UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

PAINTEQ, LLC,

Plaintiff,

v. Case No. 8:20-cv-2805-VMC-AAS

OMNIA MEDICAL, LLC,

Defendant.
_____/

ORDER

This matter comes before the Court pursuant to the claim construction hearing held on January 30, 2023. For the reasons stated below, the claims are construed as set forth herein.

I. Background

PainTEQ is a Florida LLC that provides services and solutions to the interventional pain management community. (Doc. # 10 at 1-2). One such service is the LinQ™ posterior joint fusion procedure, which allows for fusion and stabilization of the sacroiliac joint ("SI Joint") in patients. (Id. at 2). According to PainTEQ, the manufacturers, distributers, and sellers of SI joint fusion implants and instrumentation focused primarily on spinal

surgeons, instead of the interventional pain management community. (Id. at 3).

Omnia "develops novel products that reduce operative time through safe and reproducible instrumentation, while achieving superior surgical outcomes." (Doc. # 20 at 24). One such product is the PsiF™ System which is used for surgical procedures in SI repair. (Id.). The PsiFTM System includes components designed to practice the method of at least one claim of the '539 Patent. (Id.).

There are two patents at issue in this action: U.S. Patent No. 10,426,539 "Method and Implant System for Sacroiliac Joint Fixation and Fusion" (the '539 Patent) and U.S. Design Patent No. D905,232 "Surgical Cannula" (the D232 Patent). The '539 Patent is a utility patent that is directed to instruments and methods for fusing a SI Joint to repair the joint or to alleviate pain in the pelvis or spine. (Doc. # 56-1 at 2). The D232 Patent is a design patent that contains one claim for "the ornamental design for a surgical cannula, as shown and described." and includes ten figures showing the design from all views. (Doc. # 56-2 at 1). Orthocision filed its application for the '539 Patent on March 26, 2019, and the patent was issued on October 1, 2019. (Doc. # 56-1). Orthocision filed its application for the D232 Patent on June

11, 2020, and the patent was issued on December 15, 2020. (Doc. # 56-2).

Omnia is the exclusive licensee of intellectual property owned by Orthocision, including the '539 Patent and the D232 Patent. (Doc. # 20 at 25). As the exclusive licensee, Omnia Medical has the right to use the licensed intellectual property and to enforce, litigate, initiate court proceedings, and/or settle all past, present, and future claims arising from or related to the licensed intellectual property. (Id.).

PainTEQ and Omnia entered into a business relationship that began around December 2016. (Id.). This relationship was solidified by the Stocking Agreement between the companies. (Id.). As part of this relationship, PainTEQ initially served as the exclusive distributor for Omnia implants and instrumentation for SI joint fusion procedures in the interventional pain community. (Doc. # 10 at 3). However, according to PainTEQ, Omnia was unable to supply enough implants to meet demand. (Id.). Subsequently, PainTEQ ended the relationship with Omnia. (Id. at 4). In the process of finding a new supplier, PainTEQ created a new SI procedure, which it dubbed the LinQ™ procedure. (Id.).

As relevant to Omnia's patent claims, the crux of Omnia's allegations is that PainTEQ's LinQ™ Products "are unlicensed and unauthorized copies or near copies of Omnia Medical's PsiF™ System tools." (Id. at 25). After PainTEQ terminated the Stocking Agreement in February 2019, Omnia discovered in September 2019 that PainTEQ was selling equipment substantially similar to Omnia's, and distributing a Surgical Technique Guide that uses images of equipment identical to Omnia's. (Id. at 27).

Omnia alleges that PainTEQ has infringed and continues to infringe the '539 Patent by making, using, selling, offering to sell, and marketing its LinQ™ Products. (Id. at 27-28). Similarly, Omnia alleges that the surgical cannula contained in the LinQ™ products infringes the D232 Patent. (Id. at 30).

On April 8, 2020, PainTEQ filed suit in state court against Omnia Medical, LLC, and Chad Subasic. (Doc. # 1-1). Omnia removed the case to federal court on November 20, 2020. (Doc. # 1). The second amended complaint – the operative complaint, filed on December 4, 2020 – alleges claims for breach of contract, trade secret misappropriation, tortious interference with business relationships, and defamation. (Doc. # 10). On December 18, 2020, in addition to its answer

and affirmative defenses, Omnia filed counterclaims against PainTEQ for breach of contract, patent infringement, trademark infringement, unfair competition, and copyright infringement. (Doc. # 20 at 23).

Omnia filed its claim construction brief on July 28, 2021. (Doc. # 52). PainTEQ filed its opposition brief on August 16, 2021 (Doc. # 56), and Omnia replied on August 26, 2021. (Doc. # 57). The Court held a Markman hearing on January 30, 2023, where the parties presented evidence on the meaning of disputed language in the patent in suit. The Court now determines the meaning of this disputed language.

II. Legal Standard

"Patent infringement actions are composed of two phases." Alps S., LLC v. Ohio Willow Wood Co., No. 8:08-cv-1893-MSS-MAP, 2010 WL 2347046, at *1 (M.D. Fla. May 19, 2010) report and recommendation adopted, No. 8:08-cv-1893-MSS-MAP, 2010 WL 2293274 (M.D. Fla. June 7, 2010). "First, in the claim construction phase, the court determines the scope and meaning of the patent claims as a matter of law, and second, the claims are compared to the allegedly infringing device." Id. (citing Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998)).

The construction of claims is based primarily on intrinsic evidence: the claim language, the specification, and the prosecution history. Id. The claim language itself is first in importance when construing the meaning and scope of the patent. Id. Generally, the rule for claim interpretation is that:

> [T]erms in the claim are to be given their ordinary and accustomed meaning. General descriptive terms will ordinarily be given their full meaning: modifiers will not be added to broad terms standing alone. In short, a court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of the claim terms. Thus, if the claim is unambiguous and clear on its face, the court need not consider the other intrinsic evidence in construing the claim.

Id. (quoting Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999)). The court must determine what the claim language would have meant to "a person of ordinary skill in the art in question at the time of the invention." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). "The goal of claim construction is to give disputed terms their 'ordinary and customary meaning' as the term would mean to 'a person of ordinary skill in the art in question . . . as of the effective filing date of the patent

application.'" Targus Int'l LLC v. Grp. III Int'l, Inc., No. 20-21435-Civ-Scola, 2022 WL 18394869, at *2 (S.D. Fla. Jan. 5, 2022) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

"When the meaning of words in a claim is in dispute, the specification and prosecution history can provide relevant information about the scope and meaning of the claim." Electro Med. Sys., S.A. v. Cooper Life Scis., Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994). This is because "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips, 415 F.3d at 1313. "The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it." Vitronics Corp., 90 F.3d at 1582. The prosecution history "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." Id.

The 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 (citing Vitronics, 90 F.3d at 1582). "The [c]ourt must be careful, however, to avoid reading limitations from the specification into the claim." Ice House Am., LLC v. Innovative Packaging Techs., Inc., No. 3:05-cv-1294-VMC-TEM, 2008 WL 2856674, at *3 (M.D. Fla. July 22, 2008), clarified on denial of reconsideration, No. 3:05-cv-1294-VMC-TEM, 2008 WL 3305232 (M.D. Fla. Aug. 7, 2008).

"The claim is what limits the scope of the patent, not the specification." Id. Accordingly, "the [c]ourt [should] be equally careful to avoid reading the claims too broadly, as would be done if the [c]ourt read claim language according to its dictionary definition rather than in the context of the specification." Id.

Courts may also rely on claim differentiation to construe terms. "The doctrine of claim differentiation create[s] a presumption that each claim in a patent has a different scope." Versa Corp. v. Ag-Bag Intern. Ltd., 392 F.3d 1325, 1330 (Fed. Cir. 2004) (internal citation omitted). "The difference in meaning and scope between claims is presumed to be significant [t]o the extent that the absence of such difference in meaning and scope would make a claim superfluous." Id. (internal citation omitted). However, "the

written description and prosecution history overcome any presumption arising from the doctrine of claim differentiation." Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed. Cir. 2000).

The court may also consider extrinsic evidence. Alps S., LLC, 2010 WL 2347046, at *3. Extrinsic evidence is evidence that is external to the patent, such as expert testimony and dictionaries. Id. The purpose of this evidence is to:

> provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.

Phillips, 415 F.3d at 1318. While "the Court may also rely upon extrinsic evidence, such as treatises and dictionaries, to illuminate the meaning of claim terms, . . . it is considered less reliable, and thus, holds less weight in claim construction." Targus Int'l LLC, 2023 WL 110356, at *3 (citing Phillips, 415 F.3d at 1318).

III. Analysis

The claims at issue in this matter are three disputed terms recited in Claim 26 of the '539 Patent, as well as

the D232 Patent. The Court will address the '539 Patent first, before moving on to the D232 Patent.

A. <u>The '539 Patent</u>

The '539 Patent is a utility patent that is directed to instruments and methods for fusing the SI Joint to repair the joint or to alleviate pain in the pelvis or spine. (Doc. # 56-1 at 2). Claim 26 claims:

> a method for repairing a sacroiliac joint of a patient, comprising:
>
> a. creating an incision in the patient's skin in a position proximal to the patient's sacroiliac joint to allow access to the posterior portion of the sacroiliac joint;
>
> b. inserting a working channel into said incision and spreading said posterior portion of the sacroiliac joint with an inserted end of said working channel;
>
> c. creating a void in said posterior portion of the sacroiliac joint; and
>
> d. inserting a single fusion implant into said void along a path that is substantially parallel to articular surfaces of the sacroiliac joint, said fusion implant having at least one **fixation element for engagement with bone tissue in an articular surface** of at least one of an ilium and a sacrum in said sacroiliac joint, wherein said **at least one fixation element engages with said articular surface** of at least one of said ilium and said sacrum and no further implants or fusion

> devices are introduced into the sacroiliac joint or surrounding tissues.

(Doc. # 56-1 at 60) (emphasis added).

1. "Fixation Element"

PainTEQ's Proposed Construction	Omnia's Proposed Construction	Court's Construction
Helical anchors, lateral blades, flukes, claws, hooks, and screw structures, which fix the position of the fusion implant and provide for compression across the sacroiliac joint	Stabilization part	Helical anchors, lateral blades, flukes, claws, hooks, and screw structures, or equivalent structures

Omnia contends the phrase "fixation element" should be given its plain meaning and that the doctrine of claim differentiation supports its proposed construction. (Doc. # 57 at 7). PainTEQ's position is that Orthocision acted as its own lexicographer to define its fixation element as helical anchors, lateral blades, flukes, claws, hooks, and screws structures, clearly disavowing surface texture features as part of this definition. (Doc. # 56 at 9). Thus, according to PainTEQ, "stabilization part" is an overly broad term as it encompasses the type of fixation elements that Orthocision disavowed.

In general, the starting point for claim construction is "the words of the claims themselves[.]" Vitronics, 90 F.3d at 1582. However, "[a]lthough words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer, and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Id.; see also Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996) ("A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning." (citations omitted)).

Here, although Omnia focuses on the plain meaning of the phrase "fixation element," both the specification and the prosecution history indicate that Orthocision intended to limit the phrase to structures that pierce or penetrate.

Specifically, the '539 Patent specification consistently describes the "fixation element" as a component of the fusion implant that mechanically compresses the joint. (Doc. # 56-1 at 2:31-35, 11:45-48, 11:60-65, 21:25-27). Similarly, the

specification notes that the fixation elements "can be in the form of helical anchors, claw or fluke anchors, blades, screws, and/or other fixation elements[.]" (Id. at 2:32–34). When listing examples of such fixation elements, the specification focuses on helical anchors (Id. at 22:32), lateral flukes (Id. at 24:22–25), screws (Id. at 26:20–22), lateral blades (Id. at 27:26–28), and flukes (Id. at 30:1–5). While the Court acknowledges that the specification indicates that these examples do not limit the invention, considering the examples in tandem with the prosecution history reflects an intent to exclude embodiments that provide fixation through surface texture features. Put differently, while "fixation features" are not specifically limited to helical anchors, lateral flukes, screws, blades, and flukes, the specification nevertheless indicates that such features include only embodiments that provide fixation in the same manner as the aforementioned embodiments: specifically, by penetrating or piercing the articular surface of the bone to mechanically compress the SI Joint.

Indeed, the prosecution history similarly indicates that the term "fixation element" is focused on embodiments that pierce or penetrate the bone to mechanically compress the joint. On March 21, 2018, Orthocision submitted claims 32

(issued as claim 1) and 49 (issued as claim 12) to the US Patent & Trademark Office. (Doc. # 56-9). The listing of claims included:

> A method for repairing a sacroiliac joint of a patient, comprising:
>
> . . .
> inserting a fusion implant into said void . . . said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of in said sacroiliac joint, wherein said at least one fixation element first penetrates said ilium at said articular surface and said fusion implant compresses the sacroiliac joint.
> . . .
> A method for repairing a sacroiliac joint of a patient using an intra-articular joint fusion device for connecting the sacrum and ilium, comprising:
> . . .
> Inserting a fusion implant into said void . . . said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint[.]

(Id. at 2, 4-5). Thereafter, the USPTO rejected claim 32 under 35 U.S.C. § 112(a) as failing to comply with the written description requirement. (Doc. # 56-10 at 5). However, interpreting the claims, the USPTO determined, based on the specification, that "[r]egarding the fixation element . . .

the structure determined to perform the function of fixation and engaging with bone tissue is determined to be a helical anchor or functional equivalents thereof." (Id. at 3).

In its April 1, 2019, response, Orthocision disagreed with the examiner's interpretation, and contended that:

> There are several forms of fixation elements disclosed and described in the present application in addition to helical anchors. Such fixation elements include lateral blades, flukes, claws, hooks, and screws (see, e.g., paragraphs 202-228 FIGS. 56-70 of the present application). Clearly, the description of fixation elements for engagement with bone tissue is not limited to helical anchors and equivalents thereof. One of ordinary skill in the art would understand that the lateral blades, flukes, claws, hooks, and screws structures shown in FIGS. 56-70 and described in paragraphs [0202]-[0228] will perform the function of engaging with bone tissue.

(Doc. # 56-11 at 14-15). Subsequently, the USPTO allowed claims 32 and 49, noting that "the structure corresponding to the function of fixation and engagement with bone tissue will include those elements disclosed and described in the application as listed by the application in the Arguments/Remarks of 4/1/2019." (Doc. # 56-12 at 3). While Orthocision made "corrections to dependencies, addressing antecedent basis issues, and inadvertent clerical errors," in a July 12, 2019, post-allowance amendment, it did not

contradict or otherwise comment on the examiner's interpretation of fixation element as including helical anchors, blades, flukes, claws, hooks, and screws. (Doc. # 56-13 at 13) ("The present amendments have no effect on the scope of the claims and do not raise any new issues."). The Court thus finds that Orthocision acted as its own lexicographer when it advanced to the USPTO an interpretation of "fixation elements" that included helical anchors, blades, flukes, claws, hooks, and screws.

2. "For engagement with bone tissue in an articular surface"

PainTEQ's Proposed Construction	Omnia's Proposed Construction	Court's Construction
Configured for interlocking with bone tissue in the articular surface in a piercing or penetrating manner	Configured to move the fixation element into position so as to come into operation with the bone tissue in the articular surface	Configured for interlocking with bone tissue in the articular surface in a piercing or penetrating manner

Omnia contends the phrase "for engagement with bone tissue in an articular surface" should be given its plain meaning and that the doctrine of claim differentiation supports its proposed construction. (Doc. # 52 at 8-9). According to Omnia, the term "engagement" is broader than PainTEQ's proposed construction and encompasses more than

fixation elements which interlock with bone tissue or interlock in a piercing or penetrating manner. (Id. at 9). PainTEQ's position is that Orthocision acted as its own lexicographer to limit the meaning of "engagement with bone tissue in an articular surface" and disavowed alternative meanings during prosecution. (Doc. # 56 at 16).

"Disavowal requires that "the specification [or prosecution history] make[] clear that the invention does not include a particular feature[.]" Hill-Rom Servs., Inc. v. Stryker Corp., 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotations omitted). "[A] disclaimer/disavowal can occur from a simple statement differentiating the patent in question from prior art and that language of a specification or patent claim can, *by itself*, function as a disclaimer/disavowal." Zipshade Indus. (B.V.I.) Corp. v. Lowes Home Centers, LLC, No. 2:14-cv-05934-ODW (JC), 2017 WL 2766163, at *12 (C.D. Cal. June 26, 2017) (emphasis in original); see Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed. Cir. 1997) ("An argument contained in an [Information Disclosure Statement] which purports to distinguish an invention from the prior art thus may affect the scope of the patent ultimately granted.").

In an October 10, 2017, office action the USPTO rejected three of Orthocision's claims in its application for the '757

Patent, which is the parent patent. (Doc. # 56-19 at 9). All three of the rejected claims included the "engage with bone tissue" language. (Doc. # 56-18 at 6, 8). The USPTO explained that the Vestgaarden patent anticipated those claims. (Doc. # 56-19 at 9). In its response, Orthocision argued that Vestgaarden did not anticipate the claims at issue, distinguishing the Vestgaarden patent by noting that the Vestgaarden stabilizers "do not engage or penetrate the articular surfaces of the facet joint." (Doc. # 56-20 at 16). Instead, the Vestgaarden stabilizers "sandwich between the [bone] facets, not engaging the articular surfaces." (Id.). The prosecution history draws a distinction between an embodiment that "sandwiches" and an embodiment that "engages." Put differently, Orthocision's use of the term "engage" indicates that the term excludes stabilization elements that sandwich between bone facets. Based on the prosecution history of the '757 Patent, "engage" should not be construed as a broad term; rather, it is limited to piercing or penetrating.

3. Engages with said articular surface

PainTEQ's Proposed Construction	Omnia's Proposed Construction	Court's Construction
Interlocks with bone tissue in the articular surface	The fixation element comes into operation with the bone tissue in the articular surface	Interlocks with bone tissue in the articular surface

As discussed at the Markman hearing, the only difference between the phrase "for engagement with bone tissue in an articular surface" and "engages with articular surface" is that the former discusses a functional capacity, and the latter refers to the implementation of that functional capacity. The construction of the latter term therefore mirrors the second. For the reasons set forth above, the Court construes "engages with said articular surface" as "interlocks with bone tissue in the articular surface."

B. The D232 Patent

The D232 Patent is a design patent, not a utility patent. In claim construction for design patents, the Court need not "attempt to provide a detailed verbal description of the claimed design, as is typically done in the case of utility patents." Egyptian Goddess, Inc. v. Swisa, Inc., 543 F.3d 665, 679 (Fed. Cir. 2008). This is largely because of the "recognized difficulties entailed in trying to describe a

design in words[.]" Id. Therefore, the Federal Circuit has expressly affirmed minimal claim constructions that forego detailed verbal descriptions and rely primarily on the illustration included in the patent. See Unique Indus. Inc. v. 965207 Alberta Ltd., 722 F. Supp. 2d 1, 8 (D.D.C. 2009) (collecting cases).

A design patent protects only the novel, ornamental features of the patented design. OddzOn Product, Inc. v. Just Toys, Inc., 122 F.3d 1396, 1405 (Fed. Cir. 1997). "Where a design contains both functional and non-functional elements, the scope of the claim must be construed in order to identify the non-functional aspects of the design as shown in the patent." Id.; see Richardson v. Stanley Works, Inc., 597 F.3d 1288, 1293 (Fed. Cir. 2010) (finding that the district court properly factored out the functional aspects of a design patent during claim construction).

However, the mere fact that certain elements of a design are functional does not preclude those elements from having protectable ornamentation. For example, in Ethicon v. Endo-Surgery, Inc. v. Covidien, Inc., 796 F.3d 1312, 1332 (Fed. Cir. 2015), the Federal Circuit found that although the patent holder's design patents did not protect the general design concept of the functional elements of the patent, those

elements "nevertheless ha[d] some scope – the particular ornamental designs of those underlying elements." Id. at 1334. Thus, courts must be careful not to "perform[] [the] functionality analysis at too high a level of abstraction, focusing on the general concepts [of the functional elements] rather than the ornamental designs adorning those elements." Id.

Further, the Federal Circuit has also explained that, as part of claim construction, it may be helpful for the district court to point out "various features of the claimed design as they relate to the accused design and the prior art." Egyptian Goddess, 543 F.3d at 680; see Lanard Toys Ltd. v. Dolgencorp LLC, 958 F.3d 1337, 1342-43 (Fed. Cir. 2020) (holding the district court did not err in claim construction of a design patent where it "pointed out the ornamental and functional features of the design as well as the various features as they relate to the prior art").

Omnia is the exclusive licensee of the D232 Patent, which recites one claim for "the ornamental design for a surgical cannula, as shown and described." (Doc. # 56-2 at 1). The ten exemplary figures are reproduced below:

FIG. 1

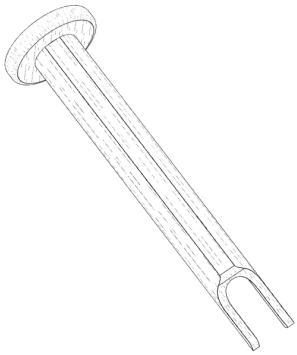


FIG. 2

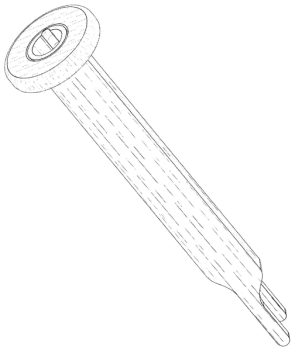


FIG. 3

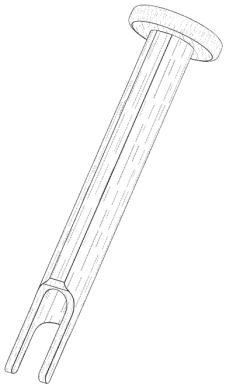


FIG. 4

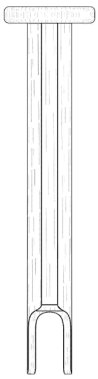


FIG. 5

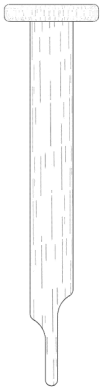


FIG. 6

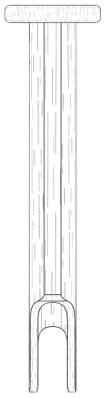


FIG. 7

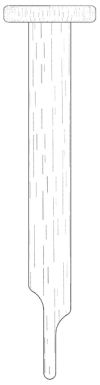


FIG. 8

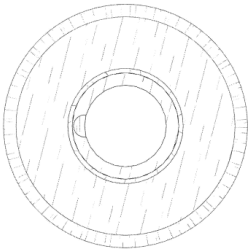


FIG. 9

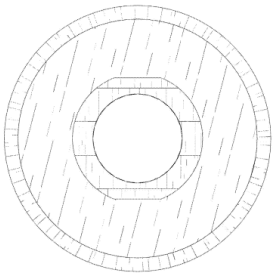
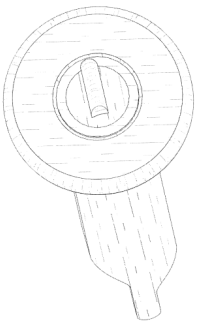


FIG. 10



(Id. at 4–13). The Court will not undertake a detailed written description of the D232 Patent and relies on these exemplary drawings.

The central dispute between the parties as to the D232 Patent involves the extent to which each feature of the cannula is ornamental as opposed to functional. Omnia contends that every element of the D232 Patent contributes to its ornamentation and thus it is improper to "filter out" functional features. (Doc. # 52 at 11). According to Omnia, because there are different possible designs for each element of the surgical cannula, each functional element also contains a degree of ornamentation. PainTEQ argues that four features of the D232 Patent are essential to the use or purpose of the surgical cannula and thus should be distinguished as functional. (Doc. # 56 at 21). Those four elements are the barrel of the surgical cannula; the distal end; the proximal end; and the flat faces on the cannula. (Id. at 21–23).

For the purposes of claim construction, the Court is thus tasked with distinguishing the underlying functional elements of the design, which are not protected, from the particular ornamental features of those elements, that are protected.

The Federal Circuit has set forth a list of factors for courts to consider in determining whether a design claim was dictated by function, including:

> whether the protected design represents the best design; whether alternative designs would adversely affect the utility of the specified article; whether there are any concomitant utility patents; whether the advertising touts particular features of the design as having specific utility; and whether there are any elements in the design or an overall appearance clearly not dictated by function.

PHG Techs., LLC v. St. John Companies, Inc., 469 F.3d 1361, 1367 (Fed. Cir. 2006). While acknowledging that these factors were introduced to assist courts in assessing validity, the Federal Circuit has nevertheless explained that they "serve as a useful guide for claim construction functionality as well." Sport Dimension, Inc. v. Coleman Co., 820 F.3d 1316, 1322 (Fed. Cir. 2016).

Further, "[w]hen there are several ways to achieve the function of an article of manufacture, the design of the article is more likely to serve a primarily ornamental purpose." L.A. Gear, Inc. v. Thom McAn Shoe Co., 988 F.2d 1117, 1123 (Fed. Cir. 1993). Indeed, courts may take certain functional elements into account during claim construction where the scope of the patent is "limit[ed] . . . to its

overall ornamental visual impression[.]" OddzOn, 122 F.3d at 1405; see Sport Dimension, 820 F.3d at 1322 (rejecting the district court's claim construction when it eliminated functional features from the claim entirely and noting that functional features should not be filtered out when they "contribute to the overall ornamentation of the design"). And the Federal Circuit has cautioned against an approach that focuses on the "aggregation of separable elements" instead of "the overall ornamentation of a design." Sport Dimension, 820 F.3d at 1322.

Here, the Court concludes that the dimensions of the barrel of the cannula, as well as the circularity and dimensions of the proximal end are ornamental features. The remainder of the features are functional and outside the scope of the patent. The Court will address each feature in turn.

Beginning with the barrel of the surgical cannula, Omnia's position is that the ornamental features are the proportions and slenderness ratio of the barrel of the cannula. (Doc. # 57 at 12). In contrast, PainTEQ contends that the proportions of the barrel are functional because they are dictated by its intended purpose; that is, the cannula must be "long enough to reach the surgical site from above the patient, it must be wide enough to accommodate

passage of the fusion implant and the instruments used in performing the surgery, and it must be narrow enough to accomplish 'minimally invasive surgery.'" (Doc. # 56 at 21). PainTEQ also highlights the functionality of the smooth outer surface and contours of the barrel, as well as the guidance slot within the barrel of the cannula. (Id. at 22).

The Court agrees with PainTEQ that the smooth outer surface and contours of the barrel, and the guidance slot within the barrel, are dictated by their functionality. Because the cannula is inserted and extracted from the surgical site, the smooth outer surface and contours are essential to the design. See Ethicon Endo-Surgury, 796 F.3d at 1328 (explaining that a feature is functional where it is essential to the use of an article). Likewise, the '511 Patent – a utility patent – claims the guidance slot as a functional feature; specifically, as a stopping mechanism. (Doc. # 56-23 at 42:1-3); see PHG Techs., 469 F.3d at 1367 (noting that the existence of utility patents can inform a court's functionality analysis). The '539 Patent specifically explains that the slot "prevents the surgical implement from advanc[ing] too far into the SI joint or the ilium and sacrum, thereby preventing damage to the tissue of the patient." (Doc.

56-1 at 14:42-45). These features of the cannula are thus essential to its function.

However, while the Court finds that the general shape of the barrel is dictated by functionality, PainTEQ does not provide any support for the proposition that the precise proportions of the cannula are purely functional. See Sport Dimension, 820 F.3d at 1322 (explaining that features with a functional purpose can nevertheless be considered ornamental). The Court thus concludes that the specific dimensions of the cannula is an ornamental feature.

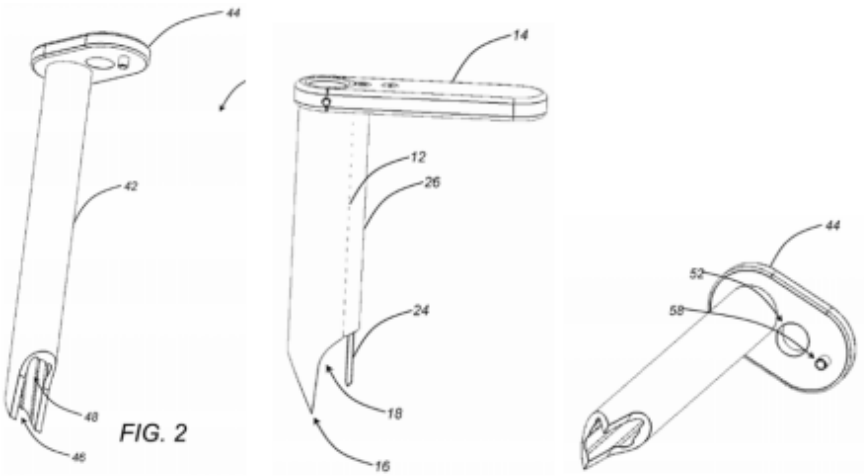
Next, as to the tangs, or arms, at the distal end of the surgical cannula, Omnia's position is that the ornamental feature is the length, width, and bluntness of the tangs. (Doc. # 57 at 13). PainTEQ, on the other hand, contends that the bluntness and the contours of the tangs are essential to its function. The Court agrees with PainTEQ that the tangs are dictated by their functionality. Omnia contends that "there are many different options for the ornamental design of the tangs," including having sharper ends. (Doc. # 57 at 13). But in its application to the USPTO for the '129 Patent, Orthocision explicitly stated that the tangs were blunt so as not to penetrate the bone. (Doc. # 56-25 at 18). The bluntness of the tangs is thus a functional, rather than ornamental,

feature. The shape and size of the tangs are also integral to their function. The '129 Patent explains that the "instrumentation described herein will work with a patient of any size because the arms set the width of the SI joint to a uniform distance regardless of the size or scale of the sacrum or ilium." (Doc. # 56-26 at 9:41-44). In other words, the shape and size of the tangs are specifically designed to ensure that the cannula is compatible with all patients. This feature is thus dictated by function, rather than ornamentation.

As to the proximal end, Omnia does not identify which feature is ornamental; rather, it contends that "there are various ways to design" that feature. (Doc. # 57 at 13). PainTEQ, however, contends that the circular collar that extends around the barrel at the proximal end of the cannula serves to prevent the over-insertion of certain implants and tools. (Doc. # 56 at 23).

The Court agrees with PainTEQ that the proximal end insofar as it is a stopping mechanism is dictated by its function. The '129 Patent provides that the "stop abuts against the channel collar of the working channel to prevent over penetration of the penetration tip into the SI Joint, thereby avoiding damage to the soft tissue and nerves on the

anterior side of the SI Joint." (Doc. # 56-26 at 9:7–11). The proximal end is thus functional. However, while the inclusion of the stopping mechanism on the cannula is dictated by functionality, the exact shape and size of the proximal end are not. Specifically, PainTEQ has not established that the circularity of the proximal end is essential to its function. Indeed, a review of the prior art reveals multiple ways to design the stopping mechanism, as shown below:

U.S. Patent No. 10,779,958


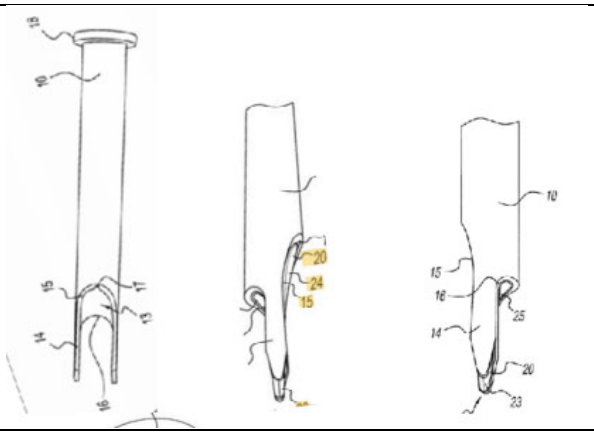
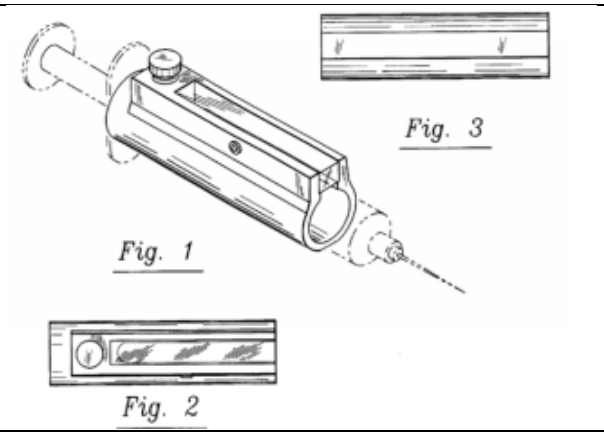
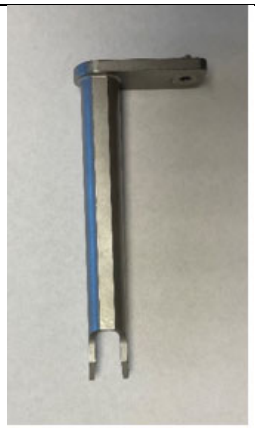
Pioneer Surgical Cannula

(Doc. # 56-28).

Thus, the Court finds that the circular shape and precise dimensions of the proximal end are ornamental.

Finally, as to the flat face which runs along the barrel of the cannula, Omnia does not identify which feature is ornamental; rather, it contends that "there are various ways to design" that feature. (Doc. # 57 at 13). PainTEQ contends that the flat faces of the barrel are functional "because they enable the surgeon to index the working channel during placement of the tangs inside the SI Joint." (Doc. # 56 at 23-24).

While PainTEQ does not point to a description in the utility patents touting the functional purpose of the flat face, it emphasizes that such a feature is present in the prior art (Doc. # 56 at 24), as shown below:

U.S. Patent No. 11,020,129

D397,217

Pioneer Surgical Cannula


(Doc. # 56-28). As is evident from the above, the flat face on the barrel of the cannula is well-established in the prior art. As it pertains to the flat face on the barrel, the overall appearance of Orthocision's design is distinct from the prior art only in the precise proportions of the flat face in relation to the barrel. The Court thus finds that the flat face itself is purely functional; however, like with the barrel itself, the size and proportions of the flat face in relation to the barrel are ornamental features.

Accordingly, it is

ORDERED, ADJUDGED, and **DECREED:**

The claim language in dispute in this case shall be construed as set forth in this Order.

DONE and **ORDERED** in Chambers in Tampa, Florida, this 30th day of June, 2023.

VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE