

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DENTSPLY SIRONA INC.,
Petitioner

v.

OSSEO IMAGING, LLC,
Patent Owner

Case IPR2025-00787

U.S. Patent No. 8,498,374

**PATENT OWNER PRELIMINARY RESPONSE
PURSUANT TO 37 C.F.R. § 42.107(a)**

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

LIST OF EXHIBITSv

I. INTRODUCTION1

II. THE '374 PATENT AND THE CHALLENGED CLAIMS.....3

 A. THE '374 PATENT3

 B. THE CHALLENGED CLAIMS.....4

 C. LEVEL OF ORDINARY SKILL IN THE ART6

III. LEGAL PRINCIPLES7

IV. ARGUMENT9

 A. THE ASSSERTED REFERENCES FAIL TO ANTICIPATE
 AND/OR RENDER OBVIOUS THE CHALLENGED CLAIMS9

 1. The '374 Patent Was Repeatedly Upheld as Valid By Other
 Tribunals.....9

 2. The Preamble is Limiting12

 3. Arguments that Substantially Overlap with Petitioner's
 Arguments Were Already Addressed and Overcome in the
 Planmeca Action and Have Significant Weaknesses13

 4. A POSA Would Not Know to Utilize Densitometric Modeling
 Based on Arai 84216

 5. Pelc 080 Fails to Address the Shortcomings of Arai 842.....18

 6. A POSA Would Not Combine Arai 842 with Cann18

7. Arai 842 in Combination with Cann and Other Asserted References Fails to Render the '374 Patent Obvious	20
8. Petitioner Mischaracterizes Arai 842 in a Critical Way	23
9. Dr. Sonka's Declaration Contains Inconsistencies Regarding Arai 842	23
10. Dr. Pelc Himself Admitted That None of His Patents Relate to Dental Imaging	24
B. THE BOARD DID NOT HAVE THE BENEFIT OF REFERRING TO ALMOST FIVE YEARS OF LITIGATION UPHOLDING THE CHALLENGED CLAIMS WHEN THE '659 IPR WAS INSTITUTED	26
C. SUBSTANTIALLY THE SAME PRIOR ART WAS PREVIOUSLY PRESENTED TO THE OFFICE.....	28
V. CONCLUSION.....	30

TABLE OF AUTHORITIES

	Page(s)
<u>Cases</u>	
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH</i> , 2020 WL 740292 (P.T.A.B. Feb. 13, 2020)	28, 29
<i>American Imaging Services, Inc. v. Intergraph Corp.</i> , 2000 WL 772725 (C.A. Fed. June 12, 2000)	12
<i>Bicon, Inc. v. Straumann Co.</i> , 441 F.3d 945 (Fed. Cir. 2006)	12
<i>Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.</i> , 800 F.3d 1375 (Fed. Cir. 2015)	7, 8
<i>E-One, Inc. v. OshKosh Corp.</i> , IPR2019-00161 (P.T.A.B. May 15, 2019)	13
<i>Guest Tek Interactive Ent. Ltd. v. Nomadix, Inc.</i> , 2019 WL 7212601 (P.T.A.B. Dec. 27, 2019)	8
<i>Harmonic Inc. v. Avid Tech., Inc.</i> , 815 F.3d 1356 (Fed. Cir. 2016)	7
<i>Impact Selector Int’l, LLC v. Petromac IP Ltd.</i> , IPR2019-01660 (P.T.A.B. Apr. 17, 2020)	7
<i>In re Magnum Oil Tools Int’l, Ltd.</i> , 829 F.3d 1364 (Fed. Cir. 2016)	7, 8
<i>Osseo Imaging, LLC v. Planmeca USA Inc.</i> , 116 F.4th 1335 (Fed. Cir. 2024)	7
<i>Tech. Licensing Corp. v. Videotek, Inc.</i> , 545 F.3d 1316 (Fed. Cir. 2008)	8

Statutes

35 U.S.C. § 1012
35 U.S.C. § 1028
35 U.S.C. § 312(a)(3)7
35 U.S.C. § 314(a).....3, 7, 27
35 U.S.C. § 316(e).....8
35 U.S.C. § 325(d).....3, 28

Regulations

37 C.F.R. § 42.107(a)1

EXHIBIT LIST

<i>Exhibit #</i>	<i>Description</i>
2018	Declaration of Dr. Omid Kia in Support of Patent Owner Preliminary Response

Patent Owner Osseo Imaging, LLC (“Osseo” or “Patent Owner”) respectfully requests that the Board decline to initiate *Inter Partes* Review of U.S. Patent No. 8,498,374 (Case IPR2025-00787). Petitioner Dentsply Sirona Inc. (“Dentsply” or “Petitioner”) fails to meet its burden to establish a likelihood that it will prevail if the Board institutes a proceeding.

I. INTRODUCTION

Petitioner filed three petitions for *inter partes* review against the Osseo Patents.¹ In this Case IPR2025-00787, Petitioner challenges claims 1-24 (the “challenged claims”) of the ’374 Patent, entitled “Dental and Orthopedic Densitometry Modeling System and Method.” *See* EX1001.

The Osseo Patents are the subject of a pending district court litigation involving Petitioner, *Osseo Imaging, LLC. v. Dentsply Sirona Inc. et al.*, Case No. 1:23-cv-07952-PKC-LB (E.D.N.Y.), filed October 25, 2023 (the “District Court Action”). There is a pending Motion to Dismiss that was fully briefed as of

¹ U.S. Patent Nos. 6,381,301, 6,944,262 and 8,498,374 (the “’301 Patent,” the “’262 Patent,” and the “’374 Patent,” respectively) (the ’301 Patent, ’262 Patent, and ’374 Patent, collectively, the “Osseo Patents”). *See* EX1001, EX1002, and EX1003.

November 8, 2024 in the District Court Action², and no response to the complaint is currently due.

The validity of the '374 Patent is not a novel issue. Rather, the '374 Patent has been unsuccessfully challenged on numerous occasions in various forums. Each and every time, the challenged claims of the '374 Patent were confirmed as valid, including by the Federal Circuit. Although some of the prior art references here are nominally different than those asserted in the prior challenges, the basic theories for invalidity – that it would have been obvious to combine art allegedly showing tomographic imaging for dental structures with art showing the use of bone density data – are the same. Either the same prior art or substantially the same prior art asserted by Petitioner was considered in the prior proceedings as well as during prosecution of the '374 Patent. Institution of the Petition would be a lengthy process and inefficient use of the Board's time and resources only to arrive at the same conclusion as the Federal Circuit along with Federal Judges, a jury, and the patent examiner that considered every other prior challenge to the validity of the '374 Patent.

² Petitioner's Motion to Dismiss in the District Court Action seeks to invalidate the Osseo Patents under 35 U.S.C. § 101. An identical Motion to Dismiss was filed and subsequently denied by the Court in the Northern District of Georgia in *Osseo Imaging, LLC. v. Carestream Dental LLC*, Case No. 1:23-cv-03116-LMM. See EX2014.

For at least these reasons, Osseo respectfully requests that the Board exercise its discretion under 35 U.S.C. §§ 314(a) and 325(d) to decline to institute the Petition.

II. THE '374 PATENT AND THE CHALLENGED CLAIMS

A. THE '374 PATENT

The '374 Patent, entitled “Dental and Orthopedic Densitometry Modeling System and Method,” was issued on July 30, 2013 and consists of twenty four claims, three of which are independent. *See* EX1001. The application that matured to the '374 Patent, United States Patent Application No. 13/619,356, was filed on September 14, 2012.

The '374 Patent relates to an orthopedic imaging system and, more particularly, to a system that uses scanning X-ray beam techniques to create and store tomographic, densitometric models of an object. *See* EX1001 at 1:25-27; 2:15-28; 3:19-20; Fig. 2; claims 1, 13, 21. The system includes one or more controllers and/or computers that are coupled to X-ray equipment that capture multiple scans or slices of an object, for example, the facial anatomy of a patient, placed between an X-ray source and a detector array and that merge the scans or slices to create therefrom and store tomographic densitometry models of the object. *See* EX1001 at Abstract; 2:22-25; 2:57-3:3; 3:60-4:16; 4:38-47; 4:58-60; claims 1, 5, 6, 11–13, 15, 19, 21; Figs. 1-2.

The tomographic densitometry models of the object obtained at different times are stored for comparison to assess, for example, changes in bone structure and/or density in the time between scanning sessions. *See* EX1001 at Abstract; 3:3-5; 3:14-16; 4:50-53; 5:9-11; 5:25-27; Fig. 2; claims 5-6, 11-12, 15, 19. In such instances, the system may use color-coding to represent differing bone densities in an image of the model for better visualization. *See* EX1001 at Abstract; 3:3-5; 4:51-52; 5:27-32.

B. THE CHALLENGED CLAIMS

Independent claim 1 of the '374 Patent recites:

A system for tomographically modeling a dental structure, the system comprising:

a controller with a microprocessor and a memory device connected to the microprocessor, said controller being adapted for storing computed tomographic models of a dental structure;

an input device connected to the microprocessor;

a positioning motor connected to the microprocessor and responsive to commands from said microprocessor;

X-ray equipment including an X-ray source, a detector array, and a restricted beam device;

a convertor for converting a signal from said detector array, said convertor being connected to said detector array and to said microprocessor;

and an output device connected to said microprocessor and adapted for receiving a tomographic model from said microprocessor.

EX1001 at 5:34-50. Claims 2-12 of the '374 Patent depend directly or indirectly on claim 1.

Independent claim 13 of the '374 Patent recites:

A tomographic modeling system comprising:
a controller with a microprocessor and a memory device connected to the microprocessor, said controller being adapted for creating, storing, and comparing 3D digital tomographic models of an object without the use of fiducial markers of said object;
an input device connected to the microprocessor;
a positioning motor connected to the microprocessor and responsive to commands from said microprocessor;
X-ray equipment including an X-ray source, a detector array, and a restricted beam device;
a convertor for converting a signal from said detector array, said convertor being connected to said detector array and to said microprocessor; and
an output device connected to said microprocessor and adapted for receiving a tomographic model from said microprocessor.

EX1001 at 6:45-61. Claims 14-20 of the '374 Patent depend directly or indirectly on claim 13.

Independent claim 21 of the '374 Patent recites:

A system for tomographically modeling a dental structure, which system comprises:
a controller with a microprocessor and a memory device connected to the microprocessor, said controller being adapted for creating, storing, and comparing 3D digital tomographic models of a dental structure without the use of fiducial markers of said dental structure;
an input device connected to the microprocessor;
a positioning motor connected to the microprocessor and responsive to commands from said microprocessor;
X-ray equipment including an X-ray source, a detector array, and a restricted beam device;
a convertor for converting a signal from said detector array, said convertor being connected to said detector array and to said microprocessor; and
an output device connected to said microprocessor and adapted for receiving a tomographic model from said microprocessor.

EX1001 at 7:18-8:13. Claims 22-24 of the '374 Patent depend directly or indirectly on claim 21.

C. LEVEL OF ORDINARY SKILL IN THE ART

As Dr. Omid Kia explains, a person of ordinary skill in the art (a “POSA”) at the time of the effective filing date in 1999 would be an individual with a bachelor’s degree in electrical and computer engineering or an equivalent technical degree, and with at least 3–5 years of experience in diagnostic imaging systems. EX2018 at ¶ 8.

Dr. Sonka’s definition of a POSA would “include a person with an advanced medical degree, such as an MD, DDS, or DMD if also combined with an undergraduate degree in Computer Science, Engineering, Medical Physics, Physics, or a related field, and/or an advanced degree in Computer Science, Engineering, Medical Physics, Physics, or a related field. *See* EX1007 at ¶ 53. Dr. Sonka’s definition is problematic for several reasons, including that an advanced medical degree would not be necessary or helpful, that its use of “and/or” is confusing as to what it modifies and why it is not simply “or”, and that it omits any experience in diagnostic imaging systems as a supplement to or replacement for the advanced degrees. Nevertheless, Dr. Kia meets the criteria of a POSA even under Dr. Sonka’s definition, at least because of his advanced degrees in electrical engineering. *See* EX2018 at ¶ 9.

As confirmed by the Federal Circuit, Dr. Kia would have been a person with at least ordinary skill in the art at the time of filing of the '301 Patent. *Osseo Imaging, LLC v. Planmeca USA Inc.*, 116 F.4th 1335, 1341 (Fed. Cir. 2024) (holding that “[i]t is undisputed that Dr. Kia’s qualifications meet that of a person of ordinary skill in the art in this case.”); EX2018 at ¶¶ 9-10.

III. LEGAL PRINCIPLES

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden never shifts to the Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015); *Impact Selector Int’l, LLC v. Petromac IP Ltd.*, IPR2019-01660, Paper 12, 6 (P.T.A.B. Apr. 17, 2020) (“It is Petitioner’s burden to prove unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner.”).

The petition must “identif[y], in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim.” 35 U.S.C. § 312(a)(3). In addition, “the information presented in the petition” “[must] show[] that 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); *In re Magnum*

Oil Tools Int'l, Ltd., 829 F.3d 1364, 1380 (Fed. Cir. 2016) (holding that the Board cannot “raise, address, and decide unpatentability theories never presented by the petitioner”). “[T]he petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.” 35 U.S.C. § 316(e).

The petitioner also has the initial burden of production to show that an asserted reference qualifies as prior art under 35 U.S.C. § 102. *Dynamic Drinkware*, 800 F.3d at 1378–79. Once the petitioner has met that initial burden, the burden of production shifts to the patent owner to argue or produce evidence that either the asserted reference does not render the challenged claims unpatentable, or the reference is not prior art. *Id.* at 1379–80 (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008)). Once the patent owner has met that burden of production in demonstrating, for example, entitlement of the challenged claims to a filing date that antedates the asserted reference, the burden of going forward again shifts to the petitioner to persuade the Board that the challenged claims are not entitled to the benefit of the earlier filing date. *See Tech Licensing Corp.* at 1328 (describing burdens in the context of an invalidity challenge in district court); *Guest Tek Interactive Ent. Ltd. v. Nomadix, Inc.*, No. IPR2019-01191, 2019 WL 7212601, at *6 (P.T.A.B. Dec. 27, 2019).

IV. ARGUMENT

Petitioner argues that the Osseo Patents are invalid as anticipated or obvious in view of U.S. Patent No. 6,118,842 (“Arai 842”); Christopher Cann, “Precise Measurement of Vertebral Mineral Content Using Computed Tomography,” *Journal of Computer Assisted Tomography* 4(4) 493500 (August 1980) (“Cann”); International Publication No. WO/94/10908 (“Pelc 908”); Stephen Rothman, *DENTAL APPLICATIONS OF COMPUTERIZED TOMOGRAPHY: SURGICAL PLANNING OF IMPLANT PLACEMENT* (Quintessence Books 1998) (“Rothman”); International Publication No. WO 01/39667 (“Massie”); U.S. Patent No. 5,533,080 (“Pelc 080”); U.S. Patent No. 6,363,163 (“Xu”); and/or International Publication No. WO 98/36683 (“Milestone”) (collectively, the “Asserted References”). *See generally* Petition; *see also* EX1013; EX1014; EX1015; EX1016; EX1017; EX1018; EX1019; EX1020.

A. THE ASSERTED REFERENCES FAIL TO ANTICIPATE AND/OR RENDER OBVIOUS THE CHALLENGED CLAIMS

1. The ’374 Patent Was Repeatedly Upheld as Valid By Other Tribunals

The validity of the challenged claims has already been adjudicated and confirmed. In *Osseo Imaging, LLC v. Planmeca USA Inc.*, 1- 17-cv-01386 (D. Del. 2017) (the “Planmeca Action”), the ’374 Patent was upheld as valid and nonobvious over prior art during three separate stages of the case – first when Planmeca USA

Inc. (“Planmeca”)’s Motion for Summary Judgment of No Infringement and Invalidity in View of Prior Art was denied, second when the jury found that Planmeca had failed to prove by clear and convincing evidence that the ’374 Patent was invalid, and third when Planmeca’s post-trial motions for judgment as a matter of law were denied by the Federal Judge. *See* EX2002; EX2003; EX2004. This verdict was then affirmed by the Federal Circuit in a precedential decision dated September 4, 2024. *See* EX2005. The Federal Circuit affirmed that substantial evidence supports the jury’s verdict of non-obviousness of the challenged patent claims of the ’374 Patent, finding:

Substantial evidence supports the jury’s findings necessary to support the verdict that the Asserted Patents are not invalid as obvious. First, Dr. Kia disputed Dr. Pelc’s conclusions regarding obviousness. J.A. 5056 at 1127:3– 22. Dr. Kia then testified on the differences between tomosynthesis and computed tomography. J.A. 5057–60 at 1128:10–1131:13. This discussion served as a backdrop against which Dr. Kia explained that densitometry, or bone density data, and tomosynthesis are incompatible with each other because tomosynthesis scans can produce blurry anatomical images. J.A. 5060–63 at 1131:14–1134:6. Based on this entire discussion, Dr. Kia concluded it would not have been obvious to a person of ordinary skill in the art to combine the tomosynthesis concept in Guenther with the densitometry concepts in Mazess and Fontevraud. *See* J.A. 5056 at 1127:3–22 (noting “one of ordinary skill in the art would not look to bone general density for a solution for a problem related to tomosynthesis”); J.A. 5068 at 1139:9–18; J.A. 5064–69 at 1135:13–1140:13. Thus, the jury heard evidence demonstrating that it would not have been obvious to a skilled artisan to combine the prior art references. The jury could reasonably rely on such evidence to find that Planmeca did not meet its burden to establish by clear and convincing evidence that the asserted claims of the

Asserted Patents are invalid for obviousness. Accordingly, we affirm the district court's denial of JMOL.

Id. at *17-18. (emphasis added).

In support of its invalidity arguments, Planmeca relied on the testimony of its expert, Dr. Norbert Pelc, whose patent documents Petitioner now asserts as prior art.³ In his invalidity opinion, Dr. Pelc alleged, among other things, that the '374 Patent was anticipated and/or obvious in view of U.S. Patent No. 5,214,686 to Webber ("Webber 686"), U.S. Patent No. 5,500,884 to Guenther *et al.* ("Guenther 884"), U.S. Patent No. 6,315,445 to Mazess *et al.* ("Mazess 445"), U.S. Patent No. 6,898,302 to Brummer ("Brummer 302"), and U.S. Patent No. RE 36,162 to Bisek *et al.* ("Bisek 162"). *See* EX2006; EX2007; *see also generally* EX2008. Planmeca unequivocally lost on *each* ground – a fact that Petitioner fails to even mention. Indeed, Petitioner attempts to significantly downplay the Planmeca Action, only referencing it in the context of claim construction, and entirely neglects to acknowledge its outcome, including the upholding of the '374 Patent's validity. *See* Petition at 20. This is likely intentional because (i) Petitioner's arguments for invalidity here are essentially the same as those asserted by Planmeca and (ii) Petitioner relies on prior art that is substantially the same as the prior art relied upon in the Planmeca Action.

³ Dr. Pelc is a named inventor of Pelc 908 and Pelc 080. *See* EX1015; EX1018.

2. The Preamble is Limiting

Petitioner argues that the preambles of Claims 1, 13, and 21 of the '374 Patent are “non-limiting statement[s] of purpose.” Petition at 33-34, 52. This is incorrect. The preambles are limiting in that they recite the essential structure of “[a] system for tomographically modeling dental and orthopedic structure densitometry” as disclosed in the specification of the '374 Patent. *See* EX1001 at Abstract; 4:62-5:31; *see also Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006) (“...the preamble is regarded as limiting if it recites essential structure that is important to the invention or necessary to give meaning to the claim.”). In cases where the claim drafter purported to use both the preamble and the body of the claim to define the subject matter of the invention, the preamble is considered necessary to give life, meaning, and vitality to the claims. *American Imaging Services, Inc. v. Intergraph Corp.*, No. 99-1485, 2000 WL 772725, at *5 (C.A. Fed. June 12, 2000).

Here, the preambles provide an understanding of the scope and meaning of the claim elements, consistent with the specification that discusses models in the context of densitometric modeling. *See* EX2018 at ¶ 59; EX1001 at Abstract; 1:24-27; 2:31-32; 2:49-61; 3:9-13; 3:64-4:60; 4:62-5:31. As such, the preambles give “life, meaning and vitality to the claims” and should be construed as limiting. *American Imaging Services, Inc.*, 2000 WL 772725, at *5.

3. Arguments that Substantially Overlap with Petitioner’s Arguments Were Already Addressed and Overcome in the Planmeca Action and Have Significant Weaknesses

The invalidity arguments in the Petition “overlap substantially with those” in the Planmeca Action. *See E-One, Inc. v. OshKosh Corp.*, IPR2019-00161, Paper 16 at 8 (P.T.A.B. May 15, 2019). Petitioner does not dispute the claim constructions from the Planmeca Action and presents prior art and arguments here that “essentially duplicate what has been...litigated” in the Planmeca Action, leaving little point to the Board having to investigate and address the same issues again. *Id.* at 7; *see also* Petition at 20.

Petitioner relies on Arai 842 and Pelc 908 for its primary references. *See* EX1013; EX1015. Contrary to Petitioner’s arguments, the computed tomography (“CT”) system used to generate tomographic models in Arai 842 or Pelc 908 does *not* provide information regarding bone density as required by the challenged claims. *See* EX2018 at ¶¶ 54, 90; Petition at 34-35 (citing EX1007 at ¶¶ 70, 92-93, 227-229). Specifically, the Asserted References fail to disclose tomographic and densitometry modeling, including with regard to “merging information from multiple tomographic scans of an object to produce a representation of the subject, said representation depicting quantitative density differences of the object scanned, which is created by the microprocessor in the controller using densitometry from at

least one focal plane” as required by the United States District Court for the District of Delaware’s construction⁴. *See* EX1009 at 2; EX1010; EX2018 at ¶¶ 45, 60.

In fact, neither Arai 842 nor Pelc 908 mention bone density or densitometry at all. *See generally* EX1013; EX1015; *see also* EX2018 at ¶¶ 54, 90. The sole mention of “density” in Arai is regarding the estimation of subject density to dial in an X-ray energy. *See* EX1013 at 18:16-19 (“The embodiment is configured so that the exposure amount of X-rays emitted from the X-ray source is adjusted on the basis of the density of the image information stored in the frame memory”). There is no teaching of creating any model, particularly a densitometric model, in Arai. *See generally* EX1013; *see also* EX2018 at ¶ 65.

Recognizing this obvious deficiency with its prior art, Petitioner argues that the bone density data is somehow either inherently there in the opinion of their expert or is taught by other art that may be combined with Arai 842 or Pelc 908. *See* Petition at 35-36 (citing EX1007 at ¶¶ 181-185, 231). Significantly, Dr. Pelc himself (an inventor of Pelc 908), when serving as Planmeca’s expert, testified at trial that CT scans alone ***do not*** measure quantitative bone density. *See* EX2009 at 789:6-18 (Dr. Pelc explaining how pioneers in the field of quantitative computed tomography (“QCT”) “realized that CT alone was not able to quantitatively measure or compute

⁴ The United States District Court for the District of Delaware construed certain claim terms in the Planmeca Action.

bone density by itself.”); *id.* at 921:13-20 (Dr. Pelc explaining why someone imaging a skeleton using CT alone would not be able to assess bone density). As such, the very testimony of the inventor on one of Petitioner’s primary references has already undermined Petitioner’s main argument. At the very least, Pelc’s testimony in the Planmeca Action shows that this very issue has already been considered and decided, and thus it is a waste of time and resources for the Board to reexamine this issue again.

Indeed, Petitioner’s strategy of combining Arai 842 and/or Pelc 908 with either their expert’s assertion that they inherently disclose bone density data or with another reference allegedly showing densitometry is an exact replica of Planmeca’s unsuccessful arguments in the Planmeca Action. In that action Planmeca repeatedly tried – during summary judgment, the jury trial, the post-trial motions, and on appeal to the Federal Circuit – *but failed* to show that its primary references like Guenther 884, which purportedly taught tomographic imaging, either inherently disclosed a model with quantitative bone density or would have been obvious to combine with other references that allegedly taught densitometry. *See* EX2002; EX2003; EX2004; EX2005; EX2010.

The same arguments presented here by Petitioner using Arai 842 and Pelc 908 instead of Guenther 884 should and will fail for the same reasons – that it would, in fact, *not have been obvious* to one of ordinary skill in the art to make such a

combination in 1999, when the '301 Patent was filed. The cited sections of Arai 842 do not discuss or even mention tomographic modeling, only tomographic imaging. *See* Petition at 34 (citing EX1013 at 2:3-5 (“It is an object of the invention to provide an X-ray imaging apparatus which can conduct a partial CT imaging in addition to a panoramic *tomographic imaging*.”); 17:42-48 (“Plural sets of image information stored in the frame memory 240 are stored in the image memory for arithmetic 241. A predetermined arithmetic process corresponding to the selected imaging mode is conducted on image information read out from the image memory for arithmetic 241, thereby generating a *tomographic image* of the selected mode.”)) (emphasis added). For the purposes of Petitioner’s invalidity arguments, Arai 842 and Pelc 908 represent the *same* disclosures as Guenther 884, just under a different name.

4. A POSA Would Not Know to Utilize Densitometric Modeling Based on Arai 842

Petitioner’s reliance on Dr. Sonka’s opinion on this issue is misplaced and lacking in factual support. *See* Petition at 34-35. In his declaration, Dr. Sonka fails to identify any discussion of 3D tomographic models in Arai 842. Dr. Sonka’s support is limited to his assertion that Arai 842’s “‘plural sets of image information’ are tomographic slices of the imaged region, which Arai further teaches are combined by ‘arithmetic 241,’ (software) to generate a tomographic model.” EX1007 at ¶ 252. The model which Dr. Sonka refers to does not contain bone

density data and is therefore *not* a densitometric model as required by the Osseo Patents. EX2018 at ¶ 63. Nor are the “3D model[s]” he refers to thereafter. EX1007 at ¶¶ 252-253. As such, Dr. Sonka’s conclusory opinion that “the tomographic image generated by the system in Arai is a 3D image” lacks any factual support. EX1007 at ¶ 180.

A POSA would not be taught or suggested to make a dental model as claimed based on Arai 842. *See* EX2018 at ¶¶ 66-69. Arai 842 discusses using a cone or pyramid shaped x-ray beam, of the type used in Cone Beam Computed Tomography (“CBCT”). *See* EX1013 at 7:19-32; 26:39-43. This use of CBCT imposes a significant number of inaccuracies associated with cone beam geometry and various artifacts. *See* EX2018 at ¶¶ 66-69.

Furthermore, none of the features related to the use of CT for dental implant operation as discussed in Arai 842 require tomographic modeling, and particularly not densitometric modeling. *See* EX2018 at ¶ 70. The primary motivation discussed in Arai 842 is to navigate the anatomy using a panoramic image, which requires utilizing size information but has nothing to do with bone density. *See generally* EX1013; *see also* EX2018 at ¶ 81. Arai 842 does not in fact provide any insight as to the need and purpose of utilizing bone density. *See generally* EX1013; *see also* EX2018 at ¶ 71. Based on Arai, it would not have been obvious for a POSA to seek

densitometric accuracy and pursue a densitometric model from a CT. *See* EX2018 at ¶ 82.

5. Pelc 080 Fails to Address the Shortcomings of Arai 842

Dr. Sonka admits that Arai 842 does not explicitly mention densitometry and instead attempts to utilize Pelc 080 to connect CT to the calculation of bone density. *See* EX1007 at ¶ 229. However, Pelc 080 also fails to explain density, densitometry, mineral content, or any combination thereof. *See generally* EX1018. Dr. Sonka does not even cite to any portion of Pelc 080 describing the admittedly missing element from Arai 842. *See* EX1007 at ¶ 229 (Dr. Sonka stating that “[t]he underlying data disclosed in Pelc ’080, like Arai, is quantitative in nature because each voxel forming each tomographic slice has an integer, and thus quantitative, value.”).

6. A POSA Would Not Combine Arai 842 with Cann

One of the combinations Petitioner tries to form is Arai 842 as its primary reference combined with Cann in support of its obviousness arguments. *See* Petition at 35-56; EX1014. Just as the Federal Circuit affirmed a finding that it would not have been obvious to a person of ordinary skill in the art to combine the tomosynthesis concept in Guenther 884 with the densitometry concepts in Mazess 445, a combination of the CT system of Arai 842 with the densitometry

measurements allegedly disclosed in Cann would not be obvious either. *See* EX2005 at *17-18; *see also* EX2018 at ¶¶ 73-80.

A POSA considering Arai 842 would understand that the disclosure at best describes a CT scan that measures distances in the human dental structure, and not density. *See* EX1013 at 1:35-47; *see also* EX2018 at ¶ 74. Cann discusses methods for measuring density of vertebral mineral content, which is an entirely different anatomy than human dental structures. *See generally* EX1014; *see also* EX2018 at ¶ 75. Furthermore, Cann's measurement of bone density is targeted towards acquiring the correct measurement of mineral content and not the creation of a model. *See generally* EX1014; *see also* EX2018 at ¶ 75.

A POSA considering Cann would not be informed of two very important aspects of the density of hard tissue used for modeling that is present in human dental structure but absent from vertebral anatomy as disclosed by Cann – the structure of trabecular bone and voxel sizes of sub-millimeter range. *See* EX2018 at ¶¶ 76-77. Nor does Cann disclose any relevant information regarding tooth density. *See generally* EX1014; *see also* EX2018 at ¶ 79. Further, the combination of errors in measuring density, geometry of scanning and resolution of the potential result as disclosed in Cann would inform a POSA that such techniques are not only irrelevant to human dental structure but are completely incompatible for use with Arai 842. *See generally* EX1014; *see also* EX2018 at ¶ 78.

Perhaps more importantly, Petitioner's use of Cann should fail for another reason – it is *the same reference* that was already raised and overcome in the Planmeca Action. Indeed, Cann was cited and argued in the Planmeca Action *for the same purpose* that Petitioner is raising it here, *i.e.*, as allegedly discussing densitometry as required by the challenged claims. *See* EX2008 at ¶¶ 135, 194; *see also* EX2009 at 918:22-24 (“Q. Okay. And this Cann article you say teaches bone densitometry and quantitative computed tomography? A. Yes.”).

For at least these reasons, a POSA considering Arai 842 in view of Cann would not be informed of any need or method of creating a densitometric model of the human dental structure. *See* EX2018 at ¶ 80.

7. Arai 842 in Combination with Cann and Other Asserted References Fails to Render the '374 Patent Obvious

Dr. Sonka alleges that Arai 842 in combination with Cann, and in further combination with Xu and/or Milestone renders certain challenged claims obvious. *See* EX1007 at ¶ 260. Xu does not disclose dental anatomical structures, but rather discusses the application of subtraction mainly to lungs. *See* EX1019 at Abstract. Xu had to consider only a limited variability in orientation since a patient would routinely be lying down for a CT scan of the lungs. *See* EX2018 at ¶¶ 52, 85. While the variability in orientation is important to the target anatomy, the method of scanning is also crucial. *See id.* In Xu, the bed supporting the patient acts as the

reference point allowing a limited variability (since the lungs are within a known cavity in the human body). *See* EX1019 at Fig. 5A.

As an example of anatomical implications, the range of variabilities would be completely different if the bed was used but it was the patient's legs being scanned rather than the lungs. *See* EX2018 at ¶ 86. Because the legs do not have to limit their location as the lungs do, significant variability in subtraction is introduced. *See id.* More importantly, a patient sitting on a chair instead of lying on a bed introduces a large amount of variability for scanning dental structures. *See id.* A POSA would understand that the process discussed in Xu would not easily be adaptable for use with dental structures. *See id.*

Dr. Sonka opines that Milestone teaches “creating three-dimensional models.” EX1007 at ¶ 217 (citing EX1020 at Abstract). However, the abstract makes no mention of creating three-dimensional models. *See* EX1020 at Abstract. Any models referred to in Milestone comprise recognized structures for analysis of anomalies rather than a three-dimensional model. *See* EX1020 at 12:26-33 (“...the processor (or more appropriately the software operating within the processor) can determine the structures that depend from the trachea and properly identify them according to the selected model....an abnormality is, in its broadest sense, a difference (deviation) between the scanned data and the normative data which requires closer inspection by a physician.”). Furthermore, Milestone, like Xu,

discusses scanning a patient's lungs. *See* EX1020 at Fig. 1. A POSA would understand that the process discussed in Milestone would not easily be adaptable for use with dental structures. *See* EX2018 at ¶ 87.

Dr. Sonka states that Rothman “provides several examples of software capable of processing the collected data to create three-dimensional tomographic models of dental structures.” EX1007 at ¶ 207 (citing EX1016 at 14-30). However, the cited section of Rothman does not discuss the creation of three-dimensional models; rather, this discussion is limited to the creation of cross-sectional images. *See* EX1016 at 16 (“The first part of this process is for the computer to dig into the stack of axial slices and identify all the picture elements along each of the drawn cross-sectional oblique lines. These picture elements are then rearranged into images and displayed as a sequence of oblique cross sections, which are numbered from right to left.”).

Notably, Dr. Sonka repeatedly refers to Rothman's “series of axial sections, or slices,” as data that “can be reconstructed in a tomographic model of the patient's dental structures.” EX1007 at ¶ 208 (citing EX1016 at 14-15). In fact, Rothman does not discuss the use of the “series of axial sections, or slices,” for the generation of tomographic models. Instead, the “axial CT data” is used in multiplanar reformation. *See* EX1016 at 14-15.

8. Petitioner Mischaracterizes Arai 842 in a Critical Way

Petitioner alleges that Arai 842 teaches use of CT to generate a tomographic model. *See* Petition at 34. This is incorrect. Arai 842 discusses two imaging modes which *never operate simultaneously* – a CT mode and a panoramic tomographic mode. EX1013 at 2:36-49; *id.* at Abstract. In Arai 842, “the imaging mode is selected by the mode switching means, whereby the selected X-ray imaging can be conducted.” *Id.* at 2:47-49. Petitioner tries to bury this fact, erroneously stating that “Arai 842 teaches a system for tomographically modeling dental structure densitometry.” Petition at 34. Arai 842 either creates a CT image in the CT mode *or* a panoramic tomographic image in the panorama mode – it does not disclose creating a tomographic model using CT, and certainly never discloses a tomographic model showing dental structure densitometry as required by the challenged claims. *See* EX1013 at 2:36-49; EX2018 at ¶¶ 47, 65.

9. Dr. Sonka’s Declaration Contains Inconsistencies Regarding Arai 842

With respect to the “without the use of fiducial markers” limitation in claims 13 and 21 of the ’374 Patent, Dr. Sonka opines that the CT system in Arai 842 does not use a fiducial marker. *See* EX1007 at ¶ 278. However, Dr. Sonka goes on to say that a later Arai patent, U.S. Patent No. 6,243,439 (“Arai 439”), *does* disclose fiducial markers to improve accuracy. *See id.* This indicates that the older Arai

disclosure describes a system that is less accurate. Dr. Sonka's opinion that in view of the advancements throughout the 1990s, a POSA would understand the need for fiducial markers decreased and was often unnecessary for obtaining accurate comparisons is incorrect. *See id.* The named inventors of Arai 439, who were arguably more informed than a POSA, had to add fiducial markers to improve accuracy. *See* EX2018 at ¶ 84.

10. Dr. Pelc Himself Admitted That None of His Patents Relate to Dental Imaging

The named inventor of Pelc 908 and Pelc 080, Dr. Pelc himself, admitted at trial in the Planmeca Action that none of his patents or articles are related to dental imaging, and that he does not have any expertise in that field. *See* EX2009 at 903:2-9 (“Q. During your -- any of your degrees, did you take any courses focused on dental imaging? A. No. Q. What about dental care, dentistry, anything like that? A. No.”); *id.* at 903:23-25 (“Q. Thank you, did you do any work in designing of machines focused on dental imaging? A. No.”); 906:6-12 (“Q. Were any of those articles specifically focused on dental imaging? A. No. Q. I see you have listed here some courses that you have taught, x-ray computed tomography, so forth. Did you ever teach any courses on dental imaging? A. No.”); 906:17-907:2 (“Q. You're an inventor on 95 patents? A. That's correct. ***Q. Were any of those patents specifically focused on improvement in dental imaging?*** A. No. Q. If I were to do a search, say

the word teeth, you know, in any field of your 95 patents, how many patents would come up? A. I have no idea. Q. Would it surprise you that the answer is 0? A. No.”) (emphasis added).

Pelc 908 discusses a whole-body scan – not densitometric modeling using tomographic scans. *See* EX1015 at 23:6-13. The word “model” is used only twice in Pelc 908 – once to describe the curvature of the spine and a second time to model the dual energy calibration using phantoms of known densities. *See* EX1015 at 26:11-14; 40:1-6. Pelc 908 does not disclose generating a dental densitometric model using tomographic scans. *See generally* EX1015. Dr. Sonka’s assertion that Pelc 908 relates to CT modeling is incorrect – CT scans are not inherently related to modeling, and certainly not to dental densitometric modeling. *See* EX2018 at ¶ 91; EX1007 at ¶ 295.

Notably, the fact that Dr. Pelc was the expert in the Planmeca Action and he himself did not assert his patent (*i.e.*, Pelc 908, cited by Petitioner) during expert disclosures and his testimony speaks volumes as to the weakness of Petitioner’s invalidity arguments in the Petition.

Furthermore, Pelc 908 is substantially similar to Mazess 445 which Planmeca asserted as prior art in the Planmeca Action – Richard B. Mazess is a named inventor on both, and both patents were assigned to Lunar Corporation. Once again, Petitioner attempts to assert prior art that is close to or identical to the prior art

already asserted and defeated in the Planmeca Action. Petitioner’s invalidity arguments amount to nothing more than a shell game – a mere reshuffling of names and references that have already been adjudicated and overcome.

B. THE BOARD DID NOT HAVE THE BENEFIT OF REFERRING TO ALMOST FIVE YEARS OF LITIGATION UPHOLDING THE CHALLENGED CLAIMS WHEN THE ’659 IPR WAS INSTITUTED

As Petitioner has pointed out, the ’374 Patent was subject to a prior IPR, Case IPR2020-00659 (the “’659 IPR), which was filed by Kavo Dental Technologies, LLC (“Kavo”) and instituted on June 10, 2020. *See* EX2011. Petitioner relies on the same prior art and substantially the same grounds that the Board previously concluded warranted institution in the ’659 IPR. Petitioner does not explicitly rely on any changes in the law or new judicial precedent since issuance of the challenged claims that may affect patentability. *See generally* Petition. The Board’s institution of the ’659 IPR has little relevance to whether it should consider or will institute the instant IPR proceeding.

The fact that the Board instituted the ’659 IPR is not an indication of the merits of that case or of the instant case. Osseo did not present any substantive arguments in the Patent Owner Preliminary Response in the ’659 IPR. Instead, Osseo merely argued for discretionary denial of institution in view of the upcoming trial in the Planmeca Action. *See* EX2011 at 11 (“Patent Owner argues we should exercise

discretion under 35 U.S.C. § 314(a) and deny institution based on the trial scheduled for October 2020 in the Planmeca proceeding.”); 26-27 (“Patent Owner does not dispute Petitioner’s contentions at this time.”).

The ’659 IPR was then terminated as a result of settlement; as such, the Board did not reach a Final Written Decision. *See* EX2012. Since then, almost five years of litigation regarding the challenged claims have repeatedly proven their validity. At the time of the ’659 IPR, the Board did not have the benefit of referring to the outcome of the Planmeca Action or the Federal Circuit decision affirming the verdict in the Planmeca Action. Moreover, in view of its termination before a Final Written Decision was issued, Osseo never substantively responded to the petition in the ’659 IPR.

Since the Board’s decision to institute the ’659 IPR was made without having any evidence presented by Osseo or without the benefit of the testimony and findings of the Planmeca Action, it does not at all follow that this Board will or should reach the same conclusion.

In sum, the validity of the ’374 Patent has been considered not once, not twice, but *three times* – twice by judges as well as by a jury. The myriad weaknesses in Petitioner’s unpatentability challenge, including a few of which were spelled out above, further favors utilizing the discretionary power of the Director to deny institution.

C. SUBSTANTIALLY THE SAME PRIOR ART WAS PREVIOUSLY PRESENTED TO THE OFFICE

Not only are the prior art and invalidity arguments relied upon by Petitioner substantially the same as those in the Planmeca Action, they are also substantially the same as prior art considered during prosecution of the Osseo Patents, providing an additional reason for the Director to exercise discretion to deny this Petition.

“Section 325(d) provides that the Director may elect not to institute a proceeding if the challenge to the patent is based on matters previously presented to the [United States Patent and Trademark] Office” (the “Office”). *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, No. IPR2019-01469, 2020 WL 740292, at *2–3 (P.T.A.B. Feb. 13, 2020). 35 U.S.C. § 325(d) states, in pertinent part, “[i]n determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” *Advanced Bionics, LLC v. GmbH* at *2-3.

Under § 325(d), the prior art and arguments must have been previously presented to the Office during proceedings pertaining to the challenged patent. *Id.* at *3. Previously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement, in the prosecution history of the challenged patent. *Id.* The proceedings

in which the art was previously presented include, for example, examination of the underlying patent application. *Id.*

Applicant Osseo filed an Information Disclosure Statement (the “IDS”) on September 14, 2012, when the application leading to the ’374 Patent was filed. *See* EX1004 at 39. The IDS listed, amongst other patents, U.S. Patent No. 5,784,429 to Yoshinori Arai, entitled “Dental Panoramic X-ray Imaging Apparatus” (“Arai 429”), and U.S. Patent No. 5,677,940 to Masakazu Suzuki, Keisuke Mori, and Akifumi Tachibana, entitled “Digital X-ray Imaging Apparatus” (“Suzuki 940”). *See id.; see also* EX2013; EX2014. Masakazu Suzuki, Keisuke Mori, and Akifumi Tachibana are named inventors of Arai 842, which is cited by Petitioner in the present case. *See* EX1013. Pelc 080, which is also cited by Petitioner in the present case, was also listed in the IDS. *See* EX1004 at 48; EX1018.

The disclosures of Arai 842, Arai 429, and Suzuki 940 are all directed to panoramic tomographic imaging (and not tomographically modeling dental structure densitometry as taught by the ’374 Patent) and none of these references even mention densitometry. *See* EX1013 at Abstract, 2:36-49; EX2013 at Abstract; EX2014 at 1:5-9. The fact that substantially the same prior art was made of record and considered by the Office during prosecution of the ’374 Patent further supports a denial of the Petition as an inefficient use of the Board’s time and resources.

V. CONCLUSION

For at least the reasons noted above, Petitioner has not met its burden to show a reasonable likelihood that any challenged claim of the '374 Patent is unpatentable.

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CERTIFICATE OF COMPLIANCE

The undersigned certifies this document complies with the type-volume limitation of 37 C.F.R. § 42.24(b). The PATENT OWNER PRELIMINARY RESPONSE contains 6,924 words, as calculated by Microsoft Word (not including the portions exempted by 37 C.F.R. § 42.24).

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4) and 42.205(b), the undersigned certifies that on July 16, 2025, a true and correct copy of the PATENT OWNER PRELIMINARY RESPONSE was served by filing this document through the PTAB E2E portal and via email to the following counsel for the Petitioner:

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