United States District Court,
C.D. California.

MEDEGEN MMS, INC,
Plaintiff.
v.
ICU MEDICAL, INC,
Defendant.

No. SA CV 06-619 MRP (ANx)

June 21, 2007.

Megan M. La Belle, Shont E. Miller, Ted G. Dane, Munger Tolles & Olson, Los Angeles, CA, Paul L. Gale, Ross Dixon and Bell, Irvine, CA, for Plaintiff.

Diana Luo, James H.A. Pooley, Katherine Nolan-Stevaux, Kimberly N. Van Voorhis, Marc David Peters, Morrison & Foerster, Palo Alto, CA, Laura L. Kohut, Kohut & Kohut, Costa Mesa, CA, Sean Christian Platt, Paul Hastings Janofsky and Walker, San Diego, CA, for Defendant.

CLAIM CONSTRUCTION ORDER

MARIANA R. PFAELZER**, District Judge.**

I.

INTRODUCTION

In this patent infringement case, Plaintiff Medegen MMS, Inc. ("Medegen") and Defendant ICU Medical, Inc. ("ICU") seek construction of seven (7) terms found in the claims of the only patent-in-suit, U.S. Patent No. 5,730,418 (the "'418 Patent"), in accordance with Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). This Court held a *Markman* hearing on June 5, 2007, where both parties presented argument. ICU also submitted declarations and a report by its expert, Paul Diperna ("Diperna"), who did not testify at the hearing.

II.

BACKGROUND

A. Patented Technology

The technology in this case relates to needleless access connectors that interface with an intravenous

catheter to deliver medication to a patient from a Luer actuator, such as a syringe. However, early designs of these connectors suffered from the problem of unwanted fluid flow into the catheter that occurred each time the connector was used. When the actuator, a Luer tip, is inserted into the connector, the internal volume occupied by the tip of the actuator causes a positive pressure within the connector that pushes a small amount of fluid out of the connector and into the catheter, termed "ante grade" flow. Similarly, when the Luer is removed, it causes a negative pressure, also roughly equal to the volume of the actuator tip, which draws fluid into the connector through the outlet port, termed "retrograde" flow. Retrograde flow in the connector is undesirable because it may draw blood into catheter or the intravenous tubing that may clot or stagnate. Over time, this stagnated blood can impede fluid flow and present health risks to a patient, requiring either "flushing" of the tube with saline or replacement of the catheter entirely.

Several companies, including Medegen, sought to solve the problem of unwanted retrograde fluid flow by designing connectors that automatically compensate for the volume of the actuator tip upon its insertion and removal from the connector. Some of these designs aimed to "zero-out" the net fluid flow caused by the insertion of the actuator, while others sought to create a net positive, or antegrade fluid flow when the actuator tip was removed from the connector to facilitate the "flushing" of the connector, tubing and catheter every time the connector was used. The former designs might be called "minimum fluid displacement" connectors and the latter designs "positive fluid displacement" or "self-flushing" connectors, though this distinction is not always clear. This is because designing a connector that "zeros-out" or exactly offsets the volume of the actuator tip when inserted and removed is difficult, given the variety of potential actuator shapes and sizes (i.e. Luers of various standardized gauges or volumes) and the actual size variance or manufacturing tolerances that exist even within those standardized actuator sizes. Therefore, a "zero-displacement" or "minimum displacement" connector design may deliberately err on "overcompensating" or generating a net positive fluid flow by default, to avoid the risk of any retrograde flow caused by an unexpectedly large actuator tip. This design precaution carries with it the benefit of flushing the connector as well. In such cases, the design difference between a "minimum/zero displacement" connector and a "self-flushing" connector, if it exists at all, depends on the amount of positive displacement or antegrade flow generated. "Minimum/zero" displacement valves might seek to generate only a small amount of antegrade flow, perhaps enough to cover all expected actuator tip volumes or to minimize any possibility of retrograde flow, while "self-flushing" valves might be designed to guarantee a larger, or unbounded positive fluid displacement in excess of expected actuator volumes.

B. Patent Litigation and Prosecution History

The only patent-in-suit is U.S. Patent No. 5,730,418, or the '418 Patent, which issued on March 24, 1998. It claims an invention for a "Minimum Fluid Displacement Medical Connector." Medegen's predecessor, Porex Medical Products, Inc. ("Porex"), originally asserted claims from the '418 Patent against ICU in a lawsuit filed in May 2001. In December 2001, Porex filed a request for reexamination for the '418 Patent and stipulated to a voluntary dismissal of its claims without prejudice in February 2002, pending the outcome of the reexamination proceeding. FN1

FN1. On February 21, 2002, Judge Alicemarie H. Stotler dismissed all claims and causes of action pending in this case without prejudice. The dismissal order provided that: "In the event that Porex Medical Products, Inc. files a second complaint against ICU Medical, Inc. for patent infringement within ninety (90) days of the completion of the reexamination proceeding, the rights of the parties in the second action shall be exactly the same rights that the respective parties would have had were this case stayed rather than dismissed without prejudice."

On April 11, 2006, a Reexamination Certificate issued for the '418 Patent ("the '418 RC"), and Porex's successor, Medegen, re-filed its complaint less than ninety days later on July 6, 2006. The '418 RC made substantial changes to the '418 Patent. It amended three paragraphs of the specification as well as claims 1-3, 5, 6, 16-27 and 29-32, and it added new claims 33-77, most of which are dedicated to a "self-flushing," as opposed to a "minimum fluid displacement" embodiment.

At this stage, Medegen asserts thirteen claims from the '418 Patent against ICU's CLC2000 Connector, all of them dedicated to the "self-flushing" embodiment. Currently at issue are claims 27, 28, 31, 39, 41, 42, 47, 53, 54, 55, 59, 62 and 63, all of which were amended or added by the '418 RC, except claim 28, a means-plus-function term from the original '418 Patent. FN2

FN2. The representative sample of the asserted claims in the '418 Patent is as follows:

27. A self-flushing connector, comprising: a valve internal chamber; a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber; a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of the valve internal chamber through the valve outlet port at all times; an air chamber; and a plug adapted for being moved into a portion of the air chamber when the actuator is moved into the valve internal chamber and for being moved out of a portion of the air chamber when the actuator is removed from the valve internal chamber, movement of the actuator into the valve internal chamber resulting in a relatively small movement of fluid through the valve outlet port and into the valve internal chamber, and movement of the actuator out of the valve internal chamber resulting in a relatively small movement of fluid through the valve outlet port and out of the valve internal chamber.

28. A self-flushing connector, comprising: a valve inlet port adapted for receiving an actuator in an inward direction into the valve inlet port, the actuator having a lumen for introducing fluid through the valve inlet port in the inward direction; a valve outlet port adapted for transferring fluid in one of a first direction out of the self-flushing connector and a second direction into the self-flushing connector; and displacing means adapted for providing displacements of fluid within the self-flushing connector, the displacing means effecting a relatively small movement of fluid through the valve outlet port in the second direction in response to movement of the actuator in the inward direction, and the displacing means effecting a relatively small movement of fluid through the valve outlet port in the first direction in response to movement of the actuator in an outward direction opposite to the inward direction.

31. A valve for transferring fluid with minimum fluid displacement, comprising: a valve internal chamber having a volume and adapted for receiving an actuator therethrough for facilitating introduction of fluid into the valve internal chamber; a biased member abutting against one of a compressible gas and an ambient atmosphere, and adapted for being moved by the actuator, movement of the biased member resulting in displacement of one of the compressible gas and the ambient atmosphere to overcompensate a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator into the valve internal chamber; and a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with substantially all of the volume of the valve internal chamber

at all times and being adapted for allowing fluid to freely flow between substantially all of the volume of the valve internal chamber and the valve outlet port. (*See* '418 Patent at claims 27, 28 and 31.)

C. Patented Invention

Medegen's patented device, shown below in Figures 1 and 2 of the '418 Patent, essentially consists of: 1) a valve housing (12), comprised of a valve inlet port (21), a valve internal chamber (38), an air chamber (43) and valve outlet port (36); and 2) an "elastomeric" or "rubberized" plug, otherwise termed a "biased member" (14) that is contained within the valve housing. FN3 ('418 Patent at 5:8:45.) The plug, which is biased in the closed position by a shoulder seal (56) and its placement in the valve, and perhaps also with the assistance of a spring (74), has a proximal portion (47) that faces the valve inlet port and a distal end (50) that faces the air chamber. (Id.)

FN3. Though the '418 Patent claims other embodiments as illustrated by other disclosed figures, Medegen states that only the embodiments shown by Figures 1 and 2 read on the accused ICU CLC2000 connector. The Court, therefore, primarily uses the embodiment found in Figures 1 and 2 to describe the device.

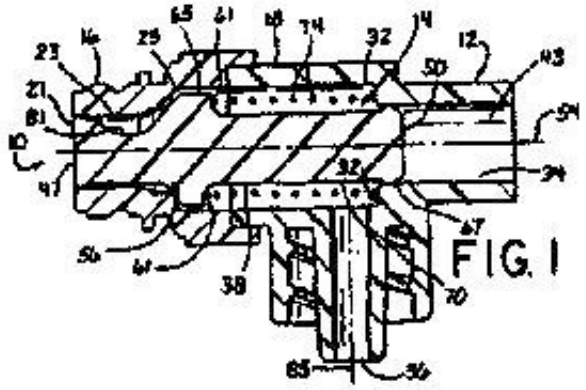


FIG. 1

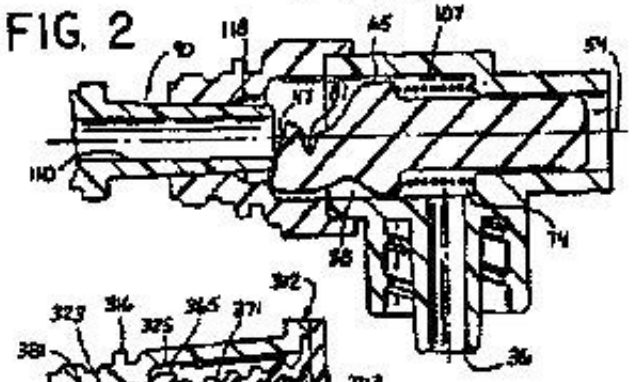


FIG. 2

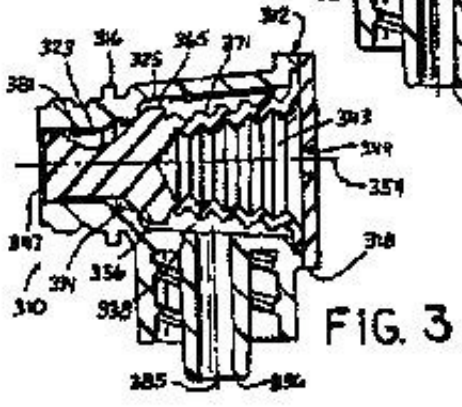


FIG. 3

As shown in Figure 2, the connector is activated when the actuator (90), a Luer or equivalent, is inserted into the connector and pushes on the proximal end of the plug toward its distal end, rotating and collapsing the plug head while pushing the distal end of the plug towards the air chamber. The movement and deformation of the proximal end of the plug opens a fluid pathway within the valve internal chamber, which is always in fluid contact with the valve outlet port, thereby establishing a fluid pathway to the patient. The movement of the cylindrical distal portion of the plug into the air chamber causes a negative fluid displacement, equal to the volume of the plug cylindrical distal portion, within the valve internal chamber that "compensates" for the positive fluid displacement, equal to the volume of the actuator tip, introduced by the insertion of the actuator. (*See, e.g.,* '418 Patent at 2:45-50.) Similarly, when the actuator is removed, the elastomeric plug or biased member returns to its original position and shape, perhaps aided with a spring, closing the fluid pathway. The plug cylindrical distal portion moves out of the air chamber to create a positive fluid displacement that "offsets" or "substantially compensates" the negative fluid displacement caused by the actuator's removal. (*See, e.g., id.* at 2:45-50; 3:1-9; 4:24-29.) The result is that "significant fluid is not displaced during actuation." (*Id.* at 2:37-38.)

It is here that the distinction between "minimum fluid displacement" and "self-flushing" connectors, if any exists, becomes relevant to this case. Medegen's '418 Patent addresses both "minimum fluid displacement" and "self-flushing" embodiments of the connector. Notably, the original '418 Patent focused primarily on the former embodiment while the reexamination significantly fleshed out the latter. For example, the name of the invented device is a "Minimum Fluid Displacement Medical Connector" and much of the specification and claims focus on a connector that "substantially compensates" or "offsets" the fluid displaced by the insertion of the actuator tip, generating what it terms "zero displacement" within the connector. (*See, e . g.,* '418 Patent at 6:67-7:4 ("In the presently preferred embodiment, the diameter of the plug cylindrical distal portion is configured to be approximately equal (or proportional) to the diameter of the actuator, to thereby yield very close compensating displacements between the two devices."); *see also id.* at 2:45-50; 3:1-9; 4:24-29; 6:62-66.) However, one section of the original specification and all of the amended claims address "self-flushing" embodiments. (*See, e.g., id.* at 7:4-12 ("If the diameters [between the plug cylindrical distal portion and the actuator] are changed, flushing can be achieved. If the volume of the plug cylindrical distal portion is slightly greater than the volume of the actuator, a small amount of retrograde flow will be created during insertion of the actuator and, subsequently, antegrade (self-flushing) flow will be produced during removal of the actuator. This antegrade flow (self-flushing) produced during removal of the actuator can be considered a desirable feature."); *see also id.* at claims 27, 28 and 53.) Elsewhere in the '418 Patent, asserted claim 31 expressly teaches a valve with "minimum fluid displacement," but also states that the plug or biased member is designed to " *overcompensate* a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator," thus it also generates a positive fluid displacement. (*See* '418 RC at claim 31, 5:64-67 (emphasis added).) Importantly, the term "overcompensate" replaced the term "offset" in the original claim as a result of the reexamination process. (*See* id.) This dichotomy in claimed invention pervades the '418 Patent and ' 418 RC and has a significant impact on the claim constructions that follow.

III.

LEGAL STANDARD

"[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court." Markman, 517 U.S. at 372. "The words of a [patent] claim are generally given their ordinary and

customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question ... as of the [patent's] effective filing date." Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed.Cir.2005) (*en banc*). In interpreting a claim, "the court should first look to the intrinsic evidence of record, i.e. the patent itself, including the claims, the specification, and if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The patent specification, in particular, is central to a determination of "the meaning of a claim term as it is used by the inventor in the context of the entirety of his invention." Comark Commc'ns v. Harris Corp., 156 F.3d 1182, 1187 (Fed.Cir.1998). The patent specification "is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention [in the specification] will be, in the end, the correct construction." *Id*. at 1316 (quoting Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998)). Although a patent claim may at times contain terms that do not appear in the specification, all "terms and phrases used in the claims must find clear support or antecedent basis in the [specification] so that the meaning of the terms in the claims may be ascertainable by reference to the [specification]." Tandon Corp. v. U.S. Int'l Trade Comm'n, 831 F.2d 1017, 1024 (Fed.Cir.1987); *see also* Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed.Cir.1997).

IV.

CLAIM CONSTRUCTION

A. Agreed Claim Terms

The parties have agreed to the construction of the following claim terms, clauses or phrases as shown in the table below. The Court therefore preliminarily accepts the following constructions:

Claim Term	Claims	Agreed Construction
"substantially all"	31	"all or almost all"
"translates"	47	"moves"
"non-slitted"	54	"not-slitted"
"displacement"	28, 31	"movement from a previous location"
"generally cylindrical shape"	62	"generally cylindrical shape"
"self-flushing"	27, 28, 41, 42, 53, 55, 55, 59, 62, 63	"a net antegrade flow, i.e. fluid flow out of the connector during removal of the actuator"

B. Disputed Claim Terms

The parties disagree on the construction of the following claim terms, clauses or phrases as shown in the table below: FN4

FN4. The parties originally asked the Court to construe the terms "air chamber" and "valve internal chamber," but later agreed at the *Markman* hearing that these terms did not require construction.

Claim Term	Claims	Medegen's Proposed Construction	ICU's Proposed Construction
"displacing means"	28, 54, 55, 59	Means-plus-function term under 35 U.S.C. s. 112, para. 6	Means plus function term under 35 U.S.C. s. 112, para. 6
		Function is: "to provide displacements of fluid within the self-flushing connector"	Same function
		Corresponding structure includes: "the housing, the plug, the plug proximal portion, the plug distal end, and air chamber"	ICU contends there is no displacing means described in the written description rendering claim 28 invalid under s. 112, para. 6. ICU further understands that Medegen may claim the corresponding structure includes a "plug" or portions of that plug, an "air chamber" and the housing, but such structure is not appropriate "means" as it would render the claim invalid.
"plug"	27, 39, 53, 54, 55, 59, 62, 63	No construction required; or, "a member moveable between an open and a closed position"	"elastomeric part that either pivots about a reduced diameter portion or buckles, to establish a fluid flow path"
"biased member"	31, 47	No construction required; or, "a member moveable between an open and closed position and biased into the closed position"	" elastomeric part that either pivots about a reduced diameter portion or buckles to establish a fluid flow path and is subject to a biasing force, such as a spring"
"minimum fluid displacement"	31	No construction required; or, "movement of a small volume of fluid through the connector"	"zero or as close to zero as possible of fluid displaced through the valve outlet port when the actuator is moved in to the valve inlet port"
"relatively small movement of fluid"	27, 28, 53	No construction required; or, "movement of a small volume of fluid relative to the volume of the fluid flow through the connector during use"	Indefinite term lacking written description; or, "fluid movement that is slightly more than zero but no more than 20 microliters"
"overcompensate"	31	No construction required; or, "generate net antegrade flow, i.e.	"make the displacement more than offset but no more than 20 microliters"

		flow out of the connector when an actuator is withdrawn"	
"planar surface adapted for being abutted by the actuator"	39	No construction required; or, "a flat surface, a portion of which may be in contact with an actuator"	"a flat surface where the lower surface of the actuator fits completely against the upper surface of the plug"

1. "displacing means"

The parties agree that "displacing means," found in asserted claims 28, 54, 55 and 59, is a means-plus-function term, subject to 35 U.S.C. s. 112, para. 6. Construction of a means-plus-function term requires two steps: 1) determining the claimed function; and 2) identifying the corresponding structure in the written description performing that function. JVW Enters., Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1330 (Fed.Cir.2005). *The parties also agree that the function is: "to provide displacements of fluid within the connector*." ('418 Patent at 12:17-26.)

The parties disagree, however, on which structure or structures disclosed in the specification, if any, are adequately described as performing the displacing function. ICU contends that the written description does not adequately describe any structure for the claimed function, but alternatively suggests that only the "plug" performs the displacement of fluid. Medegen argues that the corresponding structure "includes" the "air chamber," portions of the housing, including the valve throat, the "plug" and the "plug collapsible skirt." When pressed by the Court at the *Markman* hearing to define more specifically which structure causes the fluid displacement, Medegen's counsel stated that it was the difference between the "diameter" of the plug cylindrical distal portion, which moves into and out of the air chamber, and the diameter of the actuator. The Court believes that it is the difference between the "volumes" of the plug cylindrical distal portion and actuator tip that ultimately causes the displacement when the plug cylindrical distal portion moves during actuation, not just the "diameters." (*See, e.g.,* ' 418 Patent at 7:6-10.) FN5

FN5. The '418 Patent and counsel at the *Markman* hearing described the volume of fluid displaced by the actuator tip and plug cylindrical distal portion as being best measured in cylindrical form. Notwithstanding the specification's occasional reference to varying the "diameters" of the plug cylindrical distal portion and actuator, diameter is only one factor in calculating volume of a cylindrical displacement, which depends also on length and can vary according to Luer, plug and air chamber lengths, as well as manufacturing tolerances for each. ('418 Patent at 6:67-7:12.) Volume, therefore, is a more useful metric by which to measure the displacement function.

The claim language does not clearly define "displacing means." Claim 28, the independent claim teaching the "displacing means" term, provides that the "displacing means" displaces fluid "in response to the movement of the actuator" in the "inward" or "outward" direction. ('418 Patent at claim 28.) The only element that moves in response to the actuator is the "plug," whose proximal end collapses and cylindrical distal portion shifts towards the air chamber upon insertion of the actuator, as Figure 2 shows. Dependent claims 54, 55 and 59 were added during the reexamination and were not part of the original disclosure, providing little additional information on the definition of the term.

The specification gives some guidance on this term, particularly as it relates to creating the "displacing means" performing a "flushing" function. The specification provides that "[i]n the presently preferred embodiment, the diameter of the plug cylindrical portion is configured to be approximately equal (or proportional) to the diameter of the actuator to thereby yield very close compensating displacements between the two devices. If the diameters are changed, flushing can be achieved." ('418 Patent at 6:67-7:5.) It then provides that if the "volume of the plug cylindrical distal portion is slightly greater than the volume of the actuator, a small amount of ... antegrade (self-flushing) flow will be produced during removal of the actuator." ('418 Patent at 7:6-12.) Nowhere in these descriptions is any mention of the plug proximal portion, the air chamber or the valve throat, which are all cited by Medegen's proposed definition that, on its face, appears to encompass almost the entire device. It may be true that these other structures are involved in the displacement function or facilitate it, but the specification does not clearly link to, or associate, them in performing that function, as is required for their identification as a corresponding structure. Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc., 248 F.3d 1303, 1311 (Fed Cir.2001). The specification and claim 28 both point to the movement of the plug, specifically the "plug cylindrical distal portion" or, in other embodiments and claims that are not asserted in this case, the "plug collapsible skirt" as performing the displacement function, whose magnitude is ultimately determined by the difference between the volumes of the actuator tip and these specific structures. *The corresponding structure of "displacing means" is therefore: "the plus cylindrical distal portion or plus collapsible skirt*."

2. "plug"

The term "plug" is widely used throughout the '418 Patent, and it appears in asserted claims 27, 39, 53, 54, 59, 62 and 63. Medegen argues that this claim is unambiguous and does not require construction, or proposes the following construction: "a moveable member between an open and closed position." ICU proposes that a "plug" is an: "elastomeric part that either pivots about a reduced diameter portion or buckles, to establish a fluid flow path."

The plug constitutes a critical element of the invention. The plug's proximal end opens and closes the connector's fluid pathway, and its distal portion performs the fluid displacement minimization or "self-flushing" function by virtue of its movement into and out of the air chamber.FN6

FN6. The Court recognizes that the alternate embodiment using the "plug collapsible skirt" functions differently to achieve the same result, but the Court agrees with Medegen that this embodiment is not at issue in this case.

The main issue surrounding the construction of the term "plug" is the extent to which the definition of the term should include the limitations of being "elastomeric," "pivoting about a reduced diameter portion," or "buckling." As ICU points out, the preferred embodiment of the invention, as discussed throughout the specification and claims, all consistently discuss a plug with these characteristics or limitations. (*See, e.g.,* '418 Patent at 6:17-65 (describing a "rubber" or "elastomeric" plug); 5:46-65, 6:7-30 (describing a "pivoting" or "rotating" plug proximal end about a "reduced diameter portion"); '418 RC at 1:28-47 (same).) Medegen, while admitting that specification repeatedly describes a plug that has these features, argues that the Court should neither confine the claims to the preferred embodiments, nor read any limitations found in the specification into the claims. Philips, 415 F.3d at 1323; Teleflex, Inc. v. Ficosa North Am. Corp., 299 F.3d 1313, 1327 (Fed.Cir.2002); Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 908 (Fed.Cir.2004).

The specification and Figures of the '418 Patent show the plug to have the elastomeric, pivoting and buckling features ICU describes. The plug is always described as a single piece, having both a proximal end and distal end. The proximal end is consistently shown to have a pivoting head that buckles to establish fluid flow, in conjunction with the shifting of the whole plug toward the air chamber, upon insertion of the actuator into the connector. (*See, e.g.,* '418 Patent at 5:45-50, 6:7-22, Figures 1-9.) The '418 Patent nowhere describes a non-elastomeric or rigid plug, nor does it teach how any such plug would work with the claimed device to permit fluid flow or to provide for minimum fluid displacement. In fact, during the reexamination, Medegen stated to the PTO that "the plug proximal portion is pivotable about the reduced diameter portions" and that "this feature is shown in all the illustrated embodiments." ('418 RC Prosecution History at MED-ICU00021827.) Medegen was also careful to distinguish the "non-collapsible" plug cylindrical distal portion from the buckling proximal end and other "collapsible" plug embodiments, though this distinction was not clear to the PTO and ultimately required amendments to the specification. (*See* id. at MMS-000455.111, .218-.220.) FN7

FN7. In fact, the prosecution history shows that the PTO also struggled with and ultimately rejected several of Medegen's proposed claim amendments for lack of written description, including ones that used the terms "non-collapsible" and "non-slitted" to distinguish the plug cylindrical distal portion from the plug collapsible skirt. (*See* '418 RC Prosecution History at MMS-000455.218-.220.) The PTO's rejections are what necessitated several amendments to the specification.

Against this wealth of intrinsic disclosures outlining an elastomeric, pivoting or buckling plug, or at least its proximal end, Medegen states that these are only characteristics of the preferred embodiment and that the Court should not read these limitations from the specification into the plug claims. Combined with boilerplate language in the specification claiming that the invention's scope may exceed that described by the specification FN8, Medegen also claims that the ' 418 Patent nowhere specifically disavows non-elastomeric, non-pivoting or non-buckling plugs. Medegen further points out that prior art covered rigid, non-elastomeric plugs, especially *Collinson et al.,* U.S. Pat. No. 5,439,451, and, thus, a rigid plug would not require separate disclosure since it was known within the state of art at the time the Medegen applied for the ' 418 Patent. (*See* '418 RC Prosecution History at MMS-000455.009-011.) Finally, Medegen directs the Court to a separate, not-in-suit patent it owns, U.S. Patent No. 5,782,816, for a bending or buckling plug within a medical valve device, to argue that Medegen would not have sought to patent the buckling, elastomeric plug in the ' 418 Patent, since it would essentially be engaging in double-patenting.

FN8. (See '418 Patent at 8:47-56.)

Medegen's arguments are unconvincing. First, while the Court is cognizant of Federal Circuit precedent advising against reading limitations of specification into the claims or confining the claims to the preferred embodiment, these precedents do not provide patentees with a license to argue for claim constructions beyond what the specification will support.FN9 Bell Atlantic Network Servs., Inc. v. Covad Commc'ns Group, Inc., 262 F.3d 1258, 1273 (Fed.Cir.2001). *Philips* and related cases clearly cite to the patent's intrinsic record, especially the specification, as providing the best basis for construing the claims, stating it is "dispositive" and the "single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315-16 (citation and quotation marks omitted). Here the specification unambiguously and repeatedly refers to the plug as being elastomeric, whose proximal end pivots or buckles to establish fluid flow, providing steadfast

support for ICU's proposed construction. In a related structure, the specification, claims, Figures and prosecution history consistent indicate that the planar surface of the proximal plug head shifts towards being disposed at an angle to the actuator tip when the tip is inserted into the connector, something Medegen's repeated representations to the PTO during the reexamination and currently proposed construction also confirm. (*See, e.g.,* ' 418 Patent at claims 32, 39, and 40 and Figs. 2 and 8; '418 RC Prosecution History at MMS-000455.066, .067, .069-.070, .074, .079, .081, .300.) This rotational shift or angular disposition of the plug head during use is not possible with a rigid plug, but requires the elastomeric, pivoting or buckling plug described by the ' 418 Patent.

FN9. Medegen's counsel cited Robert C. Kahrl, *Patent Claim Construction* s. 5.03 "Preferred Embodiment" (2006), for the proposition that Federal Circuit precedent clearly advised against importing limitations of the specification into the claims or confining the claims to the preferred embodiment. *See, e.g.,* id. at 5-18.1 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898 (Fed.Cir.2004) and numerous other cases). The Court notes that while some cases within this work stand for the proposition Medegen cites, the entire chapter is prefaced by a discussion of the acute difficulty courts face in construing claims in light of "the lack of rules for determining when the specification will be treated as plenary or exemplary." *Id.* at 5-812. The chapter does an admirable job in trying to answer the critical question: "How does the practitioner distinguish a patent in which the disclosure in the specification limits the scope of the claim language from a patent in which the scope of the claim language is 'not limited to the preferred embodiment?' " *Id.* at 5-12. The author concludes that the Federal Circuit "has routinely restated a thesis and an antithesis for this question, neither providing clear guidance." *Id.* at 5-812. This Court notes this ongoing ambiguity in the case law, but cites to valid precedent holding that "the patentee does not necessarily prevent his specification from limiting the scope of his claims by labeling it the 'preferred embodiment.' " *Id.* (citing Bell Atlantic Network Servs., Inc. v. Covad Commc'ns Group, Inc., 262 F.3d 1258 (Fed.Cir.2001); Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295 (Fed.Cir.1999); Gen. Am. Transp. Corp. v. Cyro-Trans, Inc., 93 F.3d 766 (Fed.Cir.1996)).

The patent discusses no other embodiments of the invention that use a plug without these limitations, nor does it teach that other plugs with other characteristics are possible or describe how such alternative plugs would work. Thus, the preferred embodiment provides the *only* guidance on proper construction of the plug. *See, e.g.,* Irdeto Access, Inc. v. EchoStar Satellite Corp., 383 F.3d 1295, 1300-02 (Fed.Cir.2004) (finding district court could read a preferred embodiment into the claims where the specification consistently, repeatedly and exclusively described a term in the context of the preferred embodiment, despite patentee's failure to disavow other potential embodiments and its use of permissive terms and illustrative examples (citing Bell Atlantic, 262 F.3d at 1271 ("Thus, when a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term 'by implication.' "))). Even if Medegen is correct that the elastomeric plug is only part of the preferred embodiment, interpreting the plug as being non-elastomeric or rigid would read the preferred embodiment out of the claims, which is "rarely, if ever, correct." Vitronics, 90 F.3d at 1582-83; *see also* Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1581 (Fed.Cir.1996) ("We share the district court's view that it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way.") (citation omitted).

Second, the boilerplate language indicating the invention may be broader than the preferred embodiments is unhelpful in construing a term that is defined clearly, concisely and consistently everywhere else in the

patent.

Third, equally unhelpful is Medegen's argument that it is entitled to a construction of "plug" that does not include the elastomeric, pivoting and/or buckling limitations because the '418 Patent did not specifically disavow or disclaim other types of plugs. In this case, this simply means that Medegen did not describe any other type of plug as being part of its invention, even if other plugs were already known in the art. At minimum, Medegen nowhere in the ' 418 Patent described how any alternative plug, particularly a rigid plug, for example, would function in Medegen's claimed device. The different embodiments of the plug in the '418 Patent vary only in their distal end structures (i.e. a plug cylindrical distal portion versus a plug collapsible skirt), but all embodiments are clearly identified as elastomeric and all have the same pivoting and buckling proximal end that is designed to establish fluid flow through the connector.

When asked at the *Markman* hearing how a rigid plug, found in the prior art, would work in Medegen's device, Medegen's counsel only pointed to six patents it cited to the PTO during the reexamination, claiming such an implementation was already known in the art and did not need to be disclosed in Medegen's patent. Counsel then discussed how "bumps" on the rigid plugs covered by the prior art or the mere pressure of fluid coming from the actuator itself would be sufficient to open a fluid pathway if a rigid plug was used in Medegen's device, but neither explanation makes sense given the way the invention is described in the '418 Patent as functioning with an elastomeric plug. If anything, Medegen's answer implies that using a rigid plug in Medegen's device would have conflicted with prior art and that the '418 Patent deliberately refrained from describing how plugs found in the prior art would work with the claimed device. To the extent Medegen used the elastomeric, pivoting and buckling features of its plug to distinguish its plug from prior art, particularly *Collinson et. al* . (*see, e.g.,* '418 RC Prosecution History at MMS-000455.009-.011, .075-.079, .121-.125.), these characteristics should be included in the construction of the plug. *See* Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1325 (Fed.Cir.2002) ("Explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations."); Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed.Cir.1997) ("[S]ince, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection."). The Court recognizes that Medegen did not need to claim the plugs found in the prior-art as part of its own invention, but it needed to indicate in the '418 Patent that a skilled artisan could use alternative plugs and describe how such plugs would perform the functions of controlling fluid flow and achieving minimum fluid displacement in the context of its invention.

Finally, Medegen's citation to its separate patent for a bending plug within a medical valve is unavailing in defining the term "plug" in this case. It comprises extrinsic evidence that fails to show how the specification of the patent-in-suit, the '418 Patent, teaches that non-elastomeric or non-pivoting plug would work within the claimed device. Whether this other patent, in combination with the '418 Patent, contains double-patented claims for the "bendable plug" is for other proceedings to determine.

Therefore, the Court accepts ICU's proposed construction of a "plug," which is: "an elastomeric part that either pivots about a reduced diameter portion or buckles, to establish a fluid flow path."

3. "biased member"

Both parties agree that the term "biased member" can be construed similarly to a "plug" that is simply subject to a biasing force, as the two terms are used interchangeably throughout the '418 Patent. *Therefore, in light of the Court's prior construction of the term "plug," a "biased member" is: "a biased plus, or a plus*

subject to a biasing force, such as a spring."

4. "minimum fluid displacement"

The term "minimum fluid displacement" appears throughout the '418 Patent in the title, preamble, specification and claims of the '418 Patent, but only appears in one of the asserted claims, claim 31. Medegen believes this term does not require construction, but proposes the construction of: "movement of a small volume of fluid through the connector." ICU proposes a construction of "zero or as close to zero as possible of fluid displaced through the valve outlet port when the actuator is moved into the valve inlet port."

Notwithstanding Medegen's objection to any construction of this term, the Court believes construction is needed because it appears throughout the specification and claims, including asserted claim 31, and because the term describes the claimed invention itself. *See* Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1371 (Fed.Cir.2005) (holding that "when the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment"). The Court defines "minimum fluid displacement" by referring to the text of the specification and claims of the '418 Patent, which appear at times to distinguish between three different descriptions of the connector. These are: 1) a "minimum fluid displacement" connector (*see, e.g.,* '418 Patent at Cover, Abstract, 2:26, 2:40-51; 3, claims 1-16, 29-33, 43-52); 2) a "minimum fluid displacement self-flushing" connector (*see, e.g., id.* at 3:61-4:32; 5:9-10); and 3) a "self-flushing" connector (*see, e.g., id.* at claims 27, 28, 39-42, 53-77).

The Court starts with what the term "minimum fluid displacement" does not mean. The last of these descriptors, "self-flushing" has already been jointly construed by the parties as "a net antegrade flow, i.e. fluid flow out of the connector during removal of the actuator." From that definition, the term "minimum fluid displacement," by itself, cannot be read to mean the same thing as "self-flushing" or generating an unbounded amount of "net antegrade flow." So defined, the term "minimum fluid displacement" would be superfluous and there would be no reason to distinguish claims relating to a "minimum fluid displacement" connector from those reciting only a "self-flushing" connector, as the '418 Patent's specification and claims do, particularly as a result of the reexamination. (*See, e.g.,* id. at 5:55-56 (referring to "minimum fluid displacement" and "self-flushing" connectors as distinct; *compare* claims 1-16 (claiming a "minimum fluid displacement" connector") *with* claims 53-77 (claiming a "self-flushing" connector); '418 RC Prosecution History at MMS-000455.173 (distinguishing "minimum fluid displacement" and "self-flushing" embodiments to the PTO).) When the specification and claims refer to a connector that deliberately generates a net positive or antegrade flow upon removal of the actuator, they almost always term it "self-flushing," and not "minimum fluid displacement." In fact, 30 of the 44 new claims added by the ' 418 RC were directed towards distinctly named, "self-flushing" embodiments of the invention, all of which include the specific feature that when the actuator is removed from the connector, fluid flows out of the output port. Such naming distinctions in the new claims would be unnecessary if the original claims directed towards a "minimum fluid displacement" connector were sufficient to claim a distinct "self-flushing" embodiment.

When the term "minimum fluid displacement" is used by itself, as occurs in the title, preamble, several areas in the specification and several of the unasserted claims, the term refers to a connector that generates as little displacement of fluid as possible upon the insertion and removal of the actuator. The stated goal of "minimum fluid displacement" is minimizing retrograde flow upon removal of the actuator, and this is best accomplished by a connector that achieves "zero displacement" overall. For example, the specification typically defines a "minimum fluid displacement" connector as one in which "significant fluid is not

displaced during actuation," or is one that "offsets," "compensates," or "substantially compensates" the fluid displaced by the insertion and removal of the actuator for "zero displacement" overall within the connector. (*See, e.g.,* '418 Patent at 2:37-38, 2:48, 3:3-9; 4:24-29; 6:34-39; 6:62-66; 7:28-30; 8:6; 8:45.)

However, problems arise when the specification and claims mix the two terms, "minimum fluid displacement" and "self-flushing." For example, the specification discusses a "minimum fluid displacement self-flushing connector" that displaces a volume of fluid that is "approximately equal" to the fluid displaced by the insertion and removal of the actuator. (*See* '418 Patent at 3:50-4:10; 5:8-10.) In the subsequent paragraph, the specification describes that same connector as "compensate[ing]" the actuator-caused displacement or "generat[ing] an approximately zero displacement" within the connector. (*Id.*) Similarly, in asserted claim 31, which is for a "minimum fluid displacement" connector, the claim includes a biased member or plug element that "overcompensates" for the fluid displaced by the insertion and removal of the actuator tip, instead of "substantially compensating" or merely "offsetting" that fluid. (*See* '418 RC at claim 31.) Finally, the specification discloses that achieving net-zero displacement is not practically achievable because of male Luer manufacturing tolerances, requiring the design of even "minimum fluid displacement" connectors to err always on the side of producing a net flushing action, however small. ('418 Patent 2:12-15, 7:4-5.)

In these instances, the specification and claim language mix and interchange two terms that are expressly made distinct elsewhere in the '418 Patent, making a consistent construction particularly difficult. The prosecution history shows that this inconsistency was caused by the numerous "self-flushing" amendments and claims that resulted from the reexamination. Originally, only claims 27 and 28 dealt directly with a "self-flushing" connector in the '418 Patent, which was otherwise completely dedicated to a "minimum fluid displacement" connector. Those claims, by virtue of the description in the original specification, only referred to "self-flushing" as a subsumed feature of the invention, a design precaution against retrograde flow caused by unexpectedly large actuator tip volumes that had the benefit of also "flushing" the catheter tube during use. Nothing in the specification and claims of the original '418 Patent, however, clearly defined "self-flushing" as being a separate embodiment or as incorporating an unbounded amount of net-positive, antegrade fluid flow.

However, the reexamination created the ambiguity within the terms "self-flushing" and "minimum fluid displacement" when it amended 17 of the original 32 "minimum fluid displacement" claims, added 44 new claims, 30 of which were for a "self-flushing" embodiment, and added "self-flushing" language to claim 31, which was originally directed toward a "minimum fluid displacement" connector. In so doing, the term "self-flushing" ceased being a subsumed feature of "minimum fluid displacement" or a beneficial design precaution. The term took on an appreciably broader and distinct meaning, referring to a separate embodiment of the connector that potentially generated an unbounded amount of net-positive, antegrade fluid flow during use.

Medegen argues that the original "self-flushing" claims of 27 and 28 serve as the link to the new 44 "self-flushing" claims, but Medegen inappropriately relies on the new, post-reexamination claims to guide the Court's interpretation of claims 27 and 28 and the term "self-flushing." When questioned by the Court on whether Medegen could assert these new "self-flushing" claims that appeared only after the reexamination against ICU, Medegen's counsel replied, "Yes, you can. In particular, there's nothing wrong with claim 28. It went through [the reexamination] without touching the walls. And it dates back to the beginning." (*Markman* Hr'g Tr. 96:23-25, Jun. 5, 2007.) The Court perhaps could more aptly rely on the new "self-flushing" claims to construe the term, had the original '418 Patent not used the term "self-flushing" in an

appreciably different manner before the reexamination. To use the new claims to interpret the old terms would unfairly deprive ICU and the public of notice and full disclosure of what Medegen actually patented in 1996, particularly where the new claims differ in meaning or scope from the original disclosures.

Conversely, ICU seeks to have the new "self-flushing" claims and terms be read in accordance with how the term was used in the original '418 Patent-as a subsumed feature of an invention dedicated to "minimum fluid displacement" that beneficially generated a net-positive, limited antegrade fluid flow during use. This interpretation resolves the issues of term inconsistency and unfair surprise in the invention's potential scope, but it reads most of the reexamination's amendments and claims out of the patent, an extraordinary feat for a claim construction.

Finally, the Court believes that the parties' agreed-to definition of "self-flushing" as including an unbounded net-positive fluid flow is irreconcilable with the concept of a "minimum fluid displacement" invention, particularly when the original '418 Patent and the '418 RC specification and claims are compared. This incompatibility has implications for related terms like "overcompensate" and "relatively small movement of fluid," which are also construed in this Order and refer to unbounded or undefined fluid flows in a "self-flushing" embodiment of an invention that originally focused on "minimum fluid displacement."

The Court is thus faced with an inauspicious task: it must construe ambiguous terms in light of a puzzling intrinsic record and unusual prosecution history, executing a claim construction whose outcome depends largely on the resolution of issues that are unfit for that very proceeding. The best the Court can do is highlight this apparent conflict and its impact on claim construction and proceed apace, noting that other proceedings are necessary to resolve fully and fairly the issues raised here.

Returning to the parties' proposed constructions of "minimum fluid displacement," the Court finds that despite this ambiguity, ICU's construction, with some slight modification, best defines the term in accordance with the specification and claims in the context of the claimed invention, which covers both "minimum fluid displacement" and "self-flushing" connectors in distinct fashion. The term "minimum fluid displacement" refers to a connector that reduces the risk of any retrograde flow in the connector when the actuator is removed, but that also does not generate unbounded antegrade flow. Such a connector best achieves a net "zero displacement" effect upon the insertion and removal of an actuator. The term does not include "self-flushing" or unbounded positive fluid displacement, which Medegen's broad construction of "movement of a small volume of fluid through the connector" might. Medegen's construction is also ambiguous, as nowhere is it defined what a "small volume of fluid" would be or what the significance of that volume would be in the context of the invention, which is directed towards "minimum" fluid displacement, not "small" fluid displacement. Only ICU's construction incorporates the goal of minimization by describing the fluid displacement as "zero or as close to zero as possible." *The proper construction of "minimum fluid displacement" is therefore: "zero or as close to zero as possible of fluid displaced in or out of the valve outlet port when the actuator is moved into or out of the valve inlet port*."

This definition incorporates the fact that even minimum fluid displacement connectors err on the side of producing a minimal net-positive fluid flow to deal with manufacturing tolerances of Luer actuator tips. By using the phrase "as close to zero as possible," the definition provides for sufficient, but minimal positive fluid displacement or flushing while incorporating the term's required "minimization" of all fluid displacements. Alternatively, connectors directed towards generating unbounded positive fluid displacement are separately termed "self-flushing," which, while questionable in light of the prosecution history, is consistent with the specification and claims that resulted from the reexamination.

5. "relatively small movement of fluid"

The term "relatively small movement of fluid" appears in the text of asserted claims 27, 28 and 53. Medegen contends that no construction is required, or that the construction should be: "movement of a small volume of fluid relative to the volume of the fluid flow through the connector during use." ICU argues the term is indefinite and lacking sufficient written description support, and proposes the construction: "fluid movement that is slightly more than zero but no more than 20 microliters."

The two key modifiers of this term are "relatively small" and "movement." The word "movement" is used interchangeably with "displacement," both within the '418 Patent and as jointly construed by the parties and the Court. The use of the term "relatively small" immediately raises the question of, "relative to what?" Because the term is not found in the specification and is not defined in the claims, the answer is ambiguous. The word "relatively" appears unnecessary given that no meaningful comparison of fluid flow volume is made in the specification or claims In the three asserted claims, the term "relatively small" is only found in the discussion of the "plug" or "displacing means" element. It describes the fluid movement caused by the insertion and removal of the actuator in conjunction with the fluid movement caused by the moving of the "plug" or "displacing means" to/from the valve internal chamber to/from the air chamber. ('418 Patent at claims 27, 28, and 53.) Thus, "relatively small" is used in the context of describing the fluid flow caused by the insertion and removal of the actuator and the compensating movement of the "plug" or "displacing means" element.

Medegen's construction does little to resolve the ambiguity posed by the term "relatively small." It compares the volume of fluid displaced by the movement of the plug to the volume of fluid that flows through the connector during use. Unfortunately, the specification nowhere makes, nor supports this comparison. This construction also introduces another undefined term-"the volume of fluid that flows through the connector during use." As ICU points out, the volume of fluid that could flow through the connector during its use will vary widely depending on the physical volume of the syringe and the chosen fluid dose, making it an effectively unbounded reference point. Further, in the hypothetical case where an exceedingly small dose of medication is given through the connector, the ratio of fluid volume through the connector during use compared to the fluid volume displaced by the "plug" or "displacing means" may not be "relatively small," rendering the term inoperative.

ICU's proposed definition ties the term "relatively small" to the function of the "minimum fluid displacement" that occurs during the insertion and removal of the actuator. This interpretation is belied by the fact that the term is used to describe the function of "self-flushing" embodiments in claims 27, 28 and 53. ICU proposes an absolute maximum of how much fluid is "relatively small," arguing that 17 microliters is an appropriate cap justified by the specification, which refers to displacement volumes of 24, 50 and 100 microliters as "significant." ('418 Patent at 2:9-29.) The 17 microliter amount comes from ICU's expert's analysis of the known variance in the displacements caused by the tolerance range of Luer actuators, finding that a "valve with a plug designed to generate zero fluid displacement when used with the narrowest Luer would generate antegrade flow of 17 microliters if it were used with the broadest Luer." (ICU Claim Construction Br. at 10.) While ICU's methodology of anchoring the term "relatively small" to an absolute maximum volume by reference to extrinsic evidence has some merit, Medegen raises sufficient questions about the meaningfulness of ICU's 17 microliter cap, given the lack of uniformly followed industry standards for male and female Luer tolerances.

Ultimately, the Court views the term in the context of how it is used in claims 27, 28 and 53, where it describes the fluid flow caused by the insertion and removal of the actuator and the compensating movement of the "plug" or "displacing means" element in the "self-flushing" embodiment. FN10 *The term "relatively small movement of fluid" therefore means: "movement of a volume of fluid that is more than zero and is approximately equal to the volume of the actuator tip*." This definition lacks the hard upper-limit of fluid volume that ICU seeks, but defines the volume of fluid by using an approximate, yet meaningful comparison to the volume of the actuator tip, as occurs in the claims. Further refinement of this construction may occur in future proceedings.

FN10. An error in claim 53 complicates the Court's construction. In the context of "relatively small movement of fluid," claim 28 refers only to the functioning of the "displacing means," and claim 27 refers only to the movement of the "actuator," while claim 53 refers to the movement of the "actuator" and then the "plug." Claim 27, which otherwise has identical text to claim 53 in this phrase, originally referred to both the "actuator" and then the "plug" before the reexamination replaced the latter "plug" reference with a reference to the "actuator." The second reference to the "plug" in claim 53 is an error that should read "actuator."

6. "overcompensate"

The term "overcompensate" appears only in asserted claim 31. Medegen argues that this term does not require construction, or that the construction should be: "generate net antegrade flow, i.e. flow out of the connector when an actuator is withdrawn," which is closely related to the accepted definition for "self-flushing." ICU's proposed construction is: "make the displacement more than offset but no more than 20 microliters."

The term is not found in the specification or in any other claims and was introduced into claim 31 when it replaced the word "offset" during the reexamination. (*See* '418 RC at claim 31 .) The use of the word "overcompensate" instead of "offset" indicates a notable shift from the claim's prior wording, which originally comported with the concept of "minimum fluid displacement" or "zero displacement" that simply "offset," "compensated," "substantially compensated" or "approximately equalized" the fluid displaced by the insertion and removal of the actuator. As previously discussed, claim 31 was confusingly amended in such a way as to convey that the term "overcompensate" conformed more to the concept of a "self-flushing" embodiment, but this amendment occurred in a claim reciting a "minimum fluid displacement" connector. The Court notes that this use of the term "overcompensate" in this manner in claim 31, much like the use of "self-flushing," illustrates the problem of inconsistent term usage as a result of the reexamination process. Neither the term itself, nor the claim language, nor the specification defines the amount of positive fluid flow generated by a connector that "overcompensates" for the fluid displaced by the insertion and removal of the actuator. Perhaps this would not be a problem were claim 31 directed towards a "self-flushing" connector, but it is not. Claim 31 is directed only towards a "minimum fluid displacement" connector, which, as discussed above, has a fluid displacement "minimizing" purpose that is inconsistent with a connector that "overcompensates" or generates a potentially unbounded amount of positive fluid flow during actuation. This inconsistency may have future implications for the viability of claim 31 that are not addressed by claim construction.

At minimum, this inconsistency requires that the Court reject Medegen's proposed construction, which too closely equates "overcompensate" with "self-flushing" in a manner that the specification and claim 31 fail to

accomplish, particularly in a claim reciting a "minimum fluid displacement" connector. ICU's proposed definition of "more than offset" is appealing, given the use of the term in claim 31, but ICU's insistence on a bounded definition of 20 microliters is inappropriate given the specification's failure to define the term so narrowly. *The proper construction of the term "overcompensate" is therefore: "more than offset or more than compensate*."

This construction is faithful to the claim language after the reexamination and otherwise gives the term an ordinary meaning where no other meaning is indicated by intrinsic evidence. Dorel Juvenile Group, Inc. v. Graco Children's Prods., Inc., 429 F.3d 1043, 1046 (Fed.Cir.2005). The Court recognizes that it neither provides an upper bound to the term to render it unambiguous nor comports with its use in an expressly titled "minimum fluid displacement" claim, but believes it represents the best construction of the term at this stage of the proceedings.

7. "planar surface adapted for being abutted by the actuator"

This term appears only in asserted claim 39, though it exists elsewhere in the '418 Patent. Again, Medegen argues that no construction is necessary and alternatively proposes: "a flat surface, a portion of which may be in contact with an actuator." ICU proposes: "a flat surface where the lower surface of the actuator fits completely against the upper surface of the plug." The parties agree on the fact that the term refers to a "flat surface" that may be contact with an actuator, but disagree on the extent to which the "flat surface" is abutted by the actuator or is "adapted" for abutting the actuator. ICU argues that the actuator surface fits completely against the surface of the plug, while Medegen asserts that Figures 2 and 8 in the '418 Patent show that the actuator only abuts a portion of the top surface of the plug, particularly when the plug is pushed in and buckles upon the insertion of the actuator.

Upon review of the '418 Patent, *the Court does not believe further construction of this term is necessary*. The text of the specification and claims, and the illustrations in associated Figures 1-3, convey that the plain language of the patent is sufficient to give this term meaning.

IT IS SO ORDERED.

C.D.Cal.,2007.
Medegen MMS, Inc. v. ICU Medical, Inc.

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