

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

B. Braun Melsungen AG, et al.,	:	
	:	
Plaintiffs.	:	
	:	
v.	:	C.A. No. 09-347-LPS
	:	
Terumo Medical Corporation, et al.,	:	PUBLIC VERSION
	:	
Defendants.	:	

MEMORANDUM OPINION

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October 28, 2010
Wilmington, Delaware



STARK, U.S. District Judge:

This action was filed by Plaintiffs, B. Braun Melsungen AG & B. Braun Medical Inc. (collectively, “Braun”), against Defendants Terumo Medical Corporation and Terumo Corporation (collectively, “Terumo”) on May 13, 2009, alleging infringement of U.S. Patent No. 7,264,613 (“the ‘613 patent”). (D.I. 1) Pending before the Court are two motions for summary judgment filed by Braun, one summary judgment motion filed by Terumo, one motion to strike filed by Braun, and two *Daubert* motions filed by Braun. This Memorandum Opinion provides the Court’s reasoning with respect to resolution of each of these six motions.

I. Motions for Summary Judgment

The pending summary judgment motions are as follows: (1) Terumo’s Motion for Summary Judgment of Non-Infringement of Claims 1-6, 8, 20-21, and 24-35 (“Non-Infringement Motion”) (D.I. 190); (2) Braun’s Motion for Summary Judgment Regarding Terumo’s Section 112 Defenses and Counterclaims (“Validity Motion”) (D.I. 197); and (3) Braun’s Motion for Partial Summary Judgment on Terumo’s Anticipation and Obviousness Invalidity Defenses and Counterclaims for Certain Claims of the ‘613 Patent (“Invalidity Motion”) (D.I. 200).¹

¹Braun also filed a Motion for Summary Judgment of Infringement of U.S. Patent No. 7,264,613, asserting that Terumo’s Surshield Safety I.V. Catheter (“Surshield”) infringes Claims 9, 12, and 17 of Braun’s ‘613 Patent (“Infringement Motion”). (D.I. 194) In light of the Court’s claim construction order (D.I. 214), Terumo did not oppose entry of summary judgment in Braun’s favor on the Infringement Motion (D.I. 221; *see also* D.I. 248). Accordingly, the Court signed the parties’ stipulation and granted the Infringement Motion on August 5, 2010. (D.I. 238)

A. Legal Standards

A grant of summary judgment is appropriate only where “the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c)(2). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). If the moving party has carried its burden, the nonmovant must then “come forward with ‘specific facts showing that there is a genuine issue for trial.’” *Id.* at 587 (quoting Fed. R. Civ. P. 56(e) (emphasis omitted)). The Court will “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). To defeat a motion for summary judgment, the non-moving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Service*, 409 F.3d 584, 594 (3d Cir. 2005) (party opposing summary judgment “must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue”) (internal quotation marks omitted). However, the “mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;” a factual dispute is genuine only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (entry of summary judgment is mandated “against a party who fails to make a showing sufficient to establish the

existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial").

B. Terumo's Non-Infringement Motion

Terumo moves for summary judgment that its accused product, Surshield, does not infringe claims 1-6, 8, 20-21, or 24-35 of the '613 patent. (D.I. 190) Because the Court finds that genuine disputes of material fact preclude granting summary judgment in favor of Terumo with respect to non-infringement, the motion will be denied.

"Determining whether a patent claim has been infringed involves two steps: (1) claim construction to determine the scope of the claims, followed by (2) determination whether the properly construed claim encompasses the accused structure." *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). The first step, claim construction, is a matter of law for the Court. The claims in this case have been construed. (D.I. 178; D.I. 214) The second step of the infringement analysis – determining, element-by-element, whether each limitation of a claim is infringed, either literally or by application of the doctrine of equivalents – is a question of fact. *See Bai*, 160 F.3d at 1353.

To prove literal infringement, a party must show that the accused device possesses each and every element of the patent claim at issue. *See Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996). Infringement is examined on an element-by-element basis; if an element of the claim is not present in the accused device, then the device does not literally infringe the claim. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005). If the accused product includes all of the elements of a claim, or if the accused product is an equivalent under the doctrine of equivalents, the patent remains infringed despite any improvements or additional features in the accused product. *See Atlas Powder Co. v. E.I. du*

Pont de Nemours & Co., 750 F.2d 1569, 1580-81 (Fed. Cir. 1984); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 945 (Fed. Cir. 1990).

In order to establish infringement under the doctrine of equivalents, there must be an insubstantial difference between the accused system and the corresponding element of the patent-in-suit. See *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997); see also *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1260 (Fed. Cir. 1989) (patentee must prove accused device “does substantially the same thing in substantially the same way to get substantially the same result”) (internal quotation marks omitted). As with literal infringement, infringement under the doctrine of equivalents is analyzed on an element-by-element basis. See *Warner-Jenkinson*, 520 U.S. at 29.

The doctrine of equivalents is not available to a patentee who made narrowing amendments during prosecution in order to obtain allowance of the claims. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 733-34 (2002); see also *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1573 (Fed. Cir. 1997) (“When a claim has been narrowed by amendment for a substantial reason related to patentability, such as to avoid a prior art rejection, the patentee may not assert that the surrendered subject matter is within the range of equivalents.”) (internal quotation marks omitted). In such circumstances, the presumption of prosecution history estoppel may be rebutted if the patentee can show that the amendment at issue was not made for a reason of patentability, that it bore no more than a tangential relationship to the equivalent in question, or the equivalent sought was unforeseeable at the time the amendment was made. See *Festo*, 535 U.S. at 736, 740-41.

When an accused infringer moves for summary judgment of non-infringement, such relief may only be granted if one or more limitations of the claim in question does not read on an

element of the accused product, either literally or under the doctrine of equivalents. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *see also Techsearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed. Cir. 2002) (“Summary judgment of non-infringement is . . . appropriate where the patent owner’s proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial.”). Thus, summary judgment of non-infringement can only be granted if, after viewing the facts in the light most favorable to the non-movant, there is no genuine issue whether the accused product is covered by the claims. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999).

Here, Terumo asserts that, for many reasons, its Surshield does not infringe claims 1 and 20 of the ‘613 patent, either literally or under the doctrine of equivalents, or any claims that depend from claims 1 and 20. (*See generally* D.I. 191; D.I. 242; *see also* D.I. 192 Ex. E, ‘613 patent, claim 1 at col. 15 lines 13-48 & claim 20 at col. 16 lines 40-67) In Terumo’s view, Surshield does not infringe claim 1, or any claims depending from claim 1, because claim 1 requires two arms that each have a “radially extending member at an end” of the arm which “block[s] the tip” of the needle. (D.I. 191 at 14-19; *see also* D.I. 242 at 8-10) According to Terumo, Surshield does not have two arms that meet these requirements. (D.I. 191 at 3, 15) For example, Terumo cites the opinion of its expert, Dr. Joseph J. Beaman, Jr., that the structure which Braun’s expert, Dr. Gerald E. Miller, “contends is the ‘radially extending member’ does not *extend radially* from the arm. Instead, it is simply a part of the arm.” (D.I. 191 at 16; *see also* D.I. 192, Beaman Decl. ¶¶ 22, 29-30, 32 & Ex. D at 34, 38) In addition, it is Terumo’s position that while “the radially extending member must both ‘block the tip’ of the needle and be ‘at an end’ of the arm,” the “area of the arm that Dr. Miller contends blocks the tip is not at the

end of the arm.” (D.I. 191 at 16; *see also* D.I. 192, Beaman Decl. ¶¶ 23-25 & Ex. F at 235, 237-38) Moreover, from the perspective of Terumo’s expert, Dr. Miller “provided only a cursory analysis of how Arm No. 1 allegedly meets the ‘radially extending member’ limitations under the doctrine of equivalents.” (D.I. 191 at 17-18; *see also* D.I. 192, Beaman Decl. ¶ 26 & Ex. D at 43-44, 48-49)

Additionally, Terumo submits that Surshield does not infringe claim 20, or any claims that depend from claim 20, because claim 20: (1) requires an arm that is “attached to” the proximal wall, (2) includes “a radially extending wall, which is positioned at an angle to the . . . arm,” and (3) has its radially extending wall “abutting the side of the needle shaft when in the ready to use position.” (D.I. 191 at 6-19; *see also* D.I. 242 at 1-8) Terumo insists that Surshield does not have arms that satisfy these limitations. (D.I. 191 at 3) For example, in the view of Terumo’s expert, Arm No. 1 does not have a “radially extending wall, which is positioned at an angle to” the arm and is “abutting the side of the needle shaft” in the ready position. (D.I. 191 at 7; *see also* D.I. 192, Beaman Decl. ¶¶ 10-13, 29-30, 32 & Ex. D at 34, 97) Also, Terumo’s expert is of the view that Arm No. 2 is not “attached to” the proximal wall, nor is it an “arm attached to and extending distally of the proximal wall,” or any wall; rather, “it is attached to the metal component of Arm No. 1,” which is insufficient to meet the claim limitation. (D.I. 191 at 10-12; *see also* D.I. 192, Beaman Decl. ¶¶ 30, 33, Ex. D at 97, Ex. E at col. 16 lines 59-60, Ex. F at 147 & Ex. 8) Terumo’s expert also insists that Braun’s expert, Dr. Miller, “provided only a cursory analysis of how either Arm No. 1 or 2 satisfies the requirements of claim 20 under the doctrine of equivalents.” (D.I. 191 at 12-14; *see also* D.I. 192, Beaman Decl. ¶ 35 & Ex. D at 99-100)

Furthermore, because Surshield does not infringe claims 1 or 20, Terumo contends it necessarily follows as a matter of law that Surshield cannot infringe any claims that depend from claims 1 or 20, for these dependent claims include every limitation found in claims 1 or 20, along with additional limitations. (D.I. 191 at 14, 19) (citing *Wahpeton Canvas Co. Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989))

In response, Braun identifies what it contends are numerous material factual issues precluding summary judgment. (*See generally* D.I. 219) With respect to claim 1, for example (which requires a “tip protector” that has “two resilient arms . . . each comprising a radially extending member at an end thereof,” where “the two radially extending members block the tip”) (D.I. 220 Ex. 1, ‘613 patent at col. 15 lines 28-48), Braun asserts that Surshield has two arms that satisfy the limitations of claim 1, and argues there are disputed facts regarding the “radially extending member” of Arm No. 1 – namely, (1) whether Arm No. 1 has a “radially extending member” and (2) whether the “radially extending member” of Arm No. 1 is at the “end” of the arm that “blocks the tip.” (D.I. 219 at 13-20) More specifically, contrary to Terumo’s expert, Braun’s expert, Dr. Miller, opines that Arm No. 1 has a “radially extending member” at its end. (D.I. 219 at 14; *see also* D.I. 220 Ex. 2, Miller Rep., at 36-38, 47-48 & Ex. 3, Miller Dep., at 233-43, 245, 247) Also, contrary to Terumo’s expert, Dr. Miller’s opinion is that the “radially extending member” of Arm No. 1 is at the “end” of the arm and it blocks the tip while in the protective position. (D.I. 219 at 16; *see also* D.I. 220 Ex. 2, Miller Rep., at 36-38, 47-48, 96-97 & Ex. 3, Miller Dep. at 233-43, 245, 247)

In addition, with respect to claim 20 (which requires a “tip protector” that has “at least one arm attached to and extending distally of the proximal wall; the at least one arm comprising a radially extending wall, which is positioned at an angle to the at least one arm and comprises a

portion at a distal end abutting the side of the needle shaft when in the ready to use position”) (D.I. 220 Ex. 1, ‘613 patent at col. 16 lines 53-64), Braun submits that the evidence reflects that Surshield has two arms, either of which satisfy the limitations of claim 20. (D.I. 219 at 1-13) That is, in Braun’s view, because claim 20 requires only one arm, Surshield infringes claim 20 if *either* Arm No. 1 *or* Arm No. 2 satisfies the claim limitations. (*Id.* at 3) Dr. Miller opines that Surshield’s Arm No.1 has “at least one arm comprising a radially extending wall, which is positioned at an angle to the at least one arm and comprises a portion at a distal end abutting the side of the needle shaft when in the ready to use position,” and Arm No. 2 has “at least one arm attached to . . . the proximal wall.” (D.I. 219 at 3-10; *see also* D.I. 220 Ex. 2, Miller Rep., at 43, 96-99 & Ex. 3, Miller Dep., at 188, 254-56)

Moreover, Braun, of course, disputes Terumo’s contention that Dr. Miller’s doctrine of equivalents analyses were “cursory.” (D.I. 219 at 10-13, 18-20; *see also* D.I. 220 Ex. 2, Miller Rep., at 48-49, 99-102) Finally, because Terumo’s argument for summary judgment on the dependent claims is entirely premised on Terumo’s contention that the independent claims are not infringed, it follows that the disputes of fact relating to the independent claims also preclude summary judgment on the dependent claims. (D.I. 219 at 13, 20)

The record contains evidence, including the expert opinions summarized above, from which a reasonable jury could find that every limitation of claims 1 and 20, and of the claims that depend from them, are present in Terumo’s Surshield. Thus, Braun is correct that material disputes of fact make summary judgment of non-infringement inappropriate. Accordingly, the Court will deny Terumo’s Non-Infringement Motion.

C. Braun's Validity Motion

Braun has moved for partial summary judgment on Terumo's affirmative defenses and counterclaims that the '613 patent is invalid for failure to satisfy the requirements of 35 U.S.C. § 112. (D.I. 197; *see also* D.I. 244) For the reasons set forth below, the Court will deny the motion.

Braun contends that none of the multiple invalidity arguments Terumo has raised under Section 112 raise a genuine issue of material fact.² (*See generally* D.I. 198; D.I. 244) With respect to Terumo's contention that all of Braun's asserted claims are invalid due to their failure to disclose "essential elements" of the invention, Braun argues that summary judgment should be granted, because Section 112 does not impose such an "essential element" requirement.³ (D.I. 198 at 1, 4-7; *see also* D.I. 244 at 1-6) Terumo also argues that claim 1 (and the claims that depend from it) is invalid for failure to meet the enablement and written description requirements, and specifically that the limitation that the "tip protector" must "move with the first hub relative to the second hub" is not supported by the patent specification. (D.I. 198 at 1-2, 7-9; *see also* D.I. 244 at 7-9) Braun moves for summary judgment on this defense because, in Braun's view, it is based on a mis-reading of claim 1 (i.e., that claim 1 requires that the "first hub" must be the needle hub and the "second hub" must be the catheter hub, when, in Braun's

²In briefing Braun's Validity Motion, Terumo stated, "[i]n order to reduce and simplify the issues for trial, Terumo will not pursue the indefiniteness argument discussed [in] Braun's motion." (D.I. at 1 n.1) The Court will therefore not address this (now withdrawn) argument.

³*See, e.g., Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002) ("[W]e did not [in *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998)] announce a new 'essential element' test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements.").

view, the opposite is true). (D.I. 198 at 1-2, 7-9; *see also* D.I. 244 at 7-9) Finally, with respect to Terumo’s written description defense (relating to multiple-piece needle guards), Braun contends that the Court’s claim construction disposes of this argument as a matter of law. (D.I. 198 at 2, 10-11; *see also* D.I. 244 at 9-10)

Paragraph 1 of 35 U.S.C. § 112, which provides the statutory basis for the written description and enablement requirements, states in pertinent part:

The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same

Whether or not a specification satisfies the written description requirement is a question of fact.

See, e.g., ICU Med., Inc. v. Alaris Med. Sys., Inc., 558 F.3d 1368, 1376 (Fed. Cir. 2009)

(“Compliance with the written description requirement [of Section 112] is a question of fact.”);

Alcon, Inc. v. Teva Pharms. USA, Inc., 664 F. Supp. 2d 443, 468 (D. Del. 2009) (“Satisfaction of

the written description requirement is a fact-based inquiry, depending on the nature of the

claimed invention and the knowledge of one skilled in the art at the time an invention is made

and a patent application is filed.”) (internal quotation marks omitted). Enablement is a question

of law, yet one with significant factual underpinnings. *See, e.g., Old Town Canoe Co. v.*

Confluence Holdings Corp., 448 F.3d 1309, 1320 (Fed. Cir. 2006) (“Enablement is a matter of

law . . . however, this court reviews the factual underpinnings of enablement to determine

whether there was sufficient evidence to support a verdict by a jury.”); *Alcon*, 664 F. Supp. 2d at

470 (“The enablement requirement is a question of law based on underlying factual inquiries.”).

Having reviewed the record, the Court agrees with Terumo that genuine underlying disputes of material fact with respect to Terumo’s written description and enablement defenses

and counterclaims are present and necessitate resolution by trial. As Terumo points out, for example, issues of fact exist as to whether or not the specification of the '613 patent satisfies the enablement and written description requirements with respect to I.V. catheter assemblies (i) lacking a structure for holding the needle guard on the end of the needle in the protected position and/or a structure to retain the needle guard within the catheter hub as the needle is being withdrawn, and (ii) having a tip protector that moves with the needle hub relative to the catheter hub. (D.I. 222 at 3-18) There is also a genuine dispute of material fact as to whether the '613 patent enables one of skill in the art to make and use, without undue experimentation, the claimed I.V. catheter assemblies. (See D.I. 222 at 3-18; D.I. 224, Kulli Decl. ¶¶ 21-32, 36-38; see also *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1326-27 (Fed. Cir. 2007) (“Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.”) (internal quotation marks and citations omitted)).

In light of the material factual disputes, the Court will deny Braun’s Validity Motion.

D. Braun’s Invalidation Motion

Braun further seeks summary judgment on Terumo’s affirmative defenses and counterclaims asserting invalidity of the patent-in-suit due to anticipation and obviousness under 35 U.S.C. §§ 102 and 103. Specifically, Braun seeks summary judgment of no anticipation of claim 1 or claim 9, and all claims depending from them, as well as summary judgment of nonobviousness of claim 9 and its dependent claims. (D.I. 200) Braun’s Invalidation Motion will be granted in part and denied in part.

“[I]nvalidation by anticipation requires that the four corners of a single[] prior art document describe every element of the claimed invention, either expressly or inherently. Whether a prior

art reference anticipates a patent claim is a question of fact.” *TriMed, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1343 (Fed. Cir. 2010). Here, Braun asserts that neither claims 1 nor 9 of the ‘613 patent is anticipated. (D.I. 201 at 2-3, 5-6; *see also* D.I. 246 at 1, 4) In response, Terumo now “agrees that it is not offering an anticipation defense against these claims.” (D.I. 223 at 2) Thus, the Court will grant Braun partial summary judgment that claims 1 and 9 are not anticipated.

With respect to obviousness, as set forth by the Federal Circuit:

A patent is invalid if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Whether the claimed subject matter would have been obvious at the time of invention to one of ordinary skill in the pertinent art is a question of law based on underlying facts. The relevant factual inquiries include the oft-cited *Graham* [*v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)] factors:

(1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) any relevant secondary considerations. . . .

Summary judgment of obviousness is appropriate if the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors.

TriMed, 608 F.3d at 1340-41 (internal quotation marks and citations omitted).

Braun contends that claims 9-15 and 17-19 are not obvious for several reasons, including that: (1) it is improper as a matter of law for Terumo to rely upon U.S. Patent No. 3,768,126 (“Posdal”) to render claim 9 or any of its dependent claims obvious, and (2) Terumo has failed to meet its burden to show that, under this Court’s claim construction, U.S. Patent No. 5,549,570

(“Rogalsky”) discloses arms that intersect in the ready position.⁴ (D.I. 201 at 2-16; D.I. 246 at 4-8)

Terumo responds by identifying a number of underlying material factual disputes. (*See generally* D.I. 223; D.I. 224) In Terumo’s view, both the Posdal and Rogalsky prior art references teach arms that “intersect.” (*See* D.I. 223 at 1-2, 4-18; *see also* D.I. 224, Kulli Decl. ¶¶ 13, 15-18 & Ex. D, Ex. G) Moreover, Terumo argues that Braun’s motion ignores the fact that the Court’s construction of “intersect” renders claim 9 so broad that claim 9 (and its dependent claims) is obvious even without reference to Posdal or Rogalsky, in light of U.S.

⁴Specifically, Braun contends:

In his report, Terumo’s expert relies on three references to show arms that intersect in the ready position—the Braun ‘742 PCT Application, the Posdal ‘126 patent, and the Rogalsky ‘570 patent—in the combinations that he alleges render claim 9 and its dependent claims obvious. These three references are the only references Terumo’s expert identifies in his report as disclosing “arms that intersect one another and extend distally of the proximal wall in the ready to use position”. The Braun ‘742 PCT Application is not prior art to the ‘613 patent, as it claims priority to the same patent application as the ‘613 patent. The Posdal ‘126 patent, a patent to a towel-holding-clip, is outside the scope of prior art to be considered in an obviousness inquiry. The Rogalsky ‘570 patent, as shown by Terumo’s expert in his report, does not disclose arms that intersect one another in the ready to use position as required by claim 9. Accordingly, because these are the only references that Terumo’s expert relies upon to show arms that intersect in the ready to use position for his opinions that claim 9 and its dependent claims are obvious, and because the Braun PCT application is not prior art, Posdal is improper to consider because it is not analogous art, and Rogalsky does not disclose intersection, summary judgment of nonobviousness should be entered for claim 9 and its dependent claims.

(D.I. 201 at 2-3) (internal citations omitted) In response, Terumo stated that it “agrees that, because of the Court’s constructions (to which Terumo respectfully maintains its objections), it no longer intends to rely on Braun’s ‘742 PCT Application as prior art.” (D.I. 223 at 2) Accordingly, the Court will not address the ‘742 PCT Application reference.

Patent No. 4,929,241 (“Kulli”) in combination with U.S. Patent No. 5,135,504 (“McLees”). (*See* D.I. 223 at 1-2, 6, 18-20; *see also* D.I. 224, Kulli Decl. ¶ 19 & Ex. C, Ex. F)

These are genuine disputes of material fact, which a reasonable jury could resolve in favor of either Braun or Terumo. (*Compare, e.g.*, D.I. 201 at 8-12; D.I. 202 Ex. 2 ¶¶ 204, 225 *with* D.I. 224, Kulli Decl. ¶¶ 14, 221) It will be for the jury to determine the scope and content of the prior art and the differences, if any, from the scope of the asserted claims of the patent-in-suit.

II. Evidentiary Motions

Braun has filed three evidentiary motions: (1) Braun’s Motion to Strike New and Untimely Expert Opinions in Terumo’s Summary Judgment Declaration [D.I. 192] (“Motion to Strike”) (D.I. 216); (2) Braun’s Motion to Preclude Defendants from Offering Opinion Testimony from Dr. Joseph J. Beaman Regarding Copying and Safety (“Motion to Preclude Beaman Testimony”) (D.I. 258); and (3) Braun’s Motion to Preclude Defendants from Offering Opinion Testimony of Dr. John Kulli for Which He Has Not Produced All Relevant Information (“Motion to Preclude Kulli Testimony”) (D.I. 261).

A. Braun’s Motion to Strike

Braun moves, pursuant to Federal Rules of Civil Procedure 26(a)(2)(B) and 37(c)(1) to strike allegedly new, untimely, and improper opinions rendered by Terumo’s expert, contained in the June 25, 2010 Declaration of Joseph J. Beaman, Jr. (D.I. 192), which accompanies Terumo’s Non-Infringement Motion (D.I. 190). (D.I. 216; *see also* D.I. 255) Braun contends:

Dr. Beaman submitted his expert report on the issue of infringement on May 7, 2010, and he was deposed on June 2, 2010, pursuant to the Scheduling Orders in this case. (D.I. 41, 161.) On June 25, 2010, Terumo filed a Motion for Summary Judgment of Non-Infringement of Claims 1 and 20 (D.I. 191), and submitted the accompanying Beaman Summary Judgment Declaration (D.I. 192, attached hereto as Exhibit 1.) The Beaman Summary Judgment Declaration contains new

opinions that were not disclosed in Dr. Beaman's expert report, including certain new opinions that directly contradict Dr. Beaman's deposition testimony.

(D.I. 216 at 2)

In particular, Braun urges the Court to strike the following three opinions from the Beaman Declaration, all of which Braun contends are "new" opinions: (1) paragraph 21, stating that the "plastic cover" of Arm No. 1 "is not attached" to the proximal wall; (2) paragraph 33, stating that Arm No. 2 is not "attached" to the proximal wall; and (3) paragraph 32, stating several reasons why Dr. Beaman believes that "a radially extending wall which is positioned at an angle to the at least one arm" is not met in claim 20, including that the "distal tip" of the "entire metal/plastic assembly" of Arm No. 1 "cannot also be a wall positioned at an angle to the at least one arm" and that a "contoured linear component" cannot have a wall "positioned at an angle." (See D.I. 216 at 3-5; D.I. 218 Ex. 1 ¶¶ 21, 32, 33; see also D.I. 192 ¶¶ 21, 32, 33)

Finally, Braun adds that Terumo has no substantial or sufficient justification for such opinions, several of which contradict Dr. Beaman's previous deposition testimony, and that Braun would be significantly prejudiced if they are not excluded. (D.I. 216 at 6) In Braun's view, no newly-discovered facts or evidence prompted Dr. Beaman's new opinions; they are, according to Braun, simply "late-disclosed contention opinions." (*Id.* at 7) Nor did Terumo request permission to supplement Dr. Beaman's report. (*Id.*) Thus, Braun requests that these new opinions be stricken from the Beaman Declaration or that Braun be permitted to provide supplemental opinions in rebuttal. (D.I. 216 at 7; D.I. 255 at 2-3)

Terumo responds that each of the three alleged "new opinions" that are the subject of Braun's motion were fairly disclosed in Dr. Beaman's expert report, discussed at his deposition, and/or are permissible elaborations on his expert report. (See generally D.I. 240; see also *Dow*

Chem. Co. v. Nova Chems. Corp. (Canada), 2010 WL 2044931, at *2 (D. Del. May 20, 2010) (denying motion to strike based on finding that expert declarations “consist[ed] of consistent and appropriate elaborations of prior opinions and statements”))

Federal Rule of Civil Procedure 26(a)(2)(B)(i) requires that an expert’s report contain “a complete statement of all opinions the witness will express and the basis and reasons for them.” Further, Rule 26(a)(2)(c) provides that “a party must make these [expert] disclosures at the time and in the sequence that the court orders.” Parties are always under an obligation to supplement their contentions, including supplementing expert reports, when it becomes necessary to do so. *See* Fed. R. Civ. Proc. 26(e)(1)(A) (“[A]ny party who has . . . responded to an interrogatory . . . must supplement or correct its disclosure or response . . . in a timely manner if the party learns that in some material respect the disclosure or response is incomplete.”). Parties may not use their obligation to supplement as an excuse to violate the clear terms of a Scheduling Order, unilaterally buying themselves additional time to make disclosures, thereby unduly prejudicing other parties and potentially delaying the progress of a case.

Pursuant to Rule 37(c)(1), the Court has the power to exclude evidence as a sanction for a party’s failure to comply with its obligations under the rules, including the specific deadlines and obligations imposed by a scheduling order. In pertinent part, Rule 37(c)(1) provides that “[i]f a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information . . . to support evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.” In determining whether a failure to disclose is harmless courts consider such factors as: (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the

failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence (the “Pennypack factors”). See *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (citing *Meyers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 904-905 (3d Cir. 1977)).

It bears emphasis that exclusion of “critical evidence,” such as an expert report on infringement, is an “extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994) (internal quotation marks omitted); see also *Dow*, 2010 WL 2044931, at *1. The determination of whether to exclude evidence is committed to the discretion of the Court. *In re Paoli*, 35 F.3d at 749.

Here, having considered the record and these various factors, the Court concludes that the “extreme sanction” of precluding Terumo from relying on the opinions expressed in the Beaman Declaration is not warranted. Dr. Beaman’s noninfringement opinions are critical to Terumo’s defense and the Court is not persuaded that Braun is unduly prejudiced by the timing or substance of the purportedly “new” opinions. The Scheduling Order, as amended, governing this case is silent as to whether the parties may file new expert declarations in connection with summary judgment motions. Braun has failed to demonstrate that Terumo acted in flagrant disregard of a Court order or with willful deception. Accordingly, the appropriate exercise of the Court’s discretion, under all the circumstances, is to deny Braun’s Motion to Strike.

B. Braun’s *Daubert* Motions

Motions to exclude evidence are committed to the Court’s discretion. See *In re Paoli*, 35 F.3d at 749. The admissibility of expert testimony is a question of law governed by Rule 702 of the Federal Rules of Evidence and the Supreme Court’s decision in *Daubert v. Merrell Dow*

Pharms., Inc., 509 U.S. 579 (1993). Pursuant to Rule 702, in order to be admissible, expert testimony must “assist the trier of fact to understand the evidence or to determine a fact in issue.” The Supreme Court has assigned “to the trial judge the task of ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.” *Daubert*, 509 U.S. at 597. Thus, expert testimony shall be admitted at trial only if: “(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.” Fed. R. Evid. 702; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999). The Third Circuit has described these requirements as “three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit.” *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000).

Rule 702 embodies a “liberal policy of admissibility.” *See Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (internal citations omitted). Nonetheless, the burden is placed on the party offering expert testimony to show that it meets all of the standards for admissibility. *See Daubert*, 509 U.S. at 592 n.10; *In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir. 1999). Once that burden is met, a Court must consider additional factors before precluding expert testimony:

- (1) the prejudice or surprise of the party against whom the excluded evidence would have been admitted;
- (2) the ability of the party to cure that prejudice;
- (3) the extent to which allowing the evidence would disrupt the orderly and efficient trial of the case or other cases in the court; and
- (4) bad faith or wilfulness in failing to comply with a court order or discovery obligation.

Konstantopoulos, 112 F.3d at 719 (internal quotation marks omitted). As has already been noted, the exclusion of important evidence is an “extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence.” *In re Paoli*, 35 F.3d at 791-92 (internal quotation marks omitted).

1. Motion to Preclude Beaman Testimony

Braun seeks to preclude Terumo from offering opinion testimony from Dr. Joseph J. Beaman regarding: (1) whether Terumo copied the '613 patent or Braun's commercial embodiment thereof, the Introcan Safety® IV Catheter ("Introcan"); and (2) the relative or absolute safety of Braun's and Terumo's competing products. (D.I. 258; *see also* D.I. 280) According to Braun, Terumo has proffered Dr. Beaman as an expert witness to opine on non-infringement and on copying – one of the objective indicia of nonobviousness. (D.I. 259 at 1) Dr. Beaman's copying opinion seeks to recount the development history of the accused device, to show it is not a copy of the '613 patent or Introcan. (*Id.* at 1-2) Dr. Beaman also sets forth an opinion regarding the relative safety of Surshield and Introcan. (*Id.* at 2)

Braun argues that Dr. Beaman's expert opinion on copying is essentially a regurgitation of attorney arguments and, thus, is unreliable. Dr. Beaman reviewed only portions of documents selected for him by Terumo's attorneys, relied exclusively on Terumo's attorneys to tell him the contents of documents written in Japanese, and made no independent review or talked to anyone at Terumo about design of the accused device. (D.I. 259 at 1-6, 8-12; *see also* D.I. 260; D.I. 280) Moreover, in Braun's view, Dr. Beaman's expert opinion on Surshield's relative or absolute safety and that of Introcan is unhelpful because, by his own admission, Dr. Beaman is not an expert on "the safety aspects of needles," "I.V. catheters," "safety I.V. catheters," or needlesticks. (D.I. 259 at 1-3, 6-7, 11-12; *see also* D.I. 260; D.I. 280)

Terumo responds that Dr. Beaman is a highly qualified mechanical engineer, who considered myriad pieces of evidence in forming his opinion that Terumo did not copy Braun's Introcan in developing the Surshield, and in identifying four key distinctions between the devices' safety catheter designs. (D.I. 269 at 2-6, 8-11; *see also* D.I. 270) Terumo denies any

inappropriate attorney participation with respect to formation of Dr. Beaman's opinion, issues on which – Terumo points out – Dr. Beaman may be cross-examined at trial. (D.I. 269 at 2-6, 8-11; *see also* D.I. 270) Terumo continues by asserting that Dr. Beaman, as a mechanical engineer, is adequately qualified to render structural analyses and an opinion on safety and tip protector failure. His extensive analysis of both the Introcan and the Surshield, based upon their engineering design and their relative propensities to fail under stress, was, in Terumo's view, rendered well within the scope of his professional qualifications. (D.I. 269 at 2-3, 5-6, 11-12; *see also* D.I. 270)

Having reviewed Dr. Beaman's opinions, the Court concludes that Braun's concerns go to the weight to be accorded to them, matters on which Braun will be free to examine Dr. Beaman at trial. Dr. Beaman's opinions satisfy the qualifications, reliability, and fit requirements. Accordingly, Braun's motion will be denied.

2. Motion to Preclude Kulli Testimony

Finally, Braun seeks to preclude Terumo from offering opinion testimony of Dr. John Kulli for which, in Braun's view, Dr. Kulli has not produced all relevant information. (D.I. 261) Braun contends that Dr. Kulli seeks to opine on a particular prior art reference but he has asserted the attorney-client privilege to protect from disclosure evidence relating to this same prior art reference. (*See generally* D.I. 262) Dr. Kulli has retained Terumo's trial counsel to represent him in his personal capacity in an effort to shield from Braun his communications on this same subject matter. (*Id.*)

Terumo has proffered Dr. Kulli as a testifying expert to opine that the claims of the '613 patent are invalid as obvious based on, among other references, U.S. Patent No. 4,929,241 (the "'241 Patent"), a patent Dr. Kulli owns. (*Id.* at 2; *see also* D.I. 263) While information

regarding those materials was shared with Terumo's counsel, Braun complains that when it sought discovery on those materials, and communications related to them, both Dr. Kulli and Terumo's counsel refused to provide complete discovery, asserting attorney-client privilege. (D.I. 262 at 2-3) In this way, according to Braun, Terumo has prevented Braun from "testing the bases and methodology" that went into Dr. Kulli's formation of his opinion and has unfairly used the attorney-client privilege "as both a sword and a shield." (*Id.* at 6-9)

Terumo responds that Braun's motion is nothing more than a belated discovery dispute, a complaint that should have been raised sooner. (*See generally* D.I. 271) Terumo also contends that Braun cannot show severe prejudice. (*Id.*) Finally, Terumo argues that the relief sought by Braun is overbroad, and offers, as an alternative resolution that Dr. Kulli be precluded from testifying only about certain communications. (*Id.* at 20)⁵ In reply, while Braun continues to ask that the Court exclude Kulli's expert opinions, Braun offers that "at the very least [the Court] should exclude Kulli's testimony" on the communications referenced by Terumo in its proposed alternative resolution.⁶ (D.I. 282 at 8-9)

The Court agrees that the alternative resolution proposed by Terumo is an appropriate resolution to this dispute. The Court will grant Braun's motion to the extent necessary to limit Kulli's testimony in the fashion proposed by Terumo.

⁵Portions of the briefing on this motion, including the details of Terumo's proposed alternative resolution, are (as of the filing of this Memorandum Opinion) under seal.

⁶Braun has made it clear that it "has no *Daubert* objection to Kulli's opinions on his multitude of other alleged grounds for invalidity, including other obviousness allegations, that are unrelated to the subject matters for which Kulli asserts privilege." (D.I. 262 at 3)

III. CONCLUSION

The Court will enter an Order consistent with the rulings described above on each of the pending motions.

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

B. Braun Melsungen AG, et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	C.A. No. 09-347-LPS
	:	
Terumo Medical Corporation, et al.,	:	
	:	
Defendants.	:	

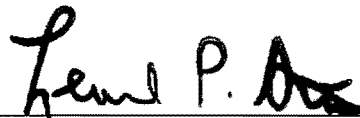
ORDER

At Wilmington this 28th day of October, 2010:

For the reasons set forth in the Memorandum Opinion issued this same date,

IT IS HEREBY ORDERED that:

1. Terumo's Non-Infringement Motion (D.I. 190) is DENIED.
2. Braun's Validity Motion (D.I. 197) is DENIED.
3. Braun's Invalidity Motion (D.I. 200) is GRANTED in part, with respect to anticipation, and DENIED in part, with respect to non-obviousness, consistent with the Memorandum Opinion.
4. Braun's Motion to Strike (D.I. 216) is DENIED.
5. Braun's Motion to Preclude Beaman Testimony (D.I. 258) is DENIED.
6. Braun's Motion to Preclude Kulli Testimony (D.I. 261) is GRANTED, to the extent that Dr. Kulli's testimony is limited in the manner discussed in the Memorandum Opinion.



Leonard P. Stark
UNITED STATES DISTRICT JUDGE