

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

ADVANCE MEDICAL DESIGNS, INC.,

Plaintiff,

v.

CORBIN CLINICAL RESOURCES, LLC

Defendant.

Civ. A. No. 1:22-cv-00789-SAG

JURY TRIAL DEMANDED

**PLAINTIFF ADVANCE MEDICAL DESIGNS, INC.'S
AMENDED RESPONSIVE CLAIM CONSTRUCTION BRIEF**

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Exhibit No.	Description
Exhibit A (previously filed DE 58-1)	U.S. Pat. No. 10,064,681 (“681 Patent”)
Exhibit B (previously filed DE 58-2)	U.S. Pat. No. 11,096,762 (“762 Patent”)
Exhibit C (previously filed DE 58-3)	U.S. Pat. No. 11,246,677 (“677 Patent”)
Exhibit D (previously filed DE 58-4)	File History of U.S. App. No. 14/677,286, Office Action of October 6, 2017 (“October 6 Office Action and Response”)
Exhibit E (previously filed DE 58-5)	U.S. Pat. No. 5,494,039 (“Onik”)
Exhibit F (previously filed DE 58-6)	File History of U.S. App. No. 14/677,286, Applicant-Initiated Interview Summary of May 4, 2018 (“May 4 Interview Summary”)
Exhibit G (previously filed DE 58-7)	File History of U.S. App. No. 14/677,286, Office Action of April 2, 2018 (“April 2 Office Action and Response”)
Exhibit H (previously filed DE 58-8)	File History of U.S. App. No. 16/377,754, Office Action of January 17, 2020 (“Jan. 17 Office Action and Response”)
Exhibit I (previously filed DE 58-9)	U.S. Pat. No. 10,743,911
Exhibit J (previously filed DE 58-10)	Merriam-Webster Dictionary Online: https://www.merriam-webster.com/dictionary/
Exhibit K (previously filed DE 58-11)	Cambridge Dictionary Online: https://dictionary.cambridge.org (definition of “frictional”).
Exhibit L (previously filed DE 58-12)	Merriam-Webster Dictionary Online: https://www.merriam-webster.com/dictionary/ (definition of “distal”).
Exhibit M (previously filed DE 58-13)	Dictionary.com: https://www.dictionary.com/ (definition of “distal”)
Exhibit N (previously filed DE 58-14)	Merriam-Webster Dictionary Online: https://www.merriam-webster.com/dictionary/ (definition of “offset”).
Exhibit O (previously filed DE 58-15)	Dictionary.com: https://www.dictionary.com/ (definition of “offset”)
Exhibit P (previously filed DE 58-16)	Communication in EPO Patent Application No. EP15773805.5
Exhibit Q (previously filed DE 58-17)	PCT WO 2015/154024 A1

Exhibit No.	Description
Exhibit R (previously filed DE 58-18)	EU Search Opinion
Exhibit S (previously filed DE 76-1)	U.S. Pat. No. 11,446,056 (“056 Patent”)
Exhibit T (previously filed DE 76-2)	U.S. Pat. No. 11,547,436 (“436 Patent”)
Exhibit U	<i>Perineologic Appoints Jim Fortune as President and Promotes Matthew Allaway, DO, to Chief Executive</i> , PRNewswire (Jan. 24, 2022), https://www.prnewswire.com/news-releases/perineologic-appoints-jim-fortune-as-president-and-promotes-matthew-allaway-do-to-chief-executive-officer-301466605.html .
Exhibit V	Declaration of Dr. Edward Yun, <i>Advance Med. Designs, Inc. v. Corbin Clinical Res., LLC</i> , No. PGR2023-00041 (PTAB July 19, 2023), EX1003.

On July 31, 2023, Plaintiff Advance Medical Designs, Inc. (“Advance Medical” or “Counterclaim Defendant”) and Defendant Corbin Clinical Resources, LLC (“Corbin” or “Counterclaim Plaintiff”) each filed an opening claim construction brief. *See* DE 75 (“Corbin Opening”); *see also* DE 76 (“Advance Medical Opening”). Pursuant to Local Rule 805(2)(g), the April 27, 2023 Scheduling Order (DE 73), and the August 25, 2023 Extension of Time (DE 80), Advance Medical, by and through its undersigned attorneys, hereby submits its responsive claim construction brief.

I. ADVANCE MEDICAL WILL LIKELY NEED TO FILE A REPLY BRIEF

The April 27, 2023 scheduling order requires each party to file “opening claim construction briefs setting forth their proposed constructions **with supporting evidence.**” DE 73 at 1 (emphasis added). Corbin failed to set forth any evidence to support its proposed constructions for terms 5-13. *See* Corbin Opening at 22-24. Corbin’s entire argument in support of its proposed construction of 9 of the 13 construed terms was the following:

The terms proposed by Advance Medical are comprised of common everyday words readily understood by a person of ordinary skill in the art. These terms do not need construing because their meaning and scope is clear from a simple reading of the patent claims. The inventor never offered alternate definitions of these terms, never identified a clear intent to modify the meaning of such terms, and never provided any indication that the plain and ordinary meaning of the terms are not sufficient. *See generally*, Asserted Patents. Therefore, there is nothing that strikes against the presumption that the plain and ordinary meaning of such claim terms should apply. *K-2 Corp. Salomon, S.A.*, 191 F.3d 1356, 1363 (Fed. Cir. 1999) (the plain and ordinary meaning is presumed to apply.)

Corbin Opening at 23-24. Corbin did not substantively discuss any of claim terms 5-13 or proffer a single piece of evidence related to its proposed constructions of these terms. *Id.*

Corbin’s request to add 52% more pages to its Responsive Brief indicates that Corbin intends to introduce supporting evidence for terms 5-13 for the first time in its Responsive Brief. The scheduling order does not provide Advance Medical an opportunity to respond. DE 81-82.

While Advance Medical did not oppose Corbin’s Motion for Additional Pages in the interest of judicial efficiency, it anticipates the need for leave to file a Reply Brief to address evidence introduced for the first time in Corbin’s Responsive Brief and indicated as much to Corbin. *See* DE 81 at ¶ 9.

Corbin’s Opening Brief also states that it intends to provide testimony from Dr. Matthew Allaway (“Allaway”), the inventor of the Asserted Patents, at the claim construction hearing. Corbin Opening at 24. While Corbin included testimony from Allaway with respect to terms 1-4 with its opening brief, it did not introduce any evidence regarding terms 5-13, including testimony from Allaway. Therefore, any testimony from Allaway regarding terms 5-13 will prejudice Advance Medical because it will be new argument to which Advance Medical will be unable to respond unless it is given leave to file a Reply Brief. Corbin also should not be permitted to introduce new arguments at the claim construction hearing through Allaway’s testimony.

II. CORBIN’S PROPOSED CONSTRUCTIONS IMPROPERLY SUBSTITUTE EXTRINSIC EVIDENCE FOR INTRINSIC EVIDENCE

A court construing a patent claim seeks to accord a claim the meaning it would have to a person of ordinary skill in the art (“POSITA”) at the time of the invention. *See, e.g. Resqnet.com, Inc. v. Lansa, Inc.*, 346 F.3d 1374, 1378 (Fed. Cir. 2003) “The inquiry into the meaning that claim terms would have to a [POSITA] at the time of the invention **is an objective one.**” *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). Therefore, a court should “look to those sources available to the public that show what a [POSITA] would have understood [the] disputed claim language to mean.” *Id.* “Those sources include ‘the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of

the art.”” See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (quoting *Innova/Pure Water*, 381 F.3d at 1116).

While “expert and inventor testimony, dictionaries, and learned treatises” may be considered, “conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to the court.” *Phillips*, 415 F.3d at 1317-18. The Federal Circuit warns that any expert testimony “that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent” should be discounted. *Id.* at 1318 (quoting *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998)).

The Court should be particularly wary of inventor testimony as extrinsic evidence. It is well-established that the testimony of an inventor “cannot be relied on to change the meaning of the claims.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 983 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996); see also *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1580 (Fed. Cir. 1996) (“*Markman* requires us to give no deference to the testimony of the inventor about the meaning of the claims.”) In particular, the Federal Circuit has explained that “[t]he subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim.” *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1346 (Fed. Cir. 2008); quoting *Markman*, 52 F.3d at 985. As the Federal Circuit explained in *Howmedica*, while “an inventor understands the invention[,]” that does not mean that he or she “understand[s] the claims, which are typically drafted by the attorney prosecuting the patent application.” 540 F.3d at 1346-47.

Corbin supports its proposed claim constructions with the subjective testimony of the Asserted Patents’ inventor, Allaway, and improper attempts to import limitations from the

specification into the claims. Throughout its opening brief, Corbin hinges its arguments on what was “intended by the inventor” or what Allaway testified was the “purpose” of the invention. Corbin Opening at 1, 14, 17, 21. But the inventor’s **subjective** intent is irrelevant. The only pertinent inquiry is what an **objective** POSITA would have understood based on the publicly available documents and knowledge. A POSITA does not have the benefit of running commentary from the inventor. Additionally, it would be extremely problematic if an inventor could change the meaning of claim terms after they had issued and after litigation had commenced with only his own, unsupported testimony.

Here, Corbin attempts to use the self-serving Allaway declaration to overrule the intrinsic evidence. But Allaway does not present one piece of evidence in support of his contentions. *See generally* DE 75-6. Corbin seeks to have this Court change the meaning of these claims based on only the word of an interested party. On the other hand, Advance Medical’s constructions are supported by the intrinsic evidence available to an objective POSITA and consistent with the fundamental tenets of claim construction.

A. Term 1: “pair of stabilization bars”

Advance Medical’s Construction	Corbin’s Construction
Plain and ordinary meaning	“two bars able to resist movement of the platform or displacement member in all directions except along the length of the probe”

The term “pair of stabilization bars” uses non-technical terms that are readily understood by the lay person. Corbin does not dispute this fact. Corbin Opening at 5-10. Rather, Corbin attempts to narrow the “pair of stabilization bars” term by improperly importing limitations from the specification into the claims. Unable to meet the exacting standard for limiting claim scope, Corbin asserts that construction is necessary for the claims to fulfill the “purpose of the invention.”

Id. at 7. But in addition to the argument being supported only by the bare assertions of Allaway, there is no legal basis for limiting claim terms based on the invention’s purpose. Corbin is attempting to limit the scope of the “stabilization bars” term without any basis in the intrinsic evidence. The result is an ambiguous and unworkable construction that will only create further disputes.

1. Corbin’s Proposed Construction is Redundant and Confusing

The only time that Corbin concerns itself with the meaning of the words of the “stabilization bars” term is when it argues that it is not improper to substitute “two” for the word “pair.” While Advance Medical agrees that there is “no other meaning of the word ‘pair’” other than two, that is an insufficient reason to require construction. “Claim construction is a matter of resolution of disputed meanings and technical scope to clarify and when necessary to explain what the patentee covered by the claims for use in the determination of infringement. **It is not an obligatory exercise in redundancy.** *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (emphasis added). For many claim terms, attempting to “construe” the claim language adds little clarity. *Phillips*, 415 F.3d at 1312-14. Where “construing” a claim term would involve simply substituting a synonym for the claim term, it is more appropriate to allow the claim language to speak for itself. *Id.* When “the ordinary meaning of claim language ... may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words” construction is unnecessary. *Id.* at 1314. Advance Medical is confident that a jury can understand the word “pair” without a construction.

Additionally, Corbin’s proposed construction introduces confusion with the phrase “able to resist movement.” There is no discussion of “resisting movement” in the ’681 Patent. *See generally* DE 58-1. Does “resist movement of the platform ... in all directions except along the

length of the probe” mean the platform cannot move at all in the prohibited directions? If the platform is able to flex in the other directions, are the stabilization bars still resisting its movement? If the platform has some tolerance for movement in the prohibited directions, are the stabilization bars still resisting their movement? Rather than provide clarity and resolve any disputes about the claim’s meaning, Corbin’s proposed construction introduces more disputes which are exacerbated by the fact the intrinsic evidence never discusses restriction of movement, as discussed below. *See infra* Section II.A.2. So there is no reference to resolve the ambiguity.

2. Corbin Attempts to Improperly Import Limitations from Specification into Claims Without Support

While Corbin briefly discusses the meaning of “pair,” it never discusses the ordinary meaning of “stabilization bars.” Despite the fact that words of patent claims “are generally given their ordinary and customary meaning,” *Phillips*, 415 F.3d at 1312 (*quoting Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (1996)), Corbin skips past the ordinary meaning of “stabilization bars” and advocates for a construction based on specific embodiments of the specification. Corbin Opening at 6-10. But Corbin’s argument violates a fundamental tenet of claim construction law – you cannot import limitations from the specification into the claims. *Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC*, 824 F.3d 999, 1009 (Fed. Cir. 2016) (“But this court does not usually limit the claim scope to preferred embodiments, lest it commit the “cardinal sin” of importing limitations from the specification into the claims.”).

Corbin makes the blanket, unsupported statement that claim terms 1-4 have “unique meaning as used in the Asserted Patents.” Corbin Opening at 1. But, as discussed above, “pair” has a readily apparent meaning and Corbin’s use of “bars” in its proposed construction indicates that it can also be easily understood. Corbin Opening at 5. Therefore, as claim construction “begins and ends in all cases with the actual words of the claim,” the only remaining word of the term is

“stabilization.” *Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372, 1375 (Fed. Cir. 2017) (quoting *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998)). But Corbin does not argue that “stabilization” is a technical term that cannot be understood by a jury or that it redefined “stabilization” in the specification. Corbin Opening at 5-10. Rather, Corbin asserts that the ’681 Patent disclaimed all stabilization bars that did not “resist movement of the platform or displacement member in all directions except along the length of the probe.” But nothing in the intrinsic evidence meets the high bar required to depart from the plain and ordinary meaning of the term “stabilization.”

Corbin points to the ’681 Patent specification in an attempt to support its disclaimer argument. Corbin Opening at 6-10. But while the specification is important to claim construction, the Federal Circuit repeatedly states that not importing limitations from the specification into a claim is a fundamental tenet of claim construction. *Phillips*, 415 F.3d at 1323, *Cont’l Circuits LLC v. Intel Corp.*, 915 F.3d 788, 797 (Fed. Cir. 2019). Using intrinsic evidence, like the specification, to depart from the plain and ordinary meaning of a claim term is appropriate **in only two instances**: lexicography and disavowal. *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014); *see also Phillips*, 415 F.3d at 1316-17.

Corbin did not act as a lexicographer to redefine “stabilization” or “stabilization bars.” To act as a lexicographer, the patentee must “clearly set forth a definition of the disputed claim term” other than its plain and ordinary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). “[T]he patentee must clearly express an intent to redefine the term.” *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) (internal quotations omitted). In other words, POSITA would have to read the specification and conclude the application clearly applied his own definition to the claim term. *Id.* at 1368.

Corbin points to the following portion of the '681 Patent specification to support its contention that it redefined the meaning of “stabilization bars:”

The position of the access needle is facilitated by locking the access needle into the subcutaneous tissue of the perineum using a sliding platform that allows the user, such as a medical practitioner or patient caregiver, to place the access needle along a sagittal transducer plane at optimal positions for obtaining prostate biopsies.

'681 Patent at 4:33-39. But this passage does not even mention the stabilization bars, let alone describe how they govern the movement of the platform. *Id.* There is nothing in the specification to indicate that “stabilization bars” were redefined to include the limitations of Corbin’s proposed construction.

In fact, Corbin’s construction appears to exclude an embodiment described in the '681 Patent specification. In the '681 Patent, FIGS. 26A-26C show an embodiment of a guide 2600 “including a stabilization bar 101, fasteners 102, probe 103, lower mount 104, and an upper mount 105.” '681 Patent at 12:27-30. In that embodiment, the “sliding platform 103 is configured to pivot at pivot point 2608 to enable, for example, normal or vertical adjustment of an access needle (not shown) in directions perpendicular to a longitudinal access of the probe.” *Id.* at 12:48-51. Corbin’s assertion that this embodiment is irrelevant because “the stabilization bars do not facilitate the pivoting movement” is inapposite. Corbin Opening at 10 n.1. If the stabilization bars “resist movement of the platform or displacement member in all directions except along the length of the probe” then the platform would not be able to move vertically regardless of what is responsible for the vertical movement. The '681 Patent also describes embodiments where the “methods may include moving the needle in x, y, and z planes.” *Id.* at 13:57-62. Because the needle is engaged with the platform or displacement member, in this embodiment, the platform would have to move in all three directions. So rather than redefine stabilization bars as a device that forces the platform

to move in only one direction, the '681 Patent contemplates multiple embodiments where the platform does just that.

The '681 Patent also did not disavow claim scope to limit the stabilization bars to ones that “resist movement of the platform or displacement member in all directions except along the length of the probe.” “The standard for disavowal of claim scope is similarly exacting.” *Thorner*, 669 F.3d at 1366. A disclaimer must be both “clear and unmistakable.” *Mass. Inst. of Tech. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1119 (Fed. Cir. 2016). And Corbin bears the burden of proving it. *TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1063-64 (Fed. Cir. 2016).

“To disavow claim scope, the specification must contain expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.” *Cont’l Circuits*, 915 F.3d at 797. (quoting *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011)) “Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language.” *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004). Importing unclaimed elements from the specification into a claim construction is improper without a clear disavowal. *Phillips*, 415 F.3d at 1323.

Corbin asserts that the fact that each claim recites and each embodiment describes “a ‘platform configured to slide on the pair of stabilization bars along at least a portion of the length’” is sufficient to prove disavowal of all other stabilization bars. Corbin Opening at 7-10, quoting '681 Patent at 15:10-16:53. But “[a]lthough the specification often describes very specific embodiments of the invention,” the Federal Circuit has “repeatedly warned against confining the claims to those embodiments.” *Phillips*, 415 F.3d at 1323. Even describing an embodiment as preferred or preferable “does not automatically lead to finding a clear disavowal of claim scope.”

Cont'l Circuits, 915 F.3d at 797, *see also Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1377 (Fed. Cir. 2005). The Federal Circuit has also “expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.” *Phillips*, 415 F.3d at 1323; *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (“Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’”) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)).

Like the cases above, Corbin argues that every embodiment and figure shows a platform configured to slide along the length of the stabilization bars. But the platform being able to slide along the length of stabilization bars is not the same thing as the stabilization bars “resisting movement of the platform or displacement member in all directions except along the length of the probe.” But regardless, it is improper to import unclaimed elements from the specification into a claim construction without clear disavowal and how something is shown in the embodiments is not itself disavowal. *Phillips*, 415 F.3d at 1323.

Similarly, Corbin submits that “no other ‘sliding’ movement – or any other movement – is contemplated in the ’681 Patent.” Corbin Opening at 8. But silence is not words or expressions of manifest exclusion or restriction sufficient to limit “stabilization bars” to Corbin’s very specific construction. Regardless, the Federal Circuit has cautioned against requiring that all features of an invention described in the specification be included in the claims:

It is common, and often permissible, for particular claims to pick out a subset of the full range of described features, omitting others. A specification can adequately communicate to a skilled artisan that the patentee invented not just the combination of all identified features but

combinations of only some of those features (subcombinations) – which may achieve stated purposes even without omitted features.

ScriptPro, LLC v. Innovations Assocs., Inc., 762 F.3d 1355, 1359 (Fed. Cir. 2014). Here, there is nothing in the '681 Patent specification that would communicate to a POSITA that the stabilization bars are limited as suggested in Corbin's proposed construction.

Corbin's reliance on the *SkinMedica* case is inapposite as it is distinguishable. Corbin Opening at 7. In *SkinMedica*, a party asserted that the construction of "beads" did not include three-dimensional cultures. *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1197 (Fed. Cir. 2013). There, the Federal Circuit found that "each time the inventors referenced culturing with beads in the specification, they unambiguously distinguished that culture method from culturing in three-dimensions" such that the "implicit disclaimer" was "so clear it equate[d] to an explicit one." *Id.* at 1202 (quoting *Thorner*, 669 F.3d at 1368). Here, the '681 Patent never distinguishes its stabilization bars from others that allow movement in more than one direction. This case more closely mirrors *Continental Circuits* where the specific embodiments alone were insufficient to show clear and unmistakable disavowal.

As such, there is no support in the intrinsic record to limit the claimed stabilization bars to bars that "resist movement of the platform or displacement member in all directions except along the length of the probe."

3. Essence of the Invention Does Not Create Disclaimer

Corbin also argues that the scope of the claims should be limited to stabilization bars that only allow the platform to move in a single direction because of Allaway's post hoc description of the purpose of the invention. Corbin Opening at 6 and 10. However, the Federal Circuit has repeatedly rejected limiting the claim scope based on the purpose or essence of the claimed invention. *See, e.g., Allen Eng'g Corp v. Bartell Indus., Inc.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002)

(“It is well settled that there is no legally recognizable or protected essential element, gist or heart of the invention in a combination patent.”) (internal quotations and citations omitted); *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330-31 (Fed. Cir. 2007) (“We sympathize with the district court’s choice, since we agree that [the feature] is an essential element of the invention ... However, we cannot endorse a construction analysis that does not identify ‘a textual reference in the actual language of the claim with which to associate a proffered claim construction.’”) (quoting *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999)).

The Federal Circuit’s decision in *Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc.*, 473 F.3d 1173 (Fed. Cir. 2006), counsels against this practice. In *Ventana*, the issue was the proper construction of the term “dispensing” in a patent claiming automated methods for staining microscope slides. *Id.* at 1176. The district court construed “dispensing” to require “direct dispensing,” because the embodiments in the specification involved direct dispensing. *Id.* at 1178. On appeal, the appellant argued that the specification, when read in its entirety, would lead to the “inescapable conclusion” that the heart of the invention involved “direct dispensing,” and that the specification implicitly defined the term “dispensing” to mean direct “dispensing” – an identical argument to that proffered by Corbin. *Id.* at 1181; Corbin Opening at 10. But the Federal Circuit in *Ventana* rejected that argument noting its previous repeated warnings against confining claims solely to disclosed embodiments. 473 F.3d at 1181. This Court should do the same and not limit the construction of “stabilization bars” based on specific embodiments.

Furthermore, Corbin’s assertions regarding the “purpose” of the ’681 Patent’s invention are solely supported by the statement of Allaway. *See* Corbin Opening at 10. As discussed above, Allaway’s assertions are of limited value here. Allaway explains his own understanding of how his invention works. DE 75-6 at ¶¶ 28-30. He does not assert that a POSITA would have

understood that the stabilization bars restrict the movement of the platform based on the specification, which is the operative inquiry. *Id.* Allaway’s testimony cannot change the plain and ordinary meaning of “stabilization bars” or the fact that there was no disavowal of claim scope in the ‘681 Patent claims.

B. Term 2: “pair of stabilization members”

Advance Medical’s Construction	Corbin’s Construction
Plain and ordinary meaning	“two stabilization bars or other structures able to resist movement of the platform or displacement member in all directions except along the length of the probe”

Corbin’s proposed construction for “pair of stabilization members” should be rejected for the same reasons as its proposed construction for “pair of stabilization bars.” Like “stabilization bars,” “stabilization member” should be given its plain and ordinary meaning unless the intrinsic evidence shows a clear and unmistakable intent to depart from that meaning through lexicography or disavowal. *Hill-Rom*, 755 F.3d at 1371; *see also Phillips*, 415 F.3d at 1316-17. No such evidence exists in the specifications of the ‘762 Patent, the ‘677 Patent, or the ‘056 Patent.

Looking first at the claims, Corbin’s proposed construction does not make sense in the context of the surrounding claim language. Claim 13 of the ‘677 Patent recites a “platform configured to slide relative to the pair of stabilization members with the pair of lateral surfaces of the platform in frictional engagement with the inner surfaces of the pair of stabilization members.” D.E. 58-3 (“‘677 Patent”) at 16:5-9. Assuming, as Corbin suggests, that “stabilization bars” and “stabilization members” are interchangeable, ‘677 Patent claim 13 can be depicted as follows where red shows the inner surfaces of the pair of stabilization members and blue shows the pair of lateral surfaces of the platform:

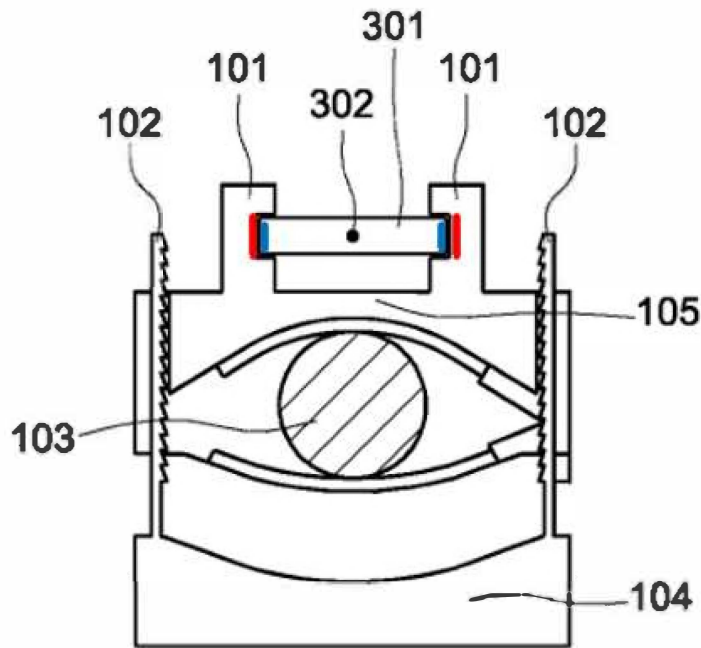


FIG. 4

'677 Patent, FIG. 4. If these surfaces are in frictional engagement, it would not prevent, but would **resist** movement of the platform along the length of the probe 103. Because Corbin's proposed construction creates an internal contradiction in '677 Patent claim 13, an objective POSITA would have never understood "stabilization members" to have that construction.

Corbin's proposed construction is also not supported by the Asserted Patents' specifications. Corbin admits that "[t]he term 'pair of stabilization members' is not found in the specification of any asserted patent." Corbin Opening at 11. In fact, "stabilization member(s)" is not found in any asserted patent. *See generally* DE 75-1 – 75-5. But Corbin asserts that all descriptions of the "stabilization bars" apply to the "stabilization members." As a threshold matter, there is no indication that a POSITA reading the asserted patents would understand "stabilization bars" to have the same characteristics as "stabilization members." It is generally assumed, in claim construction, that different claim terms have different meanings. *See CAE Screenplates Inc. v.*

Heinrich Fiedler GmbH & Co. KG, 224 F.3d 1308, 1317 (Fed. Cir. 2000) (“In the absence of any evidence to the contrary, we must presume that the use of these different terms in the claims connotes different meanings.”). Corbin admits that “stabilization members” is broader and “can include structure other than just stabilization ‘bars.’” Corbin Opening at 11. Yet, Corbin asserts, without an explanation, that all descriptions of the stabilization bars are imputed to the broader “stabilization members.”

Corbin’s contradictory constructions of “stabilization members” and “stabilization bars” are illustrative of its failure to follow the basic tenets of claim construction. It asserts that the term “stabilization members” encompasses other structures besides “bars” despite the fact that the asserted patents never describe or depict a “stabilization” structure besides the stabilization bars. *See generally* DE 75-1 – 75-5. Despite the fact that each embodiment of the Asserted Patents describes stabilization **bars**, the claim terms can have a broader scope than the specific embodiments such that stabilization **members** can include structures other than bars even though they are not described or depicted in the Asserted Patents. But Corbin asserts the opposite with regard to the directions in which the platform can move on the stabilization bars or other undepicted, undescribed structures. And Corbin has no explanation for why an independent POSITA viewing the Asserted Patents would appreciate this difference.

Even if a POSITA would assume that the “stabilization members” had the same characteristics as the “stabilization bars” described in the Asserted Patents, there is still no intrinsic evidence sufficient to depart from the plain and ordinary meaning of “stabilization members.” As Corbin acknowledges, the ’762 Patent has the same specification as the ’681 Patent. As described above, there is nothing in this specification that rises to the level of lexicography or disavowal of the plain and ordinary meaning of “stabilization.” *See supra* Section II.A.2. In fact, such a

restrictive construction would exclude embodiments described in the specification. '681 Patent at 12:27-30 and 13:57-62.

Corbin points to additional descriptions in the '056 Patent that, like the '681 Patent, describe specific embodiments, but do not rise to the level of disavowing the plain and ordinary meaning of “stabilization member.” Like the '681 Patent, most of Corbin’s citations to the '056 Patent describe embodiments where the displacement member **may** slide laterally, which is not clear and unambiguous disavowal. Corbin Opening at 12. The permissive “may” language alone indicates an intent to not disavow other movements. '056 Patent at 20:21-28 and 49-53; 22:10-24; and 28:27-30. None of these embodiments explicitly discuss restricting the movement of the displacement member in other directions. *Id.* In fact, the '056 Patent explicitly states that it should be interpreted as broader than the disclosed embodiments with respect to connection and relative movement between its elements:

[a]ll directional references (e.g., distal, proximal, front, back, side, top, bottom, fore, aft, right, left, etc.) are only used for identification purposes to aid the reader’s understanding of the implementations, and do not create limitations, particularly as to the position, orientation, or use of the embodiments described herein unless specifically set forth in the claims. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and **relative movement** between elements. As such, joinder references **do not necessarily infer that two elements are directly connected and in fixed relation to each other.**

'056 Patent at 34:63-35:8.

As such, there is no reason to depart from the plain and ordinary meaning of the term “stabilization member.”

C. Term 3: “biopsy needle”

Advance Medical’s Construction	Corbin’s Construction
“a needle or needle system capable of obtaining tissue or cell specimens”	“a needle system capable of obtaining tissue or cell specimens”

The purpose of claim construction is “to assign a fixed, unambiguous, legally operative meaning to the claim.” *Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1367 (Fed. Cir. 2004), citing *Vitronics*, 90 F.3d at 1582. But Corbin’s proposed construction, especially read in conjunction with its Opening Brief, only inserts confusion and ambiguity untethered from any intrinsic evidence in the Asserted Patents.

Tenets of claim construction require us to first look at the intrinsic evidence – the claims and specifications – in determining the proper construction of terms. *Phillips*, 415 F.3d at 1313-15. There is nothing in the intrinsic evidence that supports Corbin’s proposed construction. In fact, as discussed in Advance Medical’s opening brief, the Asserted Patent’s specifications indicate that a biopsy needle can be part of a larger biopsy instrument, but is never described as itself being a “system.” See Advance Medical Opening at 6-7. Corbin points to no intrinsic evidence that supports its contention that a “biopsy needle” is a system of multiple parts other than the fact that the title of each Asserted Patent “prescribe[s] that this invention relates to a transperineal biopsy procedure.” Corbin Opening at 14. Corbin appears to be again arguing that the gist of the invention should influence the claim construction. But as discussed above, the Federal Circuit has repeatedly prohibited this method of construing claims. See *supra* Section II.A.3.

Instead of discussing the intrinsic evidence, Corbin relies entirely on extrinsic evidence. More specifically, Corbin’s construction is only supported by the testimony of the founder and CEO of Corbin, Allaway. See DE 19 at 11, ¶ 11; see also Exhibit U. Allaway testified not just that a biopsy needle had to be a “system,” but that it was a term of art denoting a very specific system including an inner stylet that fits within an outer cannula core. See Corbin Opening at 14-16; DE 75-6 at ¶¶ 19-27. Allaway goes on to testify that “[t]he outer cannula is a hollow needle with thin walls and a sharp tip. The inner stylet slides within the outer cannula and has a sharp, piercing tip

and a specimen notch, or cut-out, just proximal of the tip.” DE 75-6 at ¶ 20. What is unclear now is what Corbin means in its proposed construction when it says “system.” Is a system any biopsy device with at least two parts or is a system required to be the specific device described by Allaway? With this ambiguity, Corbin’s construction fails to achieve claim construction’s primary purpose of providing a fixed and unambiguous meaning to the claims.

Also, while Allaway asserts that biopsy needle is a “term of art” denoting this very specific biopsy device, this is contradicted by the intrinsic evidence. None of the Asserted Patents describe this configuration of a “biopsy instrument,” “biopsy needle,” or “biopsy gun” – another term used to describe the biopsy device in the Asserted Patents. *See generally* Asserted Patents. None of the Asserted Patents’ Figures show this specific biopsy needle configuration. *Id.* There is simply nothing in the specification that remotely resembles the “biopsy needle” described by Allaway.

Allaway’s assertion is also refuted by the prosecution history. When Corbin asserted that the prior art reference Onik did not disclose its patent claim, it never contended that Onik did not disclose a biopsy needle. *See* DE 58-7 at 14-16; *see also* DE 58-8 at 29-33. Onik disclosed a biopsy needle insertion guide for use in cryosurgery. DE 58-5 at 1. In Onik, the biopsy needles are not used to take biopsies of the prostate, but rather are used to guide “cryoprobes in the prostate for cryogenic surgery of the gland.” *Id.* As such, the biopsy needles of Onik would not have the outer cannula and inner stylet described and depicted by Allaway as it would not allow insertion of the cryoprobes. But Corbin never argued in its Office Action Responses that Onik did not disclose a “biopsy needle” because what it called biopsy needles would not have an outer cannula and inner stylet. *See* DE 58-7 at 14-16; *see also* DE 58-8 at 29-33. Because Corbin accepted that Onik disclosed a “biopsy needle,” a POSITA viewing the Asserted Patents would understand that Onik’s

biopsy needle also fell under the claim term “biopsy needle,” despite the fact that it was not a “system,” let alone the specific system described by Allaway.

D. Term 4: “access needle”

Advance Medical’s Construction	Corbin’s Construction
“a needle providing access to the body”	“a needle providing access to the body comprising a lumen sized to receive a biopsy needle or other instrument therethrough”

1. The Claim Language Does Not Support Corbin’s Construction

Corbin’s arguments ignore the most important factor in claim construction – the language of the claims themselves. *Homeland Housewares*, 865 F.3d at 1375. Claim language is of “primary importance,” as it “provide[s] substantial guidance as to the meaning of particular claim terms.” *Phillips*, 415 F.3d at 1312, 1314. All claims of the Asserted Patents recite an access needle. DE 75-1 at 15:10-16:54; DE 75-2 at 15:10-18:35; DE 75-3 at 15:10-17:12; DE 75-4 at 35:33-38:28; DE 75-5 at 35:46-38:45. Many of the claims recite that the access needle is configured to receive a biopsy needle therethrough. DE 75-1 at 16:23-24; DE 75-2 at 15:28-38 and 16:5-18:35; DE 75-3 at 15:10-17:12; DE 75-4 at 35:33-38:28; DE 75-5 at 35:46-38:45. But some of the claims do not and those claims are instructive of the proper construction of “access needle.”

It is not just the claim term itself that is analyzed in claim construction. “The context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms.” *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003). “Differences among claims can also be a useful guide ... For example, 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 1314-15 (citation omitted). This concept is often referred to as claim differentiation. This “presumption is especially strong when

the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003). Here, Corbin’s construction would read the limitation of a dependent claim into an independent claim, which the Federal Circuit has ruled is improper.

In the ’681 Patent, independent claim 1 recites “[a]n apparatus ... for use in guiding an access needle.” ’681 Patent at 15:10-13. Claim 1 recites that the platform is configured to support the access needle and displace the needle along the length of the stabilization bars. *Id.* at 15:27-33. But independent claim 1 never recites a biopsy needle or any other needle other than the access needle. *Id.* at 15:10-32. Dependent claim 16, which depends from claim 1, recites “wherein the access needle is configured to receive a biopsy needle therethrough.” *Id.* at 16:23-24. Under the principle of claim differentiation, independent claim 1 must have a different, broader scope than dependent claim 16. Claim 1 must be read to not require the limitation of claim 16. But Corbin’s construction would do just that. Adopting Corbin’s proposed construction would improperly fold the limitations of claim 16 into claim 1 and render claim 16 superfluous.

The ’762 Patent similarly has an independent claim 1 that does not recite a biopsy needle, or any other needle besides the access needle. ’762 Patent at 15:10-27. Dependent claim 2 adds the additional method step of “inserting a biopsy needle through the access needle and into a first location within the prostate.” *Id.* at 15:28-30. Therefore, the step of inserting a biopsy needle through the access needle is not required in claim 1.

For the claims that already recite an access needle configured to receive a biopsy needle therethrough, Corbin’s proposed construction is superfluous and potentially confusing. Advance Medical Opening at 20-23. But for the claims that do not require a biopsy needle inserted through

the access needle, Corbin's construction violates the principle of claim differentiation and improperly renders claims of the Asserted Patents meaningless. Therefore, the claim language, the most important factor in claim construction, demonstrates that Corbin's proposed construction is improper.

2. The Intrinsic Evidence Does Not Support Corbin's Construction

Corbin does not assert that its construction represents the plain and ordinary meaning of "access needle." Nor does Corbin assert that a particular passage of the specification or other intrinsic evidence redefines "access needle" or disavows its claim scope. Rather, Corbin asserts that the cumulative effect of several embodiments describing a biopsy gun or other instrument inserted through the access needle justifies limiting the definition of "access needle." Corbin Opening at 17-22. It does not.

Similar to the "stabilization bars" term, Corbin asserts that because some embodiments describe a biopsy instrument inserted through an access needle, that is sufficient to change the definition of access needle from its plain and ordinary meaning. *Id.* But, as explained above, more is required for lexicography or disavowal. *See supra* Section II.A.3. "[T]he claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim Co.*, 358 F.3d at 906 (*quoting Teleflex*, 299 F.3d at 1327). Here, Corbin does not point to any words or expressions of manifest exclusion or restriction limiting the definition of "access needle." Rather, the specifications and claims of the Asserted Patents demonstrate to a POSITA that "access needle" should be interpreted broadly.

There are instances where the Asserted Patents describe the method of the invention without use of a second needle. For example, the specifications state that "[m]ethods may include locating a suspicious area, positioning an access needle, and obtaining one or more tissue or cell

specimens from an accurate point in the prostate.” ’681 Patent at 7:15-17. In fact, when discussing the use of a biopsy needle passed through the access needle, the Asserted Patents make clear it is not always required, stating “[i]n **some embodiments**, upon placement of the access needle into a locked position, for example, in the pelvic floor, a user may then pass a biopsy needle through the access needle to a desired location of the prostate.” ’681 Patent at 4:39-42. These statements in the specifications along with the claim differentiation discussed above (*see* Section II.D.A) indicate to a POSITA that the Asserted Patents can and do claim use of the access needle without passing a biopsy needle or other instrument therethrough. Building this feature into the term “access needle” through claim construction would contradict the intrinsic evidence.

Like with “stabilization bars,” Corbin also asserts that its construction is proper because it encompasses the “purpose” of the access needle. Corbin Opening at 17. As discussed above, there is no legal basis for creating a construction based on the gist or purposes of the invention. *See* Section II.A.3. Therefore, this argument is irrelevant.

Lastly, Corbin asserts that the prosecution history of related U.S. Patent No. 10,743,911 (“’911 Patent”) disavows the claim scope of any “access needle” other than one with a lumen sized to receive a biopsy needle. Corbin Opening at 21-22. While it is true that the prosecution history of a related patent can be relevant, nothing in the Office Action Response cited by Corbin even discusses the meaning of the term “access needle,” let alone redefines it or disavows its scope. *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1314 (Fed. Cir. 2007); *see generally* DE 75-7. Corbin directs the Court to arguments regarding claim 6 of the ’911 Patent in a December 13, 2019 Office Action Response (“Office Action Response”). Corbin Opening at 21-22. But claim 6 explicitly recites both a “needle” and an “access needle” and “wherein the needle is inserted ... through the access needle.” DE 75-7 at 3, 10. The Office Action Response simply argues that the

prior art does not disclose the explicit claim language – two needles with one inserted through the other. *Id.* Tellingly, the Office Action Response **does not** argue that the prior art does not disclose an “access needle” because its needle did not have “a lumen sized to receive a biopsy needle or other instrument therethrough.” *Id.* Nothing in this Office Action Response amounts to a clear and unmistakable disavowal of the claim scope of “access needle.”

None of the intrinsic evidence – the specifications or prosecution histories – redefines or disavows the scope of “access needle” from its plain and ordinary meaning. A POSITA, viewing the Asserted Patents and interpreting their claims would be forced to conclude that an “access needle” had the benefit of its plain and ordinary meaning. As discussed below, Allaway’s testimony is insufficient to override the intrinsic evidence.

3. Extrinsic Evidence Does Not Support Corbin’s Construction

As discussed above, the value of an inventor’s testimony is limited. *See supra* Section II.C. Allaway attempts to define an “access needle” as a form of coaxial needle and parrots Corbin’s proposed claim construction. *See* DE 75-6 at ¶ 13. But, unlike with biopsy needle, Allaway does not state that “access needle” is a term of art or imply that his definition of the term is what would be understood by an independent POSITA. *compare Id.* at ¶ 13 and *id.* at ¶ 19. Corbin’s opening brief tellingly asserts that its construction is necessary to prevent the trier of fact from “assign[ing] an overly broad meaning to this term, beyond what was **intended by the inventor.**” Corbin Opening at 17 (emphasis added). “The subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim.” *Howmedica Osteonics Corp.* 540 F.3d at 1346 (*quoting Markman*, 52 F.3d at 985). “Access needle” should be construed based on what a POSITA independently viewing the Asserted Patents would understand. Such a POSITA would not have the benefit of Allaway’s commentary on what he intended the claim term to mean post hoc.

In addition to being inconsistent with the intrinsic evidence, Allaway's testimony is also at odds with other experts in the field. Dr. Edward Yun is a board-certified Urologist who is the head of Urology at Riverside Community Hospital and a urology professor at the University of California, Irvine. Exhibit V at ¶¶ 2-3. Dr. Yun submitted an expert report in support of a post-grant review of one of the Asserted Patents. *Id.* In that report, Dr. Yun opined that his understanding, as a professional in the field, is that a needle is an access needle simply if it accesses tissue in the patient's body. *Id.* at ¶ 81. Allaway's biased assertion is insufficient to counter the "heavy presumption" that terms carry their "ordinary and customary meaning," especially when that presumption is supported by all other intrinsic and extrinsic evidence. *CCS Fitness*, 288 F.3d at 1366.

III. CORBIN FAILED TO PROVIDE SUPPORTING EVIDENCE FOR ITS PROPOSED CONSTRUCTIONS OF TERMS 5-13

As discussed above, Corbin did not present any substantive argument for terms 5-13 leaving Advance Medical unable to respond to Corbin's evidence or arguments in support of its proposed constructions. However, Corbin's arguments with respect to terms 1-4 show that it is attempting to apply the rules of claim construction inconsistently to its own benefit. This inconsistency is most evident in its proposed construction of terms 6 and 7.

- A. Terms 6 and 7: “platform configured to slide (on the [a] pair of stabilization bars [members], relative to the base, relative to the pair of stabilization members, within the channel)” and “so as to displace the access needle along the at least a portion of the length”**

Claim Term	Advance Medical’s Construction	Corbin’s Construction
platform configured to slide (on the [a] pair of stabilization bars [members], relative to the base, relative to the pair of stabilization members, within the channel)	“the platform configured to slide (on the pair of stabilization bars [members], relative to the base, relative to the pair of stabilization members, within the channel) while the access needle is engaged with the platform.”	No construction necessary – plain and ordinary meaning
so as to displace the access needle along the at least a portion of the length	“so as to displace the entire platform supporting the access needle between the front portion and the back portion of the stabilization bars”	No construction necessary – plain and ordinary meaning

Corbin makes the blanket assertion that claim terms 6 and 7, along with claim terms 5 and 8-13 are “comprised of common everyday words readily understood by a person of ordinary skill in the art” and therefore, do not require construction. Corbin Opening at 23. But Corbin fails to explain why the words in these claim terms are readily understood, but the “stabilization bars” and “stabilization members” terms require construction. Term 6 even includes the “stabilization bars” and “stabilization members” language, but Corbin asserts it does not require construction here, but does in terms 1 and 2.

Corbin also asserts that its construction of claims 1-4 is proper because the included limitations are repeatedly discussed in the specification and shown in the figures. Corbin Opening at 5-22. Yet, every embodiment and figure of the Asserted Patents shows the platform configured to slide while the access needle is engaged and the entire platform is positioned between the front portion and back portion of the stabilization bars. *See* Advance Medical Opening at 14-18; *see* DE

75-1—75-5 (collectively “Asserted Patents”) at 15:35-39, 16:18-22, 16:63-68, FIGS. 1, 2B-C, 3,-4, 6-7, 26A-C.¹ Corbin has no explanation why it contends that repeated and consistent usage is sufficient to change the meaning of terms 1-4, but not terms 6 and 7.

But terms 6 and 7 are different because unlike terms 1-4, there are clear and unmistakable disclaimers of their claim scope in the prosecution history. As discussed in Advance Medical’s opening brief, Corbin repeatedly distinguished its sliding platform from Onik’s where the needle “is inserted through the notch 31 of the needle holder assembly 28 ***once the guide is set in position against the patient’s body.***” DE 58-4 at 12 (emphasis in original). If Onik is different than the claimed invention because the needle is only inserted into the “platform” after it is locked in place, then the Asserted Patent’s claims must have the needle inserted into the platform at a time other than when the guide is set in position (that is, while it is still sliding). Corbin made no such disclaimer with respect to terms 1-4.

Corbin’s proposed constructions require uneven and contrary interpretations of the intrinsic evidence and the tenets of claim construction. Whereas Advance Medical’s proposed construction should be adopted because they apply the intrinsic evidence and tenets of the claim construction consistently. Therefore, the Court should adopt Advance Medical’s constructions.

Dated: September 15, 2023

Respectfully submitted,

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¹ Citations are to the ’681 Patent. As Corbin has stated, the contents of the ’681 Patent’s specification are included in all Asserted Patents.

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CERTIFICATE OF SERVICE

I hereby certify that on September 15, 2023, I filed a true and correct copy of the foregoing document with the CM/ECF filing system of this Court, which will serve an electronic copy to all attorneys of record.

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