

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

TYCO HEALTHCARE GROUP, LP,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 09-264-SLR
	)	
C.R. BARD, INC., and DAVOL, INC.,	)	
	)	
Defendants.	)	

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**\*\* AMENDED MEMORANDUM OPINION**

Dated: April 29, 2011  
Wilmington, Delaware

  
ROBINSON, District Judge

## I. INTRODUCTION

Plaintiff Tyco Healthcare Group LP (“plaintiff”) filed its complaint against C.R. Bard, Inc. and Davol, Inc. (collectively, “defendants”) on April 21, 2009 alleging infringement of plaintiff’s U.S. Patent No. 6,562,051 (“the ‘051 patent”). (D.I. 1) Defendants raised defenses of noninfringement, invalidity, failure to mark, obviousness-type double patenting, prosecution laches, prosecution history estoppel, and inequitable conduct. (D.I. 24) Defendants subsequently brought an unopposed motion for leave to amend and, on February 2, 2010, entered a counterclaim for false marking as defined under 35 U.S.C. § 292. (D.I. 50) Plaintiff moved to dismiss the counterclaim on the basis that defendants did not set forth sufficient allegations to support their false marking claim pursuant to Federal Rule of Civil Procedure 9(b). (D.I. 62) Plaintiffs amended their complaint, and defendants repleaded their false marking counterclaim. (D.I. 115, 143) At plaintiff’s request, the court terminated plaintiff’s motion to dismiss the superceded pleading. (D.I. 146) Plaintiff thereafter filed another motion to dismiss the counterclaim, this time attacking the court’s subject matter jurisdiction over the claim. (D.I. 157) Discovery is now closed. (D.I. 153) On November 22, 2010, the court denied plaintiff’s motion to dismiss. (D.I. 257) Currently before the court are several motions for summary judgment: (1) plaintiff’s motion for partial summary judgment regarding defendants’ obviousness-type double patenting defense (D.I. 186); (2) defendants’ motion for partial summary judgment on their false marking counterclaim (D.I. 188); (3) defendants’ motion for summary judgment of invalidity of the ‘051 patent for inadequate written description (D.I. 190); and (4) defendants’ motion

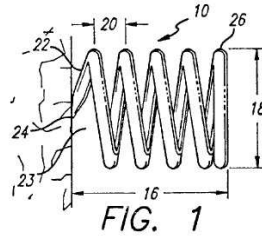
for summary judgment of noninfringement (D.I. 193). Also pending before the court are plaintiff's motions to bifurcate the counterclaim (D.I. 158) and to strike portions of defendants' expert's report (D.I. 183). Defendants also move to amend the joint claim construction chart to add an additional disputed limitation. (D.I. 185) The court has jurisdiction over these matters pursuant to 28 U.S.C. § 1338.

## **II. BACKGROUND**

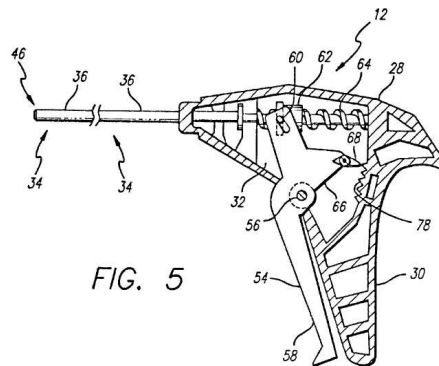
This case involves surgical fasteners used in medical procedures, commonly in the repair of hernias, or protrusions of an organ or bodily tissue through the wall of the cavity that normally contains it. Surgical fasteners may be used during a hernia repair to affix a surgical mesh to the affected tissue. A variety of surgical fastening means have been used by surgeons in hernia repair, such as sutures and staples. The present litigation concerns "tacker"-type fasteners, explained in more detail below.

### **A. The '051 Patent**

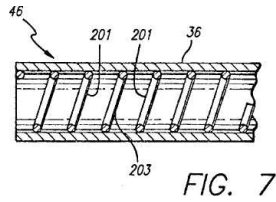
The '051 patent, entitled "Surgical Helical Fastener with Applicator," describes a helical fastener having a high retentive surface area with a first end (for enhancing penetration into tissue) and a second end comprising a coil (for receiving longitudinal and rotational forces). Preferably, the surgical fasteners are formed into the configuration of a continuous helical coil or a double continuous helical coil that is longitudinally collapsible and expandable and which can take on different configurations depending on the surgical application. (Col. 2:53-col.3:14) A coil-shaped fastener according to the invention is pictured in figure 1, as follows.



An applicator is also described for delivering the fastener into body tissue. An applicator of the invention is exemplified in figure 5, as follows.



The applicator has a proximal portion (28) having a handle (30) and actuator (32). (Col. 3:21-22, col. 7:65-67) It also has an elongate distal portion (34) for housing fasteners, comprising an outer tube (36) housing an inner rotator (38), a lock clip/indicator (40) and a load spring (42). (Col. 3:19-21, col. 8:7-9) Preferably, a thread form (201) comprising an interlock spring is provided within the outer tube of the distal end, as pictured in fig. 7, below.



This thread form “functions to engage the coils of the helical fasteners and when rotating the rotator, a fastener is driven from the distal end of the applicator” into the tissue. (Col. 3:29-35, col. 8:54-56)

Claim 1 of the '051 patent, the only independent claim, reads as follows:

1. A system for controllably discharging fasteners from an applicator, comprising:

a plurality of fasteners, said fasteners having a helical configuration;

an applicator for attaching said fasteners to tissue, said applicator including a proximal portion, a distal portion and an actuator assembly;

said distal portion having an elongate outer tube, a connecting end and a terminal end;

a proximal portion having a handle, said proximal portion attached to said connecting end of said distal portion; and

said actuator assembly including a lever and configured to controllably discharge one of said plurality of fasteners from said distal portion upon complete depression of said lever and to prohibit backstroking of said lever where said lever is partially depressed.

In describing the claimed invention, the inventors<sup>1</sup> contrasted prior art fasteners requiring deformation to hold tissue, necessitating a complex applicator system, lacking a high relative surface area for holding tissue, or requiring access to tissue from two directions. (Col. 5:65-col. 6:2; col. 2:30-35) The inventors purported to provide a

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<sup>1</sup>Lee Bolduc, Thomas A. Kramer, Brain A. Hodges, Tim McCoy, and John Lunsford.

superior means for attachment of fasteners to tissue than provided by these prior art systems. (Col. 6:5-7)

### **\*\*III. STANDARD OF REVIEW**

A court shall grant summary judgment only if “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. See *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). “Facts that could alter the outcome are ‘material,’ and disputes are ‘genuine’ if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct.” *Horowitz v. Fed. Kemper Life Assurance Co.*, 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then “must come forward with ‘specific facts showing that there is a genuine issue for trial.’” *Matsushita*, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will “view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion.” *Pa. Coal Ass’n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). If the nonmoving party fails

to make a sufficient 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.

See *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

#### **IV. DISCUSSION**

A brief survey of the patent ownership and prosecution will facilitate the court's disposition of the motions at bar.

##### **1. Ownership**

The inventors of the '051 patent worked for Origin Medisystems, Inc. ("Origin"), to which they executed an assignment of rights in their inventions in October 1994. (D.I. 187, ex. 1) In December 1999, Origin assigned certain patent rights to Sherwood Services AG ("Sherwood"), a Swiss corporation, the assignee listed on the face of the '051 patent. (*Id.*, ex. 2) Sherwood later changed its name to Covidien AG. (*Id.*, ex. 3) In December 2008, Covidien AG merged into Tyco Healthcare Group AG, also a Swiss company, and was dissolved. The resulting company was named Tyco Healthcare Group AG after the completion of the merger. (*Id.*) The '051 patent was assigned to plaintiff on April 17, 2009. (*Id.*) The present suit was filed April 21, 2009. Other patents, such as U.S. Patent No. 5,582,616 ("the '616 patent") and U.S. Patent No. 5,824,008 ("the '008 patent"), issuing from a division of the '616 patent in 1998, were assigned to plaintiff in March 2010. (*Id.*, ex. 4)

##### **2. '051 patent family and prosecution history**

The '051 patent was filed as U.S. Patent Application No. 09/968,100 ("the '100 application") on October 1, 2001. The '100 application is a continuation of U.S. Patent

Application No. 08/499,279 (“the ‘279 application”), now-issued U.S. Patent No. 6,296,656, filed July 7, 1995. The ‘279 application was, in turn, a division of U.S. Patent Application No. 08/286,878 (“the ‘878 application”), filed August 5, 1994 and now issued as the ‘616 patent. The ‘878 application included both fastener and applicator claims; the inventors elected to pursue the applicator claims in the ‘878 application and pursue the fastener claims in the ‘279 divisional application and its progeny. All of these applications share a common specification.

U.S. Patent Application No. 08/812,957 (“the ‘957 application”) was filed as a continuation of the ‘279 application on March 5, 1997. (D.I. 227, ex. 24) Eight claims were presented, numbers 60 to 67, with independent claim 60 reading as follows:

60. A system for controllably discharging fasteners from an applicator, comprising:

a plurality of fasteners;

an applicator for attaching said fasteners to tissue, said applicator including a proximal portion, a distal portion and an actuator assembly;

said distal portion having an elongate outer tube, a connecting end and a terminal end;

a proximal portion having a handle, said proximal portion attached to said connecting end of said distal portion; and

said actuator assembly including a lever and configured to controllably discharge one of said plurality of fasteners from said distal portion upon complete depression of said lever and to prohibit backstroking of said lever where said lever is partially depressed.

(*Id.* at CRB0061827-28) A double patenting rejection followed on the basis of the ‘878 application (then-issued as the ‘616 patent). (*Id.* at CRB0061846) The examiner also issued an obviousness objection in view of U.S. Patent No. 5,607,436 (“Pratt”) because,



in part, it “disclose[d] a multiple clip applier having the elements recited in claim 60.” (Id. at CRB0061847) A terminal disclaimer was filed to overcome the double patenting rejection. (Id. at CRB0061856-857) With respect to the obviousness rejection, the applicants amended claim 60 by adding the limitation from dependent claim 61 (“said applicator further including a rotator . . . configured to reside within said outer tube”) into the body of claim 60 and cancelling dependent claim 61. (Id. at CRB0061852-855) The examiner thereafter rejected claim 60 as amended on obviousness grounds in light of the combination of U.S. Patent No. RE 28,936 (“Noiles”) and Pratt. The examiner reasoned that Noiles disclosed a surgical stapler for discharging a plurality of fasteners including an applicator having proximal and distal ends and an actuator assembly, a rotator for receiving fasteners, and a system for controlling the surgical staple by controlling the thrust bar. (Id. at CRB0061878) Pratt taught the mechanism requiring the lever to be fully compressed before returning to the extended original position, and the combination of references rendered the invention obvious. (Id.)

The applicants again amended claim 60 to require that the fasteners “hav[e] a helical configuration.” (Id. at CRB0061884-87) The rotator limitation was deleted and moved back to a dependant claim (61). (Id. at CRB0061886) A Notice of Allowability was issued on August 12, 1999. (Id. at CRB0061891) The ‘957 application was, however, abandoned for failure to pay the issuance fee in April 2000 and never issued.<sup>2</sup> (Id., ex. 19 at THG012685)

As noted previously, the ‘100 application was filed on October 1, 2001 as a

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<sup>2</sup>Plaintiff cites testimony indicating that it may have lost track of the ‘957 application during the transition between companies in June 1999. (D.I. 225 at 6)

continuation of a divisional of the '878 application. As initially filed, the '100 application included the 59 claims originally contained in the as-filed grandparent '878 application. Those claims were cancelled and replaced with new claims 60-67 – the same claims that had been previously allowed in the '957 application – with remarks that the claims had been previously allowed. (*Id.*) The examiner allowed the claims without further action. The examiner's reasons for allowance were as follows: "The prior art of record closest to the claims is U.S. Patent [No.] 5,258,00 [sic] to Gianturco. The patent failed to suggest placing a plurality of coiled fastener into the applicator. Likewise U.S. Patent [No.] 5,662,683 to Kay fails to teach the above limitations." (*Id.* at THG012669)

A terminal disclaimer was not filed prior to allowance of the '100 application. Following the initiation of the present suit, and in response to defendants' having raised obviousness-type double patenting as a defense in this action, on August 5, 2010, plaintiff filed two "terminal disclaimer[s] to obviate a double patenting rejection over a 'prior' patent" with the PTO for the '051 patent, by which it disclaimed the statutory term of the '051 patent beyond the term of the '616 patent and, separately, the '008 patent. (D.I. 187, ex. 5) Those forms provide that "[t]he owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned." (*Id.*)

### **3. Double patenting**

Plaintiff moves for summary judgment that defendants' obviousness-type double patenting defense is moot in view of a terminal disclaimer filed August 5, 2010. (D.I. 186) It is defendants' position that plaintiff's terminal disclaimers are effective only

prospectively and, therefore, the '051 patent was invalid for obviousness-type double patenting prior to August 5, 2010. (D.I. 222 at 1) Defendants imply that the '051 patent was rendered valid again on this date, as it seeks to bar plaintiff “from recovering damages for any alleged infringement during the period of invalidity.” (*Id.* at 4)

Defendants admit that no Federal Circuit precedent supports their theory. (*Id.*) The Federal Circuit has specifically found that “a patentee may file a disclaimer after issuance of the challenged patent or during litigation, even **after** a finding that the challenged patent is invalid for obviousness-type double patenting.” *Boehringer Ingelheim Intern. GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1347 (Fed. Cir. 2010) (emphasis added) (citing *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005) (“A terminal disclaimer can indeed supplant a finding of invalidity for double patenting”)).<sup>3</sup> *Compare Vikase Corp. v. American Nat'l Can Co.*, 261 F.3d 1316, 1329 (Fed. Cir. 2001) (“Absent fraud or deceptive intent, the correction of inventorship does not affect the validity or enforceability of the patent for the period before the correction.”). Accordingly, the underlying purpose of the bar against obviousness-type double patenting (namely, to prevent extension of the statutory monopoly beyond its specified term) has been achieved by plaintiff’s August 5, 2010 terminal disclaimers, and plaintiff’s motion is granted. *See Syngenta Seeds, Inc. v. Monsanto Co.*, Civ. No. 02-1331, 2004 WL 2790499 (D. Del. Nov. 19, 2004).

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<sup>3</sup>Defendants cite *Perricone* in support for its motion, however, the facts of that case are readily distinguishable. In *Perricone*, the Federal Circuit declined to opine on whether a terminal disclaimer retroactively overcame the obviousness-type double patenting basis for invalidity where the district court had already invalidated the claims and no terminal disclaimer had been filed. 432 F.3d at 1375.

#### 4. Plaintiff's evidentiary motions

Plaintiff has moved to strike paragraphs 319-23 of the opening expert report of Dr. Alexander Slocum ("Slocum"), defendants' expert (D.I. 183).<sup>4</sup> The portion of Slocum's report reads, in its entirety:

##### **Failure to disclose the '008 patent**

319. The claims of the '008 patent are material to the claims of the '616 patent under the clear and convincing evidence standard.

320. The claims of the '008 patent are not cumulative of the art the examiner considered during prosecution of the '051 patent. For example, none of the art of record disclosed an applicator for applying a plurality of coil fasteners.

321. In addition, as described above, asserted claims 1 and 2 of the '051 patent are obvious in light of claim 7 of the '008 patent.

322. The claims of the '008 patent are also inconsistent with the both [sic] applicants' arguments to overcome Noiles and Pratt and the examiner's reasons for allowance described above. Specifically, the claims of the '008 patent disclose an applicator that contains a plurality of coiled fasteners.

323. I note that the examiners of the '008 and '051 patents were different.

(D.I. 183, ex. 1) Plaintiff argues that defendants did not previously plead inequitable conduct with the particularity required by Federal Rule of Civil Procedure 9(b). (D.I. 183) In response, defendants direct the court to paragraph 31 of their first amended answer, in which they stated:

31. By failing to disclose the rejection and terminal disclaimer [filed in the '957 patent], the prosecuting attorneys intentionally withheld material information from the [PTO] with specific intent to deceive the [PTO]. This allowed the applicants

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<sup>4</sup>Plaintiff filed, and subsequently withdrew, a *Daubert* motion to exclude Slocum's opinion that the '051 patent is invalid for inequitable conduct. (D.I. 182) That motion was premised on what plaintiff deemed an incorrect legal standard by which Slocum adjudged the materiality of the double patenting rejection issued during prosecution of the '957 application. (*Id.*)

to improperly gain at least three benefits. First, an additional eleven months of life of the '051 patent. . . Second, free transferability. . . Third, freedom to limit a post-issuance terminal disclaimer to only those claims obvious over the '616 patent. Pre-issuance terminal disclaimers take effect as to all claims. This failure to disclose the rejection and terminal disclaimer constitutes inequitable conduct and renders each of the claims of the '051 patent unenforceable.

(D.I. 24) Defendants also direct the court to their supplemental interrogatory response (no. 10) served on May 21, 2010, in which they additionally provided that:

Russell Kassner, prosecuting attorney for the '051 patent, committed inequitable conduct during prosecution of [the '100 application] by failing to cite the '008 patent to the examiner. The '051 patent is invalid for obviousness-type double patenting in light of the '008 patent for the reasons set forth in defendants' second supplemental response to interrogatory no. 8. Upon information and belief, Mr. Kassner, having been provided with copies of all pending and patented applications in the '051 patent family, subsequently failed to disclose the issuance of the '008 patent to the examiner of the '100 application, thereby withholding material information with specific intent to deceive the [PTO]. By avoiding a double patenting rejection, and therefore circumventing the need for a terminal disclaimer, Tyco improperly gained at least three benefits . . . . This failure to disclose the '008 patent constitutes inequitable conduct and renders each of the claims of the '051 patent unenforceable.

(D.I. 210, ex. 1 at 12-13)

As the court understands it, defendants intend to demonstrate that Mr. Kassner committed inequitable conduct by failing to disclose that claims 60-67 of the '100 application were previously rejected due to double patenting while the same claims were being examined in the '957 application. The materiality of such a fact is a legal determination; there is no summary judgment motion pending in this regard.

With respect to intent, the court agrees with plaintiff that defendants point to no resuscitation of facts that could support the inference of an intent to deceive. See *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009) (“Although ‘knowledge’ and ‘intent’ may be averred generally, our precedent, like that of

several regional circuits, requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.”).

The court was previously presented with a motion to dismiss the inequitable conduct defense premised on the fact that it was introduced at the end of the pleadings period and was not responsive to plaintiff’s amended complaint. (D.I. 156 at 5) Plaintiff never sought dismissal on the basis of the sufficiency of the pleading vis a vis Rule 9(b). (*Id.* at 5-6) Plaintiff later withdrew its motion. (D.I. 165)

Rather than challenging the claim directly, plaintiff essentially seeks to avoid trial on inequitable conduct by striking Slocum’s report, thereby hindering defendants’ ability to prove its case. It is unclear whether defendants have other evidence they wish to present on their inequitable conduct claim.<sup>5</sup> Slocum’s report is not challenged as untimely or on any other bases. Therefore, the court denies plaintiff’s motion to strike. The court will take up inequitable conduct as a bench issue.

## **B. False Marking**

Defendants’ counterclaim for false marking is at issue on three pending motions: (1) defendants’ motion for partial summary judgment (D.I. 188); (2) plaintiff’s motion to bifurcate (D.I. 158); and (3) plaintiff’s recent motion to serve a supplemental expert report by its expert Dr. Willian Durfee (“Durfee”) (D.I. 263). Defendants contend that plaintiff falsely marks its own device, the AbsorbaTack, with the ‘051 patent in violation

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<sup>5</sup>Although the court certainly appreciates succinct and tailored briefing, it notes that the parties’ combined papers on the motion to strike total about fifteen pages; the record is not necessarily fully developed with respect to the merits of defendants’ claim.

of 35 U.S.C. § 292. It is undisputed that plaintiff marks the AbsorbaTack with the '051 patent and has done so since approximately April 2008.

### **1. Standards**

To prove their claim, defendants must demonstrate that AbsorbaTack is “unpatented” relative to the '051 patent. See 35 U.S.C. § 292; *Pequignot v. Solo Cup Co.*, 608 F.3d 1356, 1361-62 (Fed. Cir. 2010) (an “unpatented article” extends to products marked with inapplicable or expired patent numbers). Additionally, defendants must prove that plaintiff marked AbsorbaTack with the '051 patent for the purpose of deceiving the public. See *Pequignot*, 608 F.3d at 1363 (combination of “a false statement and knowledge that the statement was false create a rebuttable presumption of intent to deceive”).

### **2. Procedural posture**

In the court’s view, neither party has appropriately approached the false marking issue. Defendants’ sole allegation of the required intent to deceive is that plaintiff’s in-house counsel, Joseph Bender-Zanoni, is “intimately familiar with the claim limitations,” “knew that the AbsorbaTack was not covered by the '051 patent, and marked the AbsorbaTack with the '051 patent with the intent of deceiving the public.” (D.I. 143 at ¶ 54) Arguably, this is insufficient under Rule 9(b). See, e.g., *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997) (“boilerplate and conclusory allegations will not suffice,” as parties must supply “factual allegations that make their theoretically viable claim plausible”). Yet plaintiff abandoned its substantive challenge to defendants’ pleading, instead electing to challenge defendants’ false marking claim

on standing grounds. (D.I. 146, 157)

The claim remained in the litigation whereupon plaintiff (unilaterally) determined that bifurcation was appropriate and it need not partake in discovery on the issue. Plaintiff argues in this regard that bifurcation would prevent it from having to decide “prematurely” whether to waive the attorney-client privilege with respect to defending against defendants’ allegations of intentional mismarking, and evidence regarding plaintiff’s device (the AbsorbaTack) would be confusing to a jury deciding infringement by defendant. (D.I. 233 at 7, 10)<sup>6</sup> Plaintiff’s confidence in its position is evidenced by its election to move for bifurcation after the close of fact discovery. Moreover, with less than two months remaining before trial, plaintiff filed a motion for leave to serve a supplemental expert report directed to whether AbsorbaTack is covered by the ‘051 patent claims. (D.I. 263)

Defendants now move for summary judgment, not on the entire issue of false marking, but only the mismarking component. (D.I. 189) Defendants still seek to introduce at trial evidence of plaintiff’s alleged intent to deceive the public, presumably to discredit plaintiff vis a vis its allegations that defendants’ products infringe the ‘051 patent. What is, at worst, ineffective representation and, at best, gamesmanship by the

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<sup>6</sup>The complete list of bases for plaintiff’s motion to bifurcate under Rule 42(b) is as follows: (1) bifurcating would prevent plaintiff from “having to decide prematurely whether to waive the attorney-client privilege” with respect to defending against defendants’ allegations of intentional mismarking; (2) the court has already bifurcated willfulness; (3) evidence regarding plaintiff’s device (the AbsorbaTack) would be confusing to a jury deciding infringement; (4) trial would be lengthened by including false marking; (5) a jury would be asked to decide a question of intent, “demand[ing] a substantial portion of [its] time and attention;” and (6) bifurcation would conserve judicial resources. (D.I. 158 at 4, 9)



parties has resulted in the court's taking up the issue on an incomplete record.

### 3. Defendants' motion for summary judgment

Plaintiff freely admits that it "proceeded on the assumption that false marking is not in the case" until the court ruled on its motion to bifurcate. (D.I. 226 at 11) Prior to the close of discovery, plaintiff obtained no expert opinion on whether the AbsorbaTack fastener has "the overall shape of a coil" – defendants' proposed construction for "helical configuration." (*Id.* at 12)<sup>7</sup> In its responsive papers, plaintiff cites no particular evidence with respect to the "helical configuration" term under either proposed claim construction. (*Id.* at 18-19) Plaintiff claims only that AbsorbaTack meets the '051 patent limitations under the doctrine of equivalents; it now "requests the opportunity to investigate and develop any contentions that the AbsorbaTack literally meets the 'prohibit backstroking' limitation" of the claims. (*Id.* at 14; *see also* D.I. 189 at 10-11 (citing interrogatory response)) Plaintiff's theory with respect to the "backstroking" limitation (under the doctrine of equivalents) consists of attorney argument. (D.I. 226 at 19-20) Yet plaintiff did not file a Rule 56(f) motion in response to defendants' motion documenting a need for discovery prior to judgment.

Notwithstanding plaintiff's decision not to participate in discovery, the parties dispute whether the doctrine of equivalents is applicable to a false marking analysis in the first instance. This court has formerly held that the doctrine of equivalents is inapplicable to a false marking analysis. *See Clontech Labs., Inc. v. Invitrogen Corp.*,

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<sup>7</sup>In its answering papers, plaintiff summarily states that its expert opinion on **defendants'** fastener "would apply" to its own product. The court disagrees, presumably as now does plaintiff, who moves for leave to file Durfee's supplemental report.

263 F. Supp. 2d 780, 792 (D. Del. 2003) (“While the doctrine of equivalents may be relevant in an infringement analysis, the court concludes that it does not apply in the context of a false marking claim.”), *rev’d on other grounds*, 406 F.3d 1347 (Fed. Cir. 2005). It appears as though no court has directly followed or, by contrast, declined to follow, this court’s precedent. *Compare U.S. Gypsum Co. v. Pacific Award Metals, Inc.*, 438 F. Supp. 2d 1101, 1105 n.4 (declining to decide the issue since the parties did not dispute the “unpatented” element). The court need not revisit its holding here, as plaintiff does not cite any evidence it seeks to present on the doctrine of equivalents.

As the Seventh Circuit has aptly put it, a summary judgment motion “is the ‘put up or shut up’ moment in a lawsuit, when a party must show what evidence it has that would convince a trier of fact to accept its version of events.” *Koszola v. Bd. of Educ. of City of Chicago*, 583 F.3d 1104, 1111 (7th Cir. 2004). Plaintiff did not “put up” a case in response to defendants’ motion. Its motion for leave to serve Durfee’s supplemental report was filed on December 20, 2010 – three months after defendants’ motion for summary judgment was lodged on September 10, 2010, and over two months after plaintiff filed its answering papers on October 7, 2010. Trial is set to commence February 7, 2011. Under the circumstances at bar, the court denies plaintiff’s motion. As there is no indication that plaintiff could defend against defendants’ mismarking allegation on the discovery record, defendants’ motion for summary judgment that AbsorbaTack is “unpatented” relative to the ‘051 patent (and thus mismarked under 35 U.S.C. § 292) is granted.

#### **4. Bifurcation**

Having so determined, the court has determined that a bench trial on intent and damages shall proceed immediately following the close of the currently-scheduled jury trial. The court agrees with defendants that plaintiff may have indeed faced a dilemma with respect to waiving privilege, and it was plaintiff's prerogative to raise that concern with the court (by a motion to bifurcate or otherwise) **prior** to the close of fact discovery.<sup>8</sup> Plaintiff cannot put the onus of its decision not to waive privilege on defendants for failing to move to compel on their discovery requests relating to false marking. (D.I. 171 at 4) Put another way, it was neither defendants' prerogative, nor in their best interests, to compel plaintiff to mount a case against them if plaintiff did not seek to do so on its own volition. The court does not delay resolution of defendants' claim based on plaintiff's belated motion.

The court agrees, however, that evidence regarding plaintiff's AbsorbaTack product and plaintiff's intent in marking AbsorbaTack with the '051 patent would be confusing to a jury deciding the issues of whether defendants' SorbaFix and PermaFix products infringe the '051 patent.<sup>9</sup> It is the court's determination, therefore, that the claim will be severed and tried to the court. *See, e.g., Forest Group, Inc. v. Bon Tool Co.*, 590 F.3d 1295 (Fed. Cir. 2009) (reviewing bench verdict); *DP Wagner Mfg. Inc. v.*

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<sup>8</sup>Plaintiff emphasizes that it noted in its briefing in support of its motion to dismiss that "[i]f the court does not dismiss defendants' counterclaim, [plaintiff] will file a motion to bifurcate setting forth in detail why a stay is warranted." (D.I. 92 at n.6) Plaintiff's motion to bifurcate was not actually filed until after the close of fact discovery, and plaintiff's intention to do so is of no legal relevance.

<sup>9</sup>With respect to direct infringement, the court's standard jury instructions recite: "Remember the question is whether the accused product or method infringes any of the asserted claims, and not whether the accused product or method is similar or even identical to a product or method of plaintiff."

*Pro Patch Systems, Inc.*, 434 F. Supp. 2d 445 (S.D. Tex. 2006) (equitable determination of damages tried to the court by separate hearing). Plaintiff's motion to bifurcate is granted in part and denied in part.<sup>10</sup>

### **C. Infringement**

Defendants move for partial summary judgment that SorbaFix and PermaFix (hereinafter, the "accused products") do not infringe any claims of the '051 patent.

#### **1. Accused products**

The accused products differ only in the type of material used for the fastener.<sup>11</sup> Below is a depiction of the SorbaFix device and its fasteners.

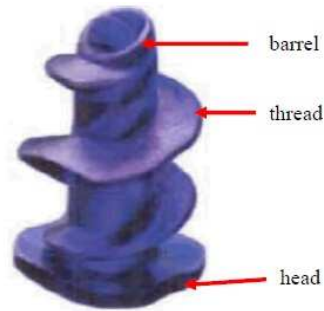


(D.I. 196, ex. D at 6) Only the fasteners are at issue with respect to defendants' motion; the fasteners are depicted in greater detail below.

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<sup>10</sup>The court's decision on bifurcation is based solely on the unusual procedural posture of this case and does not necessarily reflect the court's general views on bifurcation of a false marking claim.

<sup>11</sup>The fastener for the PermaFix is not absorbable, while the fastener for the SorbaFix is absorbable.



(D.I. 194 at 5) As shown above, the accused fasteners have a head at the proximal end and a helical thread wrapped around a hollow barrel. (D.I. 227, ex. 9 at 188:14-189:2) The hollow interior of the barrel also has helical threads not pictured above. (*Id.* at 537:20-538:10)

## 2. Claim construction

The dispute between the parties centers around whether the accused fasteners have “a helical configuration” as required by claim 1 of the ‘051 patent. To this end, plaintiff advocates a construction of “fasteners having a preformed structure shaped like a cylindrical spiral, for example a screw head or a coil spring.” (D.I. 109) Defendants propose that the claim requires fasteners “having the overall shape of a coil.” (*Id.*) As the above indicates, the parties do not dispute that the accused fasteners have a “helical” component. The court agrees with defendants, however, that “fasteners having a helical configuration” must be construed in its entirety and, when so construed, the claims require a helical fastener having the overall shape of a coil. That is, the claims do not encompass screw-type fasteners – only coiled fasteners.

The only fasteners disclosed in the ‘051 specification are coils. The summary of the invention describes three embodiments of “fasteners having a helical configuration”

– all of which are coil fasteners. The first embodiment “is formed into the configuration of a continuous helical coil.” (’051 patent at col. 2:53-55) The second embodiment is a “double continuous helical coil.” (*Id.* at col. 3:1-4) The third embodiment is a “double continuous helical coil” with “a pivot post.” (*Id.* at col. 3:9-12) Plaintiff emphasizes that the figures depict fasteners having elements beyond that of a standard coil: figure 1A depicts a fastener having a “T-bar” element (**33**); figures 2 and 3 depict a fastener having a connector bar element (**122**); and figure 4 depicts a fastener having a pivot point (**130**), as shown below.

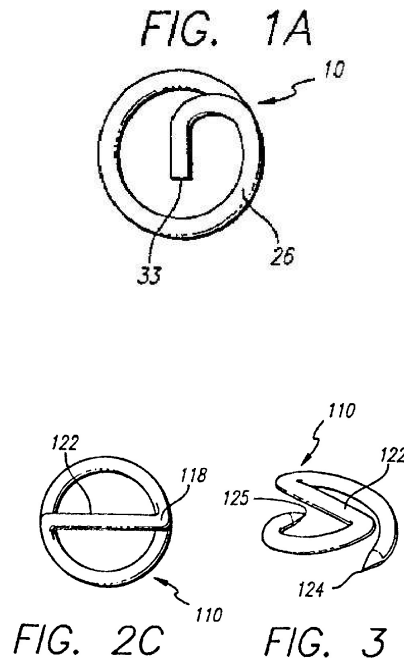
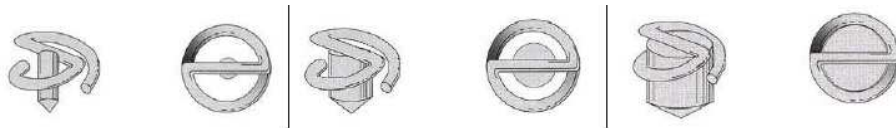




FIG. 4

While the pivot point of figure 4 is depicted to be the same thickness as the rest of the coil, plaintiff suggests that the pivot point may be so large as to resemble a screw, as depicted below.



There is no substantive discussion on the pivot point (**130**) in the specification and, thus, no specific parameters regarding its size. When addressing the above three figures, Slocum testified that the first and second fasteners could have “the overall shape of a coil;” however, he was uncomfortable characterizing the last fastener as coil-shaped. (D.I. 227, ex. 9 at 314:17-315:11) According to plaintiff, this evidences a difficulty in the consistent application of defendants’ proposed construction.

During prosecution of the ‘957 application, the examiner rejected the claims based on prior art showing staple and clip fasteners,<sup>12</sup> not screw-type fasteners. (D.I.

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<sup>12</sup>Specifically, U.S. Patent No. RE28,932 to Noiles et. al, disclosing a surgical stapling instrument, and U.S. Patent No. 5,607,436 to Pratt et. al, disclosing an apparatus for applying surgical clips.

199, ex. H) To overcome that rejection, applicants amended the claims to require “fasteners having a helical configuration.” (*Id.*, ex. I) With this amendment, the claims were allowed. As discussed previously, the ‘957 application was abandoned. When the same claims were ultimately allowed in the ‘100 application, the examiner stated that the closest prior art was U.S. Patent No. 5,258,000 to Gianturco (“Gianturco”). Gianturco describes a “wire coil fastener” for use in the tissue repair device of that invention. (Gianturco, col. 7:13-22 & fig. 7) The examiner stated in his reasons for allowance that Gianturco “failed to suggest placing a **plurality of coiled fastener[s]** into the applicator.” (D.I. 198 at JA102) (emphasis added) The examiner also cited U.S. Patent No. 5,662,683 to Kay (“Kay”), entitled “Open Helical Organic Tissue Anchor and Method of Facilitating Healing.” The examiner noted that, like Gianturco, Kay also failed to teach “the above limitations.” (D.I. 198 at JA102)

The foregoing indicates that the examiner viewed the invention of the ‘051 patent as pertaining to “coiled” fasteners, rather than “screw” fasteners. Examiners are considered “persons of scientific competence in the fields in which they work” and their findings are “informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art.” *In re Berg*, 320 F.3d 1310, 1315 (Fed. Cir. 2003). The examiner’s characterization of the invention is consistent with that of lead inventor Lee Bolduc (“Bolduc”). (D.I. 199, ex. C at 127:8-14) Bolduc testified that he had first thought to use screws as the fasteners for his device, but screws caused tissue displacement during testing. He then thought of a corkscrew design, and found that the coil spring increased the holding power of the fastener “quite a bit.” (*Id.* at



30:21-35:11)

The court appreciates that the inventor is not the hypothetical “person of ordinary skill in the art” and his subjective beliefs regarding his invention do not bear upon what is actually disclosed by the patent. It is notable, however, that the lead inventor (Bolduc), the examiner, and plaintiff itself all have the same view of the scope of the invention. In this regard, plaintiff’s U.S. Patent Application No. 11/113,879 (“the ‘879 application”) makes a distinction between “screw fasteners” and fasteners having a “helical configuration,” with specific reference to the ‘051 patent. (D.I. 199, ex. W at ¶¶ 10-12, 99; ex. V at 262:16-263:6) Plaintiff does not point to evidence that the understanding of “fasteners having a helical configuration” in the art would have changed or evolved between the priority date of the ‘051 patent (2001) and the ‘879 application (2003).

On its face, “configuration” refers to the overall shape of the fasteners, not an individual element of the fastener, such as the thread. The court finds, consistent with the foregoing intrinsic and extrinsic evidence, that a fastener must be viewed as a whole, not in the aggregate. Put most plainly, a screw is not a nail further comprising helical threads. “Fasteners having a helical configuration” is construed, therefore, to mean “fasteners having the overall shape of a coil,” to the exclusion of screw-type fasteners.<sup>13</sup>

### **3. Doctrine of equivalents**

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<sup>13</sup>Defendants’ motion that the ‘051 patent is invalid for lack of written description under plaintiff’s proposed construction of “fasteners having a helical configuration” (D.I. 190) is denied as moot.

The accused devices cannot literally infringe claim 1 of the '051 patent under the foregoing construction.<sup>14</sup> The final question before the court in this regard is whether plaintiff is estopped from asserting that the accused, screw-type fasteners are equivalent to the coiled fasteners claimed. Defendants assert that plaintiff's narrowing amendment (from "fasteners" to "fasteners having a helical configuration" during prosecution of the '957 application) precludes such an argument pursuant to *Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Company*, 535 U.S. 722, 736 (2002). (D.I. 194 at 13-17)

"A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." *Id.* at 740. What was surrendered by the applicant's amendment was "all subject matter falling between the scope of the original claim and the scope of the claim as amended" – i.e., fasteners having a **non-helical** configuration. *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1363 (Fed. Cir. 2005). The amendment facilitated allowance of the claims vis a vis staple and clip, or non-helical, prior art. It is not clear that the '051 patent was examined against screw-type fastener prior art. At least, such art was not the subject of the rejection prompting the amendment at issue.

The parties agree that screws are, generally, "helical." The court has found that the inventors used "helical configuration" to denote the coil-type fasteners described in the application. In narrowing the claims, the inventors could have surrendered only subject matter that was part of their application. On this record, there is no presumption

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<sup>14</sup>The court, therefore, need not construe additional terms to resolve the pending summary judgment motions.

that estoppel bars a claim of equivalence to screw-type fasteners.<sup>15</sup>

#### **4. Conclusion**

The “fasteners having a helical configuration” limitation is the only limitation at issue on defendants’ motion for summary judgment of noninfringement; there is no cross-motion. The parties have identified several additional disputed terms that do not find context in the infringement and validity contentions before the court on summary judgment. There is a lack of agreement as to whether the additional terms need construction or may be given their ordinary meaning. Consistent with the court’s practice, the parties will present their respective constructions during trial and the court will make its claim construction decision prior to the case going to the jury. Absent notice regarding which claims remain in dispute, the court will instruct the jury that all terms not specifically defined by the court shall be given their plain and ordinary meanings. Defendants’ motion for summary judgment of noninfringement is granted in part and denied in part.<sup>16</sup>

#### **V. CONCLUSION**

For the foregoing reasons, plaintiff’s motion to bifurcate false marking (D.I. 158) is granted in part and denied in part; plaintiff’s motion to strike portions of Slocum’s

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<sup>15</sup>Defendants criticize plaintiff for failing to demonstrate that an exception to the application of estoppel applies. No such burden arises under these circumstances.

The court notes that the parties have not addressed whether the scope of claimed equivalence (to screw-type fasteners) would ensnare the prior art. See *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009).

<sup>16</sup>Also before the court is defendants’ (contested) motion for leave to file an amended chart of disputed claim terms adding one limitation (“to controllably discharge one of said plurality of fasteners upon complete depression of said lever”). (D.I. 185) That motion is denied as moot in view of the court’s holding.

report (D.I. 183) is denied; defendants' motion for leave to file an amended chart of disputed claim terms (D.I. 185) is denied as moot; plaintiff's motion for partial summary judgment on the obviousness-type double patenting defense (D.I. 186) is granted; defendants' motion for summary judgment that AbsorbaTack is mismarked (D.I. 188) is granted; defendants' motion for summary judgment of invalidity due to inadequate written description (D.I. 190) is denied as moot; and defendants' motion for summary judgment of noninfringement (D.I. 193) is granted in part and denied in part. An appropriate order shall issue.