

Exhibit 1018

**IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

OMNIA MEDICAL, LLC,

Plaintiff,

vs.

CASE NO. 8:22-cv-000145-VMC-TGW

PAINTEQ, LLC,

Defendant.

_____/

OMNIA MEDICAL, LLC'S CLAIM CONSTRUCTION BRIEF

TABLE OF CONTENTS

TABLE OF CONTENTS	ii
TABLE OF AUTHORITIES.....	iii
I. INTRODUCTION	1
II. BACKGROUND AND RELEVANT FACTS.....	2
A. The '511 Patent.....	2
B. The D568 Patent.....	5
III. LEGAL STANDARDS.....	6
A. Claim Construction.....	6
1. The '511 Patent	6
2. The D568 Patent	7
IV. Claim Construction of the disputed terms.....	8
A. The '511 Patent.....	8
1. Disputed Terms for Claim Construction.....	8
B. The D568 Patent.....	17
2. Disputed claim constructions	17
V. CONCLUSION.....	20

TABLE OF AUTHORITIES

Cases

<i>3M Innovative Props. Co. v. Tredegar Corp.</i> , 725 F.3d 1315 (Fed. Cir. 2013)	6
<i>Crocs, Inc. v. Int’l Trade Comm’n</i> , 598 F.3d 1294 (Fed. Cir. 2010)	7
<i>Egyptian Goddess, Inc. v. Swisa, Inc.</i> , 543 F.3d 665 (Fed. Cir. 2008)(en banc).....	1, 7
<i>Ethicon Endo-Surgery, Inc. v. Covidien, Inc.</i> , 796 F.3d 1312 (Fed. Cir. 2015).....	8, 19
<i>Hupp v. Siroflex</i> , 122 F.3d 1456, 1460 (Fed. Cir. 1997)	8
<i>Karlin Tech. Inc. v. Surgical Dynamics, Inc.</i> , 177 F.3d 968 (Fed. Cir. 1999)	10, 13
<i>L.A. Gear, Inc. v. Thom McAn Shoe Co.</i> , 988 F.2d 1117 (Fed. Cir. 1993)	8
<i>Lanard Toys Limited v. Dolgencorp LLC</i> , 958 F.3d 1337 (Fed. Cir. 2020)	8
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005)(en banc)	1, 6
<i>Richardson v. Stanley Works, Inc.</i> , 597 F.3d 1288 (Fed. Cir. 2010).....	1, 7
<i>Sport Dimension, Inc. v. Coleman Co.</i> , 820 F.3d 1316, 1321-22 (Fed. Cir. 2016)	8, 18
<i>Thorner v. Sony Computer Entm’t Am. LLC</i> , 669 F.3d 1365 (Fed. Cir. 2012).....	6
<i>Vitronics Corp. v. Conceptoronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996)	6

Plaintiff, Omnia Medical, LLC (“Omnia Medical”), through its counsel pursuant this Court’s Patent Scheduling Order (D.I. 29) provides its opening Claim Construction brief relating to the contested constructions in asserted U.S. Patent No. 11,083,511 (the ‘511 Patent) and U.S. Design Patent No. D922,568 (the D568 Patent).

I. INTRODUCTION

The case law is clear that, in most circumstances, the claims of a patent should generally be given their ordinary meaning as would have been understood by a person of ordinary skill in the art. *See, Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005)(en banc). Here, both the ‘511 Patent and the D568 Patent are clear on their face and the scope of the claims are readily understood by a person of skill in the art. Thus, it is Omnia Medical’s position that the claims do not require construction, but to the extent that a construction is deemed necessary, the claims should be construed so as to provide the ordinary meaning as understood by one of skill in the art in view of the specification.

The Federal Circuit has held that the best source of construction for a design patent is the figures of the specification. *Richardson v. Stanley Works, Inc.*, 597 F.3d 1288, 1294 (Fed. Cir. 2010). Thus, the preferable course of construing a design patent claim is to avoid a detailed verbal description of the claimed design so as to prevent undue focus on specific portions of the design in lieu of focusing on the design as a whole. *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008)(en banc).

PainTEQ’s suggested constructions, however, do not comport with established case law because they seek to impermissibly import limitations into the claims or to

improperly exclude features of the claims. For the reasons presented below, PainTEQ's suggested constructions should be rejected. To the extent construction is necessary for any of the contested terms, Omnia Medical's proposed claim constructions should be adopted.

II. BACKGROUND AND RELEVANT FACTS

Omnia Medical has asserted that, *inter alia*, PainTEQ infringes the '511 Patent and the D568 Patent.

Omnia Medical is the exclusive licensee of intellectual property owned by Orthocision, Inc., including the '511 Patent and the D568 Patent. As the exclusive licensee, Omnia Medical has the right to, *inter alia*, 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.

PainTEQ, LLC ("PainTEQ") manufactures, sells, and offers to sell products for use in surgical procedures for sacroiliac ("SI") joint repair and joint fusion, including the LinQ™ SI Joint Stabilization System (the LinQ™ Products). When used as instructed by PainTEQ, the LinQ™ Products infringe the '511 Patent. The LinQ™ Products include a surgical cannula that infringes the claimed design of the D568 Patent.

A. The '511 Patent

The '511 Patent issued on August 8, 2021 from an application having an effective filing date of March 15, 2013. The '511 Patent issued with 23 claims. Claims 1, 2, 10, 14,

15, 18, and 19, which are discussed in the Joint Claim Construction and Prehearing Statement (D.I. 45) are reproduced below:

1. A method for repairing a sacroiliac joint of a patient, comprising:
 - a. creating a first incision proximal to the patient's sacroiliac joint;
 - b. inserting a working channel into said first incision, said working channel having a hollow barrel with an interior guidance slot in an interior diameter of the hollow barrel that does not traverse an outer diameter of said hollow barrel for controlling the advancement of surgical tools passed through said working channel, and having at least one tang on a distal end thereof;
 - c. creating a void in said sacroiliac joint; and
 - d. inserting a fusion implant into said void, wherein said fusion implant includes at least one protrusion that engages with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint thereby preventing pullout of the fusion implant.
2. The method of claim 1, wherein said fusion implant has a central body and said at least one protrusion that extends from said central body and fixes relative positions of said ilium and sacrum with engagement of said at least one protrusion with said ilium and sacrum.
10. A method for repairing a sacroiliac joint of a patient, comprising:
 - a. creating a first incision proximal to the patient's sacroiliac joint;
 - b. inserting a surgical channel tool into said first incision from the posterior of the patient, said surgical channel tool having two bilateral blunt tangs on a distal end thereof that are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint to stabilize the surgical channel tool as surgical instruments are passed through a surgical channel of said surgical channel tool and into the sacroiliac joint, said surgical channel including a hollow barrel having an interior guidance slot in an interior diameter of said hollow barrel for controlling the depth of advancement of surgical tools into said surgical channel and maintaining said surgical tools in proper orientation for insertion into said incision, wherein said interior guidance slot does not traverse an outer diameter of said hollow barrel;
 - c. creating a void in said sacroiliac joint;

- d. inserting a fusion implant into said void through said hollow barrel of said surgical channel tool using an inserter having a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant, said fusion implant having at least one protrusion for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint; and
- e. driving said fusion implant into said void such that said at least one protrusion engages with said bone tissue preventing pullout of the fusion implant, and said fusion implant fixes relative positions of said sacrum and said ilium.

14. The method of claim 10, wherein the inserting the fusion implant comprises:

- a. inserting the inserter into said hollow barrel of said surgical channel tool, wherein said inserter has an insertion control protrusion;
- b. engaging said insertion control protrusion with the interior guidance slot in the interior diameter of the hollow barrel for controlling the advancement of said inserter into said surgical channel tool and preventing rotation of said inserter; and
- c. advancing the inserter until said insertion control protrusion is arrested by the interior guidance slot at a pre-determined point in the hollow barrel, and said inserter is prevented from moving the fusion implant further into said sacroiliac joint.

15. The method of claim 10, wherein driving said fusion implant into said void comprises pushing said fusion implant into said void such that the at least one protrusion contacts said bone tissue.

18. A method for repairing a sacroiliac joint of a patient, comprising:

- a. creating an incision proximal to the patient's sacroiliac joint to allow access to the posterior portion of the sacroiliac joint;
- b. inserting a working channel of a surgical channel tool into said incision from the posterior of the patient, said working channel having a plurality of blunt tangs on a distal end thereof that are inserted between articular surfaces of an ilium and a sacrum of said sacroiliac joint to stabilize the surgical channel tool as surgical instruments are passed through the working channel into the sacroiliac joint, said working channel including a hollow barrel having an interior guidance slot in an interior diameter of said hollow barrel for controlling a depth of advancement of surgical tools

into said working channel and maintaining said surgical tools in proper orientation for insertion into said incision, wherein said interior guidance slot does not traverse an outer diameter of said hollow barrel;

c. inserting a fusion implant having a plurality of bone-engagement protrusions through said hollow barrel into said sacroiliac joint using an inserter having a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant, wherein said fusion implant is inserted on a path that is substantially parallel to articular surfaces of the sacroiliac joint, said inserter having an insertion control protrusion for engagement with said interior guidance slot;

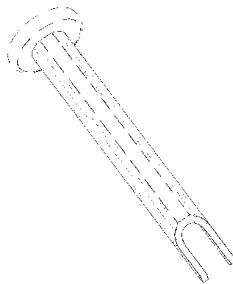
d. advancing the inserter until said insertion control protrusion is arrested by said interior guidance slot in the hollow barrel and placing said fusion implant into said sacroiliac joint, wherein said inserter is prevented from moving the fusion implant beyond a pre-determined point in said sacroiliac joint; and

e. driving said fusion implant into said sacroiliac joint such that said plurality of bone-engagement protrusions engage with said articular surfaces of said ilium and said sacrum thereby preventing pullout of the fusion implant from said sacroiliac joint.

19. The method of claim 18, wherein said engagement of said fusion implant with said bone tissue fixes the relative position of said sacrum and the ilium of said sacroiliac joint.

B. The D568 Patent

The D568 Patent issued on June 15, 2021 from an application having an effective filing date of March 25, 2015. The D568 Patent claims the ornamental design for a surgical cannula. Figure 1 from the D568 Patent is reproduced below:



III. LEGAL STANDARDS

A. Claim Construction

1. The '511 Patent

The claims of a patent “are generally given their ordinary and customary meaning” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips*, 415 F.3d at 1312-1313 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

The Federal Circuit has made it clear that it is improper to read limitations into the claims from the specification:

It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation. We do not read limitations from the specification into claims; we do not redefine words. Only the patentee can do that.

Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1365, 1366-67 (Fed. Cir. 2012) (see also, *Phillips*, 415 F.3d at 1320 (“one of the cardinal sins of patent law [is] reading a limitation from the written description into the claims”) (citations omitted)).

The courts have also acknowledged that the patent’s prosecution history generally should be considered in claim construction. *Phillips*, 415 F.3d at 1317. “Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Id.* Any disavowal of claim scope during prosecution must be clear and unmistakable. *See 3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315 (Fed. Cir. 2013).

2. The D568 Patent

The courts have consistently warned against reliance on a detailed verbal description of a design claim in patent infringement litigation. See, e.g., *Egyptian Goddess*, 543 F.3d at 679 (“[g]iven the recognized difficulties entailed in trying to describe a design in words, the preferable course ordinarily will be for a district court not to attempt to ‘construe’ a design patent claim by providing a detailed verbal description of the claimed design.”) The courts further counsel against a detailed verbal description of the claimed design, because reliance on such a description “risks undue emphasis on particular features of the design rather than examination of the design as a whole.” (See, *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1302-03 (Fed. Cir. 2010)). Instead, a design is best represented by the figures themselves and “claim construction must be adapted to a pictorial setting.” *Richardson*, 597 F.3d at 1294.

The D568 Patent claims the ornamental design for a surgical cannula, as shown and described in the ten figures included in the specification. PainTEQ asserts that every distinct element of the design is functional and that these alleged functional elements must be factored out during claim construction. While the underlying article of manufacture (i.e., the surgical cannula) serves a function, that fact should have no influence on the construction of the claimed design. “[T]he fact that the article of manufacture serves a function is a *prerequisite* of design patentability, not a defeat thereof. The function of the article [of manufacture] itself must not be confused with ‘functionality’ of the design of the article.” *Hupp v. Siroflex*, 122 F.3d 1456, 1460 (Fed. Cir.

1997) (emphasis added)(citation omitted); *see also* *L.A. Gear, Inc. v. Thom McAn Shoe Co.*, 988 F.2d 1117, 1123 (Fed. Cir. 1993) (“An article of manufacture necessarily serves a utilitarian purpose[.]”).

While courts have considered the distinction between purely function and ornamental aspects of claimed designs, courts have steered away from using claim construction to *eliminate* elements from the claimed design as functional. *See Sport Dimension, Inc. v. Coleman Co.*, 820 F.3d 1316, 1321-22 (Fed. Cir. 2016) (holding the district court’s construction was erroneous “because it eliminate[d] whole aspects of the claimed design”); *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1334 (Fed. Cir. 2015) (reversing district court’s claim construction that factored out elements as purely functional); *Lanard Toys Limited v. Dolgencorp LLC*, 958 F.3d 1337, 1342 (Fed. Cir. 2020) (upheld construction acknowledging the ornamental aspects of each functional element without eliminating entire elements of the claimed design). Thus, eliminating any aspect of a claimed design as functional is inappropriate at the claim construction stage.

IV. CLAIM CONSTRUCTION OF THE DISPUTED TERMS

B. The ‘511 Patent

3. Disputed Terms for Claim Construction

Below are the parties’ respective terms for claim construction for the ‘511 Patent as provided in the Joint Claim Construction and Prehearing Statement (D.I. 45).

U.S. Patent No. 11,083,511 Claim Numbers	U.S. Patent No. 11,083,511 Claim Term	Omnia's Preliminary Proposed Construction	PainTEQ's Preliminary Proposed Construction
10.e, 15, & 18.e	driving said fusion implant	Advancing the fusion implant	Applying a force via an impactor or torquing tool onto the fusion implant to advance the position thereof
1.d, 2, 10.d, 10.e, 15, 18.c, & 18.e	protrusion (in reference to the fusion implant)	Something that extends from a main body	A structure extending from the fusion implant configured to pierce or penetrate bone tissue
1.d, 2, 10.d, 10.e, 18.e, & 19	"engages with bone tissue," "engagement of said at least one protrusion with said ilium and sacrum," "engagement with said bone tissue," and "engage with said articular surfaces	Creates a mechanical engagement between a protrusion and the bone	Interlocking with bone tissue in a piercing or penetrating manner in order to resist retractive forces
1.d, 10.e, & 18.e	preventing pullout	Securing into position	Immobilizing (the fusion implant) against non-destructive removal via the application of a linear retraction force
1.b & 14.b	controlling the advancement	Guiding forward motion	Arresting the extent of axial progress (<i>alternate construction</i>) Controlling the depth of advancement
2, 10.e, & 19	fixes relative positions	Secures positions of the bones	Mechanically holds the relative positions

a. driving said fusion implant

No construction is necessary for the claim term “driving said fusion implant” because it is clear on its face. One of skill in the art would readily understand the meaning of “driving said fusion implant” in the context of the claim and the specification. To the extent the court believes construction is necessary, Omnia Medical’s proposed construction of “advancing the fusion implant” properly reflects the plain and ordinary meaning to the claims term as it would be understood by a person of ordinary skill in the art.

Omnia Medical’s proposed construction comports with the plain and ordinary meaning of the term “driving said fusion implant” as it is used in the claim. The plain and ordinary meaning of “driving said fusion implant” does not include “applying a force *via an impactor*” or “torqueing tool onto the fusion implant”. PainTEQ’s construction is overly complex and unnecessarily narrow. Nothing in Claims 10 or 18 requires a particular type of tool for advancing the fusion implant. Accordingly, PainTEQ’s proposed construction does not comport with the plain meaning of the claim language or by the understanding of one of ordinary skill in the art.

Claim differentiation further supports Omnia Medical’s proposed construction. The doctrine of claim differentiation is based on “the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope.” *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed. Cir. 1999). Claim 15 of the ‘511 Patent recites “driving said fusion implant

into said void comprises *pushing said fusion implant into said void such that the at least one protrusion contacts said bone tissue.*” PainTEQ’s proposed construction is narrower in scope with respect to a particular tool than the limitations in Claim 15 that depends from Claim 10. Construing the term “driving said fusion implant” to require, e.g., the use of a torquing tool when the use of such a tool is not required by a narrowing dependent claim would violate the claim differentiation doctrine.

b. “protrusion”

No construction is necessary for the claim term “protrusion” because it is clear on its face. One of skill in the art would readily understand the meaning of “protrusion” in the context of the claim and the specification. To the extent the court believes construction is necessary, Omnia Medical’s proposed construction of “something that extends from a main body” properly reflects the plain and ordinary meaning to the claims term as it would be understood by a person of ordinary skill in the art.

PainTEQ’s proposed construction of “protrusion” as meaning “a structure extending from the fusion implant configured to pierce or penetrate bone tissue” violates the basic tenets of claim construction by importing improper limitations into the claims. The specification discloses fusion implants that include several different types of protrusions, which have varying means of engaging with bone tissue and do not all require “piercing” or “penetration” (see, e.g., FIGS. 49-70 of the ‘511 Patent). Thus, PainTEQ’s proposed construction is inconsistent with the plain language of the claim and the intrinsic evidence of the application. In fact, the claims themselves defines the

function of the protrusion, e.g., as “engages with bone tissue in an articular surface,” as recited in Claim 1. Adoption of PainTEQ’s proposed construction would read this feature out of the claim and improperly narrows the function of the claimed protrusion to be limited to piercing or penetrating.

Claim differentiation further supports Omnia Medical’s proposed construction. For example, claim 1 of the ‘511 Patent includes the element “at least one protrusion that engages with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint.” Claim 3, which depends from Claim 1, recites the “protrusion includes an anchor that penetrates at least one of the patient’s ilium and the patient’s sacrum and thereby fixes relative positions of said ilium and sacrum”. PainTEQ’s offered construction improperly imports the “penetration” limitation of dependent claim 3 into Claim 1. Construing the term “protrusion” as the feature that “pierce or penetrate bone tissue” would clearly violate the claim differentiation doctrine.

c. “engages with bone tissue”

No construction is necessary for the claim term “engages with bone tissue” because it is clear on its face. One of skill in the art would readily understand the meaning of “engages with bone tissue” in the context of the claim and the specification. To the extent the court believes construction is necessary, Omnia Medical’s proposed construction of “creates a mechanical engagement between a protrusion and the bone” properly reflects the plain and ordinary meaning to the claims term as it would be understood by a person of ordinary skill in the art.

Omnia Medical's proposed construction comports with the plain and ordinary meaning of the term "engagement" as it is used in the claim. The plain and ordinary meaning of "engagement" does not include "interlocking... in a piercing or penetrating manner." As provided by Lexico.com, "engage" means "move into position so as to come into operation." An example given for this usage include "the clutch will not engage." (See <https://www.lexico.com/en/definition/engage>). Here, this ordinary definition is appropriate.

Unlike Omnia Medical's proposed construction, PainTEQ's construction is overly complex and unnecessarily narrow. Nothing in the claims or the specification suggests that engagement means "*interlocking with bone tissue in a piercing or penetrating manner in order to resist retractive forces.*" Accordingly, PainTEQ's proposed construction is not supported by any intrinsic evidence or by the understanding of one of ordinary skill in the art.

In addition, claim differentiation supports Omnia Medical's proposed construction, not PainTEQ's. Claim 11, which depends from claim 1 recites "wherein said at least one protrusion comprises a *helical anchor having a sharp end for piercing said bone tissue* in an articular surface of at least one of said sacrum and said ilium." Thus, it is clear that had Applicant intended for the term engagement to be limited to "interlocking...in a piercing or penetrating manner," Applicant would have expressly so limited Claim 1. *See, Karlin Tech.*, 177 F.3d at 971-72 (The doctrine of claim differentiation is based on "the

common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope.”)

PainTEQ’s offered construction improperly imports the “piercing” limitation of dependent claim 11 into Claim 10. Construing the term “engages with bone tissue” as requiring piercing or penetrating bone tissue would clearly violate the claim differentiation doctrine.

d. “preventing pullout”

No construction is necessary for the claim term “preventing pullout” because it is clear on its face. One of skill in the art would readily understand the meaning of “preventing pullout” in the context of the claim and the specification. To the extent the court believes construction is necessary, Omnia Medical’s proposed construction of “securing into position” properly reflects the plain and ordinary meaning to the claims term as it would be understood by a person of ordinary skill in the art.

PainTEQ’s proposed construction of “immobilizing (the fusion implant) against non-destructive removal via the application of a linear retraction force” violates the basic tenets of claim construction by importing improper limitations into the claims. The phrase “non-destructive removal via the application of a linear retraction force” includes multiple additional limitations that are not in the claims and unnecessarily limit the claims with novel steps and limitations, including “non-destructive removal” and “the application of a linear retraction force”. Nothing in the specification or the claims limits the term “preventing pullout” to “non-destructive removal via the application of a linear

retraction force.” Adoption of PainTEQ’s proposed construction improperly limits the terms of the claims without basis.

e. “controlling the advancement”

No construction is necessary for the claim term “controlling the advancement” because it is clear on its face. One of skill in the art would readily understand the meaning of “controlling the advancement” in the context of the claim and the specification. To the extent the court believes construction is necessary, Omnia Medical’s proposed construction of “guiding forward motion” properly reflects the plain and ordinary meaning to the claims term as it would be understood by a person of ordinary skill in the art.

PainTEQ’s proposed alternative constructions both violate the basic tenets of claim construction by importing improper limitations into the claims. Limiting the definition of the term “controlling the advancement” to “controlling the *depth* of advancement” is not warranted by the plain language of the claim, which does not specify the function of controlling depth. PainTEQ’s proposed constructions are also improper attempts to read limitations into the claims from the specification. The specification discusses guidance slots providing for maintaining the proper orientation of the surgical instruments (e.g., without rotation of the instrument passing through the working channel) and controlling the depth of advancement of the surgical instruments passed through the working channel. PainTEQ is attempting to selectively read limitations of one the functions of the guidance slot described in the specification into the claims, which is clearly improper.

Also, PainTEQ's alternative proposed construction of "arresting the extent of axial progress" is vague as the phrase "arresting the extent" does not make grammatical sense. "Arresting" means to stop. (See <https://www.merriam-webster.com/dictionary/arrest>). Arresting or stopping ceases an action, and the word "extent" does not refer to an action and is not a proper object of the verb "arrest". Thus, this alternative construction is confusing and does not aid in interpreting the claims.

Both of PainTEQ's proposed constructions limit the meaning of "controlling the advancement" of the guidance slot to one of multiple disclosed functions described in the specification. The constructions offered by PainTEQ selectively inject narrowing limitations from the specification. Adoption of PainTEQ's proposed construction would improperly narrow the function of the guidance slot.

Claim differentiation further supports Omnia Medical's proposed construction. For example, claim 1 of the '511 Patent includes the element "an interior guidance slot in an interior diameter of the hollow barrel ... *for controlling the advancement* of surgical tools passed through said working channel." Claim 8, which depends from Claim 1, recites the "said guidance slot controls the depth of advancement of surgical tools through said hollow barrel and maintains said one or more surgical tools in proper orientation for insertion into said incision". PainTEQ's offered construction improperly imports the "controls the depth of advancement" and "proper orientation" limitations of dependent claim 8 into claim 1. Construing the term "controlling the advancement" to require

“controlling the depth of advancement” would clearly violate the claim differentiation doctrine.

f. “fixes relative positions”

No construction is necessary for the claim term “fixes relative positions” because it is clear on its face. One of skill in the art would readily understand the meaning of “fixes relative positions” in the context of the claim and the specification. To the extent the court believes construction is necessary, Omnia Medical’s proposed construction of “secures positions of the bones” properly reflects the plain and ordinary meaning to the claims term as it would be understood by a person of ordinary skill in the art.

C. The D568 Patent

4. Disputed claim constructions

The D568 Patent recites one claim “the ornamental design for a surgical cannula, as shown and described” in ten figures.

As set forth in the Joint Claim Construction and Prehearing Statement (D.I. 45.), the parties’ positions regarding the construction of the D568 Patent are as follows.

Omnia Medical believes that no construction is necessary for the D568 Patent, aside from the disclaimed portions of the design as indicated by the dashed lines. Those structures that are depicted in dashed lines do not form part of the claimed design. It is appropriate to disclaim certain design elements using broken lines. *See, In re Owens*, 710 F.3d 1362, 1367 n.1 (Fed. Cir. 2013). The design patent claim is not limited by the disclaimed portions. *See, In re Zahn*, 617 F.2d 261, 204 USPQ 988 (Cust. & Pat.App 1980)

("Patent protection is available for an ornamental design embodied in less than a complete article.").

If further construction is deemed necessary, Omnia Medical proposes that the design be construed such that every element of the D568 Patent contributes to the overall ornamentation of the design and that it is improper to "filter out" functional elements in claim construction as "functional" elements may include ornamental aspects. Claim construction for design patents distinguishes functional aspects from ornamental aspects (e.g., the function of a tang versus the particular shape and appearance of the tang), but design structures cannot be excluded from the overall design on the basis that they serve a functional purpose: "While we agreed that certain elements of the device were functional, their functionality did not preclude those elements from having protectable ornamentation". *See, Sport Dimension*, 820 F.3d at 1321.

PainTEQ proposes that every element of the D568 Patent is functional, as outlined in red in the Joint Claim Construction and Prehearing Statement (D.I. 45) submitted April 22, 2022. PainTEQ further states that after filtering out the functional elements of the design, there are no remaining protectable elements of the D568 Patent.

The D568 Patent claims the ornamental design for a surgical cannula, as shown and described in the ten figures included in the specification. PainTEQ asserts that every element of the design is functional and that these functional elements must be filtered out during claim construction. This approach to claim construction in design patents has been widely rejected by the courts. *See, Sport Dimension*, 820 F.3d at 1321-22.

In addition, PainTEQ's allegation that every element of the D568 Patent is purely functional is misleading and inaccurate. First, as noted above, the fact that an article of manufacture is functional is not surprising. In fact, it *must* be functional in order to qualify as an article of manufacture for patentability. There is no particular test for determining when a claimed design is improperly "functional." See, *Ethicon*, 796 F.3d at 1329. However, courts have found the "availability of alternative designs" to be an important, if not dispositive, factor in assessing whether a design is dictated by function. See, *Ethicon*, 796 F.3d at 1329-30.

Here, Omnia Medical does not claim to have invented the surgical cannula. In fact, there are many surgical cannulas on the market that are not substantially similar to the design claimed in the D568 Patent. Thus, for example, while the body of the cannula performs the function of providing a cavity through which instruments may pass, the claimed shape of the body is not dictated by this function. In addition, while the tangs of the surgical cannula may assist in stabilizing the surgical cannula, this function does not dictate the shape of the tangs. Because there are many different possible designs for each element of the surgical cannula, it is evident that none of the elements of the claimed design are purely functional.

Thus, to the extent the D568 Patent requires construction the court should adopt Omnia Medical's proposed construction and construe the claim as "the ornamental design for a surgical cannula, as shown and described in Figures 1-10 and the specification of the D568 Patent."

V. CONCLUSION

For the reasons stated above, Omnia Medical's proposed claim constructions should be adopted where construction is deemed necessary. PainTEQ's proposed constructions should be rejected because they do not apply the plain and ordinary meaning of the disputed terms and improperly import limitations into the claims.

Dated: November 4, 2022.

Respectfully submitted,

/s/ Matthew G. Davis

Matthew G. Davis

Florida Bar No. 58464

mdavis@pdtlegal.com

Anna Alston Merritt

Florida Bar No. 1010102

amerritt@pdtlegal.com

PASKERT DIVERS THOMPSON

100 North Tampa Street, Suite 3700

Tampa, FL 33602

813.229.3500 (telephone)

813.229.3502 (facsimile)

Ralph E. Cascarilla

Florida Bar No. 315303

rcascarilla@walterhav.com

WALTER | HAVERFIELD LLP

1301 E. Ninth Street, Suite 3500

Cleveland, OH 44114

216.928.2908 (direct dial)

216.916.2346 (direct facsimile)

Attorneys for Omnia Medical, LLC

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I electronically filed the foregoing with the Court's CM/ECF system which will provide service via electronic mail to all registered participants listed on November 4, 2022.

/s/ Matthew G. Davis

Matthew G. Davis