

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

ROUTE 92 MEDICAL, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 25-986-CFC-CJB
	)	
BALT USA LLC,	)	
	)	
Defendant.	)	

REPORT AND RECOMMENDATION

Presently before the Court is Defendant Balt USA LLC’s (“Defendant”) motion to dismiss Plaintiff Route 92 Medical, Inc.’s (“Plaintiff”) operative First Amended Complaint (“FAC”), filed pursuant to Federal Rule of Civil Procedure 12(b)(6) (the “Motion”). (D.I. 20) The Court has reviewed the Motion, the briefing related thereto, (D.I. 21; D.I. 28; D.I. 34), and the applicable legal standard of review for motions filed pursuant to Rule 12(b)(6), *see Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009).¹ Having done so, the Court hereby RECOMMENDS that the Motion be GRANTED in the manner and for the reasons that follow:

1. Plaintiff’s FAC asserts that Defendant directly, indirectly and willfully infringes United States Patent Nos. 11,229,770 (the “9770 patent”), 11,793,972 (the “972 patent”), 11,806,032 (the “032 patent”), 11,925,770 (the “5770 patent”) and 12,343,036 (the “036 patent” and collectively with the other patents, the “asserted patents”). (D.I. 11 at ¶¶ 16, 30, 39-41, 46, 52-53, 58, 81-83, 88, 99-101) Plaintiff accuses Defendant’s Carrier™ Delivery Catheter (“Carrier”), Raptor™ Aspiration Catheter (“Raptor”) and HYBRID™ Guidewire (“Hybrid” and

¹ This case was referred to the Court by Chief United States District Judge Colm F. Connolly on January 12, 2026. (D.I. 49) The instant Motion was filed on November 4, 2025, (D.I. 20), and briefing was completed on December 9, 2025, (D.I. 34).

collectively with the Carrier and Raptor, the “accused products”) of infringement. (*Id.* at ¶ 22)

2. Defendant’s Motion challenges all claims of the FAC. (D.I. 21 at 1; D.I. 34 at 1)

3. The Court takes up Plaintiff’s claims of indirect infringement first. In order to successfully plead both induced and contributory infringement, a plaintiff must plausibly allege that, *inter alia*, the defendant had knowledge of the asserted patents (as well as knowledge that the acts at issue constituted patent infringement). *See, e.g., Portus Sing. Pte Ltd v. Schneider Elec. USA, Inc.*, Civil Action No. 23-977-JLH-CJB, 2025 WL 437055, at *9 (D. Del. Feb. 7, 2025). Here, Plaintiff concedes that its allegations relating to Defendant’s pre-suit and post-suit knowledge of the patents are insufficient under the precedent of the District Judge assigned to this matter (Chief Judge Connolly); Plaintiff acknowledges that those claims will thus ultimately be dismissed here at least on those grounds, and asks that dismissal be without prejudice. (D.I. 28 at 4, 23-25) Therefore, the Court recommends that the Motion as to Plaintiff’s indirect infringement claims be GRANTED. And in line with Plaintiff’s request (and Defendant’s silence on that point in reply), the Court recommends that such claims be dismissed without prejudice. (*Id.*; D.I. 34 at 1) It seems possible that Plaintiff might be able to plead the missing allegations with respect to pre-suit knowledge in a further amended complaint, and Federal Rule of Civil Procedure 15 admonishes that leave to amend should be freely permitted “when justice so requires.” Fed. R. Civ. P. 15(a)(2).²

4. The Court now turns to the primary assertion in Defendant’s Motion, which

² If Plaintiff does file a further amended complaint in the future, and includes indirect infringement allegations, it should be mindful of Defendant’s other assertions as to why Plaintiff’s indirect infringement claims were purportedly insufficiently pleaded. (D.I. 21 at 13-18)

concerns direct infringement (an issue, of course, that also implicates Plaintiff's indirect infringement claims, since such claims require pleading direct infringement by a third party). *See, e.g., Varian Med. Sys., Inc. v. Elekta AB*, Civil Action No. 15-871-LPS, 2016 WL 3748772, at *3 (D. Del. July 12, 2016), *report and recommendation adopted*, 2016 WL 9307500 (D. Del. Dec. 22, 2016). In order to plead direct infringement, a plaintiff must recite "some factual allegations that, when taken as true, articulate why it is plausible that the accused product infringes the patent claim." *Bot M8 LLC v. Sony Corp. of Am.*, 4 F.4th 1342, 1353 (Fed. Cir. 2021). A plaintiff therefore cannot assert a plausible claim for infringement by "reciting the claim elements and merely concluding that the accused product has those elements." *Id.* That said, a plaintiff need not necessarily "plead infringement on an element-by-element basis." *Id.* at 1352. In the end, the pleading must give the defendant "fair notice of what the . . . claim is and the ground upon which it rests." *Disc Disease Sols. Inc. v. VGH Sols., Inc.*, 888 F.3d 1256, 1260 (Fed. Cir. 2018) (internal quotation marks and citation omitted).

5. Defendant argues that all of Plaintiff's direct infringement allegations must be dismissed because: (a) all of the asserted patents contain, *inter alia*, limitations claiming physical properties (i.e., bending force, polymer composition, hardness and flexibility), and yet (b) Plaintiff simply alleges that certain of these limitations are met "on information and belief" without alleging *facts* that make it plausible that the accused products include the claimed physical properties. (D.I. 21 at 1, 9)

6. In taking up Defendant's arguments, the Court begins with asserted claim 1 of the 9770 and 5770 patents, respectively; those claims recite five bending forces that are then used to determine four flexibility slopes, and they note that the ratio of two particular slopes (i.e., the

ratio of the “third flexibility scope” to the “average tip portion flexibility slope”) is “less than about 25.” (D.I. 11, ex. 3 at cols. 80:24-81:2; *id.*, ex. 6 at col. 80:15-56; *see also* D.I. 21 at 4, 10 (Defendant focusing on these claim limitations in its opening brief in support of the Motion with respect to the 9770 and 5770 patents)) As to these claim requirements, the FAC: (a) identifies points on the Carrier that have bending forces; (b) alleges that the Carrier is a “variable stiffness, composite catheter”; and (c) asserts that “[o]n information and belief” the Carrier has five bending forces, that the differences between these bending forces equals the recited flexibility slopes, and that the ratio of the two particular slopes referenced above is less than 25. (D.I. 11 at ¶¶ 35-37 (9770 patent) (internal quotation marks and citation omitted); *id.* at ¶¶ 77-79 (5770 patent)) Defendant contends that these allegations are insufficient because “alleging where to measure bending forces, and that those forces may vary due to ‘variable stiffness,’ fails to address whether the claim limitations are met—e.g., *whether the claimed ratio of flexibility slopes determined using the measured bending forces ‘is less than about 25.’*” (D.I. 21 at 10 (emphasis added))

7. The United States Court of Appeals for the Third Circuit has explained that a plaintiff may plead on “information and belief” when “it can be shown that the requisite factual information is peculiarly within the defendant’s knowledge or control[,]” as long as such allegations are not “boilerplate and conclusory” and if “[p]laintiffs . . . accompany their legal theory with factual allegations that make their theoretically viable claim plausible.” *McDermott v. Clondalkin Grp., Inc.*, 649 F. App’x 263, 267-68 (3d Cir. 2016) (emphasis omitted) (internal quotation marks and citations omitted); *see also, e.g., Sierra Est. of Romagosa v. Trafigura Trading LLC*, Civil Action No. 22-366-JLH-CJB CONSOLIDATED, 2024 WL 4104130, at *9

(D. Del. Sept. 6, 2024); *DSM IP Assets, B.V. v. Honeywell Int’l, Inc.*, 700 F. Supp. 3d 189, 197-98 (D. Del. 2023).

8. With regard to Defendant’s position regarding the “is less than about 25” claim limitation of the 5770 patent and the 9770 patent, all that Plaintiff argues in response is that its allegations pass muster because “pre-suit testing of bending forces and flexibility slopes is [not] required to put [Defendant] on notice” and because “[t]he construction of Balt’s products is easily within Balt’s possession.” (D.I. 28 at 20-21) But this argument does not save the day for Plaintiff. That’s because, as is required for “information and belief” pleading, Plaintiff does not contend that “the requisite factual information is *peculiarly* within the defendant’s knowledge or control” (or that it would be difficult for Plaintiff to ascertain whether the publicly available accused products meet this limitation by, for example, obtaining and testing them). *See McDermott*, 649 F. App’x at 267-68 (emphasis added); *see also* (D.I. 34 at 6 (Defendant noting that the accused products are publicly available for sale and therefore the relevant facts are not *peculiarly* within its possession); D.I. 34 at 9-10). Nor has Plaintiff cited to any factual allegations from the FAC that render it plausible that the ratio of the two slopes at issue is less than 25. The Court therefore recommends that the Motion be GRANTED with respect to the 9770 and 5770 patents. *See, e.g., Integrated Eng’g. LLC v. Euro Motorparts Grp. UK Ltd.*, Case No. 8:25-cv-00882-JVS-KES, 2025 WL 3190823, at *4-5 (C.D. Cal. Sept. 4, 2025) (granting a motion to dismiss where, for two limitations of the asserted claim, the pleading only made conclusory allegations without pleading supportive facts—and noting that the defendant’s failure to obtain and test the publicly available product did not demonstrate a reasonable effort to ascertain the limitations of that product); *cf. Prowire LLC v. Apple, Inc.*, Civil Action No. 17-

223, 2017 WL 3444689, at *4-5 (D. Del. Aug. 9, 2017) (rejecting the defendant’s argument that an infringement claim was not sufficiently pleaded, where the plaintiff alleged that the magnetic resin layer of the accused product was compression-molded “on information and belief[,]” where it was clear from the “the allegations and exhibits in the complaint” that the plaintiff “did purchase and reverse engineer” the accused product, and where the plaintiff alleged that the “structure and materials of the accused inductors are things it can discern from viewing and testing an accused inductor” but where it seemed likely that “whether the magnetic resin layer is compression-molded is only something the manufacturer would know”).

9. The same is true of the allegations that Defendant calls out with respect to the other asserted patents. Below, the Court addresses those allegations as to each of the remaining patents at issue.

10. Taking up the 972 patent next, that patent’s asserted claim 1 recites that the claimed catheter’s “tapered region comprises an unreinforced polymer[.]” (D.I. 11, ex. 4 at col. 37:24-25) On this score, the FAC simply alleges that “on information and belief, the tapered region of the Carrier comprises an unreinforced polymer.” (D.I. 11 at ¶ 49) Plaintiff argues that this allegation is sufficient because it “concerns the composition of the accused product which is readily known to Balt” and because it is reasonable to infer that the tip of the Carrier is unreinforced since it has “variable stiffness” and “facilitates the advancement of the catheter.” (D.I. 28 at 21 (citing D.I. 11 at ¶¶ 48-49)) Yet here the record here does not demonstrate that the composition of the accused product—and particularly whether the tapered region at issue is made up of a polymer—is something *peculiarly* within Defendant’s knowledge. Plaintiff certainly hasn’t pleaded any facts that might articulate why this is so (nor otherwise

explained why this is so in its briefing). Moreover, it is not clear to the Court on the pleaded facts how the component's "variable stiffness" or the fact that it "facilitates advancement of the catheter" makes it plausible that the tip is unreinforced. (D.I. 21 at 11; D.I. 34 at 4)

11. The Court next turns to the allegations regarding the 032 patent. Asserted claim 1 of that patent claims a system with a catheter advancement device, wherein the device comprises a "tip segment" formed of a polymer with a "durometer less than the . . . durometer" of the polymer in an "intermediate segment[.]" (D.I. 11, ex. 5 at col. 65:4-10) Here, the FAC again only alleges that "[o]n information and belief" the "tip segment ha[s] a durometer less than the intermediate segment." (D.I. 11 at ¶ 61) And in response to Defendant's challenge here, Plaintiff makes the same argument as it posited for the 972 patent. (D.I. 28 at 21) That argument fails for the same reasons as it did with the 972 patent. (D.I. 21 at 11; D.I. 34 at 4)

12. Finally, claim 1 of the 036 patent requires that "the distal portion of the inner member [of the catheter] creates a smooth transition in flexibility between a flexibility of the guidewire to a flexibility of the catheter[.]" (D.I. 11, ex. 7 at col. 30:55-58) And again, the FAC alleges that this limitation is met by the accused products "[o]n information and belief." (D.I. 11 at ¶ 96) In responding to Defendant's argument for dismissal, Plaintiff notes that an earlier allegation in Paragraph 89 of the FAC makes reference to Defendant's marketing statement to the effect that the Carrier is "optimized for ledge effect reduction" and that the Hybrid guidewire is "intended to facilitate the insertion of catheters into intracranial vascular branches"; Plaintiff argues that this somehow creates a reasonable inference that the "smooth transition" limitation is met. (D.I. 28 at 22 (citing D.I. 11 at ¶ 89 ("Paragraph 89"))) But Paragraph 89 itself doesn't actually allege either of these facts. (D.I. 11 at ¶ 89) And even if it did, the FAC "does not

allege how these facts support inferring the alleged existence of ‘a smooth transition in flexibility’ between the guidewire and the catheter.” (D.I. 34 at 5; *see also* D.I. 21 at 12)

13. For the above-referenced reasons, then, the Court also recommends that the Motion be GRANTED with respect to the 972, 032 and 036 patents.

14. Plaintiff requests that should the Motion be granted, Plaintiff be permitted leave to amend to “add additional data.” (D.I. 28 at 23) Because it seems possible that these direct infringement-related deficiencies can be cured in another pleading, the Court recommends that the Motion be granted without prejudice with respect to Plaintiff’s direct infringement claims too. It also recommends that if the District Judge adopts the Court’s recommendation, that Plaintiff be given 14 days to file a further amended pleading in which it attempts to sufficiently plead any direct and indirect infringement allegations.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. Parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App’x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

Parties are directed to the Court’s Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the District Court’s website, located at <http://www.ded.uscourts.gov>.

Dated: August 24, 2026

Christopher J. Burke

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE