

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AERIN MEDICAL INC. and
THE FOUNDRY, LLC,

Plaintiffs,

v.

NEURENT MEDICAL INC. and
NEURENT MEDICAL LTD.,

Defendants.

C.A. No. 23-756 (JLH)

DEMAND FOR JURY TRIAL



**OPENING BRIEF IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS DEFENDANTS'
FIRST AMENDED COUNTERCLAIMS OF PATENT INFRINGEMENT, TORTIOUS
INTERFERENCE, AND UNFAIR COMPETITION**

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I. Introduction

Neurent's counterclaim alleging that use of Aerin's RhinAer[®] infringes the '262 patent, which Aerin does not concede, cannot stand even if accepted as true because the RhinAer[®] was on sale before the '262 patent's priority date. Neurent does not dispute that the RhinAer[®] was on sale or that it is not different than the RhinAer[®] accused of infringement. Neurent's only argument against the on-sale bar is that the benefit of using the RhinAer[®] to improve sleep as recited in the preamble of claim 1 of the '262 patent was only publicized after the '262 patent's priority date. But that is legally irrelevant to the on-sale bar—the question is whether the device on-sale embodies the claimed invention, not whether benefits were publicized. As a result, Neurent's infringement allegations are self-defeating—that which infringes if later, anticipates if earlier—and should be dismissed.

Neurent acknowledges that it has no evidence to support its counterclaims of tortious interference and unfair competition, so it pled them on information and belief, which was improper. These counterclaims should be dismissed because they fail to state a claim and fail to provide notice to each Plaintiff. They are also barred by preemption and *Noerr-Pennington*.

II. Nature and Stage of the Proceedings

Aerin and The Foundry filed a Complaint and an Amended Complaint against Neurent Medical Inc. and Neurent Medical Ltd. (collectively Neurent) for infringement of eight patents. D.I. 1; D.I. 17. Neurent moved for partial dismissal, D.I. 19; D.I. 20, which was denied, D.I. 74. Neurent filed an answer and counterclaims of tortious interference and unfair competition. D.I. 40, ¶¶ 42-63. Plaintiffs filed an answer, D.I. 60, and a motion to dismiss those counterclaims, D.I. 58; D.I. 59. That motion was denied as moot, D.I. 82, because Neurent filed amended counterclaims, adding a counterclaim against Aerin for infringement of the '262 patent, D.I. 81, ¶¶ 115-122. Plaintiffs move to dismiss Neurent's tortious interference and unfair competition counterclaims,

and Aerin moves to dismiss Neurent's infringement counterclaim under Fed. R. Civ. P. 12(b)(6). Plaintiffs are also filing an answer to the amended counterclaims.

III. Summary of the Argument

Neurent contends that use of the RhinAer[®] infringes the '262 patent. D.I. 81, ¶ 47. But the RhinAer[®] is prior art to the '262 patent. The RhinAer[®] has been on sale, sold, and otherwise available to the public since before April 9, 2020, the earliest priority date of the '262 patent. Because that which infringes if later, anticipates if earlier, then the '262 patent is invalid if Neurent's allegations that the RhinAer[®] infringes are accepted as true.

There are no factual issues regarding whether the RhinAer[®] was on sale before the priority date or regarding its structure and operation. Indeed, Neurent does not dispute that the RhinAer[®] was on sale before the '262 patent's priority date and does not allege that the use or structure of the RhinAer[®] on sale then was any different than the RhinAer[®] accused of infringement. Neurent only argues that the benefit of using the RhinAer[®] to improve sleep was not publicly announced until after the priority date of the '262 patent. But Neurent's position is legally wrong and does not defeat invalidity—the on-sale bar does not require that the benefits of the invalidating product be publicly disclosed. Neurent's infringement counterclaim is fatally flawed and should be dismissed.

Neurent's counterclaims of tortious interference and unfair competition acknowledge that the conclusory allegations pled on "information and belief" are not based on evidence but merely Neurent's baseless speculation. D.I. 81, 7 n.11. The counterclaims should be dismissed because they do not plausibly allege that Neurent had a valid business relationship or expectancy, that Plaintiffs intentionally or wrongfully interfered, or that Plaintiffs' alleged interference caused termination of Neurent's relationship or legitimate expectancy. These counterclaims should also be dismissed because they refer generally to "Plaintiffs" and fail to provide Aerin and The Foundry with adequate notice and because they are barred by preemption and *Noerr-Pennington*.

IV. Concise Statement of the Facts

A. Patent Infringement Counterclaim

The '262 patent was filed on January 12, 2024, and claims priority to a provisional application filed on April 9, 2020, which is thus its earliest possible priority date. D.I. 81-1, Ex. A.

Neurent asserts that use of Aerin's RhinAer[®] infringes the '262 patent. D.I. 81, ¶ 47. Aerin announced the U.S. launch of the RhinAer[®] on March 5, 2020. Ex. 1 (<https://aerinmedical.com/company-news/fda-clearance-nonsurgical-procedure-chronic-rhinitis/>).¹ Then, the RhinAer[®] included the RhinAer[®] Console (Model FG226)—the same Console accused of infringement. *See* D.I. 81, ¶ 49 (accusing RhinAer[®] Console (Model FG226)). *Compare* Ex. 4 (Instructions for Use for RhinAer[®] Console (Model FG226), 2019),² with D.I. 81-1, Ex. D (Instructions for Use for RhinAer[®] Console (Model FG226), 2022). The RhinAer[®] also included the RhinAer[®] Stylus (Model FG815), sometimes referred to as the RHIN1 Stylus.³ Aerin will refer to the RhinAer[®] Stylus (Model FG815) as the “First Generation RhinAer[®] Stylus.”

The RhinAer[®] Console was sold at least by October 18, 2019, and the First Generation RhinAer[®] Stylus was sold at least by February 11, 2020. Ex. 6 (Aerin Invoice #INV4978); Ex. 7 (Aerin Invoice #INV6151); Ex. 8 (Aerin Invoice #INV6146).⁴ Aerin provided Instructions for Use

¹ The Court may consider the press releases in Exhibits 1-3 in resolving this motion at least because they are in the record as exhibits to Aerin's answer to Neurent's amended counterclaims. *Thibault v. Del. Tech. & Cmty. Coll.*, No. CA 11-1080-MPT, 2012 WL 2073847, at *2 (D. Del. June 8, 2012) (“[The] court is not limited to the four corners of the complaint and may consider ‘matters incorporated by reference integral to the claim, items subject to judicial notice, matters of public record, orders [and] items appearing in the record of the case.’”).

² The Court may consider Exhibits 4 and 5, which are similar to the Instructions for Use that Neurent included with its amended counterclaims, D.I. 81-1, Exs. C-D, at least because they are in the record as exhibits to Aerin's answer to Neurent's amended counterclaims. *See supra* note 1.

³ Neurent is well familiar with RhinAer[®] Stylus (Model FG815) since Neurent relied on it as the predicate device for Neurent's NEUROMARK[®] System. D.I. 17-1, Ex. H at 4.

⁴ The Court may consider the invoices attached as Exhibits 6-8 at least because they appear in the record as exhibits to Aerin's answer to Neurent's amended counterclaims. *See supra* note 1.

with sales of the RhinAer[®] Console and First Generation RhinAer[®] Stylus.

In September 2022, Aerin launched an updated RhinAer[®] Stylus (Model FG1393). Ex. 2 (<https://aerinmedical.com/company/news-and-media/aerin-medical-receives-fda-clearance-of-next-generation-rhinaer-stylus-for-treatment-of-patients-with-chronic-rhinitis/>). Aerin will refer to the RhinAer[®] Stylus (Model FG1393) as the “Next Generation RhinAer[®] Stylus.”

The First Generation RhinAer[®] Stylus, which was on sale, sold, and publicly available before the '262 patent's priority date, is the same as the Next Generation RhinAer[®] Stylus that Neurent accuses of infringement in all respects relevant to Neurent's allegations. *Compare* Ex. 5 (Instructions for Use for First Generation RhinAer[®] Stylus), *with* D.I. 81-1, Ex. C (Instructions for Use for Next Generation RhinAer[®] Stylus). And the method of using the RhinAer[®] as alleged to infringe the '262 patent is the same. *See* D.I. 91, Ex. 13.⁵

Aerin's publicly available 510(k) for the Next Generation RhinAer[®] Stylus shows that the changes to the Stylus were minor and that the Next Generation RhinAer[®] Stylus was “functionally unchanged from the predicate” First Generation RhinAer[®] Stylus. *See* Ex. 9 (U.S. Food & Drug Admin., 510(k) K221907 (July 29, 2022), *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf22/K221907.pdf) at 4.⁶ The 510(k) confirms that the changes between

⁵ The Court may consider this chart, which is responsive to the chart Neurent attached to its amended counterclaims, D.I. 81-1, Ex. B, at least because it appears in the record as an exhibit to Aerin's answer to Neurent's amended counterclaims, D.I. 91, Ex. 13. *See supra* note 1.

⁶ The Court may consider this FDA document at least because it is subject to judicial notice and because it appears in the record as an exhibit to Aerin's answer to Neurent's amended counterclaims. *See supra* note 1; *Stanifer v. Corin USA Ltd.*, No. 6:14-CV-1192-ORL, 2014 WL 5823319, at *4 (M.D. Fla. Nov. 10, 2014) (taking judicial notice of documents publicly available on the FDA website on a 12(b)(6) motion); *Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 257 (E.D. Pa. 2020) (“Courts will . . . take judicial notice of certain matters of public record on a motion to dismiss; examples . . . include . . . ‘[FDA] reports published on the FDA website.’”).

styluses does not change the method of using the RhinAer[®] as alleged to infringe. *See id.* As shown here, the differences between the First Generation RhinAer[®] Stylus (top) and the Next Generation RhinAer[®] Stylus (bottom) were minor.

Ex. 3 (<https://www.businesswire.com/news/home/20220908005203/en/Aerin-Medical-Receives-FDA-Clearance-of-Next-Generation-RhinAer%C2%AE-Stylus-for-Treatment-of-Patients-with-Chronic-Rhinitis>).



Neurent wrote to Aerin alleging that “methods of use” of the “RhinAer System that includes RhinAer Stylus Model FG1393” infringe the ’262 patent. D.I. 81, ¶ 44; Ex. 10 (June 4, 2024, Letter from G. Lantier).⁷ Aerin responded, informing Neurent that Aerin’s RhinAer[®] is prior art to the ’262 patent and that, under Neurent’s theory that the RhinAer[®] infringes, the ’262 patent would be invalid as anticipated by the RhinAer[®] because it was on sale, sold, and otherwise available to the public before its priority date. Ex. 11 (June 14, 2024, Letter from K. Daley).⁸ In response, Neurent did not dispute that the RhinAer[®] was on sale, sold, or otherwise available to the public before the ’262 patent’s priority date or that the minor differences between the First Generation RhinAer[®] Stylus and the Next Generation RhinAer[®] Stylus are not relevant to Neurent’s infringement allegations. Ex. 12 (June 25, 2024, Letter from G. Lantier). Neurent did not identify any differences in methods of use or structure as between the RhinAer[®] on sale before the ’262 patent and the RhinAer[®] accused of infringement. *Id.*

⁷ The Court may consider this pre-suit letter because Neurent incorporated it by reference and made it integral by referring to it in its counterclaims, D.I. 81, at 2, ¶ 44. *See supra* note 1.

⁸ The Court may also consider the pre-suit letters at Exhibits 11 and 12 because they are related and responsive to Exhibit 10, which was incorporated by reference and is integral to Neurent’s counterclaims, D.I. 81, at 2, ¶ 44, and because they appear in the record as an exhibit to Aerin’s answer to Neurent’s amended counterclaims. *See Thibault*, 2012 WL 2073847, at *2; *Bench Walk Lighting LLC v. LG Innotek Co.*, 530 F. Supp. 3d 468, 477 (D. Del. 2021) (considering pre-suit notice letter that defendants attached to motion to dismiss).

Instead, Neurent argued that there was no “publication or statement prior to the ’262 patent’s priority date that disclosed that the RhinAer® RHIN1 Stylus was used in a method for ‘improving a patient’s sleep.’” *See id.* At the same time, Neurent conceded that there *are* publications and statements “disclosing that the RhinAer® RHIN1 Stylus improves sleep” but discounted those because they were dated after the priority date of the ’262 patent. *See id.*; *see also* D.I. 81-1, Exs. E-F. Essentially, Neurent contended that, “as of the ’262 patent’s priority date, the RhinAer® RHIN1 Stylus did not disclose” improving sleep and that such a *disclosure* was required for invalidity. *See* Ex. 12. Neurent then filed a counterclaim for infringement of the ’262 patent despite knowing that the RhinAer® was on sale before the earliest priority date.

B. Tortious Interference and Unfair Competition Counterclaims

Neurent’s tortious interference and unfair competition counterclaims are based on alleged interference with Neurent’s purported investment opportunity with [REDACTED] and with Neurent’s purported potential customer [REDACTED]. The counterclaims allege that Neurent signed a term sheet with [REDACTED] on [REDACTED]. D.I. 81, ¶ 10. The counterclaims do not allege the details of that term sheet other than to say that it allegedly “outlined the terms of [REDACTED] *potential* investment in Neurent, including the material terms and price terms for a substantial, multi-million euro investment” and “provided that Neurent’s board of directors would thereafter add a specified individual from [REDACTED].” *Id.*, ¶¶ 10-11 (emphasis added).

The counterclaims also allege that, in “October 2023, Neurent began negotiating the sale of Neuromark systems for use by [REDACTED] physicians in Texas, Louisiana, and Florida.” *Id.*, ¶ 16. They further allege that physicians evaluated the Neuromark and asked to learn more about it and that [REDACTED] procurement director “was happy with the pricing and contracting proposed by Neurent to [REDACTED].” *Id.*, ¶¶ 16, 58. No contract or term sheet with [REDACTED] was alleged.

With respect to Plaintiffs’ conduct and the basis for the tortious interference and unfair

competition claims, the counterclaims include a footnote, acknowledging that the assertions are pled on “information and belief” because Neurent does not have evidence to support them:

The following paragraphs regarding Plaintiffs’ unlawful conduct are pled on information and belief, including because they relate to conversations between Plaintiffs and others (██████████), which Plaintiffs have not yet provided to Neurent. Neurent expects that it will identify further details regarding the communications between Plaintiffs and ██████████ through discovery.

Id. at 7 n.11 (referencing “Plaintiffs Interference with Neurent’s Business Opportunities”).

The counterclaims provide few factual allegations. Regarding ██████████, they merely allege that Plaintiffs contacted ██████████ “[w]ithin hours of filing their complaint.” *Id.*, ¶ 21. And they ascribe a motive to that alleged contact—“to persuade [██████████] not to invest in Neurent”—but provide no factual allegations supporting that characterization. *Id.* The counterclaims only plead that a ██████████ representative stated in an email, “[w]ell, sorry to be the bearer of bad news but it seems Aerin filed a lawsuit against Neurent yesterday.” *Id.*, ¶ 23. They do not allege that the ██████████ representative reported that they had heard about it from Plaintiffs, and Neurent did not include the alleged email communication. The counterclaims aver that Plaintiffs communicated “misleading statements about Neurent and this lawsuit” to ██████████ but provide no support. *Id.*, ¶ 21. The counterclaims do not describe the alleged misleading statements or acknowledge that the lawsuit immediately became public and would be material in any discussions with potential investors.

Regarding ██████████, the allegations in the counterclaims are all speculation. The only thing approaching a factual allegation is the assertion that “Plaintiffs misled ██████████ into believing that, as a result of this case, Neurent would not be able to supply products or to continue conducting business and/or that purchasing products from Neurent would harm ██████████ business.” *Id.*, ¶ 31. The counterclaims do not include any factual allegation that ██████████ stated that Plaintiffs had

communicated with [REDACTED] regarding this assertion.

V. Legal Standard

Dismissal is proper under Rule 12(b)(6) if a complaint fails to state a claim on which relief can be granted. To survive a motion to dismiss, a complaint must plead “enough factual matter” that, when taken as true, “state[s] a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556, 570 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Under *Twombly-Iqbal*, a court “must accept all of the complaint’s well-pleaded facts as true, but may disregard any legal conclusions.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). The “[f]actual allegations must . . . raise a right to relief above the speculative level.” *Twombly*, 550 U.S. at 545.

VI. Argument

A. Neurent’s Counterclaim of Patent Infringement Should Be Dismissed

Taking Neurent’s allegations that use of the RhinAer[®] infringes the ’262 patent as true defeats its claim because the RhinAer[®] has been on sale, sold, and otherwise available to the public since before the ’262 patent’s priority date, and that which infringes if later, anticipates if earlier. Neurent does not dispute that the RhinAer[®] was on sale before the priority date and that it is the same as the RhinAer[®] accused of infringement but instead makes a legally erroneous argument against the on-sale bar. Neurent’s counterclaim should be dismissed.

1. Neurent’s Only Argument Against Invalidity Is Legally Wrong

As Neurent’s own pre-suit notice letter shows, Neurent does not dispute that the RhinAer[®] with the First Generation Stylus was on sale before the priority date of the ’262 patent and does not dispute that there are no structural or operational differences relevant to Neurent’s infringement allegations between it and the RhinAer[®] with the Next Generation Stylus. Ex. 12. The only

argument Neurent made regarding invalidity based on the RhinAer[®] with the First Generation Stylus is that it had not identified “*any* publication or statement prior to the ’262 patent’s priority date that disclosed that the RhinAer[®] RHIN1 Stylus was used in a method for ‘improving a patient’s sleep,’” even though it conceded that publications and statements after the priority date show that the RhinAer[®] with the First Generation Stylus improves sleep. *See id.* at 3. Neurent argued the ’262 patent could not be invalid because, “as of the ’262 patent’s priority date, the RhinAer[®] RHIN1 Stylus did not disclose the recited features.” *Id.* But when, or even if, this benefit of the RhinAer[®] became public is legally irrelevant to the on-sale bar.

For the on-sale bar, which is ultimately a question of law, the Federal Circuit has made clear that, “the question is not whether the sale . . . ‘discloses’ the invention at the time of the sale, but whether the sale relates to a device that *embodies* the invention.” *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1583 (Fed. Cir. 1986); *see also Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017) (“[A]fter the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale”), *aff’d*, 586 U.S. 123, 139 (2019).⁹ And it is well established that a prior-art device can anticipate a method. *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (“[T]he law is, and long has been, that ‘if a previously patented device, in its normal and usual operation, will perform the function which an appellant claims in a subsequent application for process patent, then such application for process patent will be considered to have been anticipated by the former patented device.’” (citation omitted)); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 424 F.3d 1276, 1285 (Fed. Cir. 2005) (ruling that precritical sale of biological material created an on-sale bar to method of use claims for that

⁹ It is not required that “a sales offer specifically identify all the characteristics of an invention offered for sale” or that the parties “recognize the significance of all of these characteristics at the time of the offer.” *Abbott Lab’ys v. Geneva Pharms.*, 182 F.3d 1315, 1319 (Fed. Cir. 1999).

material). So, the question here is not whether anything about use of the RhinAer[®] with the First Generation RhinAer[®] Stylus for improving sleep was published at the time of sale or before the priority date of the '262 patent. Instead, the question is whether the device on sale improved sleep.¹⁰ Here, Neurent concedes it did and attached proof of that to its counterclaims. *See* Ex. 12 at 3; D.I. 81-1, Exs. E-F. As a result, Neurent's only argument against invalidity is legally wrong.

2. Neurent's Infringement Allegations, Taken as True, Render the '262 Patent Invalid and Defeat Its Infringement Claim

Assuming for the purposes of this motion that use of the RhinAer[®], including the RhinAer[®] Stylus and Console, infringes the '262 patent, as Neurent alleges, the '262 patent is invalid under 35 U.S.C. § 102(a)(1), which precludes obtaining a patent if “the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.” The on-sale bar applies when, before the priority date: (1) the product is the subject of a commercial offer for sale, and (2) the invention is ready for patenting, which can be satisfied by proof of reduction to practice. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 76 (1998). Aerin's RhinAer[®], including the RhinAer[®] Stylus and Console, has been on sale and sold before the '262 patent's priority date.¹¹

An age-old axiom of patent law is “[t]hat which infringes, if later, would anticipate, if earlier.” *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889); *see also Bristol-Myers Squibb Co. v. Ben Venue Lab's, Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001) (“[I]t is axiomatic that that which would literally infringe if later anticipates if earlier.”). Accepting Neurent's allegation that Aerin's

¹⁰ “[I]mproving sleep” only appears in the preamble of claim 1 of the '262 patent. D.I. 81-1, Ex. A, 59:2-4. For purposes of this motion, the Court need not decide whether it is limiting since Neurent conceded that use of the RhinAer[®] with the First Generation RhinAer[®] Stylus improves sleep and only raised the legally irrelevant issue of *when* that benefit was publicized.

¹¹ The RhinAer[®] was ready for patenting because it was sold, and therefore reduced to practice, prior to the critical date. *Curia IP Holdings, LLC v. Salix Pharms., Ltd.*, No. CV-2119293 (ES) (JRA), 2022 WL 3444005, at n.3 (D.N.J. Aug. 17, 2022); *Abbott Lab's*, 182 F.3d at 1318.

RhinAer® infringes the '262 patent as true for this motion, then the RhinAer® also anticipates the '262 patent because it was on sale and sold before the '262 patent's priority date.

To prevail on this motion, Aerin has the burden showing that the '262 patent is invalid. The Federal Circuit has repeatedly held that a patent owner's allegation of infringement of a patent by a product that was on sale prior to the critical date of the patent satisfies the patent challenger's burden of proving invalidity. *See, e.g., Evans Cooling Sys., Inc. v. Gen. Motors Corp.*, 125 F.3d 1448, 1451 (Fed. Cir. 1997) (affirming summary judgment of invalidity and stating that while “[defendant] bore the burden of proving that the LT1 engine embodied the patented invention or rendered it obvious for purposes of the summary judgment motion, this burden is met by [plaintiff's] allegation, forming the sole basis for the complaint, that the LT1 engine infringes”), *abrogated on other grounds by Pfaff*, 525 U.S. 55; *Vanmoor v. Wal-Mart Stores, Inc.*, 201 F.3d 1363, 1366 (Fed. Cir. 2000) (affirming summary judgment of invalidity and stating that “[a]lthough [defendants] bore the burden of proving that the cartridges that were the subject of the pre-critical date sales anticipated the [asserted] patent, that burden was satisfied by [plaintiff's] allegation that the accused cartridges infringe the [asserted] patent”).

Neurent alleges that use of the RhinAer® infringes the '262 patent, D.I. 81, ¶¶ 47-54, 115, and provided a claim chart detailing those allegations, D.I. 81-1, Ex. B. Aerin's burden of showing that the RhinAer® anticipates is satisfied by Neurent's allegations that it infringes. *Leader Techs., Inc. v. Facebook, Inc.*, 770 F. Supp. 2d 686, 716 (D. Del. 2011) (“An admission by the patentee that a particular product practices the claimed invention is sufficient to satisfy the defendant's burden that the product anticipates the claim for purpose of applying the on sale bar and public use bar.” (citing *Vanmoor*, 201 F.3d at 1366)), *aff'd*, 678 F.3d 1300 (Fed. Cir. 2012).

The fact that there are minor, immaterial differences between the First Generation

RhinAer[®] Stylus and the Next Generation RhinAer[®] Stylus does not prevent the Court from ruling in Aerin's favor. *See, e.g., FMC Techs., Inc. v. OneSubsea IP UK Ltd.*, 412 F. Supp. 3d 706, 714 (S.D. Tex. 2019) (granting motion for summary judgment of invalidity where movant "presented evidence that the [prior on-sale version of the product] [was] not materially different from the accused [product]" and the nonmovant did "not contest that the two versions . . . [were] materially the same, or that the [prior version] include[d] all the claim limitations of the [asserted patent]"). Here, before Neurent even filed its counterclaim, Aerin demonstrated that the use of RhinAer[®] with the First Generation RhinAer[®] Stylus and the Next Generation RhinAer[®] Stylus are not materially different for purposes of the '262 patent claims, and Neurent did not disagree.

3. Neurent's Infringement Allegations Should Be Dismissed

Neurent's infringement allegations are self-defeating because if the infringement allegations against RhinAer[®] are taken as true, the '262 patent is invalid as anticipated by the RhinAer[®]. Under these circumstances, dismissal under Rule 12(b)(6) is appropriate.

This Court has recommended granting a motion to dismiss in a similar case. *See Quantum Loyalty Sys., Inc. v. TPG Rewards, Inc.*, No. CIVA 09-022-SLR/MPT, 2009 WL 5184350, at *8 (D. Del. Dec. 23, 2009), *R. & R. adopted as modified*, 2010 WL 1337621 (D. Del. Mar. 31, 2010). In *Quantum Loyalty*, the accused product was on sale before the asserted patent's priority date. *Id.* There, the court noted that the Federal Circuit's reasoning in *Evans Cooling* and *Vanmoor*, which involved summary judgment motions, "applies with equal force to a motion to dismiss." *Id.* The court recommended granting the motion to dismiss because "there exists no logical space between plaintiff's infringement allegation and defendant's invalidity defense; the facts cannot support one without identically buttressing the other." *Id.* The court recommended granting the motion to dismiss because "proof that the [accused] product infringes the [] patent would also prove that the product anticipates under 35 U.S.C. § 102(b)." *Id.* The same is true here. Proof that Aerin's

RhinAer® infringes also proves that it anticipates. So, the same result—dismissal—should follow.

Other courts have granted motions to dismiss on similar facts. For example, in *Curia*, 2022 WL 3444005, at *2-4, the court granted a motion to dismiss where the accused product was “manufactured and sold prior to the date of the first filed patent application” and was “prior art [that] therefore invalidate[d]” the asserted patents. *Id.* at *3 (citing *Vanmoor* and *Evans Cooling*).

The “purpose of the [12(b)(6)] rule is to allow the court to eliminate actions that are fatally flawed in their legal premises and destined to fail, and thus to spare litigants the burdens of unnecessary pretrial and trial activity.” *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 988 F.2d 1157, 1160 (Fed. Cir. 1993). Neurent’s counterclaim of patent infringement is fatally flawed and destined to fail because the RhinAer® was on sale and sold before the ’262 patent’s priority date. It should be dismissed to spare Aerin from spending unnecessary time and money defending against this baseless allegation.

B. Neurent’s Counterclaims of Tortious Interference and Unfair Competition Should Be Dismissed

Neurent’s counterclaims of tortious interference and unfair competition should be dismissed because they are improperly pled on “information and belief,” lack factual allegations necessary to state a claim, and improperly lump “Plaintiffs” together. The counterclaims are also preempted by federal patent law and barred under the *Noerr-Pennington* doctrine.

1. Neurent’s Pleading on “Information and Belief” Was Improper

Neurent’s tortious interference and unfair competition counterclaims are based on alleged conduct of Plaintiffs, which Neurent concedes it pled “on information and belief.” D.I. 81, at 7 n.11 (allegations about Plaintiffs’ alleged “unlawful conduct are pled on information and belief”); *id.*, ¶¶ 19, 29. Pleading on information and belief is appropriate only “[w]here it can be shown that the requisite factual information is peculiarly within the defendant’s knowledge or control—

so long as there are no ‘*boilerplate and conclusory allegations*’ and ‘*[p]laintiffs . . . accompany their legal theory with factual allegations that make their theoretically viable claim plausible.*’” *McDermott v. Clondalkin Grp.*, 649 F. App’x 263, 267-68 (3d Cir. 2016); *Reklam v. Bellator Sport Worldwide LLC*, No. CV 16-285-JFB-SRF, 2017 WL 5172397, at *4 (D. Del. Nov. 8, 2017), *R. & R. adopted*, 2017 WL 5985562 (D. Del. Dec. 1, 2017). The counterclaims fail this test.

First, Neurent has failed to allege, much less show, that the requisite factual information is *peculiarly* within Plaintiffs’ possession. Neurent contends that these facts “relate to conversations between Plaintiffs and others (e.g. [REDACTED] and [REDACTED]), which Plaintiffs have not yet provided to Neurent.” D.I. 81, at 7 n.11. But these alleged communications are not *uniquely* in Plaintiffs’ possession. Any alleged communications with [REDACTED] or [REDACTED] are also in their possession. Neurent apparently communicated with them both regarding Plaintiffs’ alleged communications but did not attach those communications or even describe Plaintiffs’ alleged misstatements. Because Neurent has not shown that the requisite factual information is “peculiarly within [Plaintiffs’] control,” Neurent “may not base its pleadings on ‘information and belief.’” *See Reklam*, 2017 WL 5172397, at *4; *see also McDermott*, 649 F. App’x at 267-68.

Second, Neurent’s counterclaims are laden with boilerplate, conclusory allegations that merely parrot the elements of the claims. *E.g.*, D.I. 81, ¶¶ 19, 29. “Although the court must accept as true all factual allegations in the complaint and view them in the light most favorable to Plaintiff, it must reject all conclusory allegations.” *Reklam*, 2017 WL 5172397, at *4.

Third, Neurent failed to include sufficient factual allegations that make its “belief” about Plaintiffs’ alleged wrongdoing plausible. Critically, Neurent does not identify or describe the alleged “misleading statements” it contends Plaintiffs made to [REDACTED] and [REDACTED], which are the lynchpin of its counterclaims. D.I. 81, ¶¶ 21, 31. Neurent does not allege *any* of the basic facts

about those alleged “misleading statements,” including *who* made them, *to whom* they were made, *what* they were, *why* they were “misleading,” *how* they were made, or *when* (for [REDACTED]) they were made. *Id.*, ¶¶ 17-41. The Court should dismiss these speculative and factually unsupported counterclaims and not permit them to proceed to discovery on a fishing expedition. *See Walls v. FTS Int’l, Inc.*, No. CV 17-872, 2018 WL 2240361, at *2 (W.D. Pa. May 16, 2018) (“Discovery should not be utilized as a fishing expedition for facts to support the speculative pleading of a case, particularly when the pleading is so deficient as to justify dismissal.”).

2. Neurent’s Counterclaims Fail to State a Claim

Under Delaware law,¹² a claim for tortious interference with prospective business relations requires: (1) the existence of a valid business relationship or expectancy; (2) knowledge of the relationship or expectancy on the part of the interferer; (3) intentional interference, which induces or causes a breach or termination of the relationship or expectancy; and (4) resulting damages to the party whose relationship or expectancy has been disrupted. *Elkay Interior Sys. Int’l v. Weiss*, No. CV 22-435-RGA-JLH, 2022 WL 17961568, at *3 (D. Del. Dec. 27, 2022), *R. & R. adopted*, 2023 WL 418047 (D. Del. Jan. 26, 2023). Unfair competition requires “‘a reasonable expectancy of entering a valid business relationship, with which the defendant wrongfully interferes, and thereby defeats the plaintiff’s legitimate expectancy and causes harm.’” *Id.* (quoting *Agilent Techs., Inc. v. Kirkland*, No. Civ.A. 3512-VCS, 2009 WL 119865, at *5 (Del. Ch. Jan. 20, 2009)).

[REDACTED]

No business relationship or expectancy – A “reasonable probability of a business opportunity” “must be ‘something more than a mere hope or the innate optimism of the salesman’ or a ‘mere perception of a prospective business relationship.’” *Agilent*, 2009 WL 119865, at *7

¹² Neurent has failed to identify any federal or state law giving rise to its counterclaims of tortious interference and unfair competition. Plaintiffs apply Delaware law in this motion.

(citation omitted). Neurent failed to sufficiently plead factual allegations showing that a business opportunity with [REDACTED] was reasonably probable. Neurent alleges it had “a reasonable probability and legitimate expectation that [REDACTED] would purchase Neuromark devices, including because of the favorable on-going negotiations and [REDACTED] procurement director stating that [REDACTED] was happy with the pricing and contracting proposed by Neurent to [REDACTED] D.I. 81, ¶ 58. Neurent’s own allegations, however, make it clear that Neurent had barely begun negotiating the sale of Neuromark devices when [REDACTED] declined to negotiate further. *Id.*, ¶ 33. The counterclaims allege that Neurent began negotiating the sale of the Neuromark for use by [REDACTED] physicians in Texas, Louisiana, and Florida in October 2023, had a successful meeting with [REDACTED] in Louisiana on November 22, 2023, and then negotiations were put on hold November 29, 2023. *Id.*, ¶¶ 16, 33. The counterclaims allege nothing more than early-stage negotiations with [REDACTED], so Neurent’s alleged “reasonable probability of a business opportunity” was merely the optimism of a salesman.

No intentional interference – “[A] plaintiff must prove that the defendant’s interference with the plaintiff’s business opportunity was intentional and wrongful or improper.” *IronRock Energy Corp. v. Pointe LNG, LLC*, No. CV N20C-06-121 EMD, 2021 WL 3503807, at *6 (Del. Super. Ct. July 19, 2021). Neurent failed to plausibly allege Plaintiffs intentionally or wrongfully interfered with Neurent’s opportunity with [REDACTED] one of *Aerin*’s customers. D.I. 81, ¶ 28.

The counterclaims allege that an [REDACTED] representative told Neurent that [REDACTED] “[had] been made aware of the legal case taken by Aerin against Neurent and [REDACTED] had] some concerns,” *id.*, ¶ 33, but do not even allege it was made aware by Plaintiffs. And even if it could be inferred that such awareness came from Plaintiffs, the counterclaims do not provide factual support for an allegation that any communications between Plaintiffs and [REDACTED] were misleading or included topics other than the litigation’s existence, which is public. *Id.*

Neurent's allegations of interference are merely that Plaintiffs notified [REDACTED] of the lawsuit's existence and further informed [REDACTED] that, as a result of this case, Neurent "would not be able to supply products or to continue conducting business and/or that purchasing products from Neurent would harm [REDACTED] business." *Id.*, ¶ 31. The counterclaims do not allege that [REDACTED] said these comments were made or that they were made by Plaintiffs. Regardless, the statements as pled by Neurent merely "conveyed that a threat of litigation surround[ed]" Neurent's products and stated, accurately, that a potential outcome included Neurent being enjoined from continuing infringement, like the statements in *Agilent* that were insufficient for unfair competition and tortious interference. *Agilent*, 2009 WL 119865, at *8.

No causation – The counterclaims make conclusory statements that Plaintiffs caused [REDACTED] to withdraw from purchasing Neuromark devices without providing supporting facts. D.I. 81, ¶¶ 34, 61, 72. At best, the factual allegations support an inference that [REDACTED] withdrew based on the existence of litigation and not any misleading statements. *Id.*, ¶ 33. Indeed, the pleadings allege that [REDACTED] was "on [h]old due to the law suit." *Id.*

[REDACTED] [REDACTED]

No business relationship or expectancy – The counterclaims allege that "Neurent had a reasonable probability and legitimate expectation that [REDACTED] would invest in Neurent, including because of the Term Sheet and favorable on-going negotiations between Neurent and [REDACTED] that had spanned many months." *Id.*, ¶ 68. The counterclaims merely allege that the term sheet was for a "potential investment in Neurent." *Id.*, ¶ 10 (emphasis added). A term sheet that represents only a potential investment does not show a reasonable probability of a business relationship.

No intentional interference – The only factual allegation regarding Plaintiffs' alleged communications with [REDACTED] comes from correspondence between Neurent and [REDACTED]. The counterclaims allege that a [REDACTED] representative told Neurent that "Aerin filed a lawsuit against

Neurent yesterday.” D.I. 81, ¶ 23. Neurent does not allege that [REDACTED] knowledge of the lawsuit came from Plaintiffs. But even assuming that could be inferred, the counterclaims do not provide any factual support that the communications between Plaintiffs and [REDACTED] were misleading or included topics other than the existence of the litigation. *Id.* The counterclaims can, at most, be inferred to allege that Plaintiffs notified [REDACTED] of the lawsuit. *Id.*, ¶ 21. The statements as pled, however, merely “conveyed that a threat of litigation surround[ed] [Neurent’s] products,” which is insufficient to plausibly allege improper or wrongful conduct by Plaintiffs, and it is otherwise publicly available information that Neurent would have had to disclose as part of any good-faith due diligence effort. *Agilent*, 2009 WL 119865, at *8.

No causation – The counterclaims allege that Plaintiffs caused Neurent to lose an investment from [REDACTED] but provide no factual support. D.I. 81, ¶¶ 24, 64, 75. The only alleged communication is from [REDACTED] to Neurent identifying the lawsuit, not any statements from Plaintiffs. *Id.*, ¶ 23. At best, the factual allegations support an inference that [REDACTED] withdrew based on the existence of the litigation and not any misleading statements by Plaintiffs. *Id.*

c. “Other” “Potential Investors” “Prospective Physicians”

Neurent’s “information and belief” allegations about Plaintiffs’ alleged interference and unfair competition with respect to unidentified “other potential investors” and “other prospective physicians and/or physician groups” are even more deficient because they lack *any* supporting factual allegations. D.I. 81, ¶¶ 26, 36. To allege a reasonable probability of a business opportunity, the plaintiff “must identify a specific party who was prepared to enter[] into a business relationship but was dissuaded from doing so by the defendant,” and, “[w]hile the plaintiff does not need to identify a party by name, the plaintiff must do more than offer vague statements about unknown customers.” *Alsco, Inc. v. Premier Outsourcing Plus*, No. CV 19-1631-CFC, 2020 WL 4209192, at *9-10 (D. Del. July 22, 2020), *R. & R. adopted*, 2020 WL 4501921 (D. Del. Aug. 5, 2020).

3. Neurent's Counterclaims Fail to Provide Notice to Each Plaintiff

By lumping Aerin and The Foundry together as “Plaintiffs,” with no allegations of their individual conduct, the counterclaims for tortious interference and unfair competition fail to provide each of Aerin and The Foundry with adequate notice. “[A]llegations lumping multiple defendants together without providing allegations of individual conduct are frequently (as here) insufficient to satisfy the notice pleading standard.” *Adverio Pharma GmbH v. Alembic Pharms. Ltd.*, No. CV 18-73-LPS, 2019 WL 581618, at *6 (D. Del. Feb. 13, 2019); *see also Am. Inst. for Chartered Prop. Cas. Underwriters v. Potter*, No. CV 19-1600-CFC-SRF, 2021 WL 431475, at *5 (D. Del. Feb. 8, 2021) (“[A] complaint will not survive a Rule 12(b)(6) motion if it ‘combine[s] allegations against multiple defendants’ in a manner that fails to provide each defendant with adequate notice of the basis for the underlying claims against them” (citation omitted)), *R. & R. adopted*, 2021 WL 1152982 (D. Del. Mar. 26, 2021).

The counterclaims generally refer to “Plaintiffs” without specifying which Plaintiff committed any alleged act. For example, they do not specify whether Aerin, or The Foundry, or both, is alleged to have communicated with [REDACTED] and/or [REDACTED], “[made] misleading statements about Neurent” and this lawsuit, “wrongfully persuaded [REDACTED] not to invest in Neurent,” or “wrongfully persuaded [REDACTED] not to purchase devices from Neurent.” D.I. 81, ¶¶ 21, 31. These counterclaims fail to meet the pleading standard and should be dismissed.

4. Neurent's Counterclaims Are Preempted by Federal Patent Law

“[F]ederal patent law preempts state-law tort liability for a patentholder’s good faith conduct in asserting infringement of its patent and warning about potential litigation.” *Globetrotter Software Inc. v. Elan Comput. Grp., Inc.*, 362 F.3d 1367, 1374 (Fed. Cir. 2004). “The federal patent laws thus bar state-law liability for communications concerning alleged infringement so long as those communications are not made in ‘bad faith.’” *Id.* at 1374-75.

To avoid preemption, Neurent would have had to state facts showing that Plaintiffs' infringement claims, which were allegedly communicated to [REDACTED] and [REDACTED] by reference to the litigation, were made in bad faith. It did not. Neurent has not alleged that Plaintiffs' infringement allegations are objectively baseless or that "no reasonable litigant could realistically expect success on the merits." *Dominant Semiconductors Sdn. Bhd. v. OSRAM GmbH*, 524 F.3d 1254, 1260 (Fed. Cir. 2008). Likewise, Neurent has not pled facts supporting subjective bad faith. The counterclaims make conclusory assertions that Plaintiffs' alleged communications were "misleading," but do not allege objective or subjective bad faith. D.I. 81, ¶¶ 21, 31.

5. Neurent's Counterclaims Are Barred Under *Noerr-Pennington*

The *Noerr-Pennington* doctrine grants immunity to parties "who petition[] the government for redress" and "extends to persons who petition all types of government entities, including legislatures, administrative agencies, and courts." *Arthrocare Corp. v. Smith & Nephew, Inc.*, No. CIV. 01-504-SLR, 2004 WL 896002, at *3 (D. Del. Mar. 10, 2004). Plaintiffs' alleged communications with [REDACTED] and [REDACTED] fall squarely within the *Noerr-Pennington* doctrine, which courts have extended to cover communications and actions incidental to litigation, including with third parties. *Magnetar Techs. Corp. v. Six Flags Theme Parks Inc.*, No. CIV.A. 07-127-LPS, 2011 WL 678707, at *2 (D. Del. Feb. 18, 2011); *Sliding Door Co. v. KLS Doors, LLC*, No. EDCV 13-00196 JGB, 2013 WL 2090298, at *6-7 (C.D. Cal. May 1, 2013).

Courts have recognized two exceptions to *Noerr-Pennington* immunity: one for "sham litigation" and one for "knowing and willful fraud" in the procurement of a patent. *Magnetar*, 2011 WL 678707, at *2 (citing *Noerr*, 365 U.S. 127 (1961) and *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965)). Neurent has not pled either exception.

VII. Conclusion

Plaintiffs request that the Court dismiss Neurent's amended counterclaims.

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MCCARTER & ENGLISH

Of Counsel:

J. Michael Jakes
Kathleen A. Daley
Sonja W. Sahlsten
Christopher C. Howes
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4431
(202) 408-4000
mike.jakes@finnegan.com
kathleen.daley@finnegan.com
sonja.sahlsten@finnegan.com
christopher.howes@finnegan.com

/s/ Alexandra M. Joyce

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
T: (302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

*Attorneys for Plaintiffs Aerin Medical Inc.
and The Foundry, LLC*