

UNITED STATES DISTRICT COURT
 DISTRICT OF MASSACHUSETTS

MILLIPORE CORPORATION,)	
)	
Plaintiff,)	
)	CIVIL ACTION NO.
v.)	09-10765-DPW
)	
W.L. GORE & ASSOCIATES, INC.,)	
)	
Defendant.)	

MEMORANDUM AND ORDER
 September 20, 2010

Plaintiff Millipore Corporation ("Millipore") brought this action against Defendant W.L. Gore & Associates, Inc. ("Gore") for infringement of U.S. Patent No. 7,293,477 (the "'477 Patent"). The '477 Patent relates to fluid sampling devices and kits comprising sterilized components of fluid sampling devices. In response, Gore has filed counterclaims for declaration of non-infringement, invalidity, and inequitable conduct, and has moved for summary judgment of non-infringement.

Under Federal Circuit law, "[e]valuation of summary judgment of non-infringement requires two steps-proper claim construction and comparison of those claims to the accused product." *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1350 (Fed. Cir. 2010). Both steps are presented by the motion for summary judgment now before me. After addressing the background of the

case and the relevant legal principles, I will construe the disputed claim terms and will compare the claims at issue to the accused products.

I. BACKGROUND

A. *Technical Background*

It is common practice in many industries to have manufacturing processes occur in fluid receptacles. For instance, pharmaceutical products are produced in chemical reactors and milk is pasteurized in pasteurization vats. To ensure the quality of the final product, these processes are customarily monitored by withdrawing fluid samples from time to time. Generally, it is important to keep the fluid samples unaltered, thereby requiring the withdrawal of sample fluid in a sterile manner. A sterile environment means being free from any contaminants that may affect the manufacturing process or the integrity of the sample, including bacteria, fungi, and viruses.

In order to withdraw samples from fluid receptacles, industries have used devices that were integrated with fluid receptacles. Integrated devices required laborious steam sterilization and cleaning which caused risk of sterility failure as well as significant equipment downtime. Other prior fluid sampling devices required the installation of custom fitted ports onto fluid receptacles. Customization of fluid receptacles resulted in additional costs. In light of these disadvantages,

"a need exist[ed] for a fluid sampling device that [wa]s sufficiently inexpensive in its construction to promote single-use disposability, capable of being used in standard industrial ports commonly found in fluid receptacles, and capable of several good sterile fluid sample withdrawals per sterilization cycle and/or prior to being exhausted." '477 Patent col. 1 ll. 61-67.

B. '477 Patent

On November 13, 2007, the United States Patent and Trademark Office ("PTO") issued the '477 Patent to Millipore. The '477 Patent is entitled "Disposable, Pre-Sterilized Fluid Receptacle Sampling Device" and consists of Claims 1 to 5, where Claims 1 and 5 are independent and Claims 2, 3 and 4 are dependant. '477 Patent col. 8 l. 37 - col. 10 l. 19.

As expressed in the specification, the '477 Patent "provides a fluid sampling device comprising a port insert, a plurality of flexible conduits, and a plurality of sample containers." *Id.* at col. 2 ll. 3-5. The purpose of the '477 Patent is to provide "a fluid sampling device that enables the withdrawal of several samples of fluids from a fluid receptacle, wherein said withdrawal occurs in a substantially sterile manner, and wherein inter-sample cross-contamination is substantially discouraged." *Id.* at col. 2 ll. 40-45. Users of the '477 Patent can withdraw one or more sterile fluid samples sequentially or simultaneously. Thereafter, the devices of the '477 Patent can be easily removed

and replaced with a new sampling unit. The devices of the '477 Patent are designed to be simple in construction, inexpensive to manufacture, usable with standard industrial tanks or vats, and disposable after use, thereby eliminating the need for cleaning and resterilization.

C. *Gore's Accused Products*

Millipore contends that Gore infringes the '477 Patent by making, selling, and importing its Five-Valve STA-PURE™ Fluid Sampling System and Single-Valve STA-PURE™ Fluid Sampling System (collectively, the "Accused Products"). Specifically, Millipore contends that the Five-Valve Sampler infringes Claims 1 to 5 and that the Single-Valve Sampler infringes Claim 5, both of these infringements are said to be literal as well as under the doctrine of equivalents. The Five-Valve Sampler and the Single-Valve Sampler use a similar valve structure, which is the focus of Millipore's patent infringement allegations.

D. *Procedural History*

Millipore commenced this action on May 11, 2009 against Gore alleging infringement of the '477 Patent (Count I). Gore counterclaimed on August 5, 2009 seeking declaratory judgment of non-infringement and invalidity of the '477 Patent.

On January 20, 2010, Gore filed an Opening Claim Construction Brief disputing a total of nine claim terms contained in Claims 1 and 5 of the '477 Patent. Simultaneously,

Gore filed a motion for summary judgment of non-infringement based on its proposed construction of the cap-related limitations recited in the asserted claims. For its part, Millipore filed an Opening Claim Construction Brief disputing seventeen claim terms used in Claims 1 to 5 of the '477 Patent.

On May 19, 2010, I had a hearing to discuss claim construction and address the pending motions. During the hearing, I indicated my initial inclinations on claim construction while reserving the right to refine them after taking the claim construction under advisement. I set a further hearing regarding Gore's motion for summary judgment for September 8, 2010. This memorandum will definitively resolve the outstanding claim construction questions and the pending summary judgment motion.

II. CLAIM CONSTRUCTION

At issue are disputed claim terms from Claims 1 to 5 of the '477 Patent.¹ I must construe the disputed claim terms

¹ Following the May 19, 2010 hearing, Millipore filed Supplemental Infringement Contentions modifying in part its claim construction positions. In particular, Millipore now agrees with the initial inclinations regarding construction I expressed during the hearing as to certain claim terms-i.e., "displaceable," "linearly displaceable," "shaped to fit substantially water-tight within," "port insert," "port," and "connected to." For other claim terms - i.e., "cap," "positioned adjacent," "integral locking means in the form of an anchor," and "integral block"- Millipore requests refinements in the provisional construction I offered at the hearing. For purposes of completeness and ease of understanding the disputes as they

according to the settled principles of claim construction.

A. Legal Considerations

Under Federal Circuit law, it is a "bedrock principle" that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). "[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

Claim terms are "generally given their ordinary and customary meaning." *Phillips*, 415 F.3d at 1312 (quoting *Vitronics Corp. v. Conceptronics, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). This refers to "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313. Thus, when the ordinary meaning of claim language is readily apparent, claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314. If this meaning is, however, not readily apparent, the court should

have unfolded, I will address the parties' initial claim construction as well as the current positions of the parties regarding the claim terms in dispute.

review "the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics*, 90 F.3d at 1582. *First*, the court should "look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." *Id.* *Second*, the court should "review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." *Id.* The Federal Circuit has repeatedly stated that "[c]laims must be read in view of the specification, of which they are part." *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995)) (alteration in original).

If the meaning of a claim term remains ambiguous after the intrinsic evidence is consulted, the court may "rely on extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" *Phillips*, 415 F.3d at 1317 (quoting *Markman*, 52 F.3d at 980). However, the Federal Circuit has instructed that extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Id.* at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

B. Application to the Disputed Claim Terms

1. "Elongate Members"

Millipore argues that the terms "elongate members" used in Claims 1 and 5 of the '477 Patent should be construed as "a part of extended length." Gore contends, however, that the proper construction of the "elongate members" is "a rigid and monolithic structure of extended length." Gore's argument is derived from the specification. See '477 Patent col. 4 ll. 57-58 ("[e]ach of the elongate members **30** are monolithic and rigid."). The issue is therefore whether such a limitation can be read into the claims.

Because the specification is highly relevant to the claim construction analysis, it is considered to be "the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). Nonetheless, "[w]hen consulting the specification to clarify the meaning of claim terms, courts must take care not to import limitations into the claims from the specification." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009) (en banc). The Federal Circuit has recognized that "the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice." *Phillips*, 415 F.3d at 1323.

In construing claim terms, "the court's focus [must] remain[] on understanding how a person of ordinary skill in the art would understand the claim terms." *Id.* For example, "although the specification often describes very specific embodiments of the invention," the Federal Circuit has "repeatedly warned against confining the claims to those embodiments." *Id.* In particular, "[w]hen the specification describes a single embodiment to enable the invention, [a] court will not limit broader claim language to that single application unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Abbott*, 566 F.3d at 1288 (internal quotation marks and citation omitted).

Here, I find Millipore's intention to limit the claim term to "rigid and monolithic" elongate members to be clear from the language of the claims and the specification, as well as from the prosecution history. *First*, the term "rigid" is expressly provided in Claim 1 to describe the elongate members. See '477 Patent col. 8 ll. 42-43 ("rigid elongate members").² *Second*, the specification expressly emphasizes the need for elongate members to be rigid:

The mechanisms underlying the operation of the fluid sampling device **100** call for a certain rigidity in the configuration of elongate members **30**. Aside from

² See Section II.B.10. *infra* for the construction of the term "rigid" used in Claim 1 of the '477 Patent to describe the elongate members.

durability, the rigidity allows the members to be pushed through the shaft into their open positions with sufficient and appropriate force to overcome the frictional forces that create the liquid tight seal, without the elongate members flexing, bending, crumpling, or otherwise deforming, such circumstances potential leading to sampling failures, and/or more catastrophically, breach of extant sterile conditions.

Id. at col. 7 ll. 9-18. *Third*, Millipore's intention to limit the claim term is also reflected in the prosecution history record during which Millipore expressly distinguished the '477 Patent over the Arthun device, because that product "fails to teach a rigid and/or monolithic elongate member." '477 Patent, Prosecution History Record, p. 57. Similarly, Millipore stated in the prosecution history record that "Claim 13 [issued as Claim 1] requires a rigid monolithic elongate member which is neither taught nor suggested by Arthun." *Id.* at 58.

Consequently, I construe the claim term "elongate members" as "a rigid and monolithic structure of extended length."

2. Cap-Related Limitations

The parties dispute the claim construction of the limitations related to the term "cap" used in Claims 1 and 5 of the '477 Patent. See '477 Patent col. 8 ll. 46-50 ("the elongate members having a cap and an opening to a passage of the elongate member behind the cap, the elongate members being displaceable between 'open' and 'closed' positions such that liquid can flow into the opening behind the cap") (Claim 1); *id.* col. 9 l. 20 - col. 10 l. 2 ("said one or more elongate members having a cap and

an opening to a passage of each of the one or more elongate members behind the cap") (Claim 5). Here, three aspects of the term "cap" are in dispute: (a) its function, (b) its structure, and (c) its location *vis-à-vis* the opening.

a. Function of the "Cap"

Millipore argues that the main function of the term "cap" is to create a tight seal and that the cap can, but is not required to, prevent the elongate member from being pulled out from the shaft. Gore contends, however, that the function of the cap is to create a liquid tight seal as well as to prevent the elongate member from being pulled out, both functions being inherent to the cap.

As a basis for their contentions, both parties rely on the passage of the specification that lists several features depicted in Figure 2, i.e., the cap, the anchor and the block, that "should be provided to prevent the elongate means from being prematurely moved into its open position, as well as prevent it from being moved too far past its open and/or closed positions." *Id.* at col. 7 ll. 38-41. In particular, the specification provides that "[a] cap [65³] can also be provided on the front 30A of member 30 to - in addition to creating a liquid tight seal

³ The specification of '477 Patent refers to the cap depicted in Figure 2 as "24" rather than "65." '477 Patent col. 7 ll. 51-53. The parties agree, however, that this is a typographical error and that the proper designation for the cap depicted in Figure 2 is "65."

- prevent the member 30 from being pulled out." *Id.* col. 7 ll. 51-53. The issue is therefore whether the pull-out prevention function contained in the specification can be imported into Claims 1 and 5 of the '477 Patent.

Phillips is instructive in resolving this issue. In *Phillips*, the disputed term was "baffles" recited in independent claim 1 of the patent as applied to vandalism-resistant wall panels. 415 F.3d at 1310-11. The specification of the patent discussed positioning the baffles so as to deflect projectiles, a function served by the baffles that was also recited in some of the claims but not in claim 1. *Id.* at 1325. The court found that the mere fact that the specification discussed the projectile-deflecting function of the baffles did not, however, imply that in order to qualify as baffles within the meaning of claim 1, the structures of the baffles necessarily had to serve this function in all the embodiments of all the claims; rather the function was a limitation only in the claims that specifically recited projectile-deflecting baffles. *Id.* The specification of the patent also discussed several other functions served by the baffles and depicted those in several figures. *Id.* Likewise, the court held that the mere fact that the written description of the patent at issue set forth multiple objectives to be served by the baffles did not require that the term "baffles" be construed so as to require that the baffles

serve all of the recited functions in every circumstance. *Id.* at 1326-27.

Although the present case differs from *Phillips* in the sense that the claims of the '477 Patent do not provide that the cap must perform a specific function and that the specification discloses only *one*, rather than multiple, embodiment with a cap, the logic of *Phillips* still applies. In this case, although the single embodiment described in the specification of the '477 Patent envisions a cap that would "prevent the member from being pulled out," '477 Patent col. 7 ll. 51-53, the written description does not contain a clear disavowal of embodiments lacking the pull-out prevention function. As noted in *Phillips*, "[t]he fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives." 415 F.3d at 1327 (quoting *Liebel-Flarsheim*, 358 F.3d 898, 908 (Fed. Cir. 2004)) (alteration in original). Apart from the passage of the specification relied upon by the parties, there is no evidence in either in the patent itself or in the prosecution history that the intention of the patentee was to require the cap to perform a dual function, i.e., creating a liquid tight seal and preventing the elongate member from being pulled out. What is clear from the prosecution history is that the cap was added to overcome prior art, the

Arthur invention in particular. See '477 Prosecution History Record, p. 108. But nowhere in the prosecution history is there any evidence that the patentee's intention in adding a cap was thereby to add a limitation that specifically prevented the elongate member from being pulled out.

Importantly, the specification itself indicates that the means described in Figure 2 "will vary depending on the ultimate configuration of the fluid sampling device" and that "the embodiment described in Figure 2 illustrates certain *examples* thereof." '477 Patent, col. 7 ll. 42-44 (emphasis added). Along the same lines, the specification further provides that:

Although certain embodiments of the invention are disclosed, those skilled in the art, having the benefit of the teaching of the present invention set forth herein, can affect numerous modifications thereto. These modifications are to be construed as encompassed within the scope of the present invention as set forth in the appended claims.

Id. at col. 8 ll. 29-34. It is therefore clear, at least from the specification, that the intention of the patentee was not to limit the claims to the particular embodiment described in Figure 2. In the absence of a demonstrated intention on the part of Millipore to the contrary, it would be improper to construe the cap referred to in Claims 1 and 5 of the '477 Patent as being required to prevent the elongate members from being pulled out. See *Abbott*, 566 F.3d at 1288 ("[w]hen the specification describes a single embodiment to enable the invention, [a] court will not

limit broader claim language to that single application unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.") (internal quotation marks and citation omitted); see also *Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1355 (Fed. Cir. 2003) ("Absent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that the scope of the invention is limited to that context.").

Accordingly, I construe the term "cap" as "a feature that creates a liquid tight seal and can, but is not required to, prevent the elongate member from being pulled out of the shaft."

b. Structure of the "Cap"

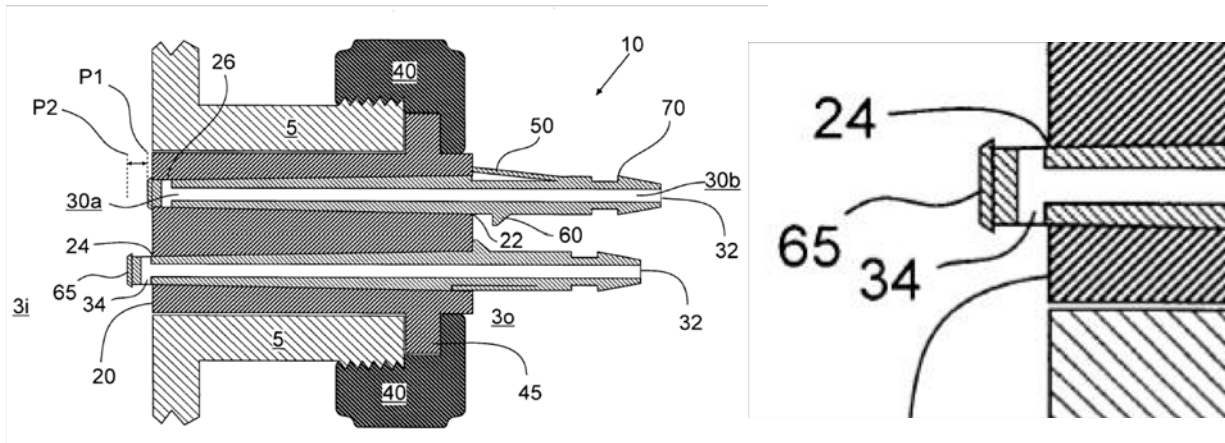
Millipore construes the term "cap" used in Claims 1 and 5 of the '477 Patent as "an element distinct from the elongate member." To the contrary, Gore contends, based on its reliance on the term "having" used in the asserted claims, that the cap is a part of the structure of the elongate members and that these two elements are therefore not distinct from each other.

The term "having" is used in Claims 1 and 5 of '477 Patent to introduce features and attributes of the elongate members. '477 Patent col. 8 ll. 46-47 ("the elongate members having a cap and an opening") (claim 1); *id.* col. 9 l. 20 - col. 10 l. 1

("said one or more elongate members having a cap and an opening to a passage"). Such features are not limited to the cap but also refer to other elements, such as the front and the rear. See *id.* col. 8 ll. 43-44 ("the elongate members having a front and a rear"). I note that other terms, such as "in fluid communication with" or "connected to," are used in the claims to refer to separate elements of the elongate members. See *id.* col. 8 ll. 54-55 ("each flexible conduit in fluid communication with an individual passage of a member"); *id.* col. 10 ll. 10-11 ("one or more sterilized flexible tubes connected to said back of each of said one or more elongate members"). The patentee could have used the term "connected to" instead of the term "having" to introduce the cap as a structure separate from the elongate members in Claims 1 and 5 of the '477 Patent. Given that the patentee chose not to do so, there is a presumption that the cap and the elongate member are part of the same structure. See *Phillips*, 415 F.3d at 1314 ("Differences among claims can also be useful in understanding the meaning of particular claim terms.").

This presumption is consistent with Figure 2 of the '477 Patent. As seen below, Figure 2 uses different shading patterns to show whether features are part of, or distinct from, other features. For instance, the elongate members "30" are designated with different shading patterns than the body "20," thereby suggesting that the elongate members and the body are separate

structures. However, the elongate members "30" and the cap "65"⁴ use the same shading patterns and therefore support the presumption that these two elements are part of the same structure.



Also consistent with the presumption that the cap is part of the elongate member is the prosecution history record. The originally presented claims did not recite a cap; the cap was added to the claims by amendment filed on May 2, 2006. Shortly after this amendment, the patent examiner listed prior art references that he found to be "pertinent." Among these references, the examiner distinguished the device Jaeger from the '477 Patent, indicating that "Jaeger samples wine, presumably in a sterile manner, *but no single "member" includes both a cap and an opening to a passage.*" '477 Patent, Prosecution History

⁴ See Note 3 *supra* for discussion on the element designated as "65" in Figure 2.

Record, p. 124 (emphasis added). Contrary to the cap disclosed in the '477 Patent, the cap and the opening provided in Jaeger were not, according to the examiner, "collectively a single member." *Id.* This passage from the prosecution history demonstrates that, in the view of the patent examiner, the cap is part of the elongate member.

Based on the language of the claims and specification of the '477 Patent, as well as on the prosecution history, I therefore construe the term "having" to mean that "the elongate members and the cap are part of the same structure."

c. Location of the Opening vis-à-vis the "Cap"

Millipore initially argued that the term "behind" used in Claims 1 and 5 of the '477 Patent should be given its ordinary meaning, namely "beyond in depth." Gore contends, however, that no construction of the term "behind" is necessary.

When the ordinary meaning of claim language as understood by a person of skill in the art is readily apparent even to lay judges, claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. "In such circumstances, general purpose dictionaries may be helpful." *Id.* Here, because the meaning of the term "behind" is readily apparent, I construe the term "behind" as "at the back of." See WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY at 199 (2002). Consequently, the

location of the opening *vis-à-vis* the cap is to be construed as "the opening is located at the back of the cap."

3. "Open" and "Closed" Clauses

The terms "open" and "closed" appear in Claims 1 to 5 of the '477 Patent to describe the position of the elongate members. See '477 Patent col. 8 ll. 48-52 ("the elongate members being displaceable between 'open' and 'closed' positions such that fluid can flow into the opening behind the cap and through said passage in each member when in said 'open' position, but not in said 'closed' position.") (Claim 1); *id.* col. 10 ll. 2-4 ("said one or more elongate members being movable within said one or more shafts from an open position to a closed position") (Claim 5).

Gore seeks to have the "open" and "closed" clauses construed as a whole to mean that "the elongate members are opened by pushing *forward* and closed by pulling them *backwards* from the open position." (emphasis added.) To the contrary, Millipore argues that the "open" and "closed" clauses should not be construed as a whole; rather the related disputed terms "moved," "moveable," "displaceable," and "linearly displaceable" should be construed separately to provide a more meaningful construction.

Contrary to Gore's contentions, neither the language of the specification nor the prosecution history supports Gore's restriction of the movement of the elongate members to "forward"

or "backwards." In fact, the patentee specifically stated in the prosecution history record that "the elongate member . . . can be opened by moving them [sic] forward or by rotating them [sic]."

'477 Patent, Prosecution History Record, pp. 57, 87, 108

(emphasis added). I turn then to construe the related claim terms.

a. "Displaceable" and "Linearly Displaceable"

The term "displaceable" appears in independent Claim 1 and the term "linearly displaceable" in dependant Claim 2 of the '477 Patent. See '477 Patent col. 8 ll. 48-50 ("the elongate members being displaceable between 'open' and 'closed' positions such that fluid can flow.") (Claim 1); *id.* col. 8 ll. 61-63 ("each of said elongate members are linearly displaceable within one of said shafts between said 'open' and 'closed' positions.") (Claim 2). Millipore initially argued that the term "displaceable" should be given its ordinary meaning, namely "physically movable out of a position." Additionally, Millipore contended that the term "linearly displaceable" contained in Claim 2 should be given the same meaning, except that it should be limited to a linear movement as distinct from a rotational movement.

The first issue is therefore to determine whether the limitation contained in Claim 2 can be read into Claim 1, thereby excluding rotational movement. Under the doctrine of claim differentiation in patent law, "the presence of a dependent claim

that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips*, 415 F.3d at 1315. Consequently, I conclude that the limitation found in Claim 2 should not be read in Claim 1. This conclusion is further supported by the prosecution history, which suggests that there is a difference between linear and rotational movement. For instance, in prosecuting the patent, Millipore characterized the elongate member of the sampling device as being "capable of linear and rotation [sic] movement to be selectively moved from a closed to open position." '477 Patent, Prosecution History Record, p. 60. Additionally, Millipore articulated the broad scope of the term "displaced" to mean that "claim 1 [as filed] is not limited to either movement [linear or rotational] and that the claims as filed have always covered both movements." *Id.* at 107.

This treatment of the term "displaceable" is consistent with ordinary usage as reflected in dictionaries. As noted in *Phillips*, a court may rely on dictionary definitions, "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." 415 F.3d at 1322-23 (quoting *Vitronics*, 90 F.3d at 1584 n.6). Because I find that the dictionary definitions provided for the term "displaceable" are not contradicted by the specification or any other patent documents, I construe this term, as Millipore now concedes, to mean "that can be displaced," i.e. "that can be

put out of place." See WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY at 654 (2002). Accordingly, I construe the term "linearly displaceable" in the same fashion with the exception that the movement be limited to linear and not rotational.

b. "Movable" or "Moved"

The terms "movable" and "moved" are found in Claim 5 of the '477 Patent. See '477 Patent col. 10 ll. 3-4 ("elongate members being movable within said one or more shafts from an open position to a closed position"); *id.* col. 10 l. 17 ("elongate members are moved to said open position"). Millipore contends that the term "movable" should be given its ordinary meaning, namely "capable of being moved." Millipore further argues that the term "moved" should be construed to refer to the past principle of the verb to move, i.e., "to change position." In making this argument, Millipore relies on dictionary definitions.

As noted above, when the meaning of claim language is readily apparent, "general purpose dictionaries may be helpful." *Phillips*, 415 F.3d at 1314. Consequently, I adopt Millipore's construction of the terms "movable" and "moved," as being respectively "capable of being moved" and the past principle of the verb to move, i.e., "to change position." See WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY at 1479-80 (2002).

4. "Positioned Adjacent"

The term "positioned adjacent" used in Claim 1 of the '477

Patent designates which end of the elongate member is nearest to the fluid receptacle. See '477 Patent col. 8 ll. 43-46 ("the elongate members having a front and a rear with the front of the elongate members being positioned adjacent a fluid receptacle"). Millipore argues that this claim term should be given its ordinary meaning, which includes "nearby," but should not require that there be contact between the elongate member and the fluid receptacle. Gore counters that the term "positioned adjacent" should be construed as "next to or adjoining, with no intervening structure between the elongate members and the fluid receptacle."

Although the term "adjacent" is a commonly understood word, I consider the intrinsic evidence for the proper construction. See *Phillips*, 415 F.3d at 1315 (referring to the specification as "the single best guide to the meaning of a disputed term"). I find that Gore's construction of the term "adjacent" to be consistent with the specification, which requires the elongate member to stop the flow of fluid when placed in the closed position. See '477 Patent col. 4 ll. 57-67 ("the elongate members **30** are . . . shaped to fit substantially *water-tight* within said shaft **26**. . . . Each elongate member **30** is movable within said shaft **26** from a closed position P₁ to an open position P₂ such that the release of fluid out of said fluid receptacle through said port insert **10** is *frustrated* when the

elongate member 30 occupies the closed position P1.") (emphasis added).

Consequently, I construe the term "adjacent" as "next to or adjoining with no intervening structure between the elongate members and the fluid receptacle."⁵ See *Boss Indus., Inc. v. Yamaha Motor Corp. U.S.A., Inc.*, No. 2008-1311, 2009 WL 1475036, at **9 (Fed. Cir. May 28, 2009) ("the correct construction of 'adjacent' in the '[477] patent is 'next to or adjoining.'").

5. "Shaped to Fit Substantially Water-Tight Within"

The term "shaped to fit substantially water-tight within" appears twice in Claim 5 of the '477 Patent. See '477 Patent col. 9 ll. 12-13 ("said body shaped to fit substantially water-tight within said port"); *id.* col. 9 ll. 15-17 ("elongate members . . . shaped to fit substantially water-tight within said one or more shafts"). Millipore initially sought to have this term construed as "object A is shaped to fit substantially water-tight within object B if object A, alone or in combination with additional parts, when disposed within object B, causes a water-tight seal." (emphasis added).

Nothing in Claim 5 of the '477 Patent suggests that parts

⁵ In the aftermath of the May 19, 2010 hearing, Millipore now requests me to specify that there can be no intervening structure "other than the cap" between the elongate members and the fluid receptacle. Because I construe the cap as part of the same structure, see Section II.B.2.b. *supra*, I reject Millipore's argument.

other than the elongate members and the body are required to be shaped to cause a water-tight seal. Millipore's addition of other parts is unsupported by intrinsic evidence. Consequently, I construe the term "shaped to fit substantially water-tight within the body," as Millipore now concedes, to mean that "the elongate member, when disposed within the body, causes a water-tight seal."

6. "Sample Gating Means"

The term "sample gating means" appears in Claim 1 of the '477 Patent. See *id.* col. 8 ll. 39-43 ("sample gating means for individually opening and closing any of said plurality of shafts to enable the flow of liquid, said sample gating means comprising a plurality of rigid elongate members positioned within the plurality of shafts."). Gore argues that the term "sample gating means" should be construed as a means-plus-function limitation pursuant to 35 U.S.C. § 112 ¶ 6 to the extent that the claims are themselves construed to cover any form of movement, i.e., both linear and rotational, between the "open" and "closed" positions.⁶ Specifically, Gore contends that, if the claims are so construed, Claim 1 does not recite sufficient structure to perform the function of enabling the flow of liquid. Millipore

⁶ Because I construe the "open" and "closed" clauses contained in Claims 1 and 5 of the '477 Patent to include both linear and rotational movement, see Section II.B.3. *supra*, I will assume that Gore contends that the term "sample gating means" should be construed as a means-plus-function limitation pursuant to 35 U.S.C. § 112 ¶ 6.

counters that the term "sample gating means" is not a means-plus-function limitation under 35 U.S.C. § 112 ¶ 6 because the claim itself does recite sufficient structure to perform the recited function.

Section 112, paragraph 6, of title 35 provides that:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112 ¶ 6.

As a general proposition, the "[u]se of the word 'means' in claim language creates a presumption that § 112 ¶ 6 applies." *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259 (Fed. Cir. 2008). This presumption is rebutted, however, "[i]f, in addition to the word 'means' and the functional language, the claim recites sufficient structure for performing the described functions in their entirety." *Id.*; see also *Phillips*, 415 F.3d at 1311 ("Means-plus-function claiming applies only to purely functional limitations that do not provide the structure that performs the recited function."). "Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure." *TriMed*, 514 F.3d at 1259-60. "Claim construction of a means-plus-function limitation

includes two steps. First, the court must determine the claimed function. Second, the court must identify the corresponding structure in the written description of the patent that performs the function." *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1332 (Fed. Cir. 2006) (internal citation omitted).

In this case, it is clear that the claimed function is "to enable the flow of liquid." See *id.* col. 8 l. 41. Contrary to Gore's contentions, I find that, regardless of whether I construe the claim to include any form of movement, i.e. either or both linear and rotational, the structure recited in Claim 1 is sufficient to perform the claimed function. Claim 1 provides that "the elongate members being displaceable between 'open' and 'closed' positions such that fluid can flow into the opening behind the cap and through said passage in each member when in said 'open' position, but not in said 'closed' position." *Id.* at col. 8 ll. 48-52. Under these circumstances, I find that the language in Claim 1 specifies the structure that enables the flow of liquid without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure. Consequently, I conclude that the term "sample gating means" is not a means-plus-function limitation under 35 U.S.C. § 112 ¶ 6.

7. "Port Insert"

The term "port insert" appears in Claim 1 of the '477

Patent. See '477 Patent col. 8 l. 38. Millipore initially argued that this term is not a claim limitation but rather a collective term for the elements of the claimed device recited in paragraph (a) of Claim 1. To support its argument that the term "port insert" is not a claim limitation, Millipore observes that this term precedes the transitional term "comprising." This fact alone supports a finding, according to Millipore, that the term "port insert" was part of a preamble, i.e., the language preceding the transitional term "comprising," thereby preventing this term from being a claim limitation.

Usually, "the preamble does not limit the claims." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). Yet, "the preamble may be limiting 'when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention.'" *Id.* (quoting *Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995)). Here, Millipore ignores the fact that Claim 1 of the '477 Patent begins with the preamble "[a] fluid sampling device comprising" before defining the term "port insert." See '477 Patent col. 8 l. 37. Under these circumstances, I conclude that the term "port insert" is not solely a part of the preamble and should be construed as a claim limitation.

Accordingly, I now turn to the construction of the term "port insert" as a claim limitation. Anticipating that the term

"port insert" might be determined to be a claim limitation, Millipore initially sought to have this term construed as "device to be mated with a port." Gore countered that the term "port insert" should be construed to mean "a structure installed into a port provided on a fluid receptacle." I note that the specification contemplates an embodiment "[w]hen the port insert is installed into a suitable port." '477 Patent col. 2 ll. 21-22. In this instance, I find that using the specification would merely interpret the meaning of a claim rather than to import limitations from the specification into the claim. See *Phillips*, 415 F.3d at 1323.

Consequently, I construe the term "port insert," as Millipore now concedes, to mean "structure installed into a suitable port."

8. "Port"

The term "port" can be found twice in Claim 5 of the '477 Patent. See '477 Patent col. 9 ll. 5-6 ("the fluid receptacle provided with a port"); *id.* col. 9 ll. 12-15 ("said body shaped to fit substantially water-tight within said port such that said first open end faces inside said fluid receptacle and said second open end faces outside said fluid receptacle"). However, Millipore initially sought to have the term "port" construed to include other parts that permit attachment of additional devices to the port, such as seals, alignment features, clamps, and

collars, which in combination permit the additional devices (here, the fluid sampling device) to be in fluid communication with a fluid receptacle.

While the language of Claim 5 itself does not provide any other language helpful in further construing the term "port," the specification provides some assistance. The specification of the '477 Patent expressly provides as follows:

Although port insert **10** is structured to fit snugly within host port, to prevent it from being popped into or out of the port during use, additional mechanical restraints are highly desirable. As shown in FIG. 2, this is accomplished by means of a threaded collar **40** that engages with and holds an annular lip **45** provided on the port insert when said collar **40** is screwed into port **5**. Other mechanical restraints - such as clamps, screws, bolts, or mated interlocking parts - are known in the art.

Id. at col. 5 ll. 11-19. From the specification, it is therefore clear that the port is distinct and separate from the mechanical restraints, such as clamps, screws, bolts, or mated interlocking parts. Construing the term "port" to include such restraints would therefore be improper.

Consequently, I adopt Gore's construction of the term "port" and construe that term, as Millipore now agrees, as "a part of a fluid receptacle that provides an opening to the receptacle."

9. "Plurality"

The term "plurality" appears in Claim 1 of the '477 Patent to refer to the plurality of shafts, elongate members, conduits,

or sample containers. See *id.* col. 8 ll. 38-60. Millipore seeks to have this term construed as "an indefinite number, two or more." Gore argues, however, that no construction is necessary and that alternatively it should be construed as "two or more."

Because the ordinary meaning of the term "plurality" is readily apparent, I may rely on dictionary definition to construe this term. See *Phillips*, 415 F.3d at 1314. The definition of the term "plurality" includes "the state of being plural," "the state of being numerous," and "a large number of quantity." See WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY at 1745 (2002). Similarly, the term "plural" can be defined as "relating to or consisting of or containing more than one." *Id.* Consequently, I adopt Milipore's claim construction of the term "plurality" and therefore construe this term to mean "an indefinite number, two or more." See *Bilstad v. Wakalopoulos*, 386 F.3d 1116, 1122 (Fed. Cir. 2004) (adopting the definition of "plurality" of the Board of Patent Appeals) ("Two may properly be referred to as a plurality and so may a large number. Thus, 'plurality' connotes an indefinite numerical range. The range is bounded by two . . . and . . . infinit[y].").

10. "Rigid"

The term "rigid" appears in Claim 1 to describe the elongate members. See '477 Patent col. 8 ll. 42-43 ("rigid elongate

members"). To the extent that any construction is necessary, I adopt the construction to which both parties agree and construe the term "rigid" as "having the quality of resisting change in form."

11. "Integral Locking Means in the Form of an Anchor"

The term "integral locking means in the form of an anchor" appears in dependant Claim 3 of the '477 Patent to further describe the fluid sampling device. See *id.* col. 8 l. 64-67 ("the fluid sampling device of claim 1, further comprising integral locking means in the form of an anchor to secure said elongate member in either open position or said closed position or both"). Millipore initially sought to have this term construed as "a part or a portion of something [here, the fluid sampling device] that performs a locking function (i.e., securing against accidental movement) and includes a device for fixing one object to another ('anchor')." Gore countered that no construction is necessary.

In this instance, the key term that needs to be construed is "anchor." The specification expressly refers to this term as follows:

[A]nchor **50** is provided to prevent the elongate member **30** from being pushed into its open position P₂ prematurely. When sampling is commenced, the anchor **50** can be moved into a position in which it no longer impedes the transit of the member **30** through the shaft.

Id. at col. 7 ll. 45-49. I find Millipore's construction of the

term "anchor" as "a device for fixing one object to another" to be inconsistent with the language of the specification and the claim terms. Here, the function of the anchor is "to prevent the elongate member from being pushed into its open position P2 prematurely," rather than merely to be "fixed" to it.

Consequently, I construe the term "integral locking means in the form of an anchor" as "an element of the fluid sampling device designed to prevent the elongate member from being pushed into its open position prematurely."⁷ In construing this term in this fashion, I use the specification to interpret the meaning of Claim 3 of the '477 Patent rather than to import limitations from the specification into the claims. See *Phillips*, 415 F.3d at 1323.

12. "Integral Block"

The term "integral block" is used in dependant Claim 4 of the '477 Patent to further describe the elements comprised in the fluid sampling device. See '477 Patent col. 9 ll. 1-3 ("The fluid sampling device of claim 1, further comprising integral block to prevent said elongate member from being pushed too far in the open position."). While Gore argued that no construction

⁷ In the aftermath of the May 19, 2010 hearing, Millipore now seeks to have the term "moved" used in lieu of "pushed" for purposes of construing the "integral locking means in the form of an anchor." Because the term "pushed" is used in the specification of '477 Patent, col. 7 l. 46, and no basis has been raised by Millipore for departing from this language, Millipore's contention must be rejected.

of this term was necessary, Millipore initially contended that the term "integral block" should be construed as "a part of something [here, the fluid sampling device] that performs a function of being an obstacle ('block'), or a motion limiting structure."

Considering that claim construction is necessary in this instance, I construe the term "integral block" in light of the claim language as "an element of the fluid sampling device designed to prevent the elongate member from being pushed too far in the open position."⁸

13. "Connected to"

The term "connected to" appears in Claim 5 of the '477 Patent to describe the relation of the flexible tubes with the elongate members. See '477 Patent col. 10 ll. 10-11 ("one or more sterilized flexible tubes connected to said back of each of said one or more elongate members"). Here again, Gore argues that no construction is necessary,. Millipore initially contended that this term should be construed as "joined or linked together" without requiring that there be contact between the two objects.

⁸ While Millipore seeks to have the term "moved" used in lieu of "pushed" for purposes of construing the "integral block," I reject this contention for the reasons expressed in Note 7 *supra*.

I agree with Millipore that the term "connected to" should be construed as "joined or linked together." See WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY at 480 (2002). However, because being "joined or linked together" in this setting specifically requires that there be contact between the tubes and the elongate members, I find, as Millipore now concedes, the remaining dimension to Millipore's initial construction irrelevant and therefore reject it.

III. INFRINGEMENT

In order "[t]o prove infringement, the patentee must show that an accused product embodies all limitations of the claim either literally or by the [doctrine of equivalents.]" *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1374 (Fed. Cir. 2009). Before turning to the doctrine of equivalents, I will therefore discuss Millipore's allegations of literal infringement with respect to Claims 1 to 5 of the '477 Patent.

A. *Literal Infringement*

It is well settled that "[l]iteral infringement of a properly construed claim is a question of fact." *Wavetronix LLC v. EIS Elec. Integrated Sys.*, 573 F.3d 1343, 1358 (Fed. Cir. 2009) (quoting *Applied*, 448 F.3d at 1332). A district court may grant "summary judgment of non-infringement only if, after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue as to whether the accused

device is encompassed by the claims." *Id.* (quoting *Combined Sys., Inc. v. Def. Tech. Corp. of Am.*, 350 F.3d 1207, 1210 (Fed. Cir. 2003)). In other words, "[i]f any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Amgen*, 580 F.3d at 1374.

Gore's principal argument that summary judgment of non-infringement should be granted turns upon construction of the cap-related limitations.⁹ As discussed in Section II.B.2. *supra*, these cap-related limitations relate to (1) the function of the cap, (2) the structure of the cap, and (3) the location of the cap *vis-à-vis* the opening. I discuss these issues in turn.

1. Function of the "Cap"

Gore contends that the Accused Products do not infringe the asserted claims of the '477 Patent because these products do not include a seal that prevents the valve from being pulled out. Having construed the term "cap" as a feature that can, but is not required to, prevent the elongate member from being pulled out, see Section II.B.2.a. *supra*, the pull-out prevention function of the cap is no longer in dispute.

The only function that remains at issue is therefore the

⁹ While several claim terms are disputed among the parties, Gore's motion for summary judgment focuses on the cap-related limitations. Gore contends that "[b]ecause Gore's accused devices do not meet any of the cap-related limitations and there is no material dispute about the structure of Gore's accused devices, Gore is entitled to summary judgment of noninfringement."

creation of a liquid tight seal by the cap. In this case, there is no dispute that the function of the silicone seal, i.e. the equivalent of the elongate member in the Accused Products, is, as with the claimed cap, to create a liquid seal. As noted in the declaration of Domenic Sciamanna, a project specialist for the Accused Products, when a valve is in the closed position, "it seals the opening on the device face and fluid cannot flow out of the tank and through the device." A fluid sampling device would not work, according to Sciamanna, if there was no liquid tight seal in closed position. Under these circumstances, a jury could reasonably find that the Accused Products perform the same function as the claimed device. Accordingly, summary judgment for literal infringement cannot be granted on this basis.¹⁰

2. Structure of the "Cap"

Gore further alleges that the Accused Products do not infringe the asserted claims of the '477 Patent because they do not have a cap that is part of the structure of an elongate member. In making this argument, Gore has relied on its proposed claim construction of the term "having" used in the Claims 1 and 5 of the '477 Patent. See '477 Patent col. 8 ll. 46-47 ("the elongate members having a cap and an opening") (Claim 1); '477 Patent col. 9 l. 21 - col. 10 l. 1. ("one or more elongate

¹⁰ Whether the silicone seal performs the function of creating a liquid tight seal in the same way as the claimed cap will be discussed in Section II.B.2., the next section *infra*.

members having a cap and an opening") (Claim 5).

As discussed in Section II.B.2.b. *supra*, I have construed the term "cap" used in Claims 1 and 5 of the '477 Patent as being part of the same structure as the elongate members, rather than as a distinct element. The silicone seal, i.e., the equivalent of the cap in the Accused Products, is clearly a structure separate from the rigid rod, i.e., the equivalent of the elongate member in the Accused Products. No reasonable jury could conclude that the silicone seal and the rigid rod of the Accused Products are part of the same structure. For this reason, I conclude that the Accused Products do not literally infringe Claims 1 and 5 of the '477 Patent.¹¹

3. Location of the Opening vis-à-vis the Cap

Finally, Gore contends that the Accused Products do not infringe the asserted claims because they do not have any opening behind the cap. In making this argument, Gore relies on the term "behind" used in Claims 1 and 5 of the '477 Patent. See '477 Patent col. 8 ll. 47-48 ("an opening to a passage of the elongate member behind the cap, the elongate members being displaced

¹¹ This finding alone is sufficient to establish that the Accused Products do not literally infringe Claims 1 and 5 of the '477 Patent. See *Becton, Dickinson and Co. v. Tyco Healthcare Grp., LP*, Nos. 2009-1053, 2009-1111, --- F.3d ----, 2010 WL 2977612, at *3 (Fed. Cir. July 29, 2010) ("To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly."). For purposes of completeness of this memorandum, I address Gore's remaining arguments regarding the location of the cap.

between 'open' and 'closed' positions such that fluid can flow into the opening behind the cap") (Claim 1); *id.* col. 9 l. 21 - col. 10 l. 2. ("an opening to a passage of each of the one or more elongate members behind the cap") (Claim 5).

Based on my construction of the term "behind" as "at the back of," see Section II.B.2.c. *supra*, I find that no jury could reasonably conclude that the opening through which the fluid flows in the Accused Products is placed behind the cap. To the contrary, the opening of the Accused Products is located in *front*, rather than in the back, of the silicone seal.¹² For this additional reason, I conclude that there can be no literal infringement.

B. Doctrine of Equivalents

Even in the absence of literal infringement, an accused process or device can still be found to infringe under the doctrine of equivalents. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.* ("*Festo I*"), 535 U.S. 722, 732 (2002) ("The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described."). Gore argues that summary judgment on non-infringement is warranted as to equivalents on two grounds: (1) prosecution

¹² I recognize that the rigid rod has an opening located in the *back* of the silicone seal. However, it does not appear that the liquid flows from that opening but rather from the opening located on the *front* of the device.

history estoppel prevents Millipore from asserting the doctrine of equivalents as to the cap-related limitations and (2) Millipore has not, in any event, introduced sufficient evidence to survive summary judgment as to equivalents.

1. Prosecution History Estoppel

It is well-settled that "[t]he doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo I*, 535 U.S. at 733. "However, prosecution history estoppel may bar the patentee from asserting equivalents if the scope of the claims has been narrowed by amendment during prosecution." *Felix v. Am. Honda Motor Co., Inc.*, 562 F.3d 1167, 1181-82 (Fed. Cir. 2009) (quoting *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139 (Fed. Cir. 2004 (en banc))). Amendment-based "[e]stoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope." *Festo I*, 535 U.S. at 736. The rationale is that "the inventor might [otherwise] avoid the PTO's gatekeeping role and seek to recapture in an infringement action the very subject matter surrendered as a condition of receiving the patent." *Id.* at 734.

To rebut this presumption, a patentee must show that (1) "the alleged equivalent would have been unforeseeable at the time of the narrowing amendment," (2) "that the rationale underlying the narrowing amendment bore no more than a tangential relation

to the equivalent in question," or (3) "that there was 'some other reason' suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.* ("Festo II"), 344 F.3d 1359, 1368 (Fed. Cir. 2003) (citing *Festo I*, 535 U.S. at 740-41). Because the applicability of the prosecution history estoppel is not a complete bar to the doctrine of equivalents, "[a] district court must look to the specifics of the amendment and the rejection that provoked the amendment to determine whether estoppel precludes the particular doctrine of equivalents argument being made." *Intervet Inc. v. Merial Ltd.*, No. 2009-1568, --- F.3d ----, 2010 WL 3064311, at *8 (Fed. Cir. Aug. 4, 2010).

I first consider whether any amendment might give rise to a presumption of surrender. The only limitation at issue here is the cap limitation. The "cap" was added on May 2, 2006 as a new limitation to the elongate member. In particular, Claim 1 was amended to recite "the elongate members having a cap and an opening to a passage of the elongate member behind the cap, the elongate members being displaceable between 'open' and 'closed' positions such that fluid can flow into the opening behind the cap." '477 Patent, Prosecution History Record, p. 102.

Likewise, Claim 13 (issued as Claim 5) was amended to recite "elongate members having a cap and an opening to a passage of each of the one or more elongate members behind the cap." *Id.* at

104. This amendment was made to overcome prior art rejections made by the patent examiner. Under these circumstances, Millipore's decision to narrow the claims by adding the cap limitation in response to an issue of patentability could give rise to a presumption of surrender.

Millipore argues, however, that it has rebutted the presumption of prosecution history estoppel as to the cap limitation, because "the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question." *Festo II*, 344 F.3d at 1368. "[T]he principle that the tangential relation criterion for overcoming the *Festo* presumption is very narrow." *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1342 (Fed. Cir. 2007). "[T]he inquiry into whether a patentee can rebut the *Festo* presumption under the 'tangential' criterion focuses on the patentee's objectively apparent reason for the narrowing amendment. . . . [which] should be discernible from the prosecution history record." *Festo II*, 344 F.3d at 1369.

In this case, Millipore relies on the following portion of the prosecution history record to show that the cap amendment was at most tangential to the equivalent in question - a silicone seal that creates a liquid tight seal that is distinct from, rather than part of, the elongate member and is located in the

back, rather than in the front, of the opening:¹³

[Referring to the claimed device as amended.] *Each member has a cap on its front end and an opening behind the cap to a passage that extends from the opening to the second end of the member. . . . The end of the elongate member adjacent the vessel are [sic] selectively sealed off from the vessel by the cap and can be opened by moving them forward or by rotating them to an open shaft position thereby exposing the opening and passage within the elongate member that allows fluid to move from the vessel through the member into a tube and then a collection bag.*

Arthun fails to teach an elongate member as claimed. Arthun uses a septum that is pierced by a hypodermic needle to allow flow into the needle and then to a sample bag. This [is] quite different from the device as claimed in the present invention.

'477 Patent, Prosecution History Record, p. 108 (emphasis added).

The recited language suggests that the "objective apparent reason" for the amendment was made to distinguish from Arthun by requiring a cap that "selectively seals off" the end of the elongate member from the vessel, with the elongate member having a cap on its front and an opening behind the cap. Arthun fails to teach an elongate member as thus claimed because it does not

¹³ Millipore's main argument in undertaking to rebut the *Festo* presumption was that "a function of pull-out prevention bears no more than a tangential relation to the rationale for Millipore's amendments to Claims 1 and 5 of the '477 Patent." Because I construe the term "cap" as a feature that can, but is not required to, prevent the elongate member from being pulled out, see Section II.B.2.a. *supra*, the pull-out prevention function of the cap is no longer at issue. Thus, the only aspects of the cap that remain in dispute are the function of creating a tight seal as well as the difference in the structure - a cap that is part of, rather than distinct from, the elongate member - and the location - a cap that is located in the front, rather than in the back, of the opening - between the silicone seal of the Accused Products and the claimed cap.

contain any cap but merely uses a needle to pierce the septum and allow flow to a sample bag. Accordingly, the "objective apparent reason" for the amendment relates to the addition of a cap that creates a liquid tight seal (function), that would be part of the elongate member (structure) and would be located in front of the opening (location). In this context, "[b]ecause the alleged equivalent focuses on the [cap] limitation, the amendment bore a direct, not merely tangential, relation to the equivalent." See *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 523 3d. 1304, 1316 (Fed. Cir. 2008); *Festo II*, 344 F.3d at 1369 ("an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim"). Consequently, Millipore is estopped from arguing that the function, the structure and the location of the claimed cap have a merely tangential, rather than a direct, relation to the silicone seal contained in the Accused Products. Because Millipore has failed to rebut the presumption of surrender of the equivalent in question, I grant summary judgment in favor of Gore.¹⁴

¹⁴ This finding that Millipore is estopped from asserting the doctrine of equivalents with regard to the cap limitation is sufficient in itself to support summary judgment against Millipore on its equivalents theory. For purposes of completeness of this memorandum, however, I briefly discuss whether Millipore has submitted sufficient evidence under this doctrine of equivalents.

2. Sufficiency of Evidence under the Doctrine of Equivalents

Gore contends that Millipore's contentions under the doctrine of equivalents fail because Millipore has not submitted, as is required under Federal Circuit's precedent, adequate particularized testimony or linking argument in support of its infringement claim.

The inquiry under the doctrine of equivalents is "whether 'the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention.'" *Wavetronix*, 573 F.3d at 1360 (quoting *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997)) (alteration in original). To prove equivalence, a patentee must "provide particularized testimony and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused device or process, or with respect to the function, way, result test." *Tex. Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996). The three-pronged "function-way-result" test requires the patentee to show "that the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product." *Wavetronix*, 573 F.3d at 1360. Because "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention," the evidence

presented by the patentee "must be applied to individual elements of the claim, not to the invention as a whole."

Warner-Jenkinson, 520 U.S. at 29; see also *Tex. Instruments*, 90 F.3d at 1567 ("Such evidence must be presented on a limitation-by-limitation basis. Generalized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice.").

Based upon my construction of the term "cap" as a feature that can, but is not required to, prevent the elongate member from being pulled out, see Section II.B.2.a. *supra*, the pull-out prevention function of the cap is no longer at issue. What remains at issue is whether the silicone seal in the Accused Products performs the function of creating a liquid tight seal in substantially the same way as the claimed cap and whether the difference in the structure and location of the cap contained in the two devices have any impact under the doctrine of equivalents.

To support a finding of infringement under the doctrine of equivalents, Millipore offers the declaration of Alexander H. Slocum, Professor of Mechanical Engineering at the Massachusetts Institute of Technology. In his declaration, Slocum fails to raise any genuine issue of material fact as to the 'insubstantiality of the differences' between the structure and location of the silicone seal of the Accused Products and of the

cap in the claimed device. Moreover, Slocum does not show whether the silicone seal performs the function of creating a liquid tight seal in the same way as the claimed cap. Instead, Slocum's analysis is focused on other aspects of Claims 1 and 5 of the '477 Patent, i.e., the sample gating means of Claim 1 and the elongate members of Claim 5, rather than on the cap limitation.

Thus, I find that Millipore has failed to present "particularized testimony and linking argument" to establish that the Accused Products achieve sealing in the same way as is claimed in the '477 Patent. Indeed, my examination of the Accused Products, which depend upon a lever mechanism for sealing, satisfies me as a matter of law that they do not. Accordingly, I grant summary judgment on this additional basis.

VI. CONCLUSION

For the reasons set forth more fully above, I GRANT summary judgment in favor of Defendant. (Dkt. No. 28.)

/s/ Douglas P. Woodlock
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MILLIPORE CORP.,

Plaintiff,

v.

W.L. GORE & ASSOCIATES, INC.,

Defendant.

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CIVIL ACTION NO.
08-12139-DPW

TABLE
September 20, 2010

No	Claim Term	Millipore's Proposed Claim Construction ¹	Gore's Proposed Claim Construction	Court's Claim Construction
1	"elongate members"	"a part of extended length"	"a rigid and monolithic structure of extended length"	"a rigid and monolithic structure of extended length"

No	Claim Term	Millipore's Proposed Claim Construction ¹	Gore's Proposed Claim Construction	Court's Claim Construction
2. a	Function of the "cap"	the "cap" can, but is not required to, prevent the elongate member from being pulled out of the shaft.	"a feature on the front of the elongate member that creates a liquid tight seal and prevents the elongate member from being pulled out of the shaft"	"a feature that creates a liquid tight seal and can, but is not required to, prevent the elongate member from being pulled out of the shaft."
b	Structure of the "Cap"	"an element, distinct from the elongate member, that creates a liquid tight seal." The "cap" may or may not be detachable from the elongate member.	"the elongate member has as part of its structure a cap and an opening to a passage behind the cap through which fluid can flow."	"the elongate members and the cap are part of the same structure"
c	Location of the Opening <i>vis-à-vis</i> the "Cap"	"beyond in depth" "beyond"	No construction of "behind" is necessary. Gore opposes Millipore's proposed construction.	"the opening is located at the back of the cap"

No	Claim Term	Millipore's Proposed Claim Construction ¹	Gore's Proposed Claim Construction	Court's Claim Construction
3	"open" and "closed" clauses	Gore seeks to have the Court interpret the entire phrases that include terms Millipore seeks to construe. Millipore identifies the terms to be construed; the extraneous terms in these entire phrases presented by the defendant do not add context that affects the analysis of whether each individual limitation is properly interpreted.	<p>1. "elongate members being displaceable between 'open' and 'closed' positions" (Claim 1)</p> <p>2. "elongate members are linearly displaceable within one of said shafts between said 'open' and 'closed' positions" (Claim 2)</p> <p>3. "said one or more elongate members being movable within said one or more shafts from an open position to a closed position" (Claim 5)</p> <p>All construed as: "The elongate members are opened by pushing them forward and closed by pulling them backwards from the open position."</p>	each claim term is to be construed separately (see below)

No	Claim Term	Millipore's Proposed Claim Construction ¹	Gore's Proposed Claim Construction	Court's Claim Construction
a	"displaceable"	"physically movable out of a position" <i>Now agrees with the Court's proposed claim construction</i>	See Gore's Proposed Construction for the "'open' and 'closed' clauses."	"that can be displaced," i.e. "that can be put out of place"
	"linearly displaceable"	"physically movable out of a position," and limited to the movement being linear and not rotational.	See Gore's Proposed Construction for the "'open' and 'closed' clauses."	"that can be displaced," i.e. "that can be put out of place," where the movement is limited to linear and not rotational
b	"movable"	"capable of being moved."	See Gore's Proposed Construction for the "'open' and 'closed' clauses."	"capable of being moved"
	"moved"	past participle of the verb to move, i.e., to change position.	See Gore's Proposed Construction for the "'open' and 'closed' clauses."	past principle of the verb to move, i.e., "to change position"

No	Claim Term	Millipore's Proposed Claim Construction ¹	Gore's Proposed Claim Construction	Court's Claim Construction
4	"positioned adjacent"	<p>The term "positioned adjacent" should be given its ordinary meaning, which includes "nearby." The term "adjacent" should not be construed to require contact between two objects.</p> <p><i>Now agrees with the Court's proposed claim construction but requests that the terms "other than the cap" be added after "no intervening structure"</i></p>	<p>"The elongate members are next to or adjoining the fluid receptacle, with no intervening structure between the elongate members and the fluid receptacle."</p>	<p>"next to or adjoining with no intervening structure between the elongate members and the fluid receptacle"</p>

No	Claim Term	Millipore's Proposed Claim Construction ¹	Gore's Proposed Claim Construction	Court's Claim Construction
5	"shaped to fit substantially water-tight within"	<p>object A is "shaped to fit substantially water-tight within" object B if object A, alone or in combination with additional parts, when disposed within object B, causes a water-tight seal.</p> <p><i>Now agrees with the Court's proposed claim construction</i></p>	No construction necessary. Gore opposes Millipore's proposed construction.	"the elongate member, when disposed within the body, causes a water-tight seal"
6	"sample gating means"	The term "sample gating means" should not be considered to be a term to be construed under 35 U.S.C. § 112, ¶ 6.	This is a 35 U.S.C. § 112(6) means-plus-function limitation.	The term "sample gating means" is not a means-plus-function limitation under 35 U.S.C. § 112 ¶ 6.

No	Claim Term	Millipore's Proposed Claim Construction ¹	Gore's Proposed Claim Construction	Court's Claim Construction
7	"port insert"	<p>The term "port insert" is not a claim limitation and is a collective term for the elements of the claimed device recited in clause (a) of Claim 1. To the extent it is determined that "port insert" is a claim limitation, the term "port insert" should be construed to mean "device to be mated with a port."</p> <p><i>Now agrees with the Court's proposed claim construction</i></p>	"A structure installed into a port provided on a fluid receptacle"	"structure installed into a suitable port"

No	Claim Term	Millipore's Proposed Claim Construction ¹	Gore's Proposed Claim Construction	Court's Claim Construction
8	"port"	<p>The "port" is a part or a portion of a fluid receptacle and it includes an opening that provides access to the interior of the receptacle. The port can include other parts that permit attachment of additional devices to the port, such as seals, alignment features, clamps, and collars, which in combination permit the additional devices (here, the fluid sampling device) to be in fluid communication with a fluid receptacle.</p> <p><i>Now agrees with the Court's proposed claim construction</i></p>	<p>"A cylindrical structure extending from the fluid receptacle that provides an opening to the receptacle."</p>	<p>"a part of a fluid receptacle that provides an opening to the receptacle."</p>

No	Claim Term	Millipore's Proposed Claim Construction ¹	Gore's Proposed Claim Construction	Court's Claim Construction
9	"plurality"	<p>"an indefinite number, two or more," and can be fewer than all of the elements in question, but not less than two."</p> <p><i>Now agrees with the Court's proposed claim construction</i></p>	<p>No construction necessary. Alternatively, "two or more." Gore opposes Millipore's proposed construction.</p>	<p>"an indefinite number, two or more"</p>
10	"rigid"	<p>"having the quality of resisting change in form"</p>	<p>No construction necessary. If the Court decides that further clarification is necessary, Gore does not oppose Millipore's proposed definition of "having the quality of resisting change or form."</p>	<p>"having the quality of resisting change in form"</p>

No	Claim Term	Millipore's Proposed Claim Construction ¹	Gore's Proposed Claim Construction	Court's Claim Construction
11	"integral locking means in the form of an anchor"	<p>"a part or a portion of something [here, the fluid sampling device] that performs a locking function (i.e., securing against accidental movement) and includes a device for fixing one object to another ('anchor')."</p> <p><i>Now agrees with the Court's proposed claim construction but requests that the term "moved" be used in lieu of the term "pushed"</i></p>	No construction necessary. Gore opposes Millipore's proposed construction.	"an element of the fluid sampling device designed to prevent the elongate member from being pushed into its open position prematurely"

No	Claim Term	Millipore's Proposed Claim Construction ¹	Gore's Proposed Claim Construction	Court's Claim Construction
12	"integral block"	<p>"a part or a portion of something [here, the fluid sampling device] that performs a function of being an obstacle ("block"), or a motion limiting structure."</p> <p><i>Now agrees with the Court's proposed claim construction but requests that the term "moved" be used in lieu of the term "pushed"</i></p>	No construction necessary. Gore opposes Millipore's proposed construction.	"an element of the fluid sampling device designed to prevent the elongate member from being pushed too far in the open position"
13	"connected to"	<p>"joined or linked together" and should not be construed to require contact between two objects.</p> <p><i>Now agrees with the Court's proposed claim construction</i></p>	No construction necessary. Gore opposes Millipore's proposed construction.	"joined or linked together"

1. In the aftermath of the May 19, 2010 hearing, Millipore filed Supplemental Infringement Contentions modifying in part its claim construction. Millipore's claim construction in *italics* is the one proposed after the May 19 hearing.