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Paper 10
Entered: October 13, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZIMMER BIOMET HOLDINGS, INC. and
ZIMMER DENTAL INC.,
Petitioner,

v.

FOUR MILE BAY, LLC,
Patent Owner.

Case IPR2015-01059
Patent 8,684,734 B1

Before BENJAMIN D. M. WOOD, RICHARD E. RICE, and TIMOTHY J. GOODSON, *Administrative Patent Judges.*

RICE, *Administrative Patent Judge*.

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

I. INTRODUCTION

Zimmer Biomet Holdings, Inc. and Zimmer Dental Inc. (collectively, "Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–3, 5–10, 12–15, and 17–27 ("the challenged claims") of U.S. Patent No. 8,684,734 B1 (Ex. 1001, "the '734 Patent"). Four Mile Bay, LLC ("Patent Owner") filed a Preliminary Response (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). Petitioner has shown a reasonable likelihood that it would prevail with respect to all of the challenged claims, and, accordingly, we institute an *inter partes* review with respect to those claims.

A. Related Proceedings

We are informed that Petitioner is named in a federal district court case involving the '734 Patent (*Four Mile Bay LLC v. Zimmer Holdings, Inc. et al.*, No. 3:14-CV-1300 (N.D. Ind.) (JVB)-(JEM)). Pet. 1; Paper 5, 2. We also are informed that Petitioner has filed a second Petition seeking *inter partes* review with respect to the '734 Patent. Pet. 1; Paper 5, 2; *see* Case IPR2015-01058, Paper 2.

B. The '734 Patent

The '734 Patent, titled "Dental Implant with Porous Body," issued from U.S. Application No. 13/571,375, filed August 10, 2012. Ex. 1001, at [54], [21], [22]. The '734 Patent states that it is a continuation-in-part of U.S. Application No. 13/195,872, filed on August 2, 2011, now U.S. Patent No. 8,297,974 B1, which is a continuation of a number of earlier-filed

applications, including U.S. Application No. 10/375,343, filed on February 27, 2003, now U.S. Patent No. 7,291,012 ("the '012 Patent"). *Id.* at [63]. Petitioner's annotated version of Figure 2 of the '734 Patent is reproduced below.

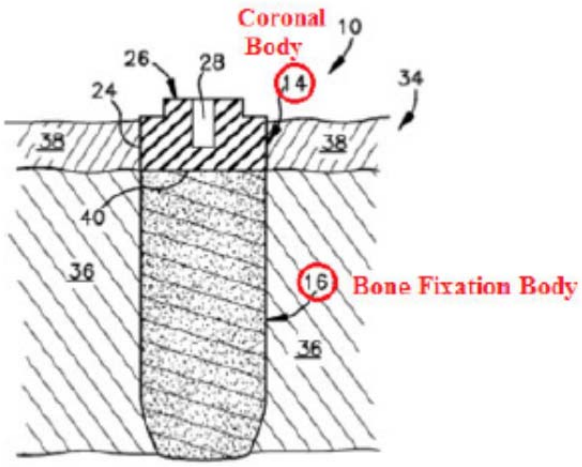

Fig. 2

Pet. 4.

As illustrated in Petitioner's annotated Figure 2, dental implant 10, which comprises coronal body 14 and bone fixation body 16, is embedded in jawbone 34 of a patient. Ex. 1001, 2:34–37, 62–63, Fig. 2. As described in the Specification, "bone fixation body 16 has a porous structure that extends from the outer surface and throughout the body." *Id.* at 3:1–2. The Specification further describes the porous structure as follows:

> Preferably, the average pore diameter of body 16 is about 40 μm to about 800 μm with a porosity from about 45% to 65%. Further, the interconnections between pores can have a diameter larger than 50–60 microns. In short, the geometric configuration of the porous structure should encourage natural bone to migrate and grow into and throughout the entire body 16.

Id. at 3:11–17. The Specification describes various materials and processes for forming the porous structure. *Id.* at 12:45–13:11. In one example, the porous structure is formed by coating a solid or hollow skeleton with a polymer, a metal, and/or a metal alloy, for example, coating a carbon skeleton with tantalum using a vapor deposition process. *Id.* at 13:1–4. The Specification additionally describes that "the porosity of the porous structure can be constant throughout the porous structure or change within the porous structure." *Id.* at 13:16–18.

C. Illustrative Claim

Claims 1, 8, 14, 20, 25, and 27 are independent. Claims 2, 3, and 5–7 depend directly from claim 1; claims 9, 10, 12, and 13 depend directly from claim 8; claims 15 and 17–19 depend directly from claim 14; claims 21–24 depend directly from claim 20; and claim 26 depends directly from claim 25. Claim 1 is illustrative of the claimed subject matter, and is reproduced below:

> 1. A dental implant, comprising:
> a coronal body having a proximal end with a connection shaped as a polygon to receive a dental component, having a distal end surface with an elongated protrusion that extends outwardly therefrom, and being formed of solid metal; and
> an elongated cylindrical porous body formed as a porous metal structure that is uniform and that includes a proximal end that engages the distal end surface of the coronal body at an interface,
> wherein the distal end surface of the coronal body has a circular shape, the proximal end of the porous body has a circular shape, and the solid metal of the circular shape of the coronal body interfaces with the porous metal structure of the

> circular shape of the porous body at the interface, and
>
> wherein the elongated protrusion of the coronal body includes a polygonal shape that extends into an opening of the porous body such that the porous metal structure completely surrounds and engages an exterior surface of the elongated protrusion that extends into the porous body.

Id. at 13:49–14:3.

D. The Asserted References

Petitioner relies upon the following references (Pet. 2–3):

Reference	**Patent No.**	**Date**	**Exhibit No.**
Otani	US 5,049,074	Sept. 17, 1991	Ex. 1008
Wagner	US 6,095,817	Aug. 1, 2000	Ex. 1009
Kaplan	US 5,282,861	Feb. 1, 1994	Ex. 1013

E. The Asserted Grounds

Petitioner challenges claims 1–3, 5–10, 12–15, and 17–27 of the '734 Patent on the following grounds (Pet. 3):

Reference(s)	**Basis**	**Claims Challenged**
Otani and Kaplan	§ 103(a)	1, 2, 5–10, 13–15, 17–23, and 25–27
Otani, Kaplan, and Wagner	§ 103(a)	3, 12, and 24

II. ANALYSIS

We turn now to Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a) for instituting review.

A. Claim Construction

As a first step in our analysis, we determine the meaning of the claims. In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278, 1279 (Fed. Cir. 2015) ("We conclude that Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA" and "the standard was properly adopted by PTO regulation."). Under the broadest reasonable interpretation standard, and absent any special definition, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner contends that a person of ordinary skill in the art ("POSITA")

> would have had an undergraduate degree in a relevant engineering field (e.g., Mechanical Engineering, Materials Science Engineering, Biomedical Engineering) with 3–5 years of experience with dental implants or similar implants or a graduate degree in a relevant field with 1–3 years of experience with dental implants or similar implants.

Pet. 11 n.2 (citing Ex. 1002 ¶ 10). Patent Owner does not oppose Petitioner's contention. *See* Prelim. Resp. 1–12. For purposes of this Decision, we adopt Petitioner's definition of a POSITA.

1. "porous" and "porosity"

The Specification provides the following lexicographical definition of "porous": "By 'porous,' it is meant that the material at and under the surface is permeated with interconnected interstitial pores that communicate with the surface." Ex. 1001, 3:3–5. For purposes of this Decision, we regard this definition as the broadest reasonable interpretation of the term "porous."

The Specification uses the term "porosity" in accordance with its ordinary meaning as the ratio or percentage of the volume of interstices of a material relative to the volume of its mass. *See id.* at 3:11–13 (stating that the "porosity" of the porous structure of body 16 is preferably "from about 45% to 65%"); EX. 3001 (MERRIAM WEBSTER'S COLLEGIATE DICTIONARY (10th ed. 1993)), 907 (porosity: "the ratio of the volume of interstices of a material to the volume of its mass").

2. "a porous . . . structure that is uniform," "a uniform porosity," and "a uniform porous . . . structure"

Claim 1 recites "a porous . . . structure that is uniform" (Ex. 1001, 13:55–56); claims 8 and 14 each recite "a uniform porosity" (*id.* at 14:46–47, 15:9–10); and claims 20, 25, and 27 each recite "a uniform porous . . . structure" (*id.* at 16:5, 32, 58–59). Petitioner refers collectively to these claim terms as the "uniform porosity features," and contends that they "should be construed together to have the same meaning," i.e., to require "a porous body or structure having a constant porosity throughout the body or structure." Pet. 12–13.

In support of its proposed claim construction, Petitioner argues that "[t]he plain and ordinary meaning of 'uniform' is 'not varying or changing' or 'constant.'" Pet. 13 (citing Ex. 1010, 1368; Ex. 1014, 1561). Although

the term "uniform" is not used in the Specification outside of the claims, Petitioner argues that the Specification supports its construction where it "contrasts the porous structure having 'constant' porosity with a porous structure in which the porosity 'change[s] within the porous structure.'" *Id.* at 14 (quoting Ex. 1001, 13:16–18).

Petitioner acknowledges that the Board reached a different interpretation of the term "uniform" during prosecution of the '012 Patent Application (of which the '734 Patent Application is a continuation-in-part, as noted above), but argues that the Board's decision in the previous case is inapplicable here because the disclosure of the '734 Patent Application is different from the disclosure of the '012 Patent Specification:

> The Board previously determined that a "completely uniform porous structure" simply refers to a structure in which no part is non-porous. Though the construed phrase has similarities to the uniform porosity features of the '734 patent claims, the Board's finding was made in view of the different disclosure of the original patent and thus does not apply here.

Id. at 17 n.4 (citing Ex. 1003, 39–40). Petitioner asserts that the Board, in the previous case, found no support in the '012 Patent Application for the appellant's argument that the claim term "completely uniform porous structure" required constant porosity and pore size throughout the porous structure. *Id.* at 8. Petitioner argues that the disclosure of the '734 Patent Specification, in contrast, fully supports Petitioner's proposed construction requiring a porous structure having a *constant* porosity throughout the structure. *Id.* at 14 (quoting Ex. 1001, 13:16–18).

Further, Petitioner argues that the doctrine of prosecution history disclaimer supports its proposed claim construction. *Id.* at 14–17.

According to Petitioner, the applicant amended the claims of the '734 Patent Application during prosecution to recite the uniform porosity features, and relied on those features to overcome the Examiner's rejection based on the Otani prior art reference. *Id.* at 15–16. Petitioner particularly relies on the following statement in the applicant's Response to the Examiner's Office Action mailed June 19, 2013:

> Independent claim 21 recites a porous metal structure that is uniform. Independent claim 28 recites a porous body with a uniform porosity. Independent claim 34 recites a porous body with a uniform porosity. Independent claim 40 recites a bone fixation body with a uniform porous metal structure. *By contrast, Otani teaches* a dental implant with a porous coating that has a "pore distribution such that the interior of the fiber material i.e. the core material side, is most dense and *the porosity gradually increases* toward the external surface" (col. 3, lines 35–38).

Id. at 15 (quoting Ex. 1004, 38–39).[1] Petitioner additionally relies on an Applicant-Initiated Interview Summary memorializing the Examiner's agreement that "requiring the porous structure to be 'uniform'" would overcome the rejections based on Otani because "the porosity of the porous layer [of Otani] changes." Ex. 1004, 51, *cited in* Pet. 15–16; *see* Ex. 1008, 3:35–39 (disclosing "a pore distribution such that the interior of the fiber material i.e. the core material side, is most dense and the porosity gradually increases towards the external surface layer"). Petitioner argues that "the Applicant clearly and unmistakably distinguished Otani's changing porosity

[1] We have corrected the quotation to conform with Exhibit 1004, while maintaining Petitioner's emphasis (shown in italics).

within the porous body from the claimed 'uniform' porous body of the claims." Pet. 16 (italics omitted).

In response, Patent Owner argues that "uniform porosity (and equivalent terms) means the entire structure is porous, the porosity of the porous layer does not change, but there is no requirement that porosity or pore size be identical throughout the body." Prelim. Resp. 7. Patent Owner relies on the disclosure in the Specification of "a completely porous structure that extends throughout the entire body from the proximal to distal ends" and an "average pore diameter of . . . about 40 μm to about 800 μm with a porosity from about 45% to 65%." *Id.* at 2–3 (citing Ex. 1001, 2:56–58, 3:9–17); *see id.* at 4–5.

Upon consideration of the competing arguments, we determine at this stage of the proceeding that the broadest reasonable interpretation consistent with the Specification of "a uniform porosity" is a porosity that is constant throughout a porous structure. We similarly determine that the broadest reasonable construction consistent with the Specification of both "a porous . . . structure that is uniform" and "a uniform porous . . . structure" is a porous structure having a constant porosity throughout the structure. As Petitioner argues, the Specification contrasts a porous structure having constant or uniform porosity with a porous structure in which the porosity changes. Ex. 1001, 13:16–18; *see* Pet. 14.

3. Other claim terms

At this stage of the proceeding, none of our determinations regarding Petitioner's proposed grounds of unpatentability requires us to interpret expressly any other claim term.

B. Asserted Obviousness

A claim is unpatentable for obviousness "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).[2] A patent claim composed of several elements, however, is not proved obvious merely by demonstrating that each of its elements was known, independently, in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, when in evidence. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

[2] Pub. L. No. 112-29, effective March 16, 2013, changed § 103. Because the '077 Patent has an effective filing date before March 16, 2013, we have quoted the unchanged version of § 103.

In the present case, Petitioner contends that claims 1, 2, 5–10, 13–15, 17–23, and 25–27 are unpatentable as obvious over Otani and Kaplan and that claims 3, 12, and 24 are unpatentable as obvious over Otani, Kaplan, and Wagner. *See* Pet. 3.

1. Overview of Otani

Otani discloses a dental implant comprising a core material and a porous layer formed on the surface of the core material. Ex. 1008, 2:50–53. Figure 10 of Otani is reproduced below.

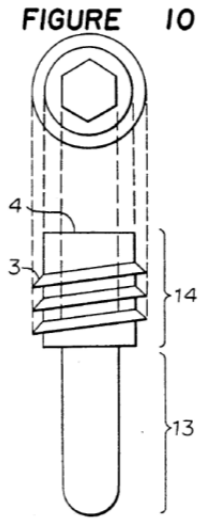

Figure 10 illustrates an embodiment of a dental implant. *Id.* at 6:23–24. A titanium rod was ground to form neck portion 14 and porous layer base portion 13. *Id.* at 6:24–26. Neck portion 14 includes hexagonal hole 4 "for fixing a crown base." *Id.* at 6:29–31. Figure 13 of Otani is reproduced below.

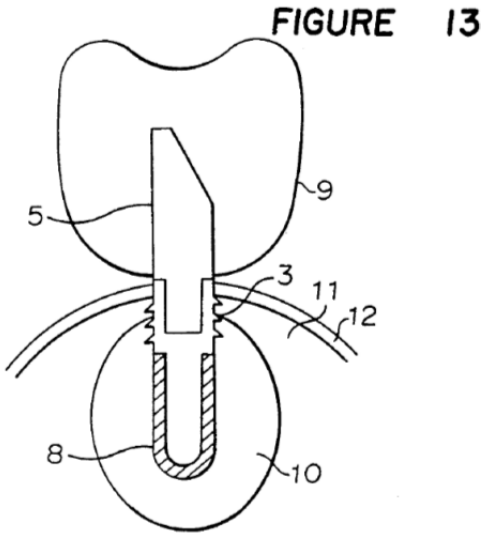

Figure 13 is a cross-sectional view illustrating crown 9 mounted on crown base 5, which is received in hole 4 of neck portion 14 (identified by element number in Figure 10 but not in Figure 13). *Id.* at 6:56–66. Also shown in Figure 13 are threads 3, porous layer 8, sponge bone 10, dense bone 11, and gingival epithelium 12. *Id.* at 6:27, 56–66. Otani teaches making the porous layer by depositing carbon among carbon fibers wound on the porous layer base portion. *Id.* at 6:36–41. The porous layer made in this manner has a porosity that "increase[s] towards the surface." *Id.* at 6:50–52.

2. Overview of Kaplan

Kaplan discloses a porous metal biomaterial for use in dental implants. Ex. 1013, 3:43–65. According to Kaplan, "[t]he open cell metal structure of the present invention offers highly interconnected, three-dimensional porosity that is uniform and consistent, a structure exceptionally similar to that of natural cancellous bone." *Id.* at 6:1–4. Kaplan's metal structure is made by chemical vapor deposition of a metallic material, such

as tantalum or niobium, into reticulated (porous) vitreous carbon foam. *Id.* at 7:20–25.

3. Overview of Wagner

Wagner discloses dental implants having different surface regions. Ex. 1009, 7:13–14, Figs. 8, 9. Figure 9 of Wagner is reproduced below.

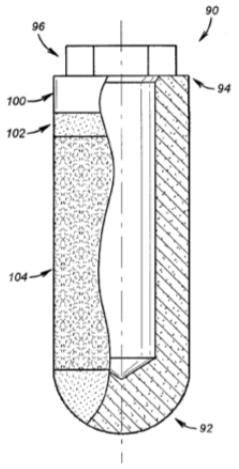

FIG. 9

As illustrated in Figure 9, implant 90 has three distinct surface regions numbered 100, 102, and 104. *Id.* at 7:13–14. Surface region 100, which is adjacent to engaging interface 96, is composed of non-porous, biocompatible metal that is substantially smooth. *Id.* at 4:65–66 (describing region 28 of Figure 1), 7:13–14 (describing surface region 100 as similar to region 28). Surface region 102, which is adjacent to region 100, is composed non-porous, biocompatible metal that is sufficiently rough to permit bone to attach thereto. *Id.* at 4:42–44 (describing region 26 of Figure 1), 7:19–20 (describing surface region 102 as similar to region 26). Surface region 104, which is adjacent to region 102 and extends to apical end 92, is coated with biocompatible material 80. *Id.* at 6:18–7:2 (describing region 74 of Figures 6A and 7A), 7:21–22 (describing surface region 104 as similar to region 74).

4. Analysis—Otani and Kaplan

Petitioner argues that Otani teaches all the limitations of independent claims 1, 8, 14, 20, 25, and 27, except the uniform porosity features, for which Petitioner relies on the teachings of Kaplan. Pet. 26–57. Petitioner contends that a POSITA would have been motivated to modify the dental implant of Otani to utilize the uniform, open cell metal structure of Kaplan for the benefits taught by Kaplan, including a structure similar to natural cancellous bone that promotes bone ingrowth. Pet. 24–25 (citing Ex. 1013, 6:1–6). Petitioner's contentions are supported by the Declaration of James Earthman, Ph.D. Ex. 1002 ¶¶ 31–34. We are persuaded that Petitioner has provided sufficient reasoning to support a legal conclusion of obviousness and that, on the record at this stage of the proceeding, the combination of Otani and Kaplan teaches all the limitations of independent claims 1, 8, 14, 20, 25, and 27.

Patent Owner's argument that Kaplan "*teaches away* from the metal porous structure claimed in the '734 Patent" is unpersuasive. Prelim. Resp. 10. Patent Owner selectively quotes from Kaplan's discussion of prior art and fails to acknowledge or address Kaplan's disclosure with respect to the uniform, open cell metal structure on which Petitioner relies. *Compare id.* at 11 (quoting Ex. 1013, 2:63–65: "Many existing metallic biomaterials, however, do not easily lend themselves to fabrication into the porous structures that are most desirable for bone implants."), *with* Pet. 23 (quoting Ex. 1013, 6:1–4: "[t]he open cell metal structure of the present invention offers highly interconnected, three-dimensional porosity that is *uniform* and consistent, a structure exceptionally similar to that of natural cancellous bone.").

Petitioner also argues persuasively that the combination of Otani and Kaplan teaches all the additional limitations of dependent claims 2, 5–7, 9, 10, 13, 15, 17–19, 21–23, and 26. Pet. 33–55. Patent Owner does not challenge Petitioner's contentions with respect to those dependent claims. Prelim. Resp. 1–12.

Having reviewed the Petition, the Preliminary Response, and the evidence of record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to its challenge to claims 1, 2, 5–10, 13–15, 17–23, and 25–27 as obvious over Otani and Kaplan.

5. Analysis—Otani, Kaplan, and Wagner

Petitioner asserts that claims 3, 12, and 24 are unpatentable as obvious over Otani, Kaplan, and Wagner. Pet. 3. Claim 3 depends from claim 1 and recites that "the coronal body includes an exterior surface that is microtextured and an exterior surface that is smooth." Claim 12 depends from claim 8 and recites that "an exterior surface of the coronal body includes a first region with a smooth outer surface and a second region with a microtextured surface that is contiguous and adjacent the first region." Claim 24 depends from claim 20 and recites "the coronal body has an outer surface with a first region adjacent a second region in which the first region is smooth and the second region is non-porous and micro-textured."

Petitioner contends that a POSITA would have been motivated, for the purpose of providing "optimum hygiene," to modify the core material of Otani's dental implant such that an external surface portion at the coronal end is non-porous and smooth as taught by Wagner. *Id.* at 59 (citing Ex. 1009, 2:41–42; Ex. 1002 ¶ 102); *see* Ex. 1009, 2:65–3:2, 4:66–5:5. Patent Owner does not argue the patentability of dependent claims 3, 12, and 24

separate from the independent claims. Prelim. Resp. 12. We are persuaded that Petitioner has provided sufficient reasoning to support a legal conclusion of obviousness and that, on the record at this stage of the proceeding, the combination of Otani, Kaplan, and Wagner teaches all the limitations of claims 3, 12, and 24.

Having reviewed the Petition, the Preliminary Response, and the evidence of record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to its challenge to claims 3, 12, and 24 as obvious over Otani, Kaplan, and Wagner.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has established a reasonable likelihood of prevailing on its challenges to claims 1, 2, 5–10, 13–15, 17–23, and 25–27 as obvious over Otani and Kaplan; and claims 3, 12, and 24 as obvious over Otani, Kaplan, and Wagner. The Board has not made a final determination concerning patentability of any of the challenged claims.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that an *inter partes* review of claims 1–3, 5–10, 12–15, and 17–27 of the ’734 Patent is granted;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of the '734 Patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the trial is limited to the following grounds: claims 1, 2, 5–10, 13–15, 17–23, and 25–27 as obvious over Otani and Kaplan; and claims 3, 12, and 24 as obvious over Otani, Kaplan, and Wagner.

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