# Becton, Dickinson & Co. v. Tyco Healthcare Group, LP

United States Court of Appeals for the Federal Circuit
July 29, 2010, Decided
2009-1053, 2009-1111

#### Reporter

616 F.3d 1249 \*; 95 U.S.P.Q.2D (BNA) 1752 \*\*

BECTON, DICKINSON AND COMPANY, Plaintiff-Cross Appellant, <u>v</u>. <u>TYCO HEALTHCARE GROUP</u>, LP, Defendant-Appellant.

Subsequent History: Rehearing denied by, Rehearing, en banc, denied by <u>Becton</u>, <u>Dickinson</u> & <u>Co</u>. <u>v</u>. <u>Tyco</u> <u>Healthcare Group</u>, LP, 2010 U.S. App. LEXIS 26895 (Fed. Cir., Oct. 4, 2010)

**Prior History:** Appeals from the United States District Court for the District of Delaware in case no. 02-CV-1694, Chief Judge Gregory M. Sleet.

Becton Dickinson & Co. v. Tyco Healthcare Group LP, 2008 U.S. Dist. LEXIS 82915 (D. Del., Oct. 14, 2008)

**Disposition:** REVERSED.

**Counsel:** WILLIAM F. LEE, Wilmer Cutler Pickering Hale and Dorr LLP, of Boston, Massachusetts, argued for plaintiff-cross appellant. With him on the brief were WILLIAM G. MCELWAIN, AMY K. WIGMORE, TODD C. ZUBLER and ARTHUR W. COVIELLO, of Washington, DC.

FRANK P. PORCELLI, Fish & Richardson P.C., of Boston, Massachusetts, argued for defendant-appellant. With him on the brief were JOHN M. SKENYON, and JUANITA R. BROOKS, of San Diego, California.

**Judges:** Before GAJARSA, LINN, and MAYER, Circuit Judges. Opinion for the court filed by Circuit Judge MAYER. Dissenting opinion filed by Circuit Judge GAJARSA.

**Opinion by: MAYER** 

# **Opinion**

[\*\*1753] [\*1250] MAYER, Circuit Judge.

<u>Tyco Healthcare Group</u>, LP ("<u>Tyco</u>") appeals a judgment of the United States District Court for the District of Delaware entered after a jury determined that <u>Tyco</u>'s Monoject Magellan(tm) safety needles and blood collection devices literally infringed claims 1-4, 6, 12, 13, 15, 24 and 27 of U.S. Patent No. 6,348,544 (the "'544 patent"). Because we conclude that the district court incorrectly construed the "spring means" limitation of the asserted claims and erred in denying <u>Tyco</u>'s motion for judgment as a matter of law ("JMOL"), we reverse.

### **BACKGROUND**

Becton, Dickinson and Company ("Becton") is the assignee of the '544 patent, which is directed toward a safety needle designed to prevent accidental needle stick injuries. The safety shield, or needle guard, of the patented invention is initially positioned at the base of the needle, next to the needle hub. This is called the "first position" and is shown in figure 2 of the '544 patent.

The guard is mounted on or close to the needle cannula and is attached to the needle hub by a hinged arm. When the guard is in the first position, the hinged arm is folded. When the needle has been removed from a patient, the health care worker pushes the hinged arm forward, causing the hinged arm to unfold and the guard to move along the needle cannula toward the tip of the needle. When the guard covers the needle tip, it is said to be in its [\*\*1754] "second position" as shown in figure 4.

## [\*1251]

To facilitate the movement of the guard toward the needle tip, the '544 patent discloses a "spring means" for "urging [the] guard along [the] needle cannula." The specification describes two embodiments in which a spring moves the guard down the needle cannula. The specification does not attribute any movement of the guard to the hinged arm of the safety needle.

On December 23, 2002, Becton filed suit against <u>Tyco</u>, alleging infringement of the '544 patent by <u>Tyco</u>'s Monoject Magellan(tm) safety needles and blood collection devices. Becton subsequently answered <u>Tyco</u>'s first set of interrogatories, including interrogatory 3, which called for an infringement claim chart "fully explain[ing] how each claim element is met either literally or under the doctrine of equivalents in each <u>Tyco</u> product accused of infringement." In response, Becton identified the living hinges in <u>Tyco</u>'s accused devices as satisfying the "spring means" limitation of asserted claims 1 and 24 and stated that "[o]nce released, the spring means urges the guard along the needle cannula toward" the tip of the needle. Later, in updated infringement charts served on <u>Tyco</u> just prior to the close of fact discovery, Becton reiterated its assertion that "[o]nce released, the spring means urges the guard along the needle cannula" toward the needle tip.

After the close of fact discovery, Becton issued its only expert report on infringement. Becton's expert, Charles A. Garris, Jr., explained his theory as to how the hinges in the hinged arm of <u>Tyco</u>'s accused devices functioned as springs:

The hinged arm [in <u>Tyco</u>'s accused products] is . . . folded and assembled with the other components of the safety assembly. I expect to explain that folding of the hinged arm imparts stress to the hinge that results in a certain amount of stored energy. In the accused <u>Tyco</u> Monoject Magellan(tm) devices, the force of this stored energy is initially restrained by a latching mechanism. Once unlatched, the stored energy is released, causing the safety guard to be urged (i.e., moved) along the needle cannula toward the tip of the needle.

On May 3, 2004, <u>Tyco</u> moved for summary judgment of non-infringement, arguing that the spring means limitation of the asserted claims required a spring separate from the hinged arm structure. The district court denied this motion, however, rejecting <u>Tyco</u>'s argument that a proper construction of the spring means limitation requires "a separate spring [which] must move the guard along the cannula toward the second position." <u>Becton, Dickinson</u> & <u>Co. v. Tyco Healthcare Group</u>, *LP*, No. 02-1694 GMS, 2004 U.S. Dist. LEXIS 18637 at \*12 (D. Del. Sept. 16, 2004) ("Summary Judgment Decision").

On October 26, 2004, a jury returned a verdict finding literal infringement by both [\*1252] of <u>Tyco</u>'s accused products. <sup>1</sup> The jury found that the infringement was willful as to the Magellan safety needle, but not as to the Magellan blood collector; it also found that the patent was not invalid for lack of an adequate written [\*\*1755] description. <u>Tyco</u> subsequently moved for a new trial, arguing that Becton had improperly changed its theory of infringement during trial. The district court agreed, noting that the only infringement theory disclosed by Becton prior to trial was that "once unlatched" the hinges in the hinged arm caused the safety guard to move down the needle cannula:

From the outset, [this] case was postured on the assertion that <u>Tyco</u>'s Monoject Magellan devices infringed the "spring means" limitation of the ['544] patent because, after the devices are unlatched, the hinged arms move the guard toward the cannula of the needle. Dr. Garris' expert statement, [Becton's] summary judgment motion,

<sup>&</sup>lt;sup>1</sup> The district court concluded that Becton had waived the right to assert infringement under the doctrine of equivalents.

and [Becton's] pretrial memorandum in support of its claim of infringement and for damages, all make clear that the "after unlatching" theory was the only basis for *Tyco*'s alleged infringement.

<u>Becton</u>, <u>Dickinson</u> & <u>Co</u>. <u>v</u>. <u>Tyco Healthcare Group</u>, LP, No. 02-1694 GMS, 2006 U.S. Dist. LEXIS 14999 at \*34-35 (D. Del. Mar. 31, 2006) ("New Trial Decision").

During trial, however, Becton reversed course, arguing that the living hinges in the hinged arm moved the guard before the hinged arm was unlatched. 2006 U.S. Dist. LEXIS 14999, [WL] at \*38-40. Because Becton had "advanced a new theory of infringement at trial" and its actions were "inconsistent with substantial justice . . . and resulted in actual prejudice," the district court granted *Tyco*'s motion for a new trial. 2006 U.S. Dist. LEXIS 14999, [WL] at \*40.

In January 2007, prior to the start of the second trial, <u>Tyco</u> filed a petition in the United States Patent and Trademark Office ("PTO") requesting reexamination of the '544 patent based on Netherlands Patent Publication No. 9000909. The examiner in charge of the reexamination issued an office action in which she found that the "spring means" limitation in claims 1 and 24 of the '544 patent was a "means-plus-function" limitation and required that the spring means be a separate structural element from the hinged arm. See 35 U.S.C. § 112, P 6. <u>Tyco</u> then filed a motion asking the district court to adopt the PTO's construction of the disputed claims, but the court denied this motion on November 21, 2007. <sup>2</sup>

At the second trial, the district court instructed the jury that the spring means limitation required that "once the hinged arm is unlatched for the first time, the 'spring means' must move the guard along the needle toward the needle tip." The trial court also instructed the jury that "[t]he spring is not required to move the guard all the way to the tip of the needle but must, by itself, move the guard for some distance."

On November 30, 2007, a jury returned a verdict of infringement as to both of <u>Tyco</u>'s accused products. <u>Tyco</u> thereafter filed motions seeking JMOL and a new trial. The district court denied these motions, however, explaining that although it was a "close issue," Becton had "adduced enough circumstantial evidence from which the jury could reasonably conclude that the living hinges of <u>Tyco</u>'s products are [\*1253] springs that, by themselves, move the guard toward the needle tip once unlatched." See <u>Becton, Dickinson</u> & <u>Co. v. Tyco Healthcare Group</u>, LP, No. 02-1694 GMS, 2008 U.S. Dist. LEXIS 82915 at \*10 (D. Del. Oct. 14, 2008) (footnote omitted) ("JMOL Decision").

<u>Tyco</u> then appealed to this court, challenging the district court's interpretation of the asserted claims and the denial of its motions for JMOL and a new trial. Becton filed a conditional cross-appeal, arguing that if the district court's judgment is reversed, it should be granted a new trial on the issue of whether <u>Tyco</u> infringed the '544 patent by manufacturing--rather than selling--the Magellan needles and blood collectors. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

#### DISCUSSION

Precedent requires that this court conduct a *de novo* review of claim construction. See Cybor Corp.  $\underline{v}$ . FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). We review the denial of a JMOL motion "under the law of the regional circuit where the appeal from the district court would normally lie." *Muniauction, Inc.*  $\underline{v}$ . Thomson Corp., 532 F.3d 1318, 1323 (Fed. Cir. 2008). In the Third Circuit, when determining whether to grant a JMOL motion "[t]he question is not whether there is literally no evidence supporting the party [\*\*1756] against whom the motion is directed but whether there is evidence upon which the jury could properly find a verdict for that party." *Lightning Lube, Inc.*  $\underline{v}$ . Witco Corp., 4 F.3d 1153, 1166 (3d Cir. 1993) (citations and internal quotation marks omitted). "Although judgment as a matter of law should be granted sparingly," it is mandated "where the record is critically deficient of the minimum quantum of evidence" necessary to support a jury verdict. Eshelman  $\underline{v}$ . Agere Sys., Inc., 554 F.3d 426, 433 (3d Cir. 2009) (internal quotation marks omitted).

<sup>&</sup>lt;sup>2</sup> Following the second trial, the PTO issued a final office action affirming the examiner's conclusion that the spring means limitation was a means-plus-function limitation.

I.

To establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." Southwall Techs., Inc. <u>v</u>. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995). Thus, "[i]f any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." Amgen Inc. <u>v</u>. F. Hoffmann-La Roche, Ltd., 580 F.3d 1340, 1374 (Fed. Cir. 2009). <u>Tyco</u> argues that its Monoject Magellan(tm) safety needle and blood collection devices do not literally infringe the '544 patent because they lack the added spring member required by the asserted claims. We agree. The unambiguous language of the asserted claims, as well as the disclosure in the specification, requires an added spring element that moves the safety guard toward the tip of the needle. <sup>3</sup>

Claim 1, which has been treated as representative, calls for a "spring means connected to said hinged arm for urging said guard along said needle cannula toward" the tip of the needle. Following a *Markman* hearing, the district court correctly construed this limitation to require that: "The hinged arm is connected to a spring that moves the guard along the cannula toward" the tip of the needle. By its plain terms, this construction contemplates [\*1254] that the spring means and the hinged arm are separate structures which are "connected to" each other. The district court erred, however, when it later held that its claim construction did not require a spring means that was a distinct structural element from the hinged arm. See Summary Judgment Decision, 2004 U.S. Dist. LEXIS 18637 at \*12 (rejecting <u>Tyco</u>'s argument that a proper construction of the spring means limitation requires "a separate spring [which] must move the guard along the cannula toward the second position").

Claim construction "begins and ends in all cases with the actual words of the claim." Renishaw PLC <u>v</u>. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998). The unequivocal language of the asserted claims of the '544 patent requires a spring means that is separate from the hinged arm. Claim 1 recites:

1. A shieldable needle assembly comprising:

a needle cannula having a proximal end and a distal tip;

a guard having a proximal end, an opposed distal end and a side wall extending there between, said guard being slidably movable along said needle cannula from a first position substantially adjacent said proximal end of said needle cannula to a second position where said distal tip of said needle cannula is intermediate said opposed proximal and distal ends of said guard;

a hinged arm having proximal and distal segments articulated to one another for movement between a first position where said segments are substantially collapsed onto one another and a second position where said segments are extended from one another, said proximal segment of said hinged arm being articulated to a portion of said needle assembly adjacent said proximal end of said needle cannula, said distal segment of said hinged arm being articulated to said guard, said proximal and distal segments of said hinged arm having respective lengths for permitting said guard to move from said first position to said second position on said needle cannula, and for preventing said guard from moving distally beyond said second position; and

spring means connected to said hinged arm for urging said guard along said needle cannula toward said second position. [\*\*1757]

'544 patent col.7 II.7-35 (emphases added).

Claim 1 lists four separate elements: 1) a needle, 2) a guard that rides on the needle, 3) a hinged arm attached to the guard, and 4) a spring means "connected to" the hinged arm. Where a claim lists elements separately, "the

<sup>&</sup>lt;sup>3</sup> <u>Tyco</u> also contends that a separate spring is required because the spring means limitation is in means-plus-function format, see 35 U.S.C. § 112, P 6, and the only structures disclosed in the specification for performing the recited function of moving the guard toward the tip of the needle are added spring members. We need not reach this argument, however, because we conclude that--regardless of whether the asserted claims invoke section 112, paragraph 6--an added spring element is required by the plain language of the claims.

clear implication of the claim language" is that those elements are "distinct component[s]" of the patented invention. Gaus <u>v</u>. Conair Corp., 363 F.3d 1284, 1288 (Fed. Cir. 2004); Engel Indus., Inc. <u>v</u>. Lockformer Co., 96 F.3d 1398, 1404-05 (Fed. Cir. 1996) (concluding that where a claim provides for two separate elements, a "second portion" and a "return portion," these two elements "logically cannot be one and the same"). There is nothing in the asserted claims to suggest that the hinged arm and the spring means can be the same structure. See CAE Screenplates, Inc. <u>v</u>. Heinrich Fiedler GmbH & Co., 224 F.3d 1308, 1317 (Fed. Cir. 2000) ("In the absence of any evidence to the contrary, we must presume that the use of . . . different terms in the claims connotes different meanings.").

The specification, moreover, confirms that the spring means is a separate element from the hinged arm, as the only elements disclosed in the specification as "spring means" for urging the guard forward are separate structures from the hinged arm and its hinges. There is no suggestion that the hinged arm or its hinges [\*1255] can function as springs, because nothing in the specification describes the hinges as moving the guard or even helping to move the guard. Nothing in the specification indicates that the hinges in the hinged arm might contain sufficient stored energy to enable them to move the safety guard toward the tip of the needle. To the contrary, the specification cautions that it is undesirable to allow stored energy to act for any extended period on the plastic parts of the needle assembly. See '544 patent col.5 II.12-13 (explaining that "stored energy acting on plastic can affect the reliability and performance of the part"). In short, the specification comports with the plain language of the claims, fully supporting the conclusion that the spring means is a separate structural component of the patented invention. See Astrazeneca AB  $\underline{v}$ . Mut. Pharm. Co., 384 F.3d 1333, 1336 (Fed. Cir. 2004) ("A long line of cases indicates that evidence intrinsic to the patent--particularly the patent's specification, including the inventors' statutorily-required written description of the invention--is the primary source for determining claim meaning."); Vitronics Corp.  $\underline{v}$ . Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (The specification is "is the single best guide to the meaning of a disputed [claim] term.").

Indeed, Becton's assertion that the spring means and the hinged arm can be the same structure renders the asserted claims nonsensical. Independent claim 1 of the '544 patent describes the spring means as being "connected to" the hinged arm and independent claim 24 describes it as "extending between" the hinged arm and a mounting means. <sup>4</sup> If the hinged arm and the spring means are one and the same, then the hinged arm must be "connected to" itself and must "extend between" itself and a mounting means, a physical impossibility. A claim construction that renders asserted claims facially nonsensical "cannot be correct." *Schoenhaus <u>v. Genesco, Inc.</u>*, 440 F.3d 1354, 1357 (Fed. Cir. 2006); see Bd. of Regents <u>v. BENQ Am. Corp.</u>, 533 F.3d 1362, 1370 (Fed. Cir. 2008) (refusing to adopt a claim construction that "would effect [a] nonsensical result").

Furthermore, if the hinged arm and spring means are not separate structures, then the asserted claims are clearly invalid as obvious over the prior art. See Whittaker Corp. v. UNR Indus., Inc., 911 F.2d 709, 712 (Fed. Cir. 1990) ("[C]laims are generally construed so as to sustain their validity, if possible."). The first three elements of Becton's claimed invention--the needle, the protective guard, and the hinged arm--were disclosed in several prior art patents. See U.S. Patent Nos. 4,911,706; 4,898,589; 4,790,828. The Hagen patent, U.S. Patent No. 4,735,618, specifically discloses a safety needle, a guard and a hinged arm, which includes hinges comprised of thinned pieces of plastic. What distinguished the claimed invention from the prior art was the addition of a spring means separate from the hinged arm. See '544 patent col.1 II.33-34 (discussing "prior art needle shields [that] are hingedly attached to the hub of the needle cannula"). [\*\*1758]

There can be no literal infringement where a claim requires two separate structures and one such structure is missing from an accused device. See Gaus, 363 F.3d at 1288-90 (concluding that where a claim called for "an electrical operating unit and a pair of spaced-apart electrically exposed conductive probe networks," it required that the two elements be "separate" structures in the accused device). Because the unequivocal language of the asserted claims of the '544 patent requires both a [\*1256] hinged arm and a spring means, there can be no literal infringement by *Tyco*'s accused products which, as the district court correctly concluded, do not contain a spring

<sup>&</sup>lt;sup>4</sup> Claim 24 calls for a "spring means extending between said mounting means and said hinged arm for urging said guard toward said second position."

means that is a separate structural element from the hinged arm and its hinges. See Summary Judgment Decision, 2004 U.S. Dist. LEXIS 18637 at \*9. <sup>5</sup>

In rejecting <u>Tyco</u>'s argument that the asserted claims require an added spring member, the district court noted that "the abstract of the '544 patent states that a spring *may* be provided to assist movement of the guard toward the distal shielded position. It does not state that a spring *must* be provided." *Summary Judgment Decision*, 2004 U.S. Dist. LEXIS 18637 at \*12 (emphases added). It is true that the '544 patent states that "a spring may be provided to assist movement of the guard." This language, however, refers to the fact that the patent has three independent claims and only two of them include a spring means limitation. Independent claim 17, which is not now asserted against <u>Tyco</u>, contains the identical hinged arm limitation found in independent claims 1 and 24 but, unlike the asserted claims, does not contain an added spring means limitation. <sup>6</sup> Thus, while all three independent claims require a hinged arm comprised of two plastic segments which are "articulated to" each other, "articulated to" the guard, and "articulated to" the needle assembly, only the asserted claims call for an added spring member.

[\*1257] Claims must be "interpreted with an eye toward giving effect to all terms in the claim." *Bicon, Inc.*  $\underline{v}$ . *Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006). If the spring means limitation contained in claims 1 and 24--but not in claim 17--is not to be read out of the asserted claims, it must require an additional element beyond that which is already called for by the hinged arm limitation. *See Cat Tech LLC*  $\underline{v}$ . *TubeMaster, Inc.*, 528 F.3d 871, 885 (Fed. Cir. 2008) (refusing to adopt a claim construction which would render a claim limitation meaningless); *Elekta Instrument S.A.*  $\underline{v}$ . *O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1305-07 (Fed. Cir. 2000) (refusing to adopt a claim construction which [\*\*1759] would render claim language superfluous). Simply put, a claim construction that does

<sup>5</sup> On appeal, Becton contends that the district court did not find that <u>Tyco</u>'s accused devices lacked a spring that was a distinct structural element from the hinged arm. This argument is belied by the record. In denying <u>Tyco</u>'s motion for summary judgment, the district court stated:

<u>Tyco</u>... sells the Monoject Magellan(tm) safety products, including the Monoject safety needle products and the Monoject SBC products.... The Monoject safety needle products *do not have a separate spring* that moves the guard toward the second position.... The Monoject SBC products *do not have a separate spring* that moves the guard toward the second position.

Summary Judgment Decision, 2004 U.S. Dist. LEXIS 18637 at \*9 (emphases added).

Although the district court later referenced two of the hinges of the hinged arm as possible springs in its March 2006 decision denying <u>Tyco</u>'s JMOL motion following the first trial, the district court never altered its original finding that the accused products do not contain an added spring element. Furthermore, as will be discussed more fully in section III, there is nothing in the '544 patent to suggest that the hinges are not part of the hinged arm or that they function as springs that move the safety guard down the needle cannula.

<sup>6</sup> Claim 17, which includes a clip feature not found in the asserted claims, recites:

A shieldable needle assembly comprising:

a needle cannula having a proximal end and a sharply pointed distal tip,

a guard having a proximal end, an opposed distal end and a side wall extending there between, said guard being slidably movable along said needle cannula . . . [and] said guard including a clip retained between said side wall and said needle cannula, said clip being configured to cover said tip when said guard is in said second position on said needle cannula; and

a hinged arm having proximal and distal segments articulated to one another for movement between a first position where said segments are substantially collapsed onto one another and a second position where said segments are extended from one another, said proximal segment of said hinged arm being articulated to a portion of said needle assembly adjacent said proximal end of said needle cannula, said distal segment of said hinged arm being articulated to said guard, said proximal and distal segments of said hinged arm having respective lengths for permitting said guard to move from said first position to said second position on said needle cannula, and for preventing said guard from moving distally beyond said second position.

'544 patent col.8 II.34-64 (emphases added).

not require a spring member in addition to the hinged arm structure renders the spring means limitation functionally meaningless. See Bicon, 441 F.3d at 950 ("Allowing a patentee to argue that physical structures and characteristics specifically described in a claim are merely superfluous would render the scope of the patent ambiguous, leaving examiners and the public to guess about which claim language the drafter deems necessary to his claimed invention . . . .").

II.

Furthermore, even under the trial court's erroneous claim construction, Becton adduced no credible evidence establishing literal infringement by <u>Tyco</u>'s accused products. The thrust of Becton's infringement argument was that the hinges in <u>Tyco</u>'s needles contain stored energy and that when the hinged arm is unlatched, the hinges act as "springs" that cause the guard to move down the needle cannula. The fatal defect in this theory is that Becton failed to produce any evidence that this posited movement ever occurred. Becton did not provide any test data or even a single live demonstration showing that: 1) the hinges in the accused devices contained stored energy, or 2) they moved the guard even one millimeter down the needle cannula.

Living hinges are thinned pieces of plastic that have a long "flex-life," meaning that they can bend or flex repeatedly without breaking. Depending on how they are manufactured, such hinges can contain differing amounts of stored energy. The hinges in certain prior art safety needles contained stored energy. Becton, however, failed to produce evidence demonstrating that the hinges in <u>Tyco</u>'s accused devices contained any such stored energy. <u>Tyco</u>'s expert, Mary Boyce, testified without contradiction that any stored energy imparted to the hinges during the manufacturing process quickly dissipates.

An important feature of living hinges is that they have "memory," *i.e.*, they "remember" past positions and seek to return to them after being bent. Although the hinged arm in <u>Tyco</u>'s safety needle is initially molded in a flat configuration, it is bent into a folded position during the manufacturing process. During the final step of the manufacturing process, the fully-assembled needle, with the hinged arm folded and latched, is placed in a sealed package and sterilized with gamma radiation. This irradiation changes the molecular structure of the hinges so that the folded position of the hinged arm has become the neutral or "relaxed" position to which the hinged arm, if moved, will tend to return.

At trial, <u>Tyco</u> demonstrated repeatedly that once the hinged arms in the accused devices were unlatched, <sup>7</sup> the hinges never pushed the guard down the needle cannula. [\*1258] No "spring" from the living hinges was ever demonstrated. To the contrary, if at any time during the period when the guard was being manually pushed down the needle cannula the user removed his finger from the hinged arm, the hinged arm moved *backwards* toward its original folded position. Instead of pushing the guard toward the tip of the needle, as required by the asserted claims, the living hinges in the accused devices tended to move the hinged arm backwards toward the needle hub.

Thus, as the district court correctly acknowledged, Becton's "direct evidence regarding the movement of the guard [was] insufficient to support the jury's finding of infringement." *JMOL Decision*, 2008 U.S. Dist. LEXIS 82915 at \*11 n.2. The court, however, refused to set aside the jury's verdict. It reasoned that because the accused devices have

<sup>&</sup>lt;sup>7</sup> The district court did not err in instructing the jury that the spring must move the guard "once the hinge is unlatched for the first time." Prior to the first trial, Becton's sole infringement contention was that "once unlatched" the hinges in the hinged arm caused the guard to move toward the tip of the needle. During trial, however, Becton reversed course, arguing that the living hinges moved the guard down the needle cannula before the hinged arm was unlatched. Even though Becton's expert had only testified about guard movement after unlatching, Becton attempted to persuade the jury that infringement could be established by pre-unlatching movement. Because Becton had improperly changed its theory of infringement, the district court concluded that *Tyco* had been unfairly prejudiced and granted its motion for a new trial. See New Trial Decision, 2006 U.S. Dist. LEXIS 14999 at \*40 (explaining that Becton had "advanced a new theory of infringement at trial" and that its actions were "inconsistent with substantial justice . . . and resulted in actual prejudice"). When the second trial commenced, the district court, aware that Becton had previously attempted to rely on an improper theory regarding pre-unlatching movement, correctly instructed the jury that infringement could be established only by showing movement of the guard after the hinged arm was unlatched.

a latch that holds the hinged arm in a folded position, the hinges might contain some stored [\*\*1760] energy that might be capable of moving the guard some distance down the needle cannula. 2008 U.S. Dist. LEXIS 82915, [WL] at \*10-15.

It is undisputed that the accused devices contain a latch. It is also beyond cavil that a living hinge can contain stored energy and that if that hinge is held back by a latch and then released, it could act as a spring. Not every hinge contains stored energy, however, and not every device with a latch acts as a spring. A door, for example, can have both hinges and a latch, but does not necessarily spring open when unlatched. Although Becton had ample opportunity to do so, it failed to demonstrate either that the hinges in <u>Tyco</u>'s safety needles contained any stored energy or that they pushed the guard forward after the latch was released. Instead, as <u>Tyco</u> explained at trial, the latches on the accused safety needles were designed not to restrain stored energy, but to prevent the shield from being accidently activated or dislodged prior to use.

The Magellan products were initially developed by Specialized Health Products, Inc. ("SHPI"), a small Utah company that designs safety needles for several larger medical companies, including both *Tyco* and Becton. Mark Ferguson, an SHPI mechanical engineer, testified that the Magellan safety needles and blood collection devices were specifically designed *not* to include a "spring assist" feature. Instead, they were intended to allow for "full manual control of the activation of the [safety] guard." The reason for this was that many "clinicians . . . didn't care for the abrupt activation of spring-assisted devices." Furthermore, a spring-assisted blood collection device can activate so rapidly that blood remaining on a needle after use can splatter, increasing the risk of disease transmission. Ferguson stated unequivocally that "[t]he living hinges in the [\*1259] Magellan [products] are not springs," and that "[a]n operator, the nurse or [the] doctor, is the only thing . . . that moves the guard toward the needle tip."

Contrary to Becton's assertions, the testimony of Garris, Becton's expert, is insufficient to support the jury's verdict. See 2008 U.S. Dist. LEXIS 82915, [WL] at \*11 n.2 (emphasizing that "Garris" testimony regarding the spring assist of *Tyco*'s Monoject Magellan devices is entitled to little, if any, weight, because it is directed to a combination of forces that cause movement of the guard, not the spring by itself). Garris, in preparing his expert report, artificially created a "spring" movement in the hinges. At his deposition, Garris admitted that he had repeatedly extended and refolded the hinged arms of the accused devices. Garris was never able to demonstrate that the hinges in the accused products, as manufactured and sold, contained stored energy which moved the guard toward the needle tip. To the contrary, Garris produced no test evidence and no measurements showing that the hinges contained stored energy or that they moved the guard even the smallest distance after unlatching.

Becton claims that video clips of <u>Tyco</u>'s expert, Boyce, removing the latch from an accused needle demonstrates that a spring moves the needle guard down the needle cannula. As the district court correctly concluded, however, "Dr. Boyce's videos . . . are not sufficient to support the jury's verdict." *Id.* Boyce did a series of tests in which she attempted to cut the latch off of an accused needle while the hinged arm was still latched. In these tests, however, the guard never moves to the position it would be in after an actual device is unlatched. Nothing in the Boyce videos, therefore, demonstrates that the hinges in the accused devices, as manufactured and sold, move the guard toward the tip of the needle after the hinged arm is unlatched.

Becton also asserts that a force-displacement test conducted by Boyce "shows that the living hinges exert a force immediately after unlatching that helped the artificial finger move the guard forward." As a preliminary matter, it should be noted that even if it had been established that the hinges "helped" the artificial finger move the guard, this would not be sufficient to meet the trial court's claim construction, which required that the hinged arm move the guard "by itself at least some distance toward the tip of the needle. <sup>8</sup> Even [\*\*1761] more fundamentally, Becton

<sup>&</sup>lt;sup>8</sup> The trial court correctly instructed the jury that the spring means was required to move the guard "by itself" for some distance down the needle cannula. The court gave this instruction because, as discussed previously, the only infringement theory disclosed by Becton prior to trial was that once the hinged arm was unlatched, the hinges moved the guard toward the needle tip. Significantly, Becton did not assert that the hinges in the hinged arm only moved the guard when the guard was also being

[\*1260] never argued at trial that Boyce's force displacement test showed that the hinges contributed in any way to the movement of the guard. No witness, either on direct or cross-examination, testified that Boyce's tests reflected any such movement. Unsupported attorney argument, presented for the first time on appeal, is an inadequate substitute for record evidence. See Gemtron Corp. <u>v</u>. Saint-Gobain Corp., 572 F.3d 1371, 1380 (Fed. Cir. 2009) (emphasizing that "unsworn attorney argument . . . is not evidence").

Becton makes much of the fact that "the accused devices themselves were in evidence, and the jury was able to examine them." The jury, however, was not free to disregard the overwhelming record evidence showing that no movement of the guard occurred after the hinged arm was unlatched and instead to "infer" that the hinges might contain some stored energy that might be capable of moving the guard down the needle cannula. It is inconceivable that the jury, by examining the accused devices, could see the hinges move the guard when Becton, despite repeated opportunities to do so, was unable to demonstrate that such movement ever occurred. A jury verdict based on inferences wholly unsupported by the record cannot stand. See Lightning Lube, 4 F.3d at 1166 (JMOL is appropriate "if, upon review of the record, it is apparent that the verdict is not supported by legally sufficient evidence.").

III.

In its quixotic quest to establish infringement of the '544 patent, Becton argues that <u>Tyco</u>'s accused needles do, in fact, have springs that are separate structures from the hinged arm. In support, it contends that the hinges in the hinged arm are separate structures from the hinged arm itself. This argument is unavailing. A "hinged arm," by definition, must include at least one hinge. Becton, in fact, concedes in its brief on appeal that the middle hinge, which connects the proximal and distal segments of the hinged arm "is part of the hinged arm." It argues, however, that the two other hinges of the hinged arm--one which connects the arm to the needle hub and one which connects the arm to the guard--are separate structures from the hinged arm and can therefore satisfy the spring means limitation of the asserted claims. <sup>9</sup> An insurmountable problem with this theory is that the spring means limitation requires not only a spring, but a spring that moves the guard down the needle cannula. See '544 patent col.7 II.33-35 (requiring that the spring means "urge" the guard down the needle cannula). Thus, even if the hinges other than the middle hinge were separate structures from the hinged arm (which they are [\*1261] not) and Becton had produced evidence that the hinges moved the guard down the needle cannula (which it did not), Becton never established that any hinge other than the middle hinge connecting the two segments of the hinged arm caused such

pushed down the cannula by a health care worker. During the second trial, however, Becton attempted to assert yet another new infringement theory, which was that the hinged arm did not actually move the guard by itself, but only helped to move the guard when a health care worker was already pushing the guard down the needle cannula. Recognizing that this "combination of forces" theory was a "new argument" on Becton's part, the district court properly instructed the jury that to establish infringement Becton was required to show that the spring "by itself moved the guard at least some distance toward the tip of the needle.

A further problem with Becton's newly-minted "combination of forces" theory is that Becton never provided any objective evidence demonstrating that the hinges of the hinged arm assisted the user's finger in moving the safety guard down the needle cannula. Although Becton argued that the user's finger and the hinges worked in tandem to move the safety guard, it never established that the hinges actually contributed to this movement. Becton provided no test data that reliably distinguished between movement caused by the user's finger and movement caused by the hinged arm itself.

<sup>9</sup> We do not agree with Becton's assertion that some of the hinges of the hinged arm can be considered separate structures from the hinged arm itself. The hinged arm limitation requires the hinged arm to have two segments which are "articulated to" each other; it also requires that these segments be "articulated to" the guard and "articulated to" the needle assembly. The hinged arm limitation thus includes not only the two plastic segments of the arm, but also the hinges that articulate the segments to each other, to the needle guard and to the needle hub. *See, e.g.*, McGraw-Hill Dictionary of Sci. & and Tech. Terms 142 (6th ed. 2003) (defining an "articulated structure" as "a structure in which relative motion is allowed to occur between parts, usually by means of a hinged or sliding joint or joints").

Becton, moreover, fails to explain why the middle hinge is part of the hinged arm but the other two hinges are not. There is nothing in the language of the asserted claims or the specification of the '544 patent to suggest that all three hinges are not part of the hinged arm structure.

movement. In other words, even if the hinges other than the middle hinge could be considered separate structures from the hinged arm, there is no evidence that they [\*\*1762] function as springs that move the guard down the needle cannula.

We likewise reject Becton's argument that the district court erred in granting <u>Tyco</u>'s motion for an order *in limine* precluding Becton from presenting evidence that <u>Tyco</u>'s accused products infringed the '544 patent during the manufacturing process. After Boyce, <u>Tyco</u>'s expert, submitted her expert report concluding that any energy imparted to the hinges in <u>Tyco</u>'s accused products quickly dissipates, Becton attempted to rely on the fact that the hinges might contain some stored energy during the manufacturing process. Because Becton's argument--that a version of <u>Tyco</u>'s products that existed temporarily during the manufacturing process might infringe the '544 patent-was not properly raised during discovery, the district court did not abuse its discretion in precluding Becton from presenting evidence regarding this theory at trial. <sup>10</sup> See Acumed LLC <u>v</u>. Advanced Surgical Servs., Inc., 561 F.3d 199, 211 (3d Cir. 2009) (In order to show that a trial court abused its discretion in issuing an evidentiary ruling, "an appellant must show that the court's decision was arbitrary, fanciful or clearly unreasonable." (citations and internal quotation marks omitted)).

### CONCLUSION

Accordingly, the judgment of the United States District Court for the District of Delaware is reversed.

#### **REVERSED**

**Dissent by: GAJARSA** 

## **Dissent**

GAJARSA, Circuit Judge, dissenting.

The majority avoids the critical issue upon which this decision turns; *i.e.*, whether 35 U.S.C. § 112, P 6 governs the claim construction of the "spring means" limitation. In a brief footnote, the majority sweeps and brushes aside the means-plus-function analysis as unnecessary in light of the "plain language of the claims." Maj. Op. 8 n.3. Without having analyzed the scope of the claims, the majority somehow concludes that the claim language covers only devices having separate "spring means" and "hinged arm" structures. Then applying this simplistic claim construction to analyze the sufficiency of the evidence, the majority improperly overturns the jury's verdict finding infringement. For these reasons, I respectfully dissent.

Although the majority ignores the issue completely, the parties have vigorously contested the claim construction of the "spring means" limitation and have made this issue the focal point of their legal position before the district court and this court. The limitation reads: "a spring means connected to said hinged arm for urging said guard along said needle cannula toward said second position." '544 patent, [\*1262] col.7 II.33-35. The parties disagree over whether the "spring means" language should be construed as a means-plus-function limitation pursuant to § 112, P 6. The majority, however, dismisses the means-plus-function analysis entirely in a single footnote, asserting that the language of the claims is "unambiguous":

<sup>&</sup>lt;sup>10</sup> In its complaint, Becton asserted that <u>Tyco</u> "has made . . . and continue[s] to make, use, sell and/or offer for sale . . . products which infringe one or more claims of the '544 patent." The argument that a product infringes as it is manufactured and sold, however, is very different from the argument that an *interim*, version of <u>Tyco</u>'s product, which existed only temporarily during the manufacturing process could infringe the asserted claims, even if that product did not infringe when the manufacturing process was complete or when the item was sold.

**Tyco** . . . contends that a separate spring is required because the spring means limitation is in means-plus-function format, see 35 U.S.C. § 112, P 6 . . . We need not reach this argument, however, because we conclude that--regardless of whether the asserted claims invoke section 112, paragraph 6--an added spring element is required by the plain language of the claims.

Maj. Op. 8 n.3. First, it is unclear what the majority means by "an added spring element." An "added spring element" does not appear in the "plain language of the claims," specification, or prosecution history of the patent. Second, claim construction is necessary to determine the scope of the claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). The majority opinion injects ambiguity into the claims and fails to construe the claims as required by our case law. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996). It is impossible for the majority to determine [\*\*1763] the scope of the claims without undertaking a means-plus-function analysis. Accordingly, the majority's claim construction is premised upon an inadequate foundation.

If a claim element "contains the word means' and recites a function," there is a presumption that the claim is in means-plus-function form. *Envirco Corp. <u>v. Clestra Cleanroom, Inc., 209 F.3d 1360, 1364</u> (Fed. Cir. 2000). That presumption can be rebutted, however, if the claim also "recites sufficient structure to perform the claimed function." <i>Id.* If the claim term "is one that is understood to describe structure . . . [it] is simply a substitute for the term means for." *Lighting World, Inc. <u>v. Birchwood Lighting, Inc., 382 F.3d 1354, 1360</u> (Fed. Cir. 2004).* 

To determine whether the claim term should be construed as a means-plus-function limitation, we begin by evaluating how the term "spring" is used in the specification and the intrinsic record. *Phillips*, 415 F.3d at 1315 ("[T]he specification is always highly relevant" and is "the single best guide to the meaning of a disputed term"). Next, the court should consider whether the "spring means" limitation contains additional structure to rebut the means-plus-function presumption. *See Sage Prods., Inc.* <u>v</u>. *Devon Indus., Inc.*, 126 F.3d 1420, 1427 (Fed. Cir. 1997) (holding that where a claim recites a function, but goes on to elaborate sufficient structure, the claim is not in means-plus-function format).

In this case, the written description defines the term "spring means" as a type of device that imparts a function of urging the safety guard toward the needle tip. A "spring" as defined in the written description denotes a type of device with a generally understood meaning in the mechanical arts. See Greenberg  $\underline{v}$ . Ethicon Endo-Surgery, Inc., 91 F.3d 1580, 1583 (Fed. Cir. 1996). Each embodiment described in the patent employs a type of spring; e.g., coil springs, plastic springs, hinged springs, and over-centered springs. '544 patent, col.3 II.5-7; id. at col. 4 II. 40-42; id. at col. 5 II.9-16; id. at col.6 II. 38-42. None of the embodiments employ any structure other than springs. Indeed, the patent contains no suggestion that the claims include urging mechanisms other than springs. Accordingly, the intrinsic evidence demonstrates that the '544 patent [\*1263] defines "spring means" as a particular structure--a spring.

Next, the court in a proper claim analysis should consider whether the claims elaborate sufficient structure to rebut the means-plus-function presumption. The '544 patent claims state that the function of the "spring means" is for "urging the guard along said needle cannula." *Id.* at col. 7 II.34-35. The claims go on to recite additional structure to achieve that function. Claim 1 recites "spring means connected to *said hinged arm*," *id.* at col.7 II.34-35 (emphasis added), and claim 24 recites "spring means extending between *said mounting means and said hinged arm*," *id.* at col.10 II.17-20 (emphasis added). Thus, the claim language demonstrates that the combination of the "spring means" and "hinged arm" perform the "urging" function. Accordingly, the claims include additional structural limitations to rebut the means-plus-function presumption.

<u>Tyco</u> obviously disagrees with this conclusion; however, its reliance on <u>Unidynamics Corporation v. Automatic Products International</u>, 157 F.3d 1311, 1314 (Fed. Cir. 1998) is unavailing. This court in <u>Unidynamics</u> applied § 112, P 6 to the claim limitation "spring means tending to keep the door closed." In that case, the patent's written description stated that "[t]he spring . . . is <u>an example</u> of spring means tending to keep the door closed." <u>Id.</u> at 1319 (emphasis added). Accordingly, the "spring means" was not defined solely as a spring structure, but as any type of

structure to perform the function. Furthermore, the *Unidynamics* court noted that the claim language did not provide additional structure following the "spring means" language. *Id.* It merely recited a function of "tending to keep the door closed." *Id.* Therefore, the court there properly concluded that "spring means" was a means-plus-function limitation because neither the claim language nor the written description provided sufficient structure to rebut the § 112, P 6 presumption. *Id.* 

In this case, however, the written description defines "spring means" as a spring structure. For example, each embodiment employs a spring structure; e.g., coil springs, plastic springs, hinged springs, and over-centered springs. Unlike *Unidynamics*, the spring is not just an example of a spring means to perform the function; it is the only type of structure [\*\*1764] disclosed in the written description. Moreover, the claim language itself provides additional structure following the "spring means" language. For example, claim 1 recites "spring means connected to *said hinged arm*," '544 patent, col.7 II.34-35 (emphasis added), and claim 24 recites "spring means extending between *said mounting means* and *said hinged arm*," id. at col.10 II.17-20 (emphases added). Unlike *Unidynamics*, the claim language itself includes additional structure; e.g., the hinged arm and mounting means--to perform the function of urging the guard along the needle cannula. Here, the means-plus-function presumption is rebutted and the claims should not be construed according to § 112, P 6. Therefore, the district court correctly construed the "spring means" limitation according to its ordinary meaning: "[t]he hinged arm is connected to a spring that moves the guard along the cannula toward the second position." **Becton**, **Dickinson** & **Co. v. Tyco Healthcare Group**, *LP*, No. 02-1694-GMS, 2004 U.S. Dist. LEXIS 18637, 2004 WL 2075413, at \*4 (D. Del. Sept. 16, 2004).

The majority first approves of the district court's claim construction, see Maj. Op. 8-9, but then proceeds to improperly import an extraneous limitation into the claims, which is contrary to our case law. See Comark Commc'ns, Inc. <u>v</u>. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. [\*1264] 1998). The majority asserts that "the unequivocal language of the asserted claims of the '544 patent requires a spring means that is separate from the hinged arm" because they are written as separate limitations in the claim language. Maj. Op. 9. However, the unequivocal language articulates no requirement for separate structures. It merely recites "a spring means connected to said hinged arm for urging said guard along said needle cannula toward said second position." The majority's limitation requiring two separate structures is not supported anywhere in the intrinsic or extrinsic record. Such a claim interpretation violates our established tenants of claim construction prohibiting the court from reading extraneous limitations into the claims. E.I. du Pont de Nemours & Co. <u>v</u>. Phillips Petroleum, 849 F.2d 1430, 1433 (Fed. Cir. 1998) ("It is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim . . . . But this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.") (citation omitted).

The majority relies on CAE Screenplates, Inc.  $\underline{v}$ . Heinrich Fiedler GmbH & Co., 224 F.3d 1308, 1317 (Fed. Cir. 2000), which states that "we must presume that the use of . . . different terms in the claims connotes different meanings." (emphases added). While this is correct, the majority fails to recognize that "the use of two terms in a claim requires that they connote different meanings, not that they necessarily refer to two different structures." Applied Med. Res. Corp.  $\underline{v}$ . U.S. Surgical Corp., 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006) (emphases added); see also Intellectual Prop. Dev., Inc.  $\underline{v}$ . UA-Columbia Cablevision of Westchester, Inc., 336 F.3d 1308, 1320 (Fed. Cir. 2003). Indeed, it is well established that a single structure in an accused device may satisfy two different claim limitations. Intellectual Prop., 336 F.3d at 1320 n.9 ("[W]e see no reason why, as a matter of law, one claim limitation may not be responsive to another merely because they are located in the same physical structure"); In re Kelley, 305 F.2d 909, 915-16, 49 C.C.P.A. 1359, 1962 Dec. Comm'r Pat. 681 (CCPA 1962) (stating that two claim terms may read upon the same physical structure). In the absence of evidence requiring two structures, the claim language must be interpreted broadly to read upon an accused product containing the two claim terms, regardless of whether those elements are encompassed in one or two structures.

In the '544 patent, nothing in the claim language, written description or prosecution history requires that the [\*\*1765] "spring means" and "hinged arm" be separate structures. The plain language of the claims includes no such "separate structures" limitation. To the contrary, the written description contemplates that the "spring means" and "hinged arm" be included as part of the same "hinged arm assembly." See, e.g., '544 patent, col.4 II.40-44

(stating that a spring may be encompassed "between" the joints of the hinged arm assembly); *id.* at col.5 II.66-68 ("proximal and distal segments . . . of [the] hinged arm assembly . . . can be articulated about [the] hinges."). In other words, the "hinged arm assembly" is described as a structure with the "spring means" and "hinged arm" as components of that structure. There is no support in the written description requiring that the "spring means" and "hinged arm" be separate structures themselves. Accordingly, a proper claim construction does not require two separate structures for the "spring means" and "hinged arm." The majority's ruling improperly imports an extraneous limitation into the claims and fails to give the claim language its full, literal scope. By injecting this additional and extraneous limitation, the majority sidesteps the required analysis of whether the "spring [\*1265] means" limitations are prescribed by § 112, P 6.

In addition to applying a wholly simplistic claim construction, the majority fails to consider substantial evidence on the record supporting the jury's determination of infringement. The majority opinion states that:

The thrust of Becton's infringement argument was that the hinges in <u>Tyco</u>'s needles contain stored energy and that when the hinged arm is unlatched, the hinges act as "springs" that cause the guard to move down the needle cannula. The fatal defect in this theory is that Becton failed to produce any evidence that this posited movement ever occurred. Becton did not provide any test data or even a single live demonstration showing that: 1) the hinges in the accused devices contained stored energy, or 2) they moved the guard even one millimeter down the needle cannula.

Maj. Op. 16. However, the majority turns a blind eye to sufficient evidence supporting the jury's determination of infringement. In reviewing a motion for judgment as a matter of law ("JMOL") under Third Circuit law, we overturn a jury verdict "only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153, 1166 (3d Cir. 1993). In this case, the majority fails to view the evidence in the light most favorable to Becton and fails to draw reasonable inferences from the evidence introduced at trial. Had the majority properly analyzed the jury verdict, it would have concluded that there is sufficient evidence on the record supporting the finding of infringement.

First, the accused devices themselves were entered in evidence, and the jury was able to examine them. The jury requested and received additional samples of the accused safety needles during its deliberations. Observation of the device is sufficient to determine whether the accused devices have a spring that, by itself, moves the guard towards the needle tip once the hinged arm is unlatched. The jurors directly examined the devices and concluded that they infringed. The jury's factual findings based on direct examination of the accused devices are entitled to deference. See, e.g., Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1329 (Fed. Cir. 2002) (affirming the jury's infringement verdict where the accused device was available to the jury).

Second, Becton's expert, Mr. Garris, testified that the accused devices contain a spring that, by itself, moves the guard once unlatched. To show that the living hinges were responsible for motion, Becton's expert demonstrated the activation of a *Tyco* Safety Needle and Blood Collector before the jury. Mr. Garris testified that a small movement occurs upon unlatching, which is caused by the living hinges. The jury is entitled to credit this testimony, particularly given that the jury viewed the device and could examine the action of the guard and the needle. We as an appellate court cannot and should not reweigh the reasonable evidentiary conclusions found by a jury and reverse its judgment.

<u>Tyco</u> argues that Mr. Garris's opinion "was based entirely on a combination of forces working at the same time to move the guard, and not motion caused by the spring itself," as required by the district court. But this is incorrect. There is testimony in the record that the court's claim construction allows for a combination of forces "to get the process started;" e.g., to push the guard over the latch. Mr. Garris also testified that once the hinged arm is unlatched, the living hinge "springs [\*1266] up", moving the guard "a little bit" in the direction of the needle tip.

#### 616 F.3d 1249, \*1266; 95 U.S.P.Q.2D (BNA) 1752, \*\*1765

Third, the jury is allowed to infer from the evidence that the living hinge, by itself, moves the guard towards the needle tip based on the fact that <u>Tyco</u> included a latch on its product. Mr. Garris testified that the latch "restrains" the stored energy imparted to the living hinges at the time that they are folded. Mr. Garris testified that:

[I]t is very obvious that there is a spring. And in the folding process, it's very clear that energy was put in. So without doing anything, it was very clear that there was a spring which was biased in a way that would make the guard go toward the tip of the cannula.

Mr. Garris also explained that the latch functions to "hold back the spring force and prevent [] the hinged arm from deploying" while a health care worker is giving an injection.

Fourth, Becton presented evidence that the hinged arm of the accused products is, in fact, biased against the latch at the time of their use and, hence, will extend to move the guard forward once unlatched. Moreover, Becton played a video clip that shows *Tyco*'s expert removing the latch of a Safety Needle while holding the guard in its initial position. The evidentiary video shows that once the latch is removed and the guard is released, the spring, by itself, moves the guard toward the needle tip a small but visible distance. The jurors could reasonably have concluded that this videotaped evidence is sufficient to show infringement.

In sum, there is substantial evidence--the jury's self-examination of the accused needle guards, the expert testimony regarding the "spring" in the guard, the presence of the latch to restrain the guard's movement, and the video tape evidence showing movement of the guard in the absence of the latch--to support the jury's finding of infringement. Accordingly, applying the test of the Third Circuit as outlined in *Lightning Lube*, it is improper to disturb the jury's finding of infringement. The district court was correct in denying the JMOL.

In conclusion, the majority opinion is severely flawed in several aspects. Most importantly, it fails to conduct a claim construction analysis to determine whether construction of the "spring means" limitation is governed by § 112, P 6. Indeed, the majority puts the cart before the horse by concluding that the claim language covers only devices having two separate structures, but fails to undertake a proper claim construction analysis. The majority then applies its simplistic claim construction to its infringement analysis in reviewing the denial of JMOL. Contrary to Third Circuit law, the majority fails to view the evidence in the light most favorable to Becton and improperly overturns the jury's verdict finding infringement. The majority climbs Jacob's Ladder in search of perfection in the jury verdict, but, by substituting its own fact finding for that of the jury, it fails to allow the jury to perform its proper function. For these reasons, I dissent from the judgment of the majority opinion.

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