

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOLOGIC, INC.
Requester, Respondent

v.

SMITH & NEPHEW, INC.¹
Patent Owner, Appellant

Appeal 2015-007845
Inter partes Reexamination Control 95/001,933
Patent US 7,226,459 B2²
Technology Center 3900

Before STEVEN D.A. McCARTHY, JEFFREY B. ROBERTSON and
DANIEL S. SONG, *Administrative Patent Judges*.

SONG, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ Smith & Nephew, Inc. is the Patent Owner and the real party in interest (Appeal Brief of Patent Owner (hereinafter "App. Br.") 2).

² Patent US 7,226,459 B2 (hereinafter "the '459 patent") issued June 5, 2007 to Cesarini et al.

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STATEMENT OF THE CASE

Claims 1–16, 19–22 and 25–33 of the '459 patent are subject to reexamination and stand rejected (Right of Appeal Notice³ (hereinafter "RAN") PTOL-2066). The Patent Owner appeals under 35 U.S.C. §§ 134(b) and 315 from the Examiner's rejections with respect to all of the rejected claims (App. Br. 2). In addition to its Appeal Brief, the Patent Owner also relies on its Rebuttal Brief (hereinafter "Reb. Br.") and a declaration of Mr. Arthur G. Erdman. The Requester relies on its Respondent Brief (hereinafter "Resp. Br.") as well as declarations from Mr. Hal Walbrink in support of the Examiner's rejections. We have jurisdiction under 35 U.S.C. §§ 134(b) and 315.

The '459 patent is involved in the legal action *Smith & Nephew, Inc. v. Interlace Medical, Inc., and Hologic, Inc.*, 10-cv-10951 (D.Mass) (App. Br. 2). An oral hearing with the Appellant's representative was held before the Patent Trial and Appeal Board on December 14, 2015, a transcript of which having been entered into the record on January 4, 2016.

We AFFIRM.

The '459 patent is directed to a surgical instrument including a cutting member for cutting tissue (Abs.). Representative independent claims 1 and 32 read as follows (Claims App., italics added):

1. A surgical instrument, comprising:
a cutting member including an implement for cutting tissue; and

³ The Examiner's Answer incorporates the RAN by reference. Hence we cite to the RAN herein.

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a drive coupled to the cutting member to *simultaneously rotate, translate, and reciprocate* the cutting member in response to only a rotational force applied to the drive in a single direction *and to cut tissue during simultaneous rotation and translation of the cutting member*;

wherein the drive includes a drive member attached to the cutting member, *the drive member including a helical groove*, and the drive includes a translation piece disposed in the groove such that rotary driving of the drive member results in simultaneous reciprocation of the drive member relative to the translation piece.

32. A surgical instrument, comprising:

a cutting member including an implement for cutting tissue;

a drive coupled to the cutting member to *simultaneously rotate, translate, and reciprocate* the cutting member in response to only a rotational force applied to the drive in a single direction *and to cut tissue during simultaneous rotation and translation of the cutting member*; and

an outer tubular member, the cutting member being received within the outer tubular member, the outer tubular member including a cutting window disposed proximate to a tip of the outer tubular member.

REJECTIONS

1. The Examiner rejects claims 32 and 33 under 35 U.S.C. § 102(b) as anticipated by Middle⁴ (RAN 4–6).

The Examiner also rejects various claims under 35 U.S.C. § 103(a) as follows:

⁴ U.S. Patent No. 5,490,860, issued February 13, 1996.

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2. Claims 1–14, 19, 25 and 27–31 as obvious over Kaplan⁵ in view of the knowledge of a person of ordinary skill in the art (RAN 7–11).
3. Claims 1, 2, 4–16, 19, 25 and 27–31 as obvious over Middle in view of Kaplan (RAN 12–14).
4. Claims 1, 2, 4–16, 19, 25 and 27–31 as obvious over Middle in view of Saadat⁶ (RAN 14–16).
5. Claims 1, 2, 4–14, 19–22, 25 and 27–31 as obvious over Middle in view of Galloway⁷ (RAN 16–18).
6. Claims 1, 2, 4–16, 19, 21, 22, 25 and 27–31 as obvious over Middle in view of Spear⁸ (RAN 19–20).
7. Claims 11 and 12 as obvious over Kaplan in view of Hutchins⁹ (RAN 21–22).
8. Claims 1, 2, 4–12, 19–22, 25 and 27–31 obvious over Kaplan in view of Galloway (RAN 22–24).
9. Claims 1, 2, 4–14, 19, 21, 22, 25 and 27–31 as obvious over Kaplan in view of Spear (RAN 24–26).
10. Claim 26 as obvious over Middle in view of anyone of Kaplan, Saadat, Galloway or Spear (RAN 27).

⁵ U.S. Patent No. 6,402,701 B1, issued June 11, 2002.

⁶ U.S. Patent No. 5,899,915, issued May 4, 1999.

⁷ U.S. Patent No. 6,119,973, issued September 19, 2000.

⁸ U.S. Patent Application Publication No. 2001/0039963, published November 15, 2001.

⁹ U.S. Patent No. 2,708,437, issued May 17, 1955.

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ISSUES

The following issues have been raised in the present appeal.

1. Whether the Examiner erred in interpreting the claim limitation "simultaneously rotate, translate, and reciprocate."
2. Whether the Examiner erred in concluding that it would have been obvious to modify the device of Middle to incorporate a helical groove.
3. Whether the Examiner erred in concluding that it would have been obvious to modify the device of Kaplan to incorporate a helical groove.
4. Whether the Examiner erred in finding that Galloway is reasonably pertinent to a problem with which the inventor was involved.

PRINCIPLES OF LAW

Claims are to be given their broadest reasonable interpretation consistent with the specification, reading claim language in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). This is the standard for claim interpretation in both original examination and re-examination. *See In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984); *see also In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007) ("During reexamination, as with original examination, the PTO must give claims their broadest reasonable construction consistent with the

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specification. Therefore, we look to the specification to see if it provides a definition for claim terms, but otherwise apply a broad interpretation.").

"[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). In addition,

[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

Id. at 417.

FINDINGS OF FACT

The record supports the following findings of fact (FF) by a preponderance of the evidence.

1. The Specification of the '459 patent states:
 - A. In another aspect, a method of cutting tissue includes positioning an outer member such that tissue is located within the outer member, engaging the tissue with an inner member received within the outer member, and *simultaneously rotating and translating* the inner member to cut the tissue. One or more of the following features may be included. The *translating is reciprocating*.
(Col. 1, l. 64–col. 2, l. 3, emphasis added).

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B. In another aspect, a method of cutting tissue includes applying a tangential cutting force to tissue with a member, and mechanically driving the member to undergo *simultaneous rotation and translation*. The method may include that the *translation is reciprocation*.
(Col. 2, ll. 11–15, emphasis added).

C. The cutting edge of conventional arthroscopic surgical instruments, such as rotary shears, have difficulty initiating a cut into semi-rigid tissue tend to bounce away from the tissue. . . . *The simultaneous rotating and reciprocating* inner member of the surgical instrument of the invention overcomes these difficulties.
(Col. 2, ll. 16–26, emphasis added).

D. The helical member **150** also *moves in an axial direction, e.g., reciprocates*, as a result of the interaction of the translation piece **145** with the helical channels **156, 158**, as described below.
(Col. 4, ll. 19–22, emphasis added).

E. The coupling of the follower **145a** to the helical channels **156, 158** causes the helical member **150** to also translate. Thus, the inner member **185** *simultaneously rotates and reciprocates to cut the tissue*.
(Col. 4, ll. 59–62, emphasis added).

2. Middle:

- A. Discloses a power cutting tool having a cutting blade, one embodiment moving the cutting blade in both rotational motion and reciprocating motion (Middle, Abs.; col. 2, ll. 37–40).
- B. Discloses that the power cutting tool includes motor 16 that rotates drive mandrel 24 and causes drive piston 30 to rotate and reciprocate, drive piston 30 including groove 38 that

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interacts with follower 40 (Middle, col. 2, ll. 62–66; col. 5, ll. 29–40; col. 8, ll. 48–54; Figs. 1, 3, 4, 9).

- C. States "[i]t can be seen that each complete revolution of piston **30** will cause piston **30** to go through two complete reciprocation cycles. Varying the number of forward and rear bends of cam groove **38** can vary the number of complete reciprocation cycles per revolution." (Middle, col. 7, ll. 26–33).
- D. Discloses that the power cutting tool is provided with a plurality of replaceable tool assemblies that can be connected via collar 62 with J-groove 72 and lock pin 70 (Middle, Abs.; col. 9, ll. 17–27; Fig. 2).
- E. States "[i]nstead of balls **40**, a different cam follower element could be used, such as one or more cam follower pins (not shown) projecting radially inwardly through sleeve **64** into continuous cam groove **38**." (Middle, col. 5, ll. 37–40).

3. Kaplan:

- A. Discloses a biopsy device for extracting tissue that provides reciprocating and rotational motion of a needle (Kaplan, Abs.).
- B. Discloses that biopsy instrument 250 includes motor 130 that rotates cam 194 having angled track 202 into which follower 210 extends thereby imparting reciprocating and rotational motion of the needle (Kaplan, col. 14, ll. 9–25; Fig. 10; *see also* col. 12, l. 55–col. 13, l. 3).

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- C. Discloses multiple different embodiments including one embodiment in which helical groove 240 is provided to effectuate reciprocal motion, but in which sleeve 236 includes projections 238 captured within housing 102 to prevent rotation of the sleeve (Kaplan, col, 13, ll. 51–67; Fig. 8).
- D. States "[u]sing the foregoing modifications and variations of the cam profiles, various combinations of these cam profiles can produce various motion [sic] of the needle **122**." (Kaplan, col. 15, ll. 29–31).

ANALYSIS

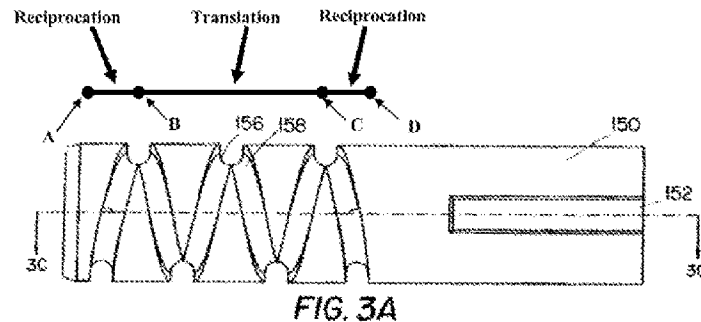
We address the various arguments of the Patent Owner *infra* in an order that differs slightly from the order presented in the Patent Owner's main brief. Only those arguments actually made by the Patent Owner have been considered and any arguments not made are deemed to be waived. *See* 37 C.F.R. § 41.67(c)(1)(vii).

Claim Interpretation

One issue raised in the present appeal is whether the claim limitation "simultaneously rotate, translate, and reciprocate" has been properly interpreted by the Examiner. The Patent Owner argues that the rejected claims require three separate, distinct motions, that is, rotation, translation and reciprocation, and "claim terms translation and reciprocation **must have separate and distinct meanings** as those terms are used separately in the claims and specification to describe entirely different motions." (App. Br.

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12; *see also* Decl. Erdman ¶¶9, 12, 14). Because the claims recite that cutting of tissue occurs "during simultaneous rotation and translation," the Patent Owner argues that "the importance of this difference in terminology is enhanced." (App. Br. 12; *see also id.* at 16). The Patent Owner submits an annotated version of Figure 3A of the '459 patent as representative of the proper claim interpretation (*Id.* at 14; *see also id.* at 15; Reb. Br. 4). The annotated version of Figure 3A of the '459 patent is reproduced below.



(App. Br. 14).

Annotated Figure 3A reproduced from the Patent Owner's Appeal Brief shows a top view of helical member 150 with added text "Reciprocation" for line segment between points A and B near one end of helical channels 156, 158; "Translation" for line segment between points B and C identifying a middle portion of the helical channels; and "Reciprocation" for line segment between points C and D near an opposite end of the helical channels.

The Patent Owner argues that the entirety of the record establishes that:

- (1) the claim term translate/translation is defined as the act of moving the cutting member from one point to another point along the axis and
- (2) the claim term reciprocate/reciprocation is defined as the act of changing direction of the cutting

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member including a deceleration phase and an acceleration phase. These definitions are consistent with the illustrative embodiment of the specification where the translation occurs along a cutting window.

(*Id.* at 19).

The Examiner disagrees with the Patent Owner and finds that there are no unique definitions for the terms rotate, translate or reciprocate in the Specification of the '459 patent, and thus, applies the common meanings of these terms, which are:

Translating: 1a: to bear, remove, or change from one place, state, form, or appearance to another.

Reciprocating: *intransitive verb* 2: to move forward and backward alternately.

(RAN 32–33, *quoting* Merriam-Webster on-line edition).

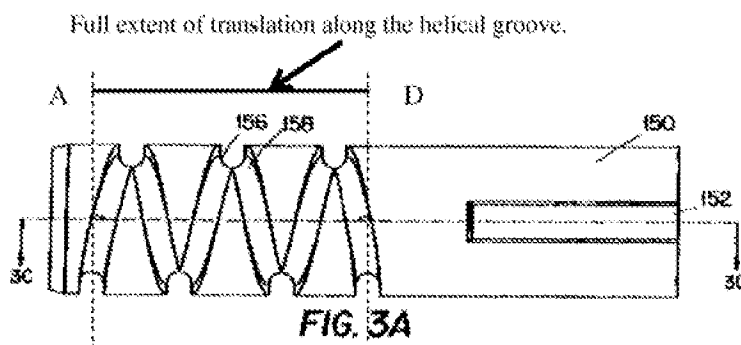
The Examiner finds that "it would have been clear to one skilled in the art that the movement from one place to another as understood from the '459 patent specification is a linear translation of the cutting member." (*Id.* at 33). The Examiner finds that Patent Owner's annotations of Figure 3A arbitrarily define translational movement and states:

[i]t is unclear why translational movement ends before the full extent of the helical groove. At the point where Patent Owner asserts reciprocation, i.e. linear extents between A-B and C-D, the cutter would still move in a linear direction along the axis of the helical groove. This linear movement, even including deceleration or acceleration of velocity, would still be understood by one skilled in the art to be translational movement.

(*Id.*; *see also id.* at 35).

The Examiner also provides an alternative annotation of Figure 3A of the '459 patent, which is reproduced below (*id.* at 33).

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(*Id.* at 34).

Annotated Figure 3A from the RAN reproduced above shows a top view of helical member 150 with added text "Full extent of translation along the helical groove" for line segment between points A and D.

The Examiner further finds that:

[r]egarding reciprocate, it would have been clear to one skilled in the art that the moving forward and backward alternately of the cutting member, i.e. alternating the linear translation from point A to D and then from point D to A, is the reciprocal motion as claimed. . . . one skilled in the art would understand from the claim, drawings and description of the '459 patent that reciprocate refers to an alternating of the linear movement of the cutter resulting in the cutter moving in a repeating forward and backward motion.

(*Id.* at 34–35).

We agree with the Examiner's interpretation of the pertinent claim limitation and find that the Patent Owner's asserted interpretation as illustrated in its annotation of Figure 3A is not the broadest reasonable interpretation in view of the specification as it would be understood by one of ordinary skill in the art.¹⁰

¹⁰ Requester's declarant Mr. Walbrink states at a person of ordinary skill in the art is "a degreed engineer having at least 5 year experience in handheld,

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While the Patent Owner asserts that the Examiner is improperly interpreting "translation" to be the same as "reciprocation" (Reb. Br. 2) thereby rendering the limitation "translation" superfluous (App. Br. 17), the Patent Owner mischaracterizes the position of the Examiner and overlooks the fact that these terms are not mutually exclusive of one another, and are not redundant to each other. As the Examiner explains:

the rejection above and previous responses to Patent Owner do not equate or render translation and reciprocation the same. Rather, the rejection and previous responses characterize each motion distinctly and describe how *translation occurs when the cutting member moves in a linear direction either forward or backward*. The cutting member *reciprocates because this forward and backward linear translation alternates* as long as the drive is rotating. Patent Owner is mischaracterizing the rejection above and previous responses to arguments.

(RAN 38, emphasis added).

The Patent Owner concedes that reciprocation includes a translation component, but argues that the recited "translation" of the claim is not the same as the translation present in reciprocation.¹¹ The Patent Owner argues

mechanical medical device design and development or a person having at least 10 years [of] experience in handheld, mechanical medical device design and development." (1st Decl. Walbrink ¶10; 2nd Decl. Walbrink ¶6). The Patent Owner agrees with Mr. Walbrink in arguing that the limitations at issue should be understood based on definitions from "a dictionary directed to individuals of ordinary skill in the art such as a degreed engineer with 5 years of experience in hand-held, mechanical devices or a person having at least 10 years of experience in such devices." (App. Br. 16).

¹¹ During the oral hearing, the representative of the Patent Owner argued as follows:

MR. CROSBY: . . . So if, as the Examiner says, the translation is a part of reciprocation, the reciprocating motion, we're not

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that "[w]hereas translation refers to the movement of the cutting member from one position to another position before the drive mechanism causes it to reciprocate, reciprocation is not translation, and reciprocation does not occur during the claimed translation." (App. Br. 13).

However, the review of the specification of the '459 patent indicates that the Examiner's interpretation is the broadest reasonable one. The specification of the '459 patent states that the inner member simultaneously

denying that it includes translation, but what we're saying is that the claim recites translation separate and apart from reciprocation.

So, in addition to merely reciprocating, the axial motion has to do some translation that is separate and apart from the reciprocation motion.

JUDGE SONG: Separate and apart from the translation that is in the reciprocating motion?

MR. CROSBY: Right. . . .

(Hearing Transcript, pg. 13, l. 20–pg. 14, l. 6).

MR. CROSBY: Now, I believe it was Judge Song had asked me a specific question about where do we recite that the reciprocating motion actually includes translation.

JUDGE SONG: That's correct.

MR. CROSBY: And to be clear, in our brief what we did is we avoided calling the motion of reciprocation translation to avoid the confusion.

But what we did say, and on page 13 of our brief, it is actually footnote 4, the Patent Owner, it says, and I quote, "the Patent Owner is not arguing that reciprocation does not include any linear movement component, just that the claimed reciprocation motion does not include the claimed translation motion."

(Hearing Transcript, pg. 51, l. 18–pg. 52, l. 6).

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rotates and translates, and that a feature may be included wherein "translating is reciprocating" or "translation is reciprocation." (FF 1A, 1B). The specification of the '459 patent also characterizes reciprocation as a movement in the axial direction (FF 1D). While the Patent Owner notes that these statements refer to an optional feature (Reb. Br. 2),¹² that is not determinative as to the broadest reasonable interpretation of "simultaneously rotate, translate, and reciprocate." In this regard, the above noted disclosures in the Specification of the '459 patent are entirely consistent and make sense in the context of the Examiner's interpretation wherein the claim limitation "translate" and "reciprocate" are not mutually exclusive of each other, or redundant to each other, translating requiring movement of the cutting member in a linear or axial direction (forward or backward), while reciprocating requires linear movement to alternate between forward and backward directions.

¹² During the oral hearing, the representative of the Patent Owner further stated:

MR. CROSBY: In a specific, different specific embodiment. I mean, to be honest with you, I don't know what that statement was intended to mean, you know, it was articulated to me that the reference there translating is reciprocating simply is a reference that the reciprocation is in the axial direction and not the rotating direction.

But, you know, I will be honest with you, it is an awkward statement, but it is also not in the claims. If we wanted to say that translating is reciprocating, we could have put that limitation in the claims.

(Hearing Transcript, pg. 17, ll. 11–20).

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On the other hand, the Patent Owner's interpretation requiring "reciprocate" to reference only change in direction, and for the recited "translation" to exclude the admitted translation motion of reciprocation, is problematic because the Specification of the '459 patent is silent as to such a specific meaning; does not disclose where translation ends and reciprocation begins, or vice versa; and is silent as to how such determination is made. The Patent Owner asserts that "neither the specification, nor the 'to cut tissue' clause of the claims make reference to reciprocation, which further evidences the distinction made explicit in the claims between translation and reciprocation." (App. Br. 16). However, this assertion is contradicted by the specification of the '459 patent itself, which states that it is "[t]he simultaneous rotating and reciprocating [of the] inner member," which overcomes the difficulty of initiating a cut (FF 1C), and further states that the inner member "simultaneously rotates and reciprocates to cut the tissue." (FF 1E).

Correspondingly, we are not persuaded that the interpretation advocated by the Patent Owner is the broadest reasonable interpretation consistent with the Specification, reading the claim language in light of the Specification as it would be understood by those of ordinary skill in the art. The Examiner's interpretation is reasonably broader and entirely consistent with the Specification of the '459 patent that includes the above noted disclosures (FF 1A–1E).

The Patent Owner concludes:

[i]n sum, the '459 patent specification, claim language, figures, the declaration of the Patent Owner's expert witness, and the testimony of the Requester's expert witness all demonstrate that

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(1) the claim term translate/translation is defined as the act of moving the cutting member from one point to another point along the axis and (2) the claim term reciprocate/reciprocation is defined as the act of changing direction of the cutting member including a deceleration phase and an acceleration phase.

(App. Br. 19).

As to the Patent Owner's articulated definition of translate/translation in point "(1)," we fail to appreciate any material difference between the Patent Owner's definition and that applied by the Examiner, which as noted above, is "to bear, remove, or change from one place, state, form, or appearance to another." (RAN 32–33). Indeed, the Requester "agrees [the Patent Owner's definition] is an appropriate construction of 'translation' that is consistent with the broadest reasonable construction in view of the specification. It is also consistent with the correct construction applied by the Examiner." (Resp. Br. 2).

As to the articulated definition of reciprocate/reciprocation in point "(2)," the Patent Owner further asserts that a person of skill in the art would understand that translation occurs at a substantially constant linear velocity, but:

[a]t the point where the cutting member begins to decelerate, it stops translating and begins reciprocating according to the claims, and at the point where cutting member stops accelerating in the opposite direction, it stops reciprocating and begins translating according to the claims. Thus, reciprocation is a unique motion that requires a "deceleration phase" and an "acceleration phase."

(App. Br. 13; *see also* Decl. Erdman, ¶¶13, 14, 17).

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However, the claims do not include limitations pertaining to velocity, and the Specification of the '459 patent never mentions velocity or acceleration. *In re Self*, 671 F.2d 1344, 1348 (CCPA 1982) ("Many of appellant's arguments fail from the outset because, . . . they are not based on limitations appearing in the claims . . ."). While it is true that changing the direction of motion as required by reciprocation necessitates deceleration/acceleration, and thus, changes in velocity, as already discussed above, reciprocation speaks to the directional nature of the translation motion, that is, that the motion changes direction in an alternating fashion. Neither change in acceleration nor change in velocity is precluded by the broadest reasonable interpretation of translation.

The Patent Owner also objects to the Examiner's reliance on "a lay dictionary (Merriam-Webster) — not a dictionary directed to individuals of ordinary skill in the art such as a degreed engineer with 5 years of experience in hand-held, mechanical devices or a person having at least 10 years of experience in such devices." (App. Br. 16). However, the Patent Owner does not set forth a definition from such a dictionary or even assert that such a dictionary exists. As discussed above, the definition of translation proffered by the Patent Owner does not materially differ from the definition relied upon by the Examiner.

Finally, there is some dispute as to the meaning of the modifying term "simultaneously." (RAN 38–39; App. Br. 19; Resp. Br. 3–4, 7–9; Reb. Br. 5–6). However, the issues raised by the parties as to the interpretation of "simultaneously" do not materially impact the broadest reasonable claim interpretation discussed above.

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Rejection 1

Claims 32 and 33 stand rejected as anticipated by Middle. The Examiner finds that Middle discloses a cutting member that simultaneously rotates, translates and reciprocates, and cuts tissue during simultaneous rotation and translation thereby anticipating these claims (RAN 5). The Examiner further finds that the drive piston of Middle moves linearly and changes direction and that this linear movement satisfies the translational movement limitation (*id.* at 40).

The Patent Owner argues that in Middle, the cutter 58 undergoes "rotation/reciprocation motion [which] is [] optimized for chipping/chiseling bone—not for initiating a cut into semi-rigid tissue, nor for slicing and removing large volumes of semi-rigid tissue as is the claimed instrument of the '459 patent." (App. Br. 22). The Patent Owner argues that "[a]ccordingly, Middle is designed to cut during either reciprocation or rotation, not during translation." (*id.* at 22; *see also* Reb. Br. 6).

We are not persuaded by the Patent Owner's argument. As noted by the Requester, "Middle plainly discloses that the cutter 58 is not as limited as Patent Owner contends and in fact cuts tissue. For example, Middle states: '[t]his invention is in the field of power operated tools used during surgery for cutting, drilling, and similar functions, as applied to muscle, bone, or other types of tissue.' (Middle at 1:6–34.)" (Resp. Br. 10). In addition, in view of the claim interpretation of reciprocation for the reasons discussed *supra*, we also disagree with the Patent Owner's assertion that Middle does not cut during translation merely because Middle describes its motion as a

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reciprocating motion (*see* App. Br. 22–23, *citing* Middle, col. 2, ll. 62–66; col. 8, ll. 58–65; *see also* Decl. Erdman ¶¶24, 25).

We further agree with the Examiner that even using the Patent Owner's narrow claim interpretation, Middle still anticipates claims 32 and 33 because Middle discloses nearly straight portions in the cam groove that would correspond to the Patent Owner's interpretation of a translation portion (RAN 42, *quoting* Third Party Requester's Response filed November 20, 2013, pgs. 14–15; *see also* annotated Figure 3 of Middle).

The Patent Owner responds that Middle's cam groove is a continuous sine wave which does not have any straight or nearly straight portions so that movement therefrom is reciprocation without translation (App. Br. 7, 23). The Patent Owner's argument is contrary to Figure 3 of Middle, which clearly discloses nearly straight portions between the apexes (*see* Middle, Fig. 3; *see also* RAN 42). Moreover, the claims at issue do not require the translation movement to be generated from straight grooves, or maintain a constant translational speed as already discussed.

Therefore, in view of the above, we affirm Rejection 1.

Rejection 3

Claims 1, 2, 4–16, 19, 25 and 27–31 stand rejected as obvious over Middle in view of Kaplan (RAN 12–14). The Examiner finds that Middle discloses most of the limitations of these claims, but fails to disclose a groove that is helical (*id.* at 12–13; *see also* FF 2A–2C). In rejecting the claims as obvious, the Examiner relies on helical grooves disclosed in Figure 8 of Kaplan (*id.* at 14, *quoting* Request, pgs. 76–78; *see also* FF 3A–3C),

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concluding that substitution of the helical groove would have allowed for "a slower reciprocation and a longer translation motion of the cutting element."

(*Id.* at 48). Specifically, it is the position of the Examiner that:

Middle provides that the shape of the cam groove is simply a design choice and that it can be modified so as to vary the number of reciprocations per rotation of the drive piston. (*See, e.g.*, Middle 7:26–30 ("It can be seen that each complete revolution of piston 30 will cause piston 30 to go through two complete reciprocation cycles. Varying the number of forward and rear bends of cam groove 38 can vary the number of complete reciprocation cycles per revolution.")) The cam groove depicted in Figures 3 and 4 of Middle provides more than one reciprocation per rotation of the piston. One of ordinary skill in the art who desired to have less than one reciprocation per rotation, which is also an obvious design choice, would know that the shape of the groove in Middle should be modified into the helical groove shown at Figure 8 of Kaplan. This modification is the simplest and most predictable modification that could be made to the cam groove shown in Figures 3 and 4 to achieve less than one reciprocation per rotation of the piston. . . . Indeed, Kaplan specifically teaches that the different grooves shown in its specification can be used on any of its embodiments. (Kaplan at 15:29–31 ("Using the foregoing modifications and variations of the cam profiles, various combinations of these cam profiles can produce various motion [sic] of the needle 122."))

(*Id.* at 14, *quoting* Request, pgs. 76-78; *see also* FF 2B, 2C; RAN 50).

The Patent Owner argues that "there is no explanation from the prior art for why a person having ordinary skill in the art would desire to have 'less than one reciprocation per rotation.'" (App. Br. 25). However, we agree with the Examiner that:

the combination of these references is a substitution for the intended purpose of achieving the same function, i.e.

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reciprocating. Additionally, the substitution allows for the expansion of modifications already envisioned by Middle, i.e. to vary the number of reciprocations per rotation of the drive piston. See Middle column 7 lines 26-30.

(RAN 51).

While the Patent Owner questions the articulated rationale of having less than one reciprocation per rotation, as noted above, Middle specifically teaches varying "the number of complete reciprocation cycles per revolution." (Middle, col. 7, ll. 26–30). Moreover, Kaplan teaches interchangeability of different grooves and varying motion of a cutting device by varying cam profiles (Kaplan, col. 15, ll. 29–31). While the specific reason for having less than one reciprocation per rotation is not explicitly stated in Middle, this indicates that such ratio was one variable that would have been considered in the normal course of designing such medical tools, for example, to account for the depth or amount of the tissue to be cut. Thus, there are ample teachings in the art that such a substitution would have been a predictable variation that was within the skill of those in the art, which would have yielded predictable results, and thus, would have been obvious to one of ordinary skill in the art. *KSR*, 550 U.S. at 416–17.

The Patent Owner also asserts that Middle arguably teaches away from the motivation because it "teaches only varying the forward and rear bends to vary the number of reciprocations per revolution." (App. Br. 25; *see also* FF 2C). However, we agree with the Requester (Resp. Br. 11–12) that this argument is unpersuasive because Middle does not criticize, discredit, or otherwise discourage the solution claimed. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Moreover, the Patent Owner argues

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Middle separately without considering the teachings of Kaplan or the skill of those in the art who would have appreciated that helical grooves such as that shown in Kaplan can be used for varying the number of reciprocations per revolution. *In re Merck*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

The Patent Owner also argues that the Examiner "ignores the evidence presented by the Professor Erdman that in his opinion, Middle cannot be modified to accommodate a helical groove without removing the quick release mechanism." (App. Br. 26, *citing* Decl. Erdman ¶¶27). Mr. Erdman identifies numerous modifications that would have had to be made to the device of Middle in order to combine the references in the manner suggested by the Examiner so as to incorporate a helical groove in the device of Middle (*see* Decl. Erdman ¶¶27–30). According to the Patent Owner, these modifications would have rendered the device inoperative and resulted in removing the quick release mechanism, which would have fundamentally changed the principle of operation so as to render the device unsuitable for its intended purpose (App. Br. 26; *see also* Reb. Br. 7).

However, we find the Patent Owner's argument unpersuasive and agree with the Examiner that "[m]uch of Patent Owner's opinion is based on flawed bodily incorporation." (RAN 50). *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) ("The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art"). We also do not perceive that the modifications

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identified by the Patent Owner's declarant, mainly pertaining to sizing and fitment of various components, would have been beyond the ordinary skill of those in the art, and agree with Mr. Walbrink's statement that "[a]ssuming that all of the modifications that Patentee suggests would be required . . . [such modifications] would require only routine engineering from one of skill in the art." (2nd Decl. Walbrink ¶18; *see also id.* ¶26).

We also agree with the Examiner that the proffered evidence does not convincingly establish that the quick release feature must be removed to make the proposed substitution operative (RAN 49–50). In this regard, the Patent Owner's assertion is based on Mr. Erdman's statement:

[h]owever, the modified device with the new follower does not readily work with a quick release system. Specifically, it is not clear how the new follower would be positioned in and/or coupled to the drive mechanism sleeve 64 and/or the quick release collar 62 to accommodate the modified piston 30 with the helical groove. Additionally, it is not clear how the new follower would be aligned on the modified piston 30 to properly ride in the helical groove when a new surgical implement assembly B is inserted.

(Decl. Erdman ¶36).

However, this opinion is not credible because a similar mechanism already disclosed in Middle, which utilizes a collar with J-groove and a lock pin, can be used (*see* FF 2D). In this regard, while the axial length of the piston of Middle may have to be extended (along with other components), the incorporation of a helical groove does not alter the circular profile of such modified piston. In addition, even if a ball type follower disclosed in Middle cannot be utilized in a helical groove, Middle also specifically

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discloses that a different cam follower element such as a pin may be used (FF 2E).

Therefore, we are not persuaded by the Patent Owner's arguments and agree with the Examiner that the suggested substitution would have been obvious to one of ordinary skill in the art, and a predictable variation that was within the skill of those in the art, which would have yielded predictable results. *KSR*, 550 U.S. at 416–17. Correspondingly, we affirm Rejection 3.

Rejection 4

Claims 1, 2, 4–16, 19, 25 and 27–31 stand rejected as obvious over Middle in view of Saadat (RAN 14–16). The Examiner finds that Middle discloses the limitations of these claims, but fails to disclose a groove that is helical (*id.* at 15). The Examiner relies on Saadat for disclosing a medical apparatus having a linear actuator mechanism with a lead screw that includes right and left handed helical grooves that connect to form one continuous channel (*id.* at 15, *citing* Saadat, Fig. 5, col. 7, ll. 7–22). The Examiner finds that because Middle teaches that the shape of the cam groove is a design choice, "one of ordinary skill in the art who desired to have less than one reciprocation per rotation, which is also an obvious design choice, would know that the shape of the groove in Middle should be modified, with predictable results, into the helical groove shown at Figure 5 of Saadat." (*Id.* at 16, *quoting* Request, pgs. 79–80; *see also* FF 2C).

The Patent Owner argues that "no motivation or rationale is provided why one would modify Middle to have such a groove. Changing Middle eliminates its claimed advantage of being able to rapidly change cutting implements." (App. Br. 26). The Patent Owner's arguments are

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substantively similar to those already addressed relative to Rejection 3, and are similarly unpersuasive. Correspondingly, we affirm Rejection 4.

Rejection 5

Claims 1, 2, 4–14, 19–22, 25 and 27–31 stand rejected as obvious over Middle in view of Galloway (RAN 16–18). The Examiner finds that "Middle meets the claim limitations as described above but fails to include the groove being helical and the follower having an arched bridge shape, the translation piece including a sealing cap, and a swiveling translation piece in the helical groove." (*Id.* at 17). Claim 20 requires that the follower have an arched bridge shape; claim 21 requires that the translation piece have a sealing cap and the follower swivels; and claim 22 requires that the translation piece swivels (App. Br., Claims App.).

The Examiner relies on Galloway for disclosing a reciprocating apparatus with a helical groove and follower that includes the recited follower and translation piece of claims 20–22 (RAN 17). In rejecting the claims as obvious, the Examiner concludes that a person of ordinary skill in the art "would have been motivated to combine the teachings in Galloway with the device of Middle at least for the reason that both references are directed to mechanisms for converting a purely rotary motion into a translating and reciprocating motion." (*Id.* at 17, *quoting* Request, pgs. 82–90, which cites Middle, col. 2, ll. 37–40, Galloway, Figs. 3–7, col. 2, ll. 38–41, and [1st] Decl. Walbrink ¶70; *see also* 2nd Decl. Walbrink ¶32; 1st Decl. Walbrink ¶71).

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The Patent Owner argues that "Middle never speaks of translation." (App. Br. 27). However, this argument is unpersuasive for the reasons already discussed above relative to claim interpretation and Rejection 1.

The Patent Owner also argues that "Galloway is directed to winding fibers such as glass fibers on a rotating collet to produce a package or spool of fibers," and thus, is not analogous art (*id.* at 27; *see also* Decl. Erdman ¶¶64–65). The Examiner disagrees, finding Galloway to be reasonably pertinent to the problem addressed, and states:

[o]ne skilled in the art would have looked toward Galloway as being reasonably pertinent to solving the problem [of] achieving more than just rotational motion in a cutting implement. Galloway achieves rotational, translational, and reciprocal motion all through the rotation of the cam (10). Galloway's mechanism would have been reasonably pertinent to one skilled in the art in order to solve the problem of incorporating more than just rotation into a tissue cutting instrument.

(RAN 54).

We generally agree with the Examiner. A technical problem with which the inventor was involved is conversion of rotational motion into simultaneous rotational, translational and reciprocatory motions (*see* FF 1A–1E). As generally discussed above relative to Rejection 1, the device of Middle converts rotational motion to rotate, translate and reciprocate a cutting member for cutting tissue. Middle also fairly suggests that the shape of the cam groove is a design choice which can be modified to vary the number of reciprocations per rotation of the drive piston (FF 2C).

This knowledge would have led one of ordinary skill in the art to seek out teachings regarding cam grooves designed to convert rotational motion

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into simultaneous rotational, translational and reciprocatory motion, particularly cam grooves capable of varying the number of reciprocations per rotation. One of ordinary skill in the art, being a degreed engineer (*see* 1st Decl. Walbrink ¶10; 2nd Decl. Walbrink ¶6) familiar with general engineering references such as Mark's Standard Handbook for Mechanical Engineers (*see* Decl. Erdman ¶16), would have known that helical cam mechanisms were known outside the particular field of mechanically-driven medical devices. Galloway discloses such a mechanism for converting a purely rotary motion into rotating, translating and reciprocating motions, the mechanism having a helical groove and follower. Thus, Galloway is reasonably pertinent to the technical problem with which the inventor was involved. *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379-80 (Fed. Cir. 2007).

A person of ordinary skill in the art would have had a reason to implement the helical groove disclosed in Galloway in the device of Middle to convert rotational motion to rotating, translating and reciprocating motions, especially in view of the suggestion in Middle to vary the number of reciprocations per rotation. Correspondingly, we affirm Rejection 5.

Rejection 10

Claim 26 stands rejected as obvious over Middle in view of Kaplan, Saadat, Galloway or Spear (RAN 27). Claim 26 recites "the inner drive hub defines a slot and the drive member includes a key received in the slot rotary coupling the drive member to the inner drive hub." (App. Br., Claims App.). The Examiner concludes that:

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it would have been obvious to one skilled in the art to reverse the arrangement of the tongue and the slot on the device of Middle. The reversal of the parts would have only required routine engineering and a motivation for the reversal would have been in order to provide a closed end rather than open ended connection for the proximal terminal portion of the drive shaft 48.

(RAN 27).

The Patent Owner does not submit specific arguments directed to the substance of this rejection, but rather, argues that "for the reasons discussed above[,] none of these combinations teach or suggest all the limitations of claim 26." (App. Br. 28). Therefore, in view of the affirmed rejections discussed *supra*, we affirm Rejection 10 as to the combination of Middle in view of Kaplan, Saadat or Galloway.

Rejection 2

Claims 1–14, 19, 25 and 27–31 stand rejected as obvious over Kaplan in view of the knowledge of a person of ordinary skill in the art (RAN 7–11). Each of these claims except for claim 3 stands rejected based on the affirmance of one or more of the rejections addressed *supra*. Claim 3 depends from claim 2, which, in turn, depends from claim 1. Claim 2 recites a surgical instrument including a drive further comprising "an inner drive hub coupled to the drive member such that the drive member rotates with the inner drive hub while being free to translate relative to the inner drive hub." Claim 3 recites that "the inner drive hub defines a slot and the drive member includes a key received in the slot rotary coupling the drive member to the inner drive hub." We limit our discussion of Rejection 2 to claims 1–3.

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The Examiner finds that helical grooves are well known in the art, Kaplan showing such a helical groove in Figure 8, so that it would have been obvious to use the helical groove of Figure 8 as the groove of Figures 10 and 24 of Kaplan (*id.* at 9, *quoting* Request, pgs. 65–66). In this regard, the Examiner finds that:

the incorporation of a helical groove as taught by FIG. 8 is made as providing an alternate mechanism for achieving the reciprocation and translation already present in the embodiment of FIG. 10. This incorporation would have predictable results since the embodiment of FIG. 10 already includes a reciprocating movement.

(*Id.* at 47).

The Examiner further finds that while Kaplan discloses inner drive hub 214 coupled to drive 194 "such that the drive member rotates with the inner drive hub while being free to translate relative to the inner drive hub (see Kaplan fig. 10 double ended arrow)" (*id.* at 8) as recited in claim 2, it does not disclose that the inner drive hub defines a slot and that the drive member includes a key received in the slot as recited in claim 3 (*id.* at 9). The Examiner concludes that "[w]hether the coupling 214 has the slot and the cam 194 (the drive member) has the key, or vice versa, was an obvious design choice within the knowledge of a person of ordinary skill in the art." (*Id.* at 10, *quoting* Request, pgs. 66–67).

The Patent Owner disagrees and argues that:

[t]here is absolutely no reason one would remove or otherwise modify the biopsy needle or any other portion of the Kaplan device. There is no reason to provide a helical groove. The device works perfectly fine as a biopsy instrument. Indeed, the specification explicitly teaches against using the biopsy needle to cut during rotation and translation when a helical groove is

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present. In Figure 8 of Kaplan, which uses a helical groove, rotation is explicitly prohibited.

(App. Br. 25).

However, the Patent Owner's argument is not persuasive. The present rejection is based on substituting the groove shown in Figure 10 of Kaplan for achieving reciprocation and translation from rotation with the helical groove shown in Figure 8 to achieve the same, predictable result. *KSR*, 550 U.S. at 416–17. While the Patent Owner argues that the mechanism in Figure 8 of Kaplan prevents rotation, we observe that it is the specific implementation of sleeve 236 with projections 238 that prevents rotation of the sleeve (FF 3C). The helical groove relied upon by the Examiner as providing a substitute for the groove of Figure 10 does not prevent rotation of anything. To any extent the Patent Owner may be arguing that Kaplan teaches away from such a substitution, we agree with the Examiner that Kaplan is merely teaching an implementation without a rotation feature, and that teaching of an alternative embodiment does not constitute teaching away (*see* RAN 45).

Therefore, in view of the above, we likewise affirm Rejection 2 as to claims 1–3, the Examiner's rejection of remaining claims having already been affirmed *supra*, and thus, being moot.

Rejection 8

Claims 1, 2, 4–12, 19–22, 25 and 27–31 stand rejected as obvious over Kaplan in view of Galloway (RAN 22–24). In rejecting the claims as obvious, the Examiner concludes that a person of ordinary skill in the art "would have been motivated to combine the teachings in Galloway with the

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device of Kaplan at least for the reason that both references are directed to mechanisms for converting a purely rotary motion into a translating and reciprocating motion." (*Id.* at 23–24, *quoting* Request, pgs. 105–106, which cites Kaplan 13, ll. 15–16, Galloway, Figs. 3–7; col. 2, ll. 38–41, and [1st] Decl. Walbrink ¶71).

The Patent Owner argues that "no rationale is given why a skilled artisan would look to a device for winding fibers, let alone having a helical groove that permits rotation to occur during cutting, when Kaplan specifically taught against that in the device of Figure 8." (App. Br. 27). Thus, the issues raised are similar to those raised relative to Rejections 5 and 2, respectively.

As discussed relative to Rejection 5, we agree with the Examiner that a technical problem with which the inventor was involved was converting rotational motion into simultaneous rotational, translational and reciprocatory motions, so that a mechanism for such conversion, such as that disclosed in Galloway, would have been reasonably pertinent. In addition, Kaplan does not teach against the use of helical grooves as asserted by the Patent Owner. As discussed relative to Rejection 2, Kaplan teaches a specific implementation without a rotation feature by providing projections on the sleeve that are captured within the housing to prevent rotation (FF 3C).

Thus, we likewise affirm Rejection 8.

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Rejections 6, 7 and 9

The claims subject to Rejections 6, 7 and 9 have been rejected in at least one other rejection discussed and affirmed above. Correspondingly, these rejections are cumulative and we decline to reach them.

CONCLUSIONS

1. The Examiner did not err in interpreting the claim limitation "simultaneously rotate, translate, and reciprocate."
2. The Examiner did not err in concluding that it would have been obvious to modify the device of Middle to incorporate a helical groove.
3. The Examiner did not err in concluding that it would have been obvious to modify the device of Kaplan to incorporate a helical groove.
4. The Examiner did not err in finding that Galloway is reasonably pertinent to a problem with which the inventor was involved.

ORDERS

The Examiner's rejection of claims 1, 2, 4–16, 19–22 and 25–33 under Rejections 1, 3–5, 8 and 10, as well the rejection of claims 1–3 under Rejection 2, are AFFIRMED. Rejections 6, 7 and 9 are moot.

Requests for extensions of time in this *inter partes* reexamination proceeding are governed by 37 C.F.R. § 1.956. In the event neither party

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files a request for rehearing within the time provided in 37 C.F.R. § 41.79, and this decision becomes final and appealable under 37 C.F.R. § 41.81, a party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. *See* 37 C.F.R. §§ 90.1 and 1.983.

AFFIRMED

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