

IPR2023-00625

Patent No. 11,020,129

Attorney Docket No. 013438.021-13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ORTHOCISION, INC.,
Petitioner,

v.

PTL OPCO, LLC
Patent Owner.

Patent No. 11,020,129
Title: DRILL-LESS METHOD OF FUSING A SACROILIAC JOINT

Inter Partes Review No. IPR2023-00625

PATENT OWNER'S RESPONSE

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PATENT OWNER'S UPDATED EXHIBIT LIST

Exhibit	Description
2001	Declaration of Christopher J. Bovinet, D.O.
2002	C.V. of Christopher J. Bovinet, D.O.
2003	Intervertebral disk: Medline Plus Medical Encyclopedia
2004	Deposition Transcript of Mr. Troy Drewry
2005	Second Declaration of Christopher J. Bovinet, D.O.

I. INTRODUCTION

PTL Opco LLC (“Patent Owner”) hereby respectfully submits this Patent Owner’s Response to the Petition for *inter partes* review (Paper 3, the “Petition”) of claims 1, 2, 9 and 10 of the U.S. Patent No. 11,020,129 (“the ‘129 Patent”) and the Board’s decision granting institution thereof (Paper 10, “Institution Decision”).

The Petition presents five obviousness grounds against each of the challenged claims. As the analysis provided below establishes, Petitioner has not met its burden of proving unpatentability of any of the challenged claims under any of the asserted grounds.

First, for the claim limitation “a releasing means,” all five grounds rely solely on Sharma. Pet. 23. Under the proper—and legally required—construction of this means-plus-function limitation, Sharma does not teach or suggest the structure recited in the ‘129 Patent corresponding to the releasing function. This deficiency in the Petition is case-dispositive with respect to all grounds.

Second, for the limitations “an open tip” and “a cutting edge disposed at a leading edge of the open tip, the cutting edge configured to cut bone tissue in the sacroiliac joint,” the Petition relies on the following three references: Donner (Ground 1), Otte (Ground 1), and Martz (Grounds 2-5). With respect to Martz, the experts for both parties agree that the distal cutting edges in the sole embodiment

cited in Petition are configured to cut soft tissue—not bone tissue. This deficiency precludes unpatentability under Grounds 2-5.

Next, with respect to Donner, the proper claim construction of the term “open tip”—which is supported by the testimony of experts for both parties—requires that abrading head must be open to an interior void disposed behind the abrading surfaces, such that the dislodged tissue can enter therein. However, the sole embodiment of Donner’s abrading tool cited in the Petition has a dual-keel abrading head with a closed tip and no void behind the abrading surfaces. Indeed, the experts for both parties agree that under the intended method of use, Donner’s dual-keel abrading head cited in Ground 1 does not have an opening through which the dislodged tissue can enter. Thus, the prior art combination in Ground 1 that relies on Donner’s dual-keel abrading head fails to establish a *prima facie* case of obviousness.

With respect to the prior art combination in Ground 1 that relies on Otte’s box chisel, the Petition failed to articulate *any* motivation for combining Otte’s box chisel with Compton and Donner—instead, the Petition merely asserts that “[s]pinal fusion surgeries are closely related to SI Joint fusion surgeries,” which is insufficient, as a matter of law, to establish unpatentability of a patent claim. Furthermore, the Petition does not even contemplate combining Otte’s box chisel with a slide hammer (whether Sharma’s or Donner’s) and therefore fails to establish

a *prima facie* case of obviousness with respect to the limitation “the abrading device comprising: . . . an abrading head . . . *and* a slide hammer assembly.” Thus, the obviousness challenge in Ground 1 that relies on Otte’s box chisel fails.

Third, all grounds asserted in the Petition merely map the claimed structural components of the abrading device to an assortment of surgical devices without providing any rationale for combining these discrete structural components into a single abrading device, as required in claim 1. In *KSR*, the Supreme Court expressly held that this type of obviousness argument is legally improper to prove unpatentability.

Finally, Mr. Drewry’s declaration, on which the Board relied in its Institution Decision, should be given little to no weight in view of his deposition testimony, and because it merely repeats, verbatim, the conclusory statements made in the Petition, without providing any additional supporting rationale or evidence. More importantly, Mr. Drewry’s statements regarding Donner’s dual-keel abrading head and Sharma’s slide hammer assembly are based on a fundamental mischaracterization of how these cited prior art devices are intended to operate. Furthermore, during his deposition, Mr. Drewry doubled down on factually erroneous statements in his declaration—including a factually erroneous statement about basic human anatomy—which further underscores that his testimony is that of a pre-programmed automaton rather than an objective and truthful opinion of a

subject-matter expert. Without support of credible expert testimony, all grounds in the Petition are simply conclusory attorney arguments.

II. CLAIM CONSTRUCTION

1. “*open tip*”

In the Preliminary Response (Paper 7), Patent Owner proposed that the term “open tip” should be construed as “a distal end of the abrading head whose leading edge encloses an opening thereinto.” Prelim. Resp. 10. In the Institution Decision, the Board found that this construction “appears to read too much structure from the written description into the claim language.” Inst. Dec. 18. Instead of adopting either party’s proposed construction, the Board preliminarily construed the claim term “open tip” to mean that “the tip of the abrading head is open to an interior void of the abrading head.” *Id.* at 19.

At the Final Written Decision, the Board should supplement its construction of this limitation to specify that the phrase “the abrading head is *open* to an interior void” means that the abrading head has an “opening” through which the dislodged tissue can enter the interior void. Ex. 2005 at ¶28. Indeed, as the Board recognized in the Institution Decision, “some sort of ‘opening’ seems *necessary* for an ‘open tip.’” *Prelim. Resp.* at 18 (emphasis added). Further, the Board’s preliminary construction should be supplemented to specify that the phrase “*interior* void” means that the void is located on the *interior* of the abrading head—i.e., behind the

exterior abrading surfaces (or between the interior surfaces of the first pair of the opposing sides). Ex. 2005 at ¶27. As explained below, these clarifications are supported by the specification of the ‘129 Patent and the testimony of both parties’ experts.

a. Support for the proposed construction in the ‘129 Patent

With respect to the clarification proposed above pertaining to the interior void having an opening through which the dislodged tissue can enter therein, the written description of the ‘129 Patent states that “[t]he open tip 34 comprises a cutting edge 36” and further explains that “as the cutting edge 36 cuts bone tissue inside the SI Joint 3, the dislodged bone tissue *falls into the void* and may exit the abrading head 32 via the openings in the lateral sides 35.” Ex. 1001 at 6:31-38 (emphasis added). This description indicates that the tip must have an opening that enables the dislodged tissue to enter therein. Ex. 2005 at ¶28.

With respect to the second clarification pertaining to the “interior void” being disposed on the *interior* of the abrading head—i.e. behind the exterior abrading surfaces (or between the interior surfaces of the first pair of the opposing sides)—the ‘129 Patent discloses that “[t]he abrading surfaces 33 and lateral sides 35 form a box-like abrading head 32 having *a void therein*.” *Id.* at 6:31-33 (emphasis added). This disclosure establishes that the interior void is defined within the interior space behind the exterior abrading surfaces. Ex. 2005 at ¶29. These necessary aspects—

i.e., the “opening” and “interior void”—are clearly depicted in Figure 14 of the ‘129 Patent, which is reproduced and annotated below.

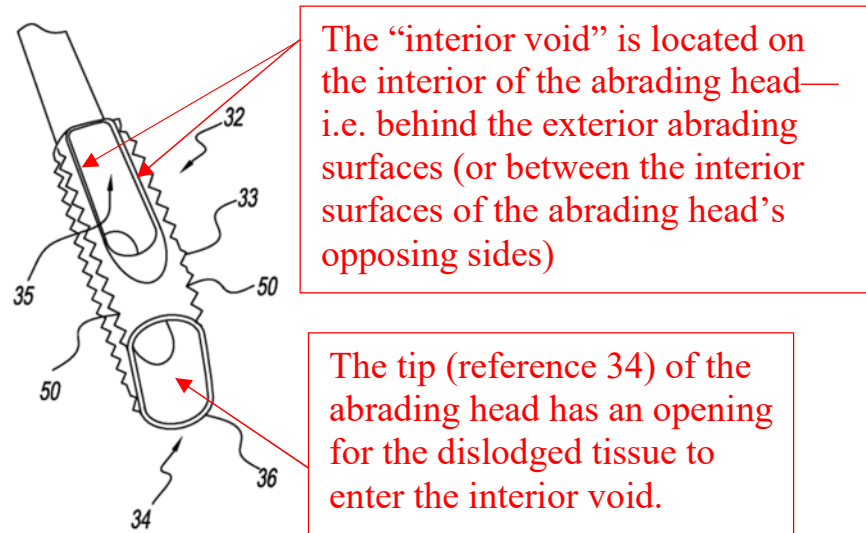


FIG. 14

b. Mr. Drewry’s testimony supports the proposed construction

During his deposition, Petitioner’s expert Mr. Drewry testified that “the distinction between an abrading head with an open tip and the one that does not have an open tip” is the presence of a void behind the cutting surface through which tissue dislodged during the cutting procedure can be removed:

[T]here’s broaches and reamers and abrading tools out there that are *closed*, and they’re just used . . . to scrape the bone off the -- the surfaces. Then there’s other applications like in the spine and SI joints where you want a void or you want space during the cutting procedure so that tissue and -- and blood and bone and everything can be evacuated out of the void while you’re doing this procedure. So, you

know, there's a lot of tools out there that provide that opening or void behind the cutting edges that allow for that tissue removal.

...

Again, the ones that are not open would typically be solid, so there wouldn't be -- there would be a tip on it. There wouldn't be a void behind the cutting surface. There would be no opening in the [instrument] to allow for this tissue removal.

Ex. 2004 at 29:9 – 30:13 (emphasis added); *see also id.* at 31:12-16 (“If I looked at an open tipped abrading instrument, . . . I’d look to see if there was a void or a space or some lack of material *behind* the cutting edges that allow for, again, *tissue removal or bone removal.*”) (emphasis added); *id.* at 35:17-21 (“[I]f you look at the end of the instrument, you can tell that it’s open because there’s a void *behind* those tapered edges that allows *for tissue removal* and kind of passage of that material during the abrading and cutting process.”) (emphasis added); *id.* at 36:19-37 (testifying that a “solid cutting tool” (i.e. without an open tip) would have “no opening or void *behind* the cutting edge or abrading edge that *allows for this tissue removal*”) (emphasis added); *id.* at 38:9-11 (testifying that a “void” is “the open space *behind* the cutting edges that *allows for bone and tissue removal* during the abrading and cutting process.”) (emphasis added).

Clearly, Mr. Drewry’s deposition testimony underscores that the location of the void being behind the abrading surfaces and the capability of the dislodged tissue to pass through that void are necessary characteristics of an “open tip.”

c. Dr. Bovinet’s declaration supports the proposed construction

With respect to the “open tip” limitation, Dr. Bovinet’s declaration submitted with this Patent Owner’s Response explains the following:

The term an “open tip” means that the distal end of the abrading head contains an opening through which the tissue debris produced by the cutting procedure can enter inside the abrading head. Conversely, if the distal end of the abrading head does not have opening providing a passage for such debris, then a POSA would not describe that abrading head as having an “open tip.”

Ex. 2004 at ¶27. Furthermore, Dr. Bovinet explained that “[i]n an abrading head having ‘a first pair of opposing sides,’ the interior void is the space between the interior surfaces of these opposing sides.” *Id.* at ¶29. Additionally, Dr. Bovinet clarified that because the abrading surfaces are located on the exterior of the first pair of opposing sides, “the interior void of the abrading head is located behind these abrading surfaces.” *Id.*

Based on the foregoing, the Board should supplement its preliminary construction of the term “open tip” with the following clarifications: *the tip of the abrading head is open to an interior void disposed behind the abrading surfaces¹ of*

¹ Alternatively, the void can be described as “the space between the interior surfaces of the first pair of the opposing sides.” Ex. 2005 at ¶31.

the abrading head and is configured to enable the dislodged tissue to enter into the interior void. Ex. 2005 at ¶32.

2. “releasing means”

a. The Board’s preliminary construction of the term “releasing means,” in light of the Boards’ preliminary construction of the term “base,” improperly disassociates the structure of this mean-plus-function limitation from the sole embodiment disclosed in the ‘129 Patent

Independent claim 1 of the ‘129 Patent recites the following means-plus-function limitation: “a releasing means for transitioning the slide hammer assembly between the locked position and the released position.” Ex. 1001 at 13:15-17. In the Institution Decision, the Board quoted—and seemingly agreed with—the explanation provided in the Preliminary Response that “*the interface between the base and the distal end of the hammer sleeve is the only location specified in the ‘129 Patent for disposing the releasing means.*” Inst. Dec. 22-23 (quoting Prelim. Resp. 12-16) (emphasis added). Indeed, in the two sentences immediately following this quotation, the Board “recongize[d] that every embodiment described in the ‘129 patent describes that the ‘releasing means’ connects a hammer sleeve to a base” and determined that under the case law set forth in *Nomos*, “such a structural configuration must be part of the corresponding structure in interpreting this means-plus-function claim element.” *Id.* at 23. Nevertheless, the Board’s preliminary construction of the limitation “releasing means”—in view of the Board’s construction of the term “base”—dissociated the recited structures from their sole

location disclosed in the ‘129 Patent—which is at the interface between the base of the slide hammer assembly and the distal end of the hammer sleeve. *Id.* at 24 (emphasis added).

Next, with respect to the construction of the term “base,” while the Board correctly recognized that “[t]he ‘129 Patent does illustrate an embodiment (at Figures 16, 17, and 21) where the base (reference 51) is part of or directly connected to the proximal end of the abrading device (reference 30),” the Board “discern[ed] no reason to limit the structure to one preferred embodiment, such as this embodiment” because “the written description does not express that this is a *required* structural configuration, but rather calls it ‘one embodiment.’” *Id.* (emphasis added). Ultimately, the Board quoted a passage from the ‘129 Patent describing that the hammer sleeve engages and disengages the base, and relying solely on this passage—which the Board itself categorized as “the *broadest* description of the ‘base’”—the Board construed the term “base” as “a structure to which the sliding hammer sleeve is engaged when locked to prevent its movement.” *Id.* at 23.

The Board’s preliminary construction of the term “base” is improper for multiple reasons. *First*, this construction fails to account for a fundamental function of the “base 51,” which is connecting the slide hammer assembly to the abrading device. Ex. 2005 at ¶36. *Second*, this construction improperly dissociates the base—which is a part of the structure that performs the “releasing” function—from its sole

location disclosed in the ‘129 Patent, which is between the proximal end of the abrading device and the distal end of the slide hammer assembly shaft. *Id.* Third, the Board’s construction of the term “base” renders the phrase “connecting the sleeve to the base” circular. The composite resulting construction speaks for itself with respect to this circularity: “*connecting the sleeve to a structure to which the sliding hammer sleeve is engaged . . .*” *Id.* Fourth, claim 1 requires that the hammer sleeve must have “a locked position,” which inherently requires that the hammer sleeve must be locked to *some* structure. Construing the term “base” as “a structure to which the sliding hammer sleeve is engaged when locked to prevent its movement” is merely redundant of this inherent requirement. *Id.*

As explained in more detail below, under the Federal Circuit case law governing construction of the means-plus-function limitations, the Board should modify its preliminary construction of the limitation “releasing means” to specify that the “releasing” structures enumerated in the ‘129 must be disposed at *the interface of the base and the distal end of the hammer sleeve* because this is the *only* location specified in the ‘129 Patent for these structures. Furthermore, if the Board still finds it necessary to expressly construe the term “base,” the construction of this term should not disassociate the “base” from its core function of connecting the slide hammer assembly to the abrading device and should not dissociate this structure from its only location disclosed in the ‘129 Patent, which is between the proximal

end of the abrading device and the distal end of the slide hammer shaft. Ex. 1001 at Figs. 16, 17, and 21.

b. Overview of the governing case law for construction of a means-plus-function limitation

i. Micro Chemical, Inc. v. Great Plains Chemical Co.

As an initial matter, in its construction analysis, the Board cited *Micro Chemical, Inc. v. Great Plains Chemical Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999) for a proposition that “[i]n conducting this analysis, [the Board] may not incorporate structure from the written description beyond that which is necessary to perform the claimed function.” Inst. Dec. 20. However, the facts in the *Micro Chemical* case are distinguishable from the present IPR. In *Micro Chemical*, the Federal Circuit reiterated the legal principle that “[w]hen *multiple embodiments* in the specification correspond to the claimed function, proper application of § 112, ¶6 generally reads the claim element to embrace each of those embodiments.” 194 F.3d at 1258 (citing *Serrano v. Telular Corp.*, 111 F.3d 1578, 1583 (Fed. Cir. 1997)) (emphasis added). Because the patent at issue in *Micro Chemical* “disclose[d] in detail *several alternative embodiments* of the invention,” the Federal Circuit held that “the district court incorrectly limited [the means-plus-function limitation] to the specific structures of the preferred embodiment,” excluding other embodiments. *Id.* (emphasis added).

Unlike the multiple-embodiment patent addressed in *Micro Chemical*, the ‘129 Patent discloses a *single* embodiment of the “releasing means” in which the sole location for the recited structures is at the interface between the base and the distal end of the hammer sleeve. Ex. 1001 at Figs. 16-18, and 21. Likewise, with respect to the “base,” the ‘129 Patent discloses a single embodiment, in which in addition to releasably connecting to a hammer sleeve, the base connects the distal end of the slide hammer’s shaft to the proximal end of the abrading device. *Id.* at Figs. 16, 17, and 21. Because the ‘129 Patent does not disclose any alternative embodiments of these structural configurations, the ‘129 Patent is clearly distinguishable from the multi-embodiment patent construed in *Micro Chemical*.

ii. Nomos Corp. v. Brainlab USA, Inc.

In *Nomos*, the Federal Circuit addressed the construction analysis of a means-plus-function limitation in a scenario in which the patent at issue disclosed a single embodiment. 357 F.3d 1364, 1368 (Fed. Cir. 2004). The specific issue before the Federal Circuit in *Nomos* was whether the means-plus-function limitation “a means for generating at least one ultrasound image” should be construed to require only “an ultrasound probe” or should also require “a fixation device that secures the probe to the treatment table.” *Id.* Notably, the patent specification did not *require* “a fixation device that secures the probe to the treatment table,” but rather provided the following description of this structural component and its designated location using

permissive terminology: “the means for generating the ultrasound image *may be* an ultrasound probe, *including* a means for mounting the ultrasound probe to a radiation therapy device.” *Id.* (quoting U.S. Pat. No. 5,411,026) (emphasis in original).

Despite the non-limiting terminology with which this structure was described in the specification, the Federal Circuit held that because this was “the *only* embodiment of the invention described in the ... patent,” “[t]his language indicates that the invention envisioned and claimed by the applicant included a fixation device that secures the probe *to the treatment table*.” *Id.* (emphasis added). For that reason, the Federal Circuit held that the construction of corresponding means-plus-function limitation must be such that “the corresponding structure is *limited* to that embodiment” and therefore must include the “fixation device that secures the probe *to the treatment table*.” *Id.* (affirming the district court’s construction) (emphasis added).

iii. Grace Instrument Indus., LLC v. Chandler Instruments Co.

Grace Instrument is another Federal Circuit decision that addresses a scenario in which a patent discloses a single location for a means-plus-function structure. 57 F.4th 1001 (Fed. Cir. 2023). There, the Federal Circuit held that, in such scenario, it is improper to “dissociate the disclosed structure from the location of the disclosed structure.” *Id.* at 1015. Notably, the patent at issue in *Grace Instrument* also used permissive language “could be,” “such as,” “etc.” to describe the location of the

relevant structure: “the rotor ‘*could be* driven to rotate with any means *such as* directly driven at the bottom of the cell body with dynamic seal, *etc.*’” *Id.* (quoting U.S. Pat. No. 7,412,877) (emphasis added). Nevertheless, the Federal Circuit held that because “the bottom of the cell body” is the *only* location of the means-plus-function structure disclosed in the patent, the construction of the means-plus-function structure must be limited to that location. *Id.* (affirming the district court’s construction).

c. Proper construction of the limitation “releasing means”

Under the case law set forth in *Nomos* and *Grace Instrument*, the structural component of the mean-plus-function limitation the “releasing means” must be limited to the sole embodiment disclosed in the ‘129 Patent. Figures 16-18 and 21 depict that the structures for “transitioning the slide hammer assembly between the locked position and the released position”—in this example, threads—are disposed at the interface of the base and the distal end of the sleeve, whereby these structures releasably connect the distal end of the hammer sleeve to the base. Ex. 1001 at FIG. 16, 17, and 21; *see also* Ex. 2005 at ¶34. The ‘129 Patent does not disclose any other embodiments or any alternative locations for these structures. Ex. 2005 at ¶34.

In the sole embodiment disclosed in the '129 Patent, the structures for “transitioning the slide hammer assembly between the locked position and the released position” are disposed at the interface between the base and the distal end of the hammer sleeve and releasably connect the distal end of the hammer sleeve to the base.

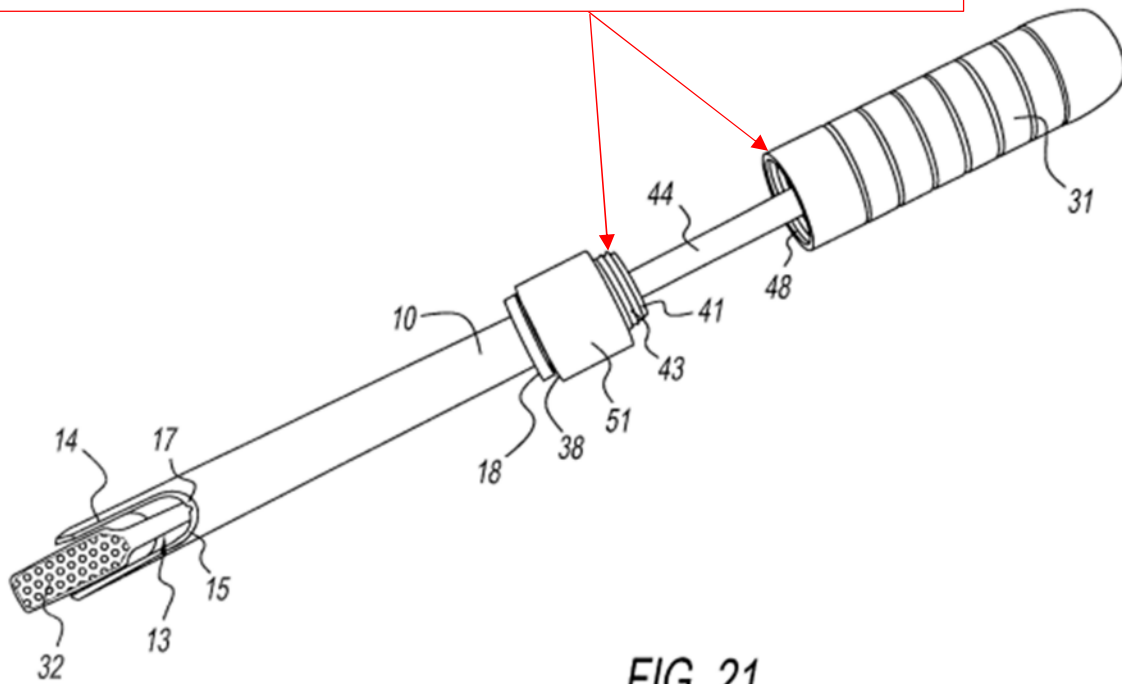
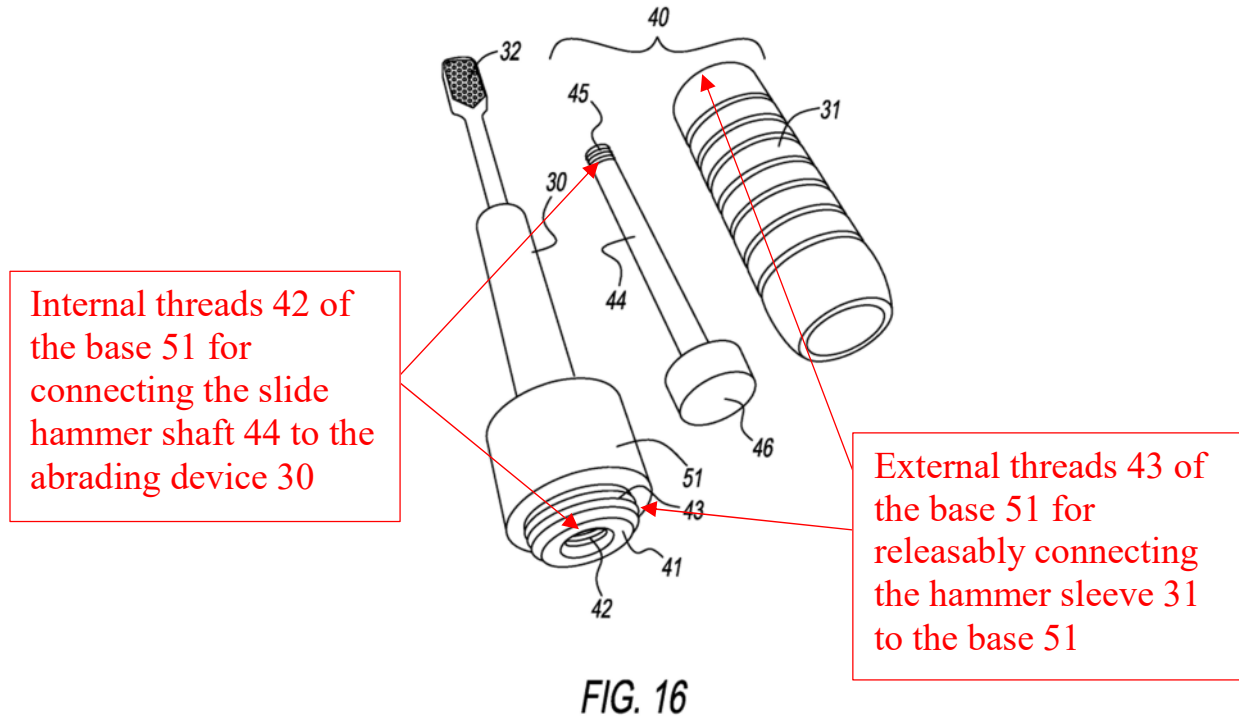


FIG. 21

For the reasons set forth above, the following proposed construction is proper under the governing principles set forth in *Nomos* and *Grace Instrument*: “a mating threaded connection, a quick disconnect attachment, a depressible tab, a latch, a clasp, a clip, or a clamp, disposed at an interface between a distal end of a hammer sleeve and a base for releasably connecting the distal end of the hammer sleeve to the base, and equivalent structures.” Ex. 2005 at ¶34.

d. Proper construction of the term “base”

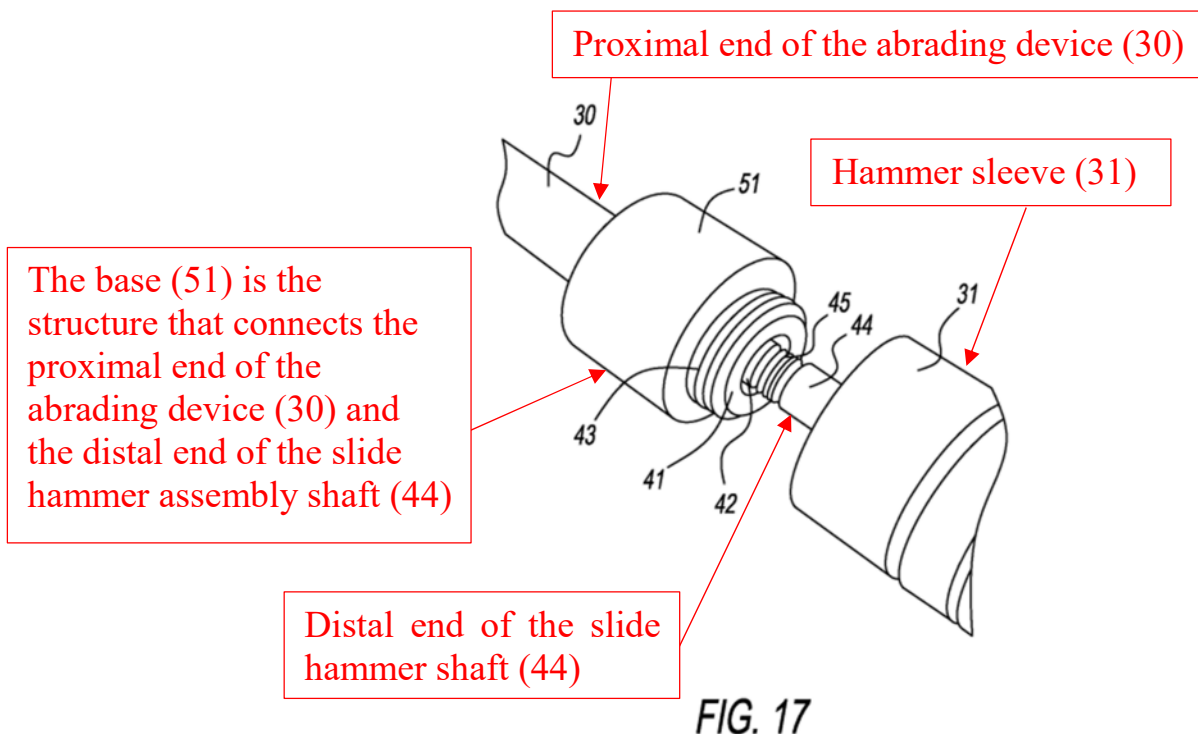
If the Board chooses to expressly construe the term “base”—which is not necessary to resolve the controversy in this case under the proper construction of the “releasing means” provided above—the Board must construe this term “in view of the specification” of the ‘129 Patent, including its drawings. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005). Figures 16 and 17 of the ‘129 Patent clearly depict that the “base 51” has two sets of threads—“internal threads 42” and “external threads 43.” Ex. 2005 at ¶35.



These two sets of threads correspond to two discrete functions that the base is configured to perform: (1) “the internal threads 43” connect the “slide hammer shaft 44” to the “abrading device 30,” and (2) “the external threads 43” releasably connect the “hammer sleeve 31” to the “base 51.” Ex. 1001 at 7:25-36; *see also* Ex. 2005 at ¶35. The Board’s preliminary construction of the term “base” only accounted for the sleeve-locking function, while wholly disassociating the base from its fundamental role as the structure that connects the slide hammer assembly to the abrading device. Such disassociation is legally improper not only under *Nomos* and *Grace Instrument*, but also under *Phillips*.

Further, as clear from Figures 17 and 21, the “base 51” is located between the proximal end of the “abrading device 30” and the distal end of the “slide hammer

shaft 44,” which location is *necessary* for the “base 51” to connect the “slide hammer shaft 44” to the “abrading device 30.”



Because the embodiment depicted in Figures 17-18 and 21 is the *only* embodiment of the “releasing means” disclosed in the ‘129 Patent, the governing legal principles set forth in *Nomos* and *Grace Instrument* require that the construction of the term “base” must be limited to the structural configuration of this embodiment. Thus, within the context of the phrase “for releasably connecting the distal end of the hammer sleeve to the base,”² the term “base” should be construed

² The construction of the limitation “releasing means” set forth in this Patent Owner’s response includes the phrase “for releasably connecting the distal end of

as “a structure that connects a proximal end of an abrading device to a distal end of a shaft of the slide hammer assembly.” Ex. 2005 at ¶37.

III. THE PETITION FAILED TO SET FORTH A *PRIMA FACIE* CASE OF OBVIOUSNESS WITH RESPECT TO ANY OF THE CHALLENGED CLAIMS

A. Grounds 1-5 fail because Sharma does not teach or suggest the limitation “releasing means”

Claim 1 of the ‘129 Patent recites the limitation “a releasing means.” Sharma is the sole reference cited in the Petition for this limitation. Pet. 23. Because Sharma does not teach or suggest the structure disclosed in the ‘129 Patent corresponding to the claimed function, the Petition fails to establish a *prima facie* case of obviousness with respect the challenged claims for the reasons explained in detail below.

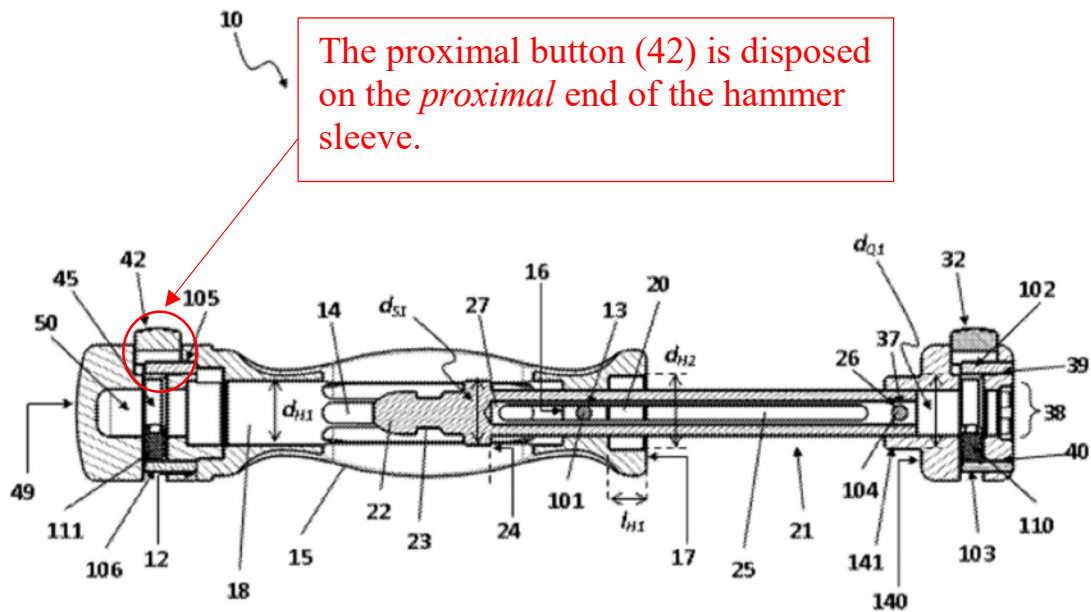
1. Under the legally required construction of the “releasing means,” Sharma does not teach or suggest this limitation

For the limitation “releasing means,” the Petition relies solely on Sharma’s “proximal button 42.” Pet. 48-50 (citing Ex. 1009 at 20:6-16; Fig. 4). With respect to the location of this proximal button, Sharma discloses that “the proximal button (42) [is] on the *proximal* impaction end (41).” Ex. 1009 at 20:13 (emphasis added).

the hammer sleeve to the base,” which accounts for the releasable base-to-sleeve connection. Accordingly, this structural configuration need not be included in the construction of the term “base” in this context.

Figure 4 of Sharma, which is reproduced and annotated below depicts that the “proximal button 42” is located on the proximal end of the hammer sleeve.

FIGURE 4



In the '129 Patent, the “releasing means” is disposed on the distal end of the hammer sleeve.

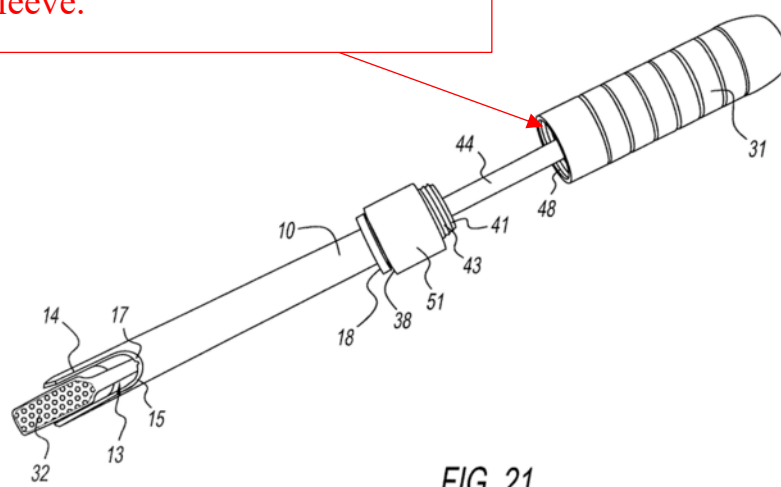


FIG. 21

Accordingly, Sharma's and the '129 Patent's locking structures are positioned in diametrically opposite locations on the hammer sleeve: Sharma's "proximal button 42" is disposed at the *proximal end* of the hammer sleeve, whereas in the '129 Patent, the connecting structure is disposed on the *distal end* of the hammer sleeve. Ex. 2005 at ¶39.

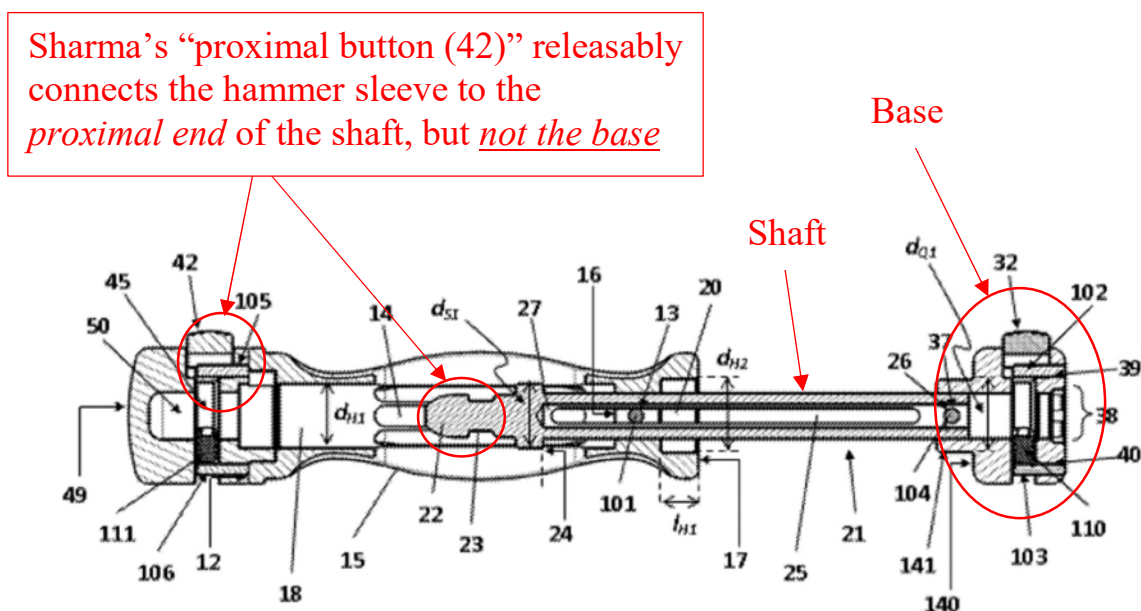
As established in Section II.2.c., *supra*, the limitation "releasing means" should be construed as "*a mating threaded connection, a quick disconnect attachment, a depressible tab, a latch, a clasp, a clip, or a clamp, disposed at an interface between a distal end of a hammer sleeve and a base . . .*" Section II.2.c., *supra* (emphasis added). Under this correct and legally required construction, Sharma does not teach or suggest the "releasing means" limitation because the "proximal button 42" is located at the proximal—rather than the distal—end of the hammer sleeve. Accordingly, Sharma's "proximal button 42" does not read on the "releasing means" limitation of claim 1. This deficiency of Sharma with respect to the "releasing means" limitation is case-dispositive and dooms all grounds asserted in the Petition.

2. Under the proper construction of the term "base," Sharma does not teach or suggest the limitation "releasing means"

In the Institution Decision, the Board found that the structural configuration of releasably connecting a hammer sleeve to a base "must be part of the

corresponding structure in interpreting [the limitation “releasing means”].” Inst. Dec. 23. Section II.2.d., *supra*, established that the term “base,” within the context of the phrase “releasably connecting a hammer sleeve to a base,” should be construed as “a structure that connects a proximal end of an abrading device to a distal end of a shaft of the slide hammer assembly.” In Sharma, the only structure that satisfies this construction is the “distal quick connect mechanism (31).” Ex. 1009 at Fig. 1; Ex. 2005 at ¶40. However, unlike the ‘129 Patent’s “releasing means,” Sharma’s “proximal button (42)” is configured to releasably connect the hammer sleeve to the “proximal end (29)” of the “central shaft (21)” rather than to the “distal quick connect mechanism (31),” which is the “base” of the slide hammer assembly. Ex. 1009 at Fig. 4, 14:19-21 (“The neck region (23) snaps in the proximal button hole (45) . . .”); *see also* Ex. 2005 at ¶40.

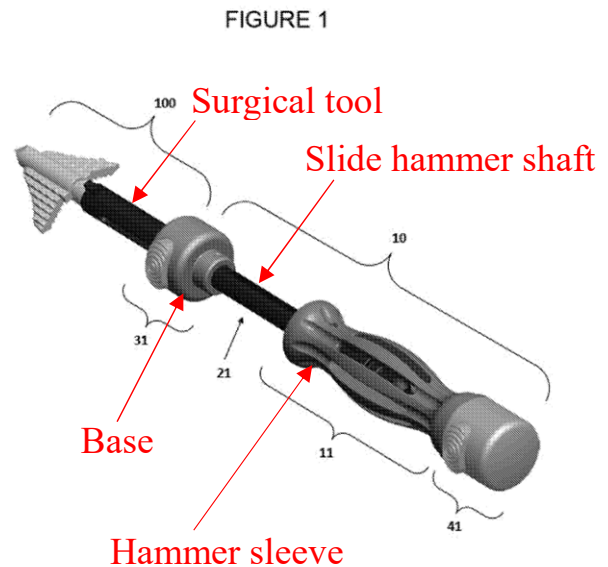
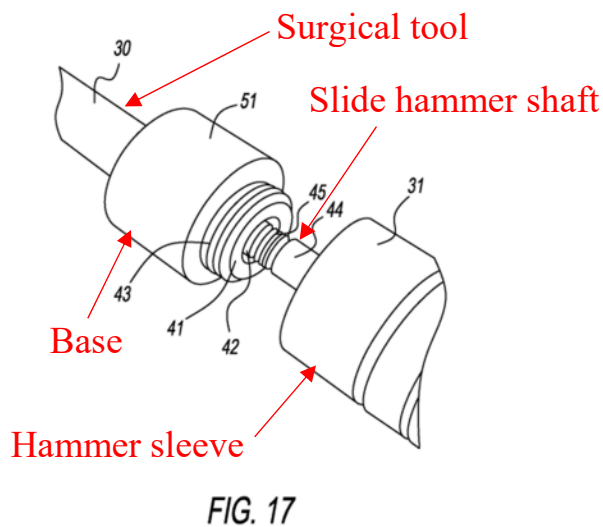
FIGURE 4



Moreover, Sharma provides the following description of how the hammer sleeve lock is configured to operate: “the central shaft is pushed into the integrated hollow handle till *the tip at the proximal end of the central shaft* clicks into the proximal impaction end locking it into place.” *Id.* at 20:6-9. Because Sharma’s “proximal button 42” locks the hammer sleeve to the proximal end of the central shaft rather than to the base (i.e., quick connect mechanism 31), Sharma does not teach a structure that “releasably connect[s] a hammer sleeve to a base.” Ex. 2005 at ¶40.

3. Setting aside the Board’s preliminary construction of the term “base,” “releasing means” claimed in ‘129 Patent is patentably distinct from Sharma’s locking mechanism

In the Institution Decision, the Board construed the structure corresponding to the “releasing means” limitation as “a mating threaded connection, a quick disconnect attachment, a depressible tab, a latch, a clasp, a clip, or a clamp, *releasably connecting a hammer sleeve to a base*, and equivalent structures.” Inst. Dec. 24 (emphasis added). Setting aside the Board’s construction of the term “base”—which is improper for a multitude of reasons discussed in Section II.2., *supra*—a POSA would understand that the slide hammer assemblies disclosed in Sharma and the ‘129 Patent have corresponding “base,” “hammer sleeve,” and “shaft” structures, which are readily apparent in the annotated side-by-side comparison provided below.



Notably, the record shows that the Board’s construction of the term “base” notwithstanding, neither expert identified the proximal end of Sharma’s central shaft as a “base.” Ex. 2004 at 62:18-19 (Mr. Drewry testifying that in “Figure 1 in Sharma, the base would be 41 and 31.”); Ex. 2005 at ¶40 (Dr. Bovinet testifying that “[i]n Sharma, the only structure that corresponds to the ‘129 Patent’s base is the “distal quick connect mechanism 31.”) (emphasis in original).

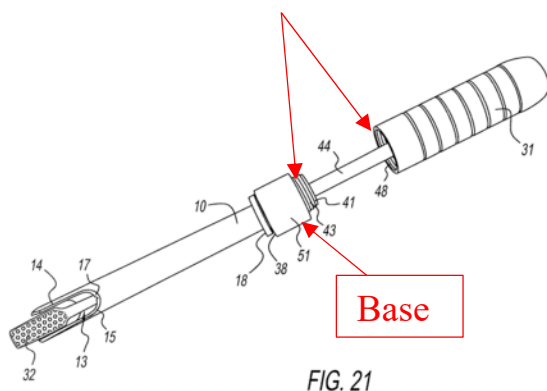
Furthermore, Dr. Bovinet explained that “although the ‘129 Patent and Sharma use different terminology, a POSA would understand that the structure that Sharma calls ‘distal quick connect mechanism (31)’ corresponds to the structure to which the ‘129 Patent refers to as the ‘base 51.” Ex. 2005 at ¶42. Dr. Bovinet expanded on this statement by explaining that both structures are analogous in their function of connecting the distal end of the slide hammer shaft to the proximal end of the surgical tool, and are analogously positioned between the proximal end of the

tool and the distal end of the slide hammer shaft.” *Id.* Finally, Dr. Bovinet opined that

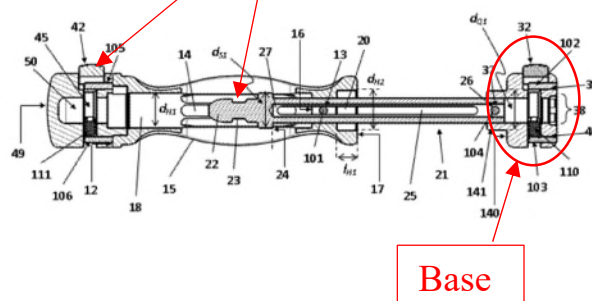
although the locking mechanisms disclosed in the ‘129 Patent and Sharma accomplish a same task of locking and releasing the hammer sleeve, their mechanisms for achieving this task have fundamentally different structures and operate under fundamentally different principles of operation. In the ‘129 Patent, the distal end of the hammer sleeve locks to the base (Ex. 1001, FIG. 21), whereas in Sharma, the proximal end of the hammer sleeve locks to the proximal end of the shaft (FIG. 4).

Id. at ¶43. The distinction explained by Dr. Bovinet is readily apparent in the annotated side-by-side comparison provided below:

The structure of the “releasing means” releasably connects hammer sleeve to the base



“Proximal button 42” releasably connects the hammer sleeve to the proximal end of the shaft.

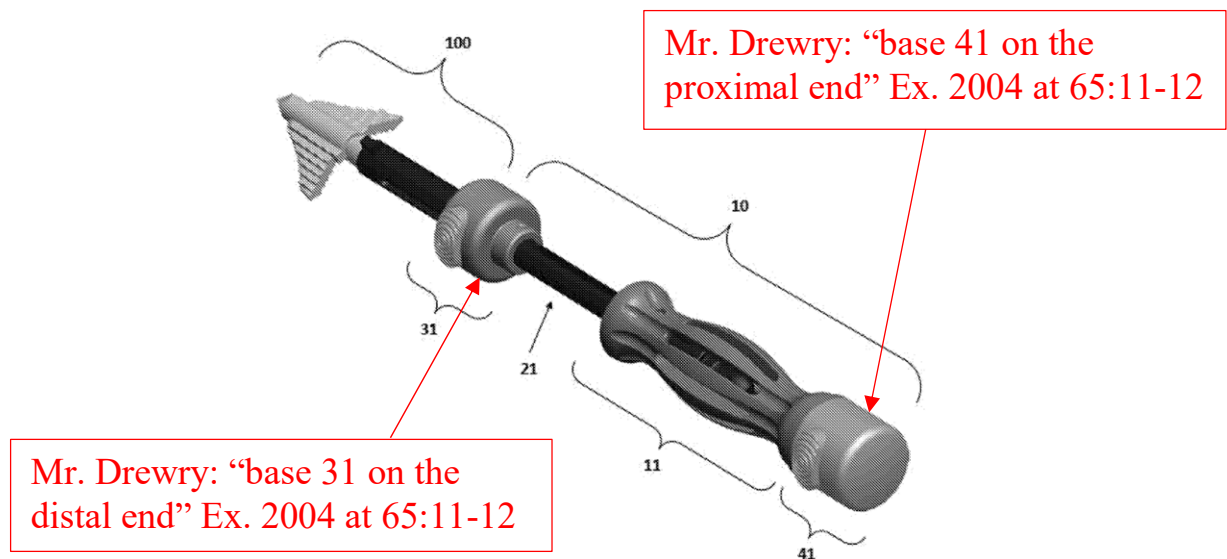


Accordingly, under the Board's preliminary construction of the limitation "releasing means" set forth in the Institution Decision (assuming the Board's preliminary construction of the term "base" is set aside), a POSA would understand that Sharma's "proximal button 42" does not releasably connect the hammer sleeve to a base of the slide hammer assembly. Ex. 2005 at ¶44. Therefore, Sharma does not teach the "releasing means" limitation of claim 1.

4. Mr. Drewry identified two possible "bases" in Sharma's slide hammer assembly—notably, Sharma's hammer sleeve does not releasably connect to either of these structures

During his deposition, Mr. Drewry was asked to identify structures of Sharma's slide hammer device corresponding to the structures disclosed in the '129 Patent. With respect to the "base" disclosed in the '129 Patent, Mr. Drewry repeatedly testified that in "Figure 1 in Sharma, the base would be 41 and 31." Ex. 2004 at 62:18-19; *id.* at 65:11-12 ("Again, there's one base 41 on the proximal end, and there's a base 31 on the distal end."). As discussed above, Sharma's "proximal button 42," which is the sole structure cited in the Petition for the limitation "releasing means," does not releasably connect the hammer sleeve to "base 31." Furthermore, the structural element that Mr. Drewry identified as "base 41" is actually "the proximal impaction end (41)" of the hammer sleeve, and the hammer sleeve is *not* configured to be "released" therefrom. Thus, according to Mr. Drewry's testimony, Sharma does not teach or suggest the structural configuration "releasably

connecting the hammer sleeve to the base” because in Sharma, the hammer sleeve does not releasably connect to either “base 31 on the distal end” or “base 41 on the proximal end.”



B. Ground 1 fails to establish a prima facie case of obviousness

1. Ground 1 fails under the “know-technique” test set forth in Intel Corp. v. PACT XPP Schweiz AG

In the Preliminary Response, Patent Owner explained a myriad of legal and factual deficiencies that doom all grounds in the Petition, including Ground 1. *See* Prelim. Resp. 32-49. Nevertheless, in the Institution Decision, the Board cited the legal principle reiterated in the Federal Circuit’s opinion in *Intel* that “[t]he motivation-to-combine analysis is a flexible one” and, based on this case law, found “no shortcomings in Petitioner’s rationale for combining the asserted prior art.” Inst. Dec. 58-60 (quoting *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1379

(Fed. Cir. 2023)). The *Intel* decision is readily distinguishable from the present case for the reasons explained below.

Intel specifically applies to the “known-technique” rationale. *Intel*, 61 F.4th at 1380. In *KSR*, the Supreme Court set forth the “known-technique” rationale as follows: “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.* (quoting *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)) (emphasis added). In *Intel*, the Federal Circuit set forth a test for the “known-technique” rationale that requires a “show[ing] that there was a known problem” in the primary reference and that the secondary reference discloses a solution that “helped address that issue.” *Id.* at 1381.

In the present case, with respect to the Compton-Donner combination, the Petition does not identify any known problem in the method of Compton that was addressed by Donner’s joint preparation tool with the dual-keel abrading head. *See* Pet. 51-52. Likewise, the Petition does not identify any known problems in the methods of Compton and Donner that were addressed by Otte’s “instruments and techniques.” *Id.* at 52-53. Finally, the Petition does not identify any problems in any of the cited references that were addressed by Sharma’s universal slap hammer. Accordingly, because the Petition does not identify any known problems in the

primary references and does not identify any known solutions to these problems in the secondary references, Ground 1 fails under the “known-technique” test set forth in *Intel*. 61 F.4th at 1380-81.

2. The Petition failed to establish the motivation to combine Compton, Donner, Otte, and Sharma

As the Federal Circuit underscored in a recent *Elekta* decision issued on September 21, 2023, the day after the Decision on Institution, the Supreme Court case law set forth in *KSR* mandates that “a motivation to combine determination . . . requires an *explicit* analysis.” *Elekta Ltd. v. ZAP Surgical Sys., Inc.*, 81 F.4th 1368, 1376 (Fed. Cir. 2023) (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)) (emphasis added). With respect to such analysis, the Federal Circuit case law sets forth the following governing principles:

a conclusory assertion with no explanation is inadequate to support a finding that there would have been a motivation to combine because this type of finding, without more, tracks the *ex post* reasoning *KSR* warned of and fails to identify any actual reason why a skilled artisan would have combined the elements in the manner claimed.

TQ Delta, LLC v. CISCO Sys., Inc., 942 F.3d 1352, 1359 (Fed. Cir. 2019) (internal quotations omitted).

In the present IPR, Petitioner failed to meet this legal standard. To show the gross inadequacy of the motivation-to-combine analysis set forth in the Petition,

each sentence of the “Motivation to Combine” section of Ground 1 is addressed below.

First paragraph (Compton-Donner combination). This paragraph begins with three conclusory sentences stating that the combination of Compton, Donner, Otte, and Sharma would have been obvious, that both Compton and Donner teach SI joint procedures using “similar instrumentation,” and that Compton and Donner have “significant overlap in both instrumentation and methodology.” Pet. 51. Notably, these sentences do not identify any specific similarities in instrumentation or any specific overlapping instruments or method steps between Compton and Donner. The only support cited for these conclusory statements are the identical conclusory statements in Mr. Derwry’s declaration, which do not provide any additional explanation or cite any supporting evidence. *Compare* Pet. 51 *with* Ex. 1017, ¶111.

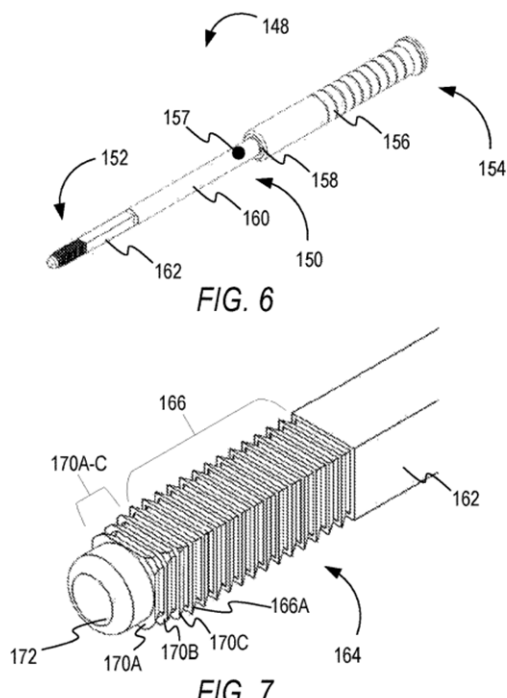
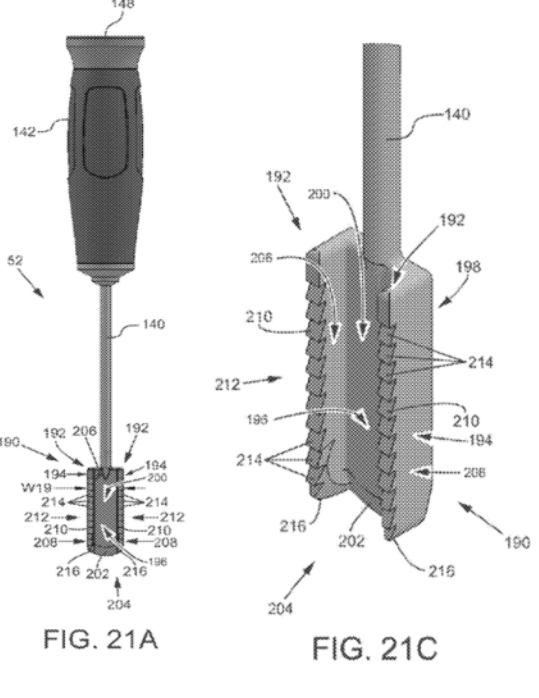
Furthermore, Petitioner’s statements regarding “significant overlap in both instrumentation and methodology” are false. As Dr. Bovinet explained in his declaration:

Upon even a cursory comparison of Compton and Donner, a POSA would recognize that Compton’s and Donner’s tools, implants, and methods are vastly different. For example, Donner’s Figures 2-4 depict a dual-arm delivery tool (16) an implant with keels (12) which is secured within the joint using a transverse anchoring element (18),

Figures 9-10 disclose cutting tools, Figures 11-12 depict a specialized “scooping” tool for gathering cartilage, Figure 51E depicts a bone tamp, and so on. In fact, Donner provides 107 figures and 30 pages of written description disclosing its various tools, implants, and their methods of use. None of these complex tools or implants are present in Compton. Likewise, Compton’s joint finder, cannula, broach, and rectangular implant are not present in Donner.

Ex. 2005 at ¶48. Thus, the Petition’s unsupported assertion about “significant overlap in both instrumentation and methodology” in Compton and Donner is false.

Next, the Petition states that “[b]oth Compton and Donner discuss using rasps and chisels for preparing the SI Joint for a fusion implant.” Pet. 52. In support for this statement, the Petition cites Compton at 4:35-53 and Donner at [0188]. *Id.* With respect to Compton, the cited portion describes “broach device 168” with reference to Figures 6-8—but does not mention a chisel. Ex. 1004 at 4:35-53. With respect to Donner, the cited paragraph describes an embodiment of a dual-keel “planar rasping head 190” depicted in Figures 21A-21C—but also does not mention a chisel. Ex. 1006 at [0188]. Thus, the statement in the Petition that “[b]oth Compton and Donner discuss using rasps *and chisels*” has no evidentiary support. For ease of reference and comparison, the cited Compton’s “broach device 168” and Donner’s “planar rasping head 190” are reproduced below.

Compton's "broach device 168"	Donner's "planar rasping head 190"
 FIG. 6 FIG. 7	 FIG. 21A FIG. 21C

Next, without providing any additional explanation, the Petition concludes that it would have been obvious to combine Donner's "joint preparation tool" with the "SI Joint method of Compton" because "the joint preparation tool of Donner prepares the SI Joint and articular surfaces of the SI Joint with a single tool, instead of *multiple separate tools such as a chisel, a rasp, and other tools.*" Pet. 52 (emphasis added). However, because Compton does not teach a separate rasp and chisel, this alleged reason for combining Donner's "joint preparation tool" with Compton's method is constructed on the premise that is factually false. (Again, the only support the Petition cites for this assertion is the identical conclusory and false statement in

Mr. Drewry’s declaration, which provides no additional explanation or evidentiary support. *Compare* Pet. 51 *with* Ex. 1017, ¶111.)

In addition to being based on a conclusory and factually false premise, the Petition failed to provide any explanation as to *how* Donner’s dual-keel rasping tool would have been used in Compton’s method to replace the rasp—i.e., “broach device 148”—whose abrading head is specifically shaped to make a “substantially rectangular pilot hole” (Fig. 15) for an implant that has a “substantially rectangular shape that matches the substantially rectangular pilot hole” (Figs. 10-11). Ex. 1004 at 5:46-48. The Federal Circuit case law dictates that unpatentability grounds that do not “clearly explain[], or cite[] evidence showing, *how* the combination of the two references was supposed to work” are legally insufficient for establishing obviousness. *Pers. Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017).

In the last two sentences of the first paragraph of Ground 1’s “Motivation to Combine” section, the Petition cites Donner’s slap hammer and concludes this paragraph with yet another generic assertion that “the joint preparation tool of Donner would be beneficially used in the method of Compton with predictable improvement in efficiency. Pet. 52. The only support for this statement is yet again the identical statement in Mr. Drewry’s declaration. *Compare id. with* Ex. 1017, ¶111. Notably, neither the Petition nor Mr. Drewry’s declaration identifies in what

way is the efficiency of Compton would be improved when combined with Donner's dual-keel abrading tool, and neither the Petition nor Mr. Drewry's declaration provides any additional reasoning for the Compton-Donner combination. Accordingly, for the reasons set forth above, unpatentability challenges in Ground 1 based on Compton-Donner combination are legally improper and fail to establish a *prima facie* case of obviousness.

Second paragraph (Otte). The second paragraph of Ground 1's "Motivation to Combine" section is dedicated to Otte. In fact, the three sentences that make up this paragraph constitute the *entirety* of the motivation-to-combine analysis with respect to Otte in the whole Petition.

The first sentence of this paragraph states that "Otte discloses methods and instruments for preparing the intervertebral disc space for implants in a spinal fusion surgery and method of preparing the spinal disc space." Pet. '52. In support of this sentence, the Petition cites paragraphs [0056]-[0059] of Otte's specification. Otte's paragraph [0056] references a surgical instrument set ("kit 10") that contains "a variety of instrument embodiments that can be used with an expandable implant." Ex. 1007 at [0056]. The remainder of paragraph [0056] cross-references other patent applications that disclose expandable implants. Paragraph [0057] identifies three separate instruments in the instrument set: (1) two embodiments of a "box-chisel," (2) an "inserter/expander," and (3) "an implant assembling/collapsing instrument"

and specifies that each of these instruments is “configured for use with a two-piece ratcheting-type implant.” *Id.* at [0057]. Paragraph [0058] simply contains the heading “Expandable Implant,” while Paragraph [0059] describes such implant.

In the next sentence, the Petition states that “[s]pinal fusion surgeries are closely related to SI Joint fusion surgeries as . . . they use similar tool sets in similar manners.” Pet. 52. Notably, this generic and conclusory statement completely ignores the fact that neither Compton nor Donner disclose any tools similar to Otte’s “insertor/expander,” “an implant assembly/collapsing instrument,” and “a two-piece ratcheting-type implant,” which the Petition cited in the immediately preceding sentence. Again, the only support the Petition provides for this generic statement regarding the “similar tool sets [being used] in similar manners” is the identical generic statement in Mr. Drewry’s declaration, which does not provide any additional explanation or evidentiary support.

The Petition ends this paragraph with a conclusory sentence stating that “[t]hus, it would be obvious to a POSITA to combine the teachings of Otte, including the disclosed instruments and techniques, with the SI Joint fusion methods of Compton and Donner.” Pet. 53. Notably, this conclusory sentence fails to identify which specific tools and techniques described in Otte are being combined with what specific method steps from Compton and what specific method steps from Donner, and why. In fact, this entire paragraph fails to state *any motivation* for making this

combination of (unspecified) instruments, techniques, and method steps. Because the Federal Circuit and Supreme Court case law mandate that “a motivation to combine determination . . . requires an *explicit* analysis”—and such analysis with respect to Otte is wholly absent in the Petition—all prior art combinations involving Otte automatically fail, as a matter of law. *Elektro Ltd. v. ZAP Surgical Sys., Inc.*, 81 F.4th 1368, 1376 (Fed. Cir. 2023) (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)) (emphasis added).

Third paragraph (Sharma). The third and final paragraph of Ground 1’s “Motivation to Combine” section is dedicated to Sharma-Compton combination. The first three sentences state that Sharma discloses a slap hammer device designed for general use in orthopedic procedures and that it would have been obvious to use Sharma’s slap hammer with “surgical instruments in an SI Joint fusion procedure, such as chisels and rasps.” Pet. 53. Next, the Petition states that “Compton discloses an orthopedic spinal procedure that includes the use of an impactor and tools that are conventionally used with hammers and slap hammers, such as a box chisel or rasp.” *Id.* Based on this premise, the Petition concludes the motivation-to-combine analysis with the following statement:

It would be obvious to a POSITA that the universal impactor with a slap hammer device would be beneficially used with the tools (e.g., the box chisel and rasp) used in the method of Compton with predictable

improvements in efficiency, particularly in view of the disclosure of the joint preparation tool of Donner.

Pet. 53. Notably, the Petition does not identify or explain any specific “predictable improvements in efficiency.” Indeed, this entire paragraph amounts to nothing more than a series of generalized statements that Sharma’s slap hammer *could* have been combined with Compton’s tools, without providing any motivation for doing so. The Federal Circuit case law directly rejects this type of generalized obviousness arguments as legally insufficient:

[such] reasoning seems to say no more than that a skilled artisan, once presented with the two references, would have understood that they *could be* combined. And that is not enough: it does not imply a motivation to pick out those two references and combine them to arrive at the claimed invention.

Personal Web Techs., LLC v. Apple, Inc., 848 F.3d 987, 994 (Fed. Cir. 2017) (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (“[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.”)) (emphasis in original).

Accordingly, for the reasons explained above, the Petition failed to establish that a POSA would have been motivated to combine any of the references cited in

Ground 1, and therefore, Ground 1 does not set forth a *prima facie* case of obviousness with respect to the challenged claims.

3. *The embodiment of Donner cited in Ground 1 does not teach or suggest the limitation “open tip”*

a. *Donner’s “tip 202” does not have an opening*

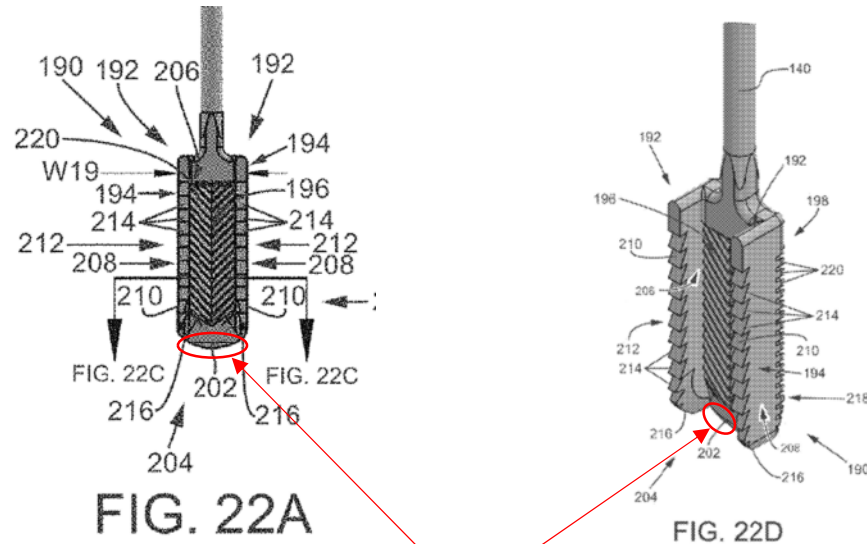
In Ground 1, the Petition relies on the embodiment of Donner’s joint preparation tool depicted in Figures 22A-22D to allege obviousness of the claimed abrading device having an “open tip.” Pet. 56. This is the *only* embodiment of Donner’s abrading head cited in the Petition.³ Identifying the tip in this embodiment is straightforward because Donner itself identifies element 202 as the “*tip* 202.” Ex. 1006 at [0188] (emphasis added). With respect to Figures 22A-22D, Donner states that they “depict *a* tooling head”—thereby underscoring that Figures 22A-22D

³ In the Institution Decision, the Board found that “Donner’s Figure 23D indisputably shows [an open tip].” Prelim. Dec. 56. This embodiment of Donner was not cited in the Petition and therefore is unavailable for the purpose of establishing a *prima facie* case of obviousness in this IPR. *See Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367 (Fed. Cir. 2015) (affirming the Board’s refusal to consider arguments based on additional embodiments of a prior art reference that “were not identified or discussed in the Petition.”)

depict the *same* single embodiment of the abrading head. *Id.* at [0190] (“reference made to FIGS. 22A-22D, which depict *a* tooling head”) (emphasis added).⁴

Figures 22A and 22D, which are reproduced and annotated below, depict that the “*tip 202*” is ***solid***, without any openings. *Id.* at [0190]. Indeed, Dr. Bovinet explained that Donner’s abrading head depicted in Figures 22A-22D does not teach or suggest an “open tip” because “tip 202 is a *closed* tip without an opening.” Ex. 2005 at ¶45 (emphasis added). Thus, the embodiment of Donner depicted in Figures 22A-22D—which is the *only* embodiment cited in the Petition—does not teach or suggest an “open tip” because Donner’s “***tip 202***” does not have an opening. Inst. Dec. 18 (“some sort of ‘opening’ seems necessary for an ‘open tip’”).

⁴ In the Institution Decision, the Board found that “Donner’s Figure 22D embodiment also illustrates that the abrading head has an open tip . . . while Donner’s Figure 22A may not disclose an ‘open tip.’” Inst. Dec. 56. Because Figures 22A-22D depict the same embodiment, this finding is incongruous with Donner. Because Figures 22A-22D depict the same single embodiment, if the abrading head in Figure 22A does not have an open tip, then neither does the abrading head in Figure 22D.

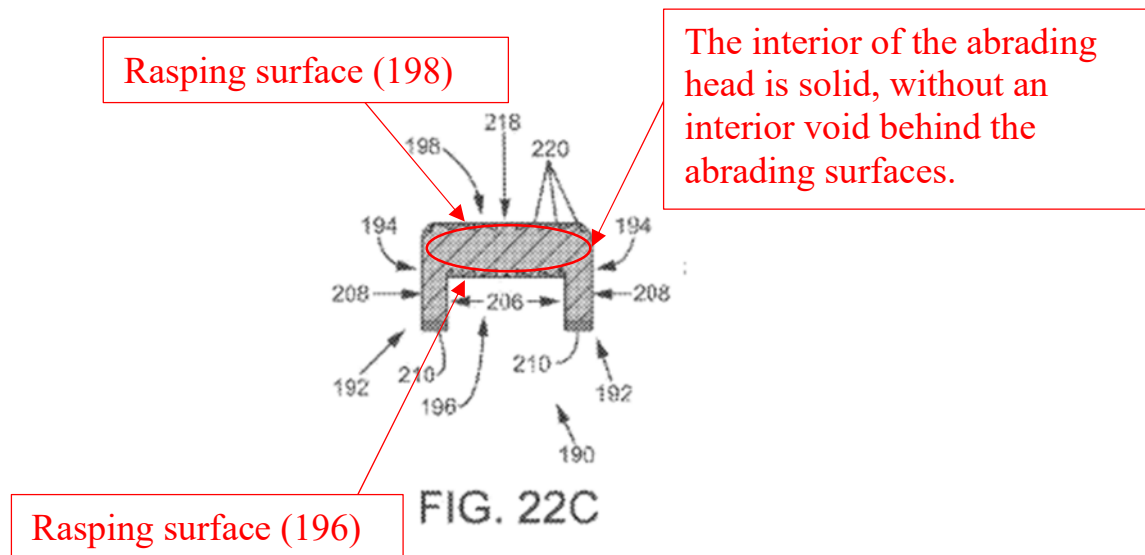


“Tip 202” is a closed tip

b. Donner’s abrading head in the embodiment of Figures 22A-22D does not have an interior void

In the Institution Decision, the Board preliminarily construed the term “open tip” to mean “the tip of the abrading head is open to an *interior* void of the abrading head.” Inst. Dec. 19 (emphasis added). Section II.1., *supra*, established that the specification of the ‘129 Patent and the testimony of both parties’ experts establish that the interior void must be located on the *interior* of the abrading head—i.e. behind the external abrading surfaces (or between the interior surfaces of the abrading head’s first pair of opposing sides). *See, e.g.*, Ex. 2004 at 31:12-16 (Mr. Drewry testifying: “If I looked at an open tipped abrading instrument, . . . I’d look to see if there was a void or a space or some lack of material *behind* the cutting edges

. . . .”) (emphasis added). Donner’s Figure 22C clearly shows that there is no void behind the opposing abrading surfaces—only solid material. Ex. 2005 at ¶46.



c. Donner’s abrading head in Figures 22A-22D does not have a tip configured to enable the dislodged tissue to enter the void

As established in Section II.1., *supra*, construction of the term “open tip” should require that the tip must be “configured to enable the dislodged tissue to enter the interior void.” Indeed, Mr. Drewry repeatedly testified that the capability of removing dislodged tissue through the void is a key characteristic that distinguishes an “open tip” from a “closed tip.” See, e.g., Ex. 2004 at 35:17-21 (“[I]f you look at the end of the instrument, you can tell that it’s open because there’s a void behind those tapered edges that allows *for tissue removal* and kind of passage of that material during the abrading and cutting process.”).

With respect to the abrading head depicted in Figures 22A-22D, Donner states that “this embodiment may be useful for simultaneously rasping the intra-articulating surfaces of the sacroiliac joint to remove cartilage or abrade the boney surfaces and make dual keel-cuts.” Ex. 1006 at [0188]. During his deposition when asked the following question in reference to Donner’s Figures 22A-22D: “Is there a void in this cutting head through which dislodged bone can exit when the cutting surfaces -- cutting ridges 210 [are] embedded in the bone and the rasping surface 196 is scraping the bone?”--Mr. Drewry answered in the negative: “Not in that configuration.” *Id.* at 115:13-18. Mr. Drewry further explained that when the cutting keels and the rasping surface are simultaneously contacting the bone—which Donner describes as the intended method of use for this embodiment—the abrading head “just abrades the tissue and you may have to go back in there afterwards and have it removed, or you flush it out with a kind of irrigation during the surgical procedure.” *Id.* at 115:5-8; *see also* Ex. 2005 at ¶46.

Dr. Bovinet agreed that “Donner’s abrading head shown in Figures 22A-22D does not have an interior void into which the bone and tissue debris can enter.” Ex. 2005 at ¶46. Thus, both parties’ experts are in agreement that Donner’s dual-keel abrading head depicted in Figures 22A-22D does not have a tip “configured to enable the dislodged tissue to enter the interior void,” which both experts agreed is a key characteristic that distinguishes an “open tip” from a closed one. Ex. 2004 at 30:5-9

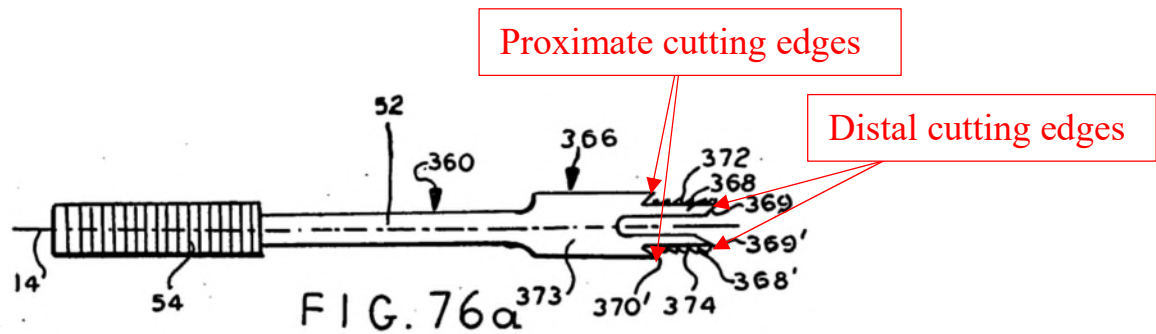
(“Again, the ones that are not open would typically be solid, so there wouldn’t be -- there would be a tip on it. There wouldn’t be a void behind the cutting surface. There would be no opening in the [instrument] to allow for this tissue removal.”); *see also* Ex. 2005 at ¶46 (“Donner teaches that both rasping surfaces (196 and 198) simultaneously contact the bone surfaces, which precludes the dislodged debris from exiting. Ex. 1006 at [0188]. This confirms that Donner’s dual-keel abrading head is a closed-tip instrument without an opening or an internal void.”)

For all the reasons set forth above, Donner’s dual-keel abrading head depicted in Figures 22A-22D—which is the only embodiment of Donner’s abrading head cited in the Petition cited for the limitation “open tip”—does not teach or suggest this claimed structural element.

C. Grounds 2-5 fail because Martz does not teach or suggest the limitation “a cutting edge disposed at a leading edge of the open tip, the cutting edge configured to cut bone tissue in the sacroiliac joint”

Claim 1 claims an abrading head having “a cutting edge disposed at a *leading* edge of the open tip, the cutting edge *configured to cut bone tissue* in the sacroiliac joint.” Ex. 1001 at 13:6-9 (emphasis added). For this limitation, Grounds 2-5 rely on the embodiment of Martz’s chisel tool depicted in Figures 76a-76c. In this embodiment, there are two sets of cutting edges: (1) the distal cutting edges 369 and 369’ disposed at the leading edge of the abrading head, and (2) the proximal cutting edges 370 and 370’, which are not disposed at the leading edge. Ex. 1008 at FIG.

76a; [0305]. Figure 76a of Martz is reproduced and annotated below, pointing out these two sets of the cutting edges.



As explained in detail in the Preliminary Response, Martz teaches that the distal cutting edges are configured to “*cut disc material* from adjacent vertebrae while guiding the proximate cutting edges to meet and cut from adjacent vertebrae.” Prelim. Resp. at 29-32 (quoting Ex. 1008 at [0304]) (emphasis added). The Petition itself acknowledges this fact: “[Martz’s chisel] *removes disc material between the adjacent vertebrae using a second cutting edge on a distal end of the chisel.*”) Pet. 46 (citing Ex. 1008 at [0093]) (emphasis added).

In the Institution Decision, the Board found that because the SI joint does not have disc material, if “the Martz chisel would have been used to prepare an SI joint,” the distal cutting edges 369 and 369’ would cut “the iliac and sacrum *bones*, not disc material.” Inst. Dec. at 58 (emphasis in original). In his deposition testimony, Mr. Drewry directly refuted this finding by explaining that the cartilage in the vertebral and the SI joint is “very similar” and “has to be removed” in both applications:

Q. And does the SI joint have similar-type cartilage that you encounter spinal applications?

A. Yes. It's similar in the sense that it is the protective coating on the bone that has to be removed. You have to get the implant in contact with bone or it won't fuse or it won't heal, so we had to get that cartilage off. The cartilage in the SI joint was very similar to the cartilage on the endplate to the vertebral bodies.

Ex. 2004 at 21:19-22:2.

Mr. Drewry further explained that at some point in his career, he “was hired as a consultant by Medtronic to come back and develop a second generation SI joint system.” *Id.* at 17:2-4. Mr. Drewry testified that for this SI joint system, his team “combined box chisels and rasps.” *Id.* at 18:5-6. The structural configuration of this combined chisel-rasp tool was analogous to Martz's chisel cited in the Petition:

[it] had two cutting blades on the front so on the -- we'll call that the distal end, . . . and then we had a secondary or -- I guess we'd call that proximal cutting edges that allowed for bony removal and decortication of the bone. So we had multiple cutting edges and rasps and teeth along the top of that instrument.

Id. at 20:7-21. When asked “what was the purpose of having this stacked configuration where you had multiple blades distally spaced from one another?”— Mr. Drewry provided the following answer:

So what we learned through a couple of decades of using these in the spine is that we could have *this first cutting edge come in and start to peel off the cartilage* on the bone, and then the rasp would follow that and start scraping any remnants off of the bone.

And then *the second or proximal cutting edges would actually cut into the bone* and provide the void or the implant geometry so that the implant would fit into the bone. So we were able to -- with one instrument we were able to remove the cartilage, decorticate the bone and provide a void that was shaped for the implant.

Id. at 21:5-15 (emphasis added).

Mr. Drewry's testimony quoted above confirms that a POSA would understand that if Martz's chisel depicted in Figure 76a were applied to an SI joint the principal of operation would remain the same as with a vertebral joint: the distal cutting edges (369 and 369') would remove the cartilage within the SI joint, while the proximal cutting edges (370 and 370') would cut into the bone. *See id.* at 21:5-15. Thus, Mr. Drewry's deposition testimony corroborates the explanation set forth in the Preliminary Response that Martz teaches that the cutting edges disposed at the leading edge of the chisel are configured to cut cartilage—not bone tissue. *See* Prelim. Resp. 29-32. Dr. Bovinet shares the same understanding, thereby further cementing that Martz does not teach or suggest the limitation "a cutting edge disposed at a leading edge of the open tip, the cutting edge configured to cut bone tissue in the sacroiliac joint." Ex. 2005 at ¶47.

Furthermore, Martz refers to the distally extending elements that terminate in the distal cutting edges and have rasp surfaces thereon as “the guide members 368 and 368’.” Ex. 1008 at [0306]. With respect to the “guide members,” Martz teaches that the distal cutting edges “cut disc material from adjacent vertebrae *guiding* the proximate cutting edges to meet and cut from adjacent vertebrae.” *Id.* at [0304] (emphasis added). Accordingly, to accomplish this “guiding” function, the guide members must be sufficiently narrowly spaced such that they can slide inside the joint space along the surfaces of the bones without cutting into the bone tissue, which would make guide members prone to getting stuck in the bone and would impede their “guiding” function for the proximate cutting edges. Thus, the guiding function of the chisel’s tip further buttresses the conclusion that if used in an SI joint, Martz’s distal cutting edges would glide along the bone surfaces cutting the soft issue away from the bones, analogously to the “peel[ing] off the cartilage” step that Mr. Drewry described during his deposition. *See* Ex. 2004 at 21:5-9.

Finally, in addition to the limitation “the cutting edge configured to cut bone tissue,” claim 1 requires a method step according to which “advancing the abrading device into the sacroiliac joint such that the open tip cuts bone tissue away from the sacrum or the ilium.” As established above, the tip of Martz’s chisel is configured to remove cartilage rather than cut bone tissue. Thus, if Martz’s chisel were used to prepare an SI joint for an implant, this limitation of claim 1 would not

be met. For all the reasons set forth above, the embodiment of Martz's chisel depicted in Figures 76a-76c, which is the only embodiment cited in the Petition, does not teach or suggest the limitation of claim 1 requiring that the cutting edge disposed at the leading edge of the open tip must "cut bone tissue." Because Grounds 2-5 rely on Martz for this limitation, they fail to set forth a *prima facie* case of obviousness with respect to the challenged claims.

IV. GROUNDS 1-5 FAIL UNDER KSR BECAUSE THE PETITION MERELY MAPS VARIOUS STRUCTURAL FEATURES OF THE CLAIMED ABRADING DEVICE TO AN ASSORTMENT OF PRIOR ART SURGICAL TOOLS, BUT FAILS TO SET FORTH A COHESIVE COMBINATION OF THEIR DISCRETE FEATURES TO ARRIVE AT A SINGLE ABRADING DEVICE OF CLAIM 1

As stated in the Preliminary Response, the governing case law constraints the Board to rendering its decisions based on the arguments advanced by the parties. Prelim. Resp. 49 (quoting *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016)). In the Institution Decision, the Board found that "[u]nder each ground for unpatentability, Petitioner has included a designated section addressing ... combining multiple tools and steps into a *single* tool." Inst. Dec. 59 (citing Pet. 51-53, 60-63, 69-70, 73-74, 81-82). This finding is factually false and unsupported by the evidence in the record.

Contrary to the Board's finding quoted above, Petitioner *did not* set forth combinations of multiple separate tools into "a single tool for SI joint preparation." Instead, as explained in the Preliminary Response, Petitioner attempted to prove

obviousness of the claimed “abrading device” having “abrading surfaces” and “an open tip” by reciting “a disjointed assortment of separate surgical tools, *without* presenting any rationale for combining or modifying them.” *Id.* at 32 (emphasis added). Specifically, the Preliminary Response explained that:

[i]n each invalidity ground, the Petition cites a first surgical instrument to allege obviousness of the “abrading surfaces” and then cites a second, different surgical instrument to allege obviousness of the “open tip.” The Petition cites these surgical instruments independently, without contemplating their combination or modification—let alone providing a reasoned rationale as to why or how these separate surgical instruments could be combined or modified.

Id. 33. Further, the Preliminary Response explained that all grounds set forth in the Petition fail as a matter of law because “it is axiomatic that ‘[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art.’” *Id.* at 32-33 (quoting *KSR*, 550 U.S. at 401).

1. Ground 1

In its analysis, the Board correctly stated that Ground 1 relies on Compton’s “broach 148 as the recited ‘abrading device.’” Inst. Dec. 46-47 (citing Pet. 54-59). The Board continued its summary of Ground 1 with the following findings:

[r]egarding the ‘open tip’ and ‘cutting edge’ ... , Petitioner points to Donner’s teaching of tooling head ... and also to Otte’s box chisel

Petitioner asserts either reference's tool would be a predictable *addition* to use with Compton's methods *and structures*.

Id. at 47 (citing Pet. 52-53) (emphasis added). The emphasized words in the last sentence quoted above are significant for two reasons.

First, the part of the Board's statement pertaining to Compton's "*structures*" is factually incorrect because the Petition only contemplates combining Donner's and Otte's tools with Compton's *method*—*not structures*. Pet. 52 ("It would be obvious to a POSITA that the joint preparation tool of Donner would be beneficially used in the *method* of Compton [I]t would be obvious to a POSITA to combine the teachings of Otte, including the disclosed instruments and techniques, with the SI Joint fusion *methods* of Compton and Donner.") (emphasis added). This conflation of the tools and methods demonstrates that the Board's finding regarding Petitioner's alleged argument with respect to "combining what were formerly multiple separate tools into a single tool for SI joint preparation" is untethered from the arguments actually set forth in the Petition and therefore is unsupported by the evidence in record. Inst. Dec. 46.

Second, as the Board recognized, Ground 1 recites Donner's and Otte's tools in "*addition*" to Compton's method. *Id.* at 47. This finding reinforces the Preliminary Response argument that the Petition simply *adds* Donner's "joint preparation tool 50" or Otte's "box chisel" to Compton's *method* but "does not contemplate any

modifications to any of these surgical devices.” Prelim. Resp. 34. In other words, Ground 1 maps the limitation “abrading surfaces” “*exclusively* [to] Compton’s ‘broach 148’” and then maps the limitation “open tip” to “Donner’s ‘joint preparation tool 50’ and Otte’s ‘box chisel’” but fails to set forth a cohesive combination of these discrete structural features of separate surgical instruments to arrive at a *single* abrading device that meets every element of claim 1. *Id.* In *KSR*, the Supreme Court unequivocally rejected this type of reasoning as legally insufficient to prove obviousness. *Id.* at 32 (quoting *KSR*, 550 U.S. at 401) (“A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art.”).

2. Ground 2

In its summary of Ground 2, the Board recognized that the Petition asserts that “Schifano teaches the claimed ‘abrading device’ in disclosing a rasp” and then for the “open tip” and “cutting edge” limitations, the Petition asserts that “Schifano’s box chisel has an ‘open tip’ and ‘cutting edge’” and “additionally points to Martz’s disclosure.” Inst. Dec. 49-50 (citing Pet. 64-68). Because Schifano’s rasp is the *sole* tool cited for the abrading device having “abrading surfaces,” Petitioner cannot prevail on Ground 2 without proving obviousness of *combining* Schifano’s rasp with the cited structural features of Schifano’s box chisel or Martz’s chisel tool into a *single* abrading device. Prelim. Resp. 34-35. The Petition does not set forth such

combination. *See* Pet. 64-68.⁵ Accordingly, Ground 2 fails as a matter of law for the same reason as Ground 1: Petitioner cannot prove obviousness of the claimed abrading device by merely mapping its various features to multiple separate surgical tools, without setting forth a cohesive combination of the cited features into a *single* abrading device.

3. Ground 3

As the Board correctly recognized, Ground 3 is analogous to Ground 2 and merely “swaps Compton ... in place of Schifano.” Inst. Dec. 50. Thus, Ground 3 fails as a matter of law for the same reasons as Grounds 1 and 2. Prelim. Resp. 35.

4. Ground 4

The Board correctly summarized Petitioner’s argument in Ground 4 with respect to the abrading device as follows: “Petitioner asserts that ... Black discloses rasp 1000 that teaches the claimed ‘abrading device,’ and Black’s box chisel 900 teaches an ‘open tip’ and ‘cutting edge’ In addition to this, Petitioner again

⁵ Instead, the Petition argues that “[t]he box chisel tool of Martz can be easily *substituted* for the box chisel and rasp of Schifano”—and then reverts back to Schifano’s separate box chisel and rasp for combining with Sharma’s slide hammer: “[i]t would be obvious to a POSITA that the universal impactor with a slap hammer device would be beneficially used with the instruments (e.g., *the box chisel and rasp*) used in the method of Schifano.” Pet. 62-63 (emphasis added).

asserts that Martz teaches an open-tipped chisel tool with a cutting edge.” Inst. Dec. 51-52 (citing Pet. 51-52). Thus, as with Grounds 1-3, Ground 4 maps the abrading device having “abrading surfaces” to a first surgical instrument—Black’s rasp 1000—and then for the “open tip” limitation, “Petitioner switches to two other surgical tools: Black’s ‘box chisel 900’ and Martz’s chisel tool.” Prelim. Resp. 35 (citing Pet. 78-79). As the Preliminary Response explained: because “the Petition lacks any discussion pertaining to combining Black’s ‘rasp 1000’ with either Black’s ‘box chisel 900’ or Martz’s chisel tool,” Ground 4 fails as a matter of law under *KSR* for the same reasons as Grounds 1-3. Prelim. Resp. 35.

5. Ground 5

The Board summarized Ground 5 as “the same case as for Ground 4, but swaps Donner ... in place of Martz.” Inst. Dec. 52 (citing Pet. 81-85). This finding is factually erroneous because for the limitations directed to the “abrading device,” Ground 5 continues to rely on the same assortment of Black’s and Martz’s tools as Ground 4. Pet. 83. In any case, Ground 5 inherits the fatal defects of Ground 4 and therefore fails as a matter of law for the same reasons as Ground 4.

V. THE BOARD SHOULD GIVE LITTLE TO NO WEIGHT TO MR. DREWRY'S DECLARATION

1. Mr. Drewry's declaration repeats, verbatim, the conclusory statements in the Petition without providing any additional supporting explanation or evidence

The Preliminary Response explained that the substantive portions of Mr. Drewry's declaration—i.e. the summary of the prior art, the motivation-to-combine sections, and the mapping of the claim limitations to the prior art—are identical to the corresponding sections of the Petition, including obvious typographical errors. Prelim. Resp. 7 (*comparing* Pet. 24-86, *with* Ex. 1017 at ¶¶65-102, 111-205). In the Institution Decision, the Board stated that the Preliminary Response “has not sufficiently explained exactly what it is about Mr. Drewry's testimony that is merely conclusory and unsupported.” Inst. Dec. 53. Section III.B.2., *supra* of this Patent Owner's Response provides ample examples of specific statements in Mr. Drewry's declaration that are conclusory, unsupported, and, in some cases, outright false.

Specifically, the Petition contains a conclusory statement that Compton and Donner “have significant overlap in both instrumentation and methodology.” Pet. 51. Mr. Drewry's declaration parrots this conclusory statement, without identifying any allegedly overlapping instruments or method steps. Ex. 1017 at ¶111. Even more problematic is that this statement is not only conclusory but false. As Dr. Bovinet explained in his declaration, which identifies specific examples of Donner's and Compton's surgical tools, “Donner provides 107 figures and 30 pages of written

description disclosing its various tools, implants, and their methods of use. None of these complex tools or implants are present in Compton. Likewise, Compton's joint finder, cannula, broach, and rectangular implant are not present in Donner." Ex. 2005 at ¶48.

Another example of Mr. Drewry's non-credible testimony involves the false statement in the Petition that "Compton and Donner discuss using rasps and chisels." Pet. 51-52 (citing Ex. 1004 at 4:35-53 and Ex. 1006 at [0188]). This identical statement is present in Mr. Drewry's declaration citing the same disclosure of Compton and Donner as the Petition. As explained in Section III.B.2, *supra*, the cited portion of Compton only describes a broach (i.e. rasp), but does not mention a chisel. Likewise, the cited portion of Donner only describes the dual-keel abrading head, but does not mention a chisel. Thus, this statement in Mr. Drewry's declaration is unsupported by the very evidence which it interprets.

Furthermore, Section III.B.2., *supra*, recites additional examples of conclusory, unsupported, and/or false statements in the Petition that are parroted in Mr. Drewry's declaration. Thus, under the precedential case law set forth in *Xerox Corp. et al. v. Bytemark, Inc.*, the Board should award little to no weight to Mr. Drewry's declaration. IPR2022-00624, Paper 12 at 5 (Feb. 10, 2023) (designated precedential).

2. Mr. Drewry's obviousness opinions with respect to Sharma and Donner are based on fundamental mischaracterizations of the prior art
a. Mr. Drewry fundamentally mischaracterized Sharma's locking mechanism

During his deposition, Mr. Drewry provided the following explanation of his understanding about how Sharma's locking mechanism functions:

Q. ... explain to me the process of unlocking the hammer sleeve 11 in Sharma.

What -- what would you do and how would it function?

A. This appears to be a button in 41 that you push to relieve ball detents and allow the slap hammer sleeve to travel up and down shaft 21.

Q. And so that would disconnect the element 41 from element 11 in Sharma.

A. Yes, sir, that's correct.

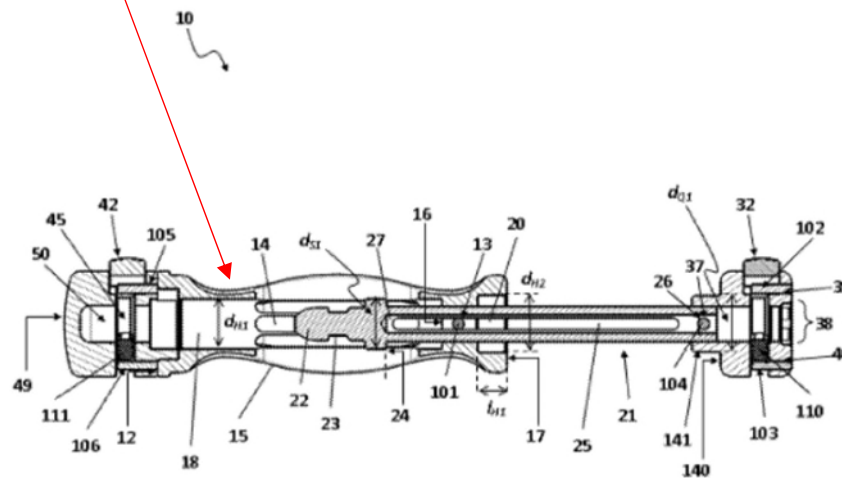
Ex. 2004 at 78:10-18.

Mr. Drewry's testimony provided above fundamentally mischaracterizes Sharma. In Sharma, the "proximal impaction end 41" (which Mr. Drewry also identified as a "base") is an integral part of the "hammer sleeve 11," and these two structures *do not disconnect* from one another. Instead, Sharma teaches that "the proximal button (42) on the proximal impaction end (41) is pressed to release the tip of the central shaft enabling the shaft to move within the integrated hollow handle," such that the hollow handle (hammer sleeve 11) and the proximal impaction end (41) travel up and down the shaft as a single unit. The fact that Sharma's hammer sleeve

11 remains attached to the proximal impaction end 41, even when the hammer sleeve is in the unlocked configuration, is clearly illustrated in Figure 4, which is reproduced and annotated below.

Hammer sleeve and the impaction end do not disconnect from one another in the unlocked configuration

FIGURE 4



b. Mr. Drewry’s testimony regarding Donner’s dual-keel abrading head depicted in Figures 22A-22D having an “open tip” and a “void” contradicts Donner’s explicitly stated method of use

During his deposition, Mr. Drewry explained that his opinion that Donner’s abrading head depicted in Figures 22A-22D had an “open tip” is based on a hypothetical scenario in which the interior abrading surface (reference 196) does not make contact with the bone, thus leaving a void between the interior abrading surface 196 of the abrading head and the bone, whereby the dislodges tissue would exit through such void. Ex. 2004 at 107:14-108:2; 115:21-116:2. This hypothetical

method of use, in which the abrading surface 196 does not contact the bone, directly contradicts the intended method of use described in Donner: “[a] planar rasping head 190 of this embodiment may be useful for *simultaneously rasping* the intra-articulating surfaces of the sacroiliac joint to remove cartilage or abrade the boney surfaces and make dual keel-cuts into either the sacrum or the ilium.” Ex. 1006 at [0190] (emphasis added).

Mr. Drewry’s testimony cited above demonstrates that he either fundamentally misunderstands how Donner’s abrading head in Figures 22A-22D is intended to function or intentionally mischaracterizes this reference to contrive a narrative that supports Petitioner’s unpatentability grounds. In either case, Mr. Drewry’s mischaracterization of key aspects of the cited prior art eviscerates his credibility.

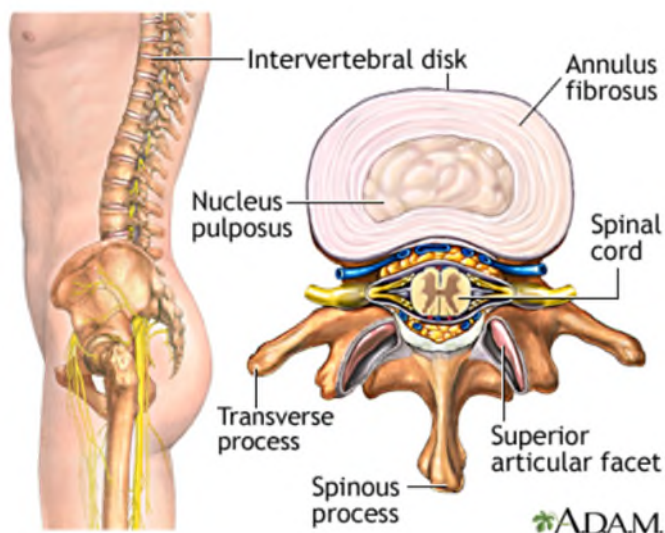
3. The Board discredited Mr. Drewry’s testimony in another IPR for applying an improper obviousness analysis—and Mr. Drewry admittedly did not change his tactics

In *Exactech, Inc. v. Zimmer, Inc.*, Mr. Drewry served as an expert witness for an IPR petitioner. IPR2022-00840, Paper 7 (PTAB Nov. 9, 2022). In that case, the patent owner argued that Mr. Drewry’s declaration was “unsupported and entitled to little weight” because it overlooked a material limitation. *Id.* at 14. Ultimately, the Board denied institution finding that the petitioner’s and Mr. Drewry’s obviousness analysis indeed overlooked that material limitation. *Id.* at 15.

In the present case, during his deposition, Mr. Drewry was asked the following question with respect to the *Exactech* IPR: “have you changed the way you approach obviousness analysis subsequent to the testimony in that case?” Ex. 2004 at 11:8-9. Mr. Drewry’s answer speaks for itself: “No, sir, I have not.” *Id.* at 11:10. This admission demonstrates Mr. Drewry’s disregard for the integrity of the IPR process and further undermines his credibility as an unbiased expert witness.

4. Mr. Drewry’s declaration misstated basic facts about human anatomy, and at his deposition, Mr. Drewry doubled down on these misstatements

Paragraph 135 of Mr. Drewry’s declaration contains the following statement: “[t]he *bone surfaces of intervertebral discs* are analogous in their structure to the articular surfaces of the sacrum and ilium in the sacroiliac joint.” Ex. 1017 at ¶135 (emphasis added). This statement is factually false because the surfaces of intervertebral discs are made of cartilage—not bone. *See* Ex. 2003 (“The annulus fibrosus is a fibrocartilaginous ring that surrounds the nucleus pulposus ...”).



Ex. 2003

During his deposition, Mr. Drewry refused to admit this factual error in his declaration and instead doubled down on this false statement. Ex. 2004 at 136:11-21. This refusal to back down from a clearly false statement in his declaration, which merely parrots the same false statement in the Petition, demonstrates that Mr. Drewry's testimony is that of an automaton pre-programmed to agree with the Petitioner's narrative—even when that narrative involves factually false statements—rather than an objective and truthful opinion of an unbiased subject matter expert. *Compare* Ex. 1017 at ¶135 with Pet. 62.

Because of the foregoing reasons, the Board should award little to no weight to Mr. Drewry's declaration.

VI. CONCLUSION

For the reasons set forth herein, the Petition failed to establish unpatentability of any of the challenged claims.

Dated: December 22, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION

Pursuant to Rule 37 C.F.R. § 42.24(d), the undersigned hereby certifies that, based upon the word count of the word-processing system used to prepare this Patent Owner Response, the number of words in this Patent Owner Response complies with 37 C.F.R. § 42.24(a)(1)(i) and is 13,111. Pursuant to 37 C.F.R. § 42.24(a)(1), this word count does not include “a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing.”

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e), the undersigned certifies that on December 22, 2023 a copy of this Patent Owner’s Response and accompanying exhibits were electronically served on the Petitioner’s counsel of record at the following email addresses:

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Dated: December 22, 2023

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