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Paper 9
Date: December 16, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

ORTHOPHOENIX, LLC,
Patent Owner

Case IPR2014-00912
Patent 6,863,672 B2

Before BENJAMIN D. M. WOOD, MICHAEL J. FITZPATRICK, and BARRY L. GROSSMAN, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner, Wright Medical Technology, Inc., filed a corrected Petition for an *inter partes* review of claims 1–26 of U.S. Patent No. 6,863,672 B2 ("the '672 patent"). Paper 6, "Pet." Patent Owner, Orthophoenix, LLC, filed a Preliminary Response pursuant to 35 U.S.C. § 313. Paper 8, "Prelim. Resp."

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that the information presented does not show that there is a reasonable likelihood that Petitioner would prevail with respect to any of the claims challenged in the Petition. *See* 35 U.S.C. § 314(a). Accordingly, we *deny* the Petition.

A. Related Matters

Patent Owner asserted the '672 patent against Petitioner in *Orthophoenix, LLC v. Wright Medical Technology, Inc.*, Case No. 1:13-cv-01007 (D. Del.)). Pet. 1; Paper 5, 2. Patent Owner has also asserted the '672 patent in lawsuits against other parties. Paper 5, 2 (citing additional lawsuits). Also, Petitioner has filed an *inter partes* review of related U.S. Patent No. 6,440,138 B1. Pet. 1 (identifying IPR2014-00908); Paper 5, 3 (same).

B. The Asserted Grounds

Petitioner appears to identify the following three grounds of unpatentability:

claims 1–26 as obvious over Shapiro (Ex. 1030[1]);

claims 1–26 as obvious over Kogasaka (Ex. 1031[2]); and

claims 1–26 as obvious over Kogasaka in view of Shapiro.

Pet. 17–18. Subsequently, however, the Petition does not present an analysis of each of these grounds. For example, with respect to the independent claims, the Petition presents only two of these grounds. *See* Pet. 18 ("Independent Claims 1, 6, 11, 15, 19, and 23 would have been obvious in view of Shapiro or in view of Kogasaka").

C. The '672 Patent

The '672 patent discloses surgical tools having "structures that are deployed inside bone and, when manipulated, cut cancellous bone to form a cavity." Ex. 1029, Abstract. The record before us, which includes the '672 patent, the Petition, a declaration by Timothy P. Harrigan (Ex. 1033), and the Preliminary Response, does not appear to provide an express definition of cancellous bone. The '672 patent, however, does refer to cancellous bone in contrast to, and softer than, cortical bone. Ex. 1029, 6:28–30. The '672 patent also describes softer, cancellous bone as being bounded by harder, cortical bone. *Id*. Petitioner agrees with such a characterization of cancellous bone. *See, e.g.*, Pet. 9.

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[1] U.S. Patent No. 5,439,464 (issued Aug. 8, 1995).
[2] U.S. Patent No. 6,371,968 B1 (issued Apr. 16, 2002).

The cavity is formed as part of a therapeutic procedure to diagnose and/or treat diseased or compromised bone, and, after being formed, the cavity is filled with a material such as bone cement or an allograft material. Ex. 1029, 3:66–4:4, 12:64–66.

Figures 1 and 2 are reproduced below.

FIG. 1

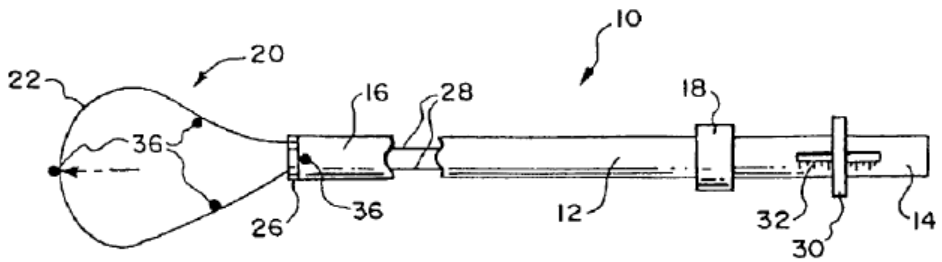
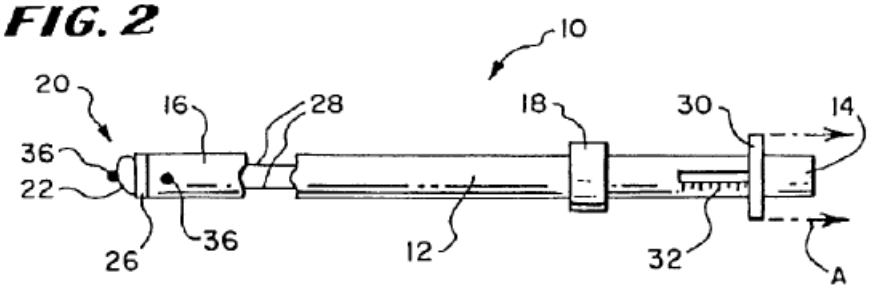


FIG. 2



Figures 1 and 2 illustrate tool 10 for forming a cavity in a targeted treatment area. *Id*. at 2:22–28. The tool comprises catheter tube 12 having proximal end 14 and distal end 16. *Id*. at 4:11–13. Handle 18 aids in gripping and maneuvering the tool. *Id*. at 4:13–14. At its distal end, the tool includes cavity forming structure 20 that comprises filament 22. *Id*. at 4:17–21. The filament can be made of resilient and inert wire such as stainless steel. *Id*. at 4:22–23. Radiological markers 36 may be arranged on the filament to permit visualization of the filament within a patient's body. *Id*. at 5:10–19. The "free ends" 28 of the filament extend through the catheter tube and are connected to controller 30 near the proximal end. *Id*. at

4:31–33. Sliding the controller toward the distal end causes deployment of the filament, and sliding it toward the proximal end causes retraction of the filament. *Id*. at 4:34–48. Figure 2 illustrates the filament being retracted. *Id*. at 2:27–28.

Figures 23 and 24 of the ’672 patent are reproduced below.

FIG. 23

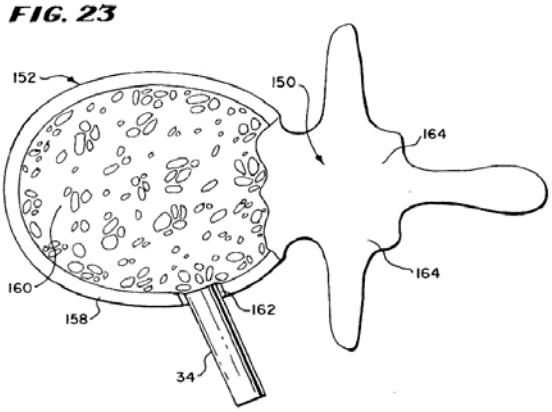
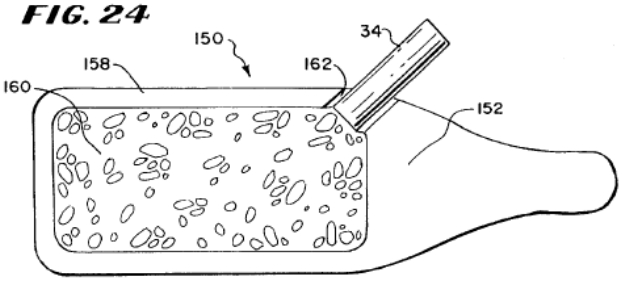


FIG. 24



Figures 23 and 24 illustrate top and side views, respectively, of human vertebra 150 with vertebral body 152, having portions removed to reveal cancellous bone 160 within the vertebral body. Ex. 1029, 3:28–31.

Cortical bone 158 surrounds the cancellous bone. *Id*. at 9:33–35. Access to the cancellous bone is achieved by drilling access portal 162 and inserting guide sheath or cannula 34 therethrough. *Id*. at 9:36–40, 9:51–52. A tool for creating a cavity in the cancelleous bone can be deployed through the cannula. *Id*. at 9:52–54.

Figure 25 is reproduced below.

FIG. 25

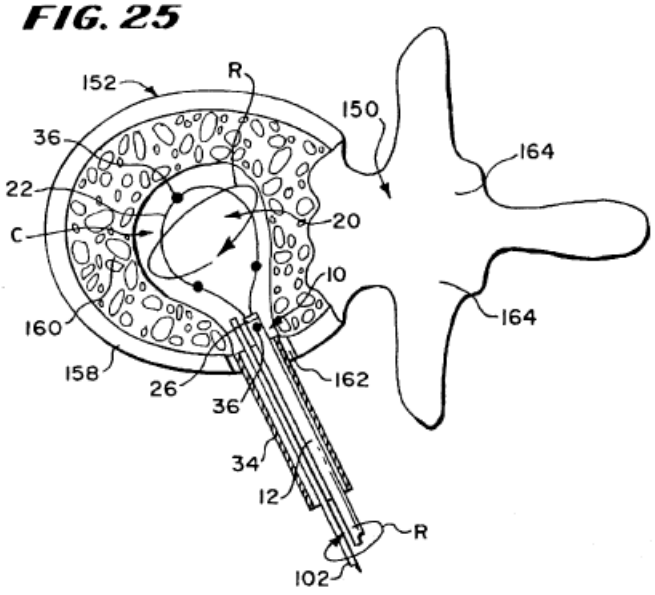


Figure 25 illustrates the tool shown in Figures 1 and 2 deployed inside the vertebra shown in Figures 23 and 24. Ex. 1029, 3:32–34. The Specification describes use of the tool in connection with Figure 25 as follows:

> Referring to FIG. 25, when the loop tool 10 is deployed outside the guide sheath 34 in the cancellous bone 160, the physician operates the controller 30 in the manner previously described to obtain a desired dimension for the loop structure 20, which can be gauged by radiologic monitoring using the on-board markers 36. The physician manually rotates the loop structure 20 through surrounding cancellous bone 160 (as indicated by arrows R in FIG. 25). The rotating loop structure 20 cuts cancellous bone 160 and thereby forms a cavity C. A suction tube 102, also deployed through the guide sheath 34, removes cancellous bone cut by the loop structure 20.

Id. at 9:62–10:6.

D. The Challenged Claims

Petitioner challenges all claims (i.e., claims 1–26) of the '672 patent. Pet. 2. Claims 1, 6, 11, 15, 19, and 23 are independent. Independent claim 1 is illustrative and reproduced below with emphasis added to limitations central to our analysis:

> 1. A method for creating a cavity in cancellous bone comprising
>
> providing a cannula having an axis that establishes a percutaneous path leading into bone,
>
> providing a shaft having an axis and a distal end portion adapted to be deployed inside the bone through the cannula, said distal end portion having *a cavity forming structure comprising a surface which directly contacts cancellous bone* in response to linear movement of the shaft along the axis of the cannula,
>
> deploying the cannula percutaneously to establish a path leading to inside bone,
>
> introducing the shaft by movement within and along the axis of the cannula to deploy the cavity forming structure inside the cancellous bone,
>
> moving the shaft linearly along, and not rotatingly about the axis of the cannula *to cause the surface to form a cavity in the cancellous bone*.

II. ANALYSIS

A. Claim Construction

"A claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). Pursuant to that standard, the claim language should be read in light of the specification, as it would be interpreted by one of ordinary skill in the art. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Thus,

we generally give claim terms their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning is the meaning that the term would have to a person of ordinary skill in the art in question.") (internal quotation marks omitted).

Petitioner proposes an express construction for "movement within and along the axis of the cannula." Pet. 10–11. Patent Owner proposes express constructions for "inside bone" and "vertebral body." It is not necessary, however, for purposes of this Decision, to construe expressly any of these terms.

B. Claims 1–26 as obvious over Shapiro

Shapiro discloses an arthroscopic spinal laminectomy or similar surgical procedure in which multiple cannulas are individually inserted, in a predetermined sequence, into predetermined areas of a patient's spinal column. Ex. 1030, Abstract. A first cannula is used for a viewing scope. *Id*. Second and third cannulas are used to "remove a portion of the ligamentum flavum[3] to expose the desired area of the patient's spinal bone and, if necessary, to remove any portion of bone necessary to expose the nerve and disc area." *Id*. "The nerves are then moved and the sequestered portion of the disc is removed." *Id*. A rongeur can be used within one of the working cannulas to suction "whatever body tissue and/or bone fragments are cut." *Id*.

[3] "Ligamentaum flavum is an elastic tissue which spans the space between adjacent vertebrae." Ex. 1030, 5:34–36.

Independent claim 1 requires "providing a shaft having an axis and a distal end portion . . . having a cavity forming structure comprising a surface which directly contacts cancellous bone" and "moving the shaft . . . to cause the surface to form a cavity in the cancellous bone." Independent claims 6, 11, 15, 19, and 23 recite similar limitations. Petitioner asserts that Shapiro teaches these limitations. Pet. 22, 28.

In particular, Petitioner points out Shapiro's teaching that "it may be necessary to use the Kerison rongeur suction punch to actually remove portions of bone, as what is required is that the ligamentum flavum ***and/or*** bone be removed to a sufficient extent to expose the spinal nerves." Pet. 23 (quoting Ex. 1029, 5:44–48). Thus, Petitioner concludes that Shapiro teaches that bone can be removed with its cutting tool. Pet. 23.

The independent claims, however, require a "cavity forming structure" that "directly contacts cancellous bone." Although Shapiro teaches that some amount of bone may be removed "to expose the spinal nerves," Shapiro does not teach that such bone would include cancellous bone.

Petitioner additionally asserts that, in view of Shapiro, it would have been obvious to a person having ordinary skill in the art to contact and cut cancellous bone. Pet. 24 (citing Ex. 1033 ¶ 68). In paragraph 68 of his declaration, Dr. Harrigan states:

> It would have been obvious to a POSA to use the instrument in *Shapiro* to contact and cut cancellous bone. For example, the instrument in *Shapiro* can be used as a side-cutting rongeur, where the tip of the device contacts and penetrates into cancellous bone tissue. This function is similar to the function of the devices shown in FIGs. 12 to 21 in the '672 patent. Given the depression caused by

> penetrating cancellous bone with the tip of the device, the action of the sleeve (48) and the cutting edge of the sleeve (50) would be able to remove cancellous bone in a precise manner. The instrument in *Shapiro* is likely to create a cavity in cancellous bone that is better-controlled for a shape and size than the instrument described in the '672 patent. Thus, a POSA would have been motivated to use *Shapiro's* tool to make a cavity in cancellous bone to avoid damage to nearby tissue outside the bone.

Ex. 1033 ¶ 68.

In the first sentence quoted above, Dr. Harrigan states his opinion that it would have been obvious to use the Shapiro cutting tool to contact and cut cancellous bone. The remainder of the relied-upon testimony, however, fails to persuade us why that would be so. The testimony explains why the cutting tool of Shapiro *could* be used to cut cancellous bone, but it does not provide sufficient reasons why it *would* have been obvious to so use it, particularly given that Shapiro does not teach contacting cancellous bone in the first instance.

Petitioner has not shown that Shapiro teaches "providing a shaft having an axis and a distal end portion . . . having a cavity forming structure comprising a surface which directly contacts cancellous bone," as required by claim 1 or the corresponding similar limitations of independent claims 6, 11, 15, 19, and 23. Petitioner has also not shown that any methods including such steps would have been obvious to a person having ordinary skill in the art.

Also, the claims require moving the shaft to cause the surface to form a cavity in the cancellous bone. Petitioner asserts that it would have been obvious to a person having ordinary skill in the art to use the instrument in Shapiro to contact

and cut cancellous bone to form a cavity therein. Pet. 29 (citing Ex. 1033 ¶ 79). In paragraph 79 of his declaration, Dr. Harrigan states:

> It would have been obvious to a POSA to use the instrument in *Shapiro* to contact and cut cancellous bone to form, for example, a cavity therein. As I explain above, the instrument in *Shapiro* can be used as a side-cutting rongeur, wherein the tip of the device contacts and penetrates into cancellous bone tissue. This function is similar to the function of the devices shown in FIGs. 12 to 21 in the '672 patent. Given the depression caused by penetrating cancellous bone with the tip of the device, the action of the sleeve (48) and the cutting edge of the sleeve (50) would be able to remove cancellous bone in a precise manner. The instrument in *Shapiro* is likely to create a cavity in cancellous bone that is better controlled for a shape and size than the instrument described in the '672 patent. Thus, a POSA would have been motivated to use *Shapiro's* tool to make a cavity in cancellous bone to avoid damage to nearby tissue outside the bone.

Ex. 1033 ¶ 79.

In the first sentence quoted above, Dr. Harrigan states his opinion that it would have been obvious to use the Shapiro cutting tool to contact and cut cancellous bone to form a cavity therein. The remainder of the relied-upon testimony, however, fails to persuade us why that would be so. The testimony explains why the cutting tool of Shapiro *could* be used to cut cancellous bone to form a cavity, but it does not provide a sufficient reason why it *would* have been obvious to so use it.

The purported reason Dr. Harrigan provides is to avoid damage to nearby tissue outside of the bone. Ex. 1033 ¶ 79. However, one could also avoid such damage by not cutting anything. What the Petition lacks is a sufficient rationale

for why, in the first instance, a person having ordinary skill would use the Shapiro cutting tool to cut a cavity in cancellous bone.

Petitioner has not shown that Shapiro teaches "moving the shaft . . . to cause the surface to form a cavity in the cancellous bone," as required by claim 1 or the corresponding similar limitations of independent claims 6, 11, 15, 19, and 23. Petitioner also has not shown that methods including such steps would have been obvious to a person having ordinary skill in the art.

For the foregoing reasons, Petitioner has not shown a reasonable likelihood of prevailing in showing that any of the independent claims or dependent claims[4] would have been obvious over Shapiro.

C. Claims 1–26 as obvious over Kogasaka

Kogasaka discloses "a cavity retaining tool for bone surgery and a cavity retaining tool for general surgery, to be used for retaining a cavity which acts as a working space during surgery." Ex. 1031, 1:11–14. Kogasaka is a lengthy document, including 70 columns of text and over one hundred figures.

One of the figures relied upon by Petitioner, and the focus of our analysis, is Figure 5, which is reproduced below.

[4] *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.").

FIG.5

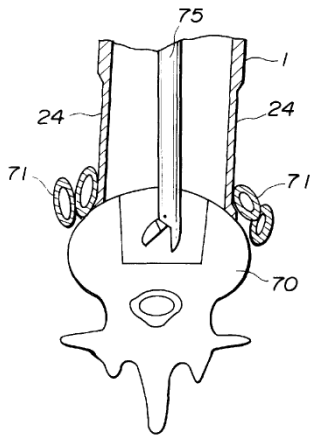


Figure 5 illustrates guide sheath or cannula 1 used to "treat the vertebra" having vertebral body 70. Ex. 1031, 16:14–16. Kogasaka's description of Figure 5 is extremely limited. It merely states:

> "FIG. 5 gives a third step necessary for the proper use of the cavity-retaining tool for bone surgery;" and
>
> "The air-tight core cylinder 4 is removed from the sheath 1, and tools for vertebral treatment are inserted through the treatment channel 11 to treat the vertebra as shown in FIG. 5."

Ex. 1031, 4:5–6, 16:13–16.

As set forth above, independent claim 1 requires "providing a shaft having an axis and a distal end portion . . . having a cavity forming structure comprising a surface which directly contacts cancellous bone" and "moving the shaft . . . to cause the surface to form a cavity in the cancellous bone," and independent claims 6, 11, 15, 19, and 23 recite similar limitations. Petitioner asserts that Kogasaka teaches these limitations. Pet. 22, 28.

In particular, Petitioner relies on Figure 5 of Kogasaka and declaration testimony of Dr. Harrigan. Pet. 24–25, 29–30. Petitioner asserts that Figure 5 "shows the curette (75) cutting in a location occupied by cancellous bone." Pet. 25 (citing Ex. 1033 ¶ 70). Paragraph 70 of Dr. Harrigan's declaration does not meaningfully support this assertion. It merely repeats the same essential assertion: "As shown in FIG. 5 (shown above) of Kogasaka, the curette (75) can be deployed inside bone through a cannula or sheath (1)." Ex. 1033 ¶ 70.

Figure 5 of Kogasaka, however, lacks any description or illustration convention to substantiate Petitioner's assertion regarding the location of the curette. In particular, Kogasaka never mentions that the curette in Figure 5 is cutting into cancellous bone of the vertebral body. Additionally, in Figure 5, it is not clear where the cutting blades of the curette are located along the axis extending perpendicularly into and out of the illustration. In other words, the curette may be positioned superior or inferior to the vertebral body.

Although Kogasaka does not further describe the treatment step shown in Figure 5, it does provide an exemplary treatment, stating:

> Take as an illustration of a case where an autograft is implanted for fixation of the front aspect of a vertebra. A lancet 76 is pushed into the L5-S intervertebral disc as shown in FIG. 6A, to cut part of a fibrous ring 61. Then, the medullar nucleus and disc are removed with, for example, a curette 75 as shown in FIG. 6B. Further, as shown in FIG. 6C, bones of L5 and S are removed with a chisel 77.

Id. at 16:16–22.

In this description, the only bone tissue that is described as being removed is "bones of L5 and S."[5] However, Kogasaka does not disclose that this bone tissue includes cancellous bone or that its removal results in a cavity formed in cancellous bone. In fact, Dr. Harrigan asserts that the entire L5 and S bones are removed. Ex. 1033 ¶ 33.

For the reasons discussed, we are not persuaded that Kogasaka discloses "providing a shaft having an axis and a distal end portion . . . having a cavity forming structure comprising a surface which directly contacts cancellous bone" or "moving the shaft . . . to cause the surface to form a cavity in the cancellous bone," as required by claim 1 or the corresponding similar limitations of independent claims 6, 11, 15, 19, and 23. Yet, Petitioner additionally asserts that it "would have been obvious" to a person having ordinary skill in the art "to use the curette in *Kogasaka* to contact and cut cancellous bone to form a cavity therein." Pet. 30 (citing Ex. 1033 ¶ 81).

In paragraph 81 of his declaration, Dr. Harrigan states:

> It would have been obvious to a POSA to use the curette in *Kogasaka* to contact and cut cancellous bone to form a cavity therein. For example, the gauges, chisels, and punches used in revision total hip surgery cut into bone and bone cement to prepare the inside of the

[5] L5 refers to the 5th lumbar vertebra, and S refers to the sacrum. *See* Ex. 1031, Fig. 7.

> femur for a new total hip. Ex. [1038[6]] at p. 3106; *see also* Figure 106-12. These tools and techniques were known widely. In revision total joint surgery, high forces are sometimes used, as evidenced by the punch in Figure 106-12 of *Evarts*, which is meant to be struck by a mallet. *Id.* at Figure 106-12. One of ordinary skill would have been motivated to use *Kogasaka's* tool to form a cavity in cancellous bone to avoid damage to nearby tissues.

Ex. 1033 ¶ 81.

In the first sentence quoted above, Dr. Harrigan states his opinion that it would have been obvious to use the Kogasaka cutting tool to contact and cut cancellous bone to form a cavity therein, but he does not persuasively explain why. Ex. 1033 ¶ 81. Although Dr. Harrigan testifies that gauges, chisels, and punches are used in revision total hip surgery to cut into bone to prepare the inside of the femur for a new total hip, citing Evarts, he does not explain the relevance of that testimony to establish obviousness of the claims. Ex. 1033 ¶ 81 (citing Ex. 1038). For example, the record lacks evidence to show that a person having ordinary skill in the art would use the Kogasaka cutting tool (which is disclosed for use within a cannula during spinal surgery) to cut into a cancellous tissue of the femur to prepare the femur for a new total hip. The record also lacks evidence to show that a person having ordinary skill in the art would use the Kogasaka cutting tool to cut

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[6] Exhibit 1038 is Evarts, McCollister C. (Ed.) *Surgery of the Musculoskeletal System*, 2nd ed. Churchill Livingstone, 1990, ISBN 0-443-08516-1, which was originally filed as Exhibit 1010. (Petitioner originally filed exhibits numbered 1001–1028 but failed to format and label them as required by our rules. It refiled replacement exhibits using new numbers 1029–1056. The Harrigan Declaration, however, cites to the old numbers.)

into cancellous tissue of any other bones, including that of vertebrae, to form a cavity therein. Thus, even if the Kogasaka cutting tool *could* be used to contact bone, including, specifically, cancellous bone, to form a cavity, Petitioner does not provide a sufficient reason for why it *would* have been obvious to so use it.

For the foregoing reasons, Petitioner has not shown a reasonable likelihood of prevailing in showing that any of the independent claims or dependent claims would have been obvious over Kogasaka.

III. CONCLUSION

Upon consideration of the Petition and Preliminary Response, we determine that there is not a reasonable likelihood that Petitioner would prevail on the ground of unpatentability raised with respect to any of the claims challenged in the Petition. We, therefore, deny the Petition. *See* 35 U.S.C. § 314(a); 37 C.F.R. §§ 42.108(b), (c).

IV. ORDER

Accordingly, it is

ORDERED that the Petition is denied and no trial is instituted.

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