

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

US ENDODONTICS, LLC,
Petitioner,

v.

GOLD STANDARD INSTRUMENTS, LLC,
Patent Owner.

Case PGR2015-00019
Patent 8,876,991 B2

Before JOSIAH C. COCKS, HYUN J. JUNG, and
TIMOTHY J. GOODSON, *Administrative Patent Judges*.

GOODSON, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 328(a) and 37 C.F.R. § 42.208

I. INTRODUCTION

US Endodontics, LLC (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting post-grant review of claims 12–16 of U.S. Patent No. 8,876,991 B2 (Ex. 1001, “the ’991 patent”). Gold Standard Instruments, LLC (“Patent Owner”) filed a Preliminary Response (Paper 14, “Prelim. Resp.”) to the Petition. On January 29, 2016, we instituted a post-grant review of claims 12–16 on certain grounds of unpatentability alleged in the Petition. *See* Paper 17 (“Dec. on Inst.”).

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 27, “PO Resp.”), and Petitioner filed a Reply (Paper 31, “Pet. Reply”). In addition, Patent Owner filed Observations on Cross Examination (Paper 37), to which Petitioner filed a Response (Paper 45). Both parties also filed motions to exclude evidence, and the briefing on those motions included oppositions and replies. *See* Papers 36, 40, 43, 44, 46, 47. The parties presented oral argument at a hearing held on October 19, 2016. Paper 53 (“Tr.”).

For the reasons explained below, upon consideration of the evidence and arguments of both parties, we determine that Petitioner has shown by a preponderance of the evidence that claims 12–16 of the ’991 patent are unpatentable. *See* 35 U.S.C. § 326(e).

A. *Related Matters*

Petitioner has filed two petitions for *inter partes* review challenging U.S. Patent No. 8,727,773 (“the ’773 patent”), which is related to the ’991 patent. We instituted review on several of the grounds presented in the first petition, and issued a Final Written Decision holding all of the challenged claims unpatentable. *US Endodontics, LLC v. Gold Standard Instruments, LLC*, Case IPR2015-00632 (PTAB Aug. 1, 2016) (Paper 78). We denied

institution on any of the grounds presented in the second petition. *US Endodontics, LLC v. Gold Standard Instruments, LLC*, Case IPR2015-01476 (PTAB Oct. 26, 2015) (Paper 13).

In addition, the '773 patent and U.S. Patent No. 8,562,341, another patent related to the '991 patent, are being asserted against Petitioner in an ongoing lawsuit in the U.S. District Court for the Eastern District of Tennessee, *Dentsply International, Inc. v. US Endodontics, LLC*, Case No. 2:14-cv-00196-JRG-DHI. Pet. 1; Paper 52, 3. The parties list a number of pending patent applications owned by Patent Owner that may be affected by this proceeding. *See* Pet. 1; Paper 52, 3–4.

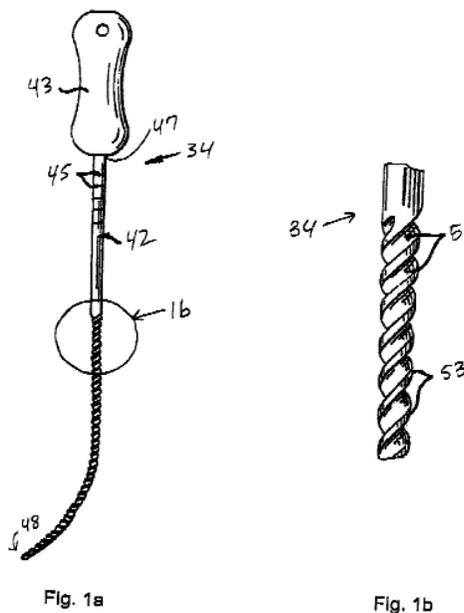
B. The '991 Patent

The '991 patent is titled “Dental and Medical Instruments Comprising Titanium.” Ex. 1001, Title. The invention is described as serving to “overcome[] the problems encountered when cleaning and enlarging a curved root canal.” *Id.* at 2:59–60. The '991 patent explains that flexibility is a desirable attribute for endodontic files, but that in the prior art, the shank portions of files of larger sizes are relatively inflexible, which impedes the therapy of a root canal. *Id.* at 2:4–26.

The '991 patent also describes that it is known in the art that endodontic files may be formed of “superelastic alloys such as nickel-titanium that can withstand several times more strain than conventional materials without becoming plastically deformed.” *Id.* at 2:43–46. The '991 patent further explains that a property termed “shape memory . . . allows the superelastic alloy to revert back to a straight configuration even after clinical use, testing or fracture (separation).” *Id.* at 2:46–49. According to the '991 patent, there remained a need for endodontic instruments that “have high

flexibility, have high resistance to torsion breakage, maintain shape upon fracture, can withstand increased strain, and can hold sharp cutting edges.”
Id. at 2:50–55.

Figures 1a and 1b, reproduced below, illustrate “a side elevational view of an endodontic instrument” (Fig. 1a), and “a partial detailed view of the shank of the endodontic instrument shown in FIG. 1a” (Fig. 1b). *Id.* at 3:26–29.



The '991 patent describes that the “endodontic instrument . . . shown in FIG. 1a . . . includes an elongate shank 42 mounted at its proximate end 47 to a handle 43.” *Id.* at 4:5–8. The '991 patent also explains that fabricating a medical instrument in accordance with the invention involves selecting a superelastic titanium alloy for the shank and subjecting the instrument to “heat-treatment” so as to “relieve stress in the instrument to allow it to withstand more torque, rotate through a larger angle of deflection, change the handling properties, or visually exhibit a near failure of the instrument.” *Id.* at 6:2–5.

C. Illustrative Claim

Claim 12, reproduced below, is the only independent claim among the challenged claims:

12. A method for manufacturing or modifying an endodontic instrument for use in performing root canal therapy on a tooth, the method comprising:

(a) providing an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank, the shank comprising a superelastic nickel titanium alloy, and

(b) after step (a), heat-treating the entire shank at a temperature above 25° C. up to but not equal to the melting point of the superelastic nickel titanium alloy,

wherein the heat treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1.

D. Instituted Grounds of Unpatentability

We instituted trial as to claims 12–16 of the '991 on the following grounds:

1. Whether claims 12–16 are unpatentable under 35 U.S.C. § 112(a) for lack of enablement;
2. Whether claims 12–16 are unpatentable under 35 U.S.C. § 112(a) for lack of written description;
3. Whether claims 12–16 are unpatentable under 35 U.S.C. § 102 as being anticipated by Luebke 2008;¹

¹ U.S. Patent App. Pub. No. 2008/0032260 A1, published Feb. 7, 2008 (Ex. 1022).

4. Whether claim 15 is unpatentable under 35 U.S.C. § 103 as obvious over Luebke 2008 alone or in view of Heath² or ISO 3630-1;³
5. Whether claims 12–14 and 16 are unpatentable under 35 U.S.C. § 102 as being anticipated by Kuhn;⁴ and
6. Whether claim 15 is unpatentable under 35 U.S.C. § 103 as obvious over Kuhn alone or in view of Heath or ISO 3630-1.

See Dec. on Inst. 37.

II. ANALYSIS

A. *Post-Grant Review Eligibility*

1. *Legal Standards for Post-Grant Review Eligibility*

The post-grant review provisions set forth in Section 6(d) of the AIA⁵ apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) (“The amendments made by subsection (d) . . . shall apply only to patents described in section 3(n)(1).”). The first-inventor-to-file provisions apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time a claim to a claimed invention that has an effective filing date on or after March 16, 2013. *See* AIA § 3(n)(1). The relevant statute defines the “effective filing date” as:

² U.S. Patent No. 5,628,674, issued May 13, 1997 (Ex. 1024).

³ International Standard ISO 3630-1, 1st ed. (1992) (Ex. 1023).

⁴ Grégoire Kuhn & Laurence Jordan, *Fatigue and Mechanical Properties of Nickel-Titanium Endodontic Instruments*, 28 J. ENDODONTICS 716 (2002) (Ex. 1030).

⁵ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”).

(A) if subparagraph (B) does not apply, the actual filing date of the patent or the application for the patent containing a claim to the invention; or

(B) the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority under section 119, 365(a), 365(b), 386(a), or 386(b) or to the benefit of an earlier filing date under section 120, 121, 365(c), or 386(c).

35 U.S.C. § 100(i)(1). Entitlement to the benefit of an earlier date under §§ 119, 120, 121, and 365 is premised on disclosure of the claimed invention “in the manner provided by § 112(a) (other than the requirement to disclose the best mode)” in the earlier application. *See* 35 U.S.C. §§ 119(e), 120.⁶

Applying these statutes to determine whether a patent is subject to the first-inventor-to-file provisions of the AIA, and therefore eligible for post-grant review, is straightforward when the application from which the patent issued was filed before March 16, 2013, or when the application was filed on or after March 16, 2013 without any priority claim. The determination is more complex, however, for a patent that issues from a “transition application,” which is an application filed on or after March 16, 2013 that claims the benefit of an earlier filing date prior to March 16, 2013. *See* MPEP § 2159.04. As a consequence of the statutes discussed above, a patent that issues from a transition application is available for post-grant review “if the patent contains . . . at least one claim that was not disclosed in compliance with the written description and enablement requirements of § 112(a) in the earlier application for which the benefit of an earlier filing date prior to March 16, 2013 was sought.” *Inguran, LLC v. Premium*

⁶ Section 386 is irrelevant here because it concerns the right of priority for international design applications. *See* 35 U.S.C. §§ 381–390.

Genetics (UK) Ltd., Case PGR2015-00017, slip op. at 11 (PTAB Dec. 22, 2015) (Paper 8).

Separate from the requirement that the patent is subject to the AIA's first-inventor-to-file provisions, an additional requirement for post-grant review eligibility is that "[a] petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent." 35 U.S.C. § 321(c); *see* 37 C.F.R. § 42.202(a). Here, Patent Owner does not dispute that the Petition was filed within the nine month filing deadline.⁷ *See* Pet. 11. Nor does Patent Owner dispute Petitioner's representation that it is not barred or estopped from requesting post-grant review of the '991 Patent. *See id.*

Patent Owner does contend, however, that the '991 patent is ineligible for post-grant review because its claims are entitled to an effective filing date of June 7, 2005. *See* PO Resp. 40. Thus, with respect to post-grant review eligibility, the only dispute is whether the '991 patent is subject to the first-inventor-to-file provisions of the AIA.

2. Facts Relevant to Post-Grant Review Eligibility

The application that issued as the '991 patent was filed on January 29, 2014, and was assigned Application No. 14/167, 311 ("the '311 application"). Ex. 1001, at [21], [22]. The '991 patent claims priority to a series of continuation and divisional applications reaching back to June 7, 2005, as well as a provisional application filed on June 8, 2004. *Id.* at [60]. Consistent with the characterization of the earlier applications in the '991 patent's priority claim, Petitioner agrees that "[t]he descriptions in the

⁷ The '991 patent issued on November 4, 2014. Ex. 1001, at [45]. The Petition was filed on August 3, 2015. *See* Paper 3, 1.

priority applications are substantively the same except for their claims; the entire family comprises continuation and divisional applications (but not continuation-in-part applications).” Pet. 32. Thus, it is undisputed that the Specification of the ’991 patent is substantively identical to the specifications of the applications to which it claims priority. *See* Prelim. Resp. 25; PO Resp. 40. It is also undisputed that the claims in the ’311 application, as filed on January 29, 2014, are identical to the claims as issued in the ’991 patent. *See* Pet. 6; Ex. 1003, 23–25.

3. *Burden of Proof on Post-Grant Review Eligibility*

In this case, eligibility hinges on whether the ’991 patent is subject to the first-inventor-to-file provisions of the AIA. That analysis, in turn, depends on whether the patent contains any claims having an effective filing date on or after March 16, 2013. In the Petition, Petitioner argued that “Patent Owner bears the ultimate burden of demonstrating entitlement to an earlier application’s filing date.” Pet. 22 (citing *In re NTP, Inc.*, 654 F.3d 1268, 1276–77 (Fed. Cir. 2011)). Petitioner argued that the ’991 patent is eligible for post-grant review because “Patent Owner will not be able to meet its burden of proving that the claims at issue are entitled to a filing date earlier than the . . . January 29, 2014 filing date.” *Id.* at 23. In our Decision on Institution, we determined that it is Petitioner, not Patent Owner, that bears the burden to prove that the ’991 patent is subject to the first-inventor-to-file provisions of the AIA and, therefore, eligible for post-grant review. Dec. on Inst. 9–12 (citing *Research Corp. Technologies, Inc. v. Microsoft Corp.*, 627 F.3d 859, 870–71 (Fed. Cir. 2010); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327–29 (Fed. Cir. 2008); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305–06 (Fed. Cir. 2008)). In the

briefing following our Decision on Institution, neither party has contested this assignment of the burden of proof on eligibility for post-grant review. Accordingly, for the same reasons explained in our Decision on Institution, we maintain our determination that Petitioner bears the burden to show that the '991 patent is eligible for post-grant review.

4. Analysis of Post-Grant Review Eligibility

Petitioner presents several arguments for why the '991 patent includes claims with an effective filing date of January 29, 2014, which is the actual filing date of the '311 application. *See* Pet. 23–32. Among these arguments is Petitioner's contention that the disclosure of the '991 patent does not satisfy the written description and enablement requirements of 35 U.S.C. § 112 for claims 12–16. *See* Pet. 31–45. Because the disclosure of the priority applications is the same as that of the '991 patent's Specification, Petitioner argues, the priority applications also fail to provide adequate support for the subject matter of claims 12–16. *Id.* at 31–32. Thus, according to Petitioner, claims 12–16 are not entitled to an effective filing date earlier than January 29, 2014. *Id.*

As we noted in our Decision on Institution, Petitioner's contention that January 29, 2014, is the effective filing date for claims 12–16 is not based on an argument that those claims are adequately supported in the '311 application but lack support in earlier applications to which priority is claimed. *See* Dec. on Inst. 12. Instead, Petitioner's contention is that neither the '311 application nor any of the earlier applications adequately supports claims 12–16, and therefore, the effective filing date for those claims is the actual filing date. *See* Pet. 31–32.

Petitioner’s argument accords with the definition of “effective filing date” set forth above, which provides in subparagraph (B) that the effective filing date is the filing date of the earliest application to which the patent is entitled to priority or to the benefit of an earlier filing date. 35 U.S.C. § 100(i)(1)(B). Subparagraph (A) provides that “if subparagraph (B) does not apply,” the effective filing date is the actual filing date of the patent containing a claim to the invention. 35 U.S.C. § 100(i)(1)(A). Under this definition, if a claim in a patent application is not entitled to an earlier filing date, then subparagraph (B) does not apply and the effective filing date is the actual filing date of the application under subparagraph (A), regardless of whether the disclosure in the application is sufficient to support the claim. Consequently, we agree with Petitioner that if claims 12–16 are shown to lack adequate § 112 support in the ’311 application and all of the earlier applications to which priority is claimed, the effective filing date for those claims is the actual filing date of the ’311 application.⁸

Our analysis of Petitioner’s enablement and written description challenges is set forth in Sections II.D.1. and II.D.2., respectively. For the reasons explained therein, we determine that Petitioner has shown that claims 12–16 are not adequately supported by the disclosure of the ’311 application. Because it is undisputed that the ’311 application has the same disclosure as the earlier applications to which the ’991 patent claims priority, *see* Pet. 32; Prelim. Resp. 25; PO Resp. 40, we also determine that Petitioner has shown that claims 12–16 are not entitled to an effective filing date

⁸ We came to the same conclusion in our Decision on Institution. *See* Dec. on Inst. 13. The parties’ briefing after that Decision does not contest that determination.

earlier than January 29, 2014. Therefore, Petitioner has met its burden to show that the '991 patent is eligible for post-grant review.

B. Claim Construction

Claims of an unexpired patent are interpreted using the broadest reasonable interpretation in light of the specification. 37 C.F.R. § 42.200(b); *see Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard).

Under the broadest reasonable interpretation claim construction standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In our Decision on Institution, for the purposes of that decision, we adopted the parties' agreed-upon construction that the phrase "heat-treating the entire shank" in claim 12 includes heat treatment in any environment. Dec. on Inst. 22. We also construed the clause in claim 12 that recites "wherein the heat treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1." We disagreed with Petitioner's argument that this "wherein" clause should not be considered limiting. *See id.* at 22. Instead, we construed the "wherein" clause as a limitation that lays out a metric for determining if a heat treatment process falls within the scope of the claim. *See id.* at 22–24.

The parties' briefing after institution does not contest those constructions, nor do the parties propose that any other term should be construed. At the hearing, Petitioner confirmed that it does not challenge the

construction of the “wherein” clause that we adopted in the Decision on Institution. *See* Tr. 7:18–23. Patent Owner agrees that our construction of the “wherein” clause was correct, but argues that the analysis in our Decision on Institution did not faithfully apply the construction that we adopted. *See id.* at 34:3–16. Patent Owner’s argument concerning the relevance of the “wherein” clause to the enablement analysis is discussed below. Accordingly, we maintain the constructions set forth in our Decision on Institution.

C. Level of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, relevant factors include the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner argues, with support from the testimony of Dr. Goldberg, that a person of ordinary skill in the art at the time of the invention of the ’991 patent would have:

- (i) a bachelor’s degree or master’s degree in materials science, metallurgy, or a related field and at least two years of experience so as to understand the structural, chemical, and mechanical properties that can be manipulated in Ni-Ti alloy materials used in dental applications, or
- (ii) a Ph.D. or equivalent degree in materials science, metallurgy, or a related field and at least one year of experience so as to understand the structural, chemical, and mechanical properties that can be manipulated in Ni-Ti alloy materials used in dental applications.

Pet. 32–33 (citing Ex. 1002 ¶ 75). Patent Owner did not contest this proposal or present a competing definition in its briefing, and stated at the

hearing that it does not object to Petitioner’s proposed definition of the level of ordinary skill in the art. Tr. 34:18–35:3. We adopt the parties’ agreed-upon definition of the level of ordinary skill in the art.

D. Asserted Grounds of Unpatentability

1. Enablement

a. Legal Principles

“Section 112 requires that the patent specification enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation.” *Invitrogen Corp. v. Clontech Labs. Inc.*, 429 F.3d 1052, 1070–71 (Fed. Cir. 2005). The Federal Circuit has explained that an enabling disclosure is “part of the *quid pro quo* of the patent bargain.” *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

Specifically, the enablement requirement under § 112

ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. The scope of the claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill without undue experimentation.

National Recovery Techs. Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195–96 (Fed Cir. 1999). “Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Factors to be considered include

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

predictability or unpredictability of the art, and (8) the breadth of the claims.

Id.

b. Summary of the Parties' Contentions Regarding Enablement

Petitioner's enablement arguments focus on the range of temperatures at which the claimed heat treatment occurs. Claim 12 recites

heat-treating the entire shank ***at a temperature above 25° C. up to but not equal to the melting point of the superelastic nickel titanium alloy***, wherein the heat treated shank has an angle greater than 10 degrees of permanent deformation after torque at 45 degrees of flexion when tested in accordance with ISO Standard 3630-1.

Ex. 1001, 10:42–48 (emphasis added). Dependent claim 14 narrows the temperature range somewhat, reciting that “the temperature is from 300° C. up to but not equal to the melting point of the superelastic nickel titanium alloy.” *Id.* at 10:53–54.

Petitioner argues that “‘heat-treating’ a superelastic, nickel-titanium endodontic instrument at as low as 25°C, or at mouth temperature (37°C), will not result in a file that exhibits the recited level of permanent deformation.” Pet. 36 (citing Ex. 1002 ¶¶ 101–102). Petitioner's declarant, Dr. Goldberg, testifies that “[i]n order to transform a Ni-Ti endodontic instrument from one which would not satisfy the ‘wherein’ clause into one that would satisfy it, one must process the alloy so as to change its transformation temperatures.” Ex. 1002 ¶ 101. Yet, according to Dr. Goldberg:

[S]ubjecting a Ni-Ti instrument to 25–37°C will not alter its transformation temperatures. Effective heat-treatment requires enough thermal energy for the individual atoms to move to different positions within the solid material. Heat-treatment at 25–37°C does not provide this energy. Significantly higher

temperatures are required: one paper explained that, with respect to one Ni-Ti alloy, the transformation temperature did not change significantly with a treatment temperature of 300°C.

Id. ¶ 102 (citing Ex. 1006, 113).

To show that the method of the '991 patent is inoperative within the claimed temperature ranges, Petitioner describes testing in which the shanks of ten ProFile brand Ni-Ti endodontic files were heat-treated at 25°C for durations between 75 minutes and twelve hours. Pet. 36–37 (citing Ex. 1015 ¶¶ 4–5). The heat-treated shanks were then subjected to flexion testing in accordance with ISO Standard 3630-1, and their permanent deformation was measured to be between 0.04 and 2.19 degrees, averaging 0.87 degrees. Pet. 37 (citing Ex. 1018, 10; Ex. 1002 ¶ 105). Similar testing was conducted with a heat-treatment at 300°C, and the results of that testing showed permanent deformation in the 300°C-treated shanks between 0.07 and 2.73 degrees, averaging 1.17 degrees. Pet. 39 (citing Ex. 1015 ¶¶ 3–5; Ex. 1018, 10; Ex. 1002 ¶ 107). Thus, none of the 25°C-treated shanks or the 300°C-treated shanks exhibited permanent deformation of greater than 10 degrees as required by the “wherein” clause of claim 12. Pet. 39.

Petitioner further argues that claims 12–16 are not enabled because undue experimentation would be required to practice the full scope of the claimed invention. Pet. 40–45. Petitioner asserts, with reference to Dr. Goldberg’s testimony, that “the results of heat treatment depend on several variables, including temperature, time, alloy composition and alloy treatment history.” Pet. 41 (citing Ex. 1002 ¶ 111). Petitioner argues that the Specification provides insufficient guidance regarding how to achieve the claimed permanent deformation result using the claimed heat treatment parameters. Pet. 45. Example 4 in the '991 patent is the only description

provided in the Specification for achieving the claimed permanent deformation. *Id.* at 41; *see also* Ex. 1001, 8:35–62 (describing heat-treatment at 500°C for 75 minutes of files comprising 54–57 weight percent nickel and 43–46 weight percent titanium). According to Petitioner, “the specification does not provide any guidance as to how variations in time and temperature, or alloy composition, may affect the results one way or another.” Pet. 45. Thus, the example disclosed in the Specification is insufficient to enable claims 12–16, which encompass a broad range of possible combinations of these variables. *Id.* at 44–45 (citing Ex. 1002 ¶ 125). In particular, the claims do not specify a duration for heat-treating, encompass temperature ranges from above 25°C (claims 12, 13, 15, 16) or 300°C (claim 14) up to but not equal to the melting point of the alloy, and either do not specify a composition for the nickel titanium alloy (claims 12–15) or include a range of 54–57 weight percent nickel (claim 16). *See* Ex. 1001, 10:35–60.

Patent Owner presents several arguments in rebuttal. *See* PO Resp. 17–33. Patent Owner argues that Petitioner’s testing does not show inoperative embodiments because “the ‘wherein’ clause limits the heat treatments encompassed by claims 12–16 to only those that result in a NiTi file that is capable of exhibiting the claimed degree of permanent deformation.” *Id.* at 17. Because none of Petitioner’s tests produced the deformation characteristic recited in the “wherein” clause, Patent Owner asserts that those tested files were outside the scope of claims 12–16. *Id.* at 18–19. Further, Patent Owner argues that Petitioner’s showing of inoperative embodiments is insufficient because Petitioner tested at only two temperatures, and “[i]t is not necessary that every permutation within a

generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention.” *Id.* at 20 (quoting *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005)).

Patent Owner also criticizes Petitioner’s testing on the basis that it did not take into account what an ordinarily skilled artisan would have gleaned from the ’991 patent’s teaching that the time period selected for heat exposure was dependent on the temperature. *Id.* at 21–22 (citing Ex. 1001, 4:16–29). “Despite the express teaching that other temperatures and times are suitable, Petitioner either intentionally did not test longer periods of time at 300°C (or other temperatures), or tested them and did not provide the results of that data.” *Id.* at 22. Finally, concerning the testing, Patent Owner points to the cross-examination testimony of Messrs. Zanes and Kozak, employees at the laboratories that carried out Petitioner’s testing, that the tested files had an initial bend before bend testing was conducted, and that the bend testing was carried out in the same direction as the initial bend. *Id.* at 22 (citing Ex. 2040, 45–48; Ex. 2041, 61–66). According to Patent Owner, conducting bend testing in the same direction as the initial bend minimized the amount of resulting deformation, which calls into question the accuracy of the data gathered. *Id.* at 22–23.

Next, Patent Owner challenges Petitioner’s showing that any experimentation would be undue. Patent Owner argues that Petitioner’s undue experimentation analysis is premised on an incorrect interpretation of the “wherein” clause. PO Resp. 24–25. With respect to the *Wands* factors, Patent Owner contends that Petitioner failed to address the quantity of experimentation that would be needed to practice the claimed invention. *Id.*

at 26–27. Patent Owner argues that Dr. Goldberg’s cross examination testimony shows that he was unsure whether the volume of testing would be undue. *Id.* at 27 (citing Ex. 2039, 182–83). Patent Owner asserts that “Petitioner has never stated that the experimentation would involve overly complex testing, testing beyond the skill of one in the art at the time of Dr. Luebke’s invention, or more testing than a person of skill in the art would be capable of performing.” *Id.* at 28. Patent Owner further argues that Petitioner does not address the guidance in the ’991 patent concerning examples for heat-treatment temperatures and durations. *Id.* at 29–31. “While Petitioner did make reference to Dr. Luebke’s Example 4, Petitioner *did not* analyze what a person of skill in the art would have gleaned from those heat treatment processes based on their knowledge of the art.” *Id.* at 31. Patent Owner also asserts that Petitioner did not address the nature of the invention, the state of the prior art, or the relative skill of those in the art. *Id.* at 31–32. Finally, regarding the *Wands* factors, Patent Owner challenges the sufficiency of Petitioner’s analysis of the unpredictability of the art and the breadth of the claims. *Id.* at 32–33.

In Reply, Petitioner submitted evidence of additional testing it carried out to address Patent Owner’s criticisms of the testing it had conducted previously. *See* Reply 5–8. Petitioner summarizes this additional testing and the results as follows:

This supplemental testing comprised the following heat treatment cycles: 40°C for each of 75 minutes, 2 hours, 4 hours, 8 hours, 12 hours, 24 hours, and 28 hours; and 300°C for 24 and 28 hours.

The samples heat treated at 40°C showed between 0.56 and 1.50 degrees of deformation, averaging 1.00 degrees, far below the 10 degrees required by the claims of the ’991 patent. Ex. 1041, p.

13. The samples heat treated at 300°C showed between 1.36 and 2.59 degrees of deformation, averaging 1.81 degrees, also far below the claimed 10 degrees. *Id.* at 13.

Id. at 6. In response to Patent Owner’s criticism regarding bending in the same direction as the initial bend, Petitioner’s additional testing procedure “called for bending in the opposite direction as any initial bend.” *Id.* at 6–7 (citing Ex. 1041, 10).

Petitioner also argues that Dr. Luebke’s testimony from a district court proceeding shows that “[e]ven [Dr.] Luebke does not believe it is possible to achieve the claimed permanent deformation for a significant portion of the claimed temperature ranges.” *See* Reply 4–5 (citing Ex. 1040, 193:12–194:12). In addition, Petitioner responds to Patent Owner’s criticisms of its *Wands* analysis. *Id.* at 11–15.

c. Analysis

(1) The Specification and the Scope of the Challenged Claims

“An enablement analysis begins with the disclosure in the specification.” *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1000 (Fed. Cir. 2008). We find that the guidance the Specification provides regarding how to achieve the deformation characteristic recited in the “wherein” clause is quite limited compared to the broad scope of claims 12–16. As summarized above, the ’991 patent sought to overcome several deficiencies of prior art endodontic files. The ’991 patent sought to fill a need for an endodontic files “that have high flexibility, have high resistance to torsion breakage, maintain shape upon fracture, can withstand increased strain, and can hold sharp cutting edges.” Ex. 1001, 2:52–55. The Specification indicates that permanent deformation after bending, the characteristic recited in the “wherein” clause of claim 12, was only one of many features of the

endodontic file with which the '991 patent was concerned. *See also id.* at 3:1–4, 6:49–60, 9:26–33.

The '991 patent includes a general description of the file (*id.* at 4:3–15, Figs. 1a, 1b) and a method of “heat-treating the shank at a temperature above 25° C. . . . Preferably, the temperature is from 400° C. up to but not equal to the melting point of the titanium alloy, and most preferably, the temperature is from 475° C. to 525° C.” (*id.* at 4:16–21). The Specification discloses preferred gases for the heat-treatment (*id.* at 4:16–19), and exemplary times and temperatures:

In one example embodiment, the shank is heat-treated for approximately 1 to 2 hours. In another example embodiment, the shank is heat-treated at 500° C. for 75 minutes. However, other temperatures are suitable as they are dependent on the time period selected for heat exposure.

Id. at 4:24–29. The patent also describes alloys that can be used (*id.* at 4:30–62, 5:12–49) and coating processes (*id.* at 6:8–36).

In addition, the Specification describes five examples. *See id.* at 7:16–9:33. In each example, one group of files is untreated, a second group is heat-treated at 500°C for 75 minutes, and a third group is “coated with titanium nitride using physical vapor deposition with an inherent heat-treatment.” *Id.* at 7:36–41, 7:62–8:1, 8:22–27, 8:49–54, 9:9–14. Each example studies a different performance characteristic of the files. Example 4 studies the “angle of permanent deformation after the flexion test (ADP) reported in degrees of deflection performed in accordance with “ISO Standard 3630-1” *Id.* at 8:39–42. Example 4 states that the “files that were heat-treated . . . at 500° C. for 75 minutes showed the highest ADP.” *Id.* at 8:57–59. Figure 6, which shows the results of the study in Example 4, indicates an angle of permanent deformation of nearly 30 degrees for the

heat-treated files (i.e., those labeled “TT” in Figure 6). *Id.* at 8:44–45, 50–52, Fig. 6. Examples 1, 2, 3, and 5 study torsion, ability to withstand strain, flexibility, resistance to torsion breakage, and fatigue. *Id.* at 7:27–29, 7:53–55, 8:12–13, 31–33, 8:67–9:1.

Thus, the only example that relates to the deformation characteristic recited in the “wherein” clause of claim 12 is Example 4. That example discloses heat-treatment at 500°C for 75 minutes and an “inherent heat-treatment,” the temperature and duration of which are not provided. *Id.* at 8:50–52. The Specification also explains that the temperature will depend on the time period of the heat-treatment. *Id.* at 4:27–29. Although the Specification discloses other, broader ranges of temperatures and times, none of these other temperatures or times is tethered to the deformation characteristic that is recited in claims 12–16. *See id.* at [57], 2:65–3:1, 4:16–21, 24–29.

The Specification’s teaching that the deformation characteristic can be achieved using heat-treatment at 500°C for 75 minutes or “inherent heat-treatment” of undisclosed parameters is a narrow disclosure compared to the scope of the challenged claims. Claims 12–16 encompass temperature ranges from above 25°C (claims 12, 13, 15, 16) or 300°C (claim 14) up to but not equal to the melting point of the alloy (which is about 1300°C, *see* Ex. 1002 ¶ 17; Tr. 35:13–15), and are not limited to any duration for the heat-treatment.

(2) *Inoperative Species*

Aside from being comparatively broad relative to what is described in the Specification, the evidence supports Petitioner’s contention that claims 12–16 include heat-treatment times and temperatures that do not provide the

deformation characteristic recited in the “wherein” clause. Under the enablement requirement, a “specification must enable one of ordinary skill in the art to practice the full scope of the claimed invention.” *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Thus, “when a range is claimed, there must be reasonable enablement of the scope of the range.” *Id.*

The inclusion in a claim’s scope of inoperative species is a relevant consideration in the enablement analysis, even though it does not, by itself, compel a determination that the claim is not enabled. *See, e.g., Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576–77 (Fed. Cir. 1984) (“Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. . . . Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid.”); *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) (“[P]atent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, . . . the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility.”) (citing *In re Angstadt*, 537 F.2d 498, 502–03 (CCPA 1976)).

Here, evidence that claims 12–16 encompass inoperative species includes Petitioner’s testing of files heat-treated at temperatures within the scope of claim 12, as well as the narrower range of claim 14. With respect to the test results submitted with the Petition, the maximum permanent deformation after flexion testing of the 25°C heat-treated shanks was 2.19

degrees, and the average was 0.87 degrees. *See* Pet. 37; Ex. 1018, 4, 10. For the 300°C heat-treated shanks, maximum deformation was 2.73 degrees and the average was 1.17 degrees. *See* Pet. 39; Ex. 1018, 4, 10. The results for both of those temperatures are significantly lower than the claimed permanent deformation of greater than 10 degrees. *See* Ex. 1001, 10:45–46.

The testing involving heat-treating at 25°C is outside of the temperature range of claim 12, which recites heat-treating “at a temperature *above* 25° C.” However, the similarity of the results from the 25°C heat-treatment to the results of the 300°C suggests that increasing the temperature of the heat-treatment from 25°C to 300°C had only a very minor effect on permanent deformation after the flexion test. Indeed, the results that Petitioner submitted with its Reply⁹ show similar results for heat-treatment at 40°C for durations between 75 minutes and 28 hours: maximum deformation was 1.50 degrees and the average was 1.00 degrees. *See* Reply 6; Ex. 1041, 2, 13. Heat-treatment at 300°C for 24 and 28 hours yielded a

⁹ Patent Owner presented arguments concerning the weight that should be given to this additional testing (*see* Paper 37 ¶¶ 8, 10, 11), but Patent Owner did not move to strike the additional testing evidence or otherwise object that Petitioner’s submission of it with the Reply was improper. Because the testing was responsive to Patent Owner’s criticisms of the testing reported in the Petition, we do not view Petitioner’s submission of the additional testing evidence with the Reply as improper, particularly in the absence of any objection from Patent Owner. *See Genzyme Therapeutic Prods. Ltd. P’ship v. Biomarin Pharma. Inc.*, 825 F.3d 1360, 1367 (Fed. Cir. 2016) (“The development of evidence in the course of the trial is in keeping with the oppositional nature of an *inter partes* review proceeding The purpose of the trial in an *inter partes* review proceeding is to give the parties an opportunity to build a record by introducing evidence—not simply to weigh evidence of which the Board is already aware.”).

maximum deformation of 2.59 degrees and an average of 1.81 degrees.
Reply 6; Ex. 1041, 2, 13.

In sum, none of the files that Petitioner heat-treated for various durations at temperatures of 25°C, 40°C, and 300°C exhibited the deformation required by the “wherein” clause. In fact, none of them exhibited even one third of the required amount of deformation. We note that although Patent Owner presented several criticisms of Petitioner’s testing, Patent Owner did not present any admissible evidence of its own in the form of experimental results showing that the recited deformation characteristic could be achieved using heat-treatment at the temperatures Petitioner tested (or any other temperatures).¹⁰ Petitioner’s testing results accord with the testimony of Dr. Goldberg that heat-treatments at temperatures at the low end of the claimed range simply cannot provide the thermal energy required to alter a file’s material properties in a manner that would allow it to achieve the claimed deformation characteristic. Ex. 1002 ¶¶ 101–102.

We have considered Patent Owner’s rebuttal to Petitioner’s evidence and arguments concerning inoperative species, but we do not find that rebuttal persuasive. Patent Owner argues that because the “wherein” clause limits the scope of claim 12, none of Petitioner’s testing was within the scope of the challenged claims because none of the testing resulted in a file that achieved the permanent deformation characteristic recited in the “wherein” clause. PO Resp. 17–19. But the presence of the “wherein” clause does not *avoid* an enablement problem in claim 12; rather, the

¹⁰ The declaration in Patent Owner’s Exhibit 2034 is excluded as evidence in this proceeding for the reasons discussed in Section II.E.1 below.

inability to achieve what is recited in the “wherein” clause using heat-treatments within the scope of the claims *contributes* to the enablement problem. For example, in *AK Steel*, the claims included steel strips containing either a Type 1 or a Type 2 coating and also required that the coating wet well. 344 F.3d at 1244. Because the evidence indicated that an ordinarily skilled artisan with the benefit of the patent’s disclosure would have been unable to achieve the claimed wetting attributes for steel strips containing a Type 1 coating without undue experimentation, the Federal Circuit concluded that the claims were not enabled. *Id.* If Patent Owner’s argument were correct, there would have been no enablement problem in *AK Steel* because the inability to achieve the claimed wetting properties using steel strips with a Type 1 coating would have simply meant that such a combination was not within the claim scope.

We also are unmoved by Patent Owner’s criticism that Petitioner’s testing did not account for what an ordinarily skilled artisan would have gleaned from the ’991 patent’s teaching that the temperature and time for the heat-treatment were interdependent. PO Resp. 21–22 (citing Ex. 1001, 4:16–29). Petitioner’s testing included a range of durations from 75 minutes (the duration of the heat-treatment in Example 4 of the ’991 patent; *see* Ex. 1001, 8:51) up to 28 hours. *See* Ex. 1041, 11.

With respect to Patent Owner’s argument that the results were skewed by Petitioner’s decision to conduct bend testing in the same direction as the initial bend (PO Resp. 22–23), the challenged claims do not specify any particular direction of the bend. In any event, Petitioner’s additional testing accounted for Patent Owner’s criticism and still produced deformations well below the amount recited in the “wherein” clause. *See* Ex. 1041, 10, 13.

Patent Owner also argued that Petitioner did not establish that the bend testing for its additional testing was conducted at room temperature, and conducting bend tests at an elevated temperature would change the outcome. *See* Tr. 48:9–51:4; Paper 37 ¶ 10. However, the report describing the additional testing states that “[a]fter heat treating and prior to bend testing, the samples were allowed to cool completely.” Ex. 1041, 11. That the samples were allowed to cool completely prior to bend testing readily implies that they were at room temperature when the testing commenced.

(3) Undue Experimentation

Dr. Goldberg explains that the deformation characteristic recited in the “wherein” clause is impacted by several factors, including alloy composition, heat-treatment temperature and duration, and history of the alloy, but the ’991 patent does not provide sufficient guidance regarding how those parameters should be selected in order to yield the claimed deformation effect. *See* Ex. 1002 ¶¶ 112–114, 121. Dr. Goldberg analyzes the teachings of the prior art and describes why those references also do not provide sufficient information to allow a skilled artisan to practice the full scope of what is claimed in the ’991 patent. *See id.* ¶¶ 114–121 (citing Ex. 1020; Ex. 1021; Ex. 1031). Dr. Goldberg testifies:

While a person of ordinary skill in the art may have been able to, through experimentation, arrive at an appropriate treatment time and temperature for a particular alloy that had certain treatment history before final heat treatment, such that the file would satisfy the “wherein” clause of the ’991 patent, doing so for all Ni-Ti alloy compositions within the claimed range would require undue experimentation.

Id. ¶ 125. We find Dr. Goldberg’s testimony credible and probative that undue experimentation would be required for an ordinarily skilled artisan to

practice the full scope of claims 12–16 with the teachings of the Specification as a guide.

The testimony of Dr. Luebke, the sole named inventor of the '991 patent, also supports Petitioner's argument that the '991 patent does not enable the full scope of the claimed temperature range without undue experimentation. In December 2015, during a deposition in Case IPR2015-00632, Dr. Luebke testified as follows:

Q Do you know whether you could heat-treat superelastic nickel-titanium files at less than 375 degrees and obtain the amount of permanent deformation claimed in your '773 patent?[¹¹]

A I suspect you could.

Q Do you know?

A I haven't -- I haven't tried to narrow in at the temperatures yet.

Q Do you believe you could heat-treat at 300 degrees and get the claimed amount of permanent deformation?

MR. DAHLGREN: Objection. Scope.

A I guess you have to try.

Q You don't know?

A I don't know.

Q Could you heat-treat at 50 degrees and get the claimed amount of permanent deformation?

MR. DAHLGREN: Objection. Scope.

A I would guess not.

Q How about 100 degrees?

¹¹ The language of the "wherein" clause in U.S. Patent No. 8,727,773 is the same as the "wherein" clause in claim 12 of the '991 patent. *See* Ex. 1011, 9:54–57.

MR. DAHLGREN: Same objections.

A I would guess not.

Q How about 150 degrees?

MR. DAHLGREN: Same objections.

A How many temperatures are we going to do?

Q A few more.

A I -- I would guess not.

Q How about 250 degrees?

MR. DAHLGREN: Same objections.

A I would guess not.

Ex. 1040, 193:4–194:12.¹²

We recognize that enablement is an objective test based on what the Specification conveys to a hypothetical person of ordinary skill in the art. Nevertheless, the inventor's testimony indicating that he does not believe it is possible to achieve the claimed deformation result through heat-treatment at 50°C, 100°C, 150°C, or 250°C, and does not know whether it could be achieved through heat-treatment at 300°C, tends to support the view that the disclosure in his '991 patent would not enable a skilled artisan to practice the full scope of the claimed invention without undue experimentation.¹³

¹² Patent Owner did not move to exclude this testimony. *See* Paper 36, 2. Accordingly, we do not address the objections Patent Owner stated during the deposition, nor the objections it presented in Paper 32. *See* 37 C.F.R. § 42.64(c) (“A motion to exclude evidence must be filed to preserve any objection.”).

¹³ The '773 patent that was the focus of the deposition excerpted above is one of the applications to which the '991 patent claims priority. *See* Ex. 1001, at [60]; Ex. 1011, at [21]. The Specification of the '991 patent is the same as the specification of the '773 patent. *See* Pet. 32; Prelim. Resp. 25; PO Resp. 40.

Similarly, in *AK Steel*, the Federal Circuit explained that “documentary and testimonial evidence from [the patentee] that despite its desire to use a Type 1 aluminum coating, it was unable to do so at the time of the effective filing date” constituted evidence that undue experimentation would be required to enable practice of the claims. *AK Steel*, 344 at 1244. Likewise, in *In re '318 Patent Infringement Litigation*, the Federal Circuit supported its holding that a patent claim for treating Alzheimer’s disease with galantamine was not enabled by pointing out that

the inventor’s own testimony reveals that an ordinarily skilled artisan would not have viewed the patent’s disclosure as describing the utility of galantamine as a treatment for Alzheimer’s disease: “[W]hen I submitted this patent, I certainly wasn’t sure, and a lot of other people weren’t sure that cholinesterase inhibitors[, a category of agents that includes galantamine,] would ever work.”

583 F.3d 1317, 1327 (Fed. Cir. 2009).

After weighing all of the evidence and arguments, we conclude that a preponderance of the evidence supports Petitioner’s contention that claims 12–16 do not comply with the enablement requirement of 35 U.S.C. § 112.

2. *Written Description*

a. *Legal Principles*

The test for a patent’s sufficiency under the written description requirement of § 112 “is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). This test “requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.

Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” *Id.*

b. Summary of the Parties’ Written Description Contentions

In its argument that claims 12–16 lack written description support, Petitioner recognizes that these are “original claims,” meaning that the claims as issued in the ’991 patent are identical to those in the ’311 application as filed. Pet. 46. Nevertheless, Petitioner highlights the following excerpt from the Federal Circuit’s en banc decision in *Ariad*:

Although many original claims will satisfy the written description requirement, certain claims may not. For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with ***genus claims that use functional language to define the boundaries of a claimed genus***. In such a case, the functional claim may ***simply claim a desired result***, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant ***has invented species sufficient to support a claim to the functionally-defined genus***.

Pet. 46 (quoting *Ariad*, 598 F.3d at 1349).

Petitioner argues that claims 12–16 fit the mold described in *Ariad* because the “wherein” clause uses functional language to claim the desired result of permanent deformation, but the ’311 application does not demonstrate “that the inventor possessed the entire class of heat treatments that might result in the recited permanent deformation (from above 25°C or from 300°C all the way to the melting temperature of Ni-Ti (1310°C), and

on an unbounded or broad range of alloy compositions and heat treatment times).” Pet. 47 (citing Ex. 1002 ¶ 132).

In rebuttal, Patent Owner argues that the Specification demonstrates Dr. Luebke’s possession of the temperature range of claim 12 because the Specification explicitly states “heat-treating the shank at a temperature above 25°C” in the Abstract, the Summary of the Invention, and in the Detailed Description. PO Resp. 36 (citing Ex. 1001, at [57], 2:65–3:1, 4:26–29). With respect to claim 14’s temperature range of “from 300°C,” Patent Owner argues that this is implicitly disclosed by the Specification’s disclosure of above 25°C. Patent Owner analogizes the facts here to *In re Wertheim*, 541 F.2d 257, 264–65 (CCPA 1976), in which the court held that a limitation reciting “between 35% and 60%” had written description support in a specification that disclosed a range of “25%–60%” and specific examples of 36% and 50%. PO Resp. 36–37. “[T]hat Dr. Luebke set forth one working example” is immaterial, according to Patent Owner, because the Specification “teaches that ‘other temperatures are suitable as they are dependent on the time period selected for heat exposure.’ That is sufficient written description for claims 12–16.” *Id.* at 39 (quoting Ex. 1001, 4:27–29).

Petitioner responds that “[i]n each of the citations to ‘heat-treating’ the shank at a temperature above 25°C in the specification, there is no mention of any degree of deformation being achieved let alone the claimed amount of deformation.” Reply 16. Concerning the range recited in claim 14, Petitioner argues that the Specification makes no mention of 300°C, let alone heat-treating at that temperature to achieve the claimed amount of permanent deformation. *Id.* at 16–17.

c. Analysis

We agree with Petitioner that the Specification does not reasonably convey to those skilled in the art that Dr. Luebke had possession of the subject matter of claims 12–16. In particular, with respect to claims 12, 13, 15, and 16, the Specification does not demonstrate possession of heat-treatment “at a temperature above 25° C. up to but not equal to the melting point of the superelastic nickel titanium alloy” that provides the deformation characteristic of the “wherein” clause. As discussed above in Section II.D.1.c.(1), the only portion of the Specification that describes heat-treatment that achieves the deformation characteristic of the “wherein” clause is in Example 4, which discloses heat-treatment at 500°C for 75 minutes and an “inherent heat-treatment,” the temperature and duration of which are not provided. Ex. 1001, 8:50–52. The portions of the Specification disclosing heat-treating the shank at a temperature above 25°C do not tie such a heat-treatment to the deformation characteristic recited in the “wherein” clause. *See id.* at [57], 2:65–3:1, 4:24–29.¹⁴ With respect to

¹⁴ At the hearing, Patent Owner argued that claims 1 and 11 as filed in the June 7, 2005 application (Ex. 2003, “the PCT application”), the earliest nonprovisional application in the ’991 patent’s priority claim, tie the temperature of “above 25°” to the claimed permanent deformation. *See* Tr. 64:1–15. Petitioner argued that Patent Owner had not relied on those portions of the PCT application in its briefing, and Patent Owner provided us with citations to its Patent Owner Response where it discussed the PCT application. *See id.* at 64:16–21, 66:1–3, 70:7–23.

Having reviewed the Patent Owner Response, we agree with Petitioner that Patent Owner did not cite or discuss claims 1 and 11 in the PCT application. The only portions of the PCT application that Patent Owner discussed were in its specification, which “has substantially the same disclosure” as the ’991 patent’s Specification. PO Resp. 40; *see also id.* at 35–37, 39.

the temperature range of claim 14, we agree with Petitioner that nothing in the Specification signals possession of heat-treatments at a temperature of 300°C to achieve permanent deformation as claimed.

“[D]isclosure of a species may be sufficient written description for a later claimed genus including that species.” *Synthes USA, LLC v. Spinal*

Our Practice Guide advises that, at oral argument, a party “may only present arguments relied upon in the papers previously submitted. No new evidence or arguments may be presented at the oral argument.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012). The Federal Circuit has held it to be a denial of procedural rights for the Board to rely in its decision on a factual assertion introduced into the proceeding only at oral argument, after the opposing party can meaningfully respond. *See Dell, Inc. v. Accelaron, LLC*, 818 F.3d 1293, 1301 (Fed. Cir. 2016). In AIA proceedings, procedural rights are owed to both petitioners and patent owners. *See SAS Institute, Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1351 (Fed. Cir. 2016). The citation to one portion of a reference does not necessarily provide adequate notice that other portions of the same reference are at issue. *See In re Nuvasive*, 841 F.3d 966, 971–72 (Fed. Cir. 2016).

In the circumstances of this case, we find that Patent Owner’s briefing did not provide adequate notice that it would rely on claims 1 and 11 of the PCT application in its argument regarding written description. Even leaving aside the lack of notice to Petitioner, Patent Owner’s argument only addresses one application in the ’991 patent’s chain of priority, and does not show that the disclosure was continued in the other applications on which Patent Owner relies. *See Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997) (“In order to gain the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112.”); *Hollmer v. Harari*, 681 F.3d 1351, 1355 (Fed. Cir. 2012) (“[I]f any application in the priority chain fails to make the requisite disclosure of subject matter, the later-filed application is not entitled to the benefit of the filing date of applications preceding the break in the priority chain.”).

Kinetics, Inc., 734 F.3d 1332, 1344 (Fed. Cir. 2013) (quoting *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1124 (Fed. Cir. 2004)). However,

[i]f the difference between members of [a species] is such that [a] person skilled in the art would not readily discern that other [species] of the genus would perform similarly to the disclosed members, i.e., if the art is unpredictable, then disclosure of more species is necessary to adequately show possession of the entire genus. In other words, predictability is a factual issue judged on a case-by-case basis.

Id. (quoting *Bilstad*, 386 F.3d at 1125). For many of the same reasons as discussed above in our enablement analysis, we find that the species disclosed in Example 4 of the Specification is insufficient to support the genus of temperature ranges recited in claims 12 and 14. Of particular note in this regard is Petitioner's testing evidence reflecting inoperative embodiments at 25°C, 40°C, and 300°C. *See* Pet. 36–40; Reply 6–7; Ex. 1018, 4, 10; Ex. 1041, 2, 13. Also germane is Dr. Luebke's testimony that he does not believe heat-treatment at temperatures of 50°C, 100°C, 150°C, or 250°C could achieve the claimed deformation characteristic, and does not know whether it could be achieved through heat-treatment at 300°C. Ex. 1040, 193:12–194:12. This evidence leads us to believe that skilled artisans would not readily discern that heat-treatment at such temperatures would perform similarly to the 500°C heat-treatment disclosed in Example 4.

Based on the arguments and evidence of record, we conclude that a preponderance of the evidence supports Petitioner's contention that claims 12–16 lack adequate written description support under 35 U.S.C. § 112.

3. Anticipation by Luebke 2008

Petitioner contends that claims 12–16 are anticipated by Luebke 2008. Pet. 48. Luebke 2008 is the published version of one of the applications to

which the '991 patent claims priority. *See id.*; Prelim. Resp. 31; Ex. 1022, at [21]; Ex. 1001, at [60]. Petitioner's reliance on Luebke 2008 as prior art depends on the challenged claims' lack of entitlement to the priority date claimed in the '991 patent. Pet. 48. Patent Owner's only argument against this asserted ground of unpatentability is that Luebke 2008 does not qualify as prior art because claims 12–16 are entitled to the claimed priority date of June 7, 2005. *See* PO Resp. 40. For the reasons discussed above in Section II.A.4, we have determined that the effective filing date of claims 12–16 is January 29, 2014. Therefore, Luebke 2008, which was published on February 7, 2008, qualifies as prior art under 35 U.S.C. § 102(a)(1).

Petitioner provides a detailed description of where each limitation of claims 12–16 is disclosed in Luebke 2008. *See* Pet. 48–52. With respect to heat-treating at a temperature above 25°C (per claim 12) or from 300°C (per claim 14) up to the melting point to achieve the deformation characteristic recited in the “wherein” clause, Petitioner points to Example 4 in Luebke 2008, which describes heat-treating files in an argon atmosphere at 500°C for 75 minutes. Pet. 49–51 (citing Ex. 1022 ¶ 41). Figure 6 of Luebke 2008, which shows the results of bend testing files subjected to that heat-treatment in the group labeled “TT,” indicates an angle of permanent deformation of about 26–30 degrees, which is within the range of “greater than 10 degrees” recited in the “wherein” clause. *Id.* at 50; Ex. 1022 ¶ 41, Fig. 6.

Petitioner also contends that its argument that Luebke 2008 anticipates claims 12–16 is consistent with its argument that those claims are not entitled to the filing date of Luebke 2008. *Id.* at 48–49 (citing *Chester v. Miller*, 906 F.2d 1574, 1577 (Fed. Cir. 1990)). We agree with Petitioner that a determination that Luebke anticipates claims 12–16 is not inconsistent

with the enablement and written description analyses set forth above, in which we determine that the disclosure of the '991 patent (and, therefore, the disclosure of Luebke 2008) fails to support the full scope of the challenged claims. *See Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) (“It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is ‘anticipated’ if *one* of them is in the prior art.”); *In re Lukach*, 442 F.2d 967, 970 (CCPA 1971) (“[T]he description of a single embodiment of broadly described subject matter constitutes a description of the invention for anticipation purposes . . . , whereas the same information in a specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure.”); *see also AK Steel*, 344 F.3d at 1245–46 (Rader, J., concurring) (determining that a patent to which the challenged patent claimed priority was anticipatory prior art because the priority claim was invalid due to inadequate support for the claimed subject matter, yet the challenged claims encompassed subject matter disclosed in the earlier patent).

We have considered the arguments and evidence of record, and we conclude that a preponderance of the evidence supports Petitioner’s contention that Luebke 2008 anticipates each of claims 12–16.

4. Remaining Grounds

Having determined that each of the challenged claims are unpatentable on three separate grounds, we need not reach the additional anticipation and obviousness grounds on which Petitioner challenges the same claims. Declining to reach those additional grounds is particularly appropriate in this case because our analysis of eligibility for post-grant

review is closely bound up with our enablement and written description analyses. As such, in the event that our reviewing court determines that we erred in the enablement and written description analyses set forth above, it is unclear whether the '991 patent would be eligible for post-grant review.

E. Motions to Exclude Evidence

1. Petitioner's Motion to Exclude

Petitioner moves to exclude Exhibits 2035, 2036, and 2038, as well as portions of Exhibits 2034 and 2047. Paper 40, 1.

Exhibit 2034 is a file history for a patent application that is related to the '991 patent. In its Patent Owner Response, Patent Owner cited a declaration within that file history to support an argument that “Dr. Luebke submitted information to the Patent Office demonstrating that a heat-treatment at 300°C resulted in a file that satisfies the permanent deformation limitation of the ‘wherein’ clause” of claim 12 of the '991 patent. PO Resp. 4; *see also id.* at 23 (arguing that the declaration and test report in Exhibit 2034 show “that files heated at 300°C for 24 hours exhibit greater than 10 degrees of permanent deformation when tested according to the ISO 3630-1 bend test”).¹⁵

Petitioner argues that the declaration in Exhibit 2034 should be excluded as inadmissible hearsay because it “was not submitted in this proceeding and Patent Owner offered no testimony, expert or otherwise, regarding the same.” Paper 40, 1–2 (citing Fed. R. Evid. 802). Further,

¹⁵ Patent Owner acknowledged at the hearing that these portions of the Patent Owner Response include a typographical error and that the declaration and testing report to which they intended to refer were on pages 381–93 of Exhibit 2034. *See* Tr. 39:16–40:7.

Petitioner argues that the test reports that are exhibits to the declaration in Exhibit 2034 constitute hearsay-within-hearsay. *Id.* at 2.

Patent Owner responds that the declaration in Exhibit 2034 was a sworn statement and the statements therein were based on Dr. Luebke's personal knowledge. Paper 43, 5. Patent Owner further argues that the test report was signed by persons at the testing facility in the ordinary course of business. *Id.* Patent Owner also argues that Petitioner cross-examined Dr. Luebke about the declaration in Exhibit 2034 as part of discovery in a related district court litigation, and that Petitioner did not request to depose Dr. Luebke in this proceeding. *Id.* Patent Owner argues that even if the declaration in Exhibit 2034 is hearsay, it is admissible under the residual exception to the hearsay rule because

(1) there are circumstantial guarantees of trustworthiness associated with submitting a declaration with the PTO; (2) the declaration was offered as evidence of a material fact; and (3) the declaration is more probative for showing that "Dr. Luebke submitted information to the Patent Office demonstrating that a heat-treatment at 300°C resulted in a file that satisfies the permanent deformation of the 'wherein' clause," than any other evidence.

Id. (citing Fed. R. Evid. 807).

In Reply, Petitioner argues that the residual exception to the hearsay rule does not apply here, because the declaration lacks "circumstantial guarantees of trustworthiness" in view of Dr. Luebke's financial stake in the outcome of this proceeding. Paper 46, 3. Further, Petitioner argues that Patent Owner "makes no representation of having made 'reasonable efforts'—as required by FRE 807—to submit declarations from Luebke" or the testing facilities. *Id.* When given an opportunity at the hearing to respond to Petitioner's Reply arguments concerning the residual hearsay

exception, Patent Owner had nothing to add to its briefing. *See* Tr. 52:17–53:14.

The Federal Rules of Evidence define hearsay as “a statement that: (1) the declarant does not make while testifying at the current trial or hearing; and (2) a party offers in evidence to prove the truth of the matter asserted in the statement.” Fed. R. Evid. 801(c). The declaration in Exhibit 2034 qualifies as hearsay under this definition. As to the first prong of the definition, the statements in that declaration were not made while testifying in this proceeding. Instead, the declaration was submitted during *ex parte* prosecution of another patent application. As to the second prong, Patent Owner relies on the statements in the declaration for the truth of the matter asserted—namely, that testing showed that the claimed deformation characteristic could be achieved after heat treatment at temperatures of 300°C. PO Resp. 4, 23; Ex. 2034 ¶¶ 3–5.

Hearsay is not admissible unless an exception applies. *See* Fed. R. Evid. 802. The residual exception provides that a hearsay statement is not excluded when several criteria are met, one of which is that “it is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts.” Fed. R. Evid. 807(a)(3). The residual hearsay exception was “meant to be reserved for exceptional cases.” *Conoco Inc. v. Dept. of Energy*, 99 F.3d 387, 392 (Fed. Cir. 1996).¹⁶ In *Conoco*, the Federal Circuit held that evidence was not admissible under the residual hearsay exception when the proponent of the evidence made no

¹⁶ *Conoco* discusses two residual hearsay exceptions under Rules 803(24) and 804(b)(5), but those provisions were subsequently combined and transferred to Rule 807. *See* Fed. R. Evid. 807, Advisory Committee Notes to 1997 Amendments.

showing that reasonable efforts could not have produced more probative evidence. *Id.* at 394.

Likewise, here, Patent Owner has made no showing that that it could not have produced, through reasonable efforts, evidence that is more probative on the point for which the declaration of Exhibit 2034 was offered. We disagree with Patent Owner's characterization of the point for which the declaration was offered—i.e., that “Dr. Luebke *submitted information to the Patent Office* demonstrating that a heat-treatment at 300°C resulted in a file that satisfies the permanent deformation of the ‘wherein’ clause.” Paper 43, 5 (emphasis added). The fact of the declaration's submission to the Patent Office in prosecution of another application is irrelevant to Patent Owner's use of the declaration for this proceeding. *See* PO Resp. 4, 23. Rather, the point for which Patent Owner offered this declaration was the description of the heat-treatment and testing in the declaration itself. *See id.*

Leaving aside whether Patent Owner could have presented, through reasonable efforts, testimony of a more disinterested witness¹⁷ regarding testing the files at a temperature of 300°C, there is no apparent reason why Patent Owner could not have offered testimony from Dr. Luebke in the form of a declaration in this proceeding. A declaration from Dr. Luebke in this proceeding would have been more probative than the declaration from ex parte prosecution in Exhibit 2034 because a declaration in this proceeding

¹⁷ Dr. Luebke is the sole named inventor of the '991 patent. Ex. 1001, at [72]. Petitioner cited testimony of Dr. Luebke from a district court proceeding indicating that he had received over a million dollars, and hoped to receive millions more, through licensing of his patent portfolio to Dentsply. *See* Reply 8–9 (citing Ex. 1043, 113–16). Patent Owner lists Dentsply Sirona Inc. as a real party-in-interest in this proceeding. Paper 52, 2. Patent Owner did not move to exclude any portion of Exhibit 1043.

would have subjected Dr. Luebke to cross-examination by Petitioner as a matter of routine discovery under the rules governing this proceeding. *See* 37 C.F.R. § 42.51(b)(1)(ii).

Further, another criteria for the residual exception to the hearsay rule is that “the statement has equivalent circumstantial guarantees of trustworthiness.” Fed. R. Evid. 807(a)(1). We are not persuaded that a declaration submitted to an Examiner during *ex parte* prosecution bears circumstantial guarantees of trustworthiness that are equivalent to the hearsay exceptions set forth in Rules 803 or 804. Patent Owner does not cite any support for that argument (*see* Paper 43, 5), and our research into case law applying the residual hearsay exception does not support Patent Owner’s position. In a case addressing whether grand-jury testimony could be admitted under the residual hearsay exception, the Eleventh Circuit held that “[a]n oath, alone, . . . is an inadequate safeguard to meet the requirement . . . that the statement have ‘equivalent circumstantial guarantees of trustworthiness.’” *U.S. v. Fernandez*, 892 F.2d 976, 981 (11th Cir. 1989); *see also Stokes v. City of Omaha*, 23 F.3d 1362, 1366–67 (8th Cir. 1994) (“Although the information in the affidavit was given under oath, it lacks the sufficient guarantees of trustworthiness required by” the residual hearsay exception). The absence of circumstantial guarantees of trustworthiness is an additional reason why we are not persuaded that the declaration in Exhibit 2034 falls within the residual hearsay exception.

For these reasons, we *grant* Petitioner’s motion to exclude pages 381–93 of Exhibit 2034 as inadmissible hearsay.

As to the remaining exhibits or portions of exhibits that Petitioner moves to exclude, we have either not relied upon them in reaching this Final

Decision, or we were unpersuaded that the exhibits undermined Petitioner's enablement, written description, and anticipation challenges. Accordingly, we *dismiss as moot* those portions of Petitioner's Motion to Exclude.

2. *Patent Owner's Motion to Exclude*

Patent Owner moves to exclude Exhibits 1005, 1006, 1016, 1017, 1020, 1021, 1025, 1034, 1036, and 1038. Paper 36, 2.

With respect to Exhibits 1006, 1020, and 1021, Patent Owner argues that these exhibits should be excluded as irrelevant under Federal Rules of Evidence 401–03 because none of these references is part of the instituted grounds. *Id.* at 3–5. Petitioner responds that these references are relevant to enablement, and points out that Dr. Goldberg cites and discusses each of these references in the portion of his declaration analyzing enablement. *See* Paper 44, 3, 5–6. In Reply, Patent Owner argues that the exhibits are not probative that experimentation would be undue because “none of these exhibits disclose the heat treatment of a superelastic nickel titanium endodontic file, subsequent bending according to the stiffness/flexibility test described in ISO 3630-1, and the measurement of an angle of permanent deformation.” Paper 47, 4.

We disagree with Patent Owner that the irrelevance of these exhibits is demonstrated by the fact that they are not included as cited references in the instituted grounds. Dr. Goldberg's citation to and discussion of these references in his testimony concerning enablement supports Petitioner's argument that they are relevant to enablement. *See* Ex. 1002 ¶¶ 113–122, 125. Patent Owner's argument that these exhibits are not probative of undue experimentation goes to the weight that the evidence should be given rather than its admissibility.

With respect to Exhibits 1005, 1016, 1017, 1025, 1034, 1036, and 1038, this Final Decision does not rely upon any the content of those exhibits. Therefore, as to those exhibits, we *dismiss as moot* Patent Owner's Motion to Exclude.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has shown by a preponderance of evidence that claims 12–16 are unpatentable under 35 U.S.C. § 112(a) for lack of enablement as well as for lack of adequate written description. Petitioner has also shown by a preponderance of evidence that claims 12–16 are unpatentable under 35 U.S.C. § 102 as being anticipated by Luebke 2008.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 12–16 of the '991 patent are held unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is *granted in part*, with the remainder *dismissed as moot*;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *denied in part*, with the remainder *dismissed as moot*;

FURTHER ORDERED that any party seeking judicial review of this decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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