IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

W.L. GORE & ASSOCIATES, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 11-515-LPS-CJB
	)	
C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,	)	
	)	
Defendants.	)	

REPORT AND RECOMMENDATION

In this action filed by Plaintiff W.L. Gore & Associates, Inc. ("Gore" or "Plaintiff") against Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard" or "Defendants"), Gore alleges infringement of U.S. Patent Nos. 5,735,892 (the "'892 Patent") and 5,700,285 (the "'285 Patent") (the "asserted patents" or the "patents-in-suit").[1] Presently before the Court is Bard's "Motion for Summary Judgment of Noninfringement as to the Affixing Limitation" (the "Motion"). (D.I. 247) The Court recommends that the Motion be DENIED.

I. BACKGROUND

A. Factual Background

1. The Asserted Patents

The asserted patents, both of which are entitled "Intraluminal Stent Graft[,]" share a common specification and relate to thin-wall intraluminal graft devices. (D.I. 96, exs. A & V)[2]

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[1] Gore also originally asserted infringement of U.S. Patent No. 8,221,487 (the "'487 Patent"), but is no longer asserting that patent. (D.I. 191 at 1-2)

[2] The asserted patents are found in a number of places in the record, including as Exhibits A and V of D.I. 96. Further citation will simply be to the "'892 Patent" or the "'285 Patent."

The patents explain that implantation of conventional vascular grafts usually required invasive surgery that caused major trauma to the patient. ('892 Patent, col. 1:9-20) As an alternative, some physicians began to use intraluminal devices that combined conventional vascular grafts with stents which were placed inside the damaged portion of the vessel using a less invasive "catheter type of delivery system." (*Id.*, col. 1:22-26, 37-38) However, the "relatively thick, bulky wall[s]" of prior art devices made them difficult to "be contracted into a small cross-sectional area for insertion into a blood vessel." (*Id.*, col. 2:10-15) The present inventions claim thin-walled stent-graft devices "useful as an inner lining for blood vessels or other body conduits[,]" and methods of making such devices. (*Id.*, col. 1:5-6)

2. The Accused Products

Gore alleges that two of Bard's stent-graft products, the FLUENCY® Plus Tracheobronchial Stent Graft ("Fluency Plus") and the FLAIR® Endovascular Stent Graft ("Flair"), infringe claims 32, 33, and 40 of the '892 Patent and claim 15 (which incorporates the elements of claims 12 and 13) of the '285 Patent. (D.I. 64 at ¶¶ 16-17, 19, 23; D.I. 191 at 1; *see also* D.I. 291 at 1)

The accused Fluency Plus and Flair devices are manufactured in a [redacted] (D.I. 248 at 4; D.I. 259, Declaration of Dr. Nigel Buller ("Buller Decl."), ex. B at ¶ 80) The metal stents are manufactured [redacted] (Buller Decl., ex. B at ¶ 80) [redacted] (*Id.* at ¶¶ 80-81) [redacted] (*Id.* at ¶ 80)

[redacted] (D.I. 248 at 4; D.I. 291 at 4; Buller Decl., ex. B at ¶¶ 83-87; D.I. 303, Declaration of Enrique Criado, M.D. ("Criado Decl."), ex. A at 42-43) [redacted] (D.I. 248 at 4-5; Buller Decl., ex. B at ¶¶ 83-88; Criado Decl., ex. A at 42-43) [redacted] (D.I. 248 at 5; D.I. 291 at 4-5; Buller Decl., ex. B at ¶ 89; Criado Decl., ex. A at 45) [redacted] (D.I. 248 at 5; D.I. 291 at 4-5; Buller Decl., ex. B at ¶ 89; Criado Decl., ex. A at 45) [redacted] (D.I. 248 at 5; Buller Decl., ex. B at ¶ 92; Criado Decl., ex. A at 46) [redacted] (D.I. 291 at 5; Buller Decl., ex. B at ¶ 92; Criado Decl., ex. A at 46) As part of this inspection, Bard looks for delamination, a defect in which the two layers of ePTFE did not bond properly and thus the two ePTFE tubes are separated. (D.I. 291 at 5; Buller Decl., ex. B at ¶¶ 98-99; Criado Decl., ex. A at 46-47; D.I. 307, ex. 2 at 471-72)

Bard's encapsulation process is patented and covered by U.S. Patent No. 6,797,217 (the "'217 Patent"). (D.I. 248 at 3 & n.1; *id.* at 5 n.3; D.I. 341 at 10; Buller Decl., ex. B at ¶¶ 107-126) Bard states that Fluency Plus and Flair are covered by at least one claim of the '217 Patent. (D.I. 341 at 9; Buller Decl., ex. B at ¶¶ 107, 117, 134)

B. Procedural History

On June 10, 2011, Gore commenced this action. (D.I. 1) On January 10, 2014, Bard timely answered Gore's Second Amended Complaint, and asserted counterclaims against Gore. (D.I. 189) On November 29, 2011, this case was referred to the Court by Chief Judge Leonard P. Stark to hear and resolve all pretrial matters, up to and including the resolution of case-dispositive motions. (D.I. 20) Fact discovery closed on December 20, 2013, and expert discovery closed on June 30, 2014. (D.I. 291 at 1) After a hearing, (D.I. 130), the Court issued a Report and Recommendation on claim construction on August 8, 2014, (D.I. 221). Objections to that Report and Recommendation are currently pending. (D.I. 222, 263)

Briefing on the instant Motion was completed on November 12, 2014, (D.I. 341), and the Court held oral argument on the Motion on January 30, 2015, (D.I. 360 (hereinafter, "Tr.")).[3] A trial date in this matter has not yet been set.

II. STANDARD OF REVIEW

A. Summary Judgment

A grant of summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). If the moving party meets this burden, the nonmovant must then "come forward with specific facts showing that there is a *genuine issue for trial*." *Id.* at 587 (emphasis in original) (internal quotation marks omitted). If the nonmoving party fails to make a sufficient

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[3] The parties have filed a prodigious number of additional motions—motions for summary judgment and *Daubert* motions seeking to exclude certain expert testimony. (D.I. 226, 229, 231, 235, 238, 241, 244, 250, 253, 256) Those motions remain pending before the Court.

showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). During this process, 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).

However, in order to defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586-87; *see also Podobnik v. U.S. Postal Serv.*, 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 and citation omitted). The "mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original). Facts that could alter the outcome are "material," and a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted). A party asserting that a fact cannot be—or, alternatively, is—genuinely disputed must support the assertion either by citing to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials"; or by "showing that the materials cited do not

establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B).

B. Infringement

The patent infringement analysis consists of two steps. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must determine the meaning and scope of the patent claims asserted to be infringed. *Id.* Claim construction is a generally a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). Second, the trier of fact must compare the properly construed claims to the allegedly infringing device. *Markman*, 52 F.3d at 976. This second step is a question of fact. *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012).

"Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device." *Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1477 (Fed. Cir. 1998). If any claim limitation is absent from the accused product, there is no literal infringement as a matter of law. *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1374 (Fed. Cir. 2009). A product that does not literally infringe a patent claim may still infringe under the doctrine of equivalents if the differences between the claimed invention and the accused product are insubstantial. *See Warner-Jenkinson Co., Inc. v. Hillton Davis Chem. Co.*, 520 U.S. 17, 24, 40 (1997); *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1322 (Fed. Cir. 2014). The patent owner has the burden of proving infringement, and must do so by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

When an accused infringer moves for summary judgment of non-infringement, such relief is only appropriate if, viewing the facts in the light most favorable to the patentee, no reasonable jury could find that every limitation recited in the properly construed claim is found in the accused device, either literally or under the doctrine of equivalents. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *see also Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001) ("[S]ummary judgment is proper only if no reasonable jury could return a verdict for the nonmoving party.") (internal quotation marks and citation omitted). Because the patentee bears the burden of proof on infringement, the accused infringer moving for summary judgment is not required to put forward evidence of non-infringement. *Exigent Tech., Inc. v. Atrana Solutions, Inc.*, 442 F.3d 1301, 1307-09 (Fed. Cir. 2006). Rather, "nothing more is required than the filing of a summary judgment motion stating that the patentee ha[s] no evidence of infringement and pointing to the specific ways in which [the] accused [products] d[o] not meet the claim limitations." *Id.* at 1309. The burden of production then shifts to the patentee to "identify genuine issues that preclude summary judgment." *Novatek, Inc. v. Sollami Co.*, 559 F. App'x 1011, 1022 (Fed. Cir. 2014) (internal quotation marks and citation omitted).

III. DISCUSSION

The asserted claims of the '892 and '285 Patents require the covering material of the stent-graft device to be "affixed" to one or more surfaces of the stent, or require the "affixing" of the covering material to a stent surface. Bard argues that its accused Fluency Plus and Flair products do not infringe because the ePTFE coverings of these devices do not meet the "affixed"/"affixing" limitations of the claims. (D.I. 248, 341) It is undisputed that the coverings

of these devices are affixed to each other through openings in the stent. (*See, e.g.*, D.I. 248 at 5; D.I. 291 at 2) In Bard's view, that is the extent of the "affixation" that occurs; it claims Gore has presented no evidence to the contrary. (D.I. 248 at 4)

Gore makes three primary arguments in response. First, Gore contends that summary judgment must be denied because Bard's Motion contradicts the Court's claim construction regarding the affixing limitation. (D.I. 291 at 6-8) Second, Gore asserts that the accused products themselves, as well as evidence regarding those products, show, at the very least, a genuine issue of material fact regarding whether the covering material of Bard's devices are affixed to the stent surfaces. (*Id.* at 9-19) Third, Gore argues that summary judgment is precluded by its doctrine of equivalents analysis. (*Id.* at 19-20)

The Court will address each of Gore's arguments below. In doing so, the Court provides further clarification of the "affixed"/"affixing" limitations, which the parties' positions have shown to be necessary. Ultimately, the Court concludes that the evidence raises a genuine issue of material fact as to non-infringement that must be submitted to a jury.

A. The Court's Claim Construction is Not Dispositive of the Issue of Infringement of the "Affixed"/"Affixing" Limitations

Claim 32 of the '892 Patent, from which asserted claims 33 and 40 depend, requires "a first tubular covering [of ePTFE] affixed to the exterior surface of the . . . stent" and "a second tubular covering [of ePTFE] affixed to the luminal surface of the . . . stent." ('892 Patent, col. 11:31-36) Dependent claim 33 of the '892 Patent specifies a method by which the coverings may be affixed to a stent surface, claiming a "tubular intraluminal graft according to claim **32** wherein the first tubular covering of [ePTFE] is affixed to the second tubular covering of [ePTFE] film through openings through the wall of the stent." (*Id.*, col. 11:40-44) Claim 12 of the '285 Patent,

which is incorporated (via claim 13) into asserted claim 15 of that patent, requires "affixing a tubular covering [of ePTFE] to the luminal surface of the . . . stent." ('285 Patent, col. 10:6-7, 12, 17-18)

During the claim construction process, the parties briefed a claim construction dispute relating to the terms "affixed" and "affixing." Bard argued for these terms to be construed to mean "secured/securing" while Gore argued for plain and ordinary meaning. (D.I. 99 at 18-19; D.I. 101 at 14-16; D.I. 111 at 16-17; D.I. 115 at 15-16) Ultimately, the parties agreed at the *Markman* hearing that "affixed" or "affixing" does not mean "merely placing on" but instead "connotes a secure connection." (D.I. 221 at 28 (internal quotation marks and citation omitted); *see also* D.I. 248 at 8) Therefore, the Court declined to construe these terms. (D.I. 221 at 28)

The Court proceeded to resolve a related dispute between the parties concerning claim 33. Gore had argued that the type of affixation described in that claim (i.e., two coverings being affixed together "through openings through the wall of the stent") amounted to a specific *way* of affixing ePTFE coverings to the surface of the stent (i.e, the type of affixation disclosed in claim 32). (*Id.* at 30) Conversely, the Court understood Bard's contrary position to be that the affixation described in claim 33 simply could not amount to a way of affixing ePTFE coverings to a stent surface. (*Id.* (citing D.I. 130 at 133-34, 140 & 142); *see also* D.I. 130 at 131-32) In articulating this position, Bard proposed a construction for the "affixed" term in claim 33: "'the first and second coverings are secured to each other through openings through the wall of the stent in addition to being secured to the exterior and luminal surfaces of the stent.'" (D.I. 221 at 29) Bard argued that Claim 33 required "two separate sets of connections: one set of connections between the first and second coverings, and a second set of connections between a

covering and the stent." (D.I. 115 at 17)

In resolving what it understood to be the dispute between the parties, the Court agreed with Gore that "dependent claim 33 describes a way in which stent coverings may be affixed to a stent surface." (D.I. 221 at 32) The primary impetus for this conclusion was the following paragraph in the asserted patents' specification:

> *Stent coverings may be affixed to a stent surface by variations on this method.* For example, ... *The inner **83** and outer **85** portions of the tubular sleeve **81** may be thermally adhered to each other through the openings in the stent wall*, or may be adhered to the stent surfaces by an adhesive such as FEP, or may be affixed to the stent by suturing the open ends **87** of the tube together.

(*Id.* at 30 (quoting '892 Patent, col. 7:51-61 (emphasis added))) Thus, as the Court's Report and Recommendation explained, the specification delineated at least three ways in which coverings may be affixed "*to a stent surface*: (1) coverings may be thermally adhered to each other through stent wall openings; (2) the coverings may be adhered to the stent surfaces by an adhesive; or (3) the open ends of the coverings may sutured together." (*Id.* (emphasis in original)) The Court noted that while independent claim 32 does not specify how the coverings must be affixed to the stent surfaces, dependent claim 33 discloses one such specific method by which that affixation may occur—that is, via affixing the ePTFE coverings together through the openings in the stent wall. (*Id.* at 31)

In opposing Bard's Motion, Gore now asserts that the Court construed the language at issue in dependent claim 33 to mean that "[a]ffixing [t]wo [c]overings [t]ogether [a]ccomplishes [a]ffixing to the [s]tent [s]urfaces[.]" (D.I. 291 at 6; *see also id.* at 7) That is, Gore interprets the Court's claim construction opinion as concluding that when such ePTFE coverings are thermally adhered to each other through stent wall openings, the fact of this adherence alone (without

anything more being required) always necessarily equates to a circumstance in which coverings are "affixed" to the stent surface. According to Gore, it follows that Bard's contrary position (that "'the mere fact graft materials may be affixed to one another through stent openings is [not] sufficient to satisfy affixing to the specific surfaces of the stent as the claims require'") directly contradicts the Court's claim construction. (*Id.* at 7 (quoting D.I. 248 at 4))

Gore inaccurately reads the Court's construction. Its interpretation appears to derive from a misunderstanding of one sentence in the Report and Recommendation. (D.I. 291 at 1, 6) In that sentence, as part of a paragraph explaining that claim 33 describes *a way* in which coverings could be affixed to a stent surface, the Court noted: "As Gore explains, it follows that 'once the two coverings are affixed to one another, they are also affixed to the relevant surfaces of the stent.'" (D.I. 221 at 31 (quoting D.I. 111 at 18; D.I. 130 at 125; *id.* at 139)) Yet this sentence was not intended to convey that any time two ePTFE coverings are "affixed" together through stent openings, that automatically means that the coverings are affixed to the stent surfaces. To the contrary, the Court's Report and Recommendation proceeds to make clear that affixing stent coverings together through openings of the stent wall is simply one method by which those coverings "*may* be affixed *to a stent surface*." (*Id.* at 32 (emphasis added); *see also id.* at 30 ("The specification thus plainly sets out three 'variations' of how coverings *may* be affixed *to a stent surface* . . . ." (emphasis added); *id.* at 30-31 (explaining that thermal adhesion, adhesion with an adhesive, and suturing "are all ways in which coverings *may* be affixed *to a stent surface*") (emphasis added)) In setting out this conclusion, the Court did not intend to suggest that the method of affixation described in claim 33 (i.e., thermal adhesion of the coverings) could result in the coverings being "affixed to the . . . surface of the . . . stent" (as required by claim 32)

if the coverings never actually made contact with the surface of the stent and were not actually secured to the stent surface.[4]

Gore's interpretation of the Court's claim construction could lead to illogical results. For instance, under its interpretation, a hypothetical stent-graft device would satisfy the "affixed"/"affixing" limitations in the asserted claims if the device included ePTFE coverings that were adhered together through stent wall openings, but otherwise hung loosely away from all of the actual stent surfaces (i.e., where no portion of the coverings had actual contact with any stent surfaces), and where the coverings were not "secured" to the stent surface. But that would make no sense, because such a device would very clearly fail to satisfy the asserted claims' requirement that the coverings be affixed "to the . . . surface of the . . . stent" or involve "affixing . . . to the . . . surface of the . . . stent[.]" ('892 Patent, col. 11:31-36; '285 Patent, col. 10:6-7; *see also* D.I. 221 at 30)[5]

In light of the claim construction issues that have arisen on summary judgment with respect to the language of claim 33 (and the other asserted claims), it is clear to the Court that further clarification as to the "affixed"/"affixing" limitations is required. *Cf. 02 Micro Int'l Ltd.*

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[4] Put another way, when the Court rejected Bard's proffered construction for the disputed term in claim 33, the Court was rejecting what it perceived to be Bard's suggestion that ePTFE coverings could never be affixed to the stent surface *solely* through the use of the method of thermally adhering those coverings to each other through the stent wall (i.e., that some *additional* method or process was required to achieve such affixation). But the Court did not intend to suggest that the use of the thermal adhesion method for adhering coverings to each other *always necessarily* results in affixation of the coverings to a stent surface.

[5] Even Gore's counsel acknowledged at oral argument that if a configuration resulted in a "big enough pocket" between the coverings and stent surface, those coverings "wouldn't be affixed to the stent surface." (Tr. at 161) But whether the coverings were entirely separated from the stent surface by a "big enough pocket" or a smaller pocket—either way they would not be affixed "to the . . . surface of the . . . stent."

v. Beyond Innovation Tech. Co., Ltd., 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it.").

B. Clarification of Construction of "Affixed"/"Affixing" Limitations

As explained above, the Court concluded in the Report and Recommendation regarding claim construction that there was no dispute that the terms "affixed"/"affixing" (as found in claims 32, 33 and 40 of the '892 Patent and claim 12 of the '285 Patent) connote a secured connection. (D.I. 221 at 28) It also concluded that in light of the '892 Patent's claim language and specification, "dependent claim 33 describes a way in which stent coverings may be affixed to a stent surface[.]" (*Id.* at 32) The Court then noted that because "claim 33 is otherwise clear as to the method of affixing disclosed therein," the term "the first tubular covering of porous [ePTFE] is affixed to the second tubular covering of porous [ePTFE] film through openings through the wall of the stent" should be afforded its plain and ordinary meaning. (*Id.*)

The Court now further clarifies its claim construction as to the "affixed"/"affixing" terms. In order for an ePTFE covering to be "affixed . . . to the . . . surface of the . . . stent" or involve "affixing . . . to the . . . surface of the . . . stent" (as required by claim 32 of the '892 Patent and claim 12 of the '285 Patent, respectively), there must be at least some contact between the covering and the stent surface. But as all parties agree, contact that amounts to nothing more than the covering touching or being located "on" the stent surface is not sufficient to satisfy the claim.[6] (*See* D.I. 249, ex. 1 at 210 (Gore's expert stating that "[t]ouching is not affixed"); Tr. at

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[6] Bard helpfully points out that the claims of the (formerly asserted) '487 Patent buttress the notion that the coverings and stent surfaces of the asserted claims require a relationship amounting to more than mere touching. (D.I. 248 at 9; D.I. 341 at 6) In the '487

162 (Gore's counsel agreeing that coverings being "on" a stent—"touch[ing]" it—is not enough to satisfy the claim); Tr. at 127, 131 (Bard's counsel explaining that being "on" is not affixed)) And there is no dispute that being "affixed" or "affixing"—as those terms are used in the relevant claims—requires being "secured" or "securing." (*See* D.I. 221 at 28)

Therefore, it follows that for the "affixed" or "affixing" claim limitations at issue to be met, the covering(s) must contact the stent surface, and must be secured to the stent surface. As for claim 33, it requires that a stent-graft device must have two coverings affixed to each other through openings through the stent wall, and those coverings must contact the exterior and luminal surfaces of the stent in a manner providing a secure connection with the stent surface. (*See* Tr. at 162 (Gore's counsel acknowledging that for the limitation to be satisfied, the coverings must be "on[,] plus, touch it and in such a way that they are secured"); *id.* at 166 (Bard's counsel explaining that Gore does not "have to just prove adjacency or on, they have to prove on[,] plus. And the plus is a secure connection"))

C. The Evidence Raises a Genuine Issue of Material Fact as to Whether Bard's Devices Satisfy the "Affixed" or "Affixing" Limitations

The Court now turns to whether a reasonable jury could find that the accused products satisfy the "affixed"/"affixing" limitations in the asserted claims. Both parties are in agreement that there is at least some contact between the coverings of Fluency Plus and Flair and the stent

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Patent, certain claims recite the covering as being "adjacent to" the stent surface. (*See, e.g.*, D.I. 96, ex. X, '487 Patent, cl. 1) Before Gore withdrew the '487 Patent from the case, "adjacent" was a disputed term presented by the parties for construction. (*See, e.g.*, D.I. 99 at 19; D.I. 101 at 17-18) During the *Markman* hearing, Gore's counsel explained Gore's view that the term "adjacent" does not specify that there is a specific connection, but instead simply conveys where the covering is "located[;]" the term "affixed[,]" in contrast, indicates "that's where [the covering] is located, and it's held in place there. It's affixed there." (D.I. 130 at 147)

surfaces of those devices. (*See, e.g.*, D.I. 291 at 11 (citing D.I. 307, ex. 4 at 18-19, 92-93) (Gore citing to deposition testimony of Bard witness Scott Randall, Bard's Director of R&D, stating that the ePTFE coverings are "on" the luminal and exterior surfaces of the Flair device); *id.* at 15 n.7 (citing D.I. 307, ex. 2 at 470-71 & ex. 3 at 180-81) (Gore citing to testimony of Bard's experts Dr. Nigel Buller and Robert Calcote, wherein the witnesses state that the ePTFE coverings of the Flair and Fluency Plus devices are "'in contact'" with the stent surfaces of the devices in certain places); Tr. at 134, 166 (Bard's counsel acknowledging that some ePTFE touches the stent surfaces of the accused products)) Thus, at least for purposes of this Motion, this necessary precursor to the requisite affixation is met.

The key question here is whether Gore has pointed to evidence that would allow a jury to determine that the coverings are "on[,] plus"—that they not only have contact with the stent surfaces, but that the nature of that contact results in the coverings being "secured" to the stent surfaces. Gore contends that it has done so, largely by pointing to evidence purportedly showing that Bard's coverings are "held tightly enough to the stent surfaces to be considered 'affixed' or 'secured' to those surfaces[.]" (D.I. 291 at 19; *see also id.* at 10)

For its part, Bard disagrees that such a relationship between stent-graft materials could ever equate to a covering that is "affixed" to a stent surface. (D.I. 341 at 4-5 ("Gore argues incorrectly that if a graft is 'held tightly' to the stent, it must also be 'affixed' to the stent surface")) At times, Bard appears to suggest that its coverings must either be physically adhered or bonded to the stent surface in order to satisfy the limitation. (*See* D.I. 248 at 10-11 [redacted]; *see also* D.I. 341 at 4-5) Bard argues that

Gore has presented no evidence demonstrating the requisite affixation, and the evidence that Gore has put forward is not relevant. (D.I. 341 at 1 ("Evidence that a graft is generally held to the stent is not evidence that the graft material has a 'secure connection' to a stent surface . . . ."); *see also id.* at 4-5; Tr. at 120, 125)

Contrary to Bard's position, a jury could find the "affixed"/"affixing" limitations satisfied by a stent sufficiently enveloped in coverings (that are themselves bonded together through stent openings) such that those coverings are held sufficiently tight to the stent surface. Indeed, as Gore points out, "[n]one of the methods disclosed in the specification results in direct adhesion between all portions of the stent surface and the coverings, and two of the three methods work by surrounding and capturing the stent." (D.I. 291 at 4) These two methods are thermal adhesion [redacted] and suturing. The specification describes the latter method, suturing, as a way in which "[s]tent coverings may be affixed to a stent surface" and explains that an ePTFE tubular covering which has been "inverted back into itself and fitted over the inner and outer surfaces of a stent . . . . may be affixed to the stent by suturing the open ends of the tube together." ('892 Patent, col. 7:52-56, 60-61) In other words, suturing is one method by which the coverings may touch the stent and be secured to the stent. (D.I. 291 at 4)[7] The thermal adhesion method is another.[8]

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[7] In fact, during the claim construction process, Bard itself pinpointed this suturing method as a way in which to "affix[] a covering to the stent"—a method that "secure[s] the covering to the stent." (D.I. 101 at 15)

[8] In demonstrating its view regarding the nature of the affixation sufficient to satisfy the claims, Gore also cites to deposition testimony of Bard's expert Dr. Buller. This particular testimony suggests that Dr. Buller believes that items "held firmly" together are "affixed together." (D.I. 291 at 13 (citing D.I. 307, ex. 2 at 488) (Dr. Buller explaining that the coverings are affixed during the compression process when they are tightly wrapped with tape and offering the comparison that "in your workshop at your home, in your garage, you might sort of clamp

With that said, then, the Court concludes that the existing, remaining dispute between the parties—whether Gore's evidence demonstrates that a sufficiently secure connection exists between the accused products' ePTFE coverings and stent surface—is a fact question that a jury should resolve. It is, after all, in the province of the jury to determine the proper application of the "affixed"/"affixing" limitations to the accused device. *See PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998); *Genentech, Inc. v. Trustees of Univ. of Pa.*, 871 F. Supp. 2d 963, 971 (N.D. Cal. 2012). A court may not "under the rubric of claim construction, [] give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product." *PPG Indus.*, 156 F.3d at 1355; *see also Genentech, Inc.*, 871 F. Supp. 2d at 971. "Rather, after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact." *PPG Indus.*, 156 F.3d at 1355; *see also Genentech, Inc.*, 871 F. Supp. 2d at 971. Here, the Court has construed the "affixed"/"affixing" claim terms. To the extent Bard challenges Gore's evidence as to whether the requisite secured connection is wanting, that is a question "for the finder of fact." (*See* D.I. 341 at 3 (Bard noting that "Gore assured the Court that it recognized that whether the 'covering' was 'affixed' to the surface of the stent was a fact issue. [] It is . . . ." (internal citation omitted)))

Of course, if the quantum and nature of Gore's evidence on this point was such that no reasonable fact finder could rule in its favor on infringement, then the matter should not proceed to the jury at all. But after reviewing the evidence Gore has put forward (and giving Gore the

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things together, and therefore, *you'd say they're held firmly, they're affixed together*, and that's already occurred") (emphasis in original))

benefit of all reasonable inferences), the Court concludes this is not the case. Gore has presented sufficient evidence to at least raise a genuine issue of material fact as to whether the "affixed" or "affixing" limitations are met.

One such category of evidence relates to Bard's '217 Patent. Bard has repeatedly pointed to the design of the Fluency Plus and Flair products as direct evidence, purportedly unrebutted by Gore, showing that the coverings of its accused devices are not affixed to any stent surface. (D.I. 248, 341) Bard asserts that it "uses its own patented encapsulation method which is designed to form, and results in, gaps that separate the stent surface from the graft material, thus allowing relative movement between the two." (D.I. 248 at 3 (footnote omitted))[9] Bard states that the '217 Patent covers this encapsulation process. (*Id.* at 3 & n.1; *id.* at 5 n.3; D.I. 341 at 10; Buller Decl., ex. B at ¶¶ 107-126, 134) It does not point to any specific portion of the patent as describing the gaps that the process purportedly creates.[10]

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[9] (*See also* D.I. 248 at 8 ("Bard's patented encapsulation process creates space around the polished stent surfaces specifically designed to ensure there is no securement so that the stent may move relative to the graft material"); Tr. at 115, 133, 166 (Bard's counsel explaining that Bard deliberately designed the devices to create "pockets" between the ePTFE coverings and the stent, and to not have the coverings affixed to the stent, a design choice that increases the "flexibility" of the devices))

[10] During oral argument, Bard pointed to, *inter alia*, Dr. Buller's expert report in support of its position that the coverings of the accused products do not affix to stent surfaces. (Tr. at 117) Dr. Buller opined that "Bard specifically designed its encapsulation process to avoid affixing ePTFE to a stent surface" such that "the resulting pockets around the stent [of the Flair device] add flexibility to the stent graft." (Bard's "Summary Judgment and *Daubert* Hearing" Presentation at Section 2, Slide 11 (quoting Buller Decl., ex. B at ¶ 134)) In support of this proposition, Dr. Buller cited to "[e].g., U.S. Patent No. 6,245,099 [the "'099 Patent"]." (*Id.* (quoting Buller Decl., ex. B at ¶ 134)) The Abstract of the '099 Patent describes a method for creating endoluminal vascular devices that "permits a stent device to be encapsulated between two layers of ePTFE with unbonded slip pockets to accommodate movement of the structural members of the stent." (*Id.* at Section 2, Slide 12 (quoting '099 Patent at Abstract)) But Bard has not specifically cited to the '099 Patent as one that covers the accused products here, and Dr.

Yet in response, Gore contends that the '217 Patent is a piece of evidence that actually *supports* its infringement argument—amounting to some evidence "confirm[ing] that Bard affixes its coverings to the stent surfaces as taught by Gore's asserted patents." (D.I. 291 at 9) For one, Gore points out that the patent does not refer to "gaps," "spaces" or "pockets" around the stent struts. (Tr. at 158; *see also* Gore's "Dispositive Motions Hearing" Presentation at Section 2, Slide 37) Gore also highlights language in the patent's specification that describes preferred embodiments of the invention as "an intraluminal stent 20 which is at least partially encapsulated within a substantially monolithic *ePTFE covering **14** over at least an entire circumferential portion of the luminal and abluminal surfaces of the intraluminal stent **12**.*" (D.I. 308, ex. 50 (the '217 Patent), col. 7:15-20 & FIG. 4 (*quoted in* Gore's "Dispositive Motions Hearing" Presentation at Section 2, Slide 38) (emphasis added); Tr. at 158-59) And Gore notes that when Bard first filed its application for the '217 Patent, the United States Patent and Trademark Office ("PTO") rejected original claim 1 as obvious over the '892 Patent. (D.I. 291 at 8-9; D.I. 307, ex. 10 at WLG-11-515_00939615) The PTO's Office Action regarding the '217 Patent explained that the '892 Patent "'substantially teaches the basic claimed process of making an encapsulated stent-graft[.]'" (D.I. 291 at 8-9 (quoting D.I. 307, ex. 10 at WLG-11-515_00939615)) Bard's patent was later allowed after it added a requirement for a winding step (which is not found in the asserted patents). (D.I. 291 at 9 n.3; D.I. 307, ex. 10 at WLG-11-515_00939628) Having reviewed the '217 Patent, the Court finds that a reasonable fact finder

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Buller does not clearly do so either—instead, like Bard, he states that it is the '217 Patent that covers the accused products. (Buller Decl., ex. B at ¶¶ 107, 117, 134; *see also* Tr. at 158 (Gore's counsel noting that Bard "point[s] to [] the '217 Patent . . . . [as] the one they say they're practicing"))

could agree with Gore's position.[11]

Next, Gore points to the accused products themselves (samples of which were provided to the Court at oral argument), (Tr. at 9-10), which purportedly show the "coverings are held very tightly to the stent surfaces . . .there's no movement that [] can [be] appreciate[d] at all or achieve[d] between the coverings and the stent surface because they're so tightly affixed to the stent surfaces." (Tr. at 146-47) Likewise, Gore presents photographs of the devices which it claims illustrate that "[t]he coverings are held so tightly that each stent strut[] is clearly visible through the coverings." (D.I. 291 at 10 (citations omitted)); *cf. Bernard Dalsin Mfg. Co. v. RMR Prods., Inc.*, 10 F. App'x 882, 889 (Fed. Cir. 2001) (explaining that, *inter alia* "photographs of the [accused] device . . . raise a genuine issue of material fact as to whether the [] device includes structure equivalent to the" limitations at issue). And indeed, at least to the naked eye, both the actual accused products and the referenced images thereof could reasonably be said to demonstrate what Gore suggests.

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[11] Bard also cites to scanning electron microscope (or "SEM") images taken by its expert, Robert Calcote, as key support for its position that it does not "affix" coverings to the stent surfaces. (D.I. 248 at 4 ("Here the unrebutted direct evidence, including SEM imaging, shows . . . the graft materials are not secured at all to the surfaces of the stent."); *see also id.* at 5, 9; D.I. 341 at 1 (referring to the images as "stark, unassailable evidence that Bard . . . cannot infringe"); *id.* at 3) Dr. Buller likewise cites to the images as "clearly demonstrat[ing] the lack of affixation between ePTFE and stent in the" accused devices. (Buller Decl., ex. B at ¶¶ 130, 225) The images depict pockets of space between the stent and the ePTFE covering (albeit with loose bits of ePTFE remaining on various portions of the stent). (D.I. 248 at 10) Mr. Calcote prepared these images after "having cross sections of the stent grafts cut with wire cutters[.]" (D.I. 260, Calcote Declaration ("Calcote Decl."), ex. A at ¶ 139) But Gore counters that Mr. Calcote himself created the "spaces" or "gaps" shown in the SEM images "when he crudely chopped Bard's devices apart using a wire cutter." (D.I. 291 at 15 n.7 (citing Criado Decl., ex. C at 20); Tr. at 155-56) The Court agrees that in light of Mr. Calcote's wire-cutting technique, a reasonable jury could conclude that the images may not be an entirely accurate representation of the relationship between the coverings and stent surfaces in an intact device.

Further, Gore cites to deposition testimony of Bard witnesses that could suggest a tight enough fit between the materials to amount to a secure connection. (D.I. 291 at 11-12) Bard's Director of R&D (and its Rule 30(b)(6) designee regarding the accused devices) Mr. Randall stated that the coverings are not "attached to the stent" but also explained that the coverings "encapsulate the stent so the stent can't go anywhere because the bonded layers are around it." (D.I. 307, ex. 4 at 65; *see also id.* at 279-80) And Bard's Director of Clinical Affairs, John Reviere, testified that he understood that "all surfaces of the stent, except the ends, were encased in ePTFE[,]" (*id.*, ex. 5 at 21 (testifying as to Fluency Plus)), and that it was his "understanding" that "layers of ePTFE are affixed to the stent such that they don't separate from the stent when it's in operation[,]" (*id.* at 37 (testifying as to Flair)). (*See also id.* at 36 (Mr. Reviere confirming his understanding that the "the exterior surface of the FLAIR stent [is] also covered with ePTFE"))[12]

In addition, Gore cites to the opinions of its experts Dr. Criado and Dr. Gorman on this issue. (D.I. 291 at 16-18) Dr. Criado offers adequate support for his opinion that the ePTFE coverings of the accused products have contact with the stent surface, amounting to a secure connection. For example, he cites to: (1) Bard documents that refer to the stent as being "encapsulated" within ePTFE; (2) the testimony of Bard's witnesses that the coverings do not come detached from the device; and (3) photographs of the devices purportedly demonstrating that "[t]he coverings are so taut against the stent that one is able to see the entire outline of the

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[12] Although Bard's experts clearly opined that Bard's coverings are not affixed to the stent surfaces, (*see, e.g.*, Buller Decl., ex. B at ¶¶ 130, 225; Calcote Decl., ex. A at ¶ 139), Gore cites to testimony by Dr. Buller that a jury might consider in evaluating Gore's position that a sufficiently secure connection exists. (D.I. 291 at 13) Dr. Buller testified that the coverings are put on the stent surfaces and they "stay[] in the place where [they are] put to a degree." (*Id.* at 13-14 (citing D.I. 307, ex. 2 at 470))

stent frame by looking at the exterior or interior of the device" such that the coverings "exert pressure on the intervening stent[.]" (Criado Decl., ex. C at 27-33, 41-47; *see also id.*, ex. A at 90-108, 131-49, 183-92, 224-32) Dr. Gorman's conclusions are similar, and are based on his "observations" of the accused devices and on SEM images of the devices developed by Mr. Calcote. (D.I. 305, Declaration of Robert C. Gorman, M.D. ("Gorman Decl."), ex. A at 19-20 ("Moreover, the coverings were held so tightly to the stent structure that the stent struts were clearly visible through the coverings, and could be seen exerting outward pressure on the coverings when the devices were expanded.") & ex. C at 27-28; *see also* D.I. 307, ex. 14 at 291 (Dr. Gorman testifying that he observed no movement of the coverings relative to the stent in the accused devices))[13]

Bard disagrees with the conclusions of Dr. Criado and Dr. Gorman. Yet that dispute goes to the weight of the testimony and may be properly dealt with on cross-examination. Indeed, it is unsurprising that Bard's experts offer competing opinions to those put forward by Gore's experts. It will be the task of the jury to determine which experts' testimony should be

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[13] Bard counters that these experts' claims are "unsupported and conclusory" and therefore fail to raise an issue of fact. (D.I. 248 at 11-12; *see also* D.I. 341 at 6-7) In doing so, Bard cites to *Regents of Univ. of Minn. v. AGA Med. Corp.*, 717 F.3d 929, 941 (Fed. Cir. 2013) for the well-settled proposition that "'[c]onclusory expert assertions cannot raise triable issues of material fact on summary judgment.'" (D.I. 248 at 12) However, in *Regents*, the expert's testimony was "supported by no explanation or reasoning." *Regents of the Univ. of Minn.*, 717 F.3d at 941 (internal quotation marks and citation omitted). Instead, the expert had simply stated that he did not agree with a particular position, but provided absolutely no explanation as to why. *Regents of Univ. of Minn. v. AGA Med. Corp.*, 835 F. Supp. 2d 711, 720 (D. Minn. 2011). Here, the opinions of Dr. Criado and Dr. Gorman do not suffer from the same glaring deficiency—they explain in some detail the facts supporting their conclusions that Bard's devices satisfy the "affixed"/"affixing" limitations. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 763 F. Supp. 2d 671, 684 (D. Del. 2010) (finding that where an expert provided "sufficient explanation" as to his conclusion why specific structural elements of the accused products were said to infringe, this generated a genuine issue of material fact for trial).

embraced. *See B-K Lighting, Inc. v. Fresno Valves & Castings, Inc.*, 375 F. App'x 28, 32 (Fed. Cir. 2010) ("This conflict in expert declarations . . . created a genuine issue of material fact that made summary judgment inappropriate."); *Transcenic, Inc. v. Google, Inc.*, C.A. No. 11-582-LPS, 2014 WL 7275835, at *2 (D. Del. Dec. 22, 2014) (summary judgment motions presenting a "'battle of the experts'" were not amenable to resolution prior to the presentation of evidence, including testimony) (citations omitted).

After viewing the facts in the light most favorable to Gore, and drawing all justifiable inferences in Gore's favor, the Court finds that Gore has demonstrated that a genuine issue of material fact exists as to whether the accused devices literally satisfy the "affixed" or "affixing" limitations. Therefore, the Court recommends that Bard's Motion in this regard be denied.

D. Doctrine of Equivalents

In addition to its literal infringement arguments, Gore has also alleged infringement under the doctrine of equivalents. (D.I. 291 at 19-20) A patent claim may be infringed under the doctrine of equivalents "if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co., Inc.*, 520 U.S. at 21. Under the function-way-result test, an element in the accused product is equivalent to a claim limitation if it "performs substantially the same function in substantially the same way to obtain substantially the same result." *Voda v. Cordis Corp.*, 536 F.3d 1311, 1326 (Fed. Cir. 2008) (internal quotation marks and citation omitted).

In its opening brief, Bard asserts (though only in a footnote) that Gore's equivalence theory would impermissibly vitiate the affixing limitation, and thus that "[t]he accused products also do not satisfy th[e limitation at issue] under the doctrine of equivalents." (D.I. 248 at 7 n.4)

The parties go on to further dispute the vitiation issue. (D.I. 291 at 19-20; D.I. 341 at 7-10) Gore points out that its expert, Dr. Criado, opined that the affixation of the Bard's coverings performs substantially the same function (joining the components of the stent graft together) in substantially the same way [redacted] to accomplish substantially the same result (the coverings do not come detached from the stent surfaces) as the "affixed"/ "affixing" limitations. (D.I. 291 at 19 (citing Criado Decl., ex. A at 97-99, 106-08, 138-40, 147-49, 190-92, 230-32; *see also* ex. C at 31-33, 45-57)) While Bard's briefing does not mention Dr. Criado's doctrine of equivalents analysis, (D.I. 248, 341), its expert Dr. Buller has offered a competing analysis, (*see* Buller Decl., ex. B at ¶¶ 138-50 (opining that the function of the "affixed"/"affixing" limitation is creating a well-adhered union between a covering and a stent surface, using an adhesive or other mechanism, to accomplish the result of an attachment formed between the two specific surfaces)).

Having reviewed the parties' arguments, and drawing all reasonable inferences in the light most favorable to Gore, the Court finds that genuine issues of material fact preclude summary judgment on the basis of the doctrine of equivalents. *See Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1314-15 (Fed. Cir. 2009) (finding a material issue of fact precluded summary judgment of noninfringement under the doctrine of equivalents where the parties offered conflicting expert evidence regarding the function of the limitation at issue); *Ateliers de la Haute-Garonne v. Broetje Automation-USA Inc.*, Civil Action No. 09-598-LPS, 2011 WL 4351600, at *2 (D. Del. Sept. 16, 2011); *see also Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609-10 (1950) (explaining that equivalence is a question of fact often requiring consideration of "credibility, persuasiveness and weight of evidence"). Although Bard

argues that the differences between its products and the affixation limitations in the asserted patents are substantial because the product coverings "are not securely connected to the surfaces of the stent and can move freely relative to those surfaces, " (D.I. 341 at 9), a reasonable jury could find that the relationship between the coverings and the stent surfaces is the equivalent of a secure connection (and thus that any difference between it and the limitation are insubstantial). The Court accordingly recommends that Bard's Motion be denied regarding the doctrine of equivalents. *See, e.g.*, *Robocast, Inc. v. Apple, Inc.*, 39 F. Supp. 3d 552, 561 (D. Del. 2014) (noting that certain of the defendant's arguments "are an attack on the application of the doctrine of equivalents to the accused functions" and not reaching those arguments at the summary judgment stage, in light of the Court's denial of the defendant's request for a finding of no literal infringement).

IV. CONCLUSION

For the reasons set out above, the Court recommends that Bard's Motion be DENIED.

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. The 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).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **April 14, 2015** for review by the Court, along with an explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Dated: April 7, 2015

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE