

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

**BECTON DICKINSON & CO. and MDC Investment Holdings, Inc,**  
Plaintiffs.

v.

**RETRACTABLE TECHNOLOGIES, INC,**  
Defendant.

Civil Action No. 5:07-CV-137

**Nov. 17, 2008.**

Alistair Byrne Dawson, David J. Beck, Beck Redden & Secrest, Houston, TX, William David Carter, Sr., Mercy Carter Tidwell, L.L.P., Texarkana, TX, Alexandra B. McTague, Wilmer Cutler Pickering Hale & Dorr, New York, NY, Heath A. Brooks, Mark L. Rienzi, Stephanie K. Wood, William G. McElwain, Los Angeles, CA, William F. Lee, Lisa J. Pirozzolo, Wilmer Cutler Pickering Hale & Dorr, Boston, MA, for Plaintiffs.

Roy William Hardin, George E. Bowles, Mark Richard Backofen, Monty Lee Ross, Stephen David Wilson, Locke Lord Bissell & Liddell, LLP, Dallas, TX, Deborah J. Race, Otis W. Carroll, Jr., Ireland Carroll & Kelley, Tyler, TX, G. William Lavender, Lavender Law, Texarkana, AR, for Defendant.

### ***CLAIM CONSTRUCTION ORDER***

**DAVID FOLSOM, District Judge.**

Before the Court is Plaintiffs' Opening Claim Construction Brief. Dkt. No. 49. Also before the Court is Defendant's Responsive Claim Construction Brief, Plaintiffs' Reply Brief, and the Parties' Joint Claim Construction Chart. Dkt. Nos. 52, 53 & 63. This Court held a Markman hearing on September 25, 2008. Dkt. No. 149 & 196. After considering the patents, arguments of counsel, and all other relevant pleadings and papers, the Court finds that the claims of the patents-in-suit should be construed as set forth herein.

#### **I. BACKGROUND**

Plaintiffs Becton Dickinson & Co. and MDC Investment Holdings, Inc. (collectively "Plaintiffs" or "BD") bring this patent infringement suit alleging that Defendant infringes United States Patent No. 6,179,812 ("the '812 Patent"). Dkt. No. 1 & 39. Defendant Retractable Technologies, Inc. ("RTI") denies infringement and asserts the affirmative defenses of invalidity, unenforceability, laches, failure to bring a timely claim, estoppel, and failure to adequately mark. *See* Dkt. Nos. 12 & 40. The Defendant also asserts counterclaims for declaratory judgment of invalidity, non-infringement, and unenforceability. *Id.*

#### **II. LEGAL PRINCIPLES OF CLAIM CONSTRUCTION**

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 recently 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. Conceptoronic, Inc.*, 90 F.3d 1576 (Fed.Cir.1996), and *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111 (Fed.Cir.2004). Thus, the law of claim construction remains intact. 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, construes the claims of the patents in suit below. *See Pioneer v. Samsung*, Civ. No. 2:07-CV-170, Dkt. No. 94 at 2-8 (E.D.Tex. Mar. 10, 2008) (Claim Construction Order).

### III. THE PATENTS-IN-SUIT

The '812 Patent, entitled "Retractable Needle Medical Devices," issued on January, 1992. The Abstract reads as follows:

A safety medical device having a sharpened needle is provided. After use, the needle is retracted so that the contaminated needle is shielded to prevent inadvertent contact with the contaminated needle. In one embodiment, the device includes a barrel and a plunger that is slidable within the barrel. The sharpened needle is operable between a projecting position and a retracted position. In the projecting position, the needle projects forwardly from the front end of the barrel. In the retracted position, the needle is shielded to prevent inadvertent contact with the needle. When the plunger is displaced forwardly to expel fluid from the barrel, the plunger actuates retraction so that the needle is automatically retracted after use. The needle may be included as an element of a needle assembly that is connectable with the barrel. The needle assembly includes a spring for biasing the needle toward the retracted position and a connector for attaching the needle to the barrel.

Plaintiff asserts Claim 1 of the '906 Patent, which is representative of the remaining asserted claim and contains all disputed terms. Claim 1 reads as follows:

1. A medical device comprising:

a barrel having a forward end;

a needle assembly comprising:

a needle operable between a projecting position wherein the needle projects forwardly from the barrel and a retracted position wherein the needle is enclosed within the barrel; and

a block attached to the needle;

a biasing element biasing the needle rearwardly;

a needle retainer having a rearwardly facing shoulder, the needle retainer releasably maintaining the needle

in the projecting position; and

a plunger slidably positioned in the barrel, the plunger having a forward end with an opening sized to receive the needle and a cavity for containing the needle in the retracted position, the plunger comprising

a forward end having an opening sized to receive the needle;

an actuation surface cooperable with the shoulder of the needle retainer to effectuate retraction; and

a disassociable plug disposed forwardly of the actuation surface, and sealing the opening;

wherein upon forward displacement of the plunger, the plug engages the needle assembly, dislodging the plug from the opening, and the actuation surface of the plunger engages the needle retainer displacing the needle retainer so that the needle retainer releases the needle and the biasing element propels the needle assembly rearwardly into the plunger cavity.

#### IV. CLAIM CONSTRUCTION

##### A. Agreed Terms

During the Markman hearing held on September 25, 2008, the parties agreed that the term "actuation surface" should be construed as "a surface that starts or puts something into action or motion." Dkt. No. 73 at 46. The agreed construction shall govern this case.

##### B. Disputed Terms

###### 1. "barrel"

###### a. The Parties' Proposed Constructions

<i>BD</i>	<i>RTI</i>
the elongated cylindrical portion of the syringe body through which the plunger moves during injection	portion of the body of the syringe that is connectable to the needle assembly or spring housing

###### b. The Parties' Positions

BD argues that its proposed construction defines this term according to its plain and ordinary meaning within the field. Dkt. No. 49 at 10. BD contends that barrels are commonly understood to be cylindrical in shape. *Id.* In addition, BD points to "every embodiment" in the specification and argues that each demonstrate that the barrel "is the portion of the syringe through which the plunger moves during injection." *Id.* at 10-11 (citing '812, 15:10-11, 15:62-64, 3:35-38, 6:10-15, & 8:32-47).

BD believes that RTI's construction improperly attempts to define the term by what it is "connectable to." *Id.* at 11. BD first contends that a person of ordinary skill in the art would not understand the term as requiring the barrel to be connectable to a needle assembly or spring housing. *Id.* Next, BD argues that it

would be improper to define barrel as connectable to a needle assembly when the term barrel also appears in claims that do not require a needle assembly at all. *Id.* at 12 (citing '812, claims 4, 5, & 7). Finally, BD believes that RTI's proposed construction would be too confusing because the patent describes other non-barrel parts that also connect to the needle assembly. *Id.* (citing '812, 15:53-55, 16:59-64).

Conversely, RTI believes its construction to be correct because BD disclaimed the use of barrels that did not allow the spring housing to be easily attached or removed. Dkt. No. 52 at 15. RTI contends that during prosecution of an earlier application in the '812 priority chain, BD amended a claim to require the spring holding means to be easily attached and removed from the barrel. *Id.* RTI contends that this amendment was made to overcome a rejection based on prior art and to emphasize a distinction between BD's claimed invention and the prior art. *Id.*

BD responds that RTI's disclaimer arguments are improperly based on a discussion of other claim terms in other patents. Dkt. No. 53 at 5. BD argues that RTI improperly focuses on statements made with regard to a claim that specifically required a barrel having an attachment end, while the presently asserted claim does not include such attachment limitations. *Id.*

### **c. Construction**

A prosecution disclaimer, like prosecution history estoppel, requires a clear and unmistakable disavowal of subject matter. *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1326 (Fed.Cir.2003) ("for prosecution to attach, our precedent requires that the alleged disavowing actions or statement made during prosecution be both clear and unmistakable"). No such disavowal occurred in this case.

During prosecution of U.S. Application Ser. No. 07/378,275, which is part of the priority chain of the '812 Patent, the patentee added a claim that affirmatively recited a barrel having an "attachment end." *See* Dkt. No. 52, Ex. 7 at 8. This attachment end would allow for a greater degree of interchangeability between various needles and barrels. *Id.* at 13. This attachment feature also allowed this claim to be distinguished from one piece of prior art that taught away from a "dissociable spring holding means." *Id.*

The addition of an attachment feature, however, was limited to one claim in the prior application. Conversely, the presently asserted claim does not contain any such limitation. This Court finds that statements made in a prior application regarding a limitation are not relevant to construction of the present claim in which that limitation is absent. *See Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1305-06 (Fed.Cir.2001) (finding no plausible reason why the prosecution histories of related patents would be relevant to claim construction when the "present case involves the absence of a claim term").

The specification of the '812 Patent discloses an alternative embodiment in which "attachment means may be provided for the spring housing and the barrel such that the spring housing can be attached and removed from the barrel." '812, 5:18-22. In addition, the Abstract also states that the "needle *may* be included as an element of a needle assembly that is connectable with the barrel." '812, Abs. (emphasis added). This Court, however, finds it inappropriate to limit the asserted claim to one alternative embodiment or one broad statement within the Abstract. *See Phillips*, 415 F.3d at 1323 (limitations from the specification may be imported into the claims where it is clear that the claims and embodiments in the specification are strictly coextensive).

Moreover, other non-asserted claims specifically require that a spring housing be attached to and separable

from the barrel. '812, 17:49-50, 18:12-13 (Claims 20 & 26). In addition, other claims require "connectors" allowing the needle assembly to be attached to, and presumably removed from, the barrel. ' 812, 16:42-55 (Claim 10). This Court finds no reason to depart from the principle of claim differentiation and read such limitations into asserted Claim 1. *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").

Finally, this Court is cognizant of the general rule of claim construction that favors the ordinary and customary meaning of term unless no such meaning is available. *See Phillips*, 415 F.3d at 1316-17.

For these reasons, the Court construes the term "barrel" to mean "the portion of the body of the syringe through which the plunger moves during injection."

## 2. "needle retainer"

### a. The Parties' Proposed Constructions

<i>BD</i>	<i>RTI</i>
one or more elements that maintain the needle in the projecting position	a device that holds or maintains the needle in position using resilient fingers

### b. The Parties' Positions

RTI argues that BD's proposed construction improperly attempts to broaden this term to cover any structure that retains the needle against spring pressure. Dkt. No. 52 at 6. RTI contends that the history of the '812 Patent specification "shows conclusively that the term was coined to refer specifically to [a] fingers and hook structure." *Id.* In addition, RTI argues that BD's proposed construction describes numerous other structures within the specification and is thus too imprecise. *Id.*

RTI proposes that the first time the term "needle retainer" appeared in the specification was in the sixth application in the '812 priority chain. *Id.* at 8. Prior to that time, applications had used some derivation of the term "resilient fingers." *Id.* at 7-8. RTI also contends that the only two embodiments in the current patent that use the term "needle retainer" describe the piece as having resilient fingers. *Id.* at 8-9. Thus, RTI believes that BD's proposed construction would read out the "only definitional features that the patent consistently teaches, namely resilient fingers." *Id.* at 9.

Finally, RTI argues that the patentee clearly disclaimed the use of any needle retainer that did not have resilient fingers. *Id.* at 13. RTI contends that BD used the resilient finger structure to overcome a piece of prior art that had been used by the examiner to reject certain claims during an earlier application. *Id.* (citing Ex. 6a at 11-12). RTI contends that this prior disclaimer was never rescinded, and thus applies to the '812 Patent. *Id.* at 14 (citing *Hakim v. Cannon Advent Group*, 479 F.3d 1313 (Fed.Cir.2007)).

In response, BD argues that RTI seeks to import a "resilient fingers" limitation from other patents and other claims even though such language is clearly absent from the presently asserted claim. Dkt. No. 53 at 2. Second, BD contends that disclaimer did not occur here because the prosecution history of a related patent is relevant to this claim construction only where there is a common claim term at issue. *Id.* at 2-3 (citing *Advanced Cardiovascular*, 265 F.3d at 1305-06). Here, the alleged disclaimer occurred during prosecution of a patent claim that expressly included a "resilient fingers" limitation. *Id.* at 3. BD argues that there are no

such common claim terms in dispute here and that RTI's real argument is with the absence of a claim term. *Id.* In any case, BD argues that the cited prosecution statements do not meet the requirements of a clear and unmistakable disavowal of subject matter. *Id.* at 4.

### c. Construction

There is no argument among the parties that the '812 Patent was intended to have broader claims than earlier applications. *See* Dkt. No. 53 at 4-5. A patentee has the right to refile an application and attempt to broaden claims. *Hakim*, 479 F.3d at 1317. The patentee, however, may not recapture claim scope that had previously been surrendered or disclaimed. *Id.* As discussed above, however, a prosecution disclaimer requires clear and unmistakable disavowal of subject matter. *Omega Eng'g*, 334 F.3d at 1326. No such disavowal occurred in this case.

In an earlier application, the patentee made statements in connection with a needle retainer that explicitly contained resilient fingers. *See* Dkt. No. 53 at 4. After the patent office had rejected the claimed needle retainer as anticipated by a piece of prior art, the patentee argued that the rejection was improper because the reference did not contain the recited resilient fingers. *Id.* In doing so, the patentee did not clearly and unmistakably disavow all needle retainers without resilient fingers. Instead, the patentee merely stated that an express limitation was not present in a piece of prior art.

Having found no disclaimer, this Court turns to the intrinsic evidence of the '812 Patent and related applications. The Federal Circuit has consistently held that the specification, "informed, as needed, by the prosecution history," is the "best source for understanding a technical term." *Phillips*, 415 F.3d at 1315. In addition, the prosecution history of a related patent "can be relevant if, for example, it addresses a limitation in common with the patent in suit." *Advanced Cardiovascular*, 265 F.3d at 1305. As RTI points out, the term "needle retainer" was used in related patents and thus the prosecution histories of those patents may be relevant.

The term "needle retainer" appeared for the first time in the '812 priority chain in June of 1996. *See* Dkt. No. 52 at 8. At that time, the two descriptions of the term described it as having resilient fingers. *Id.* at 9. There is nothing in the prosecution history of the prior patent, however, to suggest that the term should be limited to such an embodiment. Thus, although prior patents and applications address the same limitation, this Court finds no evidence to suggest that they limit "needle retainer" to embodiments having "resilient fingers."

Moreover, the specification of the '812 Patent suggests that the term should not be limited to an embodiment having such fingers. In one embodiment of the '812 Patent, the needle retainer provides the spring housing with "a latch means, *such as* a plurality of fingers ...." '812, 12:22-38 (emphasis added). This permissive "such as" language suggests that the needle retainer may secure the spring housing with some means other than fingers. In addition, the term "latch" provides both an indication of the function that the needle retainer performs and a broad, ordinary meaning for the term.

Finally, asserted Claim 1 requires that the needle retainer "releasably maintain" the needle in the projecting position. '812, 15:7-9. In more plain language, the needle retainer keeps the needle in the forward position until the retainer is activated or released in some way. The specification suggests varying ways in which this release can take place; it can "flex" or "break," or be "deformed," or "forcibly spread." *See e.g.* '812, 5:2-3, 5:66-6:3, 7:1-2, 7:20-23. This Court, however, finds no reason to limit the term to those preferred embodiments.

For these reasons and in accordance with legal principles discussed throughout this order, the Court construes the term "needle retainer" to mean "a latching mechanism that keeps the needle in place until activated or released."

### 3. "rearwardly facing shoulder"

#### a. The Parties' Proposed Constructions

<i>BD</i>	<i>RTI</i>
a surface of the needle retainer that faces away from the injection end of a syringe	rearwardly facing surface having the shape of or being like a human shoulder

#### b. The Parties' Positions

BD argues that its proposed construction both properly orients the "rearwardly" limitation as facing away from the injection end and properly defines the "shoulder" limitation as a surface of the needle retainer. Dkt. No. 49 at 16. In addition, BD points to the various different shapes that shoulders referenced in the specification may take (e.g. "radially protruding" or "outwardly angled." *Id.* at 6-7 (citing '812, 7:55-57, 4:57-61). BD thus contests a construction that would limit the shape of the shoulder to one "like a human shoulder." *Id.* at 7. BD contends that none of the shoulders referred to in the patent bear any resemblance to a human shoulder. *Id.*

To support its construction, RTI argues that, in ordinary use, the term shoulder describes a structure that "calls to mind a human shoulder, especially in the way it projects." Dkt. No. 52 at 16. Such a structure "generally involves a lateral extension from a longer vertical element ... although one or both surfaces could be angled." *Id.* RTI also contends that numerous prior art references and dictionary references also use the term shoulder in a similar fashion. *Id.* at 16-17.

#### c. Construction

This Court finds no intrinsic evidence to support the proposition that the "shoulder" in Claim 1 should be limited to the shape of a human shoulder. Indeed, some the "shoulders" referenced in the specification do not have such a shape. '812, 4:57-61, 7:55-57. Thus, this Court finds that the term should be construed broadly and in accordance with its plain and ordinary meaning.

In addition, the parties do not seem to dispute the fact that "rearwardly" references the plunger end of the syringe. This Court finds no reason to believe otherwise.

For these reasons and in accordance with legal principles discussed throughout this order, the Court construes the term "rearwardly facing shoulder" to mean "an angled or offset surface that faces away from the injection end of the syringe."

### 4. "disposed forwardly of the actuation surface"

#### a. The Parties' Proposed Constructions

<i>BD</i>	<i>RTI</i>
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positioned such that the plug extends beyond the actuation surface toward the injection end of the plunger

located forward of the actuation surface

## **b. The Parties' Positions**

The main dispute over this term involves whether the claimed "dissociable plug" must be in a position entirely forward of the activation surface. BD argues that Figure 4 of the '812 Patent makes it clear that "the plug extends past the actuation surface, but is not completely located forward of it..." Dkt. No. 49 at 20. RTI responds that BD's construction improperly expands the ordinary meaning of the term "forwardly." Dkt. No. 52 at 19. Although Figure 4 of the Patent admittedly shows a plug that merely extends beyond the actuation surface, RTI argues that had the Patent intended to cover such a structure it would have claimed it, which RTI contends it did not do. *Id.* at 20.

In addition, BD also claims that its construction, like the previous term, properly orients the "forwardly" limitation as being toward the injection end. Dkt. No. 49 at 20.

## **c. Construction**

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. Absent "highly persuasive evidentiary support" to the contrary, such a construction is not proper. *Id.* Figure 4 of the '812 Patent clearly shows a dissociable plug that is partially in front and partially behind the associated "actuation surface." Thus, a construction that would require the plug to be completely in front of the actuation surface would not include the embodiment depicted therein. This Court finds no persuasive evidence to suggest that such a construction is proper. Instead, the Court construes the term according to its plain and ordinary meaning.

In addition, the parties do not seem to dispute the fact that "forwardly" references the injection or needle end of the syringe. This Court finds no reason to believe otherwise.

For these reasons and in accordance with legal principles discussed throughout this order, the Court construes the term "disposed forwardly of the actuation surface" to mean "positioned so that some portion extends beyond the actuation surface toward the needle end of the syringe."

## **5. "engage/engagement"**

### **a. The Parties' Proposed Constructions**

<i>BD</i>	<i>RTI</i>
meshes, mates or contacts and works in conjunction with	meshes or mates and works in conjunction with

### **b. The Parties' Positions**

The main dispute over this term involves whether "engage" must involve a meshing or mating, or whether the term can involve mere "contact." BD argues that nothing in the claim language requires that engagement occur by meshing or mating. Dkt. No. 49 at 21. Moreover, BD points to a portion of the specification showing that engagement can be accomplished by an action that merely "abuts against." *Id.* at 22 (citing '812, 5:60-66).



RTI responds that BD's construction improperly broadens the term "engage." Dkt. No. 51 at 18. RTI supports its construction with definition from "various dictionaries." *Id.* In addition, RTI argues that all disclosed surfaces that are discussed as being engaged are "complimentary surfaces that mate with each other." *Id.* at 18-19 (citing '812, 4:61-67, 5:4-7, 7:34-37, 7:56-60, 11:19-22, and 13:6-9).

### **c. Construction**

The Patent specification is "the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315. The '812 Patent specification allows surfaces to engage each other by merely abutting against one another. ' 812, 5:60-66. In other words, the specification allows engagement to be accomplished by mere contact. Moreover, an interpretation that allows for mere "contact" would necessarily encompass "meshing" or "mating."

For these reasons and in accordance with legal principles discussed throughout this order, the Court construes the term "engage/engagement" to mean "contacts and works in conjunction with."

## **V. CONCLUSION**

Accordingly, the Court hereby **ORDERS** the disputed claim terms construed consistent herewith.

E.D.Tex.,2008.

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

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