IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEURENT MEDICAL LTD. Plaintiff, v. AERIN MEDICAL INC. Defendant.	C.A. No. 24-1070-JLH **DEMAND FOR JURY TRIAL**

OPENING BRIEF IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT OF PATENT INFRINGEMENT

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I. Introduction

Neurent's claims alleging that use of Aerin's RhinAer® infringes U.S. Patent Nos. 12,096,973 (the '973 patent), 12,096,974 (the '974 patent), and 12,098,889 (the '889 patent) (collectively, the Asserted Patents) cannot stand, even if accepted as true, because the RhinAer® was on sale before the priority date of the Asserted Patents. Neurent does not dispute that the RhinAer® was on sale prior to the priority date of the Asserted Patents. As a result, Neurent's infringement allegations are self-defeating—that which infringes if later, anticipates if earlier—and should be dismissed. Neurent's only argument against the on-sale bar is its own conclusory and self-serving allegation that there are material differences between the RhinAer® that was on sale prior to the priority date of the Asserted Patents and the RhinAer® that it accuses of infringement. But Neurent failed to plead sufficient facts to support its conclusory allegations about material differences, and instead improperly relied on "information and belief." Neurent has, therefore, failed to plead a plausible claim of infringement, and its Complaint should be dismissed.

II. Nature and Stage of the Proceedings

Neurent Medical Ltd. filed a Complaint against Aerin Medical Inc. for infringement of the three Asserted Patents. D.I. 1. But this is not the first patent infringement case between the parties. In a related case, Aerin and The Foundry filed a complaint and an amended complaint against Neurent Medical Inc. and Neurent Medical Ltd. for infringement of eight patents. *Aerin Medical Inc. & The Foundry, LLC v. Neurent Medical Inc. & Neurent Medical Ltd.*, No. 1:23-cv-00756 (D. Del.) (the -756 Action), D.I. 1, D.I. 17. In that case, Neurent moved for partial dismissal, which was denied. -756 Action, D.I. 19, D.I. 20, D.I. 74. Neurent filed an answer and counterclaims of tortious interference, unfair competition, and declaratory judgment for invalidity for each patent. -756 Action, D.I. 40, ¶¶ 42-101. Aerin and The Foundry filed an answer, -756 Action, D.I. 60, and a motion to dismiss the tort-based counterclaims, -756 Action, D.I. 58, D.I. 59. That motion was

denied as moot, -756 Action, D.I. 82, because Neurent filed amended counterclaims, adding a counterclaim against Aerin for infringement of U.S. Patent No. 11,998,262 (the ’262 patent), -756 Action, D.I. 81, ¶¶ 115-122. Aerin and The Foundry moved to dismiss Neurent’s tortious interference and unfair competition counterclaims, and Aerin moved to dismiss Neurent’s infringement counterclaim. -756 Action, D.I. 89, 90. Aerin and The Foundry also filed an answer to the amended counterclaims. -756 Action, D.I. 91.

The parties stipulated to stay the entire -756 Action until the final written decisions are issued in inter partes reviews of Aerin and The Foundry’s patents. -756 Action, D.I. 93. Neurent then filed the Complaint in this case, accusing Aerin of infringing the ’973, ’974, and ’889 patents, which are in the same family as the ’262 patent that Neurent asserted in the -756 Action and agreed to stay.

III. Summary of the Argument

Neurent contends that use of the RhinAer® infringes the Asserted Patents. D.I. 1, ¶ 36. But the RhinAer® is prior art to the Asserted Patents. The RhinAer® has been on sale, sold, and otherwise available to the public since before April 9, 2020, the earliest priority date of the Asserted Patents. There are no factual issues regarding whether the RhinAer® was on sale before the priority date. And because that which infringes if later, anticipates if earlier, the Asserted Patents are invalid if Neurent’s allegations that the RhinAer® infringes are accepted as true.

Recognizing that the RhinAer® had been on sale, sold, or otherwise available to the public before April 9, 2020, Neurent vaguely alleges there are material differences between the RhinAer® available before April 9, 2020 and the RhinAer® Neurent accuses of infringement. Neurent, however, fails to allege any facts about how any features of the RhinAer® changed, much less how those changes relate to the claims of the Asserted Patents. Instead Neurent pleads that material differences exist based “[o]n information and belief,” which was improper because the requisite

factual information is not peculiarly within Aerin's possession—it is also in Neurent's possession—and because Neurent's allegation of material differences is conclusory and devoid of any factual allegations to make its "belief" plausible. Neurent's infringement claims are fatally flawed and should be dismissed.

IV. Concise Statement of the Facts

Each of the Asserted Patents was filed on April 26, 2024, and each claims priority to a provisional application filed on April 9, 2020, which is thus the earliest possible priority date for each of the Asserted Patents. D.I. 1-1, Exs. 1-3.

Neurent asserts that use of Aerin's RhinAer® infringes the Asserted Patents. D.I. 1, ¶ 36. Aerin announced the U.S. launch of the RhinAer® on March 5, 2020. Ex. A (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. 1, ¶ 36; *see also id.*, ¶¶ 46-75, 84-103, 112-131 (accusing RhinAer® Console (Model FG226)). *Compare* Ex. B (Instructions for Use for RhinAer® Console (Model FG226), 2019),[2] *with* D.I. 1-1, Ex. 5 (Instructions for Use for RhinAer® Console

[1] The Court may consider the press release in Exhibit A in resolving this motion at least because it is in the record of the related case before the same judge as exhibits to Aerin's answer to Neurent's amended counterclaims in that case. -756 Action, D.I. 91, Ex. 1; *Creamer v. Hicks*, 61 F. App'x 121 (5th Cir. 2003) ("'[I]n deciding a motion to dismiss for failure to state a claim' . . . [a] judge may take judicial notice of the record in a prior related proceeding over which [they] presided."); *Twp. of S. Fayette v. Allegheny Cnty. Hous. Auth.*, 27 F. Supp. 2d 582, 594 (W.D. Pa. 1998) ("It is well established that courts are permitted to consider matters of which they may take judicial notice, including . . . publicly available records and transcripts from judicial proceedings 'in related or underlying cases which have a direct relation to the matters at issue.'"), *aff'd*, 185 F.3d 863 (3d Cir. 1999); *Henson v. CSC Credit Servs.*, 29 F.3d 280, 284 (7th Cir. 1994) (holding that the "district court properly considered the public court documents [filed in an earlier state court case] in deciding the defendants' motions to dismiss").

[2] The Court may consider Exhibits B and F, which are similar to the Instructions for Use that Neurent included with its Complaint, D.I. 1-1, Exs. 4-5, at least because they are in the record of the related case as exhibits to Aerin's answer to Neurent's amended counterclaims in that case. -

(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. C (Aerin Invoice #INV4978); Ex. D (Aerin Invoice #INV6151); Ex. E (Aerin Invoice #INV6146).[4] Aerin provided Instructions for Use with sales of the RhinAer® Console and First Generation RhinAer® Stylus.

In September 2022, Aerin launched an updated RhinAer® Stylus (Model FG1393). D.I. 1-1, Ex. 6. 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 Asserted Patents' 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. F (Instructions for Use for First Generation RhinAer® Stylus), *with* D.I. 1-1, Ex. 4 (Instructions for Use for Next Generation RhinAer® Stylus). And the methods of using the RhinAer® as alleged to infringe the Asserted Patents are the same. *See* Exs. G–I (updated versions of Neurent's

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756 Action, D.I. 91, Exs. 4-5; *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. Ex. J. The Court may consider Exhibit J at least because it is in the record of the related case as an exhibit to Aerin's amended complaint in that case. -756 Action, D.I. 17-1, Ex. H at 4; *see supra* note 1.

[4] The Court may consider the invoices attached as Exhibits C-E at least because they are in the record of the related case as exhibits to Aerin's answer to Neurent's amended counterclaims. -756 Action, D.I. 91, Exs. 6-8; *see supra* note 1.

infringement charts comparing the RhinAer® with the First Generation RhinAer® Stylus to the accused RhinAer® with the Next Generation RhinAer® Stylus).[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. K (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 styluses does not change the method of using the RhinAer® as alleged to infringe. *See id.*

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 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

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[5] The Court may consider these claim charts because they are responsive to the charts Neurent included in its Complaint and relied on as the basis for its infringement claims, D.I. 1, ¶¶ 46-75, 84-103, 112-131, and because they are dispositive in defeating Neurent's claims of infringement by showing that the Asserted Patents are invalid under Neurent's infringement theory. *See Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) ("[A] court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document. . . . Otherwise, a plaintiff with a legally deficient claim could survive a motion to dismiss simply by failing to attach a dispositive document on which it relied."). The Court may consider the excerpts of the documents included in the third column of the claim charts at least because they are in the record of the related case as exhibits to Aerin's answer to Neurent's amended counterclaims. -756 Action, D.I. 91, Exs. 1, 4, 5, 23; *see supra* note 1.

[6] The Court may consider this FDA document at least because it is subject to judicial notice. *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.'").

factual content that allows the court to draw the reasonable interference 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

Taking Neurent's allegations that use of the RhinAer® infringes the Asserted Patents as true defeats Neurent's claims because the RhinAer® has been on sale, sold, and otherwise available to the public since before the earliest priority date of the Asserted Patents, and that which infringes if later, anticipates if earlier. Neurent does not dispute that the RhinAer® was on sale before the priority date but instead makes conclusory allegations that the accused RhinAer® is materially different than the RhinAer® that was on sale and sold before the priority date of the Asserted Patents. Neurent failed to plead any factual allegations to support this conclusion and improperly attempted to rely on "information and belief" to mask this deficiency. Neurent has failed to adequately plead infringement, and its Complaint should be dismissed.

A. Neurent's Infringement Allegations, Taken as True, Render the Asserted Patents Invalid and Defeat Its Infringement Claim

Assuming for the purposes of this motion, as Neurent alleges, that use of the RhinAer®, including the RhinAer® Stylus and Console, infringes the Asserted Patents, the Asserted Patents are 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, 67 (1998). Aerin's RhinAer®, including the RhinAer® Stylus and Console, has been on sale and sold before the priority date of the Asserted Patents.[7]

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

To prevail on this motion, Aerin has the burden showing that the Asserted Patents are 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

[7] 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'ys v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1318 (Fed. Cir. 1999).

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 Asserted Patents and provided claim charts in the Complaint, which Neurent alleges proves those allegations, D.I. 1, ¶¶ 36-131. Aerin's burden of showing that the RhinAer® anticipates is satisfied by Neurent's allegations that the RhinAer® infringes each patent. *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).

B. 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 Asserted Patents are 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 *2-3 (citing *Vanmoor* and *Evans Cooling*).

C. Neurent's Conclusory Allegations About Alleged Differences Between the First Generation and Next Generation RhinAer® Stylus Do Not Prevent the Court from Applying the On-Sale Bar

Neurent attempts to avoid the fact that the RhinAer® it accuses of infringement invalidates its patents under Neurent's own infringement theory with conclusory allegations that differences exist between the RhinAer® that was sold prior to the priority date of the Asserted Patents and the RhinAer® that Neurent accuses of infringement. D.I. 1, ¶¶ 37-41. As an initial matter, the RhinAer® Console (Model FG226) that was sold prior to the priority date of the Asserted Patents is the same RhinAer® Console that Neurent accuses of infringement, and Neurent does not allege otherwise. And 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]").

Neurent's conclusory allegation that "Aerin's RhinAer System is materially different from earlier Aerin products, including those branded in the RhinAer product line" should be rejected

because Neurent failed to adequately plead any facts supporting its allegation. D.I. 1, ¶ 37. Under the *Twombly-Iqbal* pleading standard, the court first separates factual and legal elements of a claim, and then "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). "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. Second, the court "must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679).

Neurent did not plead sufficient facts to support its conclusory allegation that there are "material differences" between the RhinAer® that was sold prior to the priority date of the Asserted Patents and the RhinAer® it accuses of infringement. *See* D.I. 1, ¶¶ 37-41. Instead, Neurent generally alleges "[t]he modifications at least technically, functionally, structurally, and visibly changed the RhinAer System, such as by changing the stylus's shape, size, diameter, power, treatment tip and the temperature to which target tissue is heated" and makes the unsupported, conclusory leap that "[t]he modifications . . . significantly changed the methods of use for the RhinAer System." *Id.*, ¶ 37. Neurent does not identify, describe, or provide any factual allegations about those changes or how they allegedly altered the claimed methods of use of the RhinAer®.[8] And, fatally, Neurent entirely fails to allege how those changes allegedly relate to the claims of the Asserted Patents. *Cf. Infineon Techs. AG v. Volterra Semiconductor*, No. C-11-06239 MMC (DMR), 2013 WL 5366131, at *5 (N.D. Cal. July 31, 2013) (noting in the context of representative

[8] Neurent's failure to factually support its allegations about the alleged differences is even more egregious considering Neurent's intimate knowledge of the design and functionality of the RhinAer®, as evidenced by its reliance on the First Generation RhinAer® Stylus as the predicate device for Neurent's NEUROMARK® System, and the public availability of both the First Generation and Next Generation RhinAer® Stylus and their Instructions for Use.

products, that "[t]he differences must be relevant to the infringement contentions" and holding that the alleged product differences in that case "d[id] not appear to matter" to the claims); *FaceTec, Inc. v. iProov, Ltd.*, No. 2:21-CV-02252-ART-BNW, 2024 WL 4149868, at *3 (D. Nev. Sept. 10, 2024) ("Crucially, product differences do not matter if they are irrelevant to the infringement contentions."). By not pleading whether or how the changes to the RhinAer® Stylus allegedly relate to the claims of the Asserted Patents, Neurent's allegation that the differences are "material[]" is wholly unsupported, conclusory, and should be disregarded.

Rather than make factual allegations about the technical changes and why they are allegedly material to the claims of the Asserted Patents, Neurent resorts to marketing literature. For example, Neurent notes that Aerin's marketing literature referred to the Next Generation RhinAer® Stylus as "next generation" and "NEW." *See, e.g.*, D.I. 1, ¶ 38. But marketing a product as "next generation" or "new" does not prove that any changes are significant, much less material to the claims of the Asserted Patents. Neurent's unsupported, conclusory allegation that material differences exist between the First Generation and Next Generation RhinAer® Stylus should be disregarded.

D. Neurent's Conclusory Pleading of Alleged Material Differences Based on "Information and Belief" Was Improper

Neurent's allegation about the alleged material differences between the First and Next Generation RhinAer® Stylus also fail because they were improperly pled "[o]n information and belief." D.I. 1, ¶ 37 ("On information and belief, Aerin's RhinAer System is materially different from earlier Aerin products, including those branded in the RhinAer product line"); *see also id.*, ¶¶ 38, 40. 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). Neurent's allegations about the alleged material differences fail this test.

First, Neurent has failed to allege, much less show, that the requisite factual information about the differences between the First and Next Generation RhinAer® Stylus is *peculiarly* within Aerin's possession. Both the First and Next Generation RhinAer® Stylus are publicly available. In fact, Neurent has access to both the First and Next Generation RhinAer® Stylus. Neurent relied on the First Generation RhinAer® Stylus as the predicate device for Neurent's NEUROMARK® System. Ex. J. And Neurent's Complaint includes close-up photographs of the Next Generation RhinAer® Stylus. *E.g.*, D.I. 1, ¶ 46. Neurent's Complaint shows that it also relied on additional public information, including the Food and Drug Administration's clearance of Aerin's 510(k) for the Next Generation RhinAer® Stylus and the Instructions for Use for the Next Generation RhinAer® Stylus. D.I. 1, ¶¶ 37-41. Despite having the requisite factual information in its possession, Neurent failed to identify any factual support for its conclusory allegation that there are material differences between the First Generation and Next Generation RhinAer® Stylus or allege that those differences are relevant to the claims of the Asserted Patents and instead pleads those differences exist "[o]n information and belief." *Id*. Because Neurent has not shown that the requisite factual information is "peculiarly within" Aerin's control, and it is in fact in Neurent's 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 allegations regarding the alleged material differences between the First Generation and Next Generation RhinAer® Stylus are laden with boilerplate, conclusory allegations. Neurent merely identifies features of the RhinAer® Stylus that allegedly changed ("the stylus's shape, size, diameter, power, treatment tip and the temperature to which target tissue is heated"). D.I. 1, ¶ 37. Without explaining what those changes were, Neurent leaps to the conclusory allegation that these are "major changes" that "significantly changed the methods of use," without any factual information about how the method of use has allegedly changed or how those changes are relevant to the claims. *Id.*, ¶¶ 37, 40. "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. Neurent's allegations that the changes were "major" and "significant[]" are conclusory and should be rejected.

Third, Neurent failed to include sufficient factual allegations that make its "belief" about any material differences plausible. Critically, Neurent does not identify or describe any of the alleged material differences it contends exist between the First Generation and Next Generation RhinAer® Stylus, which is the lynchpin of its infringement claims because that which infringes if later, anticipates if earlier. *See Peters*, 129 U.S. at 537. Neurent generally alleges, without any citations, that "the stylus's shape, size, diameter, power, treatment tip and the temperature to which target tissue is heated" changed. D.I. 1, ¶ 37. But Neurent does not allege *any* of the basic facts about those alleged changes, including how the listed features changed, and how those changes allegedly altered the RhinAer® "technically, functionally, structurally, and visibly." *Id.* And, as discussed above, Neurent failed to allege, much less show, that any of those changes related to the claims of the Asserted Patents. Neurent's attempt to rely on "information and belief" in place of

sufficient factual allegations was improper, and the Court should dismiss these speculative and factually unsupported claims.

E. Neurent Failed to State a Claim of Infringement

Neurent failed to state a proper claim for infringement, so the Complaint should also be dismissed for that reason. Neurent acknowledges in the Complaint that Aerin had earlier RhinAer® products, and Neurent does not dispute that such RhinAer® system was on sale before the earliest priority date of the Asserted Patents. D.I. 1, ¶ 37. While the Complaint alleges that the accused RhinAer® system is materially different than "Aerin's earlier products," the Complaint does not identify any differences, let alone material ones, between the prior RhinAer® system and the one accused of infringement other than some "modifications" to the Next Generation RhinAer® Stylus. *Id.*

Neurent's failure to sufficiently plead material differences between the First Generation and Next Generation RhinAer® and its improper reliance on "information and belief" to mask that deficiency as explained in Sections VI.C and VI.D also renders its claim for infringement deficient. As courts have explained, when a plaintiff's allegations of infringement would require "prov[ing] infringement of devices that were on sale before the respective critical dates," like Neurent's allegations here, they "held no viable causes of action for infringement." *IXYS Corp. v. Advanced Power Tech., Inc.*, No. C 02-03942 MHP, 2004 WL 540513, at *6 (N.D. Cal. Mar. 18, 2004) (citing *Evans Cooling*, 125 F.3d at 1451 and *Vanmoor*, 201 F.3d at 1366). That is because "[a] piece of prior art by its nature of being *prior* cannot infringe a later patent . . . ." *Lionra Techs. Ltd. v. Fortinet, Inc.*, No. 2:22-CV-00322-JRG-RSP, 2024 WL 2214691, at n.1 (E.D. Tex. May 16, 2024) (citing *Peters*, 129 U.S. at 537).

Neurent's claims should be dismissed because they suffer from a fatal defect that even artful pleading cannot cure. 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 claims of patent infringement are fatally flawed and destined to fail because the RhinAer® was on sale and sold before the Asserted Patents' priority date. They should be dismissed to spare Aerin from spending unnecessary time and money defending against these baseless claims.

VII. Conclusion

Aerin requests that the Court dismiss Neurent's Complaint.

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MCCARTER & ENGLISH

/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 Defendant Aerin Medical Inc.

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