CIVIL MINUTES - GENERAL

Case No. SACV 17-00660 JVS (JCGx)

Date December 18, 2017

Title Spitz Technologies Corp. V. Nobel Biocare USA LLC, et al.

Present: The Honorable James V. Selna	
Karla J. Tunis	Not Present
Deputy Clerk	Court Reporter
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Not Present	Not Present

Proceedings: (IN CHAMBERS) Order on Claim Construction

Plaintiff Spitz Technologies Corporation ("STC") and Defendant Nobel Biocare USA, LLC ("Nobel USA") have submitted proposed claim constructions for six terms in one patent. (Joint Statement, Docket No. 65.) The parties have submitted opening and responsive claim construction briefs. (Pl.'s Opening Br., Docket No. 78; Def.'s Opening Br., Docket No. 77; Pl.'s Resp. Br., Docket No. 90; Def.'s Resp. Br., Docket No. 89.) The Court has considered the parties' briefs and construes the relevant claim language below.

BACKGROUND

This dispute's background is familiar to the parties and to the Court. The patent in issue is U.S. Patent No. 7,008,227 ("227 Patent"). The parties now ask the Court to construe six terms.

LEGAL STANDARD

Claim construction is "exclusively within the province of the court." <u>Markman v.</u> <u>W. Instruments, Inc.</u>, 517 U.S. 370, 372 (1996). Such construction "must begin and remain centered on" the claim language itself. <u>Interactive Gift Express, Inc. v.</u> <u>Compuserve, Inc.</u>, 256 F.3d 1323, 1331 (Fed. Cir. 2001). But extrinsic evidence may also be consulted "if needed to assist in determining the meaning or scope of technical terms in the claims." <u>Pall Corp. v. Micron Separations, Inc.</u>, 66 F.3d 1211, 1216 (Fed. Cir. 1995).

In construing the claim language, the Court begins with the principle that "the words of a claim are generally given their ordinary and customary meaning." <u>Phillips v.</u>

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<u>AWH Corp.</u>, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). This ordinary and customary meaning "is the meaning that the [claim] term would have to a person of ordinary skill in the art in question at the time of the invention, <u>i.e.</u>, as of the effective filing date of the patent application." <u>Id.</u> at 1313. "[T]he 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." <u>Id.</u>

"In some cases, the ordinary meaning of claim language as understood by a person of skill in the art 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. In such circumstances general purpose dictionaries may be helpful." <u>Id.</u> at 1314 (internal citation omitted). In other cases, "determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art." <u>Id.</u> Then "the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." <u>Id.</u> (internal quotation marks omitted). These 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." <u>Id.</u> (internal quotation marks omitted).

But it is improper to read limitations from the specification into the claim. <u>Callicrate v. Wadsworth Mfg., Inc.</u>, 427 F.3d 1361, 1368 (Fed. Cir. 2005) ("[I]f we once begin to include elements not mentioned in the claim, in order to limit such claim . . . we should never know where to stop.") (quoting <u>Phillips</u>, 415 F.3d at 1312). A court does "not import limitations into claims from examples or embodiments appearing only in a patent's written description, *even when a specification describes very specific embodiments of the invention* or even describes only a single embodiment, unless the specification makes clear that 'the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive."" <u>JVW Enters., Inc. v.</u> <u>Interact Accessories, Inc.</u>, 424 F.3d 1324, 1335 (Fed. Cir. 2005) (internal citations omitted) (emphasis added).

CLAIM CONSTRUCTION

The '227 Patent relates to the field of dental implants. (Declaration of Katherine

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Brandt ("Brandt Decl."), Docket No. 78-1, Ex. 1 at 1:05-07.)

1. "said tip portion comprises at least one cutting edge for cutting bone to form a bore"

Claim 1 recites the following:

A dental implant comprising a body portion and a head portion, said body portion comprising a tip portion remote from said head portion, said body portion of said implant having an external thread including 1) a lead thread portion adjacent said tip portion, 2) an intermediate thread portion adjacent said lead thread portion and 3) a distal thread portion, adjacent said head portion, wherein said thread of said lead thread portion, said intermediate thread portion and said distal thread portion comprises a cutting edge so that said implant is self-tapping said dental implant further comprising a central bore within said head portion and an internal thread within said bore for receiving a dental prosthesis, and wherein said tip portion comprises at least one cutting edge for cutting bone to form a bore as said implant is rotated, said body portion comprising at least one flute, said flute having a first end adjacent said at least one cutting edge of said tip portion for assisting removal of bone cuttings from said cutting edge, said body portion having a generally longitudinal axis and said cutting edge of said tip portion commencing at said axis and extending radially outwardly from said axis so that upon rotation of said implant in a patient's jaw, said implant is self-drilling and self-tapping.

(Id. at 7:56-8:11 (emphasis added).) Claim 15 further recites:

A dental implant comprising a body portion and a head portion, said body portion comprising a tip portion remote from said head portion, said body portion of said implant

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having an external thread including 1) a lead thread portion adjacent said tip portion, 2) an intermediate thread portion adjacent said lead thread portion and 3) a distal thread portion, adjacent said head portion, wherein said thread of said lead thread portion, said intermediate thread portion and said distal thread portion comprises a cutting edge so that said implant is self-tapping said dental implant further comprising a central bore within said head portion and an internal thread within said bore for receiving a dental prosthesis, and wherein said tip portion comprises at least one cutting edge for cutting bone to form a bore as said implant is rotated, said body portion comprising at least one flute, said flute having a first end adjacent said at least one cutting edge of said tip portion for assisting removal of bone cuttings from said cutting edge, said body portion having a generally longitudinal axis and said cutting edge of said tip portion commencing at said axis and extending radially outwardly from said axis so that upon rotation of said implant in a patient's jaw, said implant is self-drilling and self-tapping, and wherein said body portion comprises an outer surface and said at least one flute extends along said outer surface of said body portion in a direction substantially parallel to said axis, and wherein said external thread has a root and a root line extending through the root of the thread of said intermediate portion and said distal portion is parallel to said axis and is displaced from said axis a root distance and wherein said at least one cutting edge extends from said axis radially outwardly to a respective cutting edge end and said cutting edge end is displaced from said axis, a cutting edge distance and wherein said root distance is greater than said cutting edge distance.

(Id. at 8:57-10:05 (emphasis added).)

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STC's Proposal	Nobel's Proposal
"The apical part of the implant having at least one cutting edge sufficient to cut bone to form a bore."	"the region at the end of the implant has a bottom surface that is not flat and an edge that cuts bone to form a hole in the bone into which the implant body is placed"

A. "tip portion"

STC argues that "tip portion" means "the apical part of the implant." (Pl.'s Opening Br., Docket No. 78 at 9.) Nobel argues that "[t]here is no dispute that the term 'tip portion' refers to the region at the end of the implant remote from the head portion of the implant." (Def.'s Opening Br. Docket No. 77 at 15.) Claim 1 provides for a dental implant comprising a body portion and a head portion. (Brandt Decl., Docket No. 78-1, Ex. 1 at 7:56-57.) Both parties note that the body portion has "a tip portion remote from said head portion." (Id. at 7:57-58.) The parties stipulated that the "root end of a dental implant is referred to as the 'apical' end," and STC argues that the "tip portion," which is "remote from said head portion," is the "apical end" of the implant. (Joint Statement, Docket No. 65 at 3; Pl.'s Opening Br., Docket No. 78 at 9.)

Without further explanation, the Court finds that no construction of "said tip portion" is necessary. The parties do not dispute that "tip portion" refers to the portion of the implant remote from the head portion. (See Pl.'s Opening Br., Docket No. 78 at 9; Def.'s Opening Br. Docket No. 77 at 15.) A person of ordinary skill in the art would understand the meaning of the phrase "tip portion."

B. "comprises at least one cutting edge for cutting bone to form a bore"

STC next argues that "tip portion" is further defined in Claim 1 by the phrase "comprises at least one cutting edge for cutting bone to form a bore." (Pl.'s Opening Br., Docket No. 78 at 10.) STC argues that the latter phrase means "having at least one cutting edge sufficient to cut bone to form a bore." (Id.) Nobel contends that STC disclaimed any implant having a bottom surface that is flat during the prosecution of the '227 Patent. (Def.'s Opening Br., Docket No. 77

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at 17.) Accordingly, its construction of the term requires the Court to find that the tip portion "has a bottom surface that is not flat and an edge that cuts bone to form a hole in the bone into which the implant body is placed." (<u>Id.</u> at 15.)

"Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997). Accordingly, STC argues that the phrase "comprises at least one cutting edge for cutting bone to form a bore' means that the tip portion must have at least one cutting edge, but may include other features." (Pl.'s Opening Br., Docket No. 78 at 10.) However, a patentee may disclaim subject matter during prosecution. "[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." Omega Eng'g, Inc, v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003). Nobel contends that to distinguish its pending application's claims from U.S. Patent No. 6,048,304 to Klardie et al. ("Klardie"), STC argued in its remarks in response to the January 5, 2004 Patent and Trademark Office ("PTO") Action that "the bottom face of the Klardie implant is substantially planar and presents a flat surface which extends axially from the axis 110 radially outwardly to define what is essentially a planar, circular surface." (Def.'s Opening Br., Docket No. 77 at 16-17 (quoting Declaration of Baraa Kahf ("Kahf Decl."), Docket No. 76-2, Ex. 2 at 193).) In its remarks, STC noted that the flat surface was "not capable of boring a hole as there is no cutting surface in Klardie which would make the hole large enough to accommodated the circular face." (Kahf Decl., Docket No. 76-2, Ex. 2 at 193.) STC continued that "Klardie intends his device to be inserted in a prebored hole which presumably is at least as large as that circular face." (Id.) STC also stated that the Klardie implant has a cutting edge that "extends generally axially." (Id.) STC amended its Claim 1 to make "more clear" that its implant "as claimed includes a cutting edge which extends radially outwardly." (Id.)

The doctrine of prosecution disclaimer does not apply where "the alleged disavowal of claim scope is ambiguous." <u>Omega Eng'g</u>,334 F.3d at 1324. "It is inappropriate to limit a broad definition of a claim term based on prosecution history that is itself ambiguous." <u>Inverness Med. Switzerland GmbH v. Warner</u>

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Lambert Co., 309 F.3d 1373, 1382 (Fed. Cir. 2002). The Court is not persuaded that the prosecution history shows that STC clearly and unmistakably disclaimed implants with flat surfaces. See SanDisk Corp. v. Memorex Prod., Inc., 415 F.3d 1278, 1286 (Fed. Cir. 2005) (requiring "clear and unmistakable prosecution arguments limiting the meaning of a claim term in order to overcome a rejection before the Court] limit[s] the relevant claim term to exclude the disclaimed matter"). STC distinguished Klardie because the implant claimined in Klardie must be inserted in a prebored hole and has a cutting edge that extends axially, not radially. (See Kahf Decl., Docket No. 76-2, Ex. 2 at 193.) STC also explained that the Klardie implant must be inserted into a prebored hole because its bottom face is flat and lacks a cutting surface capable of making a hole large enough to accommodate that face. (Id.) Therefore, none of STC's statements clearly distinguishes Klardie based on its flat bottom face alone. At most, it is ambiguous whether STC disclaims a flat surface because an implant with a flat tip portion requires a prebored hole. The Court will not find that STC disclaimed an implant with a tip portions that has a flat bottom on this prosecution history alone. In any event, there is nothing to preclude a flat surface from having a cutting edge.

Nobel next argues that STC "introduces ambiguity to the claim by suggesting, without support, that the cutting edge is 'sufficient' to cut bone to form a bore." (Def.'s Opening Br., Docket No. 77 at 17.) The Court disagrees. The phrase "sufficient" in STC's proposal makes clear that the cutting edge's purpose is to cut bone to form a bore and that the cutting edge alone can cut away enough bone to form the bore for the implant. Therefore, the phrase is helpful to the finder of fact.

In sum, the Court concludes that the proper construction of Term 1 is "a tip portion having at least one cutting edge sufficient to cut bone to form a bore."

2. "said body having a generally longitudinal axis"

Claim 1 recites the following:

A dental implant comprising a body portion and a head portion, said body portion comprising a tip portion remote from said head portion, . . . *said body portion having a*

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generally longitudinal axis and said cutting edge of said tip portion commencing at said axis and extending radially outwardly from said axis so that upon rotation of said implant in a patient's jaw, said implant is self-drilling and self-tapping.

(Brandt Decl., Docket No. 78-1, Ex. 1 at 7:56-58, 8:06-11 (emphasis added).) Claim 15 further recites:

A dental implant comprising a body portion and a head portion, said body portion comprising a tip portion remote from said head portion, . . . *said body portion having a generally longitudinal axis* and said cutting edge of said tip portion commencing at said axis and extending radially outwardly from said axis so that upon rotation of said implant in a patient's jaw, said implant is self-drilling and self-tapping

(Id. at 8:57-59, 9:07-12 (emphasis added).)

STC's Proposal	Nobel's Proposal
"The central part that extends lengthwise through the implant."	"the implant body has an imaginary line running lengthwise through the center of the implant body"

Nobel argues that the phrase "said body having a generally longitudinal axis" reflects the plain and ordinary meaning of the term "axis." (Def.'s Opening Brie, Docket No. 77 at 17-18.) Nobel further argues that "axis" refers to "a central line used as an imaginary reference point." (Id. at 18.) Lending support to Nobel's proposed construction, the term "axis" is used consistently in the specification in its ordinary and customary meaning. (Id.) As Nobel points out, the patent specification describes "a longitudinal axis 16" in Figure 1, which shows a dotted line running lengthwise through the center of the implant.

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(Kahf Decl., Docket No. 76-1, Ex. 1 at 2:57-62, Fig. 1.) Nobel further notes that the specification also describes parts of the implant relative to the longitudinal axis. (Def.'s Opening Br., Docket No. 77 at 18.) For example, the patent describes cutting blades 40 and 50 as "arranged substantially symmetrically oppositely opposed about the longitudinal axis 16 and the cutting edges 42 and 52 extend outwardly from the longitudinal axis 16 to the distal end of the surface of the tip 18." (Kahf Decl., Ex. 1 at 3:10-15.) Additionally, the specification describes the flute portion 26 as extending "substantially parallel to the axis 16." (Id. at 3:26-27, 3:49-54.) These examples support the finding that the '227 Patent uses the term "axis" according to its plain and ordinary meaning.

Construing "axis" as an "imaginary line" and "longitudinal" as "running lengthwise" is consistent with the words' ordinary and customary meanings. The Oxford American College Dictionary defines "axis" in the context of geometry as "an imaginary straight line passing through the center of a symmetrical solid, and about which a plane figure can be conceived as rotating to generate the solid" and "an imaginary line that divides something into equal or roughly equal halves." (Bradt Decl., Docket No. 76-12, Ex. 11 at 772.) It also defines "longitudinal" as "running lengthwise rather than across." (Id. at 773.) Webster's New World College Dictionary similarly defines "axis" as "a real or imaginary straight line on which an object rotates or is regarded as rotating." (Bradt Decl., Docket No. 76-13, Ex. 12 at 777.) The McGraw-Hill Dictionary of Scientific and Technical Terms provides that, for mathematics, "axis" means "a line of symmetry for a

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geometric figure." (Bradt Decl., Docket No. 76-14, Ex. 13 at 782.)

STC argues that the third definition provided in the Oxford American College Dictionary for a "structure" is more applicable. (Pl.'s Opening Br., Docket No. 78 at 13.) That definition provides that an "axis" is "the straight central part of an object to which things are attached." (Brandt Decl., Docket No. 78-1, Ex. 7 at 85.) But that definition is clearly inapplicable here where the '227 Patent specification uses the term "axis" as a reference point and nowhere describes the axis as something to which things can be attached. STC's proposed construction of "axis" as a "central part" is not consistent with the term's ordinary and customary meaning, nor with the term's use throughout the '227 Patent specification.

Finally, STC criticizes Nobel's proposed construction for ignoring the word "generally" in the claim language. (Pl.'s Opening Br., Docket No. 77 at 12-13.) The term "generally" is a descriptive term "commonly used in patent claims 'to avoid a strict numerical boundary to the specified parameter." <u>Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.</u>, 340 F.3d 1298, 1310-11 (Fed. Cir. 2003) (quoting <u>Ecolab, Inc. v. Envirochem, Inc.</u>, 264 F.3d 1358, 1367 (Fed. Cir. 2001)). STC argues that "generally"must be read to modify "axis." (<u>See Pl.'s Opening Br., Docket No. 78 at 12.</u>) However, because the claim language "expressly ties the adverb 'generally [longitudinal axis]" envisions some amount of deviation from exactly [longitudinal.]" <u>See Anchor Wall Sys.</u>, 340 F.3d at 1311. Contrary to STC's assertion, the use of the term "generally" merely connotes that the axis may deviate from precisely lengthwise. The descriptive word does not change the ordinary and customary meaning of the term "axis," at all.

At the claim construction hearing, STC urged the Court to consider the practical implications of construing the term so that "generally" modified "longitudinal" but not "axis." In particular, STC argued that the Court must consider whether it would be reasonable for the claimed implant to have an axis that was "generally longitudinal," in light of the Federal Circuit's decision in <u>Quality Edge, Inc. v. Rollex Corporation</u>, 2017 WL 4082755 (Fed. Cir. Sept. 15, 2017). In that case, the Federal Circuit concluded that it would be unreasonable to find that "generally" modified the word "imperforate," which means "having no opening or aperture" and "lacking no perforations." <u>Quality Edge</u>, 2017 WL

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4082755, at *3. The Court found that it made "little sense as a technical matter to have a 'generally' imperforate wall" because a wall that is "generally" imperforate is "actually perforate." <u>Id.</u> at *4. Here, the record does not support STC's assertion that a "generally longitudinal" axis would be problematic because it would create an implant that wobbles. STC points to the background section of the '227 Patent specification, which states that "[o]btaining such a close fit is difficult given the variance of each successive drilling procedure due to wobble, etc." (Brandt Decl., Docket No 78-1, Ex. 1 at 1:55-56.) This statement concerns the drilling with successively larger drill sizes that was typically required to create a suitable size hole for an implant in the host bone. (See id. at 1:36-50.) Therefore, it lends no support to STC's position, and the Court finds its construction of Term 2 to be reasonable.

STC also argues that the phrase "said body having a generally longitudinal axis" has a broader meaning than the term "axis" alone because the phrase was originally contained in Claim 2, not Claim 1, but removed from Claim 2 and inserted into Claim 1 by the Patent Examiner. (Pl.'s Opening Br., Docket No. 78 at 11-12 (citing Brandt Decl., Docket No. 78-1, Ex. 3 at 1; Brandt Decl., Docket No. 78-1, Ex. 6 at 2).) The phrase originally in Claim 2 was "*general* longitudinal axis." (Brandt Decl., Docket No. 78-1, Ex. 3 at 1.) This amendment made it so that dependent Claim 2 was not broader than independent Claim 1, but otherwise the relevance of the Examiner's amendment to the construction of this term is not obvious to the Court.

In sum, the Court concludes that the proper construction of Term 2 is "the implant body has an imaginary line generally running lengthwise through the center of the implant body."

3. "said cutting edge of said tip portion commencing at said axis"

Claim 1 recites the following:

A dental implant comprising a body portion and a head portion, said body portion comprising a tip portion remote from said head portion, . . . said body portion having a generally longitudinal axis and *said cutting edge of said tip*

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portion commencing at said axis and extending radially outwardly from said axis so that upon rotation of said implant in a patient's jaw, said implant is self-drilling and self-tapping.

(Brandt Decl., Docket No. 78-1, Ex. 1 at 7:56-58, 8:06-11 (emphasis added).) Claim 15 further recites:

A dental implant comprising a body portion and a head portion, said body portion comprising a tip portion remote from said head portion, . . . said body portion having a generally longitudinal axis and *said cutting edge of said tip portion commencing at said axis* and extending radially outwardly from said axis so that upon rotation of said implant in a patient's jaw, said implant is self-drilling and self-tapping

(Id. at 8:57-59, 9:07-12 (emphasis added).)

STC's Proposal	Nobel's Proposal
"The cutting edge on the apical part of the implant contacts the central part of the implant to form a cutting edge of sufficient size so that the implant can cut bone to form a bore."	"the edge that cuts bone begins at the imaginary line running lengthwise through the center of the implant body"

STC and Nobel's primary dispute over the construction of Term 3 concerns where "said cutting edge" must begin. Nobel's construction requires that the cutting edge begin at the axis of the implant–the imaginary line running lengthwise through its center. (Def.'s Opening Br., Docket No. 77 at 22.) STC's construction allows for a cutting edge that begins from the implant's central part, but not necessarily its mathematical center. (Pl.'s Opening Br., Docket No. 78 at 14.) Nobel's construction finds more support in the intrinsic record.

STC argues that the '227 Patent's written description and drawings show

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that the cutting edges do not extend to the implant's theoretical axis. (Id. at 15.) Nobel disagrees. (Def.'s Opening Br., Docket No. 77 at 20.) The '227 Patent describes the cutting edges as items 42 and 52. (See Kahf Decl., Docket No. 76-1 at 3:13.) The specification states that "cutting edges 42 and 52 extend outwardly from the longitudinal axis to the distal end of the surface of the tip. (Id. at 3:13-15.) Figure 1 shows cutting edges 42 and 52 extending to the implant's axis 16.



(Kahf Decl., Docket No. 76-1, Ex. 1 at Fig. 1.) STC claims that cutting edges 42 and 52, as shown in Figure 2, curve away from the very center of the implant and do not intersect. (Pl.'s Opening Br., Docket No. 78 at 15.)

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FIG. 2

(Kahf Decl., Docket No. 76-1, Ex. 1 at Fig. 2.) But Figure 2 illustrates the flute portions 26 and 28 as the lines curving away from the very center of the implant. Figure 2 illustrates cutting edges 42 and 52 as a single line that extends through the implant's axis and end at their radially outer edges 43 and 53.

The '227 Patent's prosecution history also supports Nobel's construction. The language "commencing at said axis," was added in response to the Examiner's rejections of the original Claim 1 and a later amended Claim 1. STC first amended original Claim 1, also discussed above, to distinguish Klardie. STC's amended Claim 1 specified that the implant had an axis and the cutting edge extended radially outwardly from the axis. (Kahf Decl., Docket No. 76-2, Ex. 2 at 192.) However, the Examiner rejected the amended Claim 1 as anticipated by U.S. Patent No. 5,947,735 to Day. (Id. at 167.) Day discloses a dental implant with "a body portion having an axis and the cutting edge extending radially outwardly from the axis so that upon rotation of the implant in the jaw, the implant is self-drilling and self-tapping." (Id.) In response, STC narrowed its claim to state that "said cutting edge 'of said tip portion commencing at said axis and' extending radially outwardly from said axis so that upon rotation of said implant in a patient's jaw, said implant is self-drilling and self-tapping." (Id. at 56.) STC explained in its remarks that "it is believed that the Examiner did not interpret the words referred to above on that basis that the cutting edge commenced at the longitudinal axis. Accordingly, in the claim amended as part of this Request for Continued

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Examination, applicant has provided additional language specifying that the cutting edge commences at the axis." (Id. at 60.) Additionally, STC argued that Day has a cutting edge that extends generally longitudinally, not radially and that Day discloses a self-tapping, not self-drilling device. (Id. at 59.) Thus, STC distinguished Day for a number of reasons, including that STC's implant claimed a cutting edge that commenced at the implant's axis.¹

Nobel's proposed construction fails to account for the Court's addition of the term "generally" to the construction of Term 2. Because Term 3 refers to Term 2 by reciting "said axis," the Court amends Nobel's proposed construction to reflect the Court's construction of Term 2. Rather than merely stating that the cutting edge begins at the imaginary line running lengthwise, the Court clarifies that the line generally runs lengthwise.

In sum, the Court concludes that the proper construction of Term 3 is "the edge that cuts bone begins at the imaginary line generally running lengthwise through the center of the implant body."

4. "so that . . . said implant is self-drilling"

Claim 1 recites the following:

A dental implant comprising a body portion and a head portion, said body portion comprising a tip portion remote from said head portion, . . . said body portion having a generally longitudinal axis and said cutting edge of said tip portion commencing at said axis and extending radially outwardly from said axis *so that* upon rotation of said implant in a patient's jaw, *said implant is self-drilling* and self-tapping.

¹ Nobel also argues that only its construction is consistent with the description in the specification that "bone is cut away by the cutting edges 42 and 52 leaving a cylindrical hole." (Def.'s Resp. Br., Docket No. 89 at 9-10 (citing Kahf Decl., Docket No. 76-1, Ex. 1 at 5:48-50).) The Court does not address this argument because it finds that other intrinsic evidence is sufficient to construct the term.

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(Brandt Decl., Docket No. 78-1, Ex. 1 at 7:56-58, 8:06-11 (emphasis added).)

Claim 15 further recites:

A dental implant comprising a body portion and a head portion, said body portion comprising a tip portion remote from said head portion, . . . said body portion having a generally longitudinal axis and said cutting edge of said tip portion commencing at said axis and extending radially outwardly from said axis *so that* upon rotation of said implant in a patient's jaw, *said implant is self-drilling* and self-tapping

(Id. at 8:57-59, 9:07-12 (emphasis added).)

STC's Proposal	Nobel's Proposal
"The cutting edge on the apical part extends radially outward from the central part of the implant of sufficient size so that the implant can cut bone to form a bore."	"the implant can be placed in bone to its desired depth for clinical use, without any prior drilling of a bore"

STC argues that Term 4 defines the structure of the dental implant's cutting edge at the tip portion of the implant. (Pl.'s Opening Br., Docket No. 78 at 16.) STC explains that "[t]he cutting edge must extend from the generally longitudinal axis of sufficient length to form a cutting edge that is capable of 'self drilling' i.e. cutting bone to form a bore." (Id.) Nobel argues that "[i]ndependent claims 1 and 15 recite structural features of the cutting edge that result in an implant that is 'self-drilling' when the implant is screwed into a patient's jaw." (Def.'s Opening Br., Docket No. 77 at 9.) The crux of the parties' dispute concerns whether STC disclaimed an implant that uses drills to create a bore into which the implant is placed.

The claim language describes the implant as capable of "self-drilling."

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Nobel argues that the term "self" must mean something, and that under STC's construction it does not. (Def.'s Resp. Br., Docket No. 89 at 13.) Nobel's primary argument is that based on the '227 Patent's specification and domestic and foreign prosecution histories, "self-drilling" does not mean less drilling. (Id.) Instead, Nobel argues that any construction that allows STC to claim an implant that is placed in some kind of pre-bored hole is incorrect. (Def.'s Opening Br., Docket No. 77 at 9.)

Nobel first argues that the specification does not teach using drills to create a bore into which the implant is placed. (Id.) The specification explains that the implant can be placed in the patient's jaw with various amounts of preparation. (Kahf Decl., Docket No. 76-1, Ex. 1 at 3:58-64.) The only time a drill is mentioned for preparing the installation site is in reference to a "profiling drill" that may be used to create a "dimple" in the jaw bone at the desired location of the axis to determine the location of the implant. (Id. at 3:62-64.) After describing the options for preparing the installation of the implant, the specification describes using a tool to rotate the implant, whereby the cutting edges remove bone at the installation site, until "the implant has been installed to the desired depth." (Id. at 3:64-4:10.) Therefore, as Nobel phrases it, "the implant is placed without drilling any bore or osteotomy² in advance, because the implant creates its own hole in the jaw bone." (Def.'s Opening Br., Docket No. 77 at 9.)

This construction of "self-drilling" is consistent with the '227 Patent's prosecution history. The claims as originally filed did not contain the "selfdrilling" limitation. (See Brandt Decl., docket No. 78-1, Ex. 3). The "selfdrilling" limitation was added by amendment to distinguish Klardie. (Kahf Decl., Docket No. 76-2, Ex. 2 at 192-93.) As noted above, STC added the limitation: "said body portion having an axis and said cutting edge extending radially outward from said axis so that upon rotation of said implant in a patient's jaw, said implant is self-drilling and self-tapping." (Id. at 184.) In its remarks, STC argued that Klardie "is a self-tapping device which is intended to be installed in a bore which is pre-existing." (Id. at 192.) STC further argued that its conclusion was clear because Klardie "refers to the implant being installed using a number of drill bits to increase the hole to the minor diameter of the threaded implant followed by a tap."

An osteotomy is the surgical cutting of a bone or removal of a piece of bone. CIVIL MINUTES - GENERAL

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(<u>Id.</u>) STC went on to state that Klardie "intends his device to be inserted in a prebored hole which presumably is at least as large as that circular face." (<u>Id.</u> at 193.)

STC maintains that this prosecution history shows only that it disclaimed implants that require a pre-drill of a hole to a size at least as large as an implant's circular face. (Pl.'s Resp. Br., Docket No. 90 at 14.) However, subsequent prosecution history shows that STC disclaimed an implant that requires any drilling. After the first amendment, the Examiner rejected the amended Claim 1 as anticipated by U.S. Patent No. 4,863,383 to Grafelmann. (Kahf Decl., Docket No. 76-2, Ex. 2 at 44.) In response, STC argued that Grafelmann was not directed to the present invention because it was "absolutely void of any description as to how a bore is formed in the jaw bone." (Id. at 36.) STC argued further that "Grafelmann does not indicate expressly that his device creates a bore as with the present application, but contains several references to inserting the implant into a bore." (Id.) Finally, STC argued that "the references refer to a bore and thus require an initial boring operation prior to any attempt to install the implant. Thus, none of the prior references deal with the advantage disclosed in the current invention." (Id. at 39.) By distinguishing the prior references as requiring "an initial boring operation prior to any attempt to install the implant," STC characterized the advantage disclosed by its invention as an implant not requiring any such prior boring. Therefore, it distinguished not only Klardie but also Grafelmann for requiring prior drilling to create a bore into which an implant is placed. In light of the prosecution history, it is evident that STC disclaimed implants that required pre-boring.

Finally, Nobel also argues that the Court should reject any construction of Term 4 that encompasses implants placed into an extraction socket where bone has already been removed. But nothing in the intrinsic record supports that conclusion. During prosecution, STC disclaimed implants that required boring a hole into which an implant is placed, but did not discuss, let alone unambiguously disclaim, implants placed into extraction sockets. And Nobel identifies nowhere in the '227 Patent or its specification that forecloses such an understanding of "self-drilling."³

³ Nobel merely points to three inapplicable portions of the specification. The specification explains that "when any type of device is said to be *self-tapping*, then the device must cut its way into CV-90 (06/04) CIVIL MINUTES - GENERAL Page 18 of 25

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The proper construction does not require that the implant be placed into a surgical site that includes bone and requires the formation of a bore in that bone. (See Def.'s Resp. Br., Docket No. 89 at 14.) Rather, the proper construction forecloses an implant that uses a drill to create a bore into which the implant is placed.

The intrinsic record shows that STC disclaimed implants that require prior boring. However, it did not disclaim an implant that is capable of being placed in bone to its desired depth for clinical use, without any prior drilling of a bore, but which is placed into a bore created either by extraction or prior-drilling.⁴ The critical inquiry is whether the implant has the capacity to be inserted into bone without prior drilling. The '227 Patent is not a method patent. It claims an implant with the capacity to self-drill.

In sum, the Court finds that the proper construction of Term 4 is "the implant is generally capable of being placed in bone to its desired depth for clinical use, without any prior drilling of a bore."

5. "so that said implant is self-tapping"

Claim 1 recites the following:

A dental implant comprising a body portion and a head portion, said body portion comprising a tip portion remote from said head portion, said body portion of said implant having an external thread including 1) a lead thread portion adjacent said tip portion, 2) an intermediate thread portion adjacent said lead thread portion and 3) a distal thread

the host site." (Kahf Decl., Docket No. 76-1, Ex. 1 at 3:31-32.) It goes on to describe the removal of cut material from the installation site in the context of a device that is *self-tapping*. (Id. at 3:44-46.) Finally, the specification refers to the creation of "a suitable socket into which the implant will be placed"in its discussion of the background of the invention and how *typical implants* are placed. (Id. at 1:36-38.)

⁴ For example, while an implant might be generally capable of being inserted without prior drilling, use of prior drilling to penetrate an unusually tough layer of bone would not escape the scope of the patent.

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portion, adjacent said head portion, wherein said thread of said lead thread portion, said intermediate thread portion and said distal thread portion comprises a cutting edge *so that said implant is self-tapping* . . .

(Brandt Decl., Docket No. 78-1, Ex. 1 at 7:56-65 (emphasis added).) Claim 15 further recites:

A dental implant comprising a body portion and a head portion, said body portion comprising a tip portion remote from said head portion, said body portion of said implant having an external thread including 1) a lead thread portion adjacent said tip portion, 2) an intermediate thread portion adjacent said lead thread portion and 3) a distal thread portion, adjacent said head portion, wherein said thread of said lead thread portion, said intermediate thread portion and said distal thread portion comprises a cutting *edge so that said implant is self-tapping*...

(Id. at 8:57-66 (emphasis added).)

STC's Proposal	Nobel's Proposal
"The thread has sufficient cutting edge so that the implant can cut a screw thread in the surface of the bore."	"the implant can be placed in bone to its desired depth for clinical use, without any prior cutting of thread groves in the bone"

The '227 Patent explains that tapping typically means "using a tap to cut a thread in the surface of the bore of the hole which has been made using the drills. This produces a screw thread extending helically, proximally to the bone." (Kahf Decl., Docket No. 76-1, Ex. 1 at 1:60-63.) In contrast, the '227 Patent provides that the lead, intermediate, and distal thread portions have a "cutting edge so that said implant is self-tapping." (Id. at 7:64-65.)

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Nobel argues that its construction is consistent with the specification. (Def.'s Opening Br., Docket No. 77 at 23.) As noted above, the specification explains that "[t]ypically, when any type of device is said to be self-tapping, then the device must cut its way into the host site, in this case bone." (Kahf Decl., Docket No. 76-1, Ex. 1 at 3:31-33.) Nobel argues that its "construction is consistent with this description, in that the implant must itself cut thread grooves without any prior cutting by another instrument." (Def.'s Opening Br., Docket No. 77 at 23.)

STC argues that Nobel's construction is an attempt to improperly read limitations into the patent's claims because the claims say nothing about being placed in bone to its desired depth for clinical use or anything about prior cutting of thread grooves in the bone. (Pl.'s Opening Br., Docket No. 78 at 17.) STC does not claim to have invented the concept of a self-tapping implant, and admitted in its European patent that "self-tapping implants are known." (Def.'s Opening Br., Docket No. 77 at 23 (citing Kahf Decl., Docket No. 76-10, Ex. 9 ¶ [0010]).) The general understanding of the term confirms that "self-tapping" refers to an implant that can cut its own thread grooves. The Glossary of Oral and Maxillofacial Implants defines "self-tapping" as the "[a]bility of certain implant profile designs to cut their own threads in the osteotomy walls at the time of the implant placement." (Kahf Decl., Docket No. 76-17, Ex. 16 at 830.) The Glossary further explains that "[a] self-tapping implant may be screwed into the osteotomy without first having to pretap the thread grooves." (Id.)

Moreover, the prior art cited in the '277 Patent supports the understanding of self-tapping to mean a device that can cut thread grooves without prior cutting by another instrument. U.S. Patent No. 5,727,943 to Beaty et al. explains that "[a] self-tapping dental implant is one that can be threaded into a pre-drilled hole in a jaw bone without pre-tapping the hole." (Kahf Decl., Docket No. 76-15, Ex. 14 at 1:20-25.) Klardie also explains that "[t]o eliminate the need for a separate step prior to implantation, self-tapping screw implants have been developed." (Kahf Decl., Docket No. 76-11, Ex. 10 at 1:26-27.) Finally, Day explains that "[s]ince the implant simultaneously taps the bone during insertion, a separate tapping stage is not necessary." (Kahf Decl., Docket No. 76-18, Ex. 17 at 1:38-40.) Therefore, a person of ordinary skill in the art would understand that "self-tapping" refers to an

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implant that can tap its own threads in bone without any prior tapping.

As with the construction of the prior term, the proper construction of "self-tapping" does not mean that the claimed implant cannot use a tap; instead, it means that the implant is capable of being used without any other tap. The record does not support Nobel's position that the '227 Patent only claims an implant that never is used with a prior tap.

In sum, the Court finds that the proper construction of Term 5 is "the implant is generally capable of being placed in bone to its desired depth for clinical use, without any prior cutting of thread groves in the bone."

6. "three revolutions"

Claim 8 recites the following: "The dental implant of claim 4 wherein said lead thread portion comprises at least three revolutions." (Kahf Decl., Docket No. 76-1, Ex. 1 at 8:30-31.)

STC's Proposal	Nobel's Proposal
No construction needed. Alternatively, "three revolutions is determined by counting the thread crests."	"three complete turns of a single thread around the implant body"

STC argues that the words "three revolutions" do not need construction because they would be "readily understood by a lay juror." (Pl.'s Opening Br., Docket No. 78 at 17-18.) Nobel argues that construction is needed to explain that the three revolutions refers to turns of a single external thread on the body. (Def.'s Opening Br., Docket No. 77 at 25.)

The specification provides that "[t]he lead thread portion 20 comprises three revolutions of the thread." (Kahf Decl., Docket No. 76-1, Ex. 1 at 5:13-14.) The term "thread" is also used when describing a tap. (See id. at 1:60-63.) The specification explains that a tap is used to create a thread in the surface of the bore and that this creates "a screw thread extending helically, proximally to the bone." (Id.) Therefore, "thread" refers both to the portion of the implant that screws the

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implant to the bone, and the structure in the bone to which the implant screws. Nothing in the specification or the claims describes whether an implant may have only one or more than one thread. In the prosecution history, after rejection of its claims by the Examiner, STC changed all references to "threads" to "thread." However, STC stated that it made the changes to "make more clear what was intended to be referred to in the disclosure and what was referred to and illustrated in the drawings and disclosure as filed." (Kahf Decl., Docket No. 76-2, Ex. 2 at 191.) The Examiner did not reject the claims as being anticipated or obvious. The Examiner rejected the claims then-numbered 10-14 as indefinite and wrote that "in claim 10, if applicant defines 'a thread' as having at least three revolutions (claim 9) and 'said thread' as having 'a crest', then 'said three revolutions' should also have the crest not crests, if this is so, then a line is not defined. In claim 11, 'the thread' should read -a thread-, perhaps 'the crests' should read -crests- and it is not clear 'crests' include that of a thread of 'said distal thread portion.'" (Id. at 199-200.) Accordingly, changing "threads" to "thread" was not a disclaimer of an implant that had more than one thread, but an effort to make the claim language clear and uniform. The Court will not add a limitation to the claim based on anything less than unambiguous prosecution history. Therefore, it would be improper to limit the construction of this term to "a single thread."

STC also objects to Nobel's construction based on the use of the words "complete turns." (Pl.'s Resp. Br., Docket No. 90 at 18.) STC argues that a construction using those words would read the flute and apical cutting edge elements out of Claim 1. (Id.) The Court agrees. Claim 8 is dependent on Claim 4, which is in turn dependent on Claim 2, which is in turn dependent on Claim 1. (See Kahf Decl., Docket No. 76-1, Ex. 1 at 8:12-30.) Claim 1 includes the element "said body portion comprising at least one flute, said flute having a first end adjacent said at least one cutting edge of said tip portion for assisting removal of bone cuttings from said cutting edge." (Id. at 8:03-06.) Claim 4 provides that "said flute extends from said tip portion along said lead thread portion and said intermediate thread portion of said body portion." (Id. at 8:18-20.) Accordingly, the flute element must interrupt the thread of the lead thread portion and any construction which required the thread's rotation around the implant body to be complete would eliminate the flute portion limitation out of Claim 1.

Rather than determining the revolutions by the number of complete turns,

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the specification contemplates determining the revolutions by their crests. For example, the specification provides that "[t]he intermediate thread portion 22 commences, as shown in FIG. 1, with the crest of the forth [sic] revolution of the thread from the tip portion 19." (Kahf Decl., Docket No. 76-1 at 6:19-21.) The specification explains where the intermediate thread portion begins by referring to the crest of the fourth revolution. As such, the crest of each revolution can be counted to determine three revolutions. Therefore, STC's alternative construction, which provides an explanation of how the revolutions are to be determined, explains the meaning of Term 6 but does not improperly limit the meaning to a single thread or read out the flute portion from Claim 1.

At the claim construction hearing, Nobel noted that the proper construction of Term 6 must explain how the thread crests are to be counted. Counting from the tip, the construction can either require at least three adjacent crests or three crests of a single thread. However, if an implant had more than one thread, only counting adjacent crests would result in a lead thread tip portion with less than three revolutions. For instance, if an implant had three threads, three adjacent thread crests from the tip of the implant would only be three half-revolutions of each thread. Therefore, to properly construe the "three revolutions" limitation, it is insufficient to count three adjacent thread crests. The construction must specify that "three revolutions is determined by counting the crests of a single thread."

In sum, the Court finds that the proper construction of Claim 6 is "three revolutions is determined by counting the crests of a single thread."

Term	Disputed Claim Term	Court's Construction	
1	"said tip portion comprises at least one cutting edge for cutting bone to form a bore"	"a tip portion having at least one cutting edge sufficient to cut bone to form a bore"	

CONCLUSION

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2	"said body having a generally longitudinal axis"	"the implant body has an imaginary line generally running lengthwise through the center of the implant body"
3	"said cutting edge of said tip portion commencing at said axis"	"the edge that cuts bone begins at the imaginary line generally running lengthwise through the center of the implant body"
4	"so that said implant is self- drilling"	"the implant is generally capable of being placed in bone to its desired depth for clinical use, without any prior drilling of a bore"
5	"so that said implant is self- tapping"	"the implant is generally capable of being placed in bone to its desired depth for clinical use, without any prior cutting of thread groves in the bone"
6	"three revolutions"	"three revolutions is determined by counting the crests of a single thread"

IT IS SO ORDERED.

Initials of Preparer

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