relationships of a competitor . . . through the use [of] the governmental process*—as opposed to the *outcome* of that process—as an

---

8 We note the limited nature of our conclusion here. We are not determining, as a matter of law, that statements made in a citizen petition to the FDA are not covered by the litigation privilege. We merely find that Aquestive has not carried its burden of showing the application of the privilege on the record before us. One invoking the privilege must do more than simply point to the allegedly privileged document.

anticompetitive weapon.' " (*BE&K Construction Co. v. National Labor Relations Board* (2002) 536 U.S. 516, 526 [122 S.Ct. 2390, 153 L.Ed.2d 499] (*BE&K*), quoting *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.* (1993) 508 U.S. 49, 60-61 [113 S.Ct. 1920, 123 L.Ed.2d 611].) To meet this test, the defendant's petitioning activities thus "must be a sham both objectively and subjectively." (*BE&K*, at p. 526.)

Neurelis argues that Aquestive has not carried its burden of proving the applicability of the *Noerr-Pennington* doctrine. (See *Premier Medical*, *supra*, 136 Cal.App.4th at p. 478 [as part of the second prong of the anti-SLAPP analysis, "[d]efendants bear the burden of establishing a probability of prevailing on those defenses"].) However, the burden for Aquestive, here, is not high. Neurelis is basing two of its causes of action, in part, on statements Aquestive made in the citizen petition itself. The citizen petition is a procedure by which private entities can petition the FDA to take a specific action. (See *Apotex*, *supra*, 823 F.3d at p. 57; 21 C.F.R. § 10.30 (2021).) Therefore, Aquestive, through the citizen petition, was petitioning the government for redress and the *Noerr-Pennington* doctrine applies (see *California Transport*, *supra*, 404 U.S. at pp. 510-511) unless the petition was a sham (*BE&K*, *supra*, 536 U.S. at p. 526).

Having concluded that the *Noerr-Pennington* doctrine applies to the citizen petition, the burden shifts to Neurelis to prove the citizen petition was a sham. On the record before us, Neurelis has not carried its burden.

Neurelis argues Aquestive's submitted the citizen petition for the purpose of delaying approval of Valtoco, and, as such, Aquestive's " 'subjective motivation' " was to use the petition process " 'as an anticompetitive weapon.' " The FDA seemed to agree, to some extent, commenting that it "appear[ed] to be the case here" that the petition "was

submitted for the primary purpose of delaying approval of" a new drug application. Yet, we conclude that Neurelis has not shown that the petition was "objectively baseless." Neurelis contends the FDA noted that " 'publicly available information on the general characteristics of nasal spray product[ ]' showed that 'it [was] unlikely' " that Aquestive's complaints about Valtoco had any merit. Based on this statement from the FDA, Neurelis asserts the citizen petition was objectively baseless. But Neurelis overstates the importance of the quoted language. The FDA observed the existence of "publicly available information on the general characteristics of nasal spray products that would show it is unlikely that droplets generated by a nasal spray product would reach the alveoli of the lungs[.]" It also noted that Aquestive did not include any such information in its supplemental citizen petition. The FDA then indicated that the omission of this publicly available and pertinent data further suggested that the petition "was submitted with the primary purpose of delaying approval." However, the FDA did not conclude, as Neurelis claims, that the omitted publicly available data somehow proved that none of Aquestive's complaints in the petition had any merit. Indeed, the subject publicly available information about nasal spray products does not appear to be relevant to other issues raised in the citizen petition.[9]

---

9 For example, Aquestive requested that the FDA require Neurelis to conduct a bridging study comparing Valtoco and Diastat as well as a food effect study. In addition, Aquestive asked the FDA to determine "that Valtoco is not clinically superior to nor offers a major contribution to patient care when compared to Diastat." Neurelis neither discusses these requests of the citizen petition nor explains how the publicly available information about nasal sprays renders these requests objectively without merit.

Instead, the FDA determined that it could not summarily deny the citizen petition as requested by Neurelis because it was "unable to conclude that the petition does not, on its face, raise valid scientific or regulatory issues." (See 21 U.S.C. § 355(q)(1)(E).) Now, it may be that a petition does not have to be summarily denied to be "objectively unreasonable" under the sham exception to the *Noerr-Pennington* doctrine, but Neurelis makes no such argument. Additionally, Neurelis has not discussed the other requests in the citizen petition and explained why they support a determination that the petition was objectively unreasonable. And it is not the role of this court to scour the record and make Neurelis's arguments. (See *Keyes v. Bowen* (2010) 189 Cal.App.4th 647, 655-656; *Bains v. Moores* (2009) 172 Cal.App.4th 445, 455.)[10]

2. Malicious Prosecution

a. Background

Neurelis bases its malicious prosecution action on the three IPR petitions. To this end, in the operative complaint, Neurelis alleges that Aquestive had no reasonable belief that its three IPR petitions were based on reasonable grounds, "at least because Neurelis told Aquestive as much"; the Board denied instituting proceedings based on two of the petitions (Neurelis predicted the third IPR petition would terminate in its favor); Aquestive brought the petitions to pressure Neurelis into giving up orphan exclusivity for Valtoco; Aquestive initiated the petitions with malice; and Neurelis was

10 In denying the citizen petition, the FDA indicated that it had approved the new drug application for Valtoco.

harmed because it spent "considerable money and resources" as well as "lost executive time" responding to the petitions.

Because the malicious prosecution claim concerns the IPR petitions, we briefly discuss that petition process. Pursuant to the Leahy-Smith America Invents Act, the IPR proceeding replaces the PTO's previous inter partes reexamination. (35 U.S.C. §§ 311-319.) Congress, in enacting the IPR procedure, sought " 'to establish a more efficient and streamlined patent system that [would] improve patent quality and limit unnecessary and counterproductive litigation costs' " and " 'to create a timely, cost-effective alternative to litigation.' " (*Milwaukee Electric Tool Corp. v. Snap-On Inc.* (E.D.Wis. 2017) 271 F.Supp.3d 990, 1027.) "The purpose of this reform was to 'convert[ ] inter partes reexamination from an examinational to an adjudicative proceeding.' " (*Abbott Labs. v. Cordis Corp.* (Fed. Cir. 2013) 710 F.3d 1318, 1326.) Under the new procedure, any party other than the patent owner may request to cancel one or more claims of a patent; in doing so, the petitioner is limited to grounds that could be raised under 35 United States Code sections 102 and/or 103 and only based on prior art consisting of patents and printed publications. (35 U.S.C. § 311(a)-(b).)

Under the IPR process, a party that wants to challenge a patent must file "a petition to institute an inter partes review of [a] patent." (35 U.S.C. § 311(a).) The petition must identify "each claim challenged," the grounds for the challenge, and the evidence supporting the challenge. (35 U.S.C. § 312(a)(3).) Within three months of the filing of the petition, the patent owner may file a preliminary response setting forth arguments as to why the Board should not institute a review; alternatively the patent owner may waive the preliminary response to expedite the proceeding. (35 U.S.C. § 313; 37 C.F.R. § 42.107(a)-(b) (2021).) For the Board to institute an IPR

proceeding, the petitioner must show "that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition," a higher burden than in the predecessor reexamination proceedings where the requester was only required to show a "substantial new question of patentability." (35 U.S.C. §§ 304, 314(a).) However, if it finds no reasonable likelihood of success then it must deny the petition and notify the petitioner and patent owner in writing. (35 U.S.C. § 314(a), (c).) That determination is "final and nonappealable." (35 U.S.C. § 314(d).) The Board must decide whether to institute the IPR within three months after the patent owner's preliminary response or by the last date on which the response could have been filed if the patent owner did not file a response. (35 U.S.C. § 314(b).)

If the Board institutes the review, the proceeding is conducted before three technically-trained administrative patent judges. (See 35 U.S.C. §§ 6(a)-(c), 311.) The Board must issue its final IPR determination within one year, extendable for good cause for not more than six months. (35 U.S.C. § 316(a)(11).) Final determinations are appealable to the Federal Circuit. (35 U.S.C. §§ 141(c), 319.) To streamline later litigation and reduce the likelihood of inconsistent judgments, the petitioner is estopped from later asserting that a "claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review." (35 U.S.C. § 315(e)(2).)

Here, Aquestive filed three IPR petitions but all three challenged claims under the '876 Patent. And the three petitions were filed on the same day. In case No. IPR2019-00449, the petition ('449 Petition) challenged a subset of claims of the '876 Patent on anticipation and obviousness grounds based on specific prior art. The petition filed in case No. IPR2019-00450 ('450

Petition) challenged all of the claims of the '876 Patent and did so only on obviousness grounds based on different combinations of prior art. And the petition filed in case No. IPR2019-00451 ('451 Petition) challenged all the claims of the '876 Patent on obviousness grounds as well but based on a different combination of prior art.

In the instant matter, each of Aquestive's IPR petitions was over 90 pages long and included more than 200 pages of expert declarations and dozens of exhibits. Neurelis submitted substantive responses that were each more than 25 pages and were also accompanied by multiple exhibits.

On August 1, 2019, the Board declined to institute review in the '449 and '450 Petitions. With respect to the '449 Petition, a three-judge panel issued a unanimous 26-page decision, in which it found no "reasonable likelihood that [Aquestive] would prevail" on even one of the claims. With respect to the '450 Petition, the same three-judge panel issued a unanimous 22-page decision declining to institute review. There, the Board relied primarily on 35 United States Code section 325(d) and concluded that the same prior art arguments raised by Aquestive had already been considered (and rejected) by the PTO during prosecution of the '876 Patent. As the Board explained, "[i]t is simply not an efficient use of the Board's time and resources to revisit the same prior art disclosures that were examined in detail by the Examiner over eight years of patent prosecution."

On August 13, 2019, the Board instituted review of the '451 Petition. When the trial court decided the anti-SLAPP motion at issue here, the review on the '451 Petition was still pending. However, on August 6, 2020, the Board declared the '876 Patent invalid. (*Aquestive Therapeutics, Inc. v. Neurelis, Inc.* (Board, Aug. 6, 2020, Dec. No. IPR2019-00451) p. 68.) Neurelis appealed that decision to the Federal Circuit, and the Federal Circuit

affirmed the decision. (*Neurelis, Inc. v. Aquestive Therapeutics, Inc.* (Fed. Cir., No. 21-1038) [2021 U.S. App. LEXIS 30158]) (per curiam).)

b. Analysis

An action for malicious prosecution has three required elements: "(1) the defendant brought (or continued to pursue) a claim in the underlying action without objective probable cause, (2) the claim was pursued by the defendant with subjective malice, and (3) the underlying action was ultimately resolved in the plaintiff's favor." (*Lane v. Bell* (2018) 20 Cal.App.5th 61, 67.) The superior court determined that Neurelis established a probability of success as to each of these three elements and denied the anti-SLAPP motion as to the malicious prosecution claim. Aquestive claims the court erred in reaching this conclusion because: (1) the denial of an IPR petition cannot serve as a malicious prosecution predicate (i.e., it does not constitute an underlying action); (2) the IPR petitions did not terminate in Neurelis's favor; and (3) Neurelis did not submit sufficient evidence that Aquestive filed the IPR petitions without probable cause.

Although the parties spend the lion's share of their respective briefs disputing whether a denial of an IPR petition could serve as a predicate act for a malicious prosecution claim, we need not weigh in on that issue because Neurelis has not offered evidence that Aquestive brought the petitions without probable cause. "An action is deemed to have been pursued without probable cause if it was not legally tenable when viewed in an objective manner as of the time the action was initiated or while it was being prosecuted." (*Sycamore Ridge Apartments, LLC v. Naumann* (2007) 157 Cal.App.4th 1385, 1402.) "A prior action was not initiated without probable cause merely because it was ultimately found to lack merit; it was initiated without probable cause only if '*all* reasonable lawyers' would 'agree' that the

suit, at the time of filing, was 'totally and completely without merit' [based on] . . . . 'the facts known to the defendant' 'at the time the suit was filed.' " (*Gruber v. Gruber* (2020) 48 Cal.App.5th 529, 537-538, quoting *Jarrow Formulas, supra*, 31 Cal.4th at p. 743, fn. 13, and *Sheldon Appel Co. v. Albert & Oliker* (1989) 47 Cal.3d 863, 878; see *Soukup v. Law Offices of Herbert Hafif* (2006) 39 Cal.4th 260, 292 [" 'A litigant will lack probable cause for his action either if he relies upon facts which he has no reasonable cause to believe to be true, or if he seeks recovery upon a legal theory which is untenable under the facts known to him' "].) "Probable cause is a low threshold designed to protect a litigant's right to assert arguable legal claims even if the claims are extremely unlikely to succeed." (*Plumley v. Mockett* (2008) 164 Cal.App.4th 1031, 1047.)

Below, the superior court found: "Based on the PTO decisions, [Aquestive] failed to demonstrate a reasonable likelihood of prevailing on those petitions, supporting the element that the petitions were meritless and without probable cause." In making this finding, Aquestive maintains the court improperly conflated the first two elements of a malicious prosecution claim. It further argues that a favorable termination of an underlying claim does not establish a lack of probable cause. (See, e.g., *Crowley v. Katleman* (1994) 8 Cal.4th 666, 686 [noting "[p]rior opinions have stressed that the two elements of the tort serve different purposes"]; *Nicholson v. Lucas* (1994) 21 Cal.App.4th 1657, 1665 ["Mere proof of favorable termination does not create a conflict on the issue of probable cause, nor does proof of the existence of malice"].)

Neurelis counters that the court made no such mistake. To this end, Neurelis insists "[t]he court held that Aquestive's petitions were not just 'meritless,' but also that they were brought 'without probable cause.' " Yet, in

making this argument, Neurelis glosses over the fact that the court found a lack of probable cause based on the denial of the petitions only. The court's order points to no other "evidence" establishing a lack of probable cause. And Neurelis does not cite to any evidence in the record purporting to establish a lack of probable cause. Rather, Neurelis's claim that it has shown a lack of probable cause begins and ends with the two written decisions of the Board denying the '449 and '450 Petitions without granting a review.

Regarding the '449 Petition, Neurelis argues that the Board denied the petition because Aquestive did "not show that there is a reasonable likelihood that [it] would prevail with respect to at least one of the claims." Neurelis, however, does not explain why this denial showed that Aquestive lacked probable cause to bring the '449 Petition. It simply asks us to assume it is so. Aquestive points out that "no reasonable likelihood of prevailing" is a higher standard than "probable cause." As such, it argues that the Board's finding that Aquestive had not shown a reasonable likelihood of prevailing on the petition is not the same as establishing Aquestive did not have probable cause to bring the petition. Neurelis claims such a distinction does not matter here because Aquestive did not have probable cause to bring the '450 Petition. Neurelis further argues it is sufficient to satisfy its burden here to show that Aquestive did not have probable cause to bring the '450 Petition only. (See *Cuevas-Martinez v. Sun Salt Sand, Inc.* (2019) 35 Cal.App.5th 1109, 1121 ["a prima facie case" that the defendants "lacked probable cause for at least two of the claims in the prior action is more than sufficient to carry his anti-SLAPP burden"].) We read Neurelis's argument as a tacit admission that we should focus on the Board's decision on the '450 Petition as

evidence of a lack of probable cause.[11] Nonetheless, Neurelis directs us to a couple of comments in the Board's denial of the '449 Petition, claiming that such comments suggest a lack of probable cause.

For example, Neurelis notes that the Board stated that Aquestive had relied on "bald assertions" with insufficient record support and ignored key statements made in both the European Patent Office (for "nearly identical claims") and the PTO. However, these comments are not as significant as Neurelis represents. True, the Board did refer to "bald assertions" made by Aquestive and its expert witness, but those assertions specifically related to a single argument "that the '876 [P]atent 'does not disclose any unexpected effect' for the claimed ethanol and benzyl alcohol ranges." Specifically, it found those assertions "to be insufficiently supported by the evidence of record." Nevertheless, Neurelis does not discuss the other challenges asserted in the '449 Petition and how the Board's rejection of those other challenges showed a lack of probable cause. Such an omission is fatal to Neurelis's argument that Aquestive lacked probable cause to bring the '449 Petition. It is not enough for Neurelis to direct us to a couple sentences in a 26-page decision that reject one of the arguments made by Aquestive and

---

11 We note that Neurelis's malicious prosecution claim has evolved during its opposition to the anti-SLAPP motion. The operative complaint bases the malicious prosecution cause of action on all three IPR petitions. Yet, the '451 Petition resulted in the Board invalidating the '876 Patent. Therefore, Neurelis essentially tells us to ignore that petition. However, Neurelis all but concedes that it has no evidence that Aquestive lacked probable cause to bring the '449 Petition. These meaningful shortcomings undermine the theory that Neurelis's advances as to the IPR petitions, that they were brought only to extort Neurelis to give up orphan drug exclusivity as to Valtoco. Clearly, the Board did not share Neurelis's conclusion about the validity of the petitions.

extrapolate from those sentences that Aquestive lacked probable cause to bring the petition.

Turning to the '450 Petition, Neurelis maintains the Board denied that petition because the same prior art arguments raised by Aquestive had already been considered (and rejected) by the PTO during prosecution of the '876 Patent. Neurelis also emphasizes that the Board explained it was a waste "of the Board's time and resources to revisit the same prior art disclosures that were examined in detail by the Examiner over eight years of patent prosecution." Neurelis therefore insists the Board's reasoning in denying the '450 Petition is evidence that Aquestive lacked probable cause to bring the '450 Petition. We disagree.

The Board issued a 22-page decision denying the '450 Petition and not granting a review. In that decision, the Board explained that the institution of inter partes review was discretionary. (See *Harmonic Inc. v. Avid Tech, Inc.* (Fed. Cir. 2016) 815 F.3d 1356, 1367.) Further, the Board noted that, under 35 United States Code section 325(d), it could take into account and reject a petition because " 'the same or substantially the same prior art or arguments previously were presented to the Office."[12] The Board set forth

---

12 35 United States Code section 325(d) states: "Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of any post-grant review under this chapter, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the post-grant review or other proceeding or matter may proceed, including providing for the stay, transfer, consolidation, or termination of any such matter or proceeding. In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office."

"several non-exhaustive factors" it considered in evaluating whether to exercise its discretion under 35 United States Code section 325(d), which included:

> "(a) the similarities and material differences between the asserted art and the prior art involved during examination;
>
> "(b) the cumulative nature of the asserted art and the prior art evaluated during examination;
>
> "(c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis of the rejection;
>
> "(d) the extent of the overlap between the arguments made during the examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
>
> "(e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
>
> "(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments."

In applying these factors to the petition, the Board reviewed the prosecution history of the '876 patent family. After doing so, it found that factors (a), (c), and (d) "strongly favor[ed] exercising [its] discretion to deny the Petition under 35 U.S.C. § 325(d)." In addition, it found that factors (e) and (f) were, "at best, neutral with respect to exercising discretion under [section] 325(d)." Also, although the Board acknowledged that Aquestive offered "additional evidence in the form of the declaration testimony" of its expert witness that was not previously considered in examining the '876 Patent, the court concluded the "presence of [the] declaration" was not

"sufficient to warrant reconsideration of the same prior art that was before the Examiner during prosecution." Moreover, the Board similarly was not persuaded that a review should be granted because Aquestive and its expert witness "formulate[d] new hypothetical compounds." Simply put, the Board was not swayed that it should consider the same or similar arguments that were previously addressed in the prosecution of the '876 Patent.

We see nothing in the Board's decision denying the '450 Petition that even suggests Aquestive lacked probable cause to bring the petition. Ultimately, the Board used its discretion to deny the petition because "the same or substantially the same prior art or arguments previously were presented to the [PTO]." (35 U.S.C. § 325(d).) However, we note that 35 United States Code section 325(d) provides the Board with the *discretion* to deny the petition but does not require Board to deny the petition even if the petition is simply repeating previously made arguments. And, under the statute, the Board could appropriately exercise its discretion to grant a petition even though it raises claims based on the same prior art or arguments previously made to the PTO. Therefore, it is mere speculation to baldly conclude that a denial of a petition per the Board's discretion under 35 United States Code section 325(d) establishes a lack of probable cause to satisfy the corresponding element of a cause of action for malicious prosecution. (Cf. *Shandralina G. v. Homonchuk* (2007) 147 Cal.App.4th 395, 411 [an inference can serve as substantial evidence for a factual finding on appeal, but " ' "the inference must be a reasonable conclusion from the evidence and cannot be based on suspicion, imagination, speculation, surmise, conjecture, or guesswork" ' "]; *Gilbert v. Sykes* (2007) 147 Cal.App.4th 13, 26-27 [In the SLAPP context, we disregard evidence that is "argumentative, speculative, impermissible opinion, hearsay, or conclusory"].)

What is missing here is any evidence or explanation that the petition was so completely lacking in merit that no reasonable attorney would have thought it tenable. (See *Wilson v. Parker, Covert & Chidester* (2002) 28 Cal.4th 811, 817 ["Only those actions that ' "any reasonable attorney would agree [are] totally and completely without merit" ' may form the basis for a malicious prosecution suit"].)

In the instant matter, apart from selective quotations from the Board's decision on the petitions, Neurelis offers no evidence that Aquestive filed any of the IPR petitions without probable cause. Instead, Neurelis simply argues the petitions were meritless and, thus, "factually and legally untenable." As we addressed *ante*, Neurelis has not provided any evidence to support these assertions. Consequently, the malicious prosecution action cannot survive the anti-SLAPP motion.

DISPOSITION

The order is affirmed in part and reversed in part. This matter is remanded to the superior court with instructions to enter a revised order consistent with this opinion, denying the anti-SLAPP motion as to the UCL and defamation causes of action to the extent such claims are dependent on unprotected conduct, including statements to investors. The anti-SLAPP motion is to be granted as to the malicious prosecution claim. All allegations

concerning the citizen petition should be stricken as well. The parties are to bear their own costs on appeal.

HUFFMAN, J.

WE CONCUR:

McCONNELL, P. J.

O'ROURKE, J.