United States Court of Appeals for the Federal Circuit

RETRACTABLE TECHNOLOGIES, INC. AND THOMAS J. SHAW,
Plaintiffs-Appellees,

v.

BECTON, DICKINSON AND COMPANY,
Defendant-Appellant.

2010-1402

Appeal from the United States District Court for the Eastern District of Texas in Case No. 07-CV-0250, Chief Judge David J. Folsom.

Decided: July 8, 2011

ROY W. HARDIN, Lock, Lord, Bissell & Liddell, LLP, of Dallas, Texas, argued for plaintiffs-appellees. With him on the brief were CYNTHIA KEELY TIMMS and MARK R. BACKOFEN.

WILLIAM F. LEE, Wilmer, Cutler, Pickering, Hale, and Dorr, LLP, of Boston, Massachusetts, argued for defendant-appellant. With him on the brief were LISA J. PIROZZOLO; and WILLIAM G. MCELWAIN and HEATH A. BROOKS, of Washington, DC.

Before RADER, *Chief Judge*, and PLAGER and LOURIE, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE. Concurring opinion filed by *Circuit Judge* PLAGER. Dissenting-in-part opinion filed by *Chief Judge* RADER.

LOURIE, *Circuit Judge*.

Becton, Dickinson and Company ("BD") appeals from the final judgment of the United States District Court for the Eastern District of Texas in favor of Thomas J. Shaw and Retractable Technologies, Inc. (collectively, "RTI"). *See Retractable Techs., Inc. v. Becton, Dickinson & Co.*, No. 2:07-CV-250, Final Judgment and Permanent Injunction (ECF No. 366) (E.D. Tex. May 19, 2010) ("*Final Judgment*"). The judgment follows a trial where a jury found infringement of certain claims of RTI's U.S. Patents 5,632,733 ("the '733 patent"), 6,090,077 ("the '077 patent"), and 7,351,224 ("the '224 patent"). The jury also found that the asserted patents were not invalid for anticipation or obviousness. The district court subsequently denied BD's post-trial motions for judgment as a matter of law ("JMOL") or for a new trial on the issues of infringement and invalidity of the asserted patents. *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, Case. 2:07-CV-250, Order (ECF No. 365) (E.D. Tex. May 19, 2010) ("*JMOL Order*").

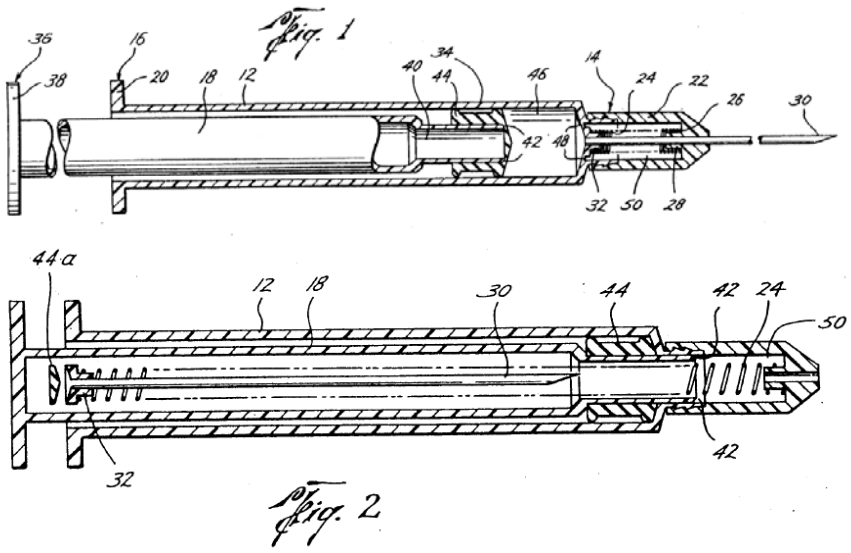
On appeal, BD challenges the district court's denial of its post-trial motions as well as the district court's claim constructions, *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, Case 2:07-CV-250, Claim Construction Order (ECF No. 122) (E.D. Tex. Jan. 20, 2009) ("*Claim Construction Opinion*"); *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, Case 2:07-CV-250, Order (ECF No. 239) (E.D.

Tex. Sept. 21, 2009) ("*Modified Claim Construction Opinion*"), and the district court's exclusion of RTI's discovery responses from evidence, *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, Case 2:07-CV-250, Order (ECF No. 262) (E.D. Tex. Oct. 8, 2009) ("*Motion in Limine Order*"); *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, Case 2:07-CV-250, Order (ECF No. 276) (E.D. Tex. Oct. 28, 2009) ("*Motion to Strike Order*"). Because the district court erred in its construction of the claim term "body" but did not otherwise err, we affirm in part and reverse in part.

BACKGROUND

This patent infringement case relates to retractable syringes, which are medical syringes that feature a needle that retracts into the syringe body after the syringe is used. The retraction of the needle reduces the risk associated with contaminated needles because the used needle, which resides in the syringe body after retraction, is less likely to accidently stick a user. RTI and BD both design and sell retractable syringes.

The parties agree that retractable syringes generally existed by the early 1990s, and, as an invalidity defense at trial, BD relied on prior art retractable syringe patents filed in 1990 and 1991, specifically U.S. Patent 5,053,010 ("McGary") and U.S. Patent 5,211,629 ("Pressly"). Figures 1 and 2 of McGary, reproduced below, generally show how a retractable syringe operates, with Figure 1 depicting a syringe prior to retraction of the needle (labeled 30) and Figure 2 depicting the syringe after retraction:



As disclosed in McGary, prior to retraction, the front end of the syringe contains a compressed spring (labeled 24) that is pushed against a retainer (labeled 32). McGary, col.5 l.6–18. The plunger contains a cutting tip (labeled 42), and after the plunger is fully extended into the syringe barrel, additional force on the plunger causes the cutting tip to penetrate through the retainer, which allows the spring to decompress and retract the needle into the syringe body. *Id.* col.5 ll.50–61.

In 1995, Thomas Shaw filed a patent application for a "Tamperproof Retractable Syringe." Shaw subsequently filed a series of continuation and continuation-in-part applications from the parent application, and these applications issued as the '733, '077, and '224 patents. The patents contain a detailed structural disclosure of a particular retractable syringe assembly. *See Claim Construction Opinion*, at 2–3. While multiple claims are at issue on appeal, claim 43 of the '224 patent, reproduced below, is generally representative of the asserted claims, reciting a syringe assembly that contains a "body" and a

"retraction mechanism" in the front end portion of the "body," where the "retraction mechanism" contains a "needle holder" and a "retainer member" that surrounds the inner head of the "needle holder":

> 43. A syringe assembly having a retractable needle that is rendered unusable after a single injection of fluid into a patient, the assembly comprising:
>
> a *hollow syringe body* comprising a barrel and having a front end portion and a back end portion, the back end portion further comprising at least one radially extending member providing finger grips for the syringe body;
>
> a retraction mechanism disposed in the front end portion, the retraction mechanism further comprising a *needle holder* having a head portion, an elongated needle holding portion, and a longitudinally extending fluid passageway through the head portion and the elongated needle holding portion, the head portion further comprising an inner head, a *continuous retainer member* surrounding the inner head, and a bridging portion disposed between the continuous retainer member and the inner head, wherein said bridging portion couples the continuous retainer member and the inner head to form a fluid seal between the fluid passageway and the barrel prior to retraction, and a compressed retraction spring surrounding at least part of the elongated needle holding portion and biasing the inner head toward the back end portion prior to retraction;

a retractable needle extending into the front end portion of the body through an opening in the front end portion of the body, the retractable needle being held in fixed relation to the elongated needle holding portion of the needle holder and in fluid communication with the longitudinally extending fluid passageway through the head portion and the needle holding portion;

a plunger reciprocally disposed inside the barrel and forming a variable chamber between the plunger and the needle holder prior to and during injection, the plunger being receivable into the barrel through the back end portion of the body and comprising an outer wall, a retraction cavity disposed inwardly of the outer wall, a plunger seal element providing sliding, sealed engagement between the plunger and the barrel and preventing fluid leakage between the plunger and the barrel, the plunger seal element being restrained from sliding longitudinally along the outer wall of the plunger, and a back end with an end cap having an outer periphery; and

a barrier disposed in the front end portion of the body that limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction;

wherein the continuous retainer member is releasable from the inner head of the needle holder when the plunger is further depressed inside the barrel following injection.

'224 patent, col.22 l.35–col.23 l.19 (emphases added). Generally, the retraction mechanism contains a needle holder and spring combination. '733 patent, col.2 l.58–col.3 l.7.[1] The needle holder contains a circular head, and a clamping or frictional force on the head holds the needle holder in position. *Id.* col.3 l.7–24. When the plunger is depressed to a "retraction position," this force causes the retraction mechanism to activate and release the needle holder. *Id.*

Important for the purposes of this appeal, the patents disclose what RTI refers to as the "bridge" embodiment. In this embodiment, the head of the needle holder contains two parts, an inner head and a retainer member that surrounds the inner head. *Id.* col.3 l.25–46. The retainer member and the inner head of the needle holder are connected by a weld that creates a bridge portion. *Id.* col. 3 ll.39–46, col.9 ll.7–17. Figure 8, reproduced below, depicts the "bridge" embodiment, with the inner head of the needle holder (labeled 72a) connected to the retainer member (labeled 66a) by a "bridge" that is created by welding the raised portion of the inner head (labeled 73) to the retainer member:

[1] Because the '077, '733, and '224 patents contain a common disclosure for the issues presented in this appeal, we will cite the '733 patent for simplicity.

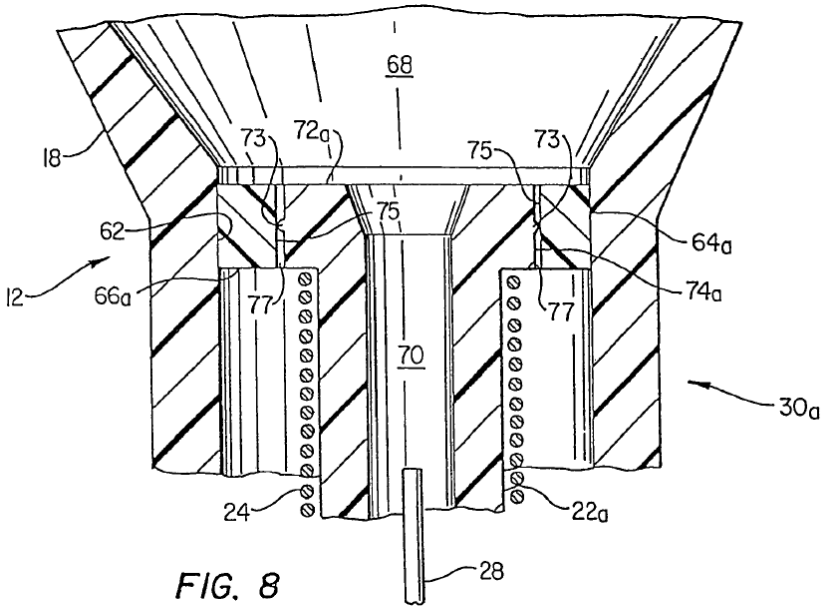


FIG. 8

In this embodiment, when the plunger is fully extended into the barrel, additional force on the plunger causes the bridging portion to be "ruptured, fractured or otherwise separated" so the weld no longer holds the needle holder in place. *Id.* col.8 ll.18–56. This allows the compressed spring (labeled 24) to expand and thereby retract the needle (labeled 28) and the needle holder (labeled 22a). *Id.*

In 2007, RTI sued BD in the Eastern District of Texas, alleging that BD's 1 mL and 3 mL Integra™ syringes infringe various claims of the '733, '077, and '224 patents. Excluding the plunger, the 3 mL syringe contains two pieces, a syringe body and a needle assembly that screws into the body. The needle assembly contains an inner hub and an outer hub that are connected to each other. The outer hub contains the threads that screw into the syringe body. The inner hub contains the needle and a spring compressed against the surface of the inner hub.

The plunger in the 3 mL Integra contains a cutter. When the needle assembly is screwed in and the plunger is fully extended in the barrel, additional force on the plunger causes the cutter to cut a portion of the inner hub of the needle assembly, allowing the spring to expand and retract the needle into the syringe body.

The 1 mL Integra operates in a similar manner. In addition to the plunger, the 1 mL Integra contains a one-piece syringe that includes the needle assembly. Instead of a cutter located at the end of the plunger, the cutter in the 1 mL syringe is located within the needle assembly. The 1 mL Integra syringe retracts the needle when the plunger applies pressure on the outer edge of the needle assembly, causing the cutter to cut a portion of the needle assembly, which allows the spring to expand and retract the needle.

In the course of the litigation, the district court construed the claims and denied the parties' dispositive motions. The court construed the term "retainer member" as "a non-retractable part of the retraction mechanism that uses some clamping or frictional force to keep the needle in the projecting position until that clamping or frictional force is released." *Claim Construction Opinion*, at 14–16; *Modified Claim Construction Opinion*, at 6–7. The district court also concluded that the claimed "retainer member" and "needle holder" need not be two separate parts. *Claim Construction Opinion*, at 14. The district court construed "body" as "a hollow outer structure that houses the syringe's components," and concluded that the term "body" was not limited to a one-piece structure. *Id.* at 6–7. Finally, the district court concluded that the patents did not disclaim the use of "cutting," *Modified Claim Construction Order,* at 8, and concluded that whether the accused devices' use of "cutting" fell

within the scope of the claims was a question of fact, not a matter of claim construction, *Motion to Strike Order*, at 8.

Prior to trial, the district court concluded that it would exclude from evidence RTI's discovery responses. *Id.* at 7. In particular, RTI refused to produce the results of a test that detailed the force required to activate retraction in a retractable syringe made by a third-party that RTI sued in 2002. *Id.* at 2. In its response, RTI stated that "[a]s there presently is no allegation that the infringing products in this case operate by the release of a frictional holding mechanism, the requested document is irrelevant and not likely to lead to the discovery of admissible evidence." *Id.* According to BD, RTI reiterated this position in a letter to the district court. The district court excluded these documents on the basis that any presentation of RTI's discovery responses "would inextricably raise" RTI's prior litigation. *Id.* at 7.

The parties then tried the case to a jury. Before the district court submitted the case to the jury, BD moved for JMOL on numerous issues, and the court denied BD's motions. *See JMOL Order*, at 1–2. The jury subsequently found that BD infringed multiple claims of the asserted patents and found that BD failed to prove that any of the asserted claims were invalid. *Id.* at 2. After trial, BD moved for JMOL of noninfringement and invalidity. *Id.* at 3–5. BD also moved, in the alternative, for a new trial on infringement and invalidity. *Id.* The district court denied BD's motions, *id.* at 5–6, and entered judgment against BD, *Final Judgment*, at 1–3.

BD timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

BD raises numerous issues on appeal. First, BD challenges the district court's construction of the terms "retainer member" and "body." Second, BD challenges the district court's conclusion that, as a matter of law, retractable syringes that operate by "cutting" are not excluded from the scope of the claims of the asserted patents. Third, BD argues that the jury's infringement finding must be set aside because it is not supported by substantial evidence. Fourth, BD challenges the district court's exclusion from evidence of RTI's discovery responses and letter to the district court. Finally, BD argues that claim 25 was anticipated or obvious as a matter of law. We address each of these issues below.

A. Standards of Review

In reviewing evidentiary rulings and denials of motions for JMOL, we apply the law of the regional circuit, in this case, the Fifth Circuit. *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1328 (Fed. Cir. 2008). Under Fifth Circuit law, we review denials of JMOL *de novo*. *Cambridge Toxicology Grp., Inc. v. Exnicios*, 495 F.3d 169, 179 (5th Cir. 2007). JMOL is appropriate only if the court finds that a "reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." FED. R. CIV. P. 50(a)(1); *see Cambridge Toxicology*, 495 F.3d at 179.

The Fifth Circuit reviews a district court's evidentiary rulings for abuse of discretion. *Jowers v. Lincoln Elec. Co.*, 617 F.3d 346, 355 (5th Cir. 2010). Any error in the admission or exclusion of evidence "should not be the basis for setting aside the judgment" unless "the substantial rights of the parties were affected." *EEOC v. Manville Sales Corp.,* 27 F.3d 1089, 1093 (5th Cir. 1994). Moreover, where the trial judge "has conducted, on the

record, a carefully detailed analysis of the evidentiary issues and the court's own ruling, appellate courts are chary about finding an abuse of discretion." *Kelly v. Boeing Petroleum Servs., Inc.*, 61 F.3d 350, 356 (5th Cir. 1995).

The proper construction of a patent's claims is an issue of Federal Circuit law, and we review a district court's claim construction *de novo*. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454–55 (Fed. Cir. 1998) (en banc). To ascertain the scope and meaning of the asserted claims, we look to the words of the claims themselves, the specification, the prosecution history, and any relevant extrinsic evidence. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315–17 (Fed. Cir. 2005) (en banc).

B. Claim Construction

BD challenges the district court's construction of "retainer member" and "body" as well as the district court's conclusion that the asserted claims do not exclude as a matter of law devices that operate by "cutting." We address each of BD's challenges below.

1. Retainer Member

BD argues that the district court erred when it concluded that the claimed "retainer member" and "needle holder" limitations need not be two separate parts. BD argues that the elements must be separate pieces because the asserted claims list the "retainer member" and "needle holder" as separate claim limitations and the specifications only describe a retainer member that is a separate part from the needle holder. BD argues that connecting two pieces via a tack weld, as disclosed in the "bridge" embodiment, is different from forming the elements as a single piece. To support that argument, BD points to the prosecution history, where the inventor allegedly repre-

sented to the U.S. Patent and Trademark Office ("PTO") that the use of a tack weld to connect two pieces does not result in a one-piece structure.

We disagree. The claims and the specifications indicate that the "needle holder" and "retainer member" need not be separately molded pieces. Claim 24 of the '733 patent, for example, claims a "needle holder," where the head of the "needle holder" has a "retainer member which can be separated from the head of the needle holder." Similarly, claim 43 of the '224 patent claims a "needle holder having a head portion" where the head portion of the needle holder "further comprises an inner head, a continuous retainer member surrounding the inner head, and a bridging portion disposed between the continuous retainer member and the inner head." These claims allow the "needle holder" and "retainer member" to structurally overlap prior to separation and indicate that the two limitations need not be separate pieces.

The specifications also indicate that the "needle holder" and the "retainer member" need not be separately molded pieces. The specifications state that the retainer member and the inner head of the needle holder can be connected by a weld, and retraction occurs when the weld is "ruptured or separated." '733 patent, col.9 ll.7–13 (disclosing a "tack weld"); *id.* col.10 l.4 (stating that "[s]onic welding could also be employed"). As part of this disclosure, the specifications disclose forming a "bridging portion" that connects the retainer member and the needle holder head by welding the elements together to form the bridging portion, and retraction occurs when the weld at the bridging portion is "ruptured, fractured or otherwise separated." *Id.* col.9 ll.38–41, col.9 ll.51–56.

The specifications further disclose a method to couple the two structures by "expos[ing] them to a temperature

of about 120°C for twenty minutes or so to allow some diffusion or incipient melting to occur where they touch." *Id.* col.9 l.65–col.10 l.1. This passage suggests that the needle holder, retainer member, and bridging portion could be formed as an integral structure in the first instance. Thus, the specifications and the claims indicate that the "retainer member" and the "needle holder" need not be two separate pieces. *See Linear Tech. Corp. v. Int'l Trade Comm'n*, 566 F.3d 1049, 1055 (Fed. Cir. 2009) (declining to construe "second circuit" and "third circuit" to require "entirely separate and distinct circuits" where "nothing in the claim language or specification" supported that construction and the specification disclosed that the circuits could share common circuit elements).

The prosecution history does not compel a contrary result. During prosecution of the application that issued as the '224 patent, the inventor argued, among other things, that the outer wall of the needle assembly disclosed in Pressly was not part of a syringe "made of" a one-piece barrel because the outer wall was fixed to the barrel "by ultrasonic welding means or other permanent attachment means following the installation of the retraction components as described in relation to FIGS. 11–13 [of Pressly]." July 17, 2000 Response and Amendment in Application Serial Number 09/617,868, at 43 (internal citations omitted).

This statement by itself, however, is not sufficient to detract from the claim language and the written disclosure. The inventor's arguments relate to whether a "barrel" is "made of" one piece. The arguments do not address whether the needle assembly and retainer member, which are different syringe components that serve different purposes, can cover distinct structural portions of an integral structure. In addition, the asserted claims lack language that limits the needle holder or the retainer

member to elements that are "made of" one piece. Ultimately, the inventor's statement, on its own, lacks the clarity required to exclude from the scope of the claims a needle holder and a retainer member that form distinct portions of a single structure. *See Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc.*, 628 F.3d 1359, 1369–70 (Fed. Cir. 2010); *Phillips*, 415 F.3d at 1317. Accordingly, the district court did not err in its construction of "retainer member."

2. Body

BD argues that the district court erred when it concluded that the claimed "body" is not limited to a one-piece structure. BD argues that the specifications describe "the invention" as including a one-piece body while criticizing prior art syringes that contain a two-piece body. BD also argues that claim differentiation does not apply in light of the written description's limiting statements.

RTI responds that the ordinary meaning of the term "body" is not limited to a one-piece body. RTI points to the different usage of the term "body" in the claims, where some claims recite a "body" and other claims recite a "one piece body." RTI also argues that while the preferred embodiments disclose a syringe with a one-piece body, that disclosure is directed to manufacturing benefits, not the other patentable aspects of the invention.

We agree with BD that the claimed "body" is limited to a one-piece structure in light of the specifications. While the patents contain an independent claim that recites a "body," '224 Patent, claim 25, with a dependent claim that limits the "body" to a "one-piece body," '224 Patent, claim 31, none of the claims expressly recite a body that contains multiple pieces. Thus, while the

claims can be read to imply that a "body" is not limited to a one-piece structure, that implication is not a strong one.

It is axiomatic that the claim construction process entails more than viewing the claim language in isolation. Claim language must always be read in view of the written description, *Phillips*, 415 F.3d at 1315, and any presumption created by the doctrine of claim differentiation "will be overcome by a contrary construction dictated by the written description or prosecution history," *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005). Thus, it is necessary to review the specifications to determine if the proper construction of the term "body" is limited to a one-piece body.

The specifications indicate that the claimed "body" refers to a one-piece body. In distinguishing prior art syringes comprised of multiple pieces, the specifications state that the prior art had failed to recognize a retractable syringe that "can be molded as one piece outer body." '733 patent, col.2 ll.26–31. Consistent with this characterization of the prior art, the Summary of the Invention states that "[t]he invention is a retractable tamperproof syringe," and that this syringe "features a one piece hollow body." *Id.* col.2 ll.45–47.

Similarly, the specifications, in describing the invention, expressly state that each syringe embodiment contains a one-piece body. *Id.* col.5 l.54–56 (describing a first syringe embodiment that "has a one piece hollow outer body"); *id.* col.10 l.8–9 (disclosing an "alternate syringe" that has "a one piece hollow outer syringe body"). In addition, each figure that depicts a syringe body shows a one-piece body. In contrast, the specifications do not disclose a body that consists of multiple pieces or indicate that the body is anything other than a one-piece body.

There is a fine line between construing the claims in light of the specification and improperly importing a limitation from the specification into the claims. *See Phillips*, 415 F.3d at 1323. In reviewing the intrinsic record to construe the claims, we strive to capture the scope of the actual invention, rather than strictly limit the scope of claims to disclosed embodiments or allow the claim language to become divorced from what the specification conveys is the invention. *Id*. at 1323–24.

In this case, while the claims leave open the possibility that the recited "body" may encompass a syringe body composed of more than one piece, the specifications tell us otherwise. They expressly recite that "the invention" has a body constructed as a single structure, expressly distinguish the invention from the prior art based on this feature, and only disclose embodiments that are expressly limited to having a body that is a single piece. Thus, a construction of "body" that limits the term to a one-piece body is required to tether the claims to what the specifications indicate the inventor actually invented. Accordingly, the district court erred when it construed "body" as encompassing bodies composed of multiple pieces.

3. Exclusion of Devices that Operate by "Cutting"

BD also appeals the district court's conclusion that the asserted claims, as a matter of law, do not exclude retractable syringes that operate by "cutting." As an initial matter, RTI argues that BD waived this claim construction argument because BD first raised the argument on appeal.

We disagree. On at least two occasions, BD presented this argument in substance to the district court. *See Claim Construction Opinion*, at 14; *Modified Claim Construction Opinion*, at 8. Thus, BD's argument is properly before this court. *See Interactive Gift Express,*

Inc. v. Compuserve, Inc., 256 F.3d 1323, 1346–47 (Fed. Cir. 2001).

Turning to the merits, BD argues that the specifications expressly criticize and distinguish prior art devices that operate by methods other than friction. BD asserts that these statements disclaim devices that operate by "cutting," and the claims should be construed accordingly.

We disagree. Nothing in the claim language indicates that the claims exclude "cutting" as a matter of law. To disavow claim scope, the specification must contain "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1335 (Fed. Cir. 2009). In general, statements about the difficulties and failures in the prior art, without more, do not act to disclaim claim scope. *See Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1315 (Fed. Cir. 2010) (concluding that statement that a prior art two-piece implant was "particularly difficult" to achieve did not disclaim two-piece implants).

As described above, the specifications disclose a "bridge" embodiment where the retainer member and needle holder are welded together and connected by a bridge. '733 patent, col.9 ll.7–56. In this embodiment, the needle retracts when the weld at the bridge portion is "ruptured, fractured or otherwise separated," allowing the spring force to cause the needle to retract into the syringe body. *Id.* col. 9 ll.51–56. Broadly, this disclosure indicates that at least some forms of "cutting" fall within the scope of the invention.

In addition to including the bridge embodiment, the specifications do not clearly exclude "cutting" from the scope of the claims. The specifications note that a problem with prior art retractable syringes is their "depend-

ence on flexing or breaking of internal parts by the plunger in order to release the retraction mechanism and use of a diaphragm at the end of the plunger which must be penetrated by a needle holding member and spring." *Id.* col.1 ll.48–52. The background section also notes that "[t]he prior art has not recognized a retraction mechanism with separable parts that relies entirely on clamping force or friction . . . ." *Id.* col.2 ll.18–26. Ultimately, these statements discuss particular problems with the prior art, and absent from these statements is a manifest exclusion of all "cutting" from the scope of the claims. Thus, we conclude that the district court did not err in concluding that the asserted patents, as a matter of law, do not disclaim devices that operate by "cutting."

C. Infringement

BD appeals the district court's denial of BD's motion for JMOL that the accused 3 mL and 1 mL Integra syringes do not infringe the asserted patents. We address each accused syringe in turn.

1. 3 mL Integra

BD raises numerous arguments on appeal as to why the jury's verdict of infringement was not supported by substantial evidence. Because we conclude that no reasonable jury could find that the 3 mL Integra meets the "body" limitation, as revised herein, literally or under the doctrine of equivalents, we decline to address BD's remaining arguments.

It is undisputed that under a construction that limits the "body" to a one-piece structure, the 3 mL Integra does not literally infringe any of the asserted claims. The issue that remains is whether RTI may pursue an infringement theory based on the doctrine of equivalents. BD argues that because the specifications criticize prior art syringes

that contain multiple bodies, RTI is precluded from asserting infringement under the doctrine of equivalents. RTI argues that it is entitled to litigate on remand the fact issue of whether the 3 mL Integra infringes under the doctrine of equivalents.

We agree with BD. While infringement under the doctrine of equivalents is a question of fact, *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609–10 (1950), whether statements in the specification limit the scope of equivalents is a question of law, *J & M Corp. v. Harley-Davidson, Inc.*, 269 F.3d 1360, 1366 (Fed. Cir. 2001). It is well settled that "when a specification excludes certain prior art alternatives from the literal scope of the claims and criticizes those prior art alternatives, the patentee cannot then use the doctrine of equivalents to capture those alternatives." *L.B. Plastics, Inc. v. Amerimax Home Prods., Inc.*, 499 F.3d 1303, 1309 (Fed. Cir. 2007) (collecting cases).

Here, statements in the specifications preclude RTI from asserting that a body constructed of two pieces infringes the asserted claims under the doctrine of equivalents. As described above, the specifications expressly recite that "the invention" has a body constructed as a single piece and expressly distinguish the invention from the prior art based on this feature. With these distinguishing statements in the specifications, RTI cannot use the doctrine of equivalents to claim subject matter that the specifications expressly state fall outside the invention. Accordingly, we reverse the district court's denial of BD's motion for JMOL and render judgment that the 3 mL Integra syringes do not infringe any of the asserted claims as a matter of law.

2. 1 mL Integra

BD argues that the 1 mL Integra does not, as a matter of law, infringe the asserted claims under BD's construction of "retainer member" and under BD's argument that the patents exclude "cutting" from the scope of the claims. Having rejected these arguments, we affirm the district court's denial of JMOL of noninfringement for the 1 mL Integra syringes.

D. Exclusion of RTI's Discovery Responses and Letter to the District Court

BD also appeals the district court's denial of BD's motion for a new trial on infringement based on the district court's exclusion from evidence of RTI's discovery responses and letter to the district court. BD argues that the district court abused its discretion by erroneously applying the balancing test in Federal Rule of Evidence 403. BD asserts that the exclusion of these documents affected its substantial rights because the documents would have exposed RTI's contradictory infringement positions and constituted evidence that BD could have used to impeach RTI's expert at trial.

We disagree. The district court, in granting BD's motion in limine, excluded from evidence references to RTI's prior patent litigation pursuant to Federal Rules of Evidence 403, 404, and 408. *Motion in Limine Order*, at 3. Subsequently, the district court assessed RTI's discovery responses and concluded that allowing BD to introduce the document would inevitably raise the previously-excluded issue of RTI's prior litigation. *Motion to Strike Order*, at 7. This conclusion was not arbitrary or clearly erroneous because RTI's statements were in response to BD's request that RTI produce documents related to RTI's prior litigation against a third party. Thus, we conclude that the district court did not abuse its discretion by

excluding RTI's discovery responses and RTI's letter to the district court regarding those responses. Accordingly, we affirm the district court's denial of BD's motion for a new trial on the issue of infringement.

E. Invalidity of Claim 25 of the '077 Patent

Finally, BD argues that the district court erred when it denied BD's motion for JMOL that claim 25 of the '077 patent was anticipated by McGary or Pressly or rendered obvious in light of these references in view of UK Patent Application GB 2197792A ("Power"). As an initial matter, RTI argues that BD waived these invalidity arguments by failing to advance the arguments in a pre-verdict motion for JMOL. *See* FED. R. CIV. P. 50(a). We disagree.

Rule 50(a)(2) requires the moving party, before the case is submitted to the jury, to "specify the judgment sought and the law and the facts that entitle the movant to the judgment." The Fifth Circuit has construed this rule liberally, concluding that oral motions that succinctly state the basis for the motion are sufficient under Rule 50 to preserve the issue. *Tharling v. City of Port Lavaca*, 329 F.3d 422, 426 n.4 (5th Cir. 2003); *see also Blackboard v. Desire2Learn, Inc.*, 574 F.3d 1371, 1379–80 (Fed. Cir. 2009) (collecting cases from the Fifth Circuit).

BD's pre-verdict motion is sufficient under Rule 50. At the close of the evidence, BD presented an oral motion to the district court that sought JMOL that claim 25 of the '077 patent was "anticipated by McGary and/or Pressly and/or obvious in light of the combination of McGary, Pressly, and Power." *JMOL Order*, at 6 n.1. The motion identified both the legal grounds for the motion as well as the underlying references for each ground, thus alerting the district court to and putting RTI on notice of BD's specific anticipation and obviousness positions. *See*

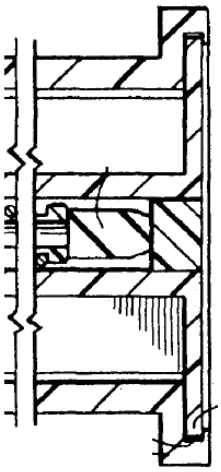
id. No more was necessary to satisfy the requirements of Rule 50(a). *See Blackboard*, 574 F.3d at 1380.

Because BD did not waive its invalidity arguments, we address each of BD's arguments below.

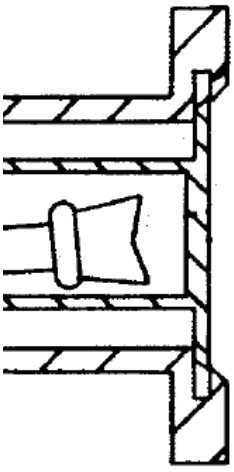
1. Anticipation

BD argues that it is entitled to JMOL that McGary and/or Pressly anticipate claim 25 of the '077 patent. The parties agree that McGary and Pressly each disclose every limitation of claim 25 with one exception. Claim 25 requires "a plunger having a retraction position obtained by pressing the thumb cap to move the plunger forward beyond the tactile first position and thereby operating the retraction mechanism and simultaneously lodging the thumb cap in the open back of the barrel thereby rendering the thumb cap inaccessible for grasping." In particular, the parties dispute whether McGary and Pressly disclose "lodging the thumb cap in the open back of the barrel thereby rendering the thumb cap inaccessible from grasping."

BD argues that both McGary and Pressly disclose the "lodging" limitation and points to Figure 13 of McGary and Figure 2 of Pressly. Reproduced below are the portions of these figures that BD claims depict the open back of the syringe barrel and the thumb cap lodged into the open back of the barrel:



McGary, Fig. 13



Pressly, Fig. 2

In response, RTI points to testimony by its technical expert that both McGary and Pressly, which the PTO considered during prosecution, do not meet the "lodging" limitation because those references require the end of the syringe body to be spread apart in order for the thumb cap to fit in the body and lock the thumb cap in place.

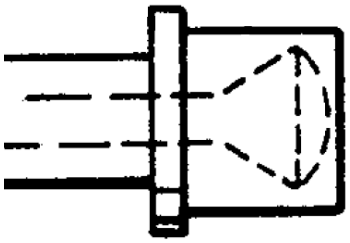
We agree with RTI. For a prior art reference to anticipate a patent claim, the reference, as read by one of ordinary skill in the art, must disclose each claim limitation. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368–69 (Fed. Cir. 2003). Whether a prior art reference anticipates a claim is a question of fact that we review for substantial evidence when the issue is tried to a jury. *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 974 (Fed. Cir. 2010).

In this case, RTI presented expert testimony that the McGary and Pressly references disclose "locking" the thumb cap and that one of ordinary skill in the art would conclude that this disclosure does not meet the "lodging

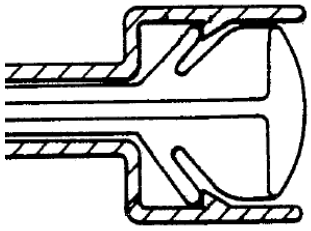
the thumb cap" limitation. J.A. 2608. While BD presented contrary expert testimony, the jury was free to credit or discredit that testimony in rendering a verdict. In addition, during prosecution of the application that issued as the '077 patent, inventor Shaw argued that Pressly, instead of disclosing a thumb cap that lodges into the back end of the open barrel, "requires locking of the plunger in accordance with the conventional wisdom of the syringe art." September 28, 1998 Response and Amendment in Application Serial Number 09/843,050, at 9–11. Thus, substantial evidence supports the jury's verdict that Pressly and McGary do not anticipate claim 25 of the '077 patent.

2. Obviousness

We reach a similar conclusion on BD's appeal of the district court's denial of its motion for JMOL that claim 25 would have been obvious as a matter of law in light of Pressly and/or McGary in view of Power. BD primarily relies on Figures 3 and 4 from Power, and reproduced below are portions of those figures that show the open end of the barrel and the thumb cap:



Power, Fig. 3



Power, Fig. 4

BD argues that Figure 3 discloses the "lodging" limitation and that Power, by also disclosing a "locking" embodiment in Figure 4, shows that it would have been

obvious to replace the "locking" embodiment in McGary or Pressly with the "lodging" embodiment in Power.

We disagree. Under the Patent Act, "[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). Although the ultimate determination of obviousness under § 103 is a question of law, it is based on several underlying factual findings, including (1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; (3) the differences between the claimed invention and the prior art; and (4) evidence of secondary factors, such as commercial success, long-felt need, and the failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When a party appeals a jury verdict of nonobviousness, we first review the jury's underlying factual findings for substantial evidence. *See Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1108 (Fed. Cir. 2003). After conducting this review, we independently review the district court's legal conclusion on obviousness. *See id.*

In this case, substantial evidence supports the jury's presumed findings on the factual issues that underlie the conclusion of nonobviousness. RTI presented expert testimony that, at the time Shaw filed his parent patent application in 1995, artisans of ordinary skill would not have been motivated to replace the "locking" mechanism disclosed in McGary and Pressly with the "lodging" mechanism for a conventional syringe disclosed in Power. J.A. 2608–10. RTI also presented expert testimony, including testimony regarding BD's internal studies from the 1990s on the impracticability of retractable syringes, that supports the jury's presumed factual findings related

to secondary considerations of nonobviousness. *Id.* at 2604–10.

Having concluded that substantial evidence supported the jury's factual findings, there only remains the ultimate legal conclusion of obviousness. Although the figures from these references, on their face, tend to show that Power's "lodging" mechanism is interchangeable with the "locking" mechanism disclosed in McGary or Pressly, we cannot, in light of the jury's underlying factual determinations, conclude that claim 25 of the '077 patent would have been obvious in 1995 to one of ordinary skill in the art. Thus, we affirm the district court's denial of BD's motion for JMOL that claim 25 of the '077 patent was obvious.

CONCLUSION

For the foregoing reasons, we reverse the district court's judgment that the 3 mL Integra infringed claims 43, 55, 60, and 61 of the '224 patent and claim 25 of the '077 patent, affirm the court's judgment that the 1 mL Integra infringes claims 43, 55, and 60 of the '244 patent and claims 1 and 24 of the '733 patent, and affirm the district court's judgment that claim 25 of the '077 patent is not invalid for anticipation or obviousness.

REVERSED IN PART AND AFFIRMED IN PART

COSTS

No costs.

United States Court of Appeals for the Federal Circuit

RETRACTABLE TECHNOLOGIES, INC. AND THOMAS J. SHAW,
Plaintiffs-Appellees,

v.

BECTON, DICKINSON AND COMPANY,
Defendant-Appellant.

2010-1402

Appeal from the United States District Court for the Eastern District of Texas in Case No. 07-CV-0250, Chief Judge David J. Folsom.

PLAGER, *Circuit Judge*, concurring.

I join the thorough and well-reasoned opinion of Judge Lourie. I write because, in the welter of all the claims in this case (both patent and litigation), the multiple patents at issue, the number of issues the parties have chosen to argue about (including the important claim construction issue), it would be easy to lose sight of a fundamental point so well made in the majority opinion: "In reviewing the intrinsic record to construe the claims, we strive to capture the scope of the actual invention, rather than . . . allow the claim language to become divorced from what the specification conveys is the invention." Majority Op. at 17. Judge Lourie articulated that

idea more fully in his excellent concurring/dissenting opinion in *Arlington Industries, Inc. v. Bridgeport Fittings, Inc*, where he said: "[T]he basic mandate is for claims to be interpreted in light of the specification of which they are a part because the specification describes what the inventors invented. The specification is the heart of the patent. In colloquial terms, 'you should get what you disclose.'" 632 F.3d 1246, 1252 (Fed. Cir. 2011) (citations omitted).

However much desired by the claim drafters, who want claims that serve as business weapons and litigation threats (*see Arlington Industries* at 1248; *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1342 (Fed. Cir. 2010)), the claims cannot go beyond the actual invention that entitles the inventor to a patent. For that we look to the written description.[1] *See* 35 U.S.C. § 112. I have written elsewhere about the curse of indefinite and ambiguous claims, divorced from the written description, that we regularly are asked to construe, and the need for more stringent rules to control the curse. *See Enzo Biochem, Inc. v. Applera Corp.*, 605 F.3d 1347, 1348-1349 (Fed. Cir. 2010) *reh'g denied* (Plager, dissenting).

I understand how a perfectly competent trial judge can be persuaded by the siren song of litigation counsel to give the jury wide scope regarding what is claimed. But it is a song to which courts should turn a deaf ear if patents are to serve the purposes for which they exist, including the obligation to make full disclosure of what is actually invented, and to claim that and nothing more.

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[1] The term "specification" is sometimes used in briefs and opinions when, depending on the context, the narrower term "written description" may be appropriate. *See* 35 U.S.C. § 112 ("The specification shall contain a written description of the invention, and . . . shall conclude with one or more claims.").

United States Court of Appeals for the Federal Circuit

RETRACTABLE TECHNOLOGIES, INC. AND THOMAS J. SHAW,
Plaintiffs-Appellees,

v.

BECTON, DICKINSON, AND COMPANY,
Defendant-Appellant.

2010-1402

Appeal from the United States District Court for the Eastern District of Texas in Case No. 07-CV-0250, Chief Judge David J. Folsom.

RADER, *Chief Judge*, dissenting in part.

This court construes "body," as used in the '224 patent and the '077 patent, to require a one-piece structure. Because the language of the claims make clear that "body" does not contain such a limitation, and it is improper to import limitations from the specification into the claims, I respectfully dissent.

I

In *Phillips v. AWH Corp.*, this court recognized as "a bedrock principle of patent law" that the claims themselves, not the written description portion of the specification, define the patented invention. 415 F.3d 1303, 1312

(Fed. Cir. 2005). Claim language is to be given its ordinary and customary meaning, as understood by a person of ordinary skill in the art at the time of the invention. *Id*. at 1312-13. In this case, neither party contends that "body" has a special, technical meaning in the field of art, and thus claim construction requires "little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314. The ordinary and customary meaning of "body" does not inherently contain a one-piece structural limitation. Moreover, neither the claim language nor the written description evinces intent by the patentee to limit the scope of "body" to one-piece bodies.

To the contrary, the language in the claims makes clear that "body" is not limited to a one-piece structure. In order for dependent claims 14 and 57 in the '224 patent to have claim scope different from independent claims 1 and 43, respectively, "body" cannot be limited to a one-piece structure. Claim 1 of the '224 patent claims "[a] syringe comprising a hollow body" with various additional limitations. '224 patent col.18 l.38. Claim 14 claims "[t]he syringe of claim 1 comprising a one-piece barrel." *Id.* col.19 l.47. Similarly, claim 43 of the '224 patent claims a syringe assembly comprising "a hollow syringe body" and other components, *id.* col.22 l.38, while claim 57 claims "[t]he syringe assembly of claim 43 wherein the body comprises a one-piece barrel," *id.* col.24 ll.23-24. Under the doctrine of claim differentiation, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips*, 415 F.3d at 1315. This presumption is "especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the depend-

ent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003). That is precisely the situation in this case. The only difference between independent claims 1 and 43 and dependent claims 14 and 57, respectively, is the addition of the "one-piece" limitation in the dependent claims, and appellants seek to read this "one-piece" limitation from the dependent claims into the independent claims. Such a reading would render the dependent claims completely superfluous.

Certainly, the claims do not stand alone and must be read in light of the specifications. *Phillips*, 415 F.3d at 1315. Nothing in the specifications, however, rebuts the strong presumption created by the claim language that "body" does not contain a one-piece structural limitation. The specifications do not reveal a special definition given by the inventor to the word "body." Nor do the specifications contain an intentional disclaimer or disavowal of claim scope by the inventor.

Although the specifications state that "[o]ne of the problems of the prior art of retractable syringes is the sheer number and complexity of parts which must be formed and assembled," '224 patent col.1 ll.55-57, reducing the number of parts required to make the syringe is only one of numerous objectives disclosed by the '224 and '077 patents. For example, other objectives include creating a retractable syringe that does not require breaking of internal parts, is not temperature sensitive, will not prematurely retract, requires relatively low thumb pressure to activate, has a high blowout pressure, and prevents reuse. *See* '244 col.1 l.57-col.3 l.5. "[T]he fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives." *Phillips*, 415 F.3d at 1327 (internal

quotations omitted). Accordingly, the fact that a one-piece body would achieve one of the objectives of the patented invention does not mean that such a limitation should be read into every claim. This is particularly true given the fact that a one-piece barrel is explicitly required in some of the dependent claims in the '224 patent.

The fact that the embodiments described in the specifications have one-piece bodies is also an insufficient basis for construing "body" to have a one-piece structural limitation. It is improper to import limitations from the specification into the claims, and this court has expressly and repeatedly warned against confining claims to specific embodiments of the invention set forth in the specification. *See Phillips*, 415 F.3d at 1323.

While portions of the specifications reference a "one piece hollow outer body," *see, e.g.,* '224 patent col.3 ll.16-17, these references do not rise to the level of an expression of manifest exclusion or an express disclaimer of claim scope. *See Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed. Cir. 2005) ("words or expressions of manifest exclusion or explicit disclaimers in the specification are necessary to disavow claim scope"). In fact, the inventor's consistent use of the modifier "one piece" (or "one-piece") both in the claims and in the written description when he intended to describe a syringe with a one-piece body strongly implies that "body," standing alone, does not inherently contain a one-piece structural limitation. *See Phillips*, 415 F.3d at 1314 (use of the term "steel baffles" "strongly implies that the term 'baffles' does not inherently mean objects made of steel"). When the inventor intended to impose a one-piece structural limitation, he did so explicitly, as shown by dependent claims 14 and 57 in the '224 patent. Consequently, this court should not impose such a structural limitation on claims that merely use the term "body" without a "one-

piece" modifier. Such a construction is contrary to the ordinary and customary meaning of the word "body," violates the doctrine of claim differentiation, and lacks support in the patents at issue.

II

Based on a construction of "body" that contains a one-piece limitation, this court reverses the district court's denial of BD's renewed motion for judgment as a matter of law and finds non-infringement of the asserted claims as a matter of law. Because I find that "body" does not contain a one-piece limitation and also find that the trial record contains substantial evidence supporting the jury's finding of infringement, I would affirm the district court's judgment that the 3mL Integra infringed claims 43, 55, 60, and 61 of the '224 patent and claim 25 of the '077 patent.