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**

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

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I. NATURE AND STAGE OF THE PROCEEDING

In this action, Neurent alleges that Aerin infringes U.S. Patent Nos. 12,096,973 ("'973 patent"), 12,096,974 ("'974 patent"), and 12,098,889 ("'889 patent") (collectively, "Asserted Patents"). D.I. 1 ("Complaint"). On November 15, 2024, Aerin moved to dismiss the Complaint under Rule 12(b)(6). D.I. 19 ("Motion"), 20 ("Aerin Br."). In support of its Motion, Aerin does not dispute that Neurent's over 200-page Complaint and its three causes of action for infringement adequately allege Aerin has and continues to willfully infringe the Asserted Patents. Instead, Aerin's Motion asks—before any discovery has taken place—that the Court make factual findings contrary to the well-pleaded allegations in the Complaint based on judicial notice and attorney argument and find at the pleading stage that the patents are invalid. Neurent opposes.

II. SUMMARY OF ARGUMENT

Aerin's request for a summary determination of invalidity at the pleading stage is improper and unsupported. The Motion should be denied for multiple reasons.

First, Aerin has not identified a basis to dismiss the Complaint under Rule 12(b)(6). Aerin asks the Court to find "that the Asserted Patents are invalid" as anticipated. Aerin Br. 7. Rule 12(b)(6), however, allows dismissal of a complaint only if, accepting the factual allegations of the complaint as true, it fails to state a claim on which relief can be granted. *See, e.g.*, *Staton Techiya, LLC v. Harman Int'l Indus., Inc.*, 2024 WL 2271861, at *3 (D. Del. May 20, 2024). Neurent's causes of action are for ***infringement***, and Aerin's Motion ***does not dispute*** Neurent adequately pleaded that Aerin infringes the Asserted Patents. As to Aerin's affirmative defense regarding validity, a patent is "presumed valid" for purposes of pleading and "a plaintiff need not [preemptively] prove the validity of the patent to bring a claim for infringement." *Celanese Int'l Corp. v. Anhui Jinhe Indus. Co.*, 2021 WL 7209494, at *6 (D. Del. Dec. 10, 2021); *Nalco Co. v.*

Chem-Mod, LLC, 883 F.3d 1337, 1350 (Fed. Cir. 2018) (A plaintiff "need not prove its case at the pleading stage.") (citation omitted); *Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 332–33 (D. Del. 2019) ("The Court, of course, is not in a position to evaluate the merits of Defendant's invalidity defense at the motion to dismiss stage … [M]any of the premises of Defendant's argument implicate factual disputes."). Aerin's request for summary determination of a fact-based invalidity defense under 12(b)(6) should be rejected.

Second, Aerin's Motion would improperly require factual determinations that are inconsistent with the well-pleaded allegations of the Complaint. Aerin alleges that the "First Generation" RhinAer Stylus anticipates the Asserted Patents because it was on sale before the priority date and is purportedly the same in all relevant respects to the "Next Generation" RhinAer Stylus accused of infringement. *See* Aerin Br. 8-9, 14-15. The Complaint, however, which must be accepted as true, alleges the opposite. It alleges the accused Next Generation RhinAer Stylus is materially different than the First Generation Stylus. It alleges—with reference to Aerin's statements and information and belief of details uniquely in Aerin's possession—that the accused product was launched after the priority date with "modifications [that] at least technically, functionally, structurally, and visibly changed" the product as compared to the "First Generation" product, including a different "shape, size, diameter, power, treatment tip and the temperature to which target tissue is heated," resulting in "significant[] change[s to] the methods of use for the [accused] RhinAer system" ***post-priority***. Complaint ¶¶36-41. When Neurent's allegations are accepted as true, as they must be, there can be no summary finding of anticipation.

Third, even if the Court were to consider Aerin's factual invalidity arguments at the motion to dismiss stage, Aerin's Motion falls well short of satisfying its burden to show invalidity by clear and convincing evidence. As an initial matter, Aerin proffers evidence that cannot be considered

at the motion to dismiss stage, including unauthenticated documents that have not been offered to the Court by any relevant witness or expert. Aerin's request that the Court simply take judicial notice of conclusions derived from these more than 400 pages of documents and credit Aerin's attorney arguments about what they mean simply because Aerin filed them in another case, attached them to its brief, or found them online is unfounded. Regardless, Aerin's allegations are insufficient to meet its burden to show an on-sale bar because they do not establish that the First and Next Generation Aerin Systems were in fact the same for purposes of the claims. To the contrary, Aerin acknowledges its First and Next Generation Systems are ***different***, Aerin Br. 4-5, and its assertions that those differences are purportedly "minor" or "immaterial," *id*. 9-11, are conclusory. Regardless, Aerin's allegations at most raise a factual dispute that must be subject to discovery, and ultimately potentially resolved at trial.

For these reasons, explained further below, the Court should deny Aerin's Motion.

III. COUNTER STATEMENT OF FACTS

A. The Complaint Accuses Aerin's Next Generation RhinAer System, Not Its First Generation System, Of Patent Infringement

Aerin infringes the Asserted Patents by making, using, supplying, distributing, selling, importing, and/or inducing others to use the ***RhinAer Stylus Model FG1393*** (the "Next Generation RhinAer Stylus," Aerin Br. 4-5) and the RhinAer Console Model FG226.[1] Complaint ¶3. The Next Generation RhinAer Stylus received FDA 510(k) clearance on July 29, 2022, and the Accused RhinAer System was launched in September 2022. *Id*. ¶36. This clearance and launch were ***over two years after*** the Asserted Patent's claimed priority date of April 9, 2020. *Id*.; *see also* Aerin Br. 4.

[1] Neurent alleges that the console when used with the accused Stylus infringes the claims; it does not accuse the Console alone of infringement. Complaint ¶¶36-41; Counts I-III.

B. The Accused Next Generation RhinAer System Is Different Than The Unaccused First Generation RhinAer System

Before launching the accused Next Generation RhinAer Stylus, Aerin sold a "First Generation" RhinAer Stylus (Model FG815, RHIN1). Aerin Br. 3-4. The Complaint does not allege that the First Generation Stylus infringes. *See, e.g.*, Aerin Br. 4. Instead, the "First Generation" and "Next Generation" RhinAer Styluses are different in multiple material respects, including shape, size, diameter, power, treatment tip, and temperature to which target tissue is heated. Complaint ¶¶37-41.

The differences between these systems were "material[]" and "major." *Id*. ¶¶37, 40. The Complaint, for example cites Aerin marketing materials and publications that show the First Generation (top) Stylus differs from the "New" Next Generation (bottom) Stylus, including with respect to the angle of the electrodes relative to the shaft (black) and the shaft's thickness relative to the treatment tip (grey):

Id. ¶38. The claim charts within the Complaint specifically demonstrate that the Next Generation RhinAer Stylus infringes due to, *inter alia*, the angle and thickness of its shaft. *See, e.g.*, *id*. pp. 17-18 ("Aerin's RhinAer System is used in a method that includes … at least six electrodes extend [that] beyond surface of the shaft and are oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy."), pp. 78-79 ("Aerin's RhinAer System is used in a method

that includes … at least one portion of the multi-electrode end effector comprises a diameter that is larger than a diameter of the shaft."). The Complaint also cites Aerin's press release that the Accused "Next Generation" RhinAer System includes "several significant benefits for physicians using the device, including '***improved visualization, easier access[,] and tissue apposition, especially in patients with narrow nasal airways***.'"[2] *Id*. ¶39. The Complaint cites Aerin's quotation of a physician who explained, "[t]his newer generation RhinAer allows me to confidently treat multiple target areas, in the office setting, even in very challenging anatomy." *Id*. Indeed, Aerin's CEO described the accused Next Generation System as having "***enhancements*** [that] will be well received." *Id*.

The Complaint explains how Aerin "inform[ed] the industry, including potential customers and patients, of the major changes Aerin had made to the design of the RhinAer System" and "believed that the changes could increase Aerin's revenue and/or profit for the RhinAer System." *Id*. ¶40. However, "[t]he purportedly 'new' product and features Aerin launched" in 2022 actually comprised Neurent's patented technology. *Id*. ¶41.

In support of the allegations of infringement, the Complaint includes infringement claim charts spanning nearly 200 pages. *See* Counts I-III. These describe why the Next Generation RhinAer Stylus, when paired with a RhinAer console, practices each of 70 asserted claims.

IV. LEGAL STANDARD

A claim for relief must contain "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), and must be "plausible." *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). "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

[2] Emphasis added throughout.

misconduct alleged." *Iqbal*, 556 U.S. at 678. "The court's determination is not whether the non-moving party will ultimately prevail, but whether that party is entitled to offer evidence to support the claims." *Cipla USA, Inc. v. Ipsen Biopharmaceuticals, Inc.*, 2023 WL 2306933, at *2 (D. Del. Mar. 1, 2023) (citation omitted).

A party moving to dismiss under Rule 12(b)(6) bears the burden. *Horatio Washington Depot Techs. v. Tolmar*, 2019 WL 1276028, at *3 (D. Del. Mar. 20, 2019). "When considering a Rule 12(b)(6) motion to dismiss, the court must accept as true all factual allegations in the complaint and view them in the light most favorable to the plaintiff." *Celanese*, 2021 WL 7209494, at *2. When considering a motion to dismiss, "[a] patent is presumed valid." *Id*. at *6 (denying motion to dismiss in view of disputes that were "factual in nature and cannot be appropriately resolved on a motion to dismiss").

To prove that a patent is invalidated by the prior public sale of a product (the on-sale bar defense) an accused infringer must establish by clear and convincing evidence that (1) before the critical date, the product was the subject of a commercial offer for sale, and (2) the invention was ready for patenting. *See Pfaff v. Wells Elecs.,* Inc., 525 U.S. 55, 67 (1998). "Whether the on-sale bar applies is a question of law based on underlying ***factual findings***." *Meds. Co. v. Hospira, Inc*., 827 F.3d 1363, 1371 (Fed. Cir. 2016) (en banc).

V. ARGUMENT

It is undisputed that the Complaint adequately pleads Aerin's infringement of the Asserted Patents. Aerin's request that the Court adopt its disputed invalidity theory to summarily dismiss the Complaint at the pleading stage is unfounded and its Motion should be denied.

A. Aerin's Request For Summary Determination Of Anticipation Despite Contested Facts Is Improper

Aerin's Motion for a summary determination that the Asserted Patents are anticipated, before there has been any discovery, and with multiple contested issues of fact, should be denied. A claim may only be dismissed under Rule 12(b)(6) if, despite accepting all allegations of the Complaint as true, it nonetheless fails to state a claim upon which relief can be granted. *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 786 (3d Cir. 2016). Here, the Complaint pleads claims for infringement, and it is undisputed that Neurent's allegations as to how Aerin infringes each asserted claim are sufficient. *See* Complaint ¶¶42-135.

In this context, Aerin's Motion does not assert that Neurent has failed to plead claims of infringement, but rather asserts that the Complaint should be dismissed because Neurent has not "prove[d]" it will prevail at trial on an anticipation defense that Aerin has not yet even pleaded. *See, e.g.*, Aerin Br. 7-9, 14. At the pleading stage, however, "a plaintiff need not prove the validity of the patent to bring a claim for infringement." *Celanese*, 2021 WL 7209494, at *6. To the contrary, a patent is "presumed valid" at the pleading stage. *See id*. Aerin, not Neurent, bears the burden to prove anticipation by clear and convincing evidence, and anticipation due to the on-sale bar requires findings of fact. *Meds. Co*, 827 F.3d at 1371 ("Whether the on-sale bar applies is a question of law based on underlying factual findings."). Aerin tellingly cites no rule or case that would require a patent owner to preemptively "prove" validity in its complaint or a court to find the complaint insufficient under Rule 12(b)(6) if it did not.

Nonetheless, as further discussed *infra* § V(B), the Complaint contains allegations that—particularly when accepted as true—show that Aerin's on-sale bar defense is meritless, and, at least, confirm there are factual disputes. Courts, including in this district, have rejected motions to dismiss asserting invalidity under Rule 12(b)(6) where, as here, there has not been discovery

and there are factual disputes between the parties. *See, e.g.*, *Celanese*, 2021 WL 7209494, at *6 ("Issues regarding whether [defendant] used the allegedly infringing processes before the priority date of the Asserted Patents are factual in nature and cannot be appropriately resolved on a motion to dismiss."); *Belcher*, 379 F. Supp. 3d at n.5 (denying motion to dismiss because "Defendants' asserted defenses (i.e., anticipation, obviousness) appear to involve disputed facts…."); *Schlumberger Tech. Corp. v. BICO Drilling Tools*, Inc., 2018 WL 2059399, at *1-4 (S.D. Tex. May 3, 2018) (denying motion to dismiss because "teachings of the prior art patents are questions of fact, and the court finds it inappropriate to make such a factual finding at this stage"). This Court should do so here.

Aerin's cited cases are not relevant. Aerin Br. 9-11. In *Quantum Loyalty Sys., Inc. v. TPG Rewards, Inc.*, 2009 WL 5184350, at *8 (D. Del. Dec. 23, 2009) (R&R), unlike here, Magistrate Judge Thynge's report and recommendation found there was no dispute that the accused products were on sale prior to the critical date. Regardless, the report and recommendation was later modified to deny the motion to dismiss because it erred in the "identification of the product at issue" and there had not been "discovery on the issue of product identification." *Quantum Loyalty Sys., Inc. v. TPG Rewards, Inc.*, 2010 WL 1337621, at *1 (D. Del. Mar. 31, 2010) (modifying R&R). In *Curia IP Holdings, LLC v. Salix Pharms.*, Ltd., 2022 WL 3444005, at *3 (D.N.J. Aug. 17, 2022), there were likewise no allegations that the accused product was different from defendant's prior products that were on sale prior to the critical date. And in *FMC Techs., Inc. v. OneSubsea IP UK Ltd.*, 412 F. Supp. 3d 706, 714-15 (S.D. Tex. 2019), there was "competent summary judgment evidence" that there was a qualifying sale of a prior art product that was not disputed to be "materially different" from the accused product. Here, in contrast, and as further discussed below, Neurent unambiguously pleads that Aerin's First Generation System is materially

different from the accused Next Generation System and there are clear disputes of fact between the parties.

B. Accepting The Allegations Of The Complaint As True, The Asserted Patents Are Not Anticipated By Aerin's First Generation Product

Neurent's assertion that the Next Generation Stylus infringes cannot satisfy Aerin's burden to show by clear and convincing evidence that Aerin's First Generation Stylus anticipates because the Complaint alleges that the products are materially different. It is undisputed that Neurent does not accuse the First Generation Stylus of infringement. Aerin Br. 3-5. Rather, Neurent alleges infringement only by Aerin's Next Generation Stylus—which received FDA clearance and was launched after July 29, 2022, after the 2019 priority date of the Asserted Patents. Complaint ¶36; *see Pfaff*, 525 U.S. at 67 (on-sale bar applies to product on-sale or ready for patenting before priority date).

The Complaint alleges that the accused Next Generation RhinAer Stylus is materially different than the First Generation product.[3] It alleges Aerin made "modifications [that] 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," that Aerin "significantly changed the methods of use for the RhinAer System," Complaint ¶37, and that Aerin marketed the accused product as "next generation" and "NEW." *Id.* ¶38. The Complaint alleges these changes were "major," "significant," and "material[]." *Id.* ¶¶36-41. The Complaint also alleges that changes Aerin made to its 2022 device were in fact invented by Neurent by 2019. *Id.* In nearly 200 pages of claim charts, the Complaint identifies how features of the Next Generation Stylus, including for example, its ***new*** shape, size,

[3] In this context, Aerin's assertion that Neurent conceded a prior art sale exists, Aerin Br. 6-9, or made "self-defeating" allegations, *id.* 8, are divorced from the actual allegations of the Complaint.

and diameter, infringe the asserted claims. *See, e.g.*, *id*. pp. 16-75, 77-142; *see also* §V.C., *infra*.

In its Motion, Aerin disagrees with the Complaint, arguing that, in its view, "[t]he First Generation RhinAer Stylus … is the same as the Next Generation RhinAer Stylus that Neurent accuses of infringement in all respects relevant to Neurent's allegations." Aerin Br. 4. But Aerin's position is directly contrary to these allegations of the Complaint, which the Court must accept as true. *Celanese*, 2021 WL 7209494, at *2. Aerin's disagreement presents a disputed issue of fact, it is not a basis for dismissal. *See Belcher*, 379 F. Supp. 3d at 332-33, n.5; *Schlumberger*, 2018 WL 2059399, at *3-4.

Inogen, Inc. v. SeQual Techs., Inc., 2010 WL 11509109, at *8-9 (S.D. Cal. Apr. 28, 2010) is in accord. There, the court denied defendant's motion for summary judgment that a prior art product anticipated under the on-sale bar when changes were made to the product accused of infringement. The plaintiff alleged defendant's "Eclipse" product infringed its patents and defendant claimed that its pre-priority sale of an earlier-generation product, "OMNI," implicated the on-sale bar. *Id*. at *1, 8. The plaintiff disputed this, arguing that "common features between the two products do not make them the same device," and pointing to "differences between the OMNI and the Eclipse with regards to size, weight, maximum system pressure and sound." *Id*. The court concluded that "because [p]laintiff has shown several differences between OMNI and the Eclipse®…[the] [d]efendant failed to prove by clear and convincing evidence that the accused product was on sale [prior to the critical date]," and denied the defendant's motion for summary judgment. *Id*. at *9. The same factual disputes are present here.

In an attempt to overcome the Complaint's allegations, Aerin argues that the Court should simply "disregard" them. Aerin Br. 9-14. The Court should reject this gambit. First, Aerin faults the Complaint for not containing sufficient allegations to overcome Aerin's anticipation defense.

Aerin Br. 9-11. As an initial matter, Aerin cites no authority that a Complaint must preemptively and definitively prove, despite defendant bearing the burden, that the asserted claims are not anticipated. To the contrary, given that a patent is presumed valid, "a plaintiff need not prove the validity of the patent" in its complaint. *Celanese*, 2021 WL 7209494, at *6; *Belcher*, 379 F. Supp. 3d at 332-33, n.5.

Regardless, though not required, the Complaint does make allegations that would disprove or at least raise questions of fact regarding Aerin's anticipation defense. These allegations are not "conclusory" or mere "legal conclusions" as Aerin alleges. Aerin Br. 9-13. Instead, as discussed above, the Complaint (1) identifies specific technical differences between the products; (2) asserts infringement based on specific aspects of the accused product that were changed; and (3) alleges that the differences between the products are material.[4] Neurent supports each of these allegations with citation to relevant documents, including Aerin's own statements and characterizations. Particularly at the pleading stage, these allegations are more than sufficient to require denial of Aerin's motion. *See Celanese*, 2021 WL 7209494, at *6; *Inogen*, 2010 WL 11509109, at *9 (denying summary judgment of on-sale bar in view of fact dispute regarding alleged differences between products).

Second, Aerin argues that three paragraphs of the Complaint should be disregarded because they were plead "on information and belief." Aerin Br. 11-14 (citing Complaint ¶¶37, 38, 40). Aerin again is wrong. As a threshold matter, pleadings based "on information and belief" are routinely permitted. 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure

[4] In this respect, *Infineon Techs. AG v. Volterra Semiconductor*, 2013 WL 5366131, at *5 (N.D. Cal. July 31, 2013) and *FaceTec, Inc. v. iProov, Ltd.*, 2024 WL 4149868, at *3 (D. Nev. Sept. 10, 2024) are distinguishable. Those cases found that defendants could not argue two products were different for purposes of identifying a "representative" product if their differences were irrelevant to the infringement allegations at issue. Here, Neurent alleges relevant product differences.

§ 1224 (4th ed.) ("[A]llegations in this form have been held to be permissible, even after the *Twombly* and *Iqbal* decisions … [P]ermitting allegations on information and belief is a practical necessity." (collecting cases)). Indeed "on information and belief" allegations are typically raised in patent infringement lawsuits where, like here, the allegations are directed to the defendant's product and technical information. *See, e.g.*, *DSM IP Assets, B.V. v. Honeywell Int'l, Inc.*, 700 F. Supp. 3d 189, 195-96 (D. Del. 2023) (declining to dismiss a claim of direct infringement that alleged facts "on information and belief" related to the defendant's methods and products).

Paragraphs 37, 38, and 40 of the Complaint (and surrounding paragraphs) make allegations regarding aspects of Aerin's device, statements, and beliefs, all of which are in Aerin's possession. Contrary to Aerin's suggestion, Aerin Br. 11-14, these paragraphs do not merely state conclusions but make allegations with citation to specific publicly available examples. *See* Complaint ¶¶37-40 (citing Aerin marketing materials). These allegations also allow, however, for the fact that although Aerin's RhinAer device may be commercially available, Aerin Br. 12-13, Aerin also has additional, confidential technical information that may even further support Neurent's allegations (such as non-public product and method specifications and non-public information about the nature, purpose, and extent of changes Aerin made to the First Generation RhinAer System). Aerin cites no authority that it is improper to plead allegations that may depend on a defendant's confidential information on information and belief.

Nor does Neurent's reference to its information and belief somehow render the specific factual allegations of the Complaint insufficient. Aerin Br. 11-12. Again, as detailed above, Neurent pleaded—across over 200 pages—detailed allegations based on the public information available, including allegations of material differences between Aerin's First and Next Generation

Systems and identification of how those new aspects of Aerin's Next Generation System infringe the asserted claims.

The Complaint is thus similar to *McDermott v. Clondalkin Grp.*, Aerin Br. 11-12, because the Complaint "explain[s] how" Aerin is liable. *McDermott v. Clondalkin Grp., Inc.*, 649 F. App'x 263, 268 (3d Cir. 2016) (finding use of "information and belief" proper where the complaint explained how defendant breached the asserted contract). The present situation is unlike *Reklam v. Bellator Sport Worldwide LLC*, 2017 WL 5172397, at *4 (D. Del. Nov. 8, 2017), where the plaintiff had a contractual right "to inspect [defendant's] books and records at any time to confirm" the allegations pled on information and belief. Here, Aerin plainly has notice of Neurent's position based on the Complaint, which confirms its motion to dismiss should be denied. *See, e.g.*, *Acera Surgical, Inc. v. Nanofiber Sols., LLC*, 2021 WL 3187374, at *3 (D. Del. July 28, 2021) (denying motion to dismiss and finding "information and belief" allegations sufficient to give defendant notice of allegations regarding the accused technology); *Nalco*, 883 F.3d at 1350 (A complaint sufficiently pleads patent infringement when it puts the defendant "on notice of what activity ... is being accused of infringement.").

C. Aerin Has Not Met Its Burden To Prove Anticipation

As discussed above, the Court should deny the Motion, which raises fact disputes inconsistent with the Complaint. But even if the Court were to consider the merits, the Motion falls well short of establishing anticipation by clear and convincing evidence.

First, Aerin's Motion is not supported by proper evidence. Contrary to Aerin's contention, Aerin Br. nn.1-6, the Court may not reach beyond the Complaint to take "judicial notice" of exhibits, including hundreds of pages of contentions in claim charts, to resolve disputed matters of fact in Aerin's favor. *See, e.g. Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 257 (E.D. Pa. 2020) ("The Third Circuit has cautioned that taking judicial notice 'should be done sparingly

at the pleadings stage. Only in the clearest of cases should a district court reach outside the pleadings for facts necessary to resolve a case at that point.'").

As a threshold matter, Aerin has not shown that each document it attaches is "not subject to reasonable dispute" and is either "(1) generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot be reasonably questioned." Fed. R. Evid. 201(b). ***None*** of Aerin's exhibits is authenticated or was submitted with an authenticating declaration. Three (Exs. C-E) are ***unauthenticated, confidential*** Aerin documents on which Neurent has had no chance to take discovery. Three (Exs. G-I) are claim charts reflecting attorney argument that contradicts the allegations of the Complaint and are thus plainly subject to "reasonable dispute."

Aerin's justifications for seeking judicial notice are insufficient. Aerin argues that the Court may take judicial notice of its exhibits because Aerin put certain of them "in the record of [a] related case" in parallel to a similar contested motion. Aerin Br. nn. 1-4. Aerin omits, however, that the Court did not consider or reach conclusions regarding those documents, including their accuracy. "The Court's task at the motion to dismiss stage is not to weigh the evidence—even the evidence that was presented to the district court in [a previous] case." *IOENGINE, LLC v. PayPal Holdings, Inc.*, 2019 WL 2121395, at *3 (D. Del. May 15, 2019) ("Evidence submitted in a prior case and facts adjudicated in that case are not subject to judicial notice and are not otherwise admissible on a motion to dismiss…."). Here, "[t]aking judicial notice of the truth of the contents of a filing from a related action" as Aerin urges, would "breach, the boundaries of proper judicial notice." *Werner v. Werner*, 267 F.3d 288, 295 (3rd Cir. 2001). Nor can Aerin justify judicial notice of claim charts containing attorney argument simply because they are "responsive to … charts … in the Complaint." Aerin Br. n.5; *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014)

(affidavits defendants attached to their motion to dismiss "clearly may not be considered"). The Court cannot take judicial notice of disputed facts. *UCB, Inc. v. Actavis Labs*, 2021 WL 1880993, at *18 n.13 (D. Del. Mar. 26, 2021) (declining to take judicial notice and "rely on [a party's] characterization of specific technical disclosures [in a patent publication] to assess" the asserted patent's validity); *Ryanair DAC v. Booking Holdings Inc.*, 636 F. Supp. 3d 490, 498 (D. Del. 2022) (declining to take judicial notice of documents submitted in another proceeding to determine whether a company was "capable of ascertaining who visits its website").

Regardless, even if the Court were to take judicial notice of the existence of the ***documents*** Aerin submitted, it may not take judicial notice of Aerin's disputed ***factual allegations***. Aerin Br. 4-5. Judicial notice may only be taken of facts "not subject to reasonable dispute." Fed. R. Evid. 201(b). Facts "may only be judicially noticed to show 'what was in the public realm at the time, not whether the contents of documents are true.'" *Sturgeon*, 438 F. Supp. 3d at 257. Thus, Aerin's extraordinary request that the Court resolve ***the ultimate factual issue underlying its defense*** in its favor, Aerin Br. 4-5, based on judicial notice of exhibits outside the Complaint and contrary to the Complaint's allegations must be rejected. *See, e.g.*, *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018) ("[U]nscrupulous use of extrinsic documents to resolve competing theories against the complaint risks premature dismissals of plausible claims that may turn out to be valid after discovery."); *Betak v. Miftakhov*, 2019 WL 5684523, at *5-6 (N.D. Cal. Nov. 1, 2019) (declining to take judicial notice of contents of prior art patent applications); *CODA Dev. S.R.O. v. Goodyear Tire & Rubber Co.*, 916 F.3d 1350, 1360 (Fed. Cir. 2019) (district erroneously took judicial notice that publication disclosed a trade secret). Thus, the Court cannot—without at least giving Neurent an opportunity to take or provide discovery—adopt Aerin's disputed contentions that "[t]he First Generation RhinAer Stylus … is the same as the Next Generation

RhinAer Stylus" or that "the methods of using RhinAer … are the same." Aerin Br. 4; *Thompson v. City of Wilmington*, 2023 WL 3318483, at *5 (D. Del. May 9, 2023) (denying a motion to dismiss that relied on documents beyond judicial notice because "discovery has not been conducted"). This is particularly the case because, as discussed *supra*, those contentions are contrary to the Complaint and raise disputed issues of fact. It is unsurprising that Aerin cites no authority that would justify such a request.[5]

Second, even with its improper exhibits, Aerin has not met its burden to show by clear and convincing evidence that the First Generation RhinAer Stylus is the same in all material respects as the accused Next Generation RhinAer Stylus. To establish an on-sale bar, a defendant must prove that a product embodying every limitation of the claimed invention was on sale before the priority date. *See Pfaff*, 525 U.S. 55, 67. In its brief, Aerin repeatedly alleges that the First Generation and Next Generation products are "the same," or changes between them were "minor," Aerin Br. 4-5, but does not support those conclusory allegations with relevant evidence.[6]

For example, Aerin's reliance on an FDA-submitted 510(k) document (Ex. K) to summarily assert differences between its devices are "minor," Aerin Br. 5, ignores that "FDA equivalence is irrelevant to patent law because it involves fundamentally different inquiries." *Johns Hopkins Univ. v. Datascope*, 543 F.3d 1342, 1349 n.3 (Fed. Cir. 2008). Ex. K does not address the specific differences between the products relevant to the limitations of the patents.

[5] Aerin's cited cases, *see* Aerin Br. nn. 1-6, generally describe the judicial notice doctrine; none supports taking judicial notice of disputed factual or legal contentions. None involved taking "judicial notice" of disputed similarities or differences between products or their "methods of use."

[6] The Motion omits that the United States Patent and Trademark Office issued the Asserted Patents despite having received documents identifying the First Generation RhinAer Stylus. *See* D.I. 1 at Ex 1 at Cover ('973 patent listing "Aerin Medical FDA 510(k) Summaries" from between 2016 and 2020); Ex. 2 at Cover (same for '974 patent); Ex. 3 at Cover (same for '889 patent).

Neither do Aerin's claim charts. For example, claim 1 of the asserted '973 patent requires, *inter alia*, electrodes "oriented at an angle less than 90 degrees relative to the shaft for the delivery of RF energy," Complaint pp. 17-18, and at least one claim of each of the three Asserted Patents includes a similar "less than 90 degrees" limitation. Complaint pp. 63-64 ('973 patent, cl. 16.a), 100-101 ('974 patent, cl. 5.b), pp. 111-112 ('974 patent, cl. 6.b), pp. 114-115 ('974 patent, cl. 7.b), pp. 186-87 ('889 patent, 15.b), pp. 196-97 ('889 patent, cl. 16.b), pp. 199-200 ('889 patent, cl. 17.b). Aerin's Motion and claim charts ***do not explain,*** let alone ***prove*** that the First Generation RhinAer Stylus purportedly embodies these claim limitations. *See* Ex. G at 2-12 ('973 patent, cl. 1.a); Ex. H at 36-39 ('974 patent, cl. 5.b), 54-57 ('974 patent, cl. 6.b), 59-61 ('974 patent, cl. 7.b); Ex. I at 64-67 ('889 patent, 15.b), 82-85 ('889 patent, cl. 16.b), 87-90 ('889 patent, cl. 17.b).

In fact, as shown in Aerin's own claim chart and in the images below, the First Generation RhinAer Stylus does ***not*** have "electrodes … oriented at an angle less than 90 degrees relative to the shaft" because the electrodes are oriented perpendicular to (i.e., at 90 degrees to) the shaft.

See id.; Complaint ¶38 (First Generation). In contrast, the treatment tip of the Next Generation RhinAer Stylus, was re-designed to angle electrodes "at an angle less than 90 degrees relative to the shaft," Complaint pp. 17-18 ('973 patent, cl. 1.a), which "facilitates tissue apposition," Ex. K.

Complaint ¶38 (Next Generation). These changes, which materially distinguish the First and Next Generation Systems related to the angle limitations of the Asserted Patents, are detailed in the same FDA document Aerin attaches to its Motion, *see* Ex. K at Device Description. They disprove Aerin's arguments, or at the very least raise questions of fact that require denial of Aerin's Motion. *See Inogen*, 2010 WL 11509109, at *8-9 (differences described in 510(k) precluded summary judgment that two products were the same for on-sale bar).

As a second (non-limiting) example, claim 1 of the '974 patent requires "at least one portion of the multi-electrode end effector comprises a diameter that is larger than a diameter of the shaft." Complaint pp. 78-79. Aerin's claim chart again contains ***no explanation or proof*** of how the First Generation RhinAer Stylus purportedly embodied this claim limitation. Ex. H at 2-13. To the contrary, as Aerin explained to the FDA, "[t]he Stylus shaft diameter has been reduced," Ex. K, and the First Generation RhinAer Stylus's end effector (top, grey above) did not "comprise[] a diameter that is larger than a diameter of the shaft," whereas the Next Generation RhinAer Stylus's (bottom) does, Complaint ¶38. Aerin's claim charts show the same. Ex. H at 2-13. Again, these distinctions defeat Aerin's anticipation argument or at least raise issues of fact that require denial of its Motion.

Aerin's conclusory arguments regarding alleged similarity of the First and Next Generation RhinAer devices are insufficient to sustain its burden, and the Court should deny its Motion.

VI. CONCLUSION

The Court should therefore deny Aerin's Motion. If the Court grants the Motion, Neurent respectfully requests leave to amend, as Aerin has not argued or shown amendment would be futile.

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December 9, 2024

CERTIFICATE OF SERVICE

I hereby certify that on December 9, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 9, 2024, upon the following in the manner indicated:

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