United States District Court,
E.D. Texas, Marshall Division.

RETRACTABLE TECHNOLOGIES, INC., and Thomas J. Shaw,
Plaintiffs.
v.
BECTON DICKINSON & CO,
Defendant.

Civil Action No. 2:07-CV-250 (DF)

Jan. 20, 2009.

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CLAIM CONSTRUCTION ORDER

Construing Terms in U.S. Patent Nos. 5,632,733**,** 6,090,077**, and** 7,351,224

DAVID FOLSOM**, District Judge.**

Before the Court are RTI's Opening Brief on Claim Construction (Dkt. No. 111), BD's Opening Claim Construction Brief (Dkt. No. 112), RTI's Reply Brief on Claim Construction (Dkt. No. 113) and BD's Notice of Supplemental Authority (Dkt. No. 116). Also before the Court are the Local Patent Rule (LPR) 4-3 Joint Claim Construction and Prehearing Statement (Dkt. No. 110) and the LPR 4-5 Joint Claim Construction Chart (Dkt. No. 114). A claim-construction hearing, in accordance with Markman v. Westview Instruments, 52 F.3d 967 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370 (1996), was held in Texarkana on December 4, 2008. *See* Dkt. No. 118 (hearing transcript). After hearing the arguments of counsel and reviewing the relevant pleadings, presentation materials, other papers, and case law, the Court finds the disputed terms of the patents-in-suit should be construed as set forth herein.

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I. BACKGROUND

In the present lawsuit, Retractable Technologies, Inc. and Thomas Shaw (collectively "RTI") contend certain safety syringes made by Becton, Dickinson and Co. ("BD") infringe claims 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"). 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. '733 at [63]; '077 at [63]; '224 at [63]. FN1

FN1. The parties have agreed on the construction of one term in the ' 011 Patent. The parties agree that "frictionally held retraction mechanism" will be construed as "a retraction mechanism held by friction." The Court has no reason to disagree and therefore adopts the parties' construction. Because no terms from the '011 Patent are in dispute this Claim Construction Order will not address the '011 Patent further.

II. LEGAL PRINCIPLES

A determination of patent infringement involves two steps: first, the patent claims are construed, and, second, the claims are compared to the allegedly infringing device. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1455 (Fed.Cir.1998) (en banc). The legal principles of claim construction were reexamined by the Federal Circuit in Phillips v. AWH Corp., 415 F.3d 1303 (Fed.Cir .2005) (en banc). The Federal Circuit in *Phillips* expressly reaffirmed the principles of claim construction as set forth in Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370 (1996), Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576 (Fed.Cir.1996), and Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111 (Fed.Cir.2004). Claim construction is a legal question for the courts. Markman, 52 F.3d at 979.

The Court, in accordance with the doctrines of claim construction that it has outlined in the past, will construe the claims of the RTI Patents below. *See Pioneer v. Samsung,* No. 2:07-CV-170, Dkt. No. 94, at 2-8 (E.D. Tex. filed Mar. 10, 2008) (claim-construction order).

III. PATENTS-IN-SUIT

The patents-in-suit are directed to particular features of a retractable syringe. The '773 Patent issued on May 27, 1997 from an application filed on September 29, 1995. The '773 Patent is a continuation-in-part of U.S. Patent App. No. 438,954, which was eventually issued as the '011 Patent. '733 at [63]. The '773 Patent abstract reads:

A tamperproof retractable non-reusable syringe has a one piece hollow outer body with a barrel for a slidable plunger, a transition zone and a smaller diameter nose portion. An elongated needle holder and spring combination is installable from the rear of the outer body, guided into the nose portion and held by cooperating inwardly and outwardly facing surfaces oriented in the direction of retraction at the most constricted part of the transition zone where the nose begins. The plunger has an opening with a dislodgable stopper for receiving parts of the retraction mechanism. The stopper and the head of the needle holder are of significantly reduced diameter from the injection fluid chamber to resist blowing out prematurely. In one embodiment the head of the needle holder is surrounded by a separable retainer member which is slidingly removed by contact with the tip of the plunger after the stopper is mostly or fully removed to avoid cumulation of force required for retraction after the injection. In a second embodiment the head of the

needle holder is clamped and held by constricting forces imposed by stress on the outer body induced by interference fit. Release occurs by slight expansion on the barrel by contact of the plunger tip with a small internal ramp in the outer barrel. Both embodiments have a plunger cap configured to enter an opening in the outer body to provide an additional tamperproof feature.

'773 Patent at [57].

The '077 Patent issued July 18, 2000 from an application filed on April 25, 1997. The '077 Patent is a continuation-in-part of both the '773 and '011 Patents. '077 at [63]. The abstract from the '077 Patent mirrors that of the '773 Patent, but contains one additional sentence: "The retraction cavity is provided with venting structure to assure that all uninjected fluid is retained within the syringe body." Id. at [57].

The '224 Patent issued April 1, 2008 from an application filed July 17, 2000. The '224 Patent is a continuation-in-part of the '007, '773, and ' 011 Patents. '224 at [63]. The '773 Patent abstract reads:

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, wherein the bridging portion couples the continuous retainer member and the inner head to form a fluid seal between a fluid passageway and the barrel prior to retraction, and a plunger reciprocally disposed inside the barrel and forming a variable chamber between the plunger and the needle holder prior to and during retraction, wherein the continuous retainer member is releasable from the inner head of the needle holder when the plunger is further depressed inside the barrel following injection.

Id. at [57].

IV. U.S. PATENT NO. 5,632,733

A. Overview

RTI has asserted claims 1, 24, and 36 of the '733 Patent against BD in this lawsuit. Dkt. No. 114. For reference, asserted claims 1 and 24 are reproduced below (terms to be construed emphasized):

1. A tamperproof retractable syringe for injecting fluid wherein the syringe has a one piece **body** and a retraction mechanism assembleable from the rear which resists high blowout pressure during an injection but can be retracted with low plunger force after injection comprising:

a one piece hollow outer **body** having a longitudinally extending wall, comprising an elongated **barrel** and **nose,** with a **transition zone** connecting the **barrel** and **nose,** the **nose** having a reduced cross sectional area relative to the **barrel** and an **inwardly facing surface** in the wall at the most constricted part of the **transition zone** where the nose begins;

a plunger assembly disposed partially within the elongated **barrel,** the plunger having a head in slidable sealed contact with the interior of the outer **body,** a forward portion and a retraction cavity therein for receiving parts of a retraction mechanism;

a **retraction mechanism sealingly disposed in the nose,** the retraction mechanism having a retractable part comprising a needle holder having an elongated **body** having a needle holding tip portion in front and a head in back, a passageway defining a fluid path into a variable fluid chamber in the **barrel** below the plunger, and a spring applying retraction force to the retractable part, said retractable part being configured to be able to retract into the retraction cavity of the plunger when retraction is initiated;

the retraction mechanism further including a nonretractable part comprising a **retainer member** surrounding the head of the needle holder, the retainer member and said head of the needle holder being removably coupled by a **bridging portion** between them;

the needle holder and spring being installable into the **nose** from the rear of the **barrel** and **releaseably installed by sliding engagement of said retainer member and said inwardly facing surface** while compressing said spring, said **sliding engagement producing a holding force** in opposition to the retraction force applied to the needle holder by said spring; and

the plunger being depressible to a first position which comprises the end of an injection cycle whereby fluid previously drawn into the variable chamber is expelled through said fluid path, and a retraction position beyond said first position wherein retraction is initiated by the forward portion of the plunger head moving through the **transition zone** in the **nose** to release the needle holder by uncoupling the **retainer member** and needle holder at said **bridging portion** thereby reducing the holding force to an amount less than the retraction force on the needle holder to cause retraction of the retractable part into the retraction cavity of the plunger.

24. A method of assembling a tamperproof retractable syringe which is well suited for automated assembly;

providing a one piece hollow syringe **body** having a longitudinally extending wall with an open back end, comprising an elongated **barrel** and **nose portion** of reduced cross sectional area relative to the **barrel,** and an **inwardly facing surface** in the wall at the most constricted part of a **transition zone** between the **barrel** and **nose** where the **nose** begins;

providing a plunger assembly having a front portion and a back portion, the front portion including a head configured for sliding sealed contact with the interior of the elongated **barrel,** said head having a retraction cavity and a leading end configured to contact and remove a **retainer member** from a needle holder to be mounted in the **nose;**

providing a needle holder having an elongated **body** portion in front and a head in back with a fluid path therethrough, the head of the needle holder having a **retainer member** which can be separated from the head of the

needle holder by contact with the leading end of the plunger, the **retainer member** having an **outwardly facing surface** configured to slidingly and frictionally engage said **inwardly facing surface** in the **nose** and hold the needle holder against a retraction force provided by the spring when the spring is compressed within the **nose;**

loading the spring followed by the needle holder into the back opening in the **barrel** part of the syringe **body** and positioning at least the forward portion of the spring and a portion of the elongated body of the needle holder within the **nose;**

moving the head end of the needle holder and the **retainer member** into the most constricted part of the transition zone where the **nose** begins; and

installing the needle holder and **retainer member** in the **nose** by sliding engagement of the **outwardly facing surface** of the **retainer member** with the **inwardly facing surface** in the wall while compressing the spring within the **nose.**

'733, 14:65-15:49, 16:64-17:37 (emphasis added).

B. Claim Construction

1. "body"

a. Parties' Positions

The parties propose the following constructions for "body," which is present in each of the asserted claims as well as the two other patents-in-suit. Dkt. No. 114. The primary dispute between the parties is whether the syringe body must be limited to a one-piece structure.

RTI	BD
A hollow outer structure that houses the syringe's components	A one-piece hollow outer structure that houses the syringe's components

RTI contends this term should not contain a one-piece limitation because many of the claims in the '733 Patent already contain such a limitation. Dkt. No. 111 at 22. To add this limitation to the definition of body itself would render the additional claim language meaningless. *Id*. RTI also contends the patentee expressly used a one-piece limitation in the '733 Patent while no such limitation is generally present in the '077 or '224 Patents. Id. at 23. In fact, the patentee in the '224 patent used the limitation to differentiate between certain claims. *Compare* '224, 22:38-40 (claim 43), *with* 24:23-25 (claim 57-"The syringe assembly of claim 43 wherein the body comprises a one-piece barrel.").

Judge Davis previously construed this term in connection with the '011 and ' 077 Patents. *See RTI v. New Medical Techs.,* Civil Action No. 4:02-CV-34, Dkt. No. 110 at 6-9 (E.D.Tex. March 8, 2008). Judge Davis, like RTI, found significant the fact that the patentee in this family of patents included the phrase "one piece" in some claims, but not in others. *Id*. at 7. As such, Judge Davis found it improper to limit the term to a preferred embodiment containing only a one-piece body. *Id*. at 8-9.

b. Court's Construction

At the outset, this Court notes that certain terms, such as barrel, pervade all of the patents-in-suit. Because all of these patents are related-the latter patents being continuations-in-part of earlier patents and patent applications-this Court finds that terms should be construed consistently throughout absent some evidence to the contrary. In addition, the specifications and claims of each patent within this family may provide guidance when construing such pervasive terms.

Regardless of whether collateral estoppels applies to the construction of this term, the Court finds no reason to deviate from Judge Davis' previous construction. *See Id*. at 6-9. Accordingly, this Court finds that "body" means "a hollow outer structure that houses the syringe's components."

2. "barrel"

a. Parties' Positions

The parties propose the following constructions for "barrel," which is present in each of the asserted claims as well as the other two patents-in-suit. Dkt. No. 114. The primary dispute between the parties is whether the syringe barrel must be cylindrical in shape.

RTI	BD
The elongated part of the syringe body including a portion within which the plunger moves during	The elongated cylindrical portion of the syringe body through which the plunger moves during

RTI contends the claimed barrel could take a number of conceivable shapes and should not be limited to a cylindrical form. Dkt. No. 111 at 26-27. RTI further argues that the '224 specification specifically contemplates a non-cylindrical barrel. *Id*. (citing '224, 10:47-50). Moreover, the principle of claim differentiation supports RTI's broad construction as certain claims specifically contain a cylindrical limitation while others do not. *Id*. at 27 (citing '224, 20:22-23 (claim 25)). Finally, RTI contends that it is improper to limit the claimed barrel to the portion of the syringe through which the plunger moves. *Id*. Instead, some claims within the '224 and ' 077 Patent suggest that the term may encompass other structures through which the plunger does not move; specifically, the term may also define the front end portion of the syringe, including the nose portion and retraction mechanism. Id. at 27-28 (citing *inter alia* '224, 22:37-40 (claim 43) & '077, 22:13-15).

In response, BD relies on numerous dictionaries, which suggest that a barrel is limited to a cylindrical shape. Dkt. No. 112 at 30-31. BD also maintains that every figure in this family of patents shows a cylindrical barrel and expressly labels the non-cylindrical parts of the syringe as a 'nose' or 'transition zone'. *Id*. Thus, BD argues that the patent figures make clear that the term is limited to a cylindrical shape and does not include narrow parts in the front end of the syringe. *Id*. In addition, BD contends that the terms barrel, nose, and transition zone should each be given distinct meanings because they are given different names and labels throughout the patent-to do otherwise would render the different labels superfluous. *Id*.

b. Court's Construction

The Federal Circuit has made it clear that when the specification discloses only a single preferred embodiment, limitations from that embodiment generally should not be imported into the claim language. Phillips v. AWH Corp., 415 F.3d at 1323 (rejecting the contention that "if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment"). Limitations from the specification may be imported into the claims where it is clear that the patentee intended for the "claims and embodiments in the specification to be strictly coextensive." *Id*. (citing SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed.Cir.2001)). Such intention is evidenced by the manner in which the patentee uses a term within the specification and the claims. *Id*. (citing Snow v. Lake Shore & M.S. Ry. Co., 121 U.S. 617, 630 (1887) (it was clear from the specification that there was "nothing in the context to indicate that the patentee contemplated any alternative" embodiment to the one presented)).

RTI is correct that all figures in the patents-in-suit generally depict syringes having a cylindrical barrel. The specification of the '224 Patent, however, makes it clear that the patentee contemplated alternative shapes. Specifically, the patent states that the "head of the needle holder is preferably circular but could conceivably be another shape with the retainer member correspondingly configured to conform to it." '224, 10:47-50. As the ' 224 Patent generally depicts a syringe having a barrel and needle holder having similar shape, such a statement evidences the patentee's belief that both the needle holder and related barrel could have a non-circular shape. Thus, the patentee may have contemplated a non-cylindrical barrel.

Moreover, claim 25 of the '224 Patent specifically recites a "substantially cylindrical barrel," which strongly suggests that the term is not inherently cylindrical. Furthermore, the absence of this "substantially cylindrical" limitation in other claims suggests that it should not be read into claims in which it is not present. *See* Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1326 (Fed.Cir.2003) ("when a patent claim does not contain a certain limitation and another claim does, that limitation cannot be read into the former claim"). The Court therefore finds that the term barrel should not be limited to a cylindrical shape.

Finally, although this Court believes that the terms barrel, nose, and transition zone are generally distinct

components within the patents-in-suit, the patents also suggest that the barrel may encompass some portion of the syringe through which the plunger does not move. Specifically, claim 25 of the '077 Patent recites a "barrel having a front end portion containing a retraction mechanism." If this front end portion of the claimed barrel contains the retraction mechanism, then it cannot logically also be a portion through which the plunger moves. Although the plunger will assuredly move through some portion of the barrel, this Court finds that it would be improper to limit the barrel to that portion.

Accordingly, this Court finds that "barrel means "the elongated part of the syringe body including a portion through which the plunger moves during injection."

3. "nose"/"nose portion"

The parties have agreed on a meaning for the term "nose," which appears in each asserted claim. The proposed construction is "the portion of the syringe at the injection end that has a reduced diameter relative to the barrel." Dkt. No. 110 at 1. The parties have further agreed that these claims require the "nose" to be distinct from the barrel and transition zone.

The parties have also agreed on a meaning for the term "nose portion," which appears in claims 24 and 36. The proposed construction is "section of the syringe body that has a reduced diameter relative to the barrel portion of the body." *Id*.

The Court has no reason to disagree and therefore adopts the parties' constructions.

4. "transition zone"

a. Parties' Positions

The parties propose the following constructions for "transition zone," which is present in each asserted claim. Dkt. No. 114.

RTI	BD
Portion of the syringe located between the barrel and the nose	Portion of the syringe with varied inner diameter located between the barrel and the nose

RTI contends this term should not be limited to the preferred embodiment, which identifies a transition zone with a sloping inner wall. Dkt. No. 111 at 21. While RTI concedes that the transition zone has a "constricted portion," it believes that the patent does not require that the transition zone have a varied inner diameter. *Id*. BD counters by arguing that the phrase "most constricted part of the transition zone" pertains to the whole invention and requires a varied inner diameter. Dkt. No. 112 at 28 (citing '733, 14:8-10).

Judge Davis previously construed this term in connection with the '011 and ' 077 Patents. *See RTI v. New Medical Techs.,* Civil Action No. 4:02-CV-34, Dkt. No. 110 at 15 (E.D.Tex. March 8, 2008). Judge Davis did not limit the term to a varied inner diameter. *Id*.

b. Court's Construction

Once again, the Court finds no reason to deviate from Judge Davis' previous construction. *See RTI v. New Medical Techs.,* Civil Action No. 4:02-CV-34, Dkt. No. 110 at 13-14 (E.D.Tex. March 8, 2008). In addition, the Court finds no reason to limit the term to the preferred embodiment. Accordingly, this Court finds that term "transition zone" means "portion of the syringe located between the barrel and the nose."

5. "inwardly facing surface"

a. Parties' Positions

The parties propose the following constructions for "inwardly facing surface," which is present in each asserted claim. Dkt. No. 114.

RTI	BD
A surface that faces the inside of the syringe	A surface in the wall that faces toward the center of the syringe and is parallel to the direction of the plunger motion

RTI contends this term should not be restricted to a surface that is parallel to the motion of the plunger, as such would improperly restrict the term to a preferred embodiment. Dkt. No. 111 at 29. RTI contends that the '733 specification attaches no significance to the fact that the preferred embodiment's surfaces happen to be parallel to the plunger's motion. *Id*. Additionally, RTI contends that claim differentiation precludes such a limitation, as the patentee chose to specifically align these surfaces in certain claims of the '011 Patent. Id. (citing '011, 13:40-43 (claim 3)).

In response, BD contends that every embodiment described or depicted in the ' 733 Patent demonstrates surfaces that are parallel to the vertical direction of the plunger motion. Dkt. No. 112 at 23-24. In addition, the Summary of the Invention within the '733 Patent also aligns these surfaces with the plunger motion. Id. (citing '733, 2:64-65 (inwardly and outwardly facing surfaces meet "along an interface oriented in the direction of retraction")). Alternatively, BD argues that during prosecution RTI took a narrower view of the scope of this term to overcome prior art. Id. As such, BD argues that RTI has surrendered broader, non-parallel coverage. Id.

b. Court's Construction

As discussed above, limitations from the preferred embodiment generally should not be imported into the claim language, unless the claims and the embodiments in the specification were meant to be strictly coextensive. Phillips, 415 F.3d at 1323. While the descriptions and depictions of the invention in the '733 Patent generally show an inwardly facing surface that is parallel to the plunger motion, this Court finds no evidence that such embodiments are strictly coextensive with the claimed invention. Indeed, the ' 011 Patent, from which the '733 Patent is a continuation-in-part, expressly claims such an orientation. '011, 13:40-43 (claim 3: "The tamperproof retractable syringe of claim 2 wherein said frictional holding [inwardly and outwardly facing] surfaces comprise a linear interface aligned in the direction of retraction."). Thus, when the patentee wished to limit the alignment of surfaces, he expressly claimed such. Accordingly, this Court finds that it would be improper to import an alignment limitation into claims where such is not expressly present.

Accordingly, this Court finds that the term "inwardly facing surface" means "a surface that faces toward the center of the syringe."

6. "retraction mechanism sealingly disposed in the nose"

The parties have agreed on a meaning for the term "retraction mechanism sealingly disposed in the nose," which appears in claim 1. The proposed construction is "a retraction mechanism sealed in the nose." Dkt. No. 110 at 1. The Court has no reason to disagree and therefore adopts the parties' construction.

7. "retainer member"

a. Parties' Positions

The parties propose the following constructions for "retainer member," which is present in each asserted claim and the '224 Patent. Dkt. No. 114. The primary dispute between the parties is whether the retainer

member must operate by means of a frictional force.

RTI	BD
A nonretractable part of the retraction mechanism that retains the retraction mechanism	A nonretractable part of the retraction mechanism, separate from the needle holder, that retains the retraction mechanism by frictional force with the wall of the syringe

RTI contends that BD's construction would not only limit the patent to a preferred embodiment, but would also limit the patent to RTI's particular commercial product, the VanishPoint(R)-syringe. Dkt. No. 111 at 8-10. The construction proposed by BD would read a frictional holding force limitation into the term. RTI believes this improper because some claims do not require any engagement or holding force, much less some kind of frictional force. *Id*. at 10 (citing '224, 20:46-54 (claim 43)). Moreover, RTI contends that the patentee explicitly stated in some claims that frictional forces were required, raising the implication that claims without such explicit statements are not limited to friction. *Id*. (comparing '733, 14:32-37 (claim 1) with 17:18-21 (claim 24) and 18:38-41 (claim 36)). RTI also contends that the specification expressly contemplates embodiments that operate using something other than friction to hold the retainer member in place. *Id*. at 11-13. Specifically, the patents teach that the holding force used in the invention, while preferably frictional, may instead rely on tack welding, sonic welding, adhesive, or clamping forces. *Id*. at 12-13 (citing '733, 9:50-53, 10:4-8, 6:47-55, and 11:49-52).

RTI also believes that BD's proposed construction is improper in another regard, it requires that the retainer member and needle holder be separate parts. *Id*. at 16-18. While one preferred embodiment teaches that the two components are separate parts, RTI argues that there is nothing in either the claims or the specification that requires such. *Id*. To the contrary, an alternative embodiment suggests that the two are welded together to form a single structure. *Id*. at 17 (citing '733, 9:7-27). Therefore, RTI contends that-despite being two components-the patents contemplate that the retainer member and needle holder may be formed into a single structure. *Id*.

In response, BD contends that the specification repeatedly describes the invention as a retracting syringe in which the needle holder is engaged and released by sliding surfaces, and therefore, friction. Dkt. No. 112 at 17. BD identifies numerous points in the specification where the holding force used in the invention is identified as a frictional force. *Id*. at 17-18 (citing ' 733, 2:67-3:6, 3:11-13, and 3:61). BD also contends that the specification uses the terms 'holding force' and 'frictional holding force' interchangeably, thus demonstrating that they are intended to have the same meaning. *Id*. (citing Tate Access Floors, Inc. v.. Maxcess Techs., Inc., 222 F.3d 958, 968 (Fed.Cir.2000)). Moreover, BD argues that the specification criticizes syringes in the prior art that operate without friction and rely instead on flexing, breaking, or penetration. *Id*. at 18 (citing '733, 1:48-54, 2:18-35). Specifically, BD contends the specification asserts that the invention was new and different because it "relies entirely on clamping force or friction...." *Id*. (quoting '733, 2:20-21).

In connection with the second issue regarding this term, that is whether the needle holder and retainer member must be separate parts, BD argues that the ' 733 claims suggest that the two components are inherently separate parts. *Id*. at 25. BD argues that a single, unitary structure cannot couple with itself or surround itself. *Id*. In addition, BD contends that the patent specification, specifically the Summary of the Invention, explains that the retraction mechanism has a "two part head." *Id*. (citing '733, 3:25-26). Finally, BD argues that melting or tacking two parts together do not make them a single part; instead, such coupling is further evidence that they are indeed two separate parts. *Id*. at 25-26.

b. Court's Construction

First, this Court finds that nothing in the specification requires the needle holder and retainer member be two separate parts. The specification states that in " *one embodiment,* the head of the holder is a two part head

comprising an inner head surrounded by a separable retainer ...." '733, 3:19-22 (emphasis added). This statement is explicitly limited to a single, preferred embodiment, thus suggesting that other embodiments of the invention may utilize a unitary structure. Such a structure is contemplated in an alternative embodiment in which the two components are initially welded together and later "ruptured or separated." *Id* . at 9:7-13.

Second, this Court finds that the invention operates through the use of a frictional or clamping force, and that the retainer member must utilize these forces. Although the claims by themselves may seem broad enough to encompass other methods of operation, the patent as a whole disavows such methods and limits itself to frictional or clamping forces. The Federal Circuit has stated that where "the general summary or description of the invention describes a feature of the invention ... and criticizes other products ... that lack the same feature, this operates as a clear disavowal of these other products...." Astrazeneca AB v. Mutual Pharm. Co., 384 F.3d 1333, 1340 (Fed.Cir.2004), *see also* SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed.Cir.2001) ("Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims ... even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.").

RTI is correct in asserting that some claims of the '733 Patent are explicitly limited to a frictional force while others do not. Claim differentiation would ordinarily require that all claims not be so limited. The specification, however, makes clear that the invention does not include the use flexing, breaking, or penetration as methods of operation. It does so by expressly criticizing other methods used in retractable syringes:

Other problems with the prior art are dependence on flexing or breaking of internal parts by the plunger in order to release the retraction mechanism and use of a diaphragm at the end of the plunger which must be penetrated by a needle holding member and spring. These structures present serious quality control and assembly problems.

'733, 1:48-54. In contrast to these less preferable methods, the specification asserts that the present invention is superior because it relies entirely on clamping or frictional forces: "The prior art has not recognized a retraction mechanism with separable parts that *relies entirely* on clamping force or friction...." '733, 2:18-20. By distinguishing itself from the prior art in such absolute terms, the patent has limited itself to a certain type of holding force-clamping or friction.

Finally, the varied embodiments in the invention demonstrate that this holding force may be utilized in different manners within the syringe. In one embodiment, a pair of frictional holding forces function to retain the needle in the projecting position: a frictional force between the wall of the syringe and the retainer member, and another between the retainer member and the needle holder. *See* '733, 6:56-67, 3:8-24. In another embodiment, the needle holder and retainer member are welded or tack molded together as discussed above. *See* ' 733, 9:50-53, 10:4-8, and 11:49-52. Although this weld or tack mold holds the needle holder and retainer member together, there is still a clamping or frictional force between the wall of the syringe and the retainer member. Without this force between the wall of the syringe and the retainer member, the syringe would be inoperable-it would be unable to retain the needle in a projecting position. Thus, the retainer member can only function through the use of a frictional or clamping force.

Accordingly, this Court finds that the term "retainer member" means "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."

8. "bridging portion"

a. Parties' Positions

The parties propose the following constructions for "bridging portion," which is present in claim 1 and in the '224 Patent. Dkt. No. 114. The primary dispute between the parties is whether the bridging portion must be limited to a ridge-like structure.

RTI	BD
The structure that joins the retainer member and the head of the needle holder	A ridge on one of the facing surfaces that joins the retainer member and the head of the needle holder

RTI contends that BD's construction improperly limits the invention to a preferred embodiment. Dkt. No. 111 at 28. While the embodiment in Figure 8 admittedly depicts a raised ridge between facing surfaces, RTI argues that nothing in the specification limits the bridging portion to such a structure. *Id*. Instead, the specification states that the bridging portion may be joined to needle holder by a tack weld, or "by providing any other form of frangible bridging portion that holds the separable ring member and needle holder together." *Id*. at 28-29 (citing '733, 9:37-40).

In response, BD argues that the specification defines the bridging portion as a "small ridge" or "raised portion" joining facing surfaces. Dkt. No. 112 at 27 (citing '733, 3:43 and '077, 10:38-39). While the bridging portion may admittedly be made of various materials, BD contends that it must have some definable structure, which the patent identifies as a ridge on one of the facing surfaces. *Id*.

b. Court's Construction

The specification describes the bridging portion as a ridge-like structure that may take the form of a single "very small raised portion" or a "series of horizontally spaced apart raised portions ." While the preferred embodiment describes the bridging portion as such ridge-like structures, the Court finds no evidence that the patentee intended to limit the term to that structure. *See* Phillips, 415 F.3d at 1323 (claims should not be limited to particular embodiments unless the inventor has indicated such a narrow construction). Additionally, the bridging portion is part of an embodiment depicted in Figure 8, which the specification distinguishes from those embodiments depicted in Figures 1-3. *See* '733, 9:7-17. It is thus apparent that Figures 1-3 do not contain the claimed bridging portion, as the adjoining surfaces of the retainer member and needle holder in those embodiments are flush with one another. Thus, if two surfaces are completely flush with one another they cannot logically be joined by a bridging portion. As such, the claimed bridging portion, whatever the form it takes, must be a distinguishable structure that both joins the two components and provides some separation between them. The separation may take the form of a "small gap between them all around" ('733, 9:30-31) as depicted in Figure 8. Conversely, the bridging portion could take the form of a "frangible web" (Dkt. No 111 at 29), the gaps of which separate the two surfaces.

Accordingly, as the Court previously ruled, the term "bridging portion" means "a structure that spans the gap between and connects the retainer member and needle holder."

9. "releaseably installed by sliding engagement of said retainer member and said inwardly facing surface"

a. Parties' Positions

The parties propose the following constructions for "releaseably installed by sliding engagement of said retainer member and said inwardly facing surface," which is present in claim 1. Dkt. No. 114.

RTI	BD
Releaseably installed by sliding the retainer member along the inwardly facing surface to engage it with the wall of the syringe	Installed and released by sliding the retainer member along the inwardly facing surface to create and the release a frictional force with the wall of the syringe

As above, this term concerns the nature of the force involved in the invention. In addition, however, the parties also dispute the meaning of the words "releaseably installed" in this term. BD contends that "releaseably installed by sliding engagement" has two functional meanings. Dkt. No. 112 at 20. First, the phrase refers to the creation of a frictional force. *Id*. Second, the word "releaseably" requires that the retainer member be releaseable in the same way that it was installed. *Id*. at 20-21. BD contends that if the retraction mechanism is "installed by sliding engagement," then it must be released in the same manner-by sliding the retainer member away from the inwardly facing surface. *Id*. at 21.

RTI disagrees and contends that the term is not so limited. Dkt. No. 111 at 14. Instead, RTI argues that one of the alternate methods of release taught by the patent could achieve the release-namely by spreading the syringe wall and allowing a one-piece needle holder to retract. *Id*. at 14-15 (citing '733, 11:49-52).

b. Court's Construction

For the reasons stated above, this Court finds that the invention operates through the use of a clamping or fictional force. This Court, however, is not persuaded that the claimed release must be accomplished in the same manner as the installation. The patent teaches alternative methods for providing release of the holding force. Specifically, the patent allows the holding force to be released by spreading the barrel apart slightly, thus releasing the retraction mechanism. *See* '733, 11:49-52 ("The barrel is flexible and is spread outwardly a slight among to the position of FIG. 6 just prior to retraction. Here the mating surfaces are separated an amount which reduces the clamping force on the needle holder."). Therefore, although the holding force is created by sliding engagement in this claim, the Patent contemplates another method of its release.

Accordingly, the Court finds that the term "releaseably installed by sliding engagement of said retainer member and said inwardly facing surface" means "installed by sliding the retainer member along the inwardly facing surface to engage it with the wall of the syringe, which creates a clamping or frictional force that can be released at a later time."

10. "sliding engagement producing a holding force"

The parties propose the following constructions for "sliding engagement producing a holding force," which is present in claim 1. Dkt. No. 114.

RTI	BD
Sliding the retainer member along the inwardly facing surface of the body to produce a force that maintains the needle holder in the projected position	Sliding the retainer member along the inwardly facing surface of the body produces a frictional force that maintains the needle holder in the projected position

Once again, the dispute between the parties center on whether the holding force must be a frictional force. RTI and BD proffer the same arguments as those discussed above in connection with the term "retainer member." Dkt. Nos. 111 at 18 & 112 at 16-20.

For the reasons stated above, this Court finds that the invention operates through the use of a clamping or fictional force. Accordingly, the Court finds that the term "continuous retainer member surrounding the inner head" means "sliding the retainer member along the inwardly facing surface of the body produces a clamping or frictional force that maintains the needle holder in the projected position."

11. "outwardly facing surface"

The parties propose the following constructions for "outwardly facing surface," which is present in claims

24 and 36. Dkt. No. 114.

RTI	BD
A surface that faces toward the outside of the syringe	A surface that faces away from the center of the syringe and is parallel to the direction of the plunger motion

The parties present arguments similar to those presented in connection to the term "inwardly facing surface." For the same reasons as stated above in connection with inwardly facing surfaces, the Court finds that the claimed outwardly facing surfaces should not be limited to a direction parallel to the plunger motion.

Accordingly, this Court finds that the term "outwardly facing surface" means "a surface that faces away from the center of the syringe."

V. U.S. PATENT NO. 6,090,077

A. Overview

RTI has asserted claims 10 and 25 of the '077 Patent against BD in this lawsuit. Dkt. No. 114. For reference, the asserted claims are reproduced below (terms to be construed emphasized):

10. A syringe plunger handle assembly and syringe barrel combination for use in a retractable syringe for injecting fluids, comprising:

a hollow syringe **body** having an elongated tubular wall comprising an elongated **barrel** portion having an open back end;

an elongated plunger disposed for reciprocation in sliding sealed contact with the **barrel** portion of the **body,** the plunger having a tubular wall defining a head portion in front, a back end portion carrying a thumb cap and hollow interior comprising a retraction cavity located between the head portion and thumb cap;

the thumb cap having an outer side adapted to reside in close association with the open back end of the plunger **barrel** when the plunger is nearly fully depressed; and

the plunger having a **vent** in fluid communication with the retraction cavity, to allow airflow from the retraction cavity.

25. A tamperproof retractable syringe structure designed for one use, comprising:

a hollow syringe **body** comprising a syringe **barrel** having an open back end, **the barrel having a front end portion containing a retraction mechanism configured for operation by a plunger;**

a plunger reciprocatably mounted in sliding sealed contact with the **barrel,** the plunger having a thumb cap at its back end for working the plunger relative to the **barrel** and **a front end configured to operate the retraction mechanism;**

the plunger having a tactile first position felt by a user pressing the thumb cap at the end of free travel of the plunger in the **barrel** when the plunger is moved forward to a stop, the plunger having a length relative to the length of the **barrel** whereby in the tactile first position of the plunger a portion of the plunger and the thumb cap extend behind the **barrel** for grasping in order to draw fluid into the **barrel** by partially withdrawing the plunger from the **barrel;**

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.

'007 Patent, 19:33-50, 20:48-21:7 (emphasis added).

B. Claim Construction

1. "body"/"barrel"

The Court construed these terms as part of its analysis of the '733 Patent, of which the '077 Patent is a continuation-in-part. The Court finds no reason to deviate from its prior constructions.

2. "vent"

The parties have agreed on a meaning for the term "vent," which appears in claim 10. The proposed construction is "an aperture that provides an opportunity or means of escape, passage, or release ." Dkt. No. 110 at 1-2. While the Court has does not disagree with the overall construction, it does believe that the word "aperture" would be unnecessarily confusing to the jury. Thus, the Court finds that the term "vent" should be construed as "an opening that provides an opportunity or means of escape, passage, or release."

3. "the barrel having a front end portion containing a retraction mechanism configured for operation by a plunger"

The parties have agreed on a meaning for the term "the barrel having a front end portion containing a retraction mechanism configured for operation by a plunger," which appears in claim 25. The proposed construction is "the section of the barrel at the injection end has a retraction mechanism that is configured to be operated by a plunger." Dkt. No. 110 at 1-2. The Court has no reason to disagree and therefore adopts the parties' construction.

4. "a front end configured to operate the retraction mechanism"

The parties have agreed on a meaning for the term "a front end configured to operate the retraction mechanism," which appears in claim 25. The proposed construction is "portion of the plunger closer to the injection end of the syringe that operates the retraction mechanism." Dkt. No. 110 at 1. The Court has no reason to disagree and therefore adopts the parties' construction.

VI. U.S. PATENT NO. 7,351,224

A. Overview

RTI has asserted claims 43, 47, 55, 60, and 61 of the '224 Patent against BD in this lawsuit. Dkt. No. 114. Claim 43 is an independent claim, upon which claims 47, 55, 60, and 61 depend. For reference, the asserted claims are reproduced below (terms to be construed emphasized):

43. A syringe assembly having a retractable needle that is rendered unusable after a single injection of fluid into a patient, the assembly comprising:

a hollow syringe **body** comprising a **barrel** and having a front end portion and a back end portion, the back end portion further comprising at least one radially extending member providing finger grips for the syringe **body;**

a retraction mechanism disposed in the front end portion, the retraction mechanism further comprising a

needle holder having a head portion, an elongated needle holding portion, and a longitudinally extending fluid passageway through the head portion and the elongated needle holding portion, the head portion further comprising an inner head, **a continuous retainer member surrounding the inner head,** and a **bridging portion** disposed between the continuous **retainer member** and the inner head, wherein said **bridging portion** couples the continuous **retainer member** and the inner head to form a fluid seal between the fluid passageway and the **barrel** prior to retraction, and a compressed retraction spring surrounding at least part of the elongated needle holding portion and biasing the inner head toward the back end portion prior to retraction;

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

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

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

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

47. The syringe assembly of claim 43 wherein the **body** further comprises a collar having an open back end, the collar extending rearwardly behind the at least one radially extending member and longitudinally separating the at least one radially extending member from the open back end, and wherein the outer periphery of the **end cap** is in close proximity to the back end of the collar following injection and during retraction.

55. The syringe assembly of claim 43 wherein the retraction cavity is **vented** behind the plunger seal element.

60. The syringe assembly claim 43 wherein the continuous retaining member has an outside mating surface making a fluid seal with the **barrel.**

The syringe assembly of claim 43 wherein the **body** and the elongated needle holder cooperate as a spring guide during compression of the retraction spring.

'224 Patent, 22:35-23:19, 23:32-39, 24:18-19, 24:33-35, 24:36-38 (emphasis added).

B. Claim Construction

1. "body"/"barrel"/"bridging portion"/"retainer member"

The Court construed these terms as part of its analysis of the '733 Patent, of which the '224 Patent is a continuation-in-part. The Court finds no reason to deviate from its prior constructions.

2. "continuous retainer member surrounding the inner head"

The parties propose the following constructions for "continuous retainer member surrounding the inner head," which is present in claim 43. Dkt. No. 114.

RTI	BD
A nonretractable part of the retraction mechanism that encircles the inner head of the needle holder, and retains the retraction mechanism	A nonretractable part of the retraction mechanism, separate from the needle holder, that encircles the inner head of the needle holder, and retains the retraction mechanism by frictional force with the wall of the syringe

RTI and BD proffer the same arguments as those discussed above in connection with the term "retainer member." Dkt. Nos. 111 at 13-14. Once again, the dispute between the parties is two-fold: (1) whether the holding force must be a frictional force, and (2) whether the needle holder and retainer member must be separate parts.

For the reasons stated above, this Court finds that the invention operates through the use of a clamping or fictional force and that there is no requirement that two components be separate parts. Accordingly, the Court finds that the term "continuous retainer member surrounding the inner head" means "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."

3. "end cap"

a. Parties' Positions

The parties offer the following constructions for "end cap," which is present in claims 43 and 47. Dkt. No. 114.

RTI	BD
Back end of the plunger	A separate piece that caps the open end of the plunger

RTI contends that BD's proposed construction improperly limits this term. Dkt. No. 111 at 30-31. RTI believes that nothing in the specification requires the end cap be a separate piece or that it cap the open end of the plunger. *Id*. Instead, RTI contends that the "force fit plug" is the separate piece that caps the end of the plunger, while the end cap is a part of the plunger itself. *Id* . (citing '224, 7:22-24 & Figs. 1-7). In addition, one claim specifically recites that "the end cap has an opening and a closure is installed in the opening." *Id*. (citing '224, 24:16-17 (claim 54)).

In response, BD contends that RTI's proposed construction does not make sense in light of the claim language. Dkt. No. 112 at 32. Specifically, the claims require a "back end with an end cap," and BD believes that RTI's construction would make this requirement nonsensical-a back end with a back end. *Id*. (citing '224, 22:65-23:9 (claim 43)).

b. Court's Construction

The Patent figures depict the end cap as a part of the plunger rather than a separate piece. *See* '224, Figs. 1-7. The Federal Circuit has held that an interpretation of a claim, which would not include a preferred embodiment disclosed in the specification, is "rarely, if ever, correct." Vitronics, 90 F.3d at 1583. This Court finds no reason to require the end cap to be a separate piece, as such a construction would not include the

embodiments depicted in Figures 1-7. This Court, however, also finds no reason to limit the term to these embodiments, in which the end cap is a part of the plunger. The Patent could conceivably cover an alternative embodiment in which the end cap was a separate piece.

In addition, the Patent states that it is the "force fit plug" rather than the end cap that closes the retraction cavity-the open end-at the back of the plunger. '224, 7:33-36. The end cap itself has a "central opening for permanently receiving [the] force fit plug." *Id*. As such, the end cap, in contradiction with the plain meaning of the word "cap," does not necessarily close the open end of the plunger. Instead, it allows the force fit plug to accomplish that function once it is permanently installed within the end cap's opening. This Court, however, also finds no reason to limit the term to this one preferred embodiment-it is possible that the Patent could cover a syringe in which the end cap and force fit plug were a single piece, rather than two separate parts.

Finally, because it is located at the back of the plunger, the Patent describes the end cap as a portion of the plunger with which the thumb contacts during depression. *Id*. ("Plunger has an end cap for depression of the plunger by the thumb.").

Accordingly, the Court finds that the term "end cap" means "a component at the back of the plunger, which may be contacted by the thumb during depression."

4. "wherein the continuous retainer member is releasable from the inner head"

a. Parties' Positions

The parties offer the following constructions for the term "wherein the continuous retainer member is releasable from the inner head," which appears in claim 43. Dkt. No. 114.

RTI	BD
The plunger releases the continuous retainer member from the inner head as the plunger is further depressed in the barrel	The plunger releases the continuous retainer member from the inner head by pushing the continuous retainer member off of the inner head as the plunger is depressed in the barrel to reduce the frictional force with the wall of the syringe

The parties' arguments in connection with this term closely mirror those proffered in connection with the term "releaseably installed by sliding engagement of said retainer member and said inwardly facing surface" construed above. *See* Dkt. Nos. 111 at 19-20 & 112 at 26-27.

b. Court's Construction

For the reasons stated above, this Court finds that the invention operates through the use of a clamping or fictional force. However, since the clamping or frictional forces are already part of this Court's construction of "continuous retainer member," this Court finds that it would be unnecessarily confusing and duplicative to include a reference to those forces in this term's construction. As also discussed above, this Court finds that that the holding force may be released by some other manner than that with which it was installed.

Accordingly, the Court finds that the term "wherein the continuous retainer member is releasable from the inner head" means "the plunger releases the continuous retainer member from the inner head as the plunger is further depressed in the barrel."

VII. CONCLUSION

The Court hereby **ORDERS** the claim terms addressed herein construed as indicated. The table below summarizes the Court's constructions:

Term	Court's Construction
	'773 Patent
body	"a hollow outer structure that houses the syringe's components." A hollow outer structure that houses the syringe's components
barrel	The elongated part of the syringe body including a portion through which the plunger moves during injection
nose	The portion of the syringe at the injection end that has a reduced diameter relative to the barrel.
nose portion	Section of the syringe body that has a reduced diameter relative to the barrel portion of the body.
transition zone	Portion of the syringe located between the barrel and the nose
inwardly facing surface	A surface that faces toward the center of the syringe
retraction mechanism sealingly disposed in the nose	A retraction mechanism sealed in the nose.
retainer member	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
bridging portion	A structure that spans the gap between and connects the retainer member and needle holder
releaseably installed by sliding engagement of said retainer member and said inwardly facing surface	Installed by sliding the retainer member along the inwardly facing surface to engage it with the wall of the syringe, which creates a clamping or frictional force that can be released at a later time
sliding engagement producing a holding force	Sliding the retainer member along the inwardly facing surface of the body produces a clamping or frictional force that maintains the needle holder in the projected position
outwardly facing surface	A surface that faces away from the center of the syringe
	'077 Patent
body	Same as above
barrel	Same as above
vent	An opening that provides an opportunity or means of escape, passage, or release
the barrel having a front end portion containing a retraction mechanism configured for operation by a plunger	The section of the barrel at the injection end has a retraction mechanism that is configured to be operated by a plunger.
a front end configured to operate the retraction mechanism	Portion of the plunger closer to the injection end of the syringe that operates the retraction mechanism.
	'224 Patent
body	Same as above
barrel	Same as above
retainer member	Same as above
bridging portion	Same as above
continuous retainer member surrounding the inner head	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
end cap	A component at the back of the plunger, which may be contacted by the thumb during depression
wherein the continuous retainer member is releasable from the inner head	The plunger releases the continuous retainer member from the inner head as the plunger is further depressed in the barrel

IT IS SO ORDERED.

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Retractable Technologies, Inc. v. Becton Dickinson & Co.

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