

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,

Petitioner,

v.

BONUTTI SKELETAL INNOVATIONS LLC,

Patent Owner.

Case IPR2015-01346

Patent 6,099,531

Before MEREDITH C. PETRAVICK, ERICA A. FRANKLIN, and
BENJAMIN D. M. WOOD, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review

37 C.F.R. § 42.108

I. INTRODUCTION

Globus Medical, Inc. (“Petitioner”) filed a Corrected Petition requesting an *inter partes* review of claims 8, 9, 46, 49, 105, 107, 109, and 111 of U.S. Patent No. 6,099,531 (Ex. 1001, “the ’531 patent”). Paper 6 (“Petition” or “Pet.”). Bonutti Skeletal Innovations LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 8 (“Prelim. Resp.”).

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon considering the Petition and Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail in showing the unpatentability of any challenged claim. Accordingly, the Petition is *denied*.

A. Related Proceedings

Petitioner states that the ’531 patent is the subject of pending litigation in *Bonutti Skeletal Innovations, LLC v. Globus Medical Inc.*, C.A. No. 1:14-cv-006650-JBS-WY (E.D. Pa.). Pet. 2. Patent Owner identifies three district court cases as related matters: *Bonutti Skeletal Innovations, LLC v. Globus Medical Inc.*, C.A. No. 2:14-cv-6650-WBS (E.D. Pa.); *Biomet, Inc. v. Bonutti Skeletal Innovations LLC*, Case 3:13-cv-00176 (N.D. Ind.); and *Bonutti Skeletal Innovations LLC v. DePuy Synthes Sales Inc.*, Civil Action No. 1:14-14680-GAO (D. Mass.). Paper 5, 1.¹

¹ Patent Owner argues that we should deny institution of *inter partes* review because the Petition fails to identify all related matters. Prelim. Resp. 36–37. In view of our analysis, we consider Patent Owner’s argument moot.

Additionally, the parties indicate that Petitioner has filed petitions requesting *inter partes* review of claims of U.S. Patent No. 8,795,363 (Case IPR2015-01333); U.S. Patent No. 8,466,066 (Case IPR2015-01335); U.S. Patent No. 7,001,385 (Case IPR2015-01339); and U.S. Patent No. 6,423,063 (Case IPR2015-01345). Pet. 3; Paper 5, 2–3.

B. The '531 Patent (Ex. 1001)

The '531 patent relates to a method and apparatus for changing the spatial relationship between bones which are interconnected at a joint in a patient's body. Ex. 1001, 1:48–50. The invention comprises a wedge member that is moved into the joint and applies force against the bones. According to the Specification, one of the bones interconnected at a joint “is moved relative to the other by expanding at least a portion of the joint with a wedge member.” *Id.* at 1:52–54. Figures 5 and 7 of the '531 patent are reproduced below:

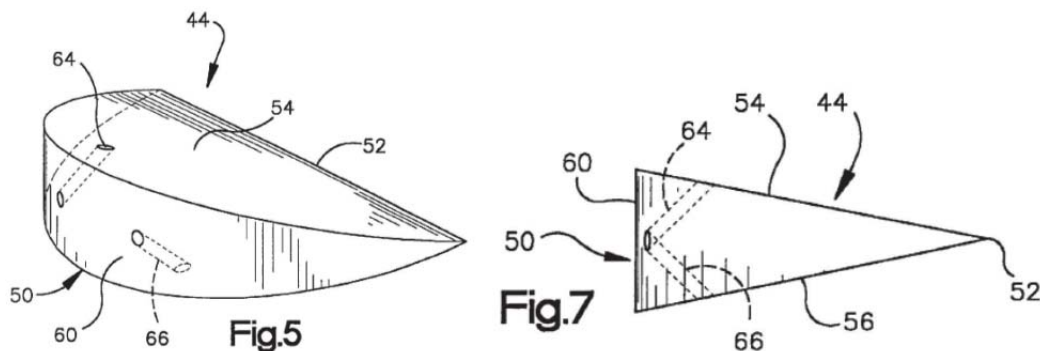


Figure 5 is a schematic pictorial illustration of a wedge member 44 of the invention, and Figure 7 illustrates a side view of the wedge member. *Id.* at 2:54–55, 58–59.

The Specification explains that in some embodiments of the invention, the wedge member 44 tapers from a thick end portion 50 to a thin end portion 52. *Id.* at 5:57–61. The Specification explains also that the major side

surfaces 54 and 56 of the wedge member 44 slope toward each other from the thick end portion 50 to the thin end portion 52 of the wedge member 44. *Id.* at 5:58–61. Additionally, the Specification describes an embodiment wherein the wedge member is formed of a rigid porous material having an open cell construction that enables bone to grow through the wedge member. *Id.* at 15:50–56.

C. Illustrative Claims

Claims 8 and 105 of the '531 patent are illustrative and reproduced below:

8. A method of changing a spatial relationship between first and second bones which are interconnected at a joint in a patient's body, said method comprising the steps of forming an opening in a portion of the patient's body to expose the joint interconnecting the first and second bones, moving the second bone relative to the first bone, said step of moving the second bone relative to the first bone includes expanding at least a portion of the joint interconnecting the first and second bones by applying force against the first and second bones with a wedge member and pivoting the first bone about an axis which extends through the joint interconnecting the first and second bones, closing the opening in the patient's body with at least a portion of the wedge member disposed between the first and second bones at the joint interconnecting the first and second bones, and, thereafter, transmitting force between the first and second bones through the wedge member to maintain the joint in the expanded condition.

105. An apparatus for use in changing the spatial relationship between first and second bones which are interconnected at a joint in a patient's body, said apparatus comprising a wedge member which is movable into the joint between the first and second bones, said wedge member having a thin end portion, a thick end portion, a first major side surface which extends from said thin end portion to said thick end portion, a second major side surface which intersects said first major side surface to form an edge at said thin end portion and extends from said thin end portion to said thick end portion, and a minor side surface which extends between said first and second major side surfaces and tapers from said thick end portion to said thin end portion, said wedge member having a plurality of passages which extend between said first and second major side surfaces for enabling bone to grow through said wedge member.

Ex. 1001, 23:9–26; 35:42–57.

D. The Prior Art

Petitioner relies upon the following prior art references:

Wagner	Wagner et al., U.S. Patent No. 5,306,309, issued Apr. 26, 1994	Ex. 1004
Dove	Dove et al., U.S. Patent No. 4,904,261, issued Feb. 27, 1990	Ex. 1005
Benezech	Alby and Benezech, FR 2,747,034 A1, published Oct. 10, 1997 (English Translation of Ex. 1006) ²	Ex. 1007
Brantigan	Brantigan, U.S. Patent No. 5,192,327, issued Mar. 9, 1993	Ex. 1008
Stone	Stone, U.S. Patent No. 6,008,433, issued Dec. 28, 1999	Ex. 1009

² Patent Owner asserts that Petitioner failed to provide a complete translation of Exhibit 1006. Prelim. Resp. 5 fn.1. According to Patent Owner, the translation, Ex. 1007, appears to omit the last five pages of Exhibit 1006. *Id.* In view of our analysis, we consider that contention moot.

Prewett Prewett et al., U.S. Patent No. 5,298,254, issued Ex. 1010
Mar. 29, 1994

Petitioner also relies upon the Declaration of Jorge A. Ochoa, Ph.D.,
P.E. (Ex. 1011).

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 8, 9, 46, 49, 105, 107,
109, and 111 of the '531 patent on the following grounds (Pet. 12):

Claims Challenged	Basis	Reference
8, 9, 107, 109, 111	§ 103(a)	Wagner
46, 49	§ 103(a)	Wagner and Dove
105	§ 103(a)	Benezech and Brantigan
105	§ 103(a)	Stone and Prewett

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity,

deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner does not propose a specific construction for any claim term. Pet. 8. With respect to claim 105, Patent Owner asserts that the broadest reasonable interpretation of the phrase “a minor side surface which extends between said first and second major side surfaces and tapers from said thick end portion to said thin end portion” does not include a minor side surface that “become[s] *thicker* between the thick end and the thin end.” Prelim. Resp. 22. According to Patent Owner, none of the embodiments depicted in Figures 1–11 show a minor side surface that becomes thicker between the thick end and the thin end of the wedge. *Id.* at 23 (citing Ex. 1001, Figs. 1–11).

Based upon our review, the Specification of the ’531 patent does not expressly define the claim term “tapers.” Thus, we adopt the ordinary and customary meaning of the term “tapers,” which is “to become progressively smaller toward one end.” Ex. 3001, MERRIAM-WEBSTER’S COLLEGIATE DICTIONARY, 10th ED. That meaning is consistent with (a) the Specification description that the wedge member 44 tapers from a thick end portion to a thin end portion, and (b) the Specification figures depicting the minor surface becoming progressively smaller from the thick end to the thin end. Ex. 1001, 5:57–61; 15:32–34; Figs. 5–7, 17. Claim 105, thus, requires a minor side surface that becomes progressively smaller from said thick end portion to said thin end portion.

In view of our analysis, we determine that express construction of additional claim terms is not necessary for purposes of this Decision.

B. Obviousness of Claims 8, 9, 107, 109, and 11 over Wagner

Petitioner asserts that claims 8, 9, 107, 109, and 11 of the '531 patent would have been obvious over Wagner. Pet. 12–28. Patent Owner disagrees. Prelim. Resp. 8–16.

Independent claim 8 recites a method of changing a spatial relationship between first and second bones which are interconnected at a joint. In particular, claim 8 requires that the step of moving the second bone relative to the first bone “includes expanding at least a portion of the joint interconnecting the first and second bones by applying force against the first and second bones with a wedge member.” Petitioner asserts that Wagner teaches this limitation. Pet. 18. According to Petitioner, Wagner’s method involves advancing the wedge member device by sliding it posteriorly in the intervertebral space, wherein “the first and second surfaces of the wedge shaped body engage the faces of the first and second vertebrae at which the device is implanted, forcing the intervertebral space open (i.e. expanding at least a portion of the joint) and moving the vertebrae apart.” *Id.* at 18 (citing Ex. 1011 ¶ 36). In other words, Petitioner asserts that Wagner describes “forcing the intervertebral space open with a wedge shaped device.” *Id.*

Patent Owner asserts that Wagner does not teach expanding at least a portion of the joint interconnecting the first and second bones, i.e., vertebrae, by applying force against the bones with the wedge member. Prelim. Resp. 8.³ According to Patent Owner, Wagner explains that the vertebrae are

³ Patent Owner argues also that despite having an opportunity to submit a Corrected Petition, Petitioner still improperly (a) incorporated arguments throughout its single-spaced claim charts, and (b) single-spaced its footnotes, in violation of the Board’s formatting rules. Prelim. Resp. 40 (citing 37 C.F.R. § 42.6). We agree and therefore have not considered Petitioner’s

spread apart during the surgical procedure prior to implantation and that the wedge member has no mechanical interaction with the vertebrae until after the implantation procedure is complete. *Id.* at 8–9 (citing Ex. 1004, 9:1–2, 32–34).

Based on the information presented, we agree with Patent Owner. Specifically, Wagner discloses an implant delivery tool 100 and reusable handle 114 for use in placing the implant between two vertebrae. Ex. 1004, 7:44–45. The delivery tool and handle are illustrated in Figures 12–14, reproduced below:

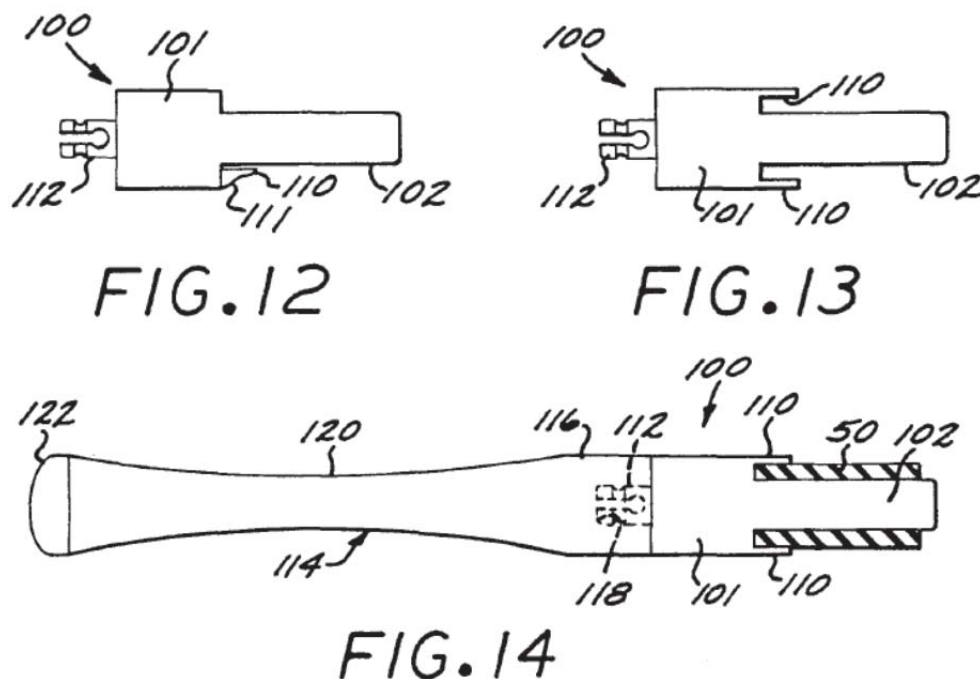


Figure 12 is an elevational view of one form of the implant delivery tool, and Figure 13 is another form of the delivery tool. *Id.* at 4:51–54. Figure 14 is a plan view of the implant delivery tool shown in Figure 13, with an

arguments improperly set forth in the claim charts or its single-spaced footnotes.

attached reusable handle 114. *Id.* at 4:55–56. Wagner describes the delivery tool as having a pair of flexible opposed arms 102 spaced apart and dimensioned “to releasably grasp and hold the implant 50 therebetween.” *Id.* at 7:46–50. As can be seen in Figure 14, the arms 102 extend beyond forward edge of implant 50.

Wagner describes also a stabilizing lip 110 extending outwardly from an edge of the base 101 and engaging the proximate end of the implant 50 to prevent it from tilting or sliding in an end-to-end fashion. *Id.* at 8:12–16. Referring to Figure 12, Wagner describes the stabilizing lip 110 may also be provided with a stop 111 that “engages the anterior edge of one of the vertebra when the implant has reached the proper position.” *Id.* at 8:16–23. As can be seen in Figure 14, without the stop 111, the stabilizing lips 110 form the outer edge of the delivery tool.

Wagner explains that the “butt end 122 of the handle 114 is rounded so that a surgeon may strike it with a hammer to urge the implant 50 into place between two vertebrae that have been slightly spread apart from their normal spacing during the surgical procedure.” *Id.* 8:65–9:2. Thus, contrary to Petitioner’s assertion, and that of its declarant Dr. Ochoa, Wagner does not describe using the implant to apply force against the vertebrae to expand a portion of the interconnecting joint. Rather, the joint is expanded prior to striking the handle with a hammer to urge the implant into place. Indeed, as discussed, the implant is situated in a somewhat recessed position within the stabilizing lips 110 and between the opposed arms 102, such that striking the handle with a hammer would cause the forward portion of the arms 102 and/or the outward portion of the stabilizing lips 110 to encounter the spaced apart vertebrae, rather than the implant itself.

Consequently, based on the information presented, Petitioner has not established sufficiently that Wagner teaches or suggests every limitation of independent claim 8. Therefore, on this record, we determine Petitioner has not set forth a reasonable likelihood that it would prevail in showing that independent claim 8, or its dependent claim 9, would have been obvious over Wagner.

Independent claim 107 also recites a method of changing a spatial relationship between first and second bones. In particular, claim 107 requires “moving the second bone relative to the first bone under the influence of force transmitted from the wedge member as the wedge member moves into the joint.” Claim 107 further recites that the “step of moving the second bone relative to the first bone includes applying force against a surface area on the first bone and against a surface area on the second bone with the wedge member as the wedge member moves into the joint.” Regarding these limitations, Petitioner asserts again that “as Wagner’s implant advances, sliding posteriorly in the intervertebral space, the first and second surfaces of the wedge shaped body engage the faces of the first and second vertebrae ... forcing the intervertebral space open (i.e., expanding at least a portion of the joint and moving the vertebrae apart.” Pet. 25, 27.

For the same reasons discussed regarding claim 8, we are not persuaded that Petitioner has established sufficiently that a person of ordinary skill in the art would have understood Wagner’s method as using the implant to apply force against the second vertebral bone relative to the first vertebral bone as the implant is moved into the joint, as required by claim 107, and its dependent claims 109 and 111. Therefore, based on the evidence presented, we determine Petitioner has not set forth a reasonable

likelihood that it would prevail in showing that claims 107, 109, and 111 would have been obvious over Wagner.

Accordingly, we decline to institute an *inter partes* review of claims 8, 9, 107, 109, and 111 of the '531 patent based on Wagner.

C. Obviousness of claims 46 and 49 over Wagner and Dove

Petitioner asserts that claims 46 and 49 of the '531 patent would have been obvious over the combination of Wagner and Dove. Pet. 29–41. Patent Owner disagrees. Prelim. Resp. 16–21.

Independent claim 46 recites a method of changing a spatial relationship between first and second bones which are interconnected at a joint. In particular, claim 46 requires “applying force against the first and second bones with a wedge member as the wedge member is moved into the joint to move the second bone from a first orientation relative to the first bone to a second orientation relative to the first bone.” Petitioner relies only on Wagner as teaching that limitation, for the same reasons discussed regarding the ground addressing claims 8, 9, 107, 109, and 111. Pet. 32–33. Thus, we disagree with Petitioner for the same reasons we discussed regarding that ground. Therefore, based on the evidence presented, we determine Petitioner has not set forth a reasonable likelihood that it would prevail in showing that independent claim 46, and its dependent claim 49, would have been obvious.

Accordingly, we decline to institute an *inter partes* review of claims 46 and 49, based on the combination of Wagner and Dove.

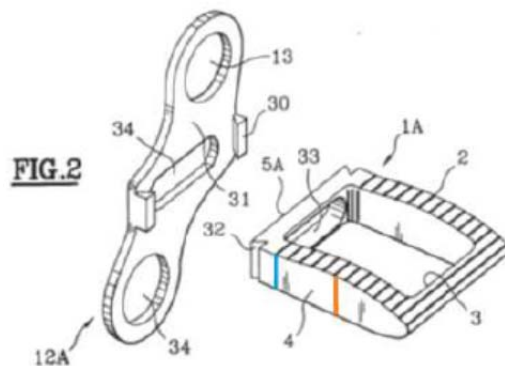
D. Obviousness of Claim 105 over Benezech and Brantigan

Petitioner asserts that claim 105 of the '531 patent would have been obvious over the combination of Benezech and Brantigan. Pet. 41–51. Patent Owner disagrees. Prelim. Resp. 21–31.

Independent claim 105 is directed to an apparatus for use in changing a spatial relationship between first and second bones which are interconnected at a joint. In particular, the apparatus comprises a wedge member which is movable into the joint to have “a minor side surface which extends between said first and second major side surfaces and tapers from said thick end portion to said thin end portion.” See, e.g., Ex. 1001, Fig. 7, (showing a side view of a wedge member 44 of the '531 patent with a minor side surface that tapers from the thick end portion 50 to thin end portion 52).

Petitioner asserts that Benezech discloses a wedge member “tapering from the anterior thick end portion of the body to the posterior thin end portion.” Pet. 46 (citing Ex. 1007, 3:3–5, 4:8–11, Fig. 2; Ex. 1011 ¶75). Petitioner does not rely on Brantigan for that claim limitation. *Id.*

Patent Owner asserts that in Benezech, instead of tapering, the minor side surface of the wedge member “gets thicker between the thick end and the thin end.” Prelim. Resp. 26. Patent Owner provided an annotated version of Benezech’s Figure 2, reproduced below:



Annotated Figure 2 illustrates an exploded perspective view of an embodiment of Benezech's setting system for vertebrae, Ex. 1007, 2:1–2, 3:23–24, with side wall 4 annotated by Patent Owner to indicate two different heights occurring from the thick end portion to the thin end portion, Prelim. Resp. 27. According to Patent Owner, "[t]he minor side surface in Benezech's Fig. 2 cage is taller at the point marked in orange (closer to the thin end) than it is at the point marked in the blue (closer to the thick end)." *Id.*

We agree with Patent Owner. As discussed above, we have adopted the ordinary and customary meaning of the term "tapers," which is "to become progressively smaller toward one end." Benezech's Figure 2 shows a rise in the height of the minor side surface as it extends from the thick end portion to the thin end portion of the wedge member. Thus, contrary to the assertions of Petitioner and Dr. Ochoa, we find that Benezech's Figure 2 does not disclose a cage, i.e., wedge member, that tapers, i.e., becomes progressively smaller, from the thick end portion to the thin end portion, as required by claim 105.

Moreover, although Benezech explains that the "cage can have various dimensions in height, in width, and in depth," the reference emphasizes that "the special profile and shape of the cage 1A in the example FIG. 2 enable the overall device to fit perfectly in the intervertebral space." Ex. 1007, 4:8–9, 5:1–3. Thus, to the extent Petitioner suggests that modifying the shape of the cage in Figure 2 to meet the claim limitation would have been obvious to a person of ordinary skill in the art, we disagree as Benezech characterizes the depicted "special profile and shape" in Figure 2 to "fit perfectly" in its intended location.

Therefore, based on the evidence presented, we determine Petitioner has not set forth a reasonable likelihood that it would prevail in showing that independent claim 105 would have been obvious over Benezech and Brantigan.

Accordingly, we decline to institute an *inter partes* review of claim 105 of the '531 patent based on the combination of Benezech and Brantigan.

E. Obviousness of Claim 105 over Stone and Prewett

Petitioner asserts that claim 105 of the '531 patent would have been obvious over the combination of Stone and Prewett. Pet. 51–59. Patent Owner disagrees. Prelim. Resp. 31–34.

As discussed, independent claim 105 is directed to an apparatus for use in changing a spatial relationship between first and second bones which are interconnected at a joint. In addition to the apparatus comprising a wedge member having “a minor side surface which extends between said first and second major side surfaces and tapers from said thick end portion to said thin end portion,” claim 105 recites further that the wedge member has “a plurality of passages which extend between said first and second major side surfaces for enabling bone to grow through said wedge member.”

In addition to disclosing a wedge member that tapers, Petitioner asserts that Stone discloses that the wedge member has a plurality of passages extending between the first and second major side surfaces. Pet. 58–59. In support of that assertion, Petitioner refers to Stone’s teaching that (a) the principal surfaces 112, 114 may be formed of a porous material which allows bone cells to grow within and throughout the pores, and (b) the body 110 of the device can be hollow and materials such as ground cancellous bone can be packed inside, wherein the holes on the principle

surface can facilitate packing of material within the body 110. *Id.* (citing Ex. 1009, 6:31–36, 7:9–14).

Patent Owner asserts Stone is “completely silent” as to whether the pores or holes on either surface of the wedge pass through the implant so as to provide passages which extend between the first and second major side surfaces for enabling bone to grow through said wedge member. Prelim. Resp. 32.

We agree with Patent Owner. Stone teaches two functions of the porous material on the principal surface(s) of the device: (1) to engage mechanically surfaces such as bone, thereby promoting contiguous bone formation and growth of bone cells around and attaching to the osteotomy device, and (2) to facilitate packing of materials such as cancellous bone with the hollow body 110 of the device. Ex. 1009, 6:30–35; 7:9–14. In view of those disclosures, contrary to the assertion of Petitioner and Dr. Ochoa, we find that a person of ordinary skill in the art would not read Stone as disclosing a plurality of passages extending between the major sides of the device. As Patent Owner asserted, Stone does not describe forming such passages. Moreover, it is unclear how having the body 110 of the device “packed” with cancellous bone would even allow for the existence of passages within it and extending between the holes on the principal surfaces.

Consequently, based on the evidence presented, we determine Petitioner has not set forth a reasonable likelihood that it would prevail in showing that independent claim 105 would have been obvious over Stone and Prewett.

Accordingly, we decline to institute an *inter partes* review of claim 105 of the ’531 patent based on the combination of Stone and Prewett.

III. CONCLUSION

For the foregoing reasons, we conclude Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing that any claim of the '531 patent is unpatentable based upon any of the asserted grounds.

IV. ORDER

In consideration of the foregoing, it is hereby ordered that the Petition is *denied*.

PETITIONER:

George D. Moustakas
David P. Utykanski
HARNESS, DICKEY & PIERCE, P.L.C.
gdmoustakas@hdp.com
dutykanski@hdp.com

PATENT OWNER:

Kevin K. McNish
Andrew G. Heinz
DESMARAIS LLP
BSIIPRService@desmaraisllp.com
kmcnish@desmaraisllp.com
aheinz@desmaraisllp.com