

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BLUE BELT TECHNOLOGIES, INC.,
Petitioner,

v.

ALL-OF-INNOVATION GMBH,
Patent Owner.

Case IPR2015-00765
Patent 7,346,417 B2

Before SALLY C. MEDLEY, KEVIN F. TURNER, and
WILLIAM M. FINK, *Administrative Patent Judges*.

FINK, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

On February 19, 2015, Blue Belt Technologies (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1, 3, 5–7, 9, 10, 16, 17, 21, 26, 40, 45, 56, and 57 of U.S. Patent No. 7,346,417 B2 (Ex. 1001, “the ’417 patent”). Paper 1 (“Pet.”). On June 5, 2015, All-Of-Innovation GmbH

(“Patent Owner”) filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). On August 3, 2015, we granted the Petition and instituted trial as to claims 1, 3, 5–7, 9, 10, 16, 17, 21, 26, 40, 45, 56, and 57 of the ’417 patent on one of the grounds of unpatentability, under 35 U.S.C. § 103, that was alleged in the Petition. Paper 10 (“Inst. Dec.”).

After institution Patent Owner filed a Patent Owner Response (“PO Resp.”). Paper 14. Petitioner filed a Reply to the Patent Owner Response. Paper 21 (“Pet. Reply”). Patent Owner also filed a Motion to Amend. Paper 15 (“Mot.”). Petitioner filed an Opposition to Patent Owner’s Motion to Amend. Paper 22 (“Opp. Mot.”). Patent Owner filed a Reply to Petitioner’s Opposition. Paper 25 (“Reply Mot.”). Patent Owner also filed a Motion for Observation on Cross-Examination. Paper 27 (“Mot. Obsv.”). Petitioner filed a Response to Petitioner’s Motion for Observation. Paper 31 (“Resp. Obsv.”) An oral hearing for IPR2015-00765 was held on April 7, 2016. The transcript of the hearing has been entered into the record. Paper 34 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). Petitioner has shown that claims 1, 3, 5–7, 9, 10, 16, 17, 21, 26, 40, 45, 56, and 57 of the ’417 patent are unpatentable. Patent Owner’s Motion to Amend is *denied*.

A. Related Proceeding

According to the Petition, the ’417 patent is involved in at least the following lawsuit: *Mako Surgical Corp. v. Blue Belt Techs., Inc.*, Case No. 14-cv-61263 (S.D. Fla.), filed May 30, 2014. Pet. 1–2.

B. The '417 Patent

The '417 patent relates to a method and system for removing tissue or other material in dentistry or surgery. Ex. 1001, 1:7–10, 6:12–19. Figure 1 is reproduced below:

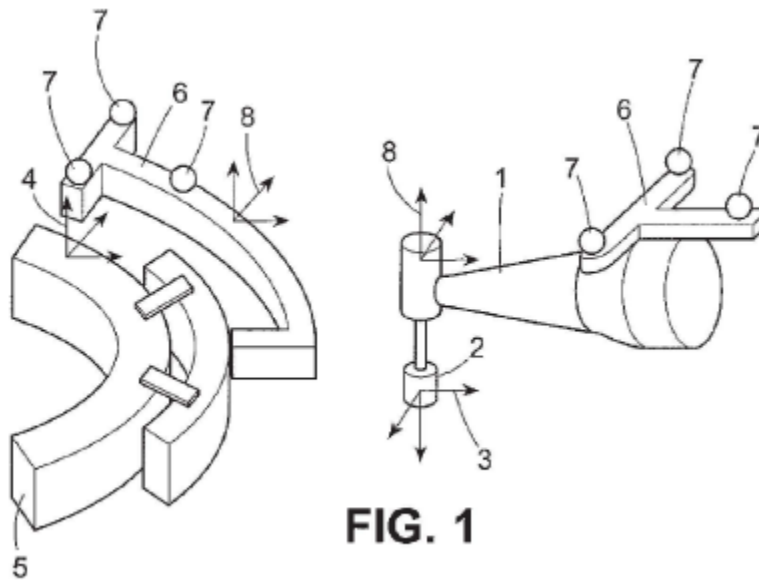


Figure 1 illustrates a medical instrument with a tissue-removing effector 2 in a position and orientation relative to a reference position of tissue object 5, in accordance with the invention. Ex. 1001, 8:50–53. The effector can be implemented as a saw blade, cutter, drill, laser, etc., which can be powered on or off according to the position of the effector relative to the reference position of the tissue object. *Id.* at 8:53–65. The effector may have one or more markers 7, such as glass spheres, secured in a fixed position relative to the effector on marker support 6. *Id.* at 8:65–9:5. In general, the markers are a set of points whose position relative to a position coordinate system can be determined. *Id.* at 9:5–10. Various measurement methods, including optical, acoustical, electromagnetic, etc., can be used. *Id.* at 9:10–15. A physician or dentist uses information obtained from, e.g.,

an X-RAY or CT-image, to plan a cut volume to allow fitted pieces to be integrated within the fitted shape of the residual tissue volume. *Id.* at 9:33–60; 10:8–12; 12:60–65. Importantly, the invention prevents accidental tissue removal outside the fitted shape by powering off the effector when its position is outside of the cutting geometry. *Id.* at 13:17–28.

C. Illustrative Claim

Claims 1 and 40 are independent claims. Claims 3, 5–7, 9, 10, 16, 17, 21, and 26 directly or indirectly depend from claim 1, and claims 45, 56, and 57 directly or indirectly depend from claim 40. Claim 1 is reproduced below.

1. A method for removing and processing material with at least one effector, wherein the effector defines a volume and has a predetermined geometry, the method comprising:

removing and processing material from an object with the effector, wherein the removing and processing comprises:

manually guiding the effector in relation to the object;

determining, using a navigation system, position and orientation of the effector in relation to at least one reference body as the effector removes material from the object;

storing data representative of the position and orientation of the effector in relation to the reference body as the effector removes the material from the object; and

supplying at least one of power and parameterization control commands to the effector as a function of at least one of a predetermined work volume for the object, volume of the material removed from the object and volume of residual material in the work volume, wherein the removed material volume and the residual material volume

are determined based on the volume and the geometry of the effector and the position and orientation of the effector data.

Ex. 1001, 17:40–63.

D. Pending Ground of Unpatentability

The pending ground of unpatentability challenges claims 1, 3, 5–7, 9, 10, 16, 17, 21, 26, 40, 45, 56, and 57 as obvious, under 35 U.S.C. § 103(a), over the combined teachings of Mushabac¹ and Klimek.² Petitioner also relies on the Declarations of Dr. Brian Davies in support of its contentions (Ex. 1002; Ex. 1012).

E. Level of Ordinary Skill in the Art

Petitioner’s declarant, Dr. Davies, testifies that a person of ordinary skill in the art, for purposes of the ’417 patent, would have had a “Master’s or Doctorate degree with a concentration in mechanical or medical engineering from an accredited engineering program with an area of emphasis of medical robotics and at least two years of relevant experience in industry.” Ex. 1002 ¶ 16. Patent Owner’s declarant, Dr. Robert Howe, testifies that a person of ordinary skill in the art would have had “at least a bachelor’s degree in mechanical, electrical, or biomedical engineering or computer science and at least five years of experience developing or researching image-guided medical devices and procedures or surgical robotics.” Ex. 2023 ¶ 21.

¹ U.S. Patent No. 5,562,448, issued Oct. 8, 1996 (Ex. 1004) (“Mushabac”).

² Klimek, et al., “A Passive-Marker-Based Optical System for Computer-Aided Surgery in Otorhinolaryngology: Development and First Clinical Experiences,” *The Laryngoscope*, Vol. 109, pp. 1509–1515, Sept. 1999 (Ex. 1005) (“Klimek”).

Having considered the testimony of the parties' declarants, we do not discern substantial differences between the parties' definitions of the level of ordinary skill. Although Dr. Davies's definition relies on more education (i.e., a Master's or Doctorate degree as opposed to a Bachelor's degree) but less experience than Dr. Howe's definition (i.e. 2 years as opposed to 5 years), Dr. Davies agrees "someone with less technical education but more practical experience" could also be considered a person of ordinary skill in the art. Ex. 1002 ¶ 16. Given this lack of apparent disagreement, we determine an express definition of the level of ordinary skill is not required, but, instead, find the level of ordinary skill in the art to be reflected in the cited references. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("[T]he absence of specific findings on the level of skill in the art does not give rise to reversible error 'where the prior art itself reflects an appropriate level and a need for testimony is not shown.'" (internal quotations omitted); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

II. ANALYSIS

A. Claim Interpretation

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1277–78 (Fed. Cir. 2015) ("We conclude that Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA."), *aff'd sub nom. Cuozzo Speed Techs. LLC v. Lee*, 136 S.Ct. 2131 (2016). Under the broadest reasonable construction standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the

entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Thus, the claims are read in light of the specification and “prosecution history in proceedings in which the patent has been brought back to the agency for a second review.” *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292 (Fed. Cir. 2015). Only those terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

1. “manually guided” or “manually guiding”

In the Decision to Institute, we construed the terms “manually guiding” and “manually guided”³ (recited in independent claims 1 and 40, respectively), as “moving/moved by hand, without robotic or kinematic support.” Inst. Dec. 9. We based this construction on the Specification and prosecution history, which, we determined, distinguished manually guiding an effector⁴ from including robot or kinematic-supported movement. *Id.* at 8 (citing, e.g., Ex. 1001, 12:22–25, 20:25–40 (claim 26); Ex. 1003, 42–43 (distinguishing the invention by “absence of robotic control of the positioning of the effector”). At that time, we specifically noted the term “manually guiding” *does not prohibit* “moving restriction” or “expensive mechanical assemblies.” Inst. Dec. 7.

Patent Owner does not dispute the construction of “manually guiding” we adopted for purposes of institution, i.e. “moving/moved by hand, without robotic or kinematic support.” See PO Resp. 5–10. However, citing its

³ As with the Decision to Institute, we hereinafter refer only to “manually guiding” for convenience purposes.

⁴ An effector can be “a cutter, a drill, or a laser.” Ex. 1001, 12:22–23.

declarant, Dr. Howe, and dictionary definitions of the word “support,” Patent Owner contends a person of ordinary skill in the art would have understood the term “kinematic support” to mean mechanical assemblies that constrain or facilitate device movement to obtain a desired position or motion. *Id.* at 5–7 (citing, e.g., Ex. 2023 ¶¶ 42–43; Ex. 2012, 1180 (definition of “support”)). For example, citing Dr. Howe, Patent Owner argues that the presence of “friction in the joints of a mechanical arm could provide kinematic support to maintain the position of the arm, or a motor could provide kinematic support for the movement of the arm.” *Id.* at 6 (citing Ex. 2023 ¶ 42).

As an initial matter, we reject Patent Owner’s attempted further construction of “kinematic support” as “mechanical assemblies that constrain or facilitate movement” as contrary to our explicit determination that the term “manually guiding” does not prohibit “moving restriction” or “expensive mechanical assemblies.” Inst. Dec. 8. In arguing for this further construction, Patent Owner also notes the “Background of the Invention [portion of the Specification] . . . describes supported systems when discussing the state of the art at the time of the invention in contrast to the claimed invention of manually guided systems.” PO Resp. 7–8 (citing Ex. 1001, 3:25–6:65). However, the background states this was because “humans lack the ability to precisely orient their hands in a 3-D-reference coordinate system.” Ex. 1001, 2:10–12. In other words, precise surgery required robotic or interactive *control* over the tissue-removing effector, which substantially increased cost. *See* Ex. 1001, 2:14–18, 2:29–31. Indeed, the “Summary of the Invention” emphasizes that with the present invention “[c]omparable results can also be achieved by guiding the

instruments manually, *without using robots.*” *Id.* at 7:10–13 (emphasis added). Consequently, as we determined in the Decision to Institute, the invention intended to eliminate the necessity to have “robotic assemblies for guiding the instruments.” Inst. Dec. 8.

As we pointed out previously, the prosecution history is consistent with this view. *See id.* For example, during prosecution the applicant stated that “[n]owhere does Glassman et al. teach or suggest manually guiding an effector to remove material from an object, *in the absence of robotic control of the positioning of the effector.*” Ex. 1003, 42–43 (emphasis added)). According to the Examiner, the “Glassman [prior art] teach[es] of *a robotic surgical system* that includes a manipulator arm that has a surgical tool.” *Id.* at 51–52 (emphasis added). As with the Specification, these file history statements support excluding robotic control, but do not support the Patent Owner’s view that the present invention excluded mechanical assemblies capable of support or passive movement restrictions.

For its part, Petitioner argues our preliminary construction goes too far in precluding “kinematic support.” PO Resp. 5–10 (explaining that neither the Specification nor claim 26 require manually guiding to be mutually exclusive of kinetic support). As noted above, in the Decision on Institution, we relied on claim 26 and the Specification, column 12, lines 22–25, in determining that manually guiding precludes kinematic support. Inst. Dec. 8. Citing Dr. Davies testimony, Petitioner contends the Specification, which states “[t]he effector . . . is guided manually . . . (but can also be kinematically supported . . .),” could reasonably be read to mean that the effector can be both manually and kinematically supported. Pet. Reply 7 (Ex. 1012 ¶ 13). We agree with Petitioner that this is a reasonable reading

of the Specification. We also agree claim 26 could reasonably be read to cover situations in which the effector is both manually arranged and kinematically arranged. *Id.* at 6. Consequently, we agree with Petitioner that our preliminary construction—by precluding “kinematic support”—is unnecessarily restrictive and not supported by the Specification or prosecution history. *See Proxyconn*, 789 F.3d at 1298. Rather, for the reasons discussed above, the record simply reflects that “‘manually guiding’ requires the movement by a person’s hand as opposed to movement controlled by a robot,” as Petitioner’s declarant testifies. Ex. 1012 ¶ 9. At most, the record supports excluding robotic control from “manually guiding.” Accordingly, we modify our preliminary construction of “manually guiding” from “moving/moved by hand, without robotic or kinematic support” (which we noted does not prohibit “moving restrictions” or “expensive mechanical assemblies”) to “moving/moved by hand without robotic control.”

B. Principles of Law

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In that regard, an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; see *Translogic*, 504 F.3d at 1259.

C. Obviousness of Claims 1, 3, 5–7, 9, 10, 16, 17, 21, 26, 40, 45, 56, and 57 over Mushabac and Klimek

For the reasons given below, after consideration of the arguments in the Petition, Patent Owner’s Response, and Petitioner’s Reply, and the evidence cited therein, we conclude that Petitioner has shown by a preponderance of the evidence that claims 1, 3, 5–7, 9, 10, 16, 17, 21, 26, 40, 45, 56, and 57 of the ’417 patent are unpatentable, under 35 U.S.C. § 103, as the subject matter of those claims would have been obvious over the combination of Mushabac and Klimek. See Pet. 13–36.

1. Mushabac (Ex. 1004)

Mushabac describes a method for preparing a dental preparation, such as a dental implant, in a patient’s jaw using a computer to generate a graphical representation of the orientation of a drill in relation to pre-existing structures. Ex. 1004, Abstract, 1:13–18. Figure 12 of Mushabac is reproduced below:

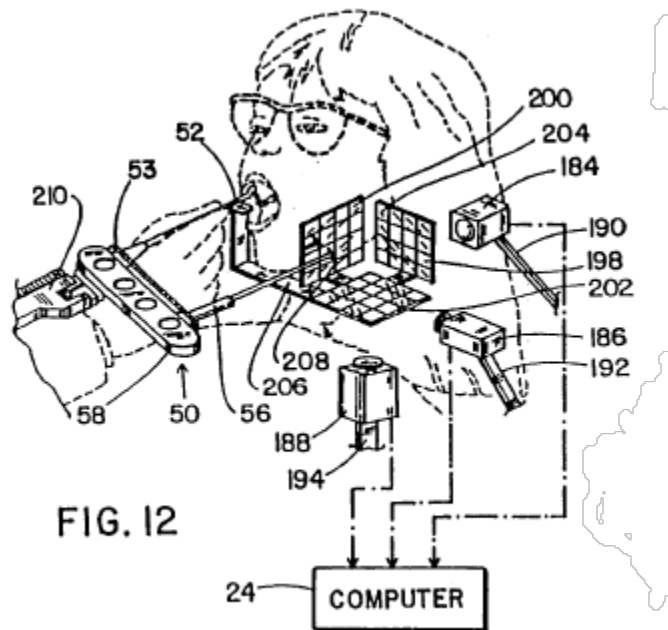


Figure 12 shows a stylus 52 connected to pantograph arm 56 in accordance with the invention. Tracking CCD cameras 184, 186, and 188 are positioned to track the stylus based on the movements of the pantograph arm 56 against reference frame plates 198, 200, and 202. Ex. 1004, 14:48–56. The stylus 52 is used for pre-operative planning (*id.* at 4:41–45, 14:55–61), but a drill is used in place of the stylus for the actual operation (*id.* at 4:45–51, 12:22–33).

In a pre-operative phase, the dentist may direct the computer to overlay a predefined tooth preparation on a three-dimensional representation of the tooth. Ex. 1004, 12:3–5. The computer may be programmed to automatically select a possible tooth preparation, or the dentist may direct the computer to alter the graphic representation of the tooth, for example, by removing a layer of material from the tooth surface. *Id.* at 12:8–17. The dentist may use the computer to select a preformed tooth preparation corresponding to an implant or inlay. *Id.* at 17:20–45.

During the operation, a dentist guides the drill (or other cutting tool) while the computer 24 monitors the location of the operating tip. Ex. 1004, 11:20–26. When the operating tip approaches a boundary defined to the computer during the pre-operative planning phase, the computer can display a color change or interrupt power to the drill. *Id.* at 11:25–34; 16:44–57. The computer 24 has memory loaded with encoded data corresponding to all preformed inlays in a kit, and, thus, may control machining operation to limit the range of motion to provide the tooth with the desired preparation. *Id.* at 17:46–65.

2. Klimek (Ex. 1005)

Klimek describes an “optical computer-aided surgery (CAS) device.” Ex. 1005, 1509. Klimek’s system includes a freehand probe, tracked by a passive-marker sensor system, linked to a computer image space on a patient’s CT or MRI scan. *Id.* at 1510. Infrared cameras track the markers attached to the surgical instrument. *Id.* Figure 3 is reproduced below:



Fig. 3. Passive-marker arrays were developed that can easily be attached to any already existing surgical instrument. Thus any instrument can be used as a navigation tool merely by simple calibration of its geometry. This saves cost and frees the surgeon from the restriction of using special pointers.

Figure 3 shows a passive marker array that can be adapted to fit on any existing surgical instrument. *Id.* at 1511. In addition, low-profile fiducial markers are attached to the patient's skin to allow the system to know the patient's position in three-dimensional space relative to infrared cameras. *Id.* at 1510.

3. Analysis

In support of this asserted ground of unpatentability, Petitioner provides explanations as to how the subject matter of claims 1, 3, 5–7, 9, 10, 16, 17, 21, 26, 40, 45, 56, and 57 is taught by Mushabac and Klimek. Pet. 13–36. Petitioner also provides a proposed rationale for combining the teachings of Mushabac and Klimek. *Id.* at 24 (citing Ex. 1002 ¶¶ 136–140).

Patent Owner does not dispute most of Petitioner's mappings of Mushabac and Klimek to the limitations of claims 1 and 40, *see id.* at 19–24 (citing Ex. 1004; Ex. 1002 ¶ 141 (claim chart)). For example, claim 1 requires an “effector, wherein the effector defines a volume and has a predetermined geometry” and “removing and processing material from an object with the effector.” Ex. 1001, 17:40–45. We determine that Petitioner has shown that Mushabac's drill 38 is such an effector, *see* Pet. 19–20 (citing, e.g., Ex. 1004, 11:20–32, 16:44–57), because “drill 38 (FIG. 1) is then used to remove a portion of the subject tooth . . . [up] to a defined boundary.” Ex. 1004, 16:44–53.

Claim 1 also requires “determining, using a navigation system, position and orientation of the effector in relation to at least one reference body.” Ex. 1001, 17:47–49. Petitioner has shown that both Mushabac and Klimek teach this limitation. Pet. 20–21 (citing, e.g., Ex. 1004, 25:44–55, 27:27–47; Ex. 1005, 1510). Regarding Klimek, for example, Petitioner

relies on its teaching of a passive marker-based optical system wherein “[t]o provide link between patient anatomy and the diagnostic image data . . . [s]pecial low-profile fiducial markers were developed.” Ex. 1005, 1510.

“Manually Guiding” Limitation

Claim 1 also requires “manually guiding the effector in relation to [an] object.” Ex. 1001, 17:46. Petitioner relies on Mushabac’s teaching that the “dentist holds either the actual drilling instrument or a practice instrument in the patient’s mouth and manipulates it while watching monitor 34.” Pet. 20 (quoting Ex. 1004, 25:35–37); *see also* Ex. 1002 ¶¶ 89–95.

Patent Owner disputes Petitioner’s contention that Mushabac teaches this limitation. PO Resp. 11–16. In particular, Patent Owner contends Mushabac does not teach manually guiding the effector, because “Mushabac discloses a mechanical pantograph arm system, which is kinematically supported, and thus outside the scope of the claims of the ’417 patent.” PO Resp. 11 (citing Ex. 2023 ¶ 51). Referring to Figure 14, reproduced below, Patent Owner argues that Mushabac discloses a six-segment support arm that provides “kinematic support” by providing enough friction to maintain its position, such that the user—e.g., a dentist, does not have to hold up the arm to keep it in place. *Id.* at 13 (citing Ex. 1004, 15:32–39, 15:60–61); *see also* Ex. 2023 ¶ 64.

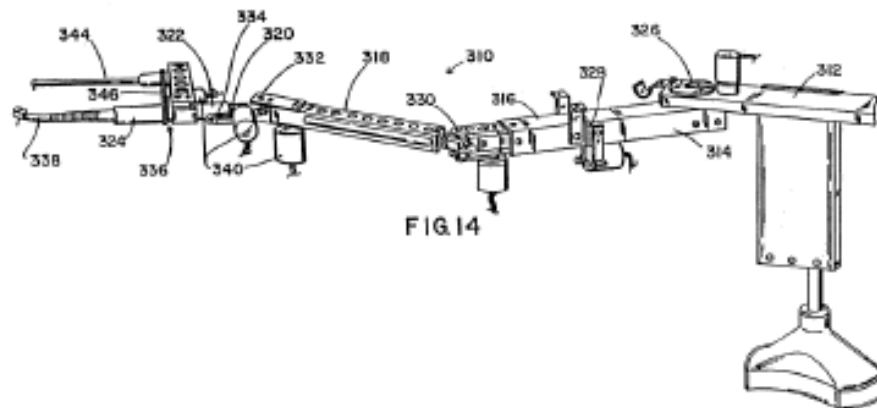


Figure 14 depicts an effector 338 and mechanical support arm 310. *See* Ex. 1004, 15:32–44. As a result of the friction used to support the movement of arm 310, Patent Owner contends, Mushabac does not disclose manually guiding the effector without kinematic support. PO Resp. 16.

Patent Owner’s position relies entirely on its interpretation of the term “kinematically supported”—in our construction of “manually guiding”—as including any mechanical linkage that provides enough friction to maintain support. PO Resp. 16. However, in the Decision to Institute, we specifically rejected Patent Owner’s proposed construction that would exclude any “expensive mechanical assemblies” or “moving restrictions.” Inst. Dec. 8–9. Thus, even under the preliminary construction of “manually guiding,” we would not be persuaded by this argument. In any event, we determine above that the construction of “manually guiding” is “moving/moved by hand without robotic control.” Although there is undisputed evidence that drill 318 is moved by hand (i.e., “manually guiding the effector”), there is no evidence that support arm 310 does anything other than passively record movement and provide frictional support. *See* Pet. Reply 10–11; Ex. 1004, 15:60–61, 15:64–16:4. That is, there is no evidence that support arm 310

provides robotic control. Accordingly, Petitioner has shown that Mushabac teaches the “manually guiding” limitation of claim 1.

Motivation to Combine

Patent Owner also contends a person of ordinary skill in the art would not have been motivated to combine Mushabac with the tracking system of Klimek. PO Resp. 16–26. However, before addressing these specific arguments, we start with Patent Owner’s last argument first, which is that the “Petition provides no articulated rationale for the proposed combination,” *id.* at 16.

An articulated rationale is a required part of an obviousness analysis. *See KSR*, 550 U.S. at 418. Here, Petitioner does propose a rationale by contending it would have been obvious to use the passive optical-based marker system of Klimek on the drill of Mushabac to obtain a more accurate, flexible, and robust navigation system than that provided by Mushabac’s optical pantograph system. *See* Pet. 24–25 (citing Ex. 1005, Figs. 1–3, 1512); Ex. 1002 ¶¶ 136–140. As an example, Petitioner contends that mounting optical markers, such as those disclosed in Klimek, directly on the drill 38 of Mushabac, would eliminate for the linkages, separate power sources, mechanical losses, and space restrictions required by Mushabac’s pantograph tracking system. Pet. 24–25; Ex. 1002 ¶ 138. We agree. We also give substantial weight to Dr. Davies’s testimony that Klimek teaches the advantages of passive marker technology as suitable for use on any common surgical instrument, such as the effector in Mushabac. *See* Ex. 1002 ¶ 137. Based on this evidence, we agree with Petitioner’s conclusion that such a combination would be a substitution of known elements with predictable results. Pet. 25; *see KSR*, 550 U.S. at 416, 418.

As for the specific arguments for why a person of ordinary skill would not have made the proposed combination, Patent Owner provides the following summary:

(1) Klimek's proposed markers are impractical for the dental procedures discussed in Mushabac; (2) the lack of reproducibility of the Klimek system makes it unusable for dental procedures; and (3) Klimek's suboptimal tracking system would not have provided any advantages or improvements to the tracking system disclosed in Mushabac and could lead to a loss of synergy by removing Mushabac's multiple functions. (Ex. 2023 at ¶¶ 84-89.) Moreover, the Petition provides no articulated rationale for the proposed combination.

PO Resp. 16; *see also id.* at 17–26. We address these in turn.

Patent Owner first argues that Klimek's proposed markers are impractical for dental procedures because Klimek requires positioning external markers (for ear, nose, and throat surgery) on scalp areas or on a mouth piece placed into a patient's mouth. PO Resp. 17 (citing Ex. 1005, 1509–10). According to Patent Owner neither of these positions is practical for dental procedures (as addressed by Mushabac) because Klimek's scalp markers would require shaving someone's head and its alternative mouth piece would prevent access to the teeth. *Id.* (citing Ex. 2023 ¶¶ 80–81). We disagree.

First, it is unnecessary for a combination to be the most desirable combination described in the prior art to provide motivation for making the combination. *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (“[T]he question is whether there is something in the prior art as a whole to suggest the *desirability*, and thus the obviousness, of making the combination, not whether there is something in the prior art as a whole to suggest that the

combination is the *most desirable* combination available.” (internal quotations omitted)). We find that the possible inconveniences alleged by Patent Owner are not sufficient to overcome the motivation in this instance.

Second, as Petitioner points out, Mushabac is not limited to dental applications, but instead “its techniques ‘may be performed in areas of surgery other than dental surgery.’” Pet. Reply 19–20 (quoting Mushabac, 26:37–39); *see also* Inst. Dec. 19. Thus, even if scalp markers would have been inconvenient for dental procedures, there is no persuasive evidence such markers are inconvenient for other types of surgery.⁵ Indeed, Klimek itself suggests they are suitable. Ex. 1005, 1514 (“The system was found to be useful in nearly all cases of revision paranasal sinus surgery with missing landmarks.”).

Patent Owner next argues the error range and “low reproducibility” of the measurements in Klimek renders it unsuitable for the dental work discussed in Mushabac. PO Resp. 18–19 (citing Ex. 1005, 1513 (discussing error ranges between 0 and 2.8 mm, with an average of 0.86 mm); Ex. 2023 ¶ 84). As such, Patent Owner contends, Klimek’s high error range would have discouraged a person of ordinary skill and teach away from combining Klimek’s optical tracker for dental procedures. *Id.* at 20 (citing Ex. 2023 ¶¶ 82–84). Here again, we disagree because Mushabac is not limited to dental applications. As Patent Owner’s declarant, Dr. Howe, concedes, what constitutes an unacceptable outlier (i.e., error) “[v]ery much depends on the

⁵ We also credit the testimony of Petitioner’s declarant, Dr. Davies, who stated that at the time of the claimed invention it would have been obvious to place such markers on a patient’s temple, which is substantially fixed and does not require shaving the patient’s head. Ex. 1012 ¶ 27.

application.” Ex. 1013, 139:17–21. As discussed in the previous paragraph, Klimek itself reports its optical marker system suitable for paranasal sinus surgery.

Furthermore, we point out that Klimek, which is dated September 1999, predates the ’417 patent’s earliest foreign application by over two years. Ex. 1001 at [22]. Dr. Davies testifies that by early 2001, persons of ordinary skill in the art had produced highly reliable passive markers similar to those described in Klimek. Ex. 1012 ¶ 29 (citing Ex. 1018). We give substantial weight to this testimony because, in describing the invention, the ’765 patent specifically contemplates using optical markers, without mentioning accuracy or reproducibility problems. See Ex. 1001, 9:5–15. Moreover, Mushabac does not disclose the required level of accuracy in quantifiable terms. Thus, there is little evidence Klimek’s system is not sufficiently accurate and reproducible for use in Mushabac’s system. Consequently, we determine that Petitioner has shown that a person of ordinary skill in the art at the time of the invention would not have been discouraged from making the proposed combination.

Finally, Patent Owner argues a person of ordinary skill would not have replaced the less effective and suboptimal Klimek optical tracking system for Mushabac’s superior pantograph-based tracking system. PO Resp. 22–23 (citing Ex. 2023 ¶¶ 88–89). However, as we pointed out, it is unnecessary for a combination to be the most desirable combination for there to be motivation to combine. *Fulton*, 391 F.3d at 1200. For example, as discussed above, Petitioner contends a benefit of using Klimek’s system is eliminating additional linkages, power sources, and space restrictions imposed by Mushabac’s system. Pet. 24–25. Even if this did result in a less

accurate system, as Patent Owner alleges (but which is not clear from the evidence), the overall combination would still be desirable if the resulting accuracy was sufficient and the skilled artisan's objective was eliminating mechanical linkages and saving space. *See In re Urbanski*, 809 F.3d 1237, 1243–44 (Fed. Cir. 2016) (“[O]ne of ordinary skill would have been motivated to pursue the desirable properties taught by Wong, even if that meant foregoing the benefit taught by Gross.”).

In sum, we determine that Petitioner has provided articulated reasoning with rational underpinning to support the proposed combination of Mushabac and Klimek.

In view of the foregoing, Petitioner has shown claim 1 to be unpatentable, under 35 U.S.C. § 103(a), by a preponderance of the evidence over Mushabac and Klimek. Regarding claim 40, which recites similar limitations to those discussed above for claim 1, including a “manually guided” limitation, as well as claims 3, 5–7, 9, 10, 16, 17, 21, 26, 45, 56, and 57, which depend directly or indirectly from claims 1 or 40, Patent Owner presents no additional patentability arguments. As noted at the outset, we have reviewed Petitioner's evidence and, based on this evidence, determine that Petitioner has shown claims 3, 5–7, 9, 10, 16, 17, 21, 26, 40, 45, 56, and 57, to be unpatentable by a preponderance of the evidence.

III. MOTION TO AMEND

Patent Owner requests, should independent claims 1 and 40 be determined to be unpatentable, that claims 1 and 40 be cancelled, and substitute claims 1 and 40 be entered. Mot. 1–19 (citing, e.g., Ex. 1001, Ex. 1003, Ex. 1004, Ex. 2012, Ex. 2013, Ex. 2015, Ex. 2022, Ex. 2023). Petitioner opposes the request. Opp. Mot. 1–24 (citing, e.g., Ex. 1012, Ex.

1014). Patent Owner replies. Reply Mot. 1–12 (citing, e.g., Ex. 1001, Ex. 1014, Ex. 2023).

A. Procedural Burdens

Patent Owner has the burden of proving patentability of a proposed substitute claim. *See Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1334 (Fed. Cir. 2015) (“[T]he Board permissibly interpreted [37 C.F.R. § 42.20(c)] as imposing the burden of proving patentability of a proposed substitute claim on the movant: the patent owner.”). Accordingly, at a minimum, Patent Owner has the burden of showing that (1) the substitute claims overcome all the grounds under which independent claims 1 and 40 were determined to be unpatentable, namely, 35 U.S.C. § 103; and (2) its request meets all the procedural requirements concerning motions to amend set forth, for example, in our rules, *Idle Free Systems, Inc. v. Bergstrom, Inc.*, Case IPR2012-00027 (PTAB June 11, 2013) (Paper 26) (informative), and *MasterImage 3D, Inc. v. RealD Inc.*, Case IPR2015-00040 (PTAB July 15, 2015) (Paper 42) (precedential).

Petitioner asserts that Patent Owner did not meet certain procedural requirements, and, thus, asserts that the Motion to Amend should be denied. Opp. Mot. 1–10. For example, Petitioner contends Patent Owner fails to provide written description support for the entire combination, in addition to failing to provide support for the added limitations “freehand” and “without mechanical support.” *Id.* at 3–8. Petitioner also contends the Motion fails to distinguish prior art in the prosecution history of the patent. *Id.* at 9–10 (citing *MasterImage3D*, slip op. at 2). However, in view of our determination on the merits below that substitute claims 1 and 40 are

unpatentable under 35 U.S.C. § 103(a), it is unnecessary to address these and other alleged deficiencies in Petitioner's motion.⁶

*B. Whether Substitute Claims are Patentable
Under 35 U.S.C. § 103(a)*

Patent Owner proposes substitute claim 1 containing the following additional limitation (underlined by Patent Owner) to the effector:

manually guiding the effector coupled to a freehand handpiece
without mechanical support in relation to the object;

Mot. 2. Patent Owner proposes a similar additional limitation to claim 40. *Id.* at 3. Patent Owner proposes constructions for the term “‘freehand’ device” as a “device that can be moved freely by hand without further mechanical devices” and the term “handpiece ‘without mechanical support’” as “handpiece whose weight will be carried by the person using the device as opposed to by some further mechanism.” *Id.* at 6–8.

⁶ It bears pointing out that Patent Owner's statement that “Dr. Howe reviewed all of the references cited in the patent and the prosecution history, but is not aware of any references that would make obvious the freehand handpiece without mechanical support” (Mot. 19) does not attempt to distinguish the prior art of record as the Board's precedent requires. *See Idle Free*, slip op. at 7 (“Some representation should be made about the specific technical disclosure of the *closest prior art* known to the patent owner, and *not just a conclusory remark that no prior art known to the patent owner renders obvious the proposed substitute claims.*” (emphasis added)). A cursory review of the prior art of record here (*see* Ex. 1001 at [56] (citing references)) discloses effectors having freehand handpieces without mechanical support—the additional limitation added to substitute claim 1. *See, e.g.*, U.S. Pat. No. 6,000,939 at 6:29–34, 7:40–53, Fig. 1 (disclosing unsupported, freehand dental drill with power interrupt if the dentist and patient move relative to each other beyond set parameters). In any event, given our determination on the merits, it is unnecessary to decide whether Patent Owner's failure to address these references is sufficient reason to deny the Motion.

Petitioner does not dispute the constructions of these terms, and we agree they are consistent with the broadest reasonable interpretation.

According to Patent Owner, the proposed substitute claims are patentable over the known prior art. *See id.* at 8–9 (citing Ex. 2023 ¶¶ 59, 108–111, 114). In particular, Patent Owner contends the ’417 patent “bridged two disparate approaches to surgery: mechanically-assisted approaches typically used for hard tissues like bones and teeth and freehand navigation approaches typically used in soft tissue procedures like neurosurgery. *Id.* at 12 (citing Ex. 2023 ¶ 31). Patent Owner contends Mushabac with its mechanical arm is not freely moveable nor without mechanical support, and adding the optical tracking system of Klimek would not change this. *Id.* at 12–13 (citing Ex. 2023 ¶¶ 58, 62). Relying on Dr. Howe, Patent Owner concludes a person of ordinary skill in the art would not have had reason to add the features recited in added limitations of claims 1 and 40—i.e., the freehand device without mechanical support—with the resulting loss in accuracy to the system disclosed in Mushabac as modified by Klimek. *Id.* at 18–19 (citing Ex. 2023 ¶¶ 112–113).

In opposing Patent Owner’s Motion, Petitioner contends substitute claims 1 and 40 are unpatentable over the combination of Mushabac, Klimek, and Melkent,⁷ which Petitioner has introduced to the proceeding in light of the proposed amendment. Opp. Mot. 2, 10. Petitioner also relies on the testimony of its declarant, Dr. Davies for support. *See* Ex. 1012 ¶¶ 39–47.

⁷ PCT Application Pub. No. WO 00/64367, published November 2, 2000 (Ex. 1014) (“Melkent”).

1. Melkent (Ex. 1014)

Melkent discloses an “image guided surgical system for displaying anatomical landmarks.” Ex. 1014, Abstract. Figure 1 of Melkent is reproduced below:

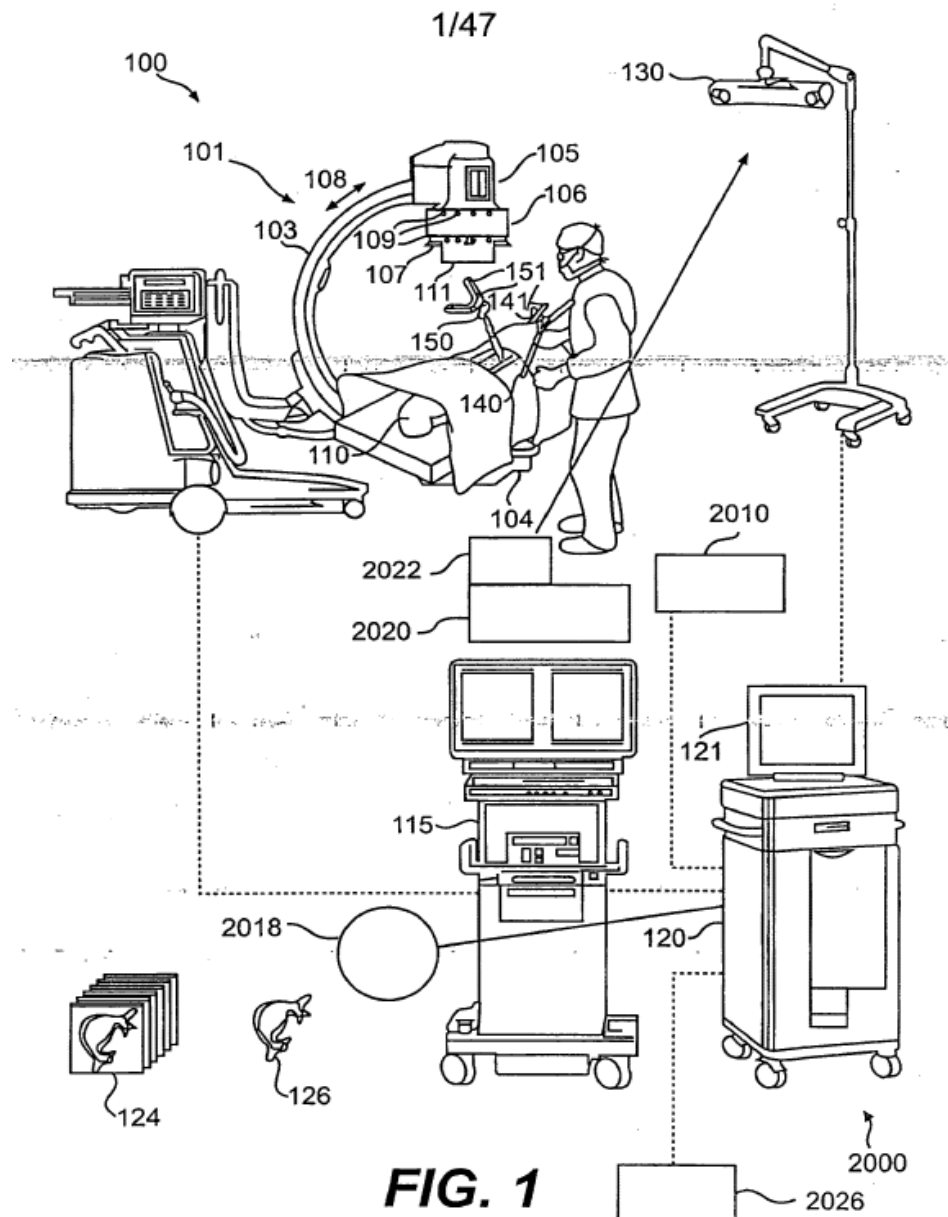


Figure 1 depicts the image guided surgery system of Melkent. *Id.* at 5:6–7. Surgical system 100 of Melkent includes surgical instrument 140 (e.g., a drill) having infrared emitters or reflectors 141 on its handle. *Id.* at 12:2–4.

Tracking sensor 130 and computer 120 are able to locate the position of instrument 140 in three-dimensional space. *Id.* at 12:4–8.

In general, system 100 can assist physicians performing surgery by displaying images of patient 110 and display 121. *Id.* at 13:7–8. In addition, representations of instrument 140 are overlaid on images of patient 110 based on the position of the instrument as determined by tracking sensor 130. *Id.* at 13:8–12. In this way, the physician is able to see the location of the instrument relative to the patient’s anatomy. *Id.*

2. Analysis

Petitioner contends Melkent teaches freehand surgical systems without mechanical support. Opp. Mot. 11–12 (citing, e.g., Ex. 1014, Fig. 1, 15:5–8; Ex. 1012 ¶ 40). For example, Petitioner contends surgical instrument 140 is described as a drill, and is depicted in Figure 1 as being held in the surgeon’s hand and without visible mechanical support. *Id.* at 12, 17 (citing Ex. 1014, Fig. 1, 12:2–4). Relying on Dr. Davies, Petitioner argues that in the system of Mushabac as modified to use Klimek’s markers, there is no longer a need for a mechanical arm, which can interfere with the surgeon’s freedom of movement. *Id.* at 14 (citing Ex. 1012 ¶ 44). Consequently, a person of ordinary skill would have been motivated to substitute the freehand surgical instrument of Melkent for the mechanical arm in Mushabac. *Id.* Moreover, Petitioner contends, a person of ordinary skill would have had a reasonable expectation of success in making such a substitution, given long-standing use of freehand tools in hard tissue surgeries. *Id.* at 15 (citing Ex. 1012 ¶ 46).

Patent Owner does not dispute that instrument 140 of Melkent describes a freehand device without support. See Reply Mot. 8 (“The

Melkent reference describes passive handheld control of a surgical instrument with a spatial location system.”). However, Patent Owner argues the addition of Melkent does not remedy the deficiencies of Mushabac and Klimek as, like Klimek, “Melkent lacks any way to control the device to only remove the precise amount of tissue that was planned,” such as by using an on/off control mechanism. *Id.* at 8–9 (citing Ex. 2022, 290). Patent Owner further contends Mushabac is not a “freehand” system “without mechanical support.” Consequently, Patent Owner argues, none of the references:

disclose these additional claim limitations in the context of a system whereby there are control commands to the effector to limit the removal of volume to a predetermined amount, the claimed invention is not rendered obvious by the prior art. *See Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 554 F.3d 1010, 1020 (Fed. Cir. 2009) (finding claims nonobvious as none of the references discloses a particular claim limitation).

Reply Mot. 9.

We are not persuaded by Patent Owner’s argument. “The test for obviousness is not . . . 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.” *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). Petitioner does not contend that any one of Mushabac, Klimek, and Melkent alone teach or suggest a freehand effector without mechanical support that is powered on or off for precise tissue removal, but rather that a person of ordinary skill in the art would have been motivated to modify Mushabac according to the teachings of Klimek, and Melkent to obtain such a freehand effector. Opp. Mot. 14–15. Thus, Petitioner relies on the combination.

Given the undisputed evidence that Melkent teaches a freehand effector without mechanical support, *Kinetic Concepts* is inapposite because there is no claim limitation allegedly not taught or suggested by at least one of the proposed references. See 554 F.3d at 1019–20 (finding substantial evidence supports a non-obviousness verdict where there was testimony that *none* of the references taught a recited limitation).

Patent Owner also contends Petitioner fails to provide sufficient motivation to combine the “three disparate references.” Reply Mot. 9. In particular, Patent Owner argues:

Despite Petitioner’s claim that the functions of the pantographic arm could be obviated by the trackers disclosed in Melkent and Klimek, the pantographic system does more than just “facilitate[] tracking of the surgeon’s movements.” (Opp. at 14.) Both parties’ experts agree that Mushabac’s pantographic arm restricts the free movement of the attached effector. (Ex. 2023 ¶¶ 69-79; Ex. 2028 at 22:16-24, 25:15-25.) Dr. Davies admits this “could result in better accuracy” as “you would not move outside of a particular desired range.” (Ex. 2028 at 27:5-7.) It was known at the time that freehand devices were less accurate than devices attached to arms or other mechanical structures for this very reason. (Ex. 2022 at 290-91; Ex. 2023 ¶ 112.) The accuracy advantage would be lost by the removal of the Mushabac arm, and a person of ordinary skill would not be motivated to remove it.

Reply Mot. 10–11.

We do not find this argument persuasive of nonobviousness. As an initial matter, as Petitioner’s declarant Dr. Davies points out, and Patent Owner’s declarant Dr. Howe concedes, neither of claims 1 and 40 specifies an accuracy level. See Ex. 1012 ¶ 7; Ex. 1013, 126:19–127:5. Therefore, the issue before us is whether—even accepting Patent Owner’s position that

freehand tools are less accurate than the supported tools, because of movement restrictions—a person of ordinary skill would have found the combination of a freehand tool as disclosed in Melkent to be desirable when substituted for the arm supported structure in Mushabac. *See Fulton*, 391 F.3d at 1200 (Fed. Cir. 2004).

We agree such a combination would be desirable. We give substantial weight to the testimony of Dr. Davies who testified that the freehand instrument, as disclosed in Melkent, was sufficiently accurate to perform spinal surgery. *See Ex. 1012 ¶ 42* (citing *Ex. 1014*, 7:10–12). Thus, while some loss of accuracy may result from going to an unsupported, freehand instrument, there is insufficient evidence to persuade us that a person of ordinary skill would find the combination of Melkent and Mushabac to be undesirable when viewed against the advantages of removing a source of interference with the surgeon’s freedom of movement resulting from Mushabac’s arm structure. *Id.* at ¶ 44.

Patent Owner further argues that the arm structure in Mushabac is integral to Mushabac’s principle of operation and its removal would be far from simple or routine. *Reply Mot. 11* (citing *Ex. 2023 ¶ 90*). According to Patent Owner:

In addition to the pantographic features that allow for accurate replication of probe motion and end effector control, the Mushabac arm also synergistically performs multiple other functions such as encoder based tracking (using trackers mounted on the arm itself) and tool support. Removal of the arm would result in a loss of this synergy, which could limit Mushabac’s utility and further reduce its accuracy.

Reply Mot. 11 (internal citations removed).

However, a reference is prior art for all that it teaches and not simply for the invention it is trying to protect. *EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985). As discussed above, Petitioner relies on Mushabac for its teaching of removing and processing material (e.g., in a tooth), manually guiding an effector (e.g., a drill), and supplying power control commands to the effector as a function of the predetermined work volume (i.e., in the regions selected for removal). *See also* Opp. Mot. 16–19. Patent Owner and Dr. Howe have not explained sufficiently why the pantographic features or the optional encoder-based tracking of the arm are necessary in the proposed combination, given the replacement of the pantograph and other tracking features with the optical sensor arrangement as taught by Klimek, as discussed above, or the infrared sensors taught by Melkent. *See* Ex. 1012 ¶¶ 46–47.

In view of the foregoing, Patent Owner has not met its burden of showing substitute claims 1 and 40 to be patentable over the combination of Mushabac, Klimek, and Melkent. Accordingly, it is unnecessary to address the parties contentions regarding the substitute claims compliance with the provisions of 35 U.S.C. § 112, first paragraph.

IV. CONCLUSION

For the foregoing reasons, we determine the following:

- (1) Petitioner has shown by a preponderance of the evidence that claims 1, 3, 5–7, 9, 10, 16, 17, 21, 26, 40, 45, 56, and 57 of the '417 patent are unpatentable over the combination of Mushabac and Klimek; and
- (2) Patent Owner has not shown that its proposed substitute claims 1 and 40 are patentable over the prior art.

IV. ORDER

In consideration of the foregoing, it is

ORDERED that claims 1, 3, 5–7, 9, 10, 16, 17, 21, 26, 40, 45, 56, and 57 of the '417 patent have been shown to be *unpatentable*;

FURTHER ORDERED that Patent Owner's Motion to Amend is *denied*; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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