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**

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

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I. Aerin Argued That Neurent Failed to Adequately Plead Infringement

Neurent repeatedly and incorrectly argues that Aerin failed to contest the sufficiency of Neurent's infringement allegations. For example, Neurent argues that "Aerin's Motion does not dispute Neurent adequately pleaded that Aerin infringes the Asserted Patents" and "Aerin's Motion does not assert that Neurent has failed to plead claims of infringement." D.I. 31 at 1, 7 (emphasis removed). Neurent apparently overlooks the entire section of Aerin's motion entitled "Neurent Failed to State a Claim of Infringement." D.I. 20 at 14-15. There, Aerin argued that "Neurent failed to state a proper claim for infringement, so the Complaint should . . . be dismissed for that reason." *Id.* at 14; *see also id.* (arguing that Neurent's "claim for infringement [is] deficient"). Neurent's argument that Aerin does not dispute the sufficiency of Neurent's infringement allegation is belied by clear arguments in Aerin's brief such as, "Neurent has, therefore, failed to plead a plausible claim of infringement" and "Neurent has failed to adequately plead infringement." *Id*. at 1, 6.

Neurent's response reveals a deeper misunderstanding of Aerin's arguments for dismissal. First, Aerin argues that Neurent has failed to state a claim upon which relief can be granted because if Neurent's allegation that Aerin's RhinAer® infringes the Asserted Patents is true, then the RhinAer® also anticipates the Asserted Patents because it was on sale and sold before the Asserted Patents' priority date. In other words, "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." *Quantum Loyalty Sys., Inc. v. TPG Rewards, Inc.*, No. CIVA 09-022-SLR/MPT, 2009 WL 5184350, at *8 (D. Del. Dec. 23, 2009), (quoting *IXYS Corp. v. Advanced Power Tech., Inc.*, No. C 02-03942 MHP, 2004 WL 540513, at *5 (N.D. Cal. Mar. 18, 2004), *R. & R. adopted as modified*, 2010 WL 1337621 (D. Del. Mar. 31, 2010). Second, Aerin argues that Neurent failed to state a claim of infringement. 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. The Complaint identifies some "modifications" to the Next Generation RhinAer® Stylus but does not explain those differences, let alone explain why they are material. *Id.* Because of this and Neurent's failure to sufficiently plead material differences between the First Generation and Next Generation RhinAer®, its infringement claim is deficient and warrants dismissal. *IXYS*, 2004 WL 540513, at *6 (explaining that where infringement allegation required "prov[ing] infringement of devices that were on sale before the respective critical dates," plaintiff "held no viable causes of action for infringement") (citing *Evans Cooling Sys., Inc. v. Gen. Motors Corp.*, 125 F.3d 1448, 1451 (Fed. Cir. 1997) and *Vanmoor v. Wal-Mart Stores, Inc.*, 201 F.3d 1363, 1366 (Fed. Cir. 2000)).

II. Aerin Met Its Burden of Proving Invalidity

Neurent repeatedly accuses Aerin of flipping the burden of proof and requiring Neurent to prove validity at the pleadings stage, but Aerin has done no such thing. In fact, Aerin clearly owned its burden, stating in its opening brief that "[t]o prevail on this motion, Aerin has the burden [of] showing that the Asserted Patents are invalid." D.I. 20 at 7. Aerin never attempted to obfuscate or flip this burden. Rather, Aerin argued that *Neurent's allegations of infringement* satisfy *Aerin's burden*. D.I. 20 at 7-8. This concept is well-established in Federal Circuit law. *See, e.g.*, *Evans Cooling*, 125 F.3d at 1451 (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 v. Wells Elecs., Inc.*, 525 U.S. 55 (1998); *Vanmoor*, 201 F.3d at 1366 (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 fails to address, much less distinguish or dispute Aerin's reliance on *Evans Cooling* or *Vanmoor* in its opposition. *See* D.I. 31.

In the Complaint, Neurent made a conclusory statement on "information and belief" that the RhinAer® that was sold prior to the priority date of the Asserted Patents is "materially different" than the RhinAer® it accuses of infringement. D.I. 1, ¶ 37. As discussed in Section IV below, Neurent did not provide sufficient factual allegations that could support its conclusory statement that there are material differences. *See id.* Even with Neurent's deficient pleading of material differences, Aerin went further to prove invalidity by submitting claim charts showing that the RhinAer® with the First Generation RhinAer® Stylus anticipates under Neurent's theory that the RhinAer® with the Next Generation RhinAer® Stylus infringes. D.I. 20-2, Exs. G-I. Aerin was able to show that the First Generation RhinAer® Stylus had the same relevant features as the Next Generation RhinAer® Stylus that Neurent identified in its infringement charts. *See id.* Contrary to Neurent's assertion otherwise, D.I. 31 at 16, Aerin did establish that First Generation RhinAer® Stylus is "the same in all material respects" as the Next Generation RhinAer® Stylus.

Aerin's claim charts show that if Neurent's infringement allegations that the RhinAer® with the Next Generation RhinAer® Stylus infringes are accepted as true, then the RhinAer® with the First Generation RhinAer® Stylus anticipates the Asserted Patents. D.I. 20-2, Exs. G-I. In response, Neurent argues that the Court should decline to consider Aerin's charts. D.I. 31 at 14-16. But the Court may consider Aerin's charts, the first two columns of which Neurent included in its complaint and the third column of which includes excerpts of documents that 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; *Creamer v. Hicks*, 61 F. App'x 121 (5th Cir. 2003) ("[I]n deciding a

motion to dismiss . . . [a] judge may take judicial notice of the record in a prior related proceeding over which [they] presided." (quoting *Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1017 (5th Cir. 1996))); *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.").

III. Dismissal is Appropriate

Neurent suggests that it is inappropriate to dismiss a complaint under Rule 12(b)(6) based on invalidity. D.I. 31 at 7-8. But Neurent cites no authority for such a categorical prohibition, and dismissal on this basis is exactly what the courts did in *Quantum Loyalty Systems*, 2009 WL 5184350, at *8 and *Curia IP Holdings, LLC v. Salix Pharmaceuticals, Ltd.*, No. CV-2119293 (ES) (JRA), 2022 WL 3444005, at *2-3 (D.N.J. Aug. 17, 2022).

Neurent then argues that dismissal would be inappropriate because Neurent pleaded that the First Generation RhinAer® Stylus is "materially different" than the Next Generation RhinAer® Stylus. D.I. 31 at 8-9. As Aerin explained in its motion, D.I. 20 at 9-14, and addresses further in Sections IV and V below, Neurent's assertion that the devices are "materially different" is conclusory without sufficient supporting factual allegations in the Complaint, and Neurent's reliance on information and belief does not cure the deficiency in the Complaint.

Neurent has, therefore, failed to adequately plead *material* differences. And the existence of immaterial differences is insufficient to survive Aerin's motion. *See, e.g.*, *BroadSoft, Inc. v. CallWave Commc'ns, LLC*, 282 F. Supp. 3d 771, 792 (D. Del. 2017) (granting motion for summary judgment of invalidity where movant demonstrated "that (1) the relevant features were publicly known and on sale in prior art versions of BroadWorks for purposes of § 102, and (2) the relevant features were materially identical in BroadWorks Anywhere and the prior art BroadWorks"); *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]"); *Cummings v. Adidas USA*, 716 F. Supp. 2d 323, 333 (S.D.N.Y. 2010) (granting motion for summary judgment of invalidity where movant "provided an abundance of evidence that the [product] that was offered for commercial sale and ready for patenting is the very same shoe plaintiffs accuse of infringement").

Neurent's reliance on *Inogen, Inc. v. SeQual Technologies, Inc.*, No. 09-2391-H (JMA), 2010 WL 11509109, at *9 (S.D. Cal. Apr. 28, 2010) is misplaced. D.I. 31 at 10. In *Inogen*, the court denied summary judgment of invalidity where the document showing the alleged offer for sale was for a product named OMNI, not the accused Eclipse, *and, importantly*, where the plaintiff had shown material differences between the OMNI and the Eclipse. *See* 2010 WL 11509109, at *9. Here, in contrast, the name of the product sold before the critical date, the RhinAer®, is the same as the accused product *and* Neurent failed to adequately plead material differences between the First Generation RhinAer® Stylus and the Next Generation RhinAer® Stylus.

IV. Neurent's Conclusory Allegations About Differences Are Not Material

Neurent argues that its Complaint "at least raise[s] questions of fact" regarding Aerin's anticipation defense because, according to Neurent, "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." D.I. 31 at 11. Neurent is incorrect on all counts. First, Neurent's Complaint merely lists features of the RhinAer® Stylus that have allegedly changed. It does not provide factual support for any of those alleged changes being material to the claims. Second, Neurent only asserts infringement based on the specific alleged changed aspects via attorney argument in its opposition brief, not in

its Complaint. Third, Neurent fails to explain how the alleged differences are relevant to the claim limitations of the Asserted Patents, rendering its allegations regarding the materiality of the differences between the First and Next Generation RhinAer® Stylus conclusory.

Neurent argues that its Complaint "identifies specific technical differences between the products." *Id*. But the alleged technical differences Neurent relies on are far from "specific." Rather, Neurent generally identifies features that differ between the products, including "shape, size, diameter, power, treatment tip, and temperature to which target tissue is heated," D.I. 1, ¶ 37, and jumps to the conclusory and unsupported assertion that Aerin "significantly changed the methods of use for the RhinAer System." D.I. 31 at 9. Neurent does not identify, describe, or provide any factual allegations about what those changes were or how they allegedly altered the claimed methods of use of the RhinAer®.

Neurent argues that its Complaint "asserts infringement based on specific aspects of the accused product that were changed." D.I. 31 at 11. Neurent's claim charts do not explain how the "new" features are relevant to the claim limitations of the Asserted Patents. Rather, Neurent's claim charts merely recite the claim language and cite Aerin documents. *See* D.I. 1, ¶¶ 36-131; *cf.* D.I. 20-2, Exs. G-I. In support of its motion, Aerin submitted updated versions of Neurent's claim charts comparing the accused Next Generation RhinAer® Stylus to the First Generation RhinAer® Stylus. D.I. 20-2, Exs. G-I. Neurent argues that Aerin's updated charts, which follow Neurent's style and substance, "***do not explain***, let alone ***prove*** that the First Generation RhinAer Stylus purportedly embodies the claim limitations." D.I. 31 at 17. But Aerin's charts explain how the claims are satisfied by the First Generation RhinAer® Stylus under Neurent's infringement theory to the same degree that Neurent's charts allegedly do so for the Next Generation RhinAer® Stylus.

Neurent's first attempt at "assert[ing] infringement based on specific aspects of the accused

product that were changed" to allege materiality comes in the form of attorney argument in its opposition brief, not in the Complaint. *See id*. at 4-5, 17-18. For the first time in its opposition, Neurent attempts to tie the allegedly "new" features of the Next Generation RhinAer® Stylus to the claim language of the Asserted Patents in an effort to explain how the Next Generation RhinAer® allegedly infringes without the First Generation RhinAer® invalidating the patents. Specifically, Neurent identified "the angle of the electrodes relative to the shaft . . . and the shaft's thickness relative to the treatment tip . . ." in its opposition as alleged material differences. *Id*. at 4. In support, Neurent cites Paragraph 38 of the Complaint, but that does not identify either of these differences, much less allege or explain how they are material to the claims. D.I. 1, ¶ 38.

For the '973 patent, Neurent argues in its opposition that 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" and that the Next Generation RhinAer® Stylus does have "electrodes 'at an angle less than 90 degrees relative to the shaft.'" D.I. 31 at 17. Neurent, however, did not plead this distinction in the Complaint, so this is merely attorney argument raised in the opposition brief, which is insufficient to survive a motion to dismiss. For the '974 patent, Neurent attempts, again for the very first time in its opposition, to show the Next Generation RhinAer® Stylus materially differs from the First Generation RhinAer® Stylus by citing a discussion of the shaft diameter in Aerin's FDA 510(k) document. *Id*. at 18 (citing D.I. 20-2, Ex. K). But again, Neurent did not plead this alleged difference or the materiality of it in the Complaint. Neurent's belated attempts to explain how the Next Generation RhinAer® Stylus infringes based on allegedly changed features from the First Generation RhinAer® Stylus were not pleaded in the Complaint and should be disregarded.

An argument in Neurent's opposition brief undermines Neurent's reliance on differences

generally identified in a 510(k) as allegedly "material" differences. Aerin argued in its motion that the 510(k) for the Next Generation RhinAer® showed that the changes from the First Generation to the Next Generation RhinAer® Stylus—primarily, "[s]haft shape," "[s]haft diameter," "[p]ower," "[t]reatment [t]ip," and "[t]issue temperature"—were minor and immaterial. D.I. 20 at 5 (citing D.I. 20-2, Ex. K at 6). In response, Neurent argued that Aerin's FDA 510(k) document "does not address the *specific differences* between the products relevant to the limitations of the patents." D.I. 31 at 16 (emphasis added) (citing D.I. 20-2, Ex. K). But this is exactly what the Complaint suffers from. The Complaint fails to plead factual support for the allegedly relevant differences and how those differences are material to infringement. Neurent identified several changes in the Complaint, including "shape, size, diameter, power, treatment tip and the temperature to which target tissue is heated" without ever explaining how any differences in those features are relevant to the claim limitations. Yet these are the very same features, other than size, that Neurent argues do "not address the specific differences between the products relevant to the limitations of the patents" when noted by Aerin. D.I. 31 at 16.

Rather than pleading how the alleged changes are relevant to its infringement claims or showing how the changes between the First and Next Generation RhinAer® are material, Neurent's Complaint relies on characterizations from Aerin's marketing materials. *See* D.I. 1, ¶¶ 38-40; D.I. 31 at 4-5, 9. But whether Aerin described the Next Generation RhinAer® Stylus as "new," as "having 'enhancements [that] will be well-received,'" or thought it could increase its revenue or profits has no bearing on whether the changes to the RhinAer® Stylus are material to the claims.

V. Pleading Material Differences on "Information and Belief" Was Improper

Neurent repeatedly argues that its pleading "on information and belief" was proper but fails to apply, much less satisfy, the Third Circuit test laid out in *McDermott v. Clondalkin Group*, 649 F. App'x 263, 267-68 (3d Cir. 2016). In that case, the Third Circuit held that 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.*'" *Id.* at 267-68 (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002)).

As discussed above in Section IV, Neurent's general allegations regarding the alleged differences between the First and Next Generation RhinAer® Stylus fail to show those differences are material to the question of infringement. Instead, Neurent pleaded those allegations of materiality on information and belief. In defense of its on information and belief pleading, Neurent argues that "[p]aragraphs 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." D.I. 31 at 12. But Neurent relied on the First Generation RhinAer® Stylus as the predicate device for Neurent's NEUROMARK® System. D.I. 20-2, Ex. J. And Neurent's Complaint includes close-up photographs of the Next Generation RhinAer® Stylus, showing that it at least had access to it. *E.g.*, D.I. 1, ¶ 46. Neurent also relied on publicly available information, including Aerin's Instruction for Use for the Next Generation RhinAer® Stylus and the Food and Drug Administration's clearance for Aerin's 510(k) for the Next Generation RhinAer® Stylus. *See* D.I. 1, ¶¶ 37-41. Despite being in possession of the requisite information, Neurent chose to plead its allegations of material differences on information and belief.

Neurent concedes that "Aerin's RhinAer device may be commercially available," D.I. 31 at 12-13, but argues that pleading on information and belief was nevertheless appropriate because "Aerin also has additional, confidential technical information that *may* even further support Neurent's allegations . . . ." D.I. 31 at 12 (emphasis added). But pleading on "information and

belief" is not a magic wand that can be waived to replace an inadequate pre-suit investigation or cure a deficient claim. Rather, Neurent must show that "the requisite factual information is *peculiarly* within the defendant's knowledge or control." *McDermott*, 649 F. App'x 267-68. Neurent's Complaint reveals it had access to the Next Generation RhinAer® Stylus and relied on various public documents regarding its functionality, undermining its current argument that the requisite information is peculiarly in Aerin's possession. Neurent's expression of hope that Aerin's additional information "*may*" support its claim, D.I. 31 at 12, reveals a fishing expedition.

Neurent also contends that "'on information and belief' allegations are typically raised in patent infringement lawsuits where . . . the allegations are directed to the defendant's product and technical information." *Id*. Neurent cites *DSM IP Assets, B.V. v. Honeywell International, Inc.*, 700 F. Supp. 3d 189, 195-96 (D. Del. 2023), and argues that the court "declin[ed] to dismiss a claim of direct infringement that alleged facts 'on information and belief' related to the defendant's methods and products." *Id*. Neurent's reliance on *DSM* is misplaced because the limitations pleaded on information and belief in *DSM* were "relate[d] to limitations that address the *process for manufacturing* the accused products" and "*details regarding the composition* of [defendant's] products that may be difficult to ascertain by testing the finished products, but which would be readily known to the manufacturer." *Id.* at 197 (emphases added). Here, in contrast, the material Neurent pleaded on information and belief was related to the design and functionality of the RhinAer®, which is readily determined from public information in Neurent's possession and that Neurent relied on in the Complaint.

Neurent's allegations of materiality pleaded on information and belief despite possessing the requisite factual information was improper, and the Court should dismiss Neurent's speculative and factually unsupported claims.

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