

**UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

DENTSPLY SIRONA INC.
Petitioner

v.

OSSEO IMAGING, LLC.
Patent Owner

U.S. PATENT NO. 6,381,301
IPR2025-00771

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 6,381,301**

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35 U.S.C. § 103	7, 8
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EXHIBIT LIST

No.	Description
Ex. 1001	U.S. Patent No. 8,498,374 (the “374 patent”).
Ex. 1002	U.S. Patent No. 6,381,301 (the “301 patent”).
Ex. 1003	U.S. Patent No. 6,944,262 (the “262 patent”).
Ex. 1004	U.S. Patent No. 8,498,374 (the “374 patent”) Prosecution History.
Ex. 1005	U.S. Patent No. 6,381,301 (the “301 patent”) Prosecution History.
Ex. 1006	U.S. Patent No. 6,944,262 (the “262 patent”) Prosecution History.
Ex. 1007	Declaration of Dr. Milan Sonka (“Sonka”).
Ex. 1008	Curriculum Vitae of Dr. Milan Sonka.
Ex. 1009	Markman Order, Dkt. 46, <i>Osseo Imaging, LLC v. Planmeca USA Inc.</i> , 1-17-cv-01386 (D. Del. 2017).
Ex. 1010	Markman Memorandum, Dkt. 44, <i>Osseo Imaging, LLC v. Planmeca USA Inc.</i> , 1-17-cv-01386 (D. Del. 2017).
Ex. 1011	Markman Transcript, Dkt. 41, <i>Osseo Imaging, LLC v. Planmeca USA Inc.</i> , 1-17-cv-01386 (D. Del. 2017).
Ex. 1012	Summary Judgment Hearing Transcript, Dkt. 143, <i>Osseo Imaging, LLC v. Planmeca USA Inc.</i> , 1-17-cv-01386 (D. Del. 2017).
Ex. 1013	U.S. Patent No. 6,118,842 (“Arai”).
Ex. 1014	Cann, et al., “Precise Measurement of Vertebral Mineral Content Using Computed Tomography,” <i>Journal of Computer Assisted Tomographs</i> 4(4) 493–500 (August 1980) (“Cann”).
Ex. 1015	International Publication No. WO 94/10908 (“Pelc”).
Ex. 1016	Stephen L.G. Rothman, DENTAL APPLICATIONS OF COMPUTERIZED TOMOGRAPHY: SURGICAL PLANNING FOR IMPLANT PLACEMENT (Quintessence Books 1998) (“Rothman”).

No.	Description
Ex. 1017	International Publication WO 01/39667 (“Massie”).
Ex. 1018	U.S. Patent No. 5,533,080 (“Pelc ‘080”).
Ex. 1019	U.S. Patent No. 6,363,163 (“Xu”).
Ex. 1020	International Publication WO 98/36683 (“Milestone”).
Ex. 1021	Jerrold T. Bushberg, <i>THE ESSENTIAL PHYSICS OF MEDICAL IMAGING</i> (Williams & Wilkins 1994) (“Bushberg”).
Ex. 1022	Genant <i>et al.</i> , “Bone Densitometry: Current Assessment,” <i>Osteoporosis International</i> S:91–97 (1993) (“Genant 1993”).
Ex. 1023	Genant <i>et al.</i> , “Current State of Bone Densitometry for Osteoporosis,” <i>Radiographics</i> 18(4):913–918 (1998) (“Genant 1998”).
Ex. 1024	U.S. Patent No. 5,214,686 (“Webber”).
Ex. 1025	21 C.F.R. § 1020.31 (April 1998).
Ex. 1026	U.S. Patent No. RE 36,162 (“Bisek”).
Ex. 1027	U.S. Patent No. 6,243,439 (“Arai ‘439”).
Ex. 1028	Godfrey N. Hounsfield, “Computed Medical Imaging,” Nobel Lecture (Dec. 8, 1979), <i>available at</i> https://www.nobelprize.org/uploads/2018/06/hounsfield-lecture.pdf .
Ex. 1029	Grant, “TOMOSYNTHESIS: A Three-Dimensional Radiographic Imaging Technique,” <i>IEEE Transactions on Biomedical Engineering</i> , BME-19(1):20–28 (Jan. 1972) (“Grant”).
Ex. 1030	U.S. Patent No. 6,073,044 (“Fitzpatrick”).
Ex. 1031	Hosie <i>et al.</i> , “A Gamma Ray Computed Tomography Scanner for the Quantitative Measurement of Bone Density,” <i>Journal of Biomedical Engineering</i> 7:30–34 (Jan. 1985) (“Hosie”).

No.	Description
Ex. 1032	World Health Organization, “Assessment of Fracture Risk and Its Application to Screening for Postmenopausal Osteoporosis,” WHO Technical Report Series 843 (1994) (“WHO 94”).
Ex. 1033	Venkatesh <i>et al.</i> , “Cone Beam Computed Tomography: Basics and Applications in Dentistry,” <i>Journal of Istanbul University Faculty of Dentistry</i> , 51(3 Suppl 1): S102-121 (December 2017) (“Venkatesh”).
Ex. 1034	Summary Judgment Answering Brief in Opposition, Dkt. 131, <i>Osseo Imaging, LLC v. Planmeca USA Inc.</i> , 1-17-cv-01386 (D. Del. 2017).
Ex. 1035	Mozzo <i>et al.</i> , “A new volumetric CT machine for dental imaging based on the cone-beam technique: preliminary results,” <i>Eur. Radiol.</i> , 8: 1558-64 (1998) (“Mozzo”).
Ex. 1036	Noo <i>et al.</i> , “Stable and Efficient Shift-Variant Algorithm for Circle-Plus-Lines Orbits in Cone-Beam C.T.,” <i>Institute of Electrical and Electronics Engineers</i> , Conference Date: Sept. 19, 1996 (“Noo”).
Ex. 1037	Lindh <i>et al.</i> , “Quantitative computed tomography of trabecular bone in the mandible,” <i>Dentomaxillofacial Radiology</i> , 25:146–150 (1996) (“Lindh”).
Ex. 1038	Sonka, M., & Fitzpatrick, J. M. (Eds.). (2000). <i>Handbook of Medical Imaging, Volume 2: Medical Image Processing and Analysis</i> . SPIE Press. (“SPIE”).

I. INTRODUCTION

Dentsply Sirona Inc. (“Dentsply” or “Petitioner”) respectfully requests *inter partes* review (“IPR”) of Claims 1–8 and 10–20 of U.S. Patent No. 6,381,301 (“the ‘301 patent”), Exhibit (“Ex.”) 1002, entitled “Dental and Orthopedic Densitometry Modeling System and Method.”

The Board previously reviewed the patentability of the currently challenged claims and instituted a trial, finding that the prior art and grounds “established the requisite reasonable likelihood of prevailing as to claims 1–9 and 10–20 of the ‘301 patent.” IPR2020-00671, Paper No. 10 at 27. Petitioner here relies on the same prior art and substantially the same grounds that the Board previously agreed warranted institution, and thus the Board should likewise institute the instant IPR proceeding.¹

The patent concedes that it uses known technology to apply known methods to create a claimed system for tomographically modeling dental and orthopedic structure. Ex. 1002 at 5:28-8:26. It touts as an advantage that the purported invention “utilizes commercially available tomography equipment.” *Id.* at 3:10-11. Yet, it admits that tomographical medical imaging was known: “Tomography or

¹ The prior IPR was terminated after institution due to settlement by the parties so the Board did not reach a Final Written Decision in the prior IPR.

sectional radiography techniques using scanning X-ray beams have previously been employed for dental applications.” *Id.* at 1:61-63. It also admits that it was known to measure bone density with “densitometry procedures” using “scanning X-ray beam techniques.” *Id.* at 2:1-3.

The patent contends as a point of novelty: “Heretofore there has not been available a system or method for applying the technology of densitometry to dental and medical applications such as the detection of caries and decalcification and the monitoring of osseointegration in connection with dental and medical prostheses.” *Id.* at 2:32-36; *see also id.* at 2:18-20 (“The present invention utilizes such densitometry modeling and mapping techniques for dental applications.”). This runs contrary to the “‘well settled’ fundamental principle ‘that the recitation of a new intended use for an old product does not make a claim to that old product patentable.’” *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1328 (Fed. Cir. 2019) (*quoting In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997)). Moreover, despite its specification’s focus on dental applications, most of the claims are not so limited.

Tomographic densitometry was not new. As described below, there exists a wealth of art. The purported invention merely takes known systems and techniques from general medical imaging and applies them in a non-inventive and predictable manner. This is not enough to impart patentability.

II. MANDATORY NOTICES

A. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1))

The real parties-in-interest are Dentsply Sirona Inc.

Dentsply Sirona's address is:

13320-B, Ballantyne Corporate Pl

Charlotte, NC 28277

B. Related Matters (37 C.F.R. § 42.8(b)(2))

U.S. Patent No. 6,381,301 was previously subject to an IPR, IPR2020-00671(the '671 IPR), which was Instituted on June 10, 2020. See IPR2020-00671 at Paper 10. The Trial was terminated due to settlement. See IPR2020-00671 at Paper 14.

Osseo Imaging ("Osseo" or Patent Owner") filed a lawsuit against Dentsply that was served on May 13, 2024. The litigation has not started as there is a pending Motion to Dismiss that was fully briefed as of November 8, 2024, and no Answer is currently due.²

² *Fintiv* analysis does not apply because the litigation has not reached the point of an Answer and there is no pending trial date or any dates for substantive filings. Petitioner reserves all rights to dispute the applicability of the *Fintiv* factors in the present proceeding.

C. Lead and Backup Counsel and Service Information (37 C.F.R. § 42.8(b)(3)-(4))

Petitioner is represented by the following counsel:

Lead Counsel	Backup Counsel
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Pursuant to 37 C.F.R. §42.10(b), Powers of Attorney have been filed with this Petition.

D. Service Information Under 37 C.F.R. §42.8(b)(4)

Physical mailing service information for lead and backup counsel is as follows:

James Murphy
Polsinelli PC
1000 Louisiana Street
Suite 6400
Houston, Texas 77002

Petitioner also consents to service by e-mail at the above e-mail addresses provided for lead and backup counsel.

E. Payment of Fees Under 37 C.F.R. §42.15

All required fees have been paid with the filing of this Petition. If there are any additional or outstanding fees, Petitioner further authorizes the U.S. Patent & Trademark Office to charge Deposit Account No. 50-1662 for these fees, including the fee set forth in 37 C.F.R. §42.15(a) for this Petition.

F. Certification of Word Count under 37 C.F.R. §42.24(d)

Petitioner certifies that the word count in this Petition, including all footnotes and annotations, is 13,887 words as counted by the word-processing program used to generate this Petition, where such word count excludes the table of contents, mandatory notices, certificate of service, list of exhibits, and this certificate of word count. This Petition is in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24(a)(1)(i).

III. GROUNDS FOR STANDING, POWER OF ATTORNEY, AND FEES.

Petitioner certifies that the '301 patent is available for *inter partes* review, and that Petitioner is not barred or estopped from requesting an *inter partes* review of the '301 Patent claims on the grounds identified in this Petition. 37 C.F.R. §42.104(a).

IV. IDENTIFICATION OF GROUNDS

In the ‘671 IPR, the Board Instituted Review of claims 1-8 and 10-20 based on the two primary references presented below, Arai and Pelc. The Board found there was a reasonable likelihood that claims 1-8 and 10-20 were rendered obvious by Arai, alone or in combination and Pelc, alone or in combination. ‘671 IPR at Paper 10 at 11-18.³ Accordingly, the Board has previously undertaken the analysis of the Grounds in this Petition and found them reasonably likely to anticipate or render obvious claims 1-8 and 10-20 of the ‘301 Patent.

Petitioner challenges claims 1–8 and 10–20 of the ‘301 patent⁴ and requests the claims be found unpatentable as follows:

Arai Grounds

³ The Board’s prior Institution reviewing claims 1-8 and 10-20 based on the same art and arguments does not implicate the *Advanced Bionics* framework because there was no Final Written Decision due to settlement.

⁴ Claim 9 was held to be invalid as indefinite in the Delaware litigation. Ex. 1010 at 14-16. Claim 9 recites “means for comparing.” Ex. 1002 at 6:1-4. The Court found that “a POSA would not know with reasonable certainty what the required structure is to perform the comparing functions.” Ex. 1010 at 16.

1. Arai (Ex. 1013, U.S. Patent No. 6,118,842) anticipates claims 1–4, and 6 under 35 U.S.C. § 102.⁵

2. Arai renders system claims 1–8 obvious under 35 U.S.C. § 103 in combination with Ex. 1014-Cann, (claims 5, 7, and 8).

3. Arai renders method claims 10–20 obvious under 35 U.S.C. § 103 in combination with Ex. 1019-Xu and/or Ex. 1020-Milestone, or additionally in combination with Cann, and in further combination with:

- Ex. 1018-Pelc ‘080 (claim 13); Ex. 1016-Rothman (claims 14–17).

Pelc Grounds

4. Pelc (Ex. 1015, WO 94/10908) anticipates claims 1–6 under 35 U.S.C. § 102.

5. Pelc renders claims 1-6 obvious under 35 U.S.C. § 103 in combination with Cann.

6. Pelc (alone or in combination with Cann) renders claims 7-8 obvious under 35 U.S.C. § 103.

⁵ Because the application on which the ‘301 patent issued was filed before March 16, 2013, it is subject to pre-AIA 35 U.S.C. §§ 102-103.

7. Pelc renders claims 10-20 obvious under 35 U.S.C. § 103 in combination with Rothman, Xu and/or Milestone, or additionally in combination with Cann.

These grounds are supported by the declaration of Dr. Milan Sanka (“Sonka”) (Ex. 1007).

V. TECHNOLOGICAL BACKGROUND

The patent claims a system and method for “tomographically modeling dental and orthopedic structure densitometry.” *See* claims 1, 10, and 20. Computed tomography was common at the time of the priority date and is the most relevant technology. Ex. 1007 (Sonka) at ¶¶56-97.

A. Computed Tomography (“CT”)

Medical X-ray imaging is based on the attenuation of X-rays as they pass through a patient’s body. *Id.* at ¶¶58-61, 67-70. Because different tissues absorb different amounts of X-ray energy, an image of internal structures can be formed by exposing a target area to X-rays and detecting the amount of energy that passes through. *Id.*

Conventional X-ray imaging results in a two-dimensional projection of all the tissues in the path of the X-rays, called a “radiograph.” *Id.* at ¶59-60. Because radiographs contain information about all tissues in the path of the X-rays, they have limited usefulness. *Id.*

Computed tomography, or “CT,” solves this issue by allowing physicians to view a *cross-sectional image* of the area of interest (*i.e.*, a “slice”). *Id.* at ¶¶62-85. These slices are called tomographic images. *Id.* Development of CT began in the 1960s, and the use of CT scanners for medical imaging was commonplace by the 1999 priority date. *Id.* at ¶¶67-85.

CT scanners work by measuring multiple X-ray transmissions through a subject at many different positions and angles. *Id.* at ¶¶68-69. Attenuation of X-ray energy through the target depends on the density and composition of the material, and the energy of the photons comprising the beam. *Id.* at ¶¶70, 88; Ex. 1021 (Bushberg) at 247. One way of increasing the accuracy of a CT scan is to use a “dual-energy” CT that acquires data at two different energy levels. Ex. 1007 (Sonka) ¶¶86-89. This provides more information because materials have unique attenuation profiles at different energy levels according to their composition. *Id.*

A computer uses the acquired data to calculate how much attenuation occurred in a small three-dimensional volume of tissue, called a “voxel.” *Id.* at ¶¶68-70. These quantitative attenuation values are then used to reconstruct a tomographic model of the scanned tissue volume. *Id.*

To standardize results across different scans and machines, it is conventional to replace the attenuation value calculated for each voxel with an integer (called the “CT number”) calculated according to a formula that relates the X-ray

attenuation through the tissue to the attenuation through two known quantities (usually air and water). *Id.* at ¶70. While the resulting quantity is called a CT number, the units are named Hounsfield units. *Id.* at ¶¶67, 70.

B. Use of CT for Bone Densitometry

Bone densitometry is the measurement of bone density. *Id.* at ¶92. It has long been known to use CT scans to provide densitometric information. *See, e.g., id.* at ¶¶92-93; Ex. 1014 (Cann) at 493; Ex. 1022 (Genant 1993) at 91-97. One technique, “quantitative CT,” uses standard clinical CT scanners to perform a scan. *See* Ex. 1023 (Genant 1998) at 915. Figure 2 of Genant 1998 shows an exemplar CT scan depicting densitometrical information.

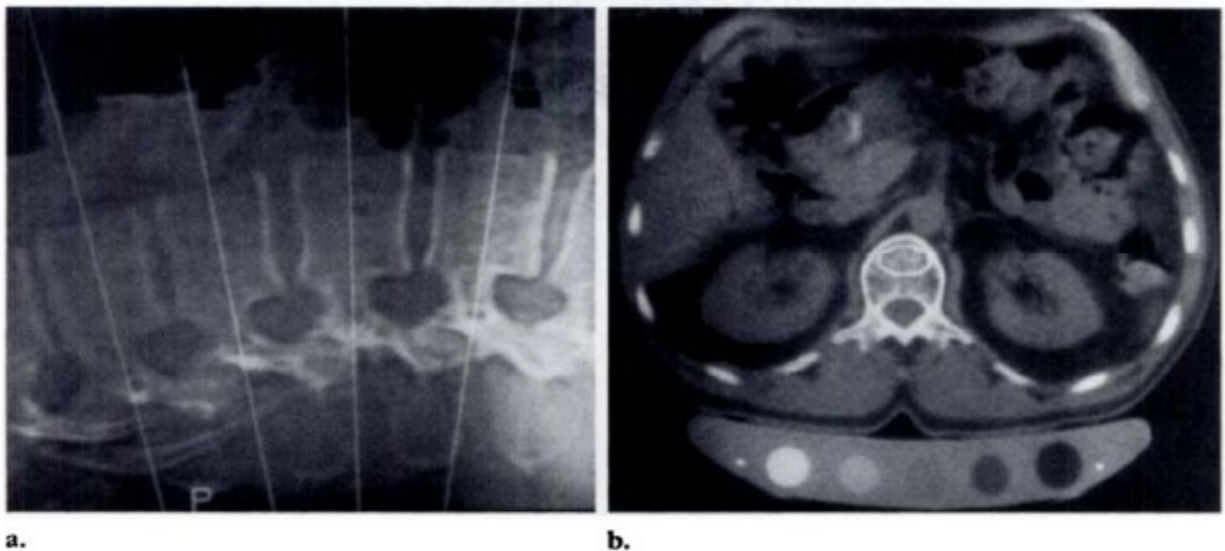


Figure 2. Evaluation of trabecular bone density with quantitative CT. (a) Lateral scout view provides a rapid and simple means of defining the midplane of four vertebral bodies. *P* = posterior. (b) A single CT scan (8–10-mm section thickness) is obtained at each level, and the classic oval region of interest is placed anteriorly in the middle of the vertebral body of three or four consecutive lumbar vertebrae. This region of interest contains purely trabecular bone. For reference, regions of interest are also placed in the compartments of the calibration standards that contain distinct solution of mineral equivalents. (Reprinted, with permission, from reference 12.)

As seen in Figure 2.b., an external bone mineral reference (“phantom”) is included in the scan to allow calibration of CT attenuation measurements to bone-equivalent values in mg/cm^3 . *Id.*; Ex. 1021 (Bushberg) at 273. However, even without a phantom, a CT scan of bone necessarily provides quantitative information regarding densitometry because the density affects attenuation of the radiation measured by the CT system and thus is reflected in the calculated CT number. Ex. 1007 (Sonka) ¶¶93-97; Ex. 1021 (Bushberg) at 246, 273. That is, “[t]he CT number for a certain pixel actually corresponds to physical properties within the patient in the corresponding voxel.” *Id.* CT numbers for bone range from ~300 to 3000, depending on density. *Id.* at 247.

VI. THE ‘301 PATENT AND PROSECUTION HISTORY

A. The ‘301 Patent Specification

The specification of the ‘301 patent is notably sparse, corresponding to a lack of patentable substance in the claims. The ‘301 patent states that it relates to a densitometry modeling system and method. Ex. 1002 at 1:7-10. The background of the invention describes known dental-specific health issues for which the purported invention may be useful, including diagnosis of caries (areas of decay), fractures, and abscesses, *id.* at 1:20-60, and the need to monitor integration of dental implants into a patient’s bone structure, *id.* at 2:21-31.

The patent does not purport to have invented any new tomographic modeling technology or techniques. To the contrary, it admits that the technology used by the claimed systems and methods was known in the prior art. “Admissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness.” *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007).

1. The ‘301 Patent Admits CT Dental Imaging Was Known.

The patent concedes, “Tomography or sectional radiography techniques using scanning X-ray beams have previously been employed for dental applications.” Ex. 1002 at 1:61-65. It expressly incorporates by reference five patents in connection with this acknowledgement, including Ex. 1024 (Webber). Webber discloses that, “Computed tomography also has been used in dental radiography to obtain a slice through a subject’s head, parallel to the plane of the subject’s teeth.” Ex. 1024 at 1:37-50.

The ‘301 patent further concedes the existence of “commercially available tomography equipment” suitable for use in the claimed invention as of the priority date. Ex. 1002 at 3:10-11; *see also id.* at 4:21-23 (incorporating prior art “[e]xamples of X-ray equipment adaptable for use with the present invention”).

2. The ‘301 Patent Admits CT Densitometry Was Known.

The ‘301 patent concedes that, “[i]n the medical field, densitometry procedures are used for measuring bone morphology density (BMD) by utilizing scanning X-ray beam techniques.” Ex. 1002 at 2:1-8. The patent states that “[e]xamples are shown in U.S. Patent No. 5,533,080,” among others. *Id.* The ‘080 patent discloses a CT system. Ex. 1018 (Pelc ‘080) at 1:22-35. It includes a controller that rotates a dual-energy X-ray source and detector array “so that the fan beam intercepts the imaged object at different angles.” *Id.* at 1:42-44. “The projections at each of these different angles together form a tomographic projection set.” *Id.* That information is processed to “reconstruct” a slice image according to reconstruction algorithms known in the art. *Id.* at 1:62-65.

B. The Claims of the ‘301 Patent

Independent claim 1 is an apparatus claim. Ex. 1002 at 5:28-44. The claim recites elements a person of ordinary skill in the art (“POSA”) would understand are common in CT devices: (1) “a controller with a microprocessor and a memory device,” (2) “an input device,” (3) “a positioning motor” that is responsive to commands from the microprocessor, (4) “X-ray equipment” including a source and a detector, (5) and an output device. The dependent claims add various well-known limitations, including the use of an analog-to-digital converter, outputting a color-coded image to a monitor or printer, and pre-programmed X-ray scan path.

Independent claims 10 and 20 are method claims reciting steps that a POSA understands are conventional, including the steps of “providing” the equipment recited in claim 1. *Id.* at 6:5-31, 7:5-8:2. Claim 10 further includes a step of inputting a pre-existing densitometry model for a patient,⁶ and claim 20 includes limitations directed to a dual-energy scan, a comparison of the pre-existing model and a present model and color-coding the output. *Id.* Only certain dependent method claims (claims 14–17) are specific to the dental area. These claims recite the predictable use of known technology to solve known problems (*e.g.*, detecting cavities (claim 14), and dental fractures (claim 15)).

C. Prosecution History

The ‘301 patent issued from U.S. Patent App. 09/452,348, filed December 1, 1999. During prosecution, the Examiner rejected all pending claims as obvious over prior art not asserted here, stating that:

[A]pplicant discloses that the state of the art in the medical field...in densitometry procedures, measuring bone morphology density (BMD) is well known. Further...comparison with a patients own history is

⁶ Claim 10 was the subject of a certificate of correction adding the phrase “including a pre-existing densitometry model” after “parameters” in step (c). Ex. 1002.

known. What applicant appears to believe to be lacking is the use of such a system for dental tomographic imaging.

Ex. 1005 (4/9/2001 Office Action) at 43. The Examiner concluded: “it would have been obvious to one of ordinary skill to apply the systems taught...to form the appropriate tomographic densitometry dental model to be outputted by the processor.” *Id.* at 44.⁷

In response, the applicant identified only one purportedly novel aspect of the invention—use of “a microprocessor having a database that includes a patient’s unique and predetermined densitometry modeling parameters for comparison to the patient’s present densitometry model”—and purported to amend the claims to include this limitation. Ex. 1005 (10/9/2001 Response) at 48-52, 55, 57.⁸ The

⁷ The prior art applied in the current Petition is new prior art compared to the prior art applied during prosecution. Accordingly, 35 U.S.C. §325(d) is inapplicable. To the extent that Patent Owner argues otherwise, Petitioner reserves all rights to dispute the applicability of 35 U.S.C. §325(d) in the present proceeding.

⁸ Despite applicant’s argument distinguishing the prior art on the basis of the patented system allowing for a comparison, a number of claims were amended or drafted such that no comparison actually is required. For instance, claim 1 of the ‘301 patent merely requires a “means for storing a pre-existing tomographical

Examiner allowed the claims because the art allegedly fails to teach or suggest...inputting or containing patient diagnostic parameters, including a pre-existing densitometry model.” Ex. 1005 (11/30/2001 Notice of Allowability) at 67.

VII. LEVEL OF SKILL IN THE ART

The 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 Medical Physics, Physics, or a related field, and at least three years of experience in using and/or designing medical imaging devices, including CT imaging systems and/or densitometry imaging systems, with education substituting for experience and *vice versa*. See Ex. 1007 (Sonka) at ¶52-55. The POSA would be generally familiar with X-ray imaging, CT, X-ray tomosynthesis, densitometry, and medical and dental imaging, including the state of the art as of the priority date. *Id.*

VIII. CONSTRUCTION OF THE CHALLENGED CLAIMS

In *inter partes* review, claim terms are given “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the

dental/orthopedic densitometry model,” *i.e.*, a memory, but not the actual performance of a comparison. See Ex. 1010 (Markman Opinion) at 11-12.

invention.” *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005); 37 C.F.R. § 42.100(b).

The United States District Court for the District of Delaware construed certain claim terms in *Osseo Imaging, LLC v. Planmeca USA Inc.*, 1-17-cv-01386 (D. Del. 2017), as follows.⁹ Ex. 1009, 1010. Dentsply was not a party to that case, but adopts those constructions for purposes of this petition.

**1. “Tomographically modeling/tomographic model(s)”
(Claims 1, 10 and 20)**

“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.” Ex. 1010 at 5. With respect to the “quantitative” aspect, the Court held that a calculation of bone mineral density (“BMD”) in terms of mass/volume, while within the scope of the claim, is not required, and that any quantitative densitometric calculation would suffice. *Id.* at 7.

⁹ “Any prior claim construction determination concerning a term of the claim in a civil action...that is timely made of record in the *inter partes* review proceeding will be considered.” 37 CFR § 42.100(b).

2. “Tomographic dental/orthopedic densitometry model/tomographical densitometry model” (Claims 1, 7, 10, 14-17 and 20)

“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.” *Id.* at 7.

3. “Densitometry” (Claims 1, 7, 8, 10 and 14-20)

“Quantitatively calculated bone density.” *Id.* at 8.

4. “Conversion means” (Claims 1, 3, and 4)

This was construed as a means-plus-function limitation. *Id.* at 10. The Court held the function is “converting a signal from the detector array” and the structure is “an analog-to-digital convertor.” *Id.*

5. “Controller” (Claims 1, 10, 12 and 20)

“One or more controllers.” The Court deemed that no construction was necessary for the term controller. *Id.* at 11. A controller, as used by the patent, is a generic term for a device having computing capability. Ex. 1002 at 3:60-4:2.

6. “Merger device” (Claim 4)

“A device that merges digitized signals into a data output suitable for processing and analyzing by a microprocessor.” Ex. 1010 at 12.

7. “Means for storing a preexisting tomographical dental/orthopedic densitometry model” (Claim 1)

The Court for construed this term as a means-plus-function limitation. *Id.* at 12-13. The function is “storing a pre-existing tomographical dental/orthopedic densitometry model” and the structure is a “computer memory.” *Id.*

As a means-plus-function claim element, it is “construed to cover the corresponding structure...described in the specification and equivalents thereof.” 35 U.S.C. § 112. The Court did not specify which structure in the ‘301 patent comprises the computer memory; however, the only plausible structure is “memory device 7,” which “can comprise any of a number of suitable hardware devices.” Ex. 1002 at 3:60-65.

8. “An output device connected to said microprocessor and adapted for receiving a tomographic model/tomographical densitometry model from said microprocessor” (Claim 1)

“One or more output devices connected to said microprocessor and adapted for receiving a tomographic model/tomographical densitometry model from said microprocessor.” Ex. 1010 at 13.

9. “Comparing” terms (Claims 18 and 20)

“No construction necessary.” *Id.* at 14. Dentsply contends that the plain meaning is “identifying differences between the current/present and pre-existing models.”

10. “Movable in response to from said microprocessor” (Claim 1)

“Movable in response to [signals] from said microprocessor.” Ex. 1009 (Markman Order) at 3.

IX. DETAILED EXPLANATION OF GROUNDS FOR INVALIDITY

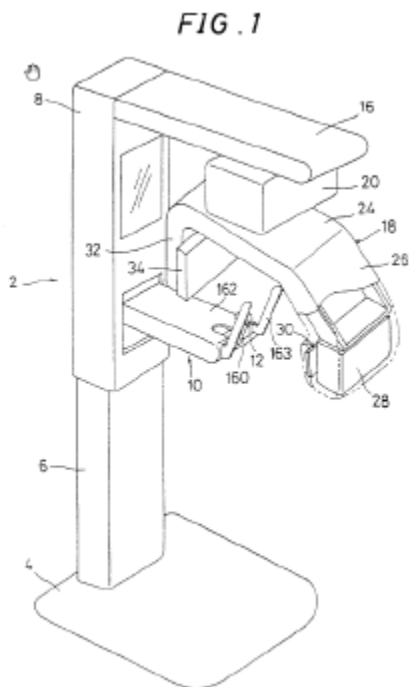
A. Description of the Prior Art

1. Arai, U.S. Patent No. 6,118,842 (Ex. 1013)

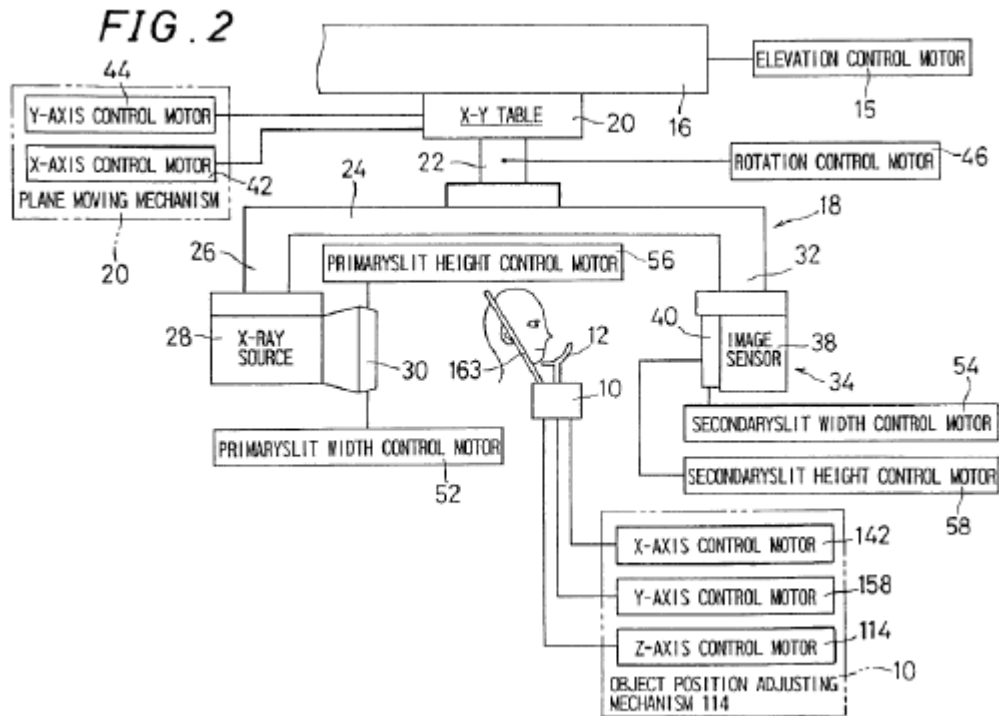
Arai was filed on December 9, 1997, and issued on September 12, 2000. Ex. 1013 at [22], [45]. It is prior art under (pre-AIA) 35 U.S.C. § 102(e).

Arai describes a dental X-ray imaging apparatus that can conduct local CT and panoramic tomographic imaging. Ex. 1013 at 2:3-5; Ex. 1007 (Sonka) at ¶¶172-73. But Arai also teaches that its apparatus may be used solely for CT imaging: “[I]t is also possible to construct a dedicated partial X-ray CT imaging apparatus by omitting function of conducting the X-ray panoramic imaging in the dual-purpose X-ray imaging apparatus.” *Id.* at 30:39-42.

The apparatus includes a frame (2, 4, 6, and 8) with a “horizontal arm 16” and “object position adjusting mechanism 10.” *Id.* at 9:49-10:40; Fig. 1; Ex. 1007 (Sonka) at ¶¶174-75. The arm holds a “moving mechanism 20” and “supporting means 18” to which an “X-ray source 28” and an “image sensor 38” are attached. *Id.* at 10:3-40.

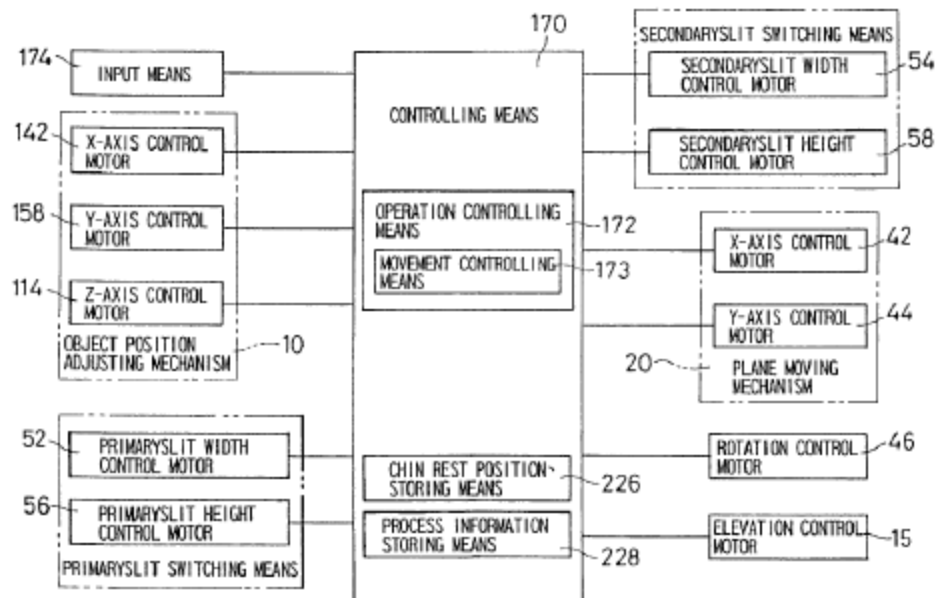


The target is positioned between the source and the sensor. *Id.* at 10:41-44;
 Fig. 2. The “primary slit means 30” restricts the width and height of X-rays emitted
 from the source. *Id.* at 10:44-47; Fig. 2.



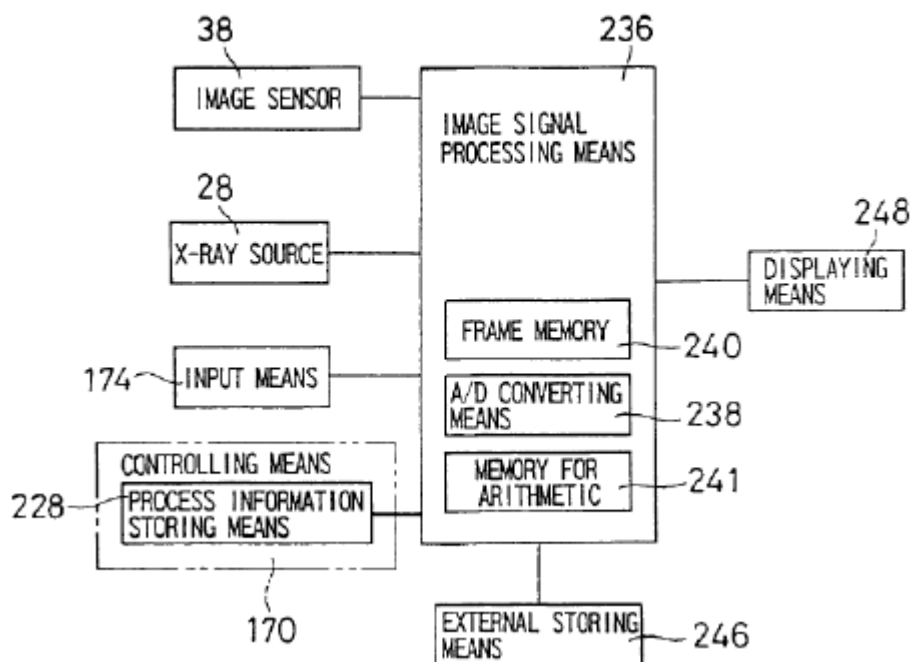
“Controlling means 170” operates motors to move the X-ray equipment in response to pre-programmed scanned paths. *See* Fig. 7. Arai discloses “X-axis control motor 42,” “Y-axis control motor 44,” and “rotation control motor 46.” *Id.* at 15:62-16:1; Ex. 1007 (Sonka) at ¶¶175-77. “The process information storing means 228 stores CT process information for obtaining a partial CT image” such that when the operator selects the CT mode, the “controlling means 170” directs the various motors to carry out the process of obtaining a CT image. *Id.* at 16:41-48; Fig. 7.

FIG. 7



The data collected from “image sensor 38” is supplied to the “image signal processing means 236,” where the analog-to-digital converter converts the analog signal from “image sensor 38” into a digital signal. *Id.* at 17:30-42. These digital signals are stored in “frame memory 240.” *See id.* The “memory for arithmetic 241” takes the plural sets of image information stored in “frame memory 240” and uses a predetermined algorithm depending on the imaging mode (CT or panoramic) to generate a tomographic image of the selected mode. *Id.* at 17:42-48; Ex. 1007 (Sonka) at ¶¶178-80. This tomographic image can then be displayed on “displaying means 248,” stored in “external storing means 246,” or both. *Id.* at 18:3-15; Fig. 9.

FIG. 9



2. Cann, “Precise Measurement of Vertebral Mineral Content Using Computed Tomography” (Ex. 1014)

Cann is an August 1980 publication titled “Precise Measurement of Vertebral Mineral Content Using Computed Tomography” by Christopher E. Cann and Harry K. Genant and published in the *Journal of Computer Assisted Tomography*. Ex. 1014. It is prior art under (pre-AIA) 35 U.S.C. §§ 102(a)-(b).

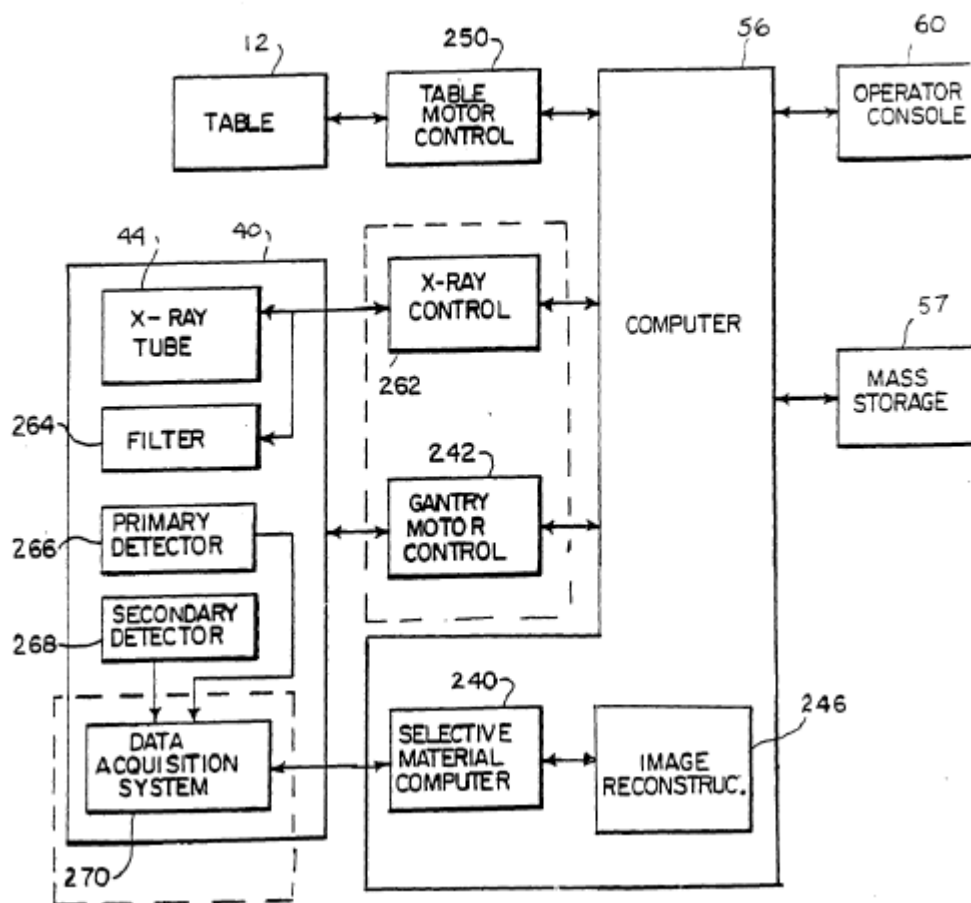
Cann discloses that, as of the 1980s, “[q]uantitative bone mass measurements [were] widely used in the assessment of skeletal status in metabolic bone disease,” including “X-ray computed tomography (CT).” *Id.* at 493. “The usefulness of CT for measuring bone mineral in the vertebrae lies in its ability to quantitatively image a thin transverse slice through the abdomen.” *Id.*

Cann describes methods of improving the accuracy and precision of quantitative CT measurements for bone density. *Id.* at 493-94. To that end, Cann teaches using a dual-energy CT scan and calibrating the system with known references. *Id.* at 493. Cann further conducted a series of experiments using a simulated human torso and a phantom for calibration, which enabled calculation of the mineral equivalent density of the bone in terms of mg K₂HPO₄/mL. *Id.* at 494-96; Table 1 (illustrating measurements in both CT number and mineral content); Ex. 1007 (Sonka) at ¶¶182-85. From these experiments, Cann concluded that the precision of bone mineral content determinations can be improved by using a calibration phantom and patient positioning software. *Id.* at 499.

3. Pelc, WO 94/10908 (Ex. 1015)

Pelc, International Publication No. WO 94/10908, titled “Compact C-Arm Tomographic Bone Scanning System,” was published on May 26, 1994. Ex. 1015 at [43]. It is prior art under (pre-AIA) 35 U.S.C. §§ 102(a)-(b). Pelc discloses an X-ray imaging system that allows “radiographic scanning or tomographic scanning of a patient for evaluation of bone density and bone morphology.” *Id.* at 1:15-17. Figure 19 depicts the system schematically.

FIG. 19

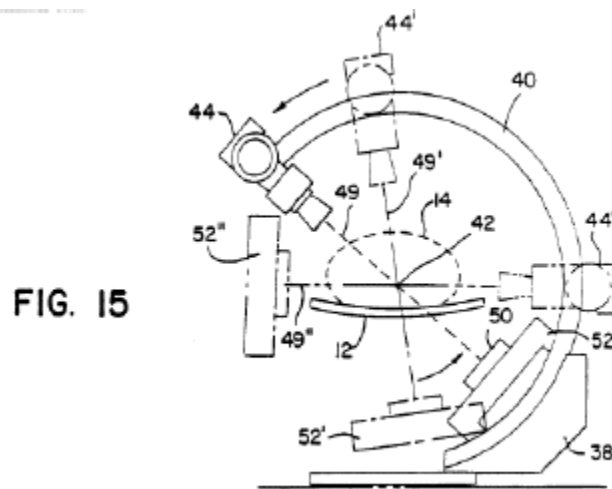


Pelc's system includes an X-ray source, an X-ray detector, and a beam-restricting device. *Id.* at 5:22-6:7; 14:24-31; Ex. 1007 (Sonka) ¶¶187-90. The source and detector are "affixed to the ends of the C-arm to provide energy attenuation measurements along an axis between those ends at the plurality of angles, such measurements being received by an electronic computer." Ex. 1015 at 5:27-31; *see also id.* at 16:23-36 (describing the detector).

The X-ray equipment is housed on a rotating c-arm mounted on a gantry pallet. *Id.* 30:3-17. A track system allows for movement of the pallet with respect

to the patient, while the c-arm allows the X-ray equipment to rotate around the patient. *Id.* at 5:22-27. The position of the pallet and C-arm is controlled by motors connected to a computer. *Id.* at 18:7-14.

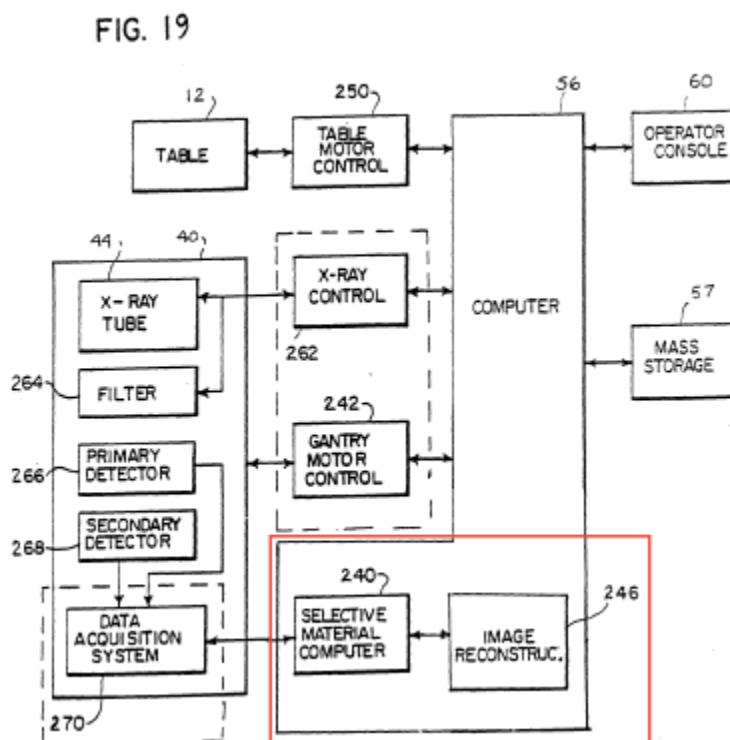
These positioning motors generate the movement required to obtain data for generating the tomographic model. Ex. 1007 (Sonka) ¶¶192-97; Ex. 1015 at 7:9-12. Pelc teaches the X-ray equipment simultaneously rotates and moves longitudinally along that axis of rotation via rails. *Id.* at 13:34-14:2; *see also id.* at 14:32-34, 21:18-35, Figs. 1, 6, 9, 15, 18, 19. Pelc's system is shown in Figure 15:



An “electronic computer controls the C-arm, the radiation source and the detector.” *Id.* at 5:32-33. Pelc describes this as a “general purpose computer,” *id.* at 35:17-21, and a “controlling computer,” *id.* at Fig. 1, 9:35-10:2.

The computer is adapted to process the collected data to reconstruct slices that can then be combined to form a tomographic model. This model may be generated from “images obtained at any two gantry angles having sufficient

separation to provide the necessary third dimensions of information.” *Id.* at 25:34-26:1. Pelc teaches an “image reconstructor 246 (implemented in computer 56) which receives corrected attenuation data from the selective material computation circuit 240 and performs high-speed image reconstruction according to methods known in the art.” *Id.* at 35:13-17. This is described schematically in Figure 19 of Pelc, reproduced below with a red annotation to show the relevant features:



Pelc further discloses “[a] mass storage device 57” which is connected to “computer 56” and which “provides a means for storing operating programs for the CT imaging system, as well as image data for future reference by the user.” *Id.* at 36:1-3. The POSA would understand that “image data” in this context refers to digital tomographic models. Ex. 1007 (Sonka) ¶¶199-200.

Pelc discloses “a computer 56 having a display terminal 58 and a keyboard 60....” Ex. 1015 at 16:8-10. Pelc further discloses that “[t]he computer 56 receives commands and scanning parameters via operator console 58 which is generally a CRT display and keyboard which allows the user to enter parameters for the scan and to display reconstructed image and other information from the computer 56.” *Id.* at 35:31-36; *see also id.* at 4:17-20; Fig. 1; Fig. 19.

Pelc teaches that one of the uses of the disclosed system is “evaluation of bone density and bone morphology.” *Id.* at 1:16-17. Pelc further states that “[s]uch bone density measurements are useful in evaluating the health of the bone and in tracking bone mineral loss in diseases such as osteoporosis.” *Id.* at 27:9-11.

4. Rothman, Dental Applications of Computerized Tomography: Surgical Planning for Implant Placement (Ex. 1016)

The treatise “DENTAL APPLICATIONS OF COMPUTERIZED TOMOGRAPHY: SURGICAL PLANNING FOR IMPLANT PLACEMENT,” by Stephen Rothman, MD (“Rothman”), was published in 1998 and is prior art under 35 U.S.C. §§ 102(a)-(b). Ex. 1016. Rothman discusses CT in the dental area. After “spinal CT became standard in the early 1980s,” Rothman teaches, “it was logical to adapt the same process to dental CT.” *Id.* at 13. “In the last decade, computerized tomography (CT) has become one of the most frequently used imaging modalities for the

preoperative evaluation of the jaw for dental implants.” *Id.* at 1. Rothman also discusses non-surgical dental applications of CT. *Id.* at 153.

Rothman discloses that computerized tomograms are ideally suited as a “guide for [dental] implant placement,” including because “with CT it is possible to generate three-dimensional images from the same data set.” *Id.* at 7; Ex. 1007 (Sonka) at ¶¶206-09. Rothman discusses the “[q]uantitative assessment of mineral content” in the mandible and uses that information to compare the preoperative and postoperative CT scan data (which had been stored on a computer). *Id.* at 57.

B. Grounds 1-3: Arai-Based Anticipation and Obviousness

1. Independent Claim 1 (System Claim)

Claim 1 is anticipated by Arai, and obvious over Arai in combination with Cann.

a. Preamble

Claim 1 recites: “A system for tomographically modeling dental and orthopedic structure densitometry, which includes....”

1) The Preamble Is Not Limiting

The preamble is not limiting. “[A] preamble is not limiting ‘where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.’” *Arctic Cat*, 919 F.3d at 1328. Because the claim defines a structurally complete invention that has the capability to model densitometry, the “for tomographically modeling dental and

orthopedic structure densitometry” language is a non-limiting statement of purpose.

2) Anticipation by Arai

To the extent that it is limiting, a system that is *capable* of tomographically modeling dental or orthopedic structure densitometry satisfies the plain meaning of the preamble, which is phrased in terms of intended use. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). Additionally, the “and” is not conjunctive, as evidenced by the claim’s own use of the disjunctive form “dental/orthopedic.”

Arai teaches a system for tomographically modeling dental structure densitometry. *See supra* § IX.A.1. Arai discloses a CT system. “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.” Ex. 1013 at 2:3-5; Figs. 1-27.

Arai’s CT system generates tomographic models. In doing so, it merges information from multiple scans of the target from at least one focal plane, which it uses to produce a representation of the subject. *See id.* at 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.”); Ex. 1007 (Sonka) ¶¶227, 348.

Arai discloses that these tomographic models are of dental structures. *See* Ex. 1013 at 23:8-11 (“dental treatment can be easily performed while observing the partial CT image”); Fig. 18; Ex. 1007 (Sonka) ¶¶228, 348.

Arai’s CT system is quantitative because CT scanners use information from multiple scans to calculate a CT number, which provides information regarding bone density. Ex. 1007 (Sonka) ¶¶70, 92-94, 229, 348. This is further supported by the ‘301 patent’s reference to the CT system disclosed in Pelc ‘080 as disclosing densitometry procedures, Ex. 1002 at 2:3-6; Ex. 1007 (Sonka) ¶¶229, 348.

3) Obviousness over Arai in View of Cann

In the Delaware litigation, Osseo argued that CT imaging does not satisfy the quantitative aspect of the Court’s construction. That is incorrect as discussed above. Nevertheless, in the alternative, it would be obvious to combine Arai and Cann. Cann teaches quantitative CT imaging, using CT to measure bone mineral density. Ex. 1014 at 493-95; Ex. 1007 (Sonka) ¶¶230, 348. Because both Arai and Cann involve CT imaging systems, it would have been obvious to a skilled artisan to use the CT system taught in Arai for the densitometry measurements disclosed in Cann. Ex. 1007 (Sonka) ¶231. A POSA would have been motivated to obtain a more accurate and precise density model. *Id.* Arai notes that it would be useful in

the field of dental diagnosis “if data such as the thickness of the jawbone are previously known prior to an implant operation or the like.” Ex. 1013 at 1:34-36. A POSA would understand that the density of the jawbone would likewise be helpful to know pre-implantation to further assess the integrity of the bone. A POSA would thus be motivated to use the system of Arai for that purpose in light of Cann. Ex. 1007 (Sonka) ¶231.

Adding a quantitative densitometrical function as described in Cann (*e.g.*, using a phantom containing bone equivalent matter to enable scanned data to be calibrated to bone density) to a CT imaging system such as Arai makes the system more versatile and saves medical professionals money and space on additional equipment, providing further motivation for the combination. *Id.* Arai itself suggests that it could be used for densitometry purposes, and the features of Arai are precisely suited to performing quantitative densitometry. *Id.*

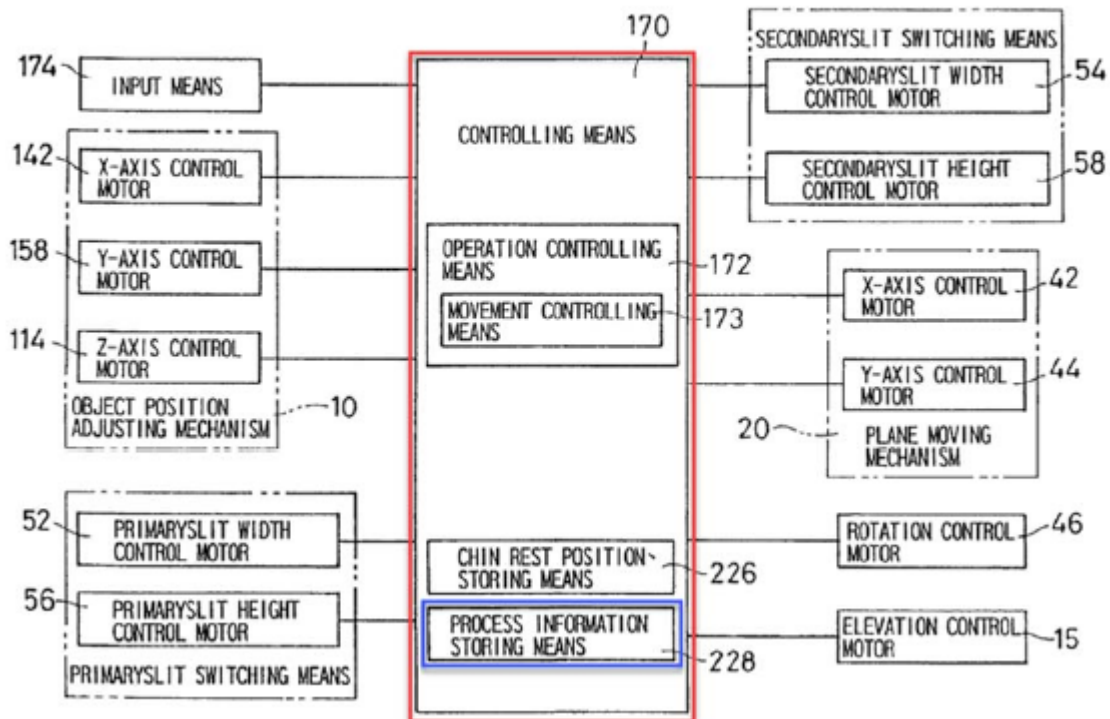
A POSA would have had a reasonable expectation of success in using the quantitative process taught by Cann in combination with Arai given the minimal modifications required, such as using a phantom, as well as the established use of CT for densitometrical purposes by the priority date (almost 20 years after Cann’s publication). *Id.* For the same reasons, incorporation of the quantitative CT function taught by Cann would not impact any of the combinations discussed below. *Id.*

b. Controller

Claim 1 recites “a controller with a microprocessor and a memory device connected to the microprocessor,” which the Court construed as one or more controllers. Ex. 1010 at 11-12. Arai discloses this limitation. It has a controller comprising “controlling means 170” and/or “image signal processing means 236.”

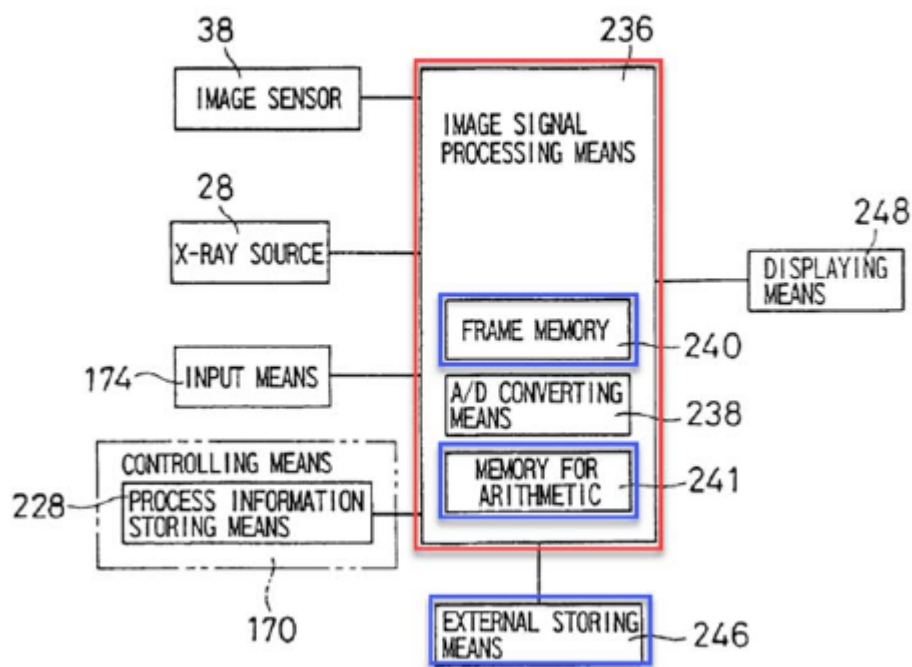
The “controlling means 170” controls motors that move the imaging equipment during a scan, and “may be configured by...a microprocessor.” Ex. 1013 at 14:48-54; *see also id.* at 15:62-16:6. Figure 7 depicts “controlling means 170” (outlined in red) having a memory device, *i.e.*, “process information storing means 228.” *Id.* at 16:6-10; 16:41-44. Moreover, a POSA would recognize that a microprocessor having the functions described in Arai necessarily would have a memory device. Ex. 1007 (Sonka) ¶¶232-35, 349.

FIG. 7



Additionally, Arai's "image signal processing means 236" controls the processing of detected image signals. Ex. 1013 at 17:29-38. "[I]mage signal processing means 236 may be configured by, for example, a microprocessor for image processing." *Id.* at 17:32-34. As shown below in Figure 9, "image signal processing means 236" (in red) has memory devices "frame memory 240," "memory for arithmetic 241," and "external storing means 246" (in blue). *Id.* at 17:29-48; Ex. 1007 (Sonka) ¶¶232-35, 349.

FIG. 9



c. Storing tomographic models of dental structure

Claim 1 further recites “said controller including means for storing a pre-existing tomographical dental/orthopedic densitometry model.” The structure required by this element is a computer memory. Ex. 1010 at 12.

Arai discloses this limitation. Arai’s “image signal processing means 236” stores CT models of dental structure in the “memory for arithmetic 241” of the “image signal processing means 236.” Ex. 1013 at 17:38-44. Arai also describes separate “external storing means 246,” which may be a hard disk or magnetooptical disk that is connected to its controller. *Id.* at 18:11-15; Ex. 1007 (Sonka) ¶¶350-51.

d. Input device

Claim 1 further recites “an input device connected to the microprocessor.” The specification of the ‘301 patent describes “input device” broadly. Ex. 1002 at 4:6-9.

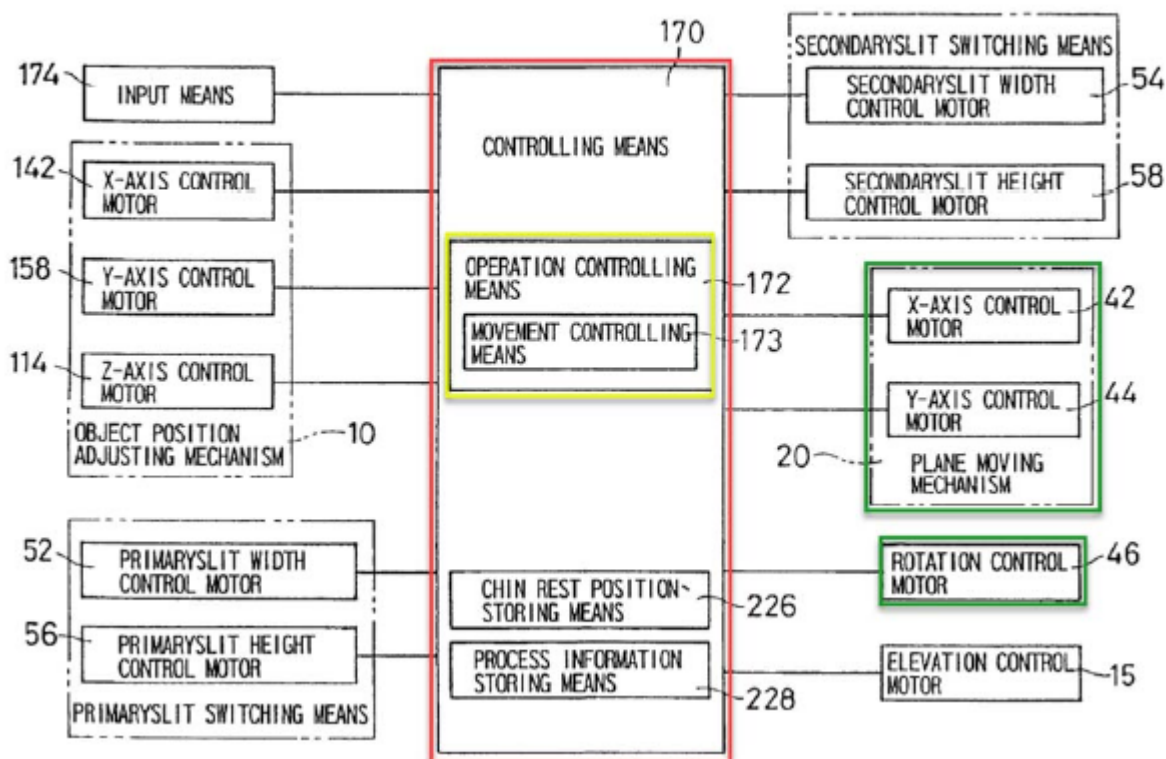
Arai discloses this limitation. Arai discloses “input means 174” and “operation panel 176,” which can be used by the operator to choose the imaging mode and input information relating to the object to be imaged. Ex. 1013 at 14:51-56 (“[I]nput means 174 comprises an operation panel 176 which is shown in Fig. 8.”); Fig. 7-9; Ex. 1007 (Sonka) ¶236, 352.

e. Positioning motor

Claim 1 further recites “a positioning motor connected to the microprocessor and movable in response to [signals] from said microprocessor.”

Arai discloses this limitation. Arai teaches “X-axis control motor 42,” “Y-axis control motor 44,” and “rotation control motor 46.” Ex. 1013 at 11:10-27. These positioning motors (in green) are responsive to signals from the controlling means’ microprocessor (in red) via “operation controlling means 172” and “movement controlling means 173” (in yellow). *Id.* at 15:62-16:6; Fig. 7. Ex. 1007 (Sonka) ¶¶237, 353.

FIG. 7



f. X-ray equipment

Claim 1 further recites “X-ray equipment including an X-ray source and a detector array.”

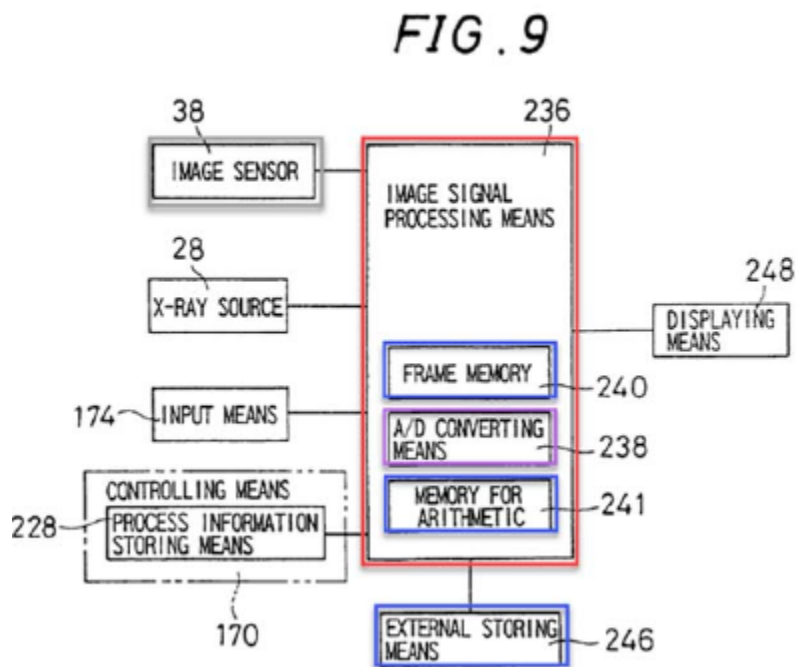
Arai discloses this limitation. The system in Arai includes an “X-ray source 28” and “image sensor 38.” Ex. 1013 at 10:27-38; Fig. 2. A POSA would understand an “image sensor” as a detector array. Ex. 1007 (Sonka) ¶¶238-39, 354.

g. Conversion means

Claim 1 further recites “conversion means for converting a signal from said detector array, said conversion means being connected to said detector array and to

said microprocessor.” The structure is “an analog-to-digital convertor.” Ex. 1010 at 10.

Arai discloses this limitation. Arai discloses “A/D converting means” for converting an analog signal from “image sensor 38” (detector array) into a digital signal. Ex. 1013 at 17:38-42 (“The image signal supplied from the image sensor 38 to the image signal processing means 236 is converted into a digital signal by the A/D converting means 238....”). Figure 9 shows that this converter (purple) is connected to the detector array (gray) and is connected to the microprocessor of “image signal processing means 236.” Ex. 1007 (Sonka) ¶¶240, 355.



h. Output device

Claim 1 recites “an output device connected to said microprocessor and adapted for receiving a tomographical densitometry model from said microprocessor.” The ‘301 patent describes “output device” broadly. Ex. 1002 at 4:39-44.

Arai discloses two output devices capable of receiving a tomographical densitometry model from the microprocessor of the image signal processing means: “external storing means 246” and “displaying means 248.” Ex. 1013 at 18:3-15; Ex. 1007 (Sonka) ¶¶241, 356-57.

2. Dependent Claim 2

Claim 2 further recites a system where “said positioning motor is adapted for positioning said X-ray equipment with respect to three axes of movement.”

Arai discloses this limitation, rendering this claim anticipated by Arai, and obvious over Arai and Cann. *See* § IX.B.1.a. Arai teaches “X-axis control motor 42,” “Y-axis control motor 44,” and “rotation control motor 46” for positioning the imaging equipment. Ex. 1013 at 11:2-27; 15:62-16:1. A POSA would understand this to mean that the positioning motor is capable of positioning said X-ray equipment with respect to three axes of movement. Ex. 1007 (Sonka) ¶¶358-60.

3. Dependent Claim 3

Claim 3 further recites “said conversion means comprises an analog-to-digital convertor connected to said detector array.” Arai discloses this limitation,

rendering this claim anticipated by Arai, and obvious over Arai and Cann. *See* § IX.B.1.a. Arai has “A/D converting means” for converting an analog signal from “image sensor 38” (detector array) into a digital signal. Ex. 1013 at 17:34-42; *see also* § IX.B.1.g; Ex. 1007 (Sonka) ¶¶361-63.

4. Dependent Claim 4

Claim 4 depends from Claim 3 and further recites “said conversion means includes a merger device connected to said analog-to-digital converter and to said microprocessor.” Arai discloses this limitation, rendering this claim anticipated by Arai, and obvious over Arai and Cann. *See* § IX.B.1.a.

The Delaware Court construed “merger device” to mean “a device that merges digitized signals into a data output suitable for processing and analyzing by a microprocessor.” Ex. 1010 at 12; *see also* Ex. 1002 at 4:32-36. Such a merger device is inherent in CT systems because CT requires merging signals from multiple scans of each target voxel so that the merged information can be used to produce the tomographic model. *See, e.g.*, Ex. 1021 (Bushberg) at 244 (“In a CT scanner, the computer orchestrates the acquisition of a large number of transmission measurements taken through the object being scanned and stores this raw data. The raw data, after some preliminary algebra, are reconstructed to produce the tomographic images.”); Ex. 1007 (Sonka) ¶¶364-68.

Arai's system includes a "merger device" as described by the '301 patent. Arai's CT system generates densitometrical tomographic models. *See* § IX.B.1.a. In doing so, it merges information from multiple scans of the target, which it uses to produce a model of the target tissue. Ex. 1013 at 17:33-48 ("Plural sets of image information stored in the frame memory 240 are stored in the image memory for arithmetic 241. A predetermined arithmetic process...is conducted on image information read out from the image memory for arithmetic 241, thereby generating a tomographic image of the selected mode."). That is, the microprocessor of Arai, as programmed to receive, store, and perform calculations on the data received from multiple acquisitions to generate tomographic models, constitutes a merger device as claimed. Ex. 1007 (Sonka) ¶¶364-68.

5. Dependent Claim 5

Claim 5 recites "wherein said X-ray equipment comprises a dual energy level, restricted beam device." This claim is obvious over Arai in view of the admitted prior art and over Arai in view of Cann.

The '301 patent admits that the use of dual-energy X-ray beams for densitometry was known (citing Bisek, U.S. Patent No. RE36,162), and that "[a]s discussed therein, dual-energy densitometry can result in a more accurate patient model." Ex. 1002 at 5:11-15. A POSA would have been motivated to modify Arai to use a dual-energy source, and had a reasonable expectation of success in making

the combination, in light of this knowledge in the art. *See* Ex. 1007 (Sonka) ¶¶369-73. Moreover, Cann discloses dual-energy CT and discusses its advantages. Ex. 1014 at 493-94. By the priority date of the ‘301 patent, a POSA thus would have recognized the value of dual-energy scans and would have been motivated to use dual-energy equipment as disclosed in Cann in connection with Arai’s system for increased accuracy and precision. *See* § IX.B.1.a. A POSA would have had an expectation of success in incorporating dual-energy imaging from Cann into the system taught in Arai given the high level of experience and knowledge in the art regarding the use of dual-energy systems. *See* Ex. 1007 (Sonka) ¶¶369-73.

Arai teaches that the X-ray source in its imaging system is a restricted beam device. “The primary slit means 30 restricts the width and height of X-rays emitted from the X-ray source 28, thereby preventing unnecessary X-rays from being emitted toward the object.” Ex. 1013 at 10:44-47. Moreover, the U.S. Food and Drug Administration (FDA) required all X-ray imaging devices to use restricted beams well before the priority date. Ex. 1007 (Sonka) ¶239; Ex. 1025, 21 C.F.R. § 1020.31, at 566 (April 1998). Accordingly, a POSA would necessarily include a restricted beam device.

6. Dependent Claim 6

Claim 6 further recites “a preprogrammed scan path for said X-ray equipment, said scan path being programmed into said microprocessor.” Arai

discloses this limitation, rendering this claim anticipated by Arai, and obvious over Arai and Cann. *See* § IX.B.1.a. Arai teaches a preprogrammed X-ray scan path stored in “process information storing means 228.” Ex. 1013, 16:41-54. Arai also teaches that “the controlling means 170” operates the motors of the CT system on the basis of the information in “information storing means 228.” *Id.* Further, a POSA would understand CT systems, such as that in Arai, necessarily include a preprogrammed scan path because computer control of data acquisition is required, given the process’s complexity. *See, e.g.*, Ex. 1021 (Bushberg) at 244 (“In a CT scanner, the computer orchestrates the acquisition of a large number of transmission measurements taken through the object being scanned and stores this raw data.”); Ex. 1007 (Sonka) ¶374-76.

7. Dependent Claim 7

Claim 7 further recites “said output device includes a color monitor adapted to receive said tomographical densitometry model output color-coded to represent densitometry.” The ‘301 patent admits that use of color images to provide densitometry information was known in the prior art, in particular in the area of display of density information: “BMD images use color to identify varying densities.” Ex. 1002 at 2:12-13. This claim is obvious over Arai (and Arai and Cann) in view of the knowledge of a POSA including AAPA. *See* § IX.B.1.a (motivation to combine Arai and Cann).

Arai discloses “displaying means 248” for receiving the tomographic model from the microprocessor associated with “image signal processing means 236.” Ex. 1013 at 18:3-8. Given the state of the art in 1999, a POSA would expect that this is a color monitor. Ex. 1007 (Sonka) ¶¶377-81. At the very least, a POSA would find the use of a color monitor obvious in light of the state of the art, or obvious to try given the limited options for monitors (gray-scale or color). *Id.* Further, color-coding the medical models generated by Arai’s CT system would also be obvious in order to provide better information. *Id.* Because displaying color-coded models was well known, a POSA would have a reasonable expectation of success in using a color monitor output device for receiving color-coded models with the CT system of Arai. *Id.* at 381.

8. Dependent Claim 8

Claim 8 recites “said output device includes a color printer adapted to print images color-coded to correspond to the densitometry of said model.” This claim is obvious over Arai (and over Arai and Cann) in view the knowledge of a POSA, including admitted prior art, for the same reasons that the use of a color monitor would have been obvious (*see* claim 7). *Id.* at ¶¶377-84; *see also* Ex. 1031 (Hosie) at 32 (discussing a printer for reproducing results displayed on the color monitor). Color-coded medical imaging was known in densitometry, as the ‘301 patent admits, and a POSA would have been motivated, and with the expectation of

success, to use a color printer with the CT system of Arai, given the ubiquity of color printers in 1999. Ex. 1007 (Sonka) ¶¶377-84.

9. Independent Claim 10 (Method Claim)

Independent claim 10 recites a method of tomographically modeling dental and orthopedic densitometry. It describes use of components that largely overlap with those recited in claim 1 in a way that would have been expected by, and obvious to, a POSA. Claim 10 is obvious over Arai in combination with Xu and/or Milestone, and alternatively in further combination with Cann. *See* § IX.B.1.a (motivation to combine Arai and Cann).

a. “A method of tomographically modeling dental and orthopedic densitometry, which includes the steps of...”

This preamble is not limiting for the same reasons discussed for claim 1. *See supra* § IX.B.1.a. To the extent it is limiting, Arai, and Arai in view of Cann, teaches a system and method for tomographically modeling dental structure densitometry for the reasons discussed above. *Id.*

b. Common structural elements with claim 1 (Claim 10(a)-(b), (d)-(e), and (j))

Claim 10’s method includes a number of steps calling for certain structural elements, which track the system of claim 1 discussed above. For instance, step 10(a) recites the step of “providing a controller” having the same characteristics of the controller claimed in element 1(a). The same is true for the “input device” of

step 10(b), equivalent to 1(b); the “memory” of step 10(d), equivalent to the 1(a)’s “means for storing”; the “X-ray equipment” of step 10(e), equivalent to 1(d); and the “output device” of step 10(j), equivalent to 1(f). The discussion above of Arai’s disclosure of these elements is incorporated here (§§ IX.B.1.b-d, f and h).

c. Inputting and storing patient diagnostic parameters and pre-existing densitometry model (Claim 10(c)-(d))

Arai discloses inputting patient diagnostic parameters, including, *e.g.*, patient characteristics and the teeth to be imaged, which are then stored in memory. Ex. 1013 at 15:16-33. Moreover, as explained below in connection with claim 18 (§ IX.B.14) below, a POSA would be motivated, in view of Xu and/or Milestone, to use Arai’s CT system to perform comparisons of a patient’s present scan results with a pre-existing densitometry model, *e.g.*, a patient’s prior scan. As a necessary part of that comparison, the prior model would need to be input into and stored in the “imaging signal processing means 236” or “external storing means 246” of Arai. Ex. 1007 (Sonka) ¶¶390-91, 425.

d. Use of the X-ray equipment (Claim 10(f)-(g))

Steps 10(f)-(g) recite positioning the target tissue in between the X-ray source and detector, and emitting X-rays through the tissue. This is the expected use of X-ray equipment and is disclosed by Arai. *See* Ex. 1013 at Figs. 2, 8 (showing patient dental structure positioned between X-ray source and detector). *See* Ex. 1007 (Sonka) ¶392.

**e. Forming and outputting a densitometrical model
(Claim 10(i) and (k)).**

Step 10(i) recites forming a tomographical densitometrical model of the tissue, and step 10(k) recites outputting the model. The purpose of Arai's system is to create and display such models, and use of Arai for its intended purpose, as discussed above, renders obvious these steps. *See supra* §§ IX.A.1, IX.B.1; *see also, e.g.*, Ex. 1013 at 17:42-48 ("thereby generating a tomographic image of the selected mode."); Ex. 1007 (Sonka) ¶393. To the extent that Osseo argues that Arai's use of CT does not satisfy the quantitative aspect of the claim construction, it would have been obvious to combine Arai with Cann as discussed with respect to claim 1 (§ IX.B.1, *supra*).

In sum, each of the limitations of claim 10 are disclosed by, or obvious over, Arai in combination with Xu and/or Milestone, and additionally in combination with Cann, and the steps claimed are how a POSA would expect to use such a combined system. Ex. 1007 (Sonka) ¶¶385-93.

10. Dependent Claim 11

Claim 11 recites: "the additional steps of emitting, detecting, digitizing, and storing signals corresponding to first and second energy levels from said X-ray source." This limitation is directed to dual energy scanning. Claim 11 is obvious over Arai in combination with Xu and/or Milestone (§ IX.B.14), and in further combination with Cann (§ IX.B.1.a) or the knowledge of a POSA. Each of the

steps of claim 11 are standard in performing a dual-energy CT scan with the equipment of Arai. *Id.* at ¶¶394-97. As discussed with respect to claim 5 (§ IX.B.5), the ‘301 patent admits that the use of dual-energy X-ray beams in medical densitometry applications was known and that “dual-energy densitometry can result in a more accurate patient model.” Ex. 1002 at 5:12-16; Ex. 1007 (Sonka) ¶¶86-89, 394-97. A POSA would have been motivated to modify Arai to use a dual-energy source in light of this knowledge in the art. Moreover, Cann discloses dual-energy CT and discusses its advantages. Ex. 1014 at 493-94. By the time of the ‘301 patent, a POSA would have, recognizing the increased accuracy of dual-energy scans, been motivated to incorporate dual-energy imaging from Cann into Arai’s CT system. Accordingly, claim 11 is obvious. Ex. 1007 (Sonka) ¶¶394-97.

11. Dependent Claim 12

Claim 12 recites the additional steps of: “a) inputting to said controller a predetermined scan path for said X-ray equipment; and b) traversing said X-ray equipment along said scan path.” Claim 12 is obvious over Arai in combination with Xu and/or Milestone (§ IX.B.14) or, additionally, in combination with Cann (§ IX.B.1.a).

Arai discloses a predetermined scan path programmed into the controller, rendering this claim obvious. *See* § IX.B.6 (claim 6). That path would necessarily have been input into the Arai system, and during normal and expected use of the

Arai system, it is the path that the X-ray equipment would follow. Ex. 1007 (Sonka) ¶¶398-400.

12. Dependent Claim 13

Claim 13, depending from claim 12, recites “providing a positioning motor connected to said microprocessor and to said X-ray equipment for moving same through three axes of movement along said scan path.” Claim 13 is obvious over Arai in combination with Xu and/or Milestone (§ IX.B.14), or additionally in combination with Cann (§ IX.B.1) and Pelc ‘080. The ‘301 patent concedes that this arrangement is not novel. Ex. 1002 at 4:17-23. For instance, incorporated reference Pelc ‘080 discloses a C-arm X-ray system that rotates around an axis and translates along that axis, during which the X-ray equipment would be understood by a POSA to move along three axes of movement. Ex. 1018 at 9:15-28; 9:62-65; 10:47-51; Ex. 1007 (Sonka) ¶¶401-04.

Arai’s system has a positioning motor connected to the processor, *see supra* § IX.B.1.e (claim 1(c)). A POSA would have been motivated to modify Arai to operate in the same manner as Pelc ‘080. *Id.* The Arai system is similar to that of Pelc ‘080. *Id.* Arai includes a motor that adjusts the X-ray equipment in the vertical direction. Ex. 1013 at 9:49-59; Figs. 1, 7. Arai’s X-ray source likewise rotates around an axis centered through the target. *Id.* at 2:62-65. As discussed above, these motors are controlled by the Arai’s “controlling means 170.” *See supra* §§

IX.A.1, B.1.e. Modification of Arai's X-ray equipment to rotate while translating vertically would allow it to image a greater volume of the object. Ex. 1007 (Sonka) ¶¶401-04. Making this modification to the operation of Arai would have been well within the skill of a POSA because all the underlying equipment is already present in Arai, and such steps were known in the prior art. *Id.*

13. Dependent Claims 14–17

Claims 14–17 recite limitations that are obvious uses of Arai's equipment in view of Rothman: “detecting incipient caries with said tomographical densitometry model;” “detecting dental fractures with said tomographical densitometry model;” “detecting apical abscesses with said tomographical densitometry model;” and “analyzing the extent of osseointegration of a dental or orthopedic prostheses with respect to a patient's dental or orthopedic structure with said tomographical densitometry model.” Claims 14–17 are obvious over Arai in combination with Xu and/or Milestone (§ IX.B.14) and Rothman, or alternatively in combination with Cann (§ IX.B.1.a).

Arai's equipment, when used to scan the teeth of a patient as shown in Arai, would provide information relating to the density of the teeth. *Id.* at ¶¶405-20. Using this information for dental purposes is disclosed by Rothman. *Id.* Incipient caries (cavities), dental fractures, apical abscesses, and extent of osseointegration of a dental or orthopedic prosthesis would be detectable as a difference in density

and would be evident from the tomographic model of the relevant dental structure. *Id.*; *E.g.*, Ex. 1016 (Rothman) at 128 (dental fractures), 54 (apical abscesses), 114-22 (osseointegration). It would have been obvious, and a POSA would have been motivated, in view of Arai's disclosure of dental diagnosis and the ability to scan particular teeth to use Arai's system for the other dental diagnosis purposes discussed in Rothman. Because Arai and Rothman are both CT for dental diagnostics, a POSA would have had a reasonable expectation of success in combining Arai with Rothman. Indeed, radiographs, which provide far less detailed information, have long been used for some of these same purposes. Ex. 1007 (Sonka) ¶¶405-20.

14. Dependent Claim 18

Claim 18 recites the additional step of "comparing said patient's current densitometry model to pre-existing densitometry model." This claim is obvious over Arai in view of Xu and/or Milestone, and alternatively in further combination with Cann.

The '301 patent admits that means for comparing tomographic models were known in the prior art. Ex. 1002 at 2:13-15. In defense of a § 112 challenge in the Delaware litigation, Osseo admitted "one of skill in the art would know how to compare two sets of data in a computer," and that, as of the priority date, there existed commercially-available software that could be purchased that was capable

of producing a comparison as claimed. Ex. 1012 (SJ Hearing Transcript) at 17:23-18:15.

A POSA would understand that comparisons of medical images, including CT images, are routinely performed for purposes of diagnosis and tracking treatment, and that medical professionals would have access to comparisons. Ex. 1007 (Sonka) ¶¶421-25. The patent admits such comparisons could be between a patient's current scan and standard models, or between the patient's current and prior scans. *Id.*; Ex. 1002 at 2:13-15.

As of the priority date of the '301 patent, it was well-known to a POSA that a microprocessor could be programmed with software to perform these comparisons. Xu, which is prior art under § 102(e) for the '301 patent, teaches a method and system that uses a computer to detect changes in three-dimensional medical scans by using temporal subtraction. Ex. 1019 at 2:22-32; 16:43-18:52 (reciting various claims covering computer algorithms to perform comparisons). Milestone, which is prior art under 35 U.S.C. § 102(a), teaches the use of software to compare volumetric or three-dimensional rendering of internal structures. Ex. 1020 at 5:15-26. Specifically, Milestone teaches that the comparison can be between two patient scans (current and previous) as well as a patient scan and scanned/stored data representing a "normal" structure. *Id.*; *see also id.* at 10:26-11:12; 13:17-22.

Arai includes memory for storing CT data (*e.g.*, “external storing means 246,” “frame memory 240,” and “memory for arithmetic 241”). *See supra* § IX.B.1.c. A POSA would have been motivated to adapt the microprocessor in Arai to perform comparisons between a pre-existing model and a patient’s current model, as stored in those memories, for the reasons discussed above, and would have had a reasonable expectation of success in doing so given the advanced state of the art as admitted by Osseo. Ex. 1007 (Sonka) ¶¶421-25.

15. Dependent Claim 19

Claim 19 recites the steps of “a) providing a color output device connected to said microprocessor; and b) color coding said densitometry model in colors corresponding to the patient’s dental or orthopedic structure density and outputting said densitometry model to said output device.” Based on Arai in combination with Xu and/or Milestone (§ IX.B.14) and the knowledge of the POSA, or, alternatively, in combination with Cann (§ IX.B.1.a), it would have been obvious to use the Arai system’s monitor and computer to perform these admittedly conventional and known steps in light of the admitted prior art, rendering the claim obvious. *See* §§ IX.B.7-8 (claims 7 and 8); Ex. 1007 (Sonka) ¶¶426-28.

16. Independent Claim 20 (Method Claim)

Claim 20 largely recites a combination of steps already addressed above.

The following table provides a reference to the relevant sections, which are incorporated by reference.

Claim 20	Prior Reference in § IX	Prior Claim(s)
Preamble	B.1.a, B.9.a	1, 10
(a) controller	B.1.b, B.9.b	1, 10
(b) input device	B.1.d, B.9.b	1, 10
(c) inputting parameters	B.9.c	10
(d) storing parameters	B.9.c	10
(e) X-ray equipment	B.1.f, B.9.b	1, 10
(f) positioning X-ray equipment	B.9.d	10
(g) emitting and detecting X-ray	B.9.d	10
(h) outputting signal	B.1.g, B.3, B.9.d	1, 3, 10
(i) digitizing signal	B.1.g, B.3, B.9.d	1, 3, 10
(j) storing digitized signal	B.1.c, B.9.e	1, 10
(k) dual-energy	B.5, B.11	5, 11
(l) merging signals to create model	B.1.a, B.4, B.9.i	1, 4, 11
(m) comparing model to pre-existing model	B.17	18
(o) output device	B.1.h, B.9.b	1, 10
(p) color-coding model	B.7, B.8, B.18	7, 8, 19
(q) outputting color-coded model	B.7, B.8, B.18	7, 8, 19

A POSA would have used Arai's CT system to perform these steps, which are routine in the use of Arai, as previously discussed. The only step not previously addressed is step (n): "adjusting said present densitometry model to account for patient parameters including age and gender." The patent specification states, in relevant part, that "tomographical densitometry models can be corrected and/or adjusted to account for patients' age, gender, physical characteristics, etc." Ex.

1002 at 4:67-5:3. The patent does not purport to have invented this practice, and the step of performing such adjustments would be something a POSA would be motivated to do in cases where such adjustment is required. Ex. 1007 (Sonka) ¶¶430-33. Accordingly, claim 20 is obvious over Arai in combination with Xu and/or Milestone (§ IX.B.14) and the knowledge of the POSA, or alternatively in combination with Cann (§ IX.B.1.a).

C. Grounds 4-7: Pelc-Based Anticipation and Obviousness

1. Independent Claim 1 (System Claim)

Claim 1 is anticipated by Pelc, and obvious over Pelc in combination with Cann.

a. Preamble

1) The Preamble is Not Limiting

The preamble is not limiting, *see supra* § IX.B.1.a.

2) Anticipation by Pelc

To the extent it is limiting, Pelc teaches a system and method for tomographic densitometry modeling of orthopedic structures that satisfies the preamble. Pelc discloses “[a]n X-ray imaging system” that “provides both scanning radiography and computed tomography....” Ex. 1015, Abstract; *see also id.* 1:13-17. Pelc teaches quantitative densitometric modeling and refers to tomographic scanning a patient “for evaluation of bone density and bone morphology.” Ex.

1015 at 1:13-17. Pelc's CT system, like all digital CT systems, is quantitative. *See supra* § IX.A.3; Ex. 1007 (Sonka) ¶¶292-96, 435-37.

3) Obviousness over Pelc in View of Cann

To the extent Osseo argues CT imaging is not quantitative, it would have been obvious to the POSA to combine Pelc with Cann, which teaches quantitative CT densitometry. Ex. 1007 (Sonka) ¶¶295-96, 436. A POSA would have been motivated to use the calibration phantom and process disclosed Cann to obtain a more accurate model of densitometry. *Id.* The POSA further would have been motivated to combine Pelc with Cann because both references relate to CT modeling, and Pelc explicitly acknowledges that the disclosed invention relates to tomographic evaluation of bone density (as does Cann). *Id.*; Ex. 1015 at 1:1317. A POSA would have had a reasonable expectation of success in using the phantom quantitative process taught by Cann in combination with Pelc given the minimal modifications required as well as the established use of CT for densitometrical purposes by the priority date. Ex. 1007 (Sonka) ¶¶295-96, 436. For the same reasons, incorporation of the quantitative CT system taught by Cann would not impact any of the combinations discussed below. *Id.*

b. Controller

Pelc discloses this limitation. It has an “electronic computer” that “controls the C-arm, the radiation source, and the detector,” Ex. 1015 at 5:31-33; *see also*

Fig. 1, 9:35-10:2 (“a controlling computer”); 18:10-12 (motor operated “under the control of computer”); 18:22-24 (same). Pelc teaches that the “computer” may be a “general purpose computer.” *Id.* at 35:17-21. This computer would be understood to necessarily include memory. Ex. 1007 (Sonka) ¶438.

c. Storing Tomographic Models of Dental Structure

The structure required by this limitation is a computer memory. Ex. 1010 at 12. Pelc discloses this limitation. Pelc’s controller has memory associated with it, as discussed above, thus, this controller is capable of storing a pre-existing CT model. § IV.B.1.b; Ex. 1007 (Sonka) ¶439. Pelc also refers to “[a] mass storage device” connected to the computer that “provides a means for storing...image data for future reference by the user.” Ex. 1015 at 36:1-3. The POSA would understand that “image data” in this context includes digital tomographic models. Ex. 1007 (Sonka) ¶439.

d. Input Device

Pelc discloses this limitation. Pelc describes “a computer 56 having a display terminal 58 and a keyboard 60 such as are well known in the art.” Ex. 1015 at 16:8-10. Pelc further discloses that “[t]he computer 56 receives commands and scanning parameters via operator console 58 which is generally a CRT and keyboard which allows the user to enter parameters for the scan and to display

reconstructed image and other information from the computer 56.” *Id.* at 35:31-36; *see also* Fig. 1; Fig. 19; Ex. 1007 (Sonka) at ¶440.

e. Positioning Motor

The Pelc system meets this limitation. Its C-arm is positioned by “actuator 63,” which is “driven by a stepper motor...under the control of computer 56....” *Id.* at 18:8-13; *see also id.* at 35:9-13 (“The control system of a CT imaging system suitable for use with the present invention has gantry motor controller 242”); *id.* at 35:28-31 (“The speed and position of table 12...is communicated to and controlled by computer 56 by means of table motor controller 250.”); Ex. 1007 (Sonka) ¶¶441-43.

f. X-ray equipment

Pelc discloses this limitation, teaching “[a] radiation source and a detector” that are “affixed to the ends of the C-arm to provide energy attenuation measurements....” Ex. 1015 at 5:27-31; *see also* 16:23-36; Ex. 1007 (Sonka) at ¶444.

g. Conversion means

The structure is “an analog-to-digital convertor.” Ex. 1010 at 10. Pelc discloses this limitation. Pelc teaches that analog-to-digital converters are in digital imaging systems: “The detector elements receiving the transmitted radiation produce electrical signals which may be converted to digital values by an analog to digital converter for the later development of an image or for other processing by

computer equipment.” Ex. 1015 at 2:1-5; *see also id.* at 33:34-34:16; Fig. 19. A POSA would understand that Pelc’s CT system, which uses a computer to process digital data for imaging purposes, necessarily includes an analog-to-digital converter that translates the analog signal information from the detector array into digital format. Ex. 1007 (Sonka) ¶¶445-46.

h. Output device

Pelc’s system meets this limitation. It includes “a CRT display...to display the reconstructed image and other information...” Ex. 1015 at 35:31-36. Pelc states that the “reconstructed slice images” generated by the computer “may be displayed on a conventional CRT tube or may be converted to a film record by means of a computer-controlled camera.” *Id.* at 4:17-20; *see also* Fig. 19; Ex. 1007 (Sonka) at ¶¶447-48.

2. Dependent Claim 2: Three Axes of Movement

The ‘301 patent concedes that this arrangement is not novel, *see* § IX.B.2. Pelc discloses this limitation, rendering this claim anticipated by Pelc, and obvious over Pelc and Cann. Pelc’s system contains an X-ray source that rotates around a single axis: “The fan beam and detector array may be mounted to the c-arm so that the fan beam and the detector array may rotate about a fan beam axis connecting the radiation source and the detector array.” Ex. 1015 at 7:9-12. Pelc further teaches that this system can simultaneously move along that axis of rotation (via

“longitudinal rails...which allow the gantry pallet...to be positioned longitudinally...”). *Id.* at 13:34-14:2; *see also* Figs. 1, 6, 9, 15, 18, 19. This translation and rotation movement teaches that the motor can position the equipment with respect to the X-, Y-, and Z- axes. Ex. 1007 (Sonka) ¶¶449-51.

3. Dependent Claim 3: Analog-to-Digital Convertor

Pelc discloses this limitation, rendering this claim anticipated by Pelc, and obvious over Pelc and Cann. As discussed above, § IX.C.1.g, Pelc teaches that analog-to-digital converters are in digital imaging systems. Ex. 1015 at 2:1-5; *see also id.* at 33:34-34:16; Fig. 19. A POSA would understand that Pelc’s CT system, which uses a computer to process digital data for imaging purposes, necessarily includes an analog-to-digital converter that translates the analog signal information from the detector array into digital format, and thus satisfies this limitation. Ex. 1007 (Sonka) ¶¶307-08, 452-54.

4. Dependent Claim 4: Merger Device

A merger device, as construed, is inherent in CT systems because CT requires merging signals from the multiple scans of each target voxel so that the merged information can be used to produce tomographic models. *See, e.g.*, Ex. 1021 (Bushberg) at 244 (“In a CT scanner, the computer orchestrates the acquisition of a large number of transmission measurements taken through the object being scanned and stores this raw data. The raw data, after some preliminary

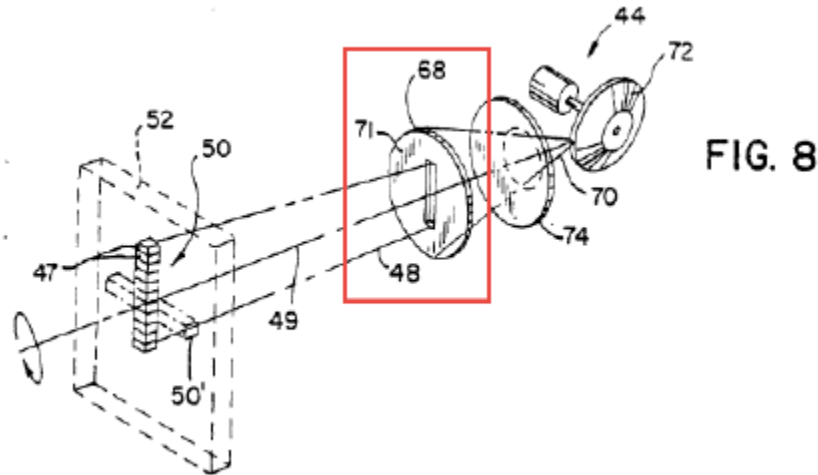
algebra, are reconstructed to produce the tomographic images.”); Ex. 1007 (Sonka) at ¶¶455-59.

Pelc’s system includes a “merger device,” rendering this claim anticipated by Pelc, and obvious over Pelc and Cann. Pelc’s CT system generates densitometrical tomographic models. § IX.C.1.a. In doing so, it merges information from multiple scans of the target, which it uses to produce a model of the target tissue. *See* Ex. 1015 at 5:27-6:1 (describing the acquisition and reconstruction of “the stored attenuation measurements into a tomographic image.”). That is, the microprocessor of Pelc, programmed to receive, store, and perform calculations on the data received from multiple scans to develop a CT model, constitutes a merger device as claimed. Ex. 1007 (Sonka) at ¶¶455-59.

5. Dependent Claim 5: Dual-Energy Beam Restricted Device

Pelc discloses the use of a dual-energy restricted beam device, rendering this claim anticipated by Pelc, and obvious over Pelc and Cann. Pelc teaches that dual-energy techniques are desirable because they “quantitatively compare the attenuation of radiation at two energies to distinguish, for example, between bone and soft tissue” and “allow the measure of bone mass....” Ex. 1015 at 2:14-19; *see also id.* at 6:25-29 (system “may produce separate attenuation measurements indicating attenuation at two energy levels.”). Pelc describes dual-energy computed tomography in detail. *See generally id.* at 33-40.

Pelc also discloses the radiation source “includes an x-ray tube together with filter and collimator...” *Id.* at 14:24-25; *see also id.* at 22:10-14. A POSA would understand this to mean the source is a restricted beam device. Ex. 1007 (Sonka) at ¶¶189-90, 460-62; *see* Fig. 8 (collimator 68 outlined in red):



Further, as of the priority date, CT devices were required to use restricted beam devices, and a POSA would understand that Pelc inherently includes a restricted beam device. Ex. 1007 (Sonka) ¶462.

6. Dependent Claim 6: Preprogrammed Scan Path

Pelc discloses a preprogrammed X-ray scan path, rendering this claim anticipated by Pelc, and obvious over Pelc and Cann. Pelc states that, “[t]he control system of a CT imaging system suitable for use with the present invention has gantry motor controller 242 which controls the rotational speed and position of the C-arm 40 and provides information to computer 56 regarding gantry position....” *Id.* at 35:9-13; *see also id.* at 35:28-36. A POSA would understand that CT systems

such as Pelc necessarily disclose a preprogrammed scan path because computer control of data acquisition is required given the process's complexity. *See, e.g.*, Ex. 1021 (Bushberg) at 244 (“In a CT scanner, the computer orchestrates the acquisition of a large number of transmission measurements taken through the object being scanned and stores this raw data.”); Ex. 1007 (Sonka) at ¶¶463-66.

7. Dependent Claim 7: Color Monitor

The ‘301 patent admits that use of color images to provide densitometry information was known in the prior art as previously discussed. § IX.B.7; Ex. 1002 at 2:12-13. This claim is obvious over Pelc (and Pelc and Cann) in view of the knowledge of a POSA including admitted prior art.

Pelc's system includes “a CRT display...to display the reconstructed image and other information...” Ex. 1015 at 35:31-36. “[R]econstructed slice images” generated by the computer “may be displayed on a conventional CRT tube or may be converted to a film record by means of a computer controlled camera.” *Id.* at 4:17-20; *see also* Fig. 19. A POSA would understand that, as of the priority date, the use of a color monitor would be obvious in light of the state of the art in 1999, or at least obvious to try given the limited options (greyscale or color). Ex. 1007 (Sonka) ¶¶467-71. Further, color-coding the medical models generated by Pelc's CT system would also be obvious to supply additional information to the user. *Id.* Because displaying color-coded models was well known, a POSA would have a

reasonable expectation of success in using a color monitor output device for receiving color-coded models with the CT system of Pelc. *Id.*

8. Dependent Claim 8: Color Printer

This claim is obvious over Pelc (and Pelc and Cann) in view of the knowledge of a POSA, including admitted prior art. The use of a color printer is an obvious variation of the Pelc system for the same reason (as discussed with respect to claim 7) that use of a color monitor would have been obvious. *See, e.g.*, Ex. 1031 (Hosie) at 32 (discussing a printer for reproducing the results displayed on the color monitor). Color-coded medical imaging was known in densitometry, as the patent admits, and a POSA would have been motivated to use a color printer to output the results of the Pelc system with every expectation of success given the ubiquity of color printers in 1999. Ex. 1007 (Sonka) ¶¶472-74.

9. Independent Claim 10 (Method Claim)

Claim 10 is obvious over Pelc in combination with Rothman and in further combination with Xu and/or Milestone (§ IX.C.14), or additionally in combination with Cann.

a. “A system for tomographically modeling dental and orthopedic densitometry....”

This preamble is not limiting for the same reasons discussed for claim 1. To the extent it is limiting, Pelc (or Pelc in combination with Cann if needed for the quantitative element) teaches the required tomographic modeling system. *See*

supra § IX.C.1.a. It would be obvious to use that system to model a dental structure as taught by Rothman.

The POSA would have been aware of the widespread use of CT imaging technology in dental applications, including with respect to densitometry. *Id.* at ¶¶292-296, 475, 478. As Rothman notes in 1998, “[i]n the last decade, computerized tomography (CT) has become one of the most frequently used imaging modalities for the preoperative evaluation of the jaw for dental implants.” Ex. 1016 at 1; *see also id.* at 3. Rothman further discloses the “[q]uantitative assessment of mineral content” in the mandible using such CT imaging technology. Ex. 1016 at 57.

The POSA would have been motivated to combine Pelc with Rothman, or Pelc with Rothman and Cann. Ex. 1007 (Sonka) ¶¶292-296, 478. Rothman extolls the benefits of using CT imaging technology for dental applications, and explicitly notes that “[m]ost commercially available CT scanners are capable of producing the high-resolution images needed for the evaluation of the jaw for dental implants.” *Id.*; Ex. 1016 at 10-11. And Rothman describes a CT imaging device similar to the one disclosed in Pelc—*i.e.*, in which the patient lies supine on a table while the X-ray equipment rotates around the patient to produce a tomographic model of a dental structure. Ex. 1016 at 13-15. Given this overlap, a POSA would have had an expectation of success in using Pelc’s system (or the Pelc and Cann

combination) for dental purposes as described in Rothman. Ex. 1007 (Sonka) ¶¶292-296.

b. The “providing” steps – common structural elements with claim 1 (Claim 10(a)-(b), (d)-(e), and (j))

Claim 10’s method includes a number of steps calling for certain structural elements, which track the system of claim 1 discussed above. Use of Pelc’s system satisfies these limitations. For instance, step 10(a) recites the step of “providing a controller” having the same characteristics of the controller claimed in element 1(a). The same is true for the “input device” of step 10(b), equivalent to 1(b); the “memory” of step 10(d), equivalent to the 1(a)’s “means for storing”; the “X-ray equipment” of step 10(e), equivalent to 1(d); and the “output device” of step 10(j), equivalent to 1(f). The discussion of these elements above is incorporated here (§§ IX.C.1.b-d, f and h). Ex. 1007 (Sonka) at ¶479.

c. Inputting and storing a patient densitometry model (Claim 10(c)-(d))

As discussed below in connection with claim 18 (§ IX.C.14), a POSA would be motivated, in view of Xu and/or Milestone, to use the Pelc CT system to perform comparisons of a patient’s present scan results with a pre-existing densitometry model, *e.g.*, a patient’s prior scan. As a necessary part of that comparison, the prior model would need to be input into and stored in the computer memory of Pelc. Ex. 1007 (Sonka) ¶¶480-81.

d. Use of the X-ray equipment (Claim 10(f)-(g))

Steps 10(f)-(g) recite positioning the target tissue in between the X-ray source and detector and emitting X-rays through that tissue. This is the expected use of the X-ray equipment and is disclosed by Pelc. *See* Ex. 1015 at Figs. 1, 6, 15 (showing patient positioned between X-ray source and detector); Ex. 1007 (Sonka) ¶482. The limitation that the tissue is “dental structure” is provided by Rothman as discussed in the preamble. *Id.*

e. Forming and outputting a densitometrical model (Claim 10(i) and (k))

Step 10(i) recites forming a tomographical densitometrical model of the tissue, and step 10(k) recites outputting the model. The purpose of Pelc’s system is to create and display such models, and use of Pelc as intended renders these steps obvious. *See supra* §§ IX.A.3, IX.C.1; *see also, e.g.*, Ex. 1015 at 5:27-6:1 (summarizing process of generating a tomographic image); Ex. 1007 (Sonka) ¶483.

In sum, each of the limitations of claim 10 are disclosed by or obvious over Pelc in combination with Rothman, Xu and/or Milestone, and additionally in combination with Cann, and the steps claimed are how a POSA would expect such a combined system to be employed. Ex. 1007 (Sonka) ¶¶475-83.

10. Dependent Claim 11: Dual-energy Scan

Pelc discloses this dual-energy limitation, rendering this claim obvious over Pelc in combination with Rothman and in further combination with Xu and/or

Milestone (§ IX.C.14), or additionally in combination with Cann. Each of the steps of claim 11—emitting, detecting, digitizing and storing signals corresponding to first and second energy levels from said X-ray source—are standard in the process of performing a CT scan with the equipment of Pelc. As discussed with respect to claim 5, Pelc discloses a dual-energy scan. § IX.C.5.; Ex. 1007 (Sonka) at ¶¶485-86.

11. Dependent Claim 12: Preprogrammed Scan Path

Pelc discloses a predetermined scan path programmed into the controller, rendering this claim obvious over Pelc in combination with Rothman and in further combination with Xu and/or Milestone (§ IX.C.14), or additionally in combination with Cann. *See supra* § IX.C.6 (claim 6). That path would necessarily have been input into the Pelc system, and during normal and expected use of Pelc, it is the path that the X-ray equipment would follow. Ex. 1007 (Sonka) ¶¶463-466, 487-89.

12. Dependent Claim 13: Three Axes of Movement

Pelc's system has a positioning motor connected to the processor, *see supra* § IX.C.1.e (claim 1(c)). The positioning motor of Pelc's system positions the X-ray equipment through X-, Y-, and Z-axes of movement along the scan path. *See supra* § IX.C.2 (claim 2). Accordingly, claim 13 is obvious over Pelc in combination with Rothman and in further combination with Xu and/or Milestone (§ IX.C.14), or additionally in combination with Cann. Ex. 1007 (Sonka) at ¶490.

13. Dependent Claims 14–17: Dental Diagnosis

Claims 14–17 recite obvious uses of Pelc’s equipment and are obvious over Pelc in combination with Rothman and in further combination with Xu and/or Milestone (§ IX.C.14), or additionally in combination with Cann.

Pelc’s equipment, when used to scan the teeth of a patient as disclosed in Rothman, would provide information relating to the density of the teeth. Ex. 1007 (Sonka) ¶¶492-505. Incipient caries (cavities), dental fractures, apical abscesses, and extent of osseointegration of a dental or orthopedic prosthesis would be detectable as a difference in density and would be evident from the tomographic model of the relevant dental structure. *Id.*; Ex. 1016 (Rothman) at 128 (dental fractures), 54 (apical abscesses), 114-22 (osseointegration). A POSA would have been motivated to use Pelc’s quantitative CT system for dental diagnosis because Rothman itself teaches the use of CT for dental scanning and the quantitative assessment of mandible mineral content. Further, Rothman discloses a device strikingly similar to that in Pelc. Thus, a POSA would also have a reasonable expectation of success in combining these references. Indeed, radiographs, which provide far less information than a tomographical densitometry model, have long been used for some of these same purposes. Ex. 1007 (Sonka) ¶493.

14. Dependent Claim 18: Comparison

This claim is obvious over Pelc and Rothman in view of Xu and/or Milestone (or additionally Cann). The ‘301 patent admits that means for comparing tomographic models were known in the prior art. Ex. 1002 at 2:13-15. Beyond that admission, the only disclosure in the specification regarding comparison is that the “array output is merged and compared to the diagnostic parameters which are stored in the computer’s memory.” *Id.* at 5:18-21. In defense of a § 112 challenge in the Delaware litigation, Osseo admitted “one of skill in the art would know how to compare two sets of data in a computer,” and that, as of the priority date, there existed commercially-available software that was capable of producing a comparison as claimed. Ex. 1012 (SJ Hearing Transcript) at 17:23-18:15.

A POSA would understand that comparisons of medical images, including CT images, are routinely performed for purposes of diagnosis and tracking treatment, and that medical professionals would desire such comparisons. Ex. 1007 (Sonka) ¶¶95-97, 210-221. As admitted by the patent, such comparisons could be between a patient’s current scan and standard models, or between the patient’s current and prior scans. *Id.*; Ex. 1002 at 2:13-15.

As of the priority date of the ‘301 patent, it was well-known to a POSA that a microprocessor could be programmed with software to perform these comparisons. Xu, which is prior art under § 102(e) for the ‘301 patent, teaches a method and system that uses a computer to detect changes in three-dimensional

medical scans by using temporal subtraction. Ex. 1019 at 2:22-32; 16:43-18:52. Milestone, which is prior art under 35 U.S.C. § 102(a), teaches the use of software to compare volumetric or three-dimensional rendering of internal structures, including comparisons between two patient scans (current and previous) as well as a patient scan and scanned/stored data representing a “normal” structure. Ex. 1020 at 5:15-26, 10:26-11:12, and 13:17-22.

Pelc includes memory for storing CT data (*e.g.*, a “mass storage device” that “provides a means for storing...image data for future reference by the user,” Ex. 1015 at 36:1-3). *See supra* § IX.C.1.c. A POSA would have been motivated to adapt the microprocessor in Pelc to perform comparisons between a pre-existing model and a patient’s current model, as stored in those memories, for the reasons discussed above, and would have had a reasonable expectation of success in doing so given the advanced state of the art as admitted by Osseo. Ex. 1007 (Sonka) ¶332, 506-10.

15. Dependent Claim 19: Color Output and Color Coding

The Pelc system has the capability to perform these steps, including color coding a model displaying it on its CRT monitor, and it would have been obvious to modify Pelc’s system and use it to perform these steps, or obvious to try. See §§ IX.C.7-8 (claims 7 and 8). Claim 19 is thus obvious over Pelc and Rothman in

view of Xu and/or Milestone, and in further view of the knowledge of the POSA (or additionally Cann). Ex. 1007 (Sonka) at ¶¶512-13.

16. Independent Claim 20 (Method Claim)

Claim 20 largely recites a combination of steps already addressed above.

The table below identifies the relevant sections, incorporated here by reference.

Claim 20	Prior Reference in § IX	Prior Claim(s)
Preamble	C.1.a, C.9.a	1, 10
(a) controller	C.1.b, C.9.b	1, 10
(b) input device	C.1.d, C.9.b	1, 10
(c) inputting parameters	C.9.c	10
(d) storing parameters	C.9.c	10
(e) X-ray equipment	C.1.f, C.9.b	1, 10
(f) positioning X-ray equipment	C.9.d	10
(g) emitting and detecting X-ray	C.9.d	10
(h) outputting signal	C.1.g, C.3, C.9.d	1, 3, 10
(i) digitizing signal	C.1.g, C.3, C.9.d	1, 3, 10
(j) storing digitized signal	C.1.c, C.9.e	1, 10
(k) dual-energy	C.5, C.11	5, 11
(l) merging signals to create model	C.1.a, C.4, C.9.i	1, 4, 11
(m) comparing model to pre-existing model	C.14	18
(o) output device	C.1.h, C.9.b	1, 10
(p) color-coding model	C.7, C.8, C.15	7, 8, 19
(q) outputting color-coded model	C.7, C.8, C.15	7, 8, 19

A POSA would have used the system of Pelc to perform these steps, which are routine and expected in the use of Pelc, as previously discussed. The only step not expressly discussed previously is step (n): “adjusting said present densitometry model to account for patient parameters including age and gender.” The patent does not purport to have invented this practice, and the step of performing such

adjustments would be something a POSA would be motivated to do in cases where such adjustment is required. Ex. 1007 (Sonka) ¶¶515-17. Accordingly, claim 20 is obvious over Pelc and Rothman in view of Xu and/or Milestone, and in further view of the knowledge of the POSA (or additionally Cann).

X. CONCLUSION

With this Petition, Petitioner has established a reasonable likelihood that the challenged claims of the '301 patent will be found unpatentable. Petitioner therefore respectfully requests that *inter partes* review of the '301 patent be granted, and that Claims 1–8 and 10–20 be held unpatentable.

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CERTIFICATE OF SERVICE
(37 C.F.R. §§ 42.6(e) and 42.105(a))

The undersigned hereby certifies that a copy of the accompanying Petition for *inter partes* review, all accompanying exhibits, and the Power of Attorney is being served via FedEx Overnight to the correspondence address of record for U.S. Patent No. 6,381,301 on March 26, 2025 upon the following:

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