No. 11-

IN THE

Supreme Court of the United States

RETRACTABLE TECHNOLOGIES, INC. AND THOMAS J. SHAW,
Cross-Respondents,

v.

BECTON, DICKINSON AND COMPANY,
Cross-Petitioner.

ON CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Retractable Technologies, Inc. and Thomas J. Shaw (collectively, "RTI") have filed a petition for a writ of certiorari seeking review of the method that the United States Court of Appeals for the Federal Circuit used to construe the term "body" in patents owned by RTI. Specifically, RTI argues that the clear statements in the specification defining the "invention" as having a "one piece hollow outer body," criticizing the "two-piece" designs in the prior art, and touting the benefits of a one-piece design were not sufficient to show that the term "body," as used in the patent claims, refers to a one-piece body.

If RTI's petition is granted, the Court should also consider the following questions, which provide alternative grounds for affirmance:

1. Whether the Federal Circuit's construction of the "lodging" limitation should be reversed because, at RTI's urging, the Federal Circuit deviated from the term's clear meaning on far weaker grounds than the court relied on to construe the ambiguous term "body."

2. Whether the Federal Circuit's construction of the "retainer member" limitation should be reversed because, at RTI's urging, the Federal Circuit deviated from the term's clear meaning on far weaker grounds than the court relied on to construe the ambiguous term "body."

3. Whether the Federal Circuit's holding that the asserted claims cover devices that work by cutting should be reversed because, at RTI's urging, the Federal Circuit disregarded a clear disclaimer of claim scope on far weaker grounds than the court relied on to construe the ambiguous term "body."

PARTIES TO THE PROCEEDINGS

Becton, Dickinson and Company was the defendant in the district court and the appellant in the court of appeals, and is the respondent and conditional cross-petitioner in this Court.

Retractable Technologies, Inc. and Thomas J. Shaw were the plaintiffs in the district court and the appellees in the court of appeals, and are the petitioners and conditional cross-respondents in this Court.

CORPORATE DISCLOSURE STATEMENT

Respondent Becton, Dickinson and Company has no parent corporation and no publicly held company owns 10% or more of its stock.

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CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

Becton, Dickinson and Company ("BD") respectfully submits this conditional cross-petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case. The Court should deny the petition for a writ of certiorari filed by RTI in Case No. 11-1154 for the reasons that will be set forth in BD's brief in opposition. If the Court grants that petition, however, it should also grant this cross-petition.

OPINIONS BELOW

The opinion of the court of appeals is reported at 653 F.3d 1296, and reproduced at pages 1a-36a of the appendix to RTI's petition ("RTI App."). The order denying RTI's petition for rehearing is reported at 659 F.3d 1369. RTI App. 89a-105a.

JURISDICTION

The judgment of the court of appeals was entered on July 8, 2011. RTI App. 1a. RTI's petition for rehearing was denied on October 31, 2011. *Id.* 89a-91a. On January 19, 2012, the Chief Justice extended the time to file a petition for a writ of certiorari to and including March 26, 2012. RTI filed its petition on March 20, 2012, and the case was docketed as No. 11-1154 on March 23, 2012. This conditional cross-petition is timely pursuant to this Court's Rule 12.5. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The text of 35 U.S.C. § 112 is reproduced at RTI App. 106a-107a. The text of 35 U.S.C. §§ 102 and 103(a)

is reproduced at pages 21a-22a of the appendix hereto ("BD App.").

STATEMENT

BD is a global leader in the design and manufacture of retractable safety syringes. RTI, which also manufactures syringes, accused BD's 3mL and 1mL Integra syringes of patent infringement. Before trial, the district court accepted RTI's proposed construction of several critical claim terms. *See* RTI App. 50a-52a, 60a-65a, 79a-80a. The case was tried to a jury on the basis of those constructions. The jury returned a verdict of infringement on most of the asserted claims, but found that the infringement was not willful. A2529-2531.[1]

On appeal, BD challenged the district court's construction of several terms and the court's denial of BD's renewed motion for judgment as a matter of law (JMOL). The Federal Circuit affirmed in part and reversed in part. It accepted RTI's construction of two claim terms and affirmed the judgment of infringement against BD's 1 mL Integra syringes. RTI App. 12a-15a, 18a-20a, 22a, 23a-29a. However, the court held that the district court incorrectly interpreted a third term, "body," and reversed the judgment of infringement against BD's 3mL Integra syringes on that basis. *Id.* 15a-18a.

RTI has petitioned for a writ of certiorari requesting review of the Federal Circuit's decision on the one term ("body") the court construed against RTI. BD opposes that petition. However, if the Court grants RTI's petition, BD requests that it grant this condi-

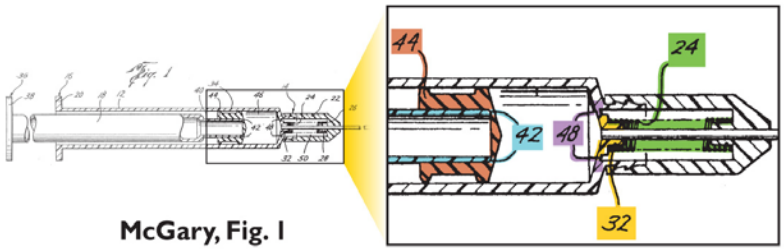
[1] "A____" refers to the Court of Appeals Appendix.

tional cross-petition as well. All the claim construction issues in this case are intertwined, and the arguments RTI made on the claim construction issues it won cannot be reconciled with the arguments it now makes in its petition for certiorari. *See, e.g.*, RTI C.A. Br. 32 (""The court must always read the claims in view of the full specification.""). Further, the issues presented in this conditional cross-petition provide alternative grounds for resolving the case in BD's favor.

A. The Prior Art

RTI was not the first to invent a retractable syringe. Well before RTI's inventions, concern about HIV and other bloodborne pathogens "resulted in intense activity" in the syringe field and produced "a number of syringes of different designs" with retracting needles. A192 1:38-42. RTI distinguished this prior art by claiming that its retractable syringe design held and released the needle in a different and specific way and offered other advantages.

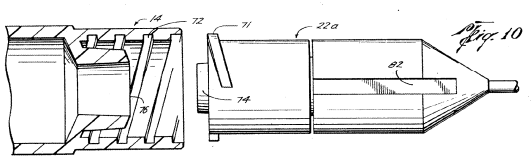
One of the patents that is prior art to RTI's patents is U.S. Patent No. 5,053,010 to McGary. A4731-4744. The McGary patent issued in 1991, nearly four years before the earliest application to which the RTI patents claim priority. BD purchased the rights to McGary in 1999 (A2798-2800; A2833), and modeled the accused products on the McGary design (A2819-2823; A2851).



McGary, Fig. 1

McGary Figure 1 illustrates a needle surrounded by a spring (24) that pushes the needle towards the back of the syringe during retraction. A4740 5:6-18. Before retraction, a "thin tab or web member" (48) holds the needle in place against the force of the coiled spring and connects the needle holder (32) to the front of the syringe body. A4740 5:66. McGary's release mechanism is a "cylindrical knife" (42) on the front end of the plunger, which is surrounded by a rubber seal (44). A4740 5:32-34, 5:50-67. When the plunger is pushed down after an injection, the knife cuts through the seal and the tab holding the needle holder and needle in place against the backwards force of the spring. The spring then drives the needle holder and needle backwards into the hollow plunger rod. A4740 5:50-67.

McGary also discloses a retractable syringe having a two-piece design, as illustrated in Figure 10:



A4736. In this two-piece design, the needle assembly (including the needle holder, needle, and spring) is housed in a separate piece that can be screwed onto the barrel of the syringe. A4741 8:32-40.

McGary is only one of many prior art patents describing retractable syringes with different mechanisms for holding and releasing the needle. For example, U.S. Patent No. 5,180,370 (1993) to Gillespie describes a retractable syringe with a needle holder that is molded as part of the syringe barrel itself, and thus held in place mechanically until the depressed plunger

breaks this hold to allow retraction by a coiled spring. A2850; A4750-A4751 4:34-5:62. U.S. Patent No. 5,180,369 (1993) to Dysarz describes a plunger that breaks a "shatter plate" to allow retraction by a spring. A2850-2851; A4595 5:57-6:37. U.S. Patent No. 5,211,629 (1993) to Pressly describes a needle holder that is initially held in place by a combination of "sacrificial tabs" and friction. A2850. Upon depression of the plunger, the tabs are broken and the friction is released by widening of the barrel. A2851; A4640 5:46-6:32.

In sum, these and other prior art patents disclose the holding of a needle holder in place against the force of a coiled spring, followed by the breaking, flexing, or penetration of internal parts to cause retraction by the spring. To obtain its patents, RTI wrote detailed claims to distinguish this prior art by emphasizing a particular way to hold and retract the needle.

B. RTI's Patent Specification

The three patents that RTI asserted against BD claim priority to an application filed in May 1995. A182. The patents share a common specification, in which RTI criticized prior art retractable syringes and highlighted several aspects of its invention that supposedly avoided the alleged shortcomings of the prior art.[2]

First, RTI asserted that prior art designs were difficult to assemble because they had too many pieces, and it specifically criticized devices with a "two-piece

[2] A patent's specification includes both the written description and the claims. 35 U.S.C. § 112. To maintain consistency with RTI's petition, this cross-petition follows the common practice of using the terms "specification" and "written description" interchangeably. *See* RTI Pet. 9 n.4.

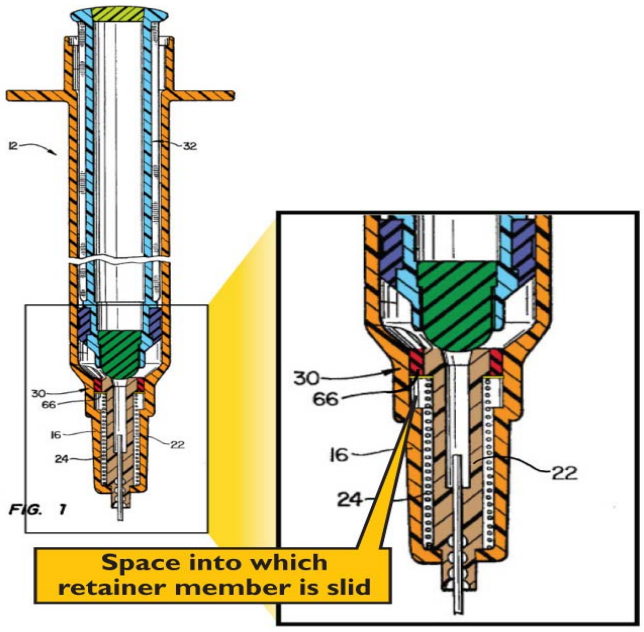
barrel," like the separate needle assembly and barrel described in McGary. A192 1:55-58, 2:1-2. According to RTI, the prior art had not recognized that syringes with a retraction mechanism relying entirely on clamping force or friction could be "molded as a one piece outer body," with the internal parts being placed into the syringe from behind. A192 2:27-39. RTI's "Summary of the Invention" thus described its own invention as follows: "*The invention* is a reliable retractable tamperproof syringe .... The syringe structure features a *one piece hollow outer body*[.]" A193 3:10-18 (emphasis added). Consistent with this statement, RTI disclosed only embodiments with a one-piece body (A195 7:1-3; A197 11:34-35, 12:63-64), and attributed their ease of manufacture to the one-piece design (A200 17:43-48).

Second, RTI criticized syringes (like McGary) that retract the needle by "flexing or breaking of internal parts" or requiring that a "diaphragm" at the end of the plunger be "penetrated." A192 1:57-61. RTI claimed that such syringes pose "serious quality control and assembly problems." A192 1:61-64. RTI thus distinguished its retractable syringes from those prior art designs, explaining that its retraction mechanism "relies entirely on clamping force or friction" that is "slidably or separably released." A192 2:27-37.

Consistent with its attempts to distinguish the prior art in these ways, RTI's patents describe two basic embodiments. Importantly, neither embodiment has a syringe body made from more than one piece, and neither relies on cutting internal parts to retract the needle after an injection.

1. RTI's "retainer member" embodiment

RTI's first embodiment relies on a doughnut-shaped "retainer member" to hold the needle in place prior to retraction. A195 8:16-23. As depicted below, the retainer member (66, red) surrounds the circular base of an elongated needle holder (22, tan). A193 3:63-4:2; A195 8:22-23. Friction between the outer surface of the retainer member and the inner surface of the syringe body that "exceeds the retraction force provided by the spring" holds the needle in place before retraction. A193 4:4-6; A195 8:1-5; A196 9:43-54.

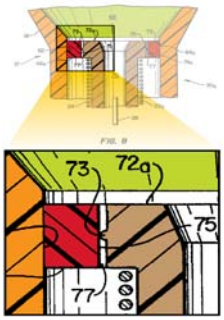


As the plunger is pushed forward at the conclusion of an injection, its front edge (light blue) pushes the doughnut-shaped retainer member off the circular head of the needle holder into an open space between the wall of the syringe and the spring. The plunger thereby releases the frictional force that held the nee-

dle holder in place. The spring can then push the needle holder and needle backwards into the hollow interior of the plunger. A196 9:60-10:27.

Photographs of RTI's commercial product (below) illustrate the first embodiment. The left photograph shows the doughnut-shaped retainer member surrounding the top of the needle holder, and the right photograph shows the end of the plunger rod that pushes the retainer member off the needle holder. *See also* A8104.

RTI's specification also describes a variation on the "retainer member" embodiment, in which a "bridging portion" connects the retainer member and the circular inner head of the needle holder. As shown in Figure 8 (right), the bridging portion (73, tan) is a "very small ridge or bridge" that connects the retainer member and inner head. A188; A193 4:10-17. This variation works in essentially the same way as the first retainer-member embodiment; the needle is held in place by friction between the retainer member and syringe wall, and is released by pushing the retainer member off the inner head of the needle holder. A197 11:4-13. In the process, a "tack weld[]" between the bridge and retainer member may "rupture[]" (A193 4:12-16), but only as a



result of the retainer member being pushed off the inner head while the frictional hold is released.

2. The non-retainer-member embodiment

The RTI patents also disclose a non-retainer-member embodiment. Instead of using a retainer member, the "one part" circular head of the needle holder in this embodiment is lodged directly into the body of the syringe (A197 11:44-45) and held in place by "cooperating friction surfaces" on the outside of the needle holder and inside of the syringe wall (A197 11:66-12:3). To release the needle, the plunger is pushed forward until it reaches a constricted area on the inside of the barrel formed by very small "ramps." A194 5:26-27; A198 13:2-11. The pressure of the plunger on these ramps pushes the barrel walls outward, "thereby reducing the clamping or friction force" between the inner wall of the syringe and circular head of the needle holder. A194 5:26-31; A198 13:12-15. The spring force then takes over and pushes the needle back into the plunger cavity. A198 5:31-35; A198 13:19-23.

C. RTI's Asserted Claims

1. The '733 and '224 patents

At trial, RTI asserted that BD infringed independent claims 1 and 24 of U.S. Patent 5,632,733 ("the '733 patent"), independent claim 43 of U.S. Patent 7,351,224 ("the '224 patent"), and dependent claims 55, 60, and 61 of the '224 patent. All of the asserted claims of the '733 and '224 patents are directed to the "two-part head" embodiment and improvement of Figures 1-3 and 8 that requires a "releasable" "retainer member" that holds the needle in place prior to retraction. For example, the "retainer member" portion of claim 43 of the '224 patent provides:

> 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 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.

A202-203 22:47-23:19. This structure and the rest of the retraction mechanism are "disposed in the front end portion" of "a hollow syringe body." A202 22:38-42.

2. The '077 patent

Claim 25 of U.S. Patent 6,090,077 ("the '077 patent"), which was the only '077 claim at issue on appeal, does not require a "retainer member." RTI pointed to only one aspect of claim 25 that allegedly differentiates it from the prior art: the manner in which the back portion of the plunger (the "thumb cap") lodges in the open back end of the syringe body when fully depressed. RTI App. 24a; A165 21:4-7.

Figures 3 and 4B of the patent (A148) show two slightly different versions of the back end of the syringe after an injection is completed and the thumb cap (48) has been fully depressed into the syringe body:

Figure 3

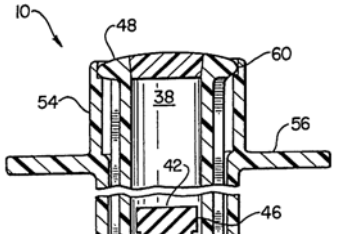
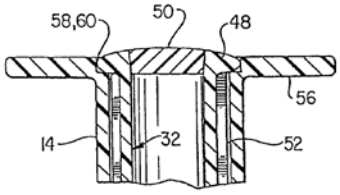
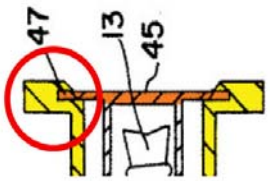


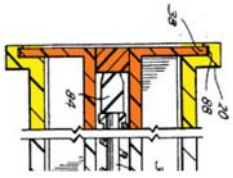
Figure 4B



The prior art likewise disclosed tucking the thumb cap of the plunger into the back end of the syringe. For example, both Pressly (left) and McGary (right) depict a lodged thumb cap that is inaccessible for grasping.



Pressly, Fig 2.



McGary, Fig. 13

A4737; A4632.

Further, a patent application by Power (Figs. 2 and 3, below left) shows lodging of a thumb cap into the back end of a syringe in a manner materially identical to the embodiments in RTI's '077 patent (below right).

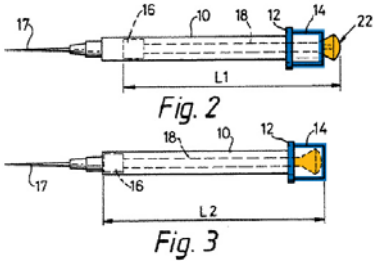
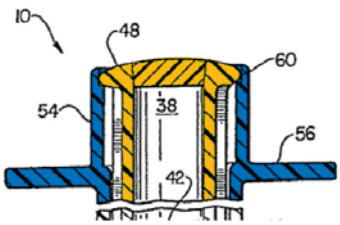


Fig. 2

Fig. 3



A7984; A148.

D. The Accused BD Devices

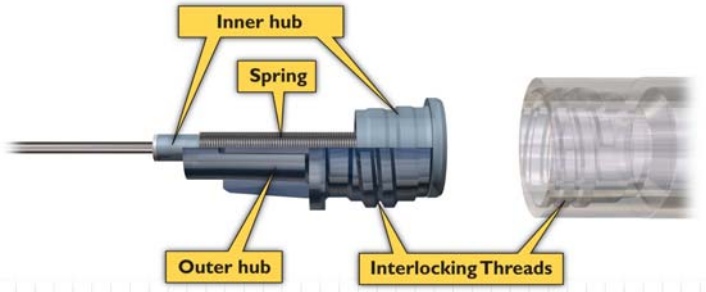
The two BD retractable syringes at issue are the 3mL Integra and the 1mL Integra. Both are based on the McGary patent, which discloses a cylindrical knife to release the needle for retraction. RTI accused the 3mL Integra of infringing the '224 and '077 patents and the 1mL Integra of infringing the '733 and '224 patents. RTI's petition for certiorari relates solely to the 3mL Integra. This conditional cross-petition relates to both,

in that it provides alternative grounds for affirming the judgment as to the 3mL Integra, as well as grounds for reversing the judgment of infringement as to the 1mL Integra.

1. The 3mL Integra

The 3mL Integra comes in two pieces. As shown below, the blue part containing the needle (the "needle assembly") can be screwed on and off the body of the syringe, as in the McGary design.

The needle assembly in the 3mL Integra (shown below) includes a needle, spring, an inner hub (elongated piece with a circular head shown in light blue), and an outer hub (piece with threads on the outside shown in dark blue). A2651.

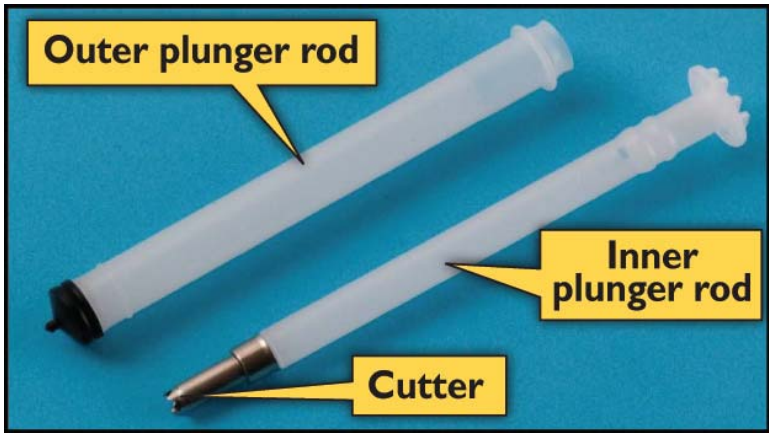


The needle is glued into the inner hub. A spring surrounds the elongated lower portion of the inner hub, and presses against the enlarged round head of the inner hub to create the force that will eventually cause retraction of the needle. A2652. The inner hub snaps into the interior of the outer hub. A2652; A2815.

Grooves on the exterior of the inner hub match bumps on the interior of the outer hub to create a "snap fit" between the inner and outer hubs. A2652. This "snap fit" is indisputably a mechanical hold, not a frictional hold as recited in the RTI patents. A2652.

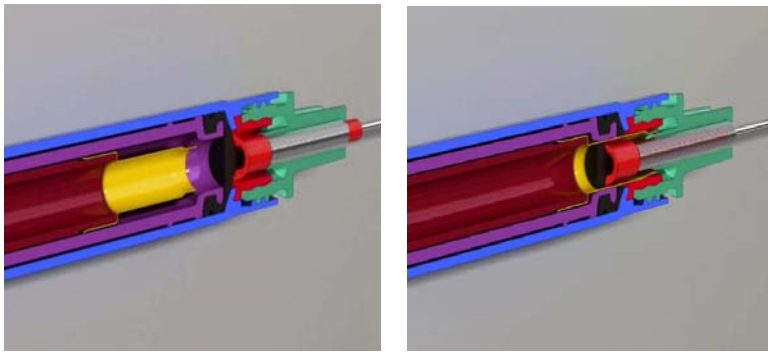
The entire needle assembly is then screwed onto the body of the syringe. Interlocking threads (similar to a nut and bolt) permit the needle assembly to be attached and detached by screwing and unscrewing the two parts. A2652-2653; A2814.

The needle in the 3mL Integra retracts when a cutter cuts through the circular portion of the inner hub, thereby permitting the spring to drive the needle backwards. A2817; A8101; A8103. As shown below, the cutter is located at the end of the inner plunger rod, which nests inside an outer plunger rod with a black rubber seal at the end. A2815-2816.



The operation of the two-piece plunger is shown below. The left image shows that, as the user pushes the plunger forward to complete an injection, the seal (black) on the end of the outer plunger rod (purple) contacts the top of the inner hub. However, the inner plunger rod with the cutter (yellow) can still travel

forward. When it does, the yellow cutter on the end of the inner plunger penetrates the black seal on the outer plunger and then cuts the red inner hub of the needle assembly into two pieces. A2618-2619; A2815-2816.

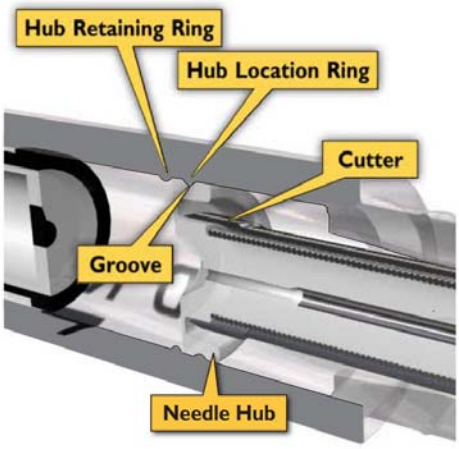


The expanding spring then drives a cut portion of one of the pieces—the inner portion of the inner hub that holds the needle—into the body of the inner plunger, as is beginning to happen in the right image above. A2817; A8101; A8103. The other piece—the outer edge of the inner hub, which RTI has incorrectly called the "retainer member" (RTI C.A. Br. 12-13)—remains exactly where it was prior to retraction; it is still snapped into the outer hub (green), which remains screwed into the end of the syringe. The needle is neither held in place by friction, nor is it released by the release of frictional forces. A2655-2656; A2817. Instead, the 3mL Integra retracts the needle using essentially the very "penetrating" mechanism that RTI *criticizes* in its patents.

2. The 1mL Integra

In the 1mL Integra, the needle is glued into a one-piece needle holder (called the "needle hub"), which snaps into the body through the rear of the syringe. As shown below, the body of the syringe has two raised

rings on its interior. A2664; A2818; A6469. The circular head of the hub has a groove that snaps onto the hub location ring to hold the needle in place. A2664; A2818.



A8102.

The 1mL Integra also retracts the needle with a cutter, although unlike the 3mL Integra that cutter is nestled in front of the hub. At the conclusion of an injection, the plunger pushes the needle holder forward into the cutter. A2818; A8102. The cutter then cuts the needle hub into two pieces to release the needle. A2818; A8102.

E. District Court Proceedings

1. Claim construction

Several claim construction disputes before the district court are relevant to RTI's petition and this conditional cross-petition.

a. Syringe "body"

The parties disputed the construction of "syringe body." BD asserted that the syringe body must be a single piece as indicated in the description of the invention, whereas RTI contended that it may be more than one piece.

In a prior Eastern District of Texas action involving two of RTI's patents, a different district judge (Davis, J.) had held that the claimed "body" was a structure "that may be one or more pieces." A704. Importantly, Judge Davis's opinion issued before *Phillips* v. *AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), in which the Federal Circuit stressed the importance of intrinsic evidence in claim construction. The district court in this case nonetheless found "no reason to deviate" from Judge Davis's prior construction, interpreting "body" to mean "a hollow outer structure that houses the syringe's components." RTI App. 52a.

b. "Retainer member"

The asserted claims of the '224 and '733 patents all require a "retainer member" and include other terms and phrases describing how the needle holder is held and released. BD argued that these terms require a retraction mechanism in which the "retainer member" is a separate part. BD also argued that the needle must be held in place by friction and retracted by releasing that same frictional force, thus excluding any device that retracts the needle by cutting a single-piece needle holder.

The district court rejected BD's argument that the retainer member must be a separate piece. A36-37. However, the district court agreed that the claims require using "some" frictional or clamping force to hold

the needle in a projecting position. A37-38. The court later clarified that the devices must work both by holding the needle in place using friction or clamping, and by releasing *that same force* to retract the needle. Specifically, the court interpreted "retainer member" and "continuous retainer member" to mean "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." BD App. 18a (emphasis added).

c. "Lodging the thumb cap in the open back end of the barrel thereby rendering the thumb cap inaccessible for grasping"

Before trial, neither party asked the district court to interpret the "lodging" element of claim 25 of the '077 patent. However, in response to compelling evidence that the prior art anticipated the claim or rendered it obvious (*see, e.g.*, A2867; A4632; A4639 3:44-49; A4640 6:37-40; A4737; A4742 9:32-38), RTI responded at trial and in post-trial proceedings with an implicit claim construction argument, suggesting for the first time that claim 25 excludes devices in which the plunger is locked into the end of the syringe. A1556; A2608. The district court did not expressly interpret this claim element, but simply denied BD's motion for JMOL by referencing RTI's brief. A9-10.

2. Trial and post-trial proceedings

At trial, the jury found claims 1 and 24 of the '733 patent, claims 43, 50, 60, and 61 of the '224 patent, and claim 25 of the '077 patent valid and infringed and awarded RTI damages of $5 million. A2529-2534. After denying BD's motion for JMOL, the district court

issued a permanent injunction, which was stayed pending appeal. A12-19.

F. Federal Circuit Proceedings

On appeal, BD argued that the term "syringe body" in RTI's patents does not include multi-piece bodies, like BD's 3mL Integra, in which the needle assembly is housed in a separate piece screwed onto the syringe barrel. BD C.A. Br. 57-62. BD also argued that, under a proper claim construction, the 3mL and 1mL Integra do not infringe the '773 and '224 patents because they do not have a separate "retainer member" and they use cutting to retract the needle. *Id.* 34-43.

BD further argued that, even under the district court's claim construction, the 3mL Integra does not infringe because it does not use friction or clamping to hold the needle in the projecting position. BD C.A. Br. 43-54. Rather, the inner hub is held to the outer hub by a mechanical snap fit that exists before the needle assembly is ever screwed onto the barrel and, if even relevant, the needle assembly is held to the barrel by the mechanical hold of interlocking threads. *Id.* 48-49. In addition, the needle and spring are released by mechanical cutting, and the only clamping or frictional forces identified by RTI are never released. *Id.* 52-54.

BD also appealed the erroneous exclusion of RTI's admission—in direct contrast to its argument at trial—that BD's Integra products do not release a frictional hold. BD C.A. Br. 54-56; *see also* A6133-6134 ("there presently is no allegation that the infringing products in this case operate by the release of a frictional holding mechanism"); A1780 n.1.

Finally, BD argued that Pressly and McGary anticipate claim 25 of the '077 patent, because RTI's only

argument to the contrary (its implicit claim construction argument excluding thumb caps that lock in place) was meritless. BD C.A. Br. 63-66. Even under RTI's construction, moreover, it would have been obvious to combine Pressly or McGary with the thumb-cap disclosure in the Power application. *Id.* 66-68.

The Federal Circuit agreed with BD that the "body" limitation does not cover multi-piece designs like BD's 3mL Integra. RTI App. 15a-18a. The court noted the ambiguity in the term "body" (*id.* 18a) and, mindful of the "fine line between construing the claims in light of the specification and improperly importing a limitation from the specification into the claims" (*id.* 17a), it turned to the clear guidance provided in the patents' shared specification (*id.* 17a-18a). The specification "do[es] not disclose a body that consists of multiple pieces or indicate that the body is anything other than a one-piece body." *Id.* 17a. To the contrary, it "expressly recite[s] that 'the invention' has a body constructed as a single structure, expressly distinguish[es] the invention from the prior art based on this feature, and only disclose[s] embodiments that are expressly limited to having a body that is a single piece." *Id.* 18a. This clear indication of claim scope showed that "the district court erred when it construed 'body' as encompassing bodies composed of multiple pieces." *Id.*

The court further held that, under the proper construction, "no reasonable jury could find that the 3mL Integra meets the 'body' limitation." RTI App. 20a. The court accordingly declined to address BD's argument that, even under the district court's claim constructions, no reasonable jury could have found that the

3mL Integra infringes because it does not use friction or clamping to hold or release the needle.[3]

The Federal Circuit ruled for RTI on the remaining issues. Without addressing many of BD's arguments on the point, it held that the asserted '224 and '773 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." RTI App. 13. For support, the court relied on passages disclosing a tack weld or other coupling between the retainer member and the needle holder. *Id.* 14a. The court acknowledged RTI's attempt to distinguish the prior art on a different limitation by arguing that the Pressly patent did not disclose "a syringe 'made of' a one-piece barrel because the outer wall was fixed to the barrel 'by ultrasonic welding means.'" *Id.* 14a-15a. But it concluded that this "statement, on its own, lacks the clarity" to establish that a retainer member and needle holder joined by similar means also remain two separate pieces. *Id.* 15a.

The Federal Circuit also held that the '224 and '773 patents cover devices that work by cutting. RTI App. 18a-20a. The court observed that "[t]o disavow claim scope, the specification must contain 'expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Id.* 19a. Although the specification criticized the prior art's "'dependence on flexing or breaking of internal parts'" and failure to "recognize[] a retraction mechanism with separable parts that relies entirely on clamping force or friction,'" the court

[3] The court did, however, affirm the exclusion of RTI's admission that BD's retraction mechanisms do not work by releasing friction. RTI App. 23a.

concluded that these statements were not "a manifest exclusion of all 'cutting' from the scope of the claims." *Id.* 19a-20a.

Finally, the Federal Circuit affirmed the judgment that claim 25 of the '077 patent is not anticipated or obvious. RTI App. 23a-29a. Noting RTI's concession that "McGary and Pressly each disclose every limitation of claim 25 with one exception," the court focused on the one disputed limitation: "lodging the thumb cap in the open back of the barrel thereby rendering the thumb cap inaccessible for grasping.'" *Id.* 24a. The court stated that the jury was free to believe RTI's expert testimony that the lodging limitation is not met by a disclosure that includes locking. *Id.* 26a. In support of this implicit claim construction, the court relied on a portion of prosecution history in which RTI tried to distinguish Pressly because it relied on the "'conventional wisdom'" that the plunger must be locked. *Id.* The court rejected BD's alternative argument that lodging was obvious in light of the Power application because, although the "references, on their face, tend to show that Power's 'lodging' mechanism is interchangeable with the 'locking' mechanism disclosed in McGary or Pressly," the court concluded that the jury could have credited RTI's evidence on secondary considerations of nonobviousness. *Id.* 28a.

Judge Plager concurred to emphasize the importance of avoiding "the curse of indefinite and ambiguous claims, divorced from the written description," that "serve as business weapons and litigation threats." RTI App. 30a-31a. Chief Judge Rader dissented from the majority's construction of "body." *Id.* 32a-36a. He agreed that "the claims do not stand alone and must be read in light of the specification[]." *Id.* 33a. But he argued that the statements relied on by the majority

"d[id] not rise to the level of an expression of manifest exclusion or an express disclaimer of claim scope. *Id.* 35a.

RTI petitioned for rehearing and rehearing en banc on the court's construction of "body." The Federal Circuit denied the petition over the dissent of three judges. Writing for herself and Chief Judge Rader, Judge Moore argued that the panel decision could not "be reconciled with [the court's] en banc decision in *Phillips*." RTI App. 94a; *see also id.* 95a. Judge Moore acknowledged that "claims are to be construed in the context of the entire patent, including the specification." *Id.* 94a. But she disagreed with the panel's conclusion that the term "body" is ambiguous and argued that the specification did not clearly disclaim multi-piece bodies. *Id.* 96a. She also stated that she would grant review on an issue not raised by RTI: "whether deference should be given to the district court's claim construction." *Id.* 98a. Judge O'Malley dissented separately to express support for revisiting the issue of deference, but she "d[id] not criticize the panel majority for its legal analysis" because "[t]he majority adhered to the broad principles of claim construction set forth in *Phillips*" and a mere disagreement over how to apply those principles in a particular case did not warrant review. *Id.* 103a.

REASONS FOR GRANTING THE CONDITIONAL CROSS-PETITION

RTI's petition seeks review of the Federal Circuit's holding that, when read in the context of the entire specification, the term "body" does not include multi-piece bodies—such as the design of BD's 3mL Integra. RTI attempts to frame this case-specific challenge as a broader legal question. RTI Pet. 2. For the reasons

given in BD's brief in opposition, this attempt to transform RTI's case-specific challenge into an attack on certain methods of claim construction is based on an incorrect reading of the Federal Circuit's opinion and, in any event, does not warrant review.

If this Court were to grant RTI's petition, however, it should also grant this conditional cross-petition so that it can consider the full-range of claim construction issues in the case. These other issues provide alternative grounds for resolving the case. They also include questions of claim construction on which RTI prevailed in the Federal Circuit based on positions that cannot be reconciled with its current arguments. None of the claim construction rulings in this case warrants further review by this Court, but if the Court were to review one, it should in fairness review them all.

I. IF THE COURT REVIEWS THE CONSTRUCTION OF "BODY," IT SHOULD ALSO REVIEW THE CONSTRUCTION OF "LODGING," BECAUSE RTI'S IMPLICIT CONSTRUCTION OF THE TERM "LODGING" CONTRADICTS ITS APPROACH TO INTERPRETING "BODY"

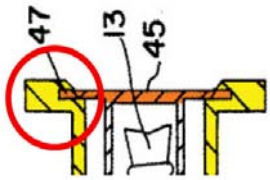
The Federal Circuit recognized that "[t]here is a fine line between construing the claims in light of the specification and improperly importing a limitation from the specification into the claims." RTI App. 17a. RTI's allegation that the Federal Circuit crossed that line in interpreting "body" does not warrant review. But if this Court were to accept RTI's erroneous premise that the Federal Circuit gave too little weight to the plain meaning of "body" and that the issue merits review, this Court should in fairness review the Federal Circuit's construction of the "lodging" limitation in claim 25 of the '077 patent, which RTI (successfully) urged should *not* be given its plain meaning. Indeed, if

the Federal Circuit had not narrowed the meaning of "lodging" at RTI's insistence, the '077 patent would be invalid, regardless of how "body" is interpreted.

A. McGary And Pressly Anticipate Claim 25 Of The '077 Patent

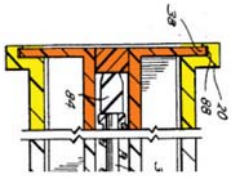
A claim is anticipated when a prior art reference discloses every claim limitation. *See, e.g.*, *Orion IP, LLC* v. *Hyundai Motor Am.*, 605 F.3d 967, 974 (Fed. Cir. 2010). Here, "[t]he parties agree that McGary and Pressly," both of which are prior art, "each disclose every limitation of claim 25" of the '077 patent, with the exception that 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 for grasping.'" RTI App. 24a. Before trial, the parties agreed that this "lodging" limitation did not need to be construed because its meaning was clear. BD, in turn, presented clear and convincing evidence at trial that McGary and Pressly disclosed that feature. A2867.

For example, Figure 2 from Pressly shows the plunger after it has been lodged in the open back end of the barrel and rendered inaccessible for grasping. A4632; A4639 3:44-49 ("FIG. 2 of the drawings … shows the net result of this invention wherein … the plunger has been locked within the barrel of the syringe."); *see also* A4640 6:37-40 (referencing Fig. 23, "it should be noted that plunger thumb push 45 has been locked within the mating section 47 of barrel 5").



Pressly, Fig 2.

Similarly, Figure 13 of McGary shows retaining the plunger in a "recess" in the back end of the barrel, where the recess is somewhat smaller than the plunger end cap and extends slightly to accept the end cap. A4737; A4742 9:32-38 ("In order to retain plunger 18 in the fully extended position within barrel 12, a retaining recess 88 may be configured on barrel flange 20 to retain radially extending flange 38 when plunger 18 is fully extended. As shown in FIG. 13, when plunger 18 is fully extended, flange 38 causes flange 20 to radially flex outward thus accommodating flange 38 within recess 88.").



McGary, Fig. 13

B. RTI's Construction Of "Lodging" Contradicts Its Construction Of "Body"

In the face of this indisputable evidence of lodging, RTI's only resort was to make an implicit claim construction argument. Specifically, its expert at trial and its JMOL opposition argued that claim 25 does not cover thumb caps that, in addition to being lodged, also lock in place. A1556; A2608. This narrowing construction, however, contradicts the approach to claim construction that RTI advocates in its petition for certiorari.

First, on the "body" limitation, RTI has emphasized the absence of an express limitation in the asserted claims stating that the term "body" does not include multi-piece bodies (*see* RTI Pet. 21; RTI C.A. Br. 48), even though the term "body" is ambiguous and requires interpretation. On the "lodging" limitation, however, RTI attributed no significance to the absence of the limiting language it seeks to read into the claims

to avoid the prior art, even though it never argued that "lodging" was ambiguous.

Second, on the "body" limitation, RTI has relied on a tenuous "claim differentiation" argument—i.e., the presumption that a claim should not be construed in a way that renders another claim superfluous—based on claims in different patents, claims that are not rendered superfluous by the Federal Circuit's construction, and dependent claims added after BD had already launched its commercial product.[4] On the "lodging" limitation, RTI has all but ignored a much more powerful claim differentiation argument based on dependent claims 26, 27, and 28 of the same patent. Claim 28 adds the requirement that "entry of the thumb cap into the opening at the back end of the barrel is not accompanied by locking of the plunger in the barrel." A165 21:17-19. Claim 26 adds the requirement that the periphery of the thumb cap be slightly smaller than the opening at the back end of the barrel. A165 21:9-11. Claim 27 adds the requirement that the back end of the barrel "does not resist entry" of the thumb cap. A165 21:13. Thus, independent claim 25 is presumed to cover devices, like McGary and Pressly, in which a plunger *is* locked into

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[4] *See Welker Bearing Co.* v. *PHD, Inc.*, 550 F.3d 1090, 1098-1099 (Fed. Cir. 2008) (claim differentiation does not preclude giving the same meaning to different claim phrases in two related patents); *Andersen Corp.* v. *Fiber Composites, LLC*, 474 F.3d 1361, 1370 (Fed. Cir. 2007) (claim differentiation presumption is rebuttable and, in any event, applies only where a particular interpretation would make some claims redundant); *ICU Med., Inc.* v. *Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1375-1376 (Fed. Cir. 2009) (rejecting claim differentiation argument where dependent claim was added late in prosecution and after introduction of the alleged infringing product).

the back end of the barrel (*see* claim 28), the periphery of the thumb cap is slightly *larger* than the opening at the back end of the barrel (*see* claim 26), and the barrel *does* resist entry of the thumb cap (*see* claim 27). And unlike RTI's far weaker claim differentiation argument on "body," nothing in the specification or file history rebuts the presumption of claim differentiation regarding "lodging."

Third, on the "body" limitation, RTI has argued that the Federal Circuit should not have considered the specification's clear guidance on the term's meaning. *See supra* pp. 5-6. On the "lodging" limitation, by contrast, RTI has argued that the claim is not anticipated because the specification states "[n]o locking teeth are needed." A163 18:5; *see* RTI C.A. Br. 63. But neither McGary nor Pressly has "locking teeth"; the plunger is locked into the back of the body because the cap is larger than the recess. Moreover, the very paragraph that mentions "locking teeth" also refers to "a one piece body." A163 18:15. RTI's locking argument thus conflicts with its "body" argument—although, unlike with locking, many other statements also support the Federal Circuit's construction of "body." RTI has also relied on prosecution history stating that "no retracting syringe … prevents reuse or disassembly without locking the plunger or having breaking or separation of parts." A3064. While this might distinguish dependent claim 28, which expressly disclaims locking, it does not limit the scope of claim 25. Indeed, if it were a disclaimer of "locking," it would also disclaim devices, such as BD's, that rely on "breaking or separation of parts" to cause retraction.

The striking tension between RTI's arguments on the "body" and "lodging" limitations highlights the extent to which RTI's actual complaint is with the *result*

that the Federal Circuit reached on the "body" limitation, rather than with the *approach* that the court used. But to the extent the Court were to accept RTI's erroneous premise that the Federal Circuit's approach to claim construction warrants review, it should review the application of that same approach—at RTI's urging—to the "lodging" limitation, for which the grounds that the Federal Circuit relied on to support RTI's narrowing construction were far weaker than the grounds that the court relied on to construe ambiguities in the term "body."

II. If The Court Reviews The Construction of "Body," It Should Also Review The "Retainer Member" and "Cutting" Rulings, Which Provide Alternative Grounds To Affirm

A. The "Retainer Member" And "Cutting" Rulings Are Also Intertwined With RTI's First Question Presented

There is also a notable tension between RTI's petition and the reality of what it (successfully) argued with respect to the "retainer member" and "cutting" issues. For example, RTI's petition argues that courts should focus on "the patent claims alone." RTI Pet. 21. But in convincing the Federal Circuit that the "retainer member" and "needle holder" of the claimed syringes do not need to be separate parts, RTI insisted that "'[t]he court must always read the claims in view of the full specification.'" RTI C.A. Br. 32 (quoting *SanDisk Corp.* v. *Memorex Prods., Inc.*, 415 F.3d 1278, 1285 (Fed. Cir. 2005)).

Likewise, RTI's petition argues that the Federal Circuit's decision reflects a broader trend of narrowing patent claims based on the specification. RTI Pet. 10-11. Not only is that an inaccurate description of the

court's decision on the "body" limitation, but it cannot be reconciled with the court's conclusion that the asserted claims of the '224 and '733 patents cover retractable syringes that work by cutting because the specification's disclaimer of cutting did not rise to the level of an "'expression[] of manifest exclusion or restriction, representing a clear disavowal of claim scope.'" RTI App. 19a (quoting *Epistar Corp.* v. *ITC*, 566 F.3d 1321, 1335 (Fed. Cir. 2009)). The Federal Circuit, in other words, applied the very rule that RTI now advocates.

As these examples illustrate, all the claim construction issues in this case are intertwined. None of these claim-specific rulings warrants review, and RTI's petition should be denied. But if it is not, the Court should also review the Federal Circuit's construction of "retainer member" and its holding that the asserted claims of the '224 and '733 patents do not exclude cutting. Reversal on either point would require affirmance of the judgment of non-infringement on the '224 and '733 patents, regardless of how "body" is construed.[5] And unlike with the "body" limitation, the court actually erred in its interpretation of "retainer member" and its decision that the claims encompass cutting.

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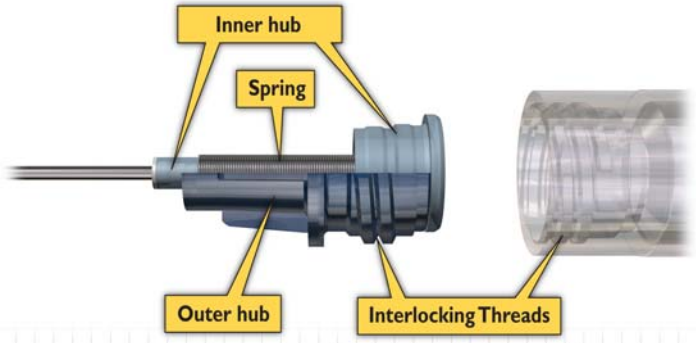
[5] Even if it did not grant this conditional cross-petition, the Court could consider these alternative grounds for affirming the Federal Circuit's judgment that BD's 3mL Integra does not infringe the '224 patent. But because a proper construction of "retainer member" and the exclusion of cutting from the claims would also require reversal of the judgment holding that BD's 1mL Integra infringes the '733 patent, granting the conditional cross-petition would ensure that BD receives full relief.

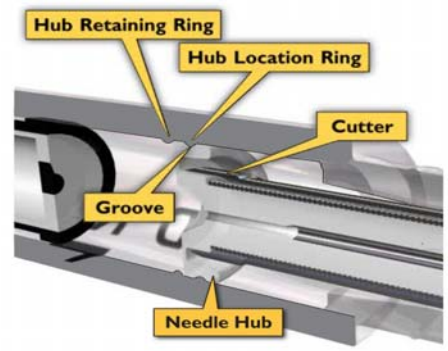
B. A Proper Construction Of Either The "Retainer Member" Or "Cutting" Elements Would Compel Affirmance And Moot The Construction Of "Body" In The '224 Patent

BD's 3mL and 1mL Integra syringes are based on the prior art design disclosed in the McGary patent and work in a fundamentally different way from the syringes claimed in the '224 and '733 patents. Prior to retraction, the BD syringes do not hold the needle and spring in place with the type of lateral frictional or clamping force used in RTI's patents. *See* BD C.A. Br. 48-51; A2652-2653; A2655; A2851-2852; A2857-2858. Rather, the spring presses vertically against the head of the "inner hub" in the 3mL Integra and the "needle hub" in the 1mL Integra. That mechanical force is released by cutting the hub into two separate pieces using a cutter, which releases the spring and causes the needle to retract.

3mL Integra



1mL Integra



BD's use of a cutter to sever a single molded piece into two separate pieces implicates two issues of claim construction on which the Federal Circuit erred. First, the Federal Circuit erroneously held that, although the "retainer member" and "needle holder" limitations are separate, they can both refer to a single part. Second, the court erroneously held that the claims do not exclude devices in which the retractable needle is released by cutting. A proper construction of either point would compel judgment of non-infringement, regardless of how "body" is construed.

C. The "Retainer Member" Must Be A Separate Part

The asserted claims of the '224 and '733 patents all require a "retainer member." At trial, RTI identified the peripheral portion of the inner hub in the 3mL Integra and the peripheral portion of the needle hub in the 1mL Integra as the "retainer member" of each device. The claims, specification, and prosecution history, however, make clear that the "retainer member" claimed in the '224 and '733 patents must be a separate part.

The Federal Circuit has held that "[w]here a claim lists elements separately, 'the clear implication of the claim language' is that those elements are 'distinct component[s]' of the patented invention." *Becton, Dickinson & Co.* v. *Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (quoting *Gaus* v. *Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004)). In *Tyco*, the court ruled that a claim separately identifying a "spring means" and "hinged arm" could not cover a device in which the spring was part of the hinged arm rather than a separate part. 616 F.3d at 1254-1255. Likewise, *Gaus* held that a claim requiring "an electrical operating unit and a pair of spaced-apart electrically exposed conductive probe networks" indicated that the "pair of probe networks is a distinct component, separate from the electrical operating unit." 363 F.3d at 1288.

Here, too, the most natural reading of the claims is that the "retainer member" is a separate part. For example, claim 1 of the '733 patent separately lists the "needle holder" as a "retractable part" and the "retainer member" as a "nonretractable part" of the "needle retraction mechanism." A179 14:16-30. The "retainer member" "surround[s] the head of the needle holder" with a "bridging portion between them," and the retainer member and the head are "removably coupled" and then "uncoupl[ed]" during retraction. A179 14:26-30, 14:45. One cannot "couple" parts of a single piece, nor would one refer to cutting something into two pieces as "uncoupling."

Independent claim 24 of the '733 patent similarly identifies the "retainer member" as a separate part. The claim language mirrors the specification's characterization of the retraction mechanism as having a needle holder with a two-part head, one part of which is a

separate retainer member. The claim's final clause, which requires "installing the needle holder *and* the retainer member in the nose," also confirms that the retainer member is a separate piece. A181 17:32-33 (emphasis added).

Independent claim 43 of the '224 patent also indicates that the "continuous retainer member" is a separate part. This claim again describes a two-part needle head:

> 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.

A202 22:47-52 (emphasis added).

The dependent claims further confirm that the retainer member is a separate part. Claim 2 of the '733 patent requires that the "bridging portion" be "a raised portion on one of the retainer member or the needle holder." A179 14:51-52. This limitation is nonsensical if applied to a unitary retainer member/needle holder because there is no way to judge whether the "raised portion" is on the retainer member or the needle holder. Further, claim 21 of the '224 patent requires "disengag[ing]" the retainer member from the needle holder head (A201 20:6-7), a word that makes no sense in the context of a single piece.

The specification reinforces the clear meaning of the claims. "Retainer member" is a coined phrase used in the specification to describe the mechanism illustrated in Figures 1-3 and 8. The specification contrasts

the separate retainer member in these embodiments with the embodiment illustrated in Figures 5-7 that has "the fewest number of easily made separate parts" because it has a "one part head" and no "retainer ring." A194 5:18-26; A197 11:44.

The Summary of Invention expressly defines the "retainer member" as a separate part: "The retainer member is a ring member *coupled* to the inner head along a sliding interface … with a friction force…. An alternate construction of the *two part* head of the needle holder comprises the separable retainer member being tack welded to the inner head of the needle holder." A193 4:3-13; *see Abbott Labs.* v. *Andrx Pharm., Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007) ("The word 'is' may signify that a patentee is serving as its own lexicographer."). In the "retainer member" embodiment shown in Figures 1-3, the "retainer member" is described and shown as a separate piece from that which is attached to the needle. In this embodiment, the retainer member holds the needle using a frictional force between the *outer* surface of the ring and the *inner* surface of the syringe body and a separate frictional force between the inner surface of the ring and the outer surface of the piece to which the needle is attached. A195 7:55-8:19. This embodiment is described as having a needle holder with a "*two part head*" consisting of the base of the piece to which the needle is attached ("the inner head") and the retainer member. A195 7:11-13 (emphasis added).

The "bridging portion" variant (Figure 8) also utilizes a separate retainer ring. The purported improvement is that a "bridging portion" is created by a tack-weld between the inner head and the retainer ring. However, the embodiment is still described as having "two parts" with "mating surfaces." A193 4:10-13; A197

11:23 ("[o]ne way to couple these *two parts*" (emphasis added)); A193 4:12-15 (tack weld occurs "along a very small ridge or bridge between mating surfaces which holds the *two part* head together" (emphasis added)); A196 10:46-48 ("bridging portion" can be on the "inner surface 75 of retainer 66a instead of being on surface 74a of the needle holder"). A single molded part cannot have two "mating surfaces."

In contrast, the "single head" embodiment of Figures 5-7 does not have a retainer member. Accordingly, the specification describes this embodiment as being advantageous compared to the retainer-member embodiment because it has "the fewest number of easily made separate parts" (A194 5:18-19)—i.e., it does not have a separate retainer ring coupled to the inner head of a needle holder by either friction or a tack weld. *See Baran* v. *Medical Device Techs., Inc.*, 616 F.3d 1309, 1314-1315 (Fed. Cir. 2010) ("detachably" construed narrowly when used in specification to distinguish one embodiment from another).

The Federal Circuit failed to address most of these points and instead placed excessive reliance on the specification's reference to tack welding and other ways to couple two separate pieces with an easily breakable bond. RTI App. 14a. But two parts joined together are still two separate parts. *See Dolly, Inc.* v. *Spalding & Evenflo Cos.*, 16 F.3d 394, 400 (Fed. Cir. 1994). Even RTI's own expert acknowledged that "Figure 8 shows the needle holder and the retainer member as *two separate pieces* joined by a bridging portion." A2650 (emphasis added). Moreover, during prosecution of a different claim, RTI distinguished prior art on the ground that the reference did not show a one-piece barrel, but rather two pieces tack welded to one another. *See* A3685 (Pressly "is not 'made of' a one-piece barrel be-

cause needle assembly (9) is fixed to barrel (5) by ultrasonic welding means").

In short, the grounds supporting the Federal Circuit's construction of "retainer member" were far weaker than those supporting its construction of "body," and if this Court were to accept RTI's invitation to construe the latter limitation, it should grant this conditional cross-petition and construe both—affirming on "body" but reversing on "retainer member."

D. The Claims Exclude Devices That Work By Cutting

The Federal Circuit's ruling that the asserted claims of the '224 and '773 patents cover cutting is also intertwined with RTI's petition. RTI's specification expressly criticized and distinguished the many prior art devices that use methods other than friction to hold and release the needle and contrasted its own "retraction mechanism with separable parts that *relies entirely on clamping force or friction*" that is "*slidably or separably released.*" A192 2:27-31 (emphasis added). This description of the claimed invention clearly disclaims devices that retract the needle in some other way (e.g., by cutting), and should have compelled a construction of the claims that excludes cutting. *See, e.g.*, *Astrazeneca AB* v. *Mutual Pharm. Co.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004) ("Where the general summary or description of the invention describes a feature of the invention … and criticizes other products … that lack that same feature, this operates as a clear disavowal of these other products[.]"); *O.I. Corp.* v. *Tekmar Co.*, 115 F.3d 1576, 1581 (Fed. Cir. 1997) (finding disclaimer where written description described only "non-smooth"

passages and contrasted with "smooth-walled" passages in the prior art).

RTI's disclaimer is not undermined by the "bridging portion" embodiment shown in Figure 8. That embodiment works by releasing friction, not by cutting. RTI's expert noted that in Figure 8 a frictional hold between the outside of the retainer member and the barrel's inner wall is "overcome[]" when the plunger contacts the retainer member, causing it to "slide[]" against the inner wall. A2650. This sliding of the retainer member by the plunger "uncouples" the retainer member from the inner head of the needle holder. A197 11:6-8. In the process, it may break a tack weld or other connection between the two parts. But the uncoupling occurs only because the frictional force that held the retainer member in a location where it could hold the needle holder has been removed.

RTI's petition alleges that, with respect to "body," the Federal Circuit too readily relied on the specification in the absence of "explicit re-definition or disclaimer." RTI Pet. 11. This assertion cannot be reconciled with the Federal Circuit's ruling on "cutting." Not only did the court require an "'expression[] of manifest exclusion or restriction, representing a clear disavowal of claim scope'" (RTI App. 19a), but when faced with just such an expression, it incorrectly demanded more. If there was error, it was not in the court's construction of the ambiguous term "body" in light of RTI's clear definition of what "[t]he invention is"—i.e., a syringe that "features a one piece hollow outer body." A193 3:12, 16-17. Rather, it was in the Court's reticence to recognize the clear disavowal in RTI's statement that the prior art failed to recognize "a retraction mechanism with separable parts that relies entirely on clamping force or friction" (A192 2:27-29)

and that "*[t]hese features* and more are found in *the inventive combination* herein further disclosed" (A193 3:6-7 (emphasis added)). If RTI's petition is granted, the Court should grant this conditional cross-petition and review the "cutting" issue as well.

CONCLUSION

RTI's petition for a writ of certiorari (No. 11-1154) should be denied. If it is granted, however, this conditional cross-petition should also be granted.

Respectfully submitted.

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APPENDICES

APPENDIX A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

Civil Action No. 2:07-CV-250
[Filed May 19, 2010]

RETRACTABLE TECHNOLOGIES INC.,
AND THOMAS J. SHAW,

Plaintiffs,

v.

BECTON, DICKINSON AND COMPANY,

Defendant.

ORDER

Before the Court is Defendant Becton, Dickinson and Company's ("BD's") Renewed Motion for Judgment as a Matter of Law or a New Trial. Dkt. No. 340. Also before the Court is the response of Plaintiffs Retractable Technologies Inc. and Thomas J. Shaw (collectively,"RTI"), as well as BD's reply. Dkt. No. 345 & 350. The Court held a hearing on February 9, 2010. Having considered the briefing, oral arguments of counsel, and all relevant pleadings and papers, the Court finds that BD's motion should be GRANTED IN PART and DENIED IN PART.

I. BACKGROUND

The Court held a jury trial from October 30, 2009, to November 9, 2009, on RTI's allegations of infringe-

ment by BD of United States Patents No. 5,632,733 ("the '733 Patent"), 6,090,077 ("the '077 Patent"), and 7,351,224 ("the '224 Patent"). The jury found infringement on at least one claim of each of these asserted patents but did not find willfulness. *See* Verdict Form, Dkt. No. 319 at 2-3. The jury did not find any of the asserted claims invalid. *Id.* at 4-5. The jury awarded a reasonable royalty of $5,000,000.00. *Id.* at 6.

II. LEGAL PRINCIPLES

Federal Rule of Civil Procedure 50 governs motions for judgment as a matter of law in jury trials and motions for new trial. Such a motion may be granted against a party if "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a). After such a motion is denied, "the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion," and it may grant a renewed motion pursuant to Rule 50(b) after the trial.

Fifth Circuit law controls review of a motion for judgment as a matter of law. *See, e.g.*, *Callicrate v. Wadsworth Mfg.*, 427 F.3d 1361, 1366 (Fed. Cir. 2005); *see also* Dkt. Nos. 340 at 2-3 & 345 at 4-5 (parties citing Fifth Circuit law). In the Fifth Circuit, entry of judgment as a matter of law post-trial under Rule 50 is appropriate if evidence supporting the movant is "uncontradicted and unimpeached" or if "the facts and inferences point so strongly and overwhelmingly in favor of one party that the Court believes that reasonable men could not arrive at a contrary verdict … ." *Med. Care Am., Inc. v. Nat'l Union Fire Ins. Co.*, 341 F.3d 415, 420 (5th Cir. 2003) (citation and quotation omitted). Grant of a new trial is proper where the jury's verdict

is "against the great weight of the evidence" or will result in a "miscarriage of justice." *See Pryor v. Trane Co.*, 138 F.3d 1024, 1026 n.3 (5th Cir. 1998) (quoting *Thompson & Co. v. Partridge*, 636 F.2d 945, 957 (5th Cir. 1981)). "If reasonable minds could differ as to the import of the evidence, however, a verdict should not be directed." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250-51 (1986).

III. THE PARTIES' POSITIONS

BD moves for judgment as a matter of law on non-infringement and invalidity, both as to RTI's claims and as to BD's declaratory judgment counterclaims. *See* Dkt. No. 340. Alternatively, BD requests a new trial on validity and infringement. *Id.* at 30.

Regarding non-infringement, BD argues that RTI failed to present evidence that:

> 1) the frictional holding and release mechanism required by claims 1 and 24 of the '733 patent and claims 43, 55, 60 and 61 of '224 patent is present in the Integra syringes;
>
> 2) the retraction mechanism of the 1mL Integra is disposed in the nose of the syringe as required by asserted claims 1 and 24 of the '733 patent;
>
> 3) BD's Integra syringes have vents that allow an opportunity or means for the escape, passage or release of air, as required by asserted claim 55 of the '224 patent;
>
> 4) the front end of the plunger contacts and removes the alleged retainer member, as required by asserted claim 24 of the '733 patent and asserted claim 25 of the '077 patent; and

> 5) after retraction, the thumb cap of the 3mL Integra is "inaccessible for grasping," as required by claim 25 of the '077 patent.

Id. at 1. BD also requests findings of invalidity as follows:

> 1) claim 25 of the '077 patent is invalid as anticipated by each of the McGary and Pressly patents and/or obvious in light of those patents in combination with the Power patent application;
>
> 2) claims 43, 60 and 61 of the '224 patent are anticipated by the McGary patent;
>
> 3) claim 55 of the '224 patent is obvious based on the combination of the McGary patent and the Gillespie patent;
>
> 4) all of the asserted claims are invalid under the written description requirement; and
>
> 5) claim 10 of the '077 patent is invalid as anticipated by the Gillespie patent.

Id. at 2.

BD also requests that claims withdrawn by RTI during trial (Claim 36 of the '733 Patent as to BD's 1mL Integra and Claim 47 of the '224 Patent as to BD's 1mL Integra and 3mL Integra) be dismissed with prejudice. *Id.* at 29.

RTI responds that it presented sufficient evidence to support the jury's finding of infringement. Dkt. No. 345 at 4. RTI also argues that BD, having "only made an oral motion," failed to properly move during trial for a judgment as a matter of law on invalidity. *Id.* at 16. RTI argues that "BD is attempting now to do the very thing that [Federal Rule of Civil Procedure 50] was

created to avoid: having presented its bare-bones motion at trial, [BD] is now attempting to take advantage of a perceived lack of responsive evidence from [RTI's] witness Mr. Sheehan." *Id.* at 17. Alternatively, RTI argues that BD's motion also fails on the merits. *See id.* at 17-26. As to claims not pursued at trial, RTI submits that "[i]n light of [the Court-ordered] time restrictions, … [RTI] dropped its infringement claims for Claim 36 of the '733 patent and Claim 47 of the '224 patent." *Id.* at 26-27. RTI argues that "[t]he Fifth Circuit has also made it clear that voluntary dismissal of claims 'should be freely granted unless the non-moving party will suffer some plain legal prejudice other than the mere prospect of a second lawsuit." *Id.* at 27 (emphasis omitted). As to BD's motion for a new trial, RTI submits that "BD simply is requesting a second bite at the apple for no apparent reason." *Id.* at 27.

BD replies as to non-infringement that the 3mL Integra does not use "clamping or frictional force to keep the needle in the projecting position," as required by the Court's claim construction. Dkt. No. 350 at 1-3. BD also argues that the alleged clamping force is not "released" when the needle is retracted because the force relied upon by RTI remains after retraction. *Id.* at 3-6. BD submits that "the patents-in-suit do not contemplate a syringe where the frictional or clamping holding force is not itself *directly* released to effectuate retraction." *Id.* at 6.

As to invalidity, BD replies that its oral Rule 50 motion at trial was sufficient. *Id.* at 6-7. BD argues that RTI has failed to overcome a presumption of enablement and that the McGary and Pressly patents render anticipated or obvious claim 25 of the '077 patent and all the asserted claims of the '224 Patent. *Id.* at 9-10. BD further argues that if the asserted claims are

read so broadly as to cover the 3mL Integra, then all asserted claims are invalid for lack of written description of such scope. *Id.* at 10.

IV. DISCUSSION

As to non-infringement, RTI presented sufficient evidence for the jury to find frictional holding and release as construed by the Court. *See* Dkt. No. 345 at 5-8; *see also* 9/21/2010 Order, Dkt. No. 239 (modifying claim construction and denying BD's motion for partial summary judgment of non-infringement). RTI also presented evidence that the retraction mechanism of the 1mL Integra is disposed in the nose of the syringe. *See* Dkt. No. 345 at 14-15. RTI showed evidence of vents that allow air to escape. *See id.* at 8-9 & 15-16. RTI further set forth evidence that the front end of the plunger contacts and removes the accused retainer member. *See id.* at 10 & 15. RTI also submitted evidence that after retraction, the thumb cap of the 3mL Integra is "inaccessible for grasping." *See id.* at 9-10; *see also* 9/21/2010 Order, Dkt. No. 239 (finding that "[t]he issue of whether a particular thumb cap is 'inaccessible for grasping' is a question of fact rather than a question of claim construction."). The jury's findings on infringement are thus supported by sufficient evidence.

As to invalidity, the Court finds that BD sufficiently preserved its motions for judgment as a matter of law. RTI complains that BD's oral motion for judgment as a matter of law at trial "did not explain anything. It did not specify the law; it did not specify the facts." Dkt. No. 345 at 17. To the contrary, BD sufficiently set forth its theories of invalidity and the prior art references at issue for purposes of Federal Rule of

Civil Procedure 50.[1] *See i4i Ltd. Partnership v. Microsoft Corp.*, --- F.3d ----, 2010 WL 801705, at *8 (Fed. Cir. Mar. 10, 2010).

As to the sufficiency of the evidence on invalidity, BD presented this prior art to the jury, and BD has not shown reason to disturb the jury's findings that BD failed to show anticipation or obviousness by clear and convincing evidence. The jury's findings in this regard were supported by sufficient evidence. *See* Dkt. No. 345 at 19-24. Similarly, BD presented its written description evidence and argument to the jury, and BD has not shown reason to disturb the jury's finding that BD failed to show lack of written description by clear and convincing evidence. The jury's finding in this regard was supported by sufficient evidence. *See id.* at 25.

In sum, BD has not shown entitlement to judgment as a matter of law as to any of the claims on which RTI presented evidence at trial, and BD's motion should be DENIED in this regard. For the same reasons, BD has

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[1] *See* 11/1 6/2009 A.M. Tr., Dkt. No. 333 at 101:13-102:15:

In addition, we believe we're entitled to a JMOL on the following validity issues: Written description on all asserted claims. Under the Court's claim construction, the claims are not limited to device that work entirely by friction, and the Court has indicated that they could hypothetically cover devices that work by cutting. Also invalidity of Claim 10 of the '077 Patent. Claim 10 is anticipated by Gillespie and/or obvious in light of the combination of Gillespie, McGary, and/or Pressly. Also invalidity of Claim 25 of the '077 patent. Claim 25 is anticipated by McGary and/or Pressly and/or obvious in light of the combination of McGary, Pressly, and Power. Also, Your Honor, invalidity of all claims of the '24—'224 patent, as anticipated in light of the McGary and/or obvious in light of the combination of McGary and Gillespie.

not shown that the Court should exercise its discretion to grant BD a new trial on validity and infringement. BD's motion for a new trial should be DENIED.

As to BD's counterclaim for a finding of non-infringement on the withdrawn claims, the September 28, 2009 Joint Final Pre-Trial Order included Claim 36 of the '733 Patent ("Claim 36") and Claim 47 of the '224 Patent ("Claim 47"). *See* Dkt. No. 244 at 8. RTI filed a written stipulation during trial stating: "For this trial, Plaintiffs do not assert Claim 36 of the '733 patent or Claim 47 of the '224 patent against the accused products." *See* 11/3/2009 Plaintiffs' Stipulation, Dkt. No. 297. BD submits that "RTI neither sought nor received consent from BD to withdraw the claims." Dkt. No. 340 at 29. RTI did not put on infringement evidence, nor did BD put on invalidity evidence, as to Claim 36 or Claim 47. RTI cites authority for its position that relates to an attempted voluntary dismissal pursuant to Federal Rule of Civil Procedure 41(a)(2) after a ruling on a motion to dismiss. *See Elbaor v. Tripath Imaging, Inc.*, 279 F.3d 314 (5th Cir. 2002). *Elbaor* is distinguishable from the case at bar, in which RTI attempted to withdraw claims during trial by unilaterally deciding to present no evidence on Claim 36 and Claim 47. BD was entitled to rely on the Joint Final Pre-Trial Order to frame the issues for trial. Under these circumstances, BD's motion for judgment as a matter of law should be GRANTED IN PART as to non-infringement of Claim 36 of the '733 Patent and Claim 47 of the '224 Patent.

V. CONCLUSION

BD's Renewed Motion for Judgment as a Matter of Law or a New Trial (Dkt. No. 340) is hereby GRANTED IN PART as to non-infringement of Claim

36 of the '733 Patent and Claim 47 of the '224 Patent. BD's motion is otherwise hereby DENIED.

IT IS SO ORDERED.

SIGNED this 19th day of May, 2010.

/s/ David Folsom
DAVID FOLSOM
UNITED STATES DISTRICT JUDGE

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

Civil Action No. 2:07-CV-250
[Filed Sept. 21, 2009]

RETRACTABLE TECHNOLOGIES INC.,
AND THOMAS J. SHAW,

Plaintiffs,

v.

BECTON, DICKINSON AND COMPANY,

Defendant.

ORDER

This case is on the Court's October 2009 trial docket. Before the Court is Defendant's Motion for Partial Summary Judgment of Non-Infringement. Dkt. No. 166. Also before the Court are Plaintiffs' response, Defendant's reply, and Plaintiffs' sur-reply. Dkt. Nos. 184, 200, and 204, respectively. The Court held a hearing on September 18, 2009. Having considered the briefing, oral arguments of counsel, and all relevant papers and pleadings, the Court finds that Defendant's motion should be DENIED but that the Court's construction of the terms "retainer member" and "continuous retainer member surrounding the inner head" should be MODIFIED.

I. BACKGROUND

The Court consolidated the above-captioned case with Civil Action No. 2:08-cv-141. *See* Dkt. No. 103. Plaintiffs Retractable Technologies Inc. and Thomas J. Shaw (collectively, "RTI") brought suit alleging infringement of U.S. Patent Nos. 5,578,011 ("the '011 Patent), 5,632,733 ("the '733 Patent"), 6,090,077 ("the '077 Patent"), and 7,351,224 ("the '224 Patent") by Defendant Becton, Dickinson and Company ("BD"). *See* Am. Compl., Dkt. No. 22; *see also* Compl., Civil Action No. 2:08-cv-141, Dkt. No. 1. Both the '011 and '733 Patents are entitled "Tamperproof Retractable Syringe," while the '077 Patent is entitled "Syringe Plunger Assembly and Barrel," and the '224 Patent is entitled "Retractable Syringe Assembly Designed for One Use." All three later patents are continuations-in-part of the '011 Patent. *See* '733 Patent at [63]; '077 Patent at [63]; '224 Patent at [63]. By way of background, the Abstract of the '224 Patent reads, in part, as follows:

> A syringe assembly having a retractable needle, the syringe assembly being rendered unusable after a single injection and having a hollow syringe body, a retraction mechanism with a spring disposed in the front portion of the syringe and 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 … .

The accused products are certain of BD's safety syringes. The Court entered its Claim Construction Order on January 20, 2009. Dkt. No. 122.

II. LEGAL PRINCIPLES

In a motion for summary judgment, the moving party has the initial burden of showing that there is no genuine issue of any material fact and that judgment should be entered as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). An issue is "material" where it involves a fact that might affect the outcome of the suit under the governing law of the underlying cause of action. *See Burgos v. S.W. Bell Tel. Co.*, 20 F.3d 633, 635 (5th Cir. 1994) (citing *Liberty Lobby*, 477 U.S. at 248)). The nonmovant is not required to respond to a motion for summary judgment until the movant first meets its burden of demonstrating that there are no factual issues warranting trial. *Ashe v. Corley*, 992 F.2d 540 (5th Cir. 1993). Once the movant has shown the absence of material fact issues, however, the opposing party has a duty to respond, via affidavits or other means, asserting specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e). "Summary judgment will not lie if the dispute about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Liberty Lobby*, 477 U.S. at 248. Patent infringement is a question of fact. *See, e.g., Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009).

III. THE PARTIES' POSITIONS

BD argues it is entitled to partial summary judgment of non-infringement as to Claims 1, 24, and 36 of the '733 Patent and Claims 43, 47, 55, 60, and 61 of the '224 Patent because "[i]t is … undisputed that the ac-

cused Integra syringes do not operate through the use of frictional or clamping forces, but instead rely upon breaking and penetration of internal parts to release the needle for retraction." Dkt. No. 166 at 6. BD also argues that not only has RTI failed to present any evidence of infringement under the doctrine of equivalents, but also "the accused syringes [cannot] be held to infringe under the doctrine of equivalents, given the patents' express criticism of devices that operate through breaking or penetrating parts, rather than entirely through a frictional mechanism." *Id.* at 7-8 (citation omitted).

Also, as to Claim 25 of the '077 Patent, BD argues that the corresponding accused syringe cannot infringe "because the Integra plunger can be grasped and pulled out of the syringe by the thumb cap after use," as purportedly demonstrated by Plaintiff Shaw during his deposition. *Id.* at 8-9. BD further argues that the accused syringe corresponding to Claim 25 of the '077 Patent cannot infringe under the doctrine of equivalents because, "such a finding would entirely vitiate the claim limitation 'inaccessible for grasping.'" *Id.* at 9 (citation omitted).

RTI responds that BD attempts to re-litigate claim construction and that "the claim construction BD now seeks that would require reduction in friction to be the release mechanism was specifically rejected twice in the Court's Order." Dkt. No. 184 at 1 (citing Dkt. No. 122 at 18 and 27). RTI argues: "Both accused BD products use friction and/or clamping *to hold* the retainer in place in the syringe body and therefore meet this limitation even though the spring force is *then released* by separation of a bridging portion between retainer member and needle holder … ." *Id.* at 1-2. RTI submits that "a specific embodiment that the Court recog-

nized was covered by the claim language releases through the breaking of the bridging portion between the retainer and the needle holder." *Id.* at 3. RTI argues that "the Court rejected Defendant's proposed construction and refused to limit how the holding force was released." *Id.* Regarding the retainer member and sliding engagement limitations, RTI submits that "[t]he Court has construed all but one of these limitations, finding that the retainer and continuous retainer limitations 'use[] some clamping or frictional force to keep the needle in the projecting position until released.'" *Id.* at 9 (quoting Dkt. No. 122 at 28-29). RTI also argues that the accused syringes also infringe under the doctrine of equivalents: "To the extent that the Integra syringes also have a mechanical component that also serves to help hold the needle in the projecting position, the structure is equivalent to and insubstantially different from one that solely uses friction and/or clamping [because] the friction and/or clamping is itself sufficient to hold the needle in the projecting position." *Id.* at 11.

As to Claim 25 of the '077 Patent, RTI argues that "[BD's] cited evidence merely establishes that the thumb cap of the [accused] syringe can be pried out of the collar after activation as opposed to being grasped." *Id.* at 12. Alternatively, RTI argues that "[e]ven if … the Court finds that prying is a subset of grasping, claim 25 would still be infringed under the doctrine of equivalents" because BD has not shown "that a thumb cap that is only accessible by prying is so fundamentally different from a thumb cap that is inaccessible for grasping that they cannot be considered equivalent structure." *Id.* at 13-14.

BD replies that RTI attempts to draw an improper distinction between holding and releasing. Dkt. No. 200 at 1. BD argues that "mechanical structures, not fric-

tion, hold the needles in place" in the accused syringes. *Id.* at 1; *see also id.* at 5. BD submits that "the Court construed the relevant claim terms to require both a frictional force that holds the needle in place and the release of that force to retract it." *Id.* at 2. BD urges that the Court "declined to limit the claim to any particular method of releasing the frictional force" but did not hold that the releasing could be done by any means, "including the cutting and breaking of internal parts criticized in the specification." *Id.* at 4.

BD presents evidence regarding the "mechanical structures" that hold a needle in place in the two accused syringes, which are the 3mL Integra syringe and the 1mL Integra syringe. Dkt. No. 200 at 6-8. As to the 3mL Integra syringe, BD submits that the needle is held by a "snap fit" and by "interlocking threads," which involve "mechanical hold[s]" rather than friction forces. *Id.* at 6. BD argues that "the requirement of a 'clamping' or 'frictional force' is not, however, satisfied by simply finding some clamping or frictional force between some surfaces in the device." *Id.* at 7. As to the 1mL Integra syringe, BD argues that although RTI's recent expert report on this issue should be stricken as untimely, even that expert's new tests "do not measure the mechanical force of the bump and groove in the 1mL syringe" and "fail to demonstrate that frictional forces (and not mechanical forces) are holding the needle in place … ." *Id.* at 8. As to the doctrine of equivalents, BD argues that "[m]echanical and frictional forces are completely different," and equating the two would "vitiate claim limitations." *Id.* at 9.

As to Claim 25 of the '077 Patent, BD reiterates that the thumb cap of the corresponding accused syringe is not "inaccessible for grasping" because "a user

can readily use his or her hand to pull the thumb cap … out of the barrel after retraction." *Id.* at 2 and 10.

In sur-reply, RTI summarizes its position as follows:

> The 3 ml has a retainer member (an upper lip on what BD calls the "inner hub") that is firmly clamped against an inside wall of the barrel, the upward clamping force being created by frictional engagement of threads. The 1 [ml] Integra uses the same frictional engagement of retainer ring against inside wall as is shown in the patent drawings—but adds a bump that enhances that frictional hold. The plunger cap of the 3 [ml] Integra tucks down into an outer collar where it is inaccessible for grasping.

Dkt. No. 204 at 1. RTI again argues that BD misinterprets the Court's claim construction and the patents in suit. *Id.* at 2. RTI further notes that the '733 Patent was a continuation-in-part "to add only one basic new embodiment and concept, namely, FIG. 8, showing the needle holder connected by a bridging portion to the retainer." *Id.* at 3. "In short," RTI argues, "BD invites error by suggesting that this Court should construe a criticism of prior art in a parent application to be so broad a disclaimer as to exclude the very subject matter added in a subsequent application." *Id.* at 4. Finally, RTI argues as to Claim 25 of the '733 Patent that while one could pry the plunger cap out of an accused syringes, the claim does not merely recite "inaccessible" but rather recites "inaccessible for grasping." *Id.* at 5.

IV. DISCUSSION

The parties main dispute, as distilled by the Court, is whether the claimed releasing must involve releasing

the frictional force that holds the needle in a projecting position. The parties' briefing and oral argument on the present motion present a claim construction dispute that the Court must resolve. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008).

The Court previously construed the term "retainer member" in the '773 Patent to mean "a non-retractable part of the retraction mechanism that uses some clamping or frictional force to keep the needle in the projecting position until released." Dkt. No. 122 at 16. To resolve the apparent dispute between the parties, the Court clarifies that the phrase "until released" refers to release of the "clamping or frictional force." The Court therefore **MODIFIES** its construction of "retainer member" to mean "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."

The Court previously construed the term "continuous retainer member surrounding the inner head" in the '224 Patent to mean "a non-retractable part of the retraction mechanism that encircles the inner head of the needle holder and uses some clamping or frictional force to keep the needle in the projecting position until released." Dkt. No. 122 at 25. In construing this term, the Court referred to its discussion and construction of the term "retainer member." *See id.* The Court hereby **MODIFIES** its construction of "continuous retainer member surrounding the inner head" to mean "a non-retractable part of the retraction mechanism that encircles the inner head of the needle holder and uses some clamping or frictional force to keep the needle in the projecting position until that clamping or frictional force is released."

The Court agrees with BD that the Court's claim constructions contemplate a frictional force that resists sliding of the needle holder, not any conceivable frictional force involved in a needle holder mechanism. Although RTI emphasizes an embodiment that includes a tack weld between the retainer member and the needle holder, the Court noted in its Claim Construction Order that even where "the needle holder and retainer member are welded or tack molded together," "there is still a clamping or frictional force between the wall of the syringe and the retainer member." Dkt. No. 122 at 16. The Court therefore rejects RTI's argument that the modifications to the Court's claim construction discussed above would read out an embodiment.

As to BD's argument that the claims require relying *entirely* or *exclusively* on clamping or frictional force to keep the needle in the projecting position, the Court refers to related discussion in its Claim Construction Order. Dkt. No. 122 at 15-16. The Court hereby clarifies that while "the retainer member can only function through the use of a frictional or clamping force," "the needle holder and retainer member [may be] welded or tack molded together" or some other mechanism may be involved in the overall operation of the needle retraction mechanism other than strictly clamping or friction.

As to whether summary judgment is appropriate, the Court finds that RTI has raised genuine issues of material fact as to whether the accused syringes infringe. *See, e.g.*, Dkt. No. 184 at 10. The Court also rejects BD's argument that the patentee waived or disclaimed (such as for purposes of the doctrine of equivalents) *any* use of breaking or penetrating to release the needle holder. BD's motion for summary judgment should therefore be denied as to Claims 1, 24, and 36 of

the '733 Patent and Claims 43, 47, 55, 60, and 61 of the '224 Patent.

As to Claim 25 of the '077 Patent, no bona fide claim construction dispute has been raised. Claim 25 recites, in relevant part, "the 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 end of the barrel *thereby rendering the thumb cap inaccessible for grasping*." '077 Patent at 21:1-7 (emphasis added). The issue of whether a particular thumb cap is "inaccessible for grasping" is a question of fact rather than a question of claim construction. Finding otherwise would invade the province of the finder of fact to compare the asserted claims to the accused syringes.

V. CONCLUSION

For at least the foregoing reasons, Defendant's Motion for Partial Summary Judgment of Non-Infringement (Dkt. No. 166) is hereby **DENIED**.

The Court hereby **MODIFIES** its construction of the terms "retainer member" and "continuous retainer member surrounding the inner head" as discussed above.

SIGNED this 21st day of September, 2009.

/s/ David Folsom
DAVID FOLSOM
UNITED STATES DISTRICT JUDGE

APPENDIX C

STATUTORY PROVISIONS

35 U.S.C. § 102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless—

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application des-

ignated the United States and was published under Article 21(2) of such treaty in the English language;[1] or

(f) he did not himself invent the subject matter sought to be patented, or

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 103(a). Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, 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. Patentability shall not be negatived by the manner in which the invention was made.

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[1] So in original. The semicolon probably should be a comma.