

**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. 6,944,262
IPR2025-00772

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 6,944,262**

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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, 2, 4 and 6 of U.S. Patent No. 6,944,262 (“the ‘262 patent”), Exhibit (“Ex.”) 1003, 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 “presented in the Petition is sufficient to demonstrate a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of claims 1, 2, 4, and 6 of the ’262 Patent.” IPR2020-00672, Paper No. 10 at 44. 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 itself concedes that it uses known technology to apply known methods to create a claimed digital modeling system for creating dental and orthopedic models. Ex. 1003 at 8:63-10:13. The patent touts as an advantage that the purported invention “utilizes commercially available tomography equipment.”

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.

Id. at 3:20-21. It admits that tomographical medical imaging was known: “[t]omography or sectional radiography techniques using scanning X-ray beams have previously been employed for dental applications.” *Id.* at 2:3-9. It also admits that it was known to measure bone density with “densitometry procedures” using “scanning X-ray beam techniques.” *Id.* at 2:10-15.

The patent contends as a point of novelty: “[h]eretofore 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 2:41-45; *see also id.* at 2:28-30 (“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 the patent specification’s focus on dental applications, the claims are not so limited.

Tomographic densitometry modeling 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. The claims recite known and obvious combinations of old elements and methods and are accordingly invalid.

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. 6,944,262 was previously subject to an IPR, IPR2020-00672 (the '672 IPR), which was Instituted on June 10, 2020. See '672 IPR at Paper 10. The Trial was terminated due to settlement. See '672 IPR 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.

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.

Petitioner reserves all rights to dispute the applicability of the *Fintiv* factors in the present proceeding.

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 13,934 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 '262 patent is available for *inter partes* review, and that Petitioner is not barred or estopped from requesting an *inter partes* review of the '262 Patent claims on the grounds identified in this Petition. 37 C.F.R. §42.104(a).

IV. IDENTIFICATION OF GROUNDS

In the '672 IPR, the Board Instituted Review of claims 1, 2, 4, and 6 based on the three primary references presented below, Massie, Arai, and Pelc. The Board found there was a reasonable likelihood that Massie anticipated and/or rendered obvious claims 1, 2, 4, and 6 of the '262 patent. '672 IPR at Paper 10 at 18-29. The Board also found that there was a reasonable likelihood that claims 1, 2, 4, and 6 were rendered obvious by Arai, in combination. '672 IPR at Paper 10 at 30-38. Finally, the Board found that there was a reasonable likelihood that Pelc, in combination, rendered claims 1, 2, 4, and 6 obvious. '672 IPR at Paper 10 at 38-44. 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, 2, 4, and 6 of the '262 Patent.³

Petitioner challenges claims 1, 2, 4, and 6 of the '262 patent and requests the claims be found unpatentable as follows:

Ground 1: Massie

Ex. 1017-The Massie Publication anticipates claims 1, 2, 4 and 6 under 35 U.S.C. §102, and renders claims 1, 2, 4 and 6 obvious under 35 U.S.C. §103 alone or in combination with Ex. 1019-Xu and/or Ex. 1020-Milestone (claims 2 and 4).⁴

Ground 2: Arai

Ex. 1013-Arai renders claims 1, 2, 4 and 6 obvious under 35 U.S.C. §103 in combination with Xu and/or Milestone, and alternatively in further combination with Ex. 1014-Cann.

³ The Board's prior Institution reviewing claims 1-24 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 Because the application on which the '262 patent was filed before March 16, 2013, the effective date of the America Invents Act ("AIA"), it is subject to 35 U.S.C. §§ 102-103 as they existed pre-AIA.

Ground 3: Pelc

Ex. 1015-Pelc renders claims 1, 2, 4 and 6 obvious under 35 U.S.C. §103 in combination with Xu and/or Milestone, and alternatively in further combination with Cann.

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

V. TECHNOLOGICAL BACKGROUND

The patent claims a “digital modeling system for creating dental or orthopedic models of patients.” *See* Claim 1. Computed tomography was common as of the priority date and is the technology most relevant here. Ex. 1007 (Sonka) ¶¶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 X-rays that pass 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 where detailed information about an area of interest is needed. *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 use of CT scanners for medical imaging was commonplace by the earliest priority date of December 1, 1999. *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 CT scan. *See* Ex. 1023 (Genant 1998) at 915. Figure 2 of Genant 1998 shows an exemplar CT scan depicting densitometrical information.

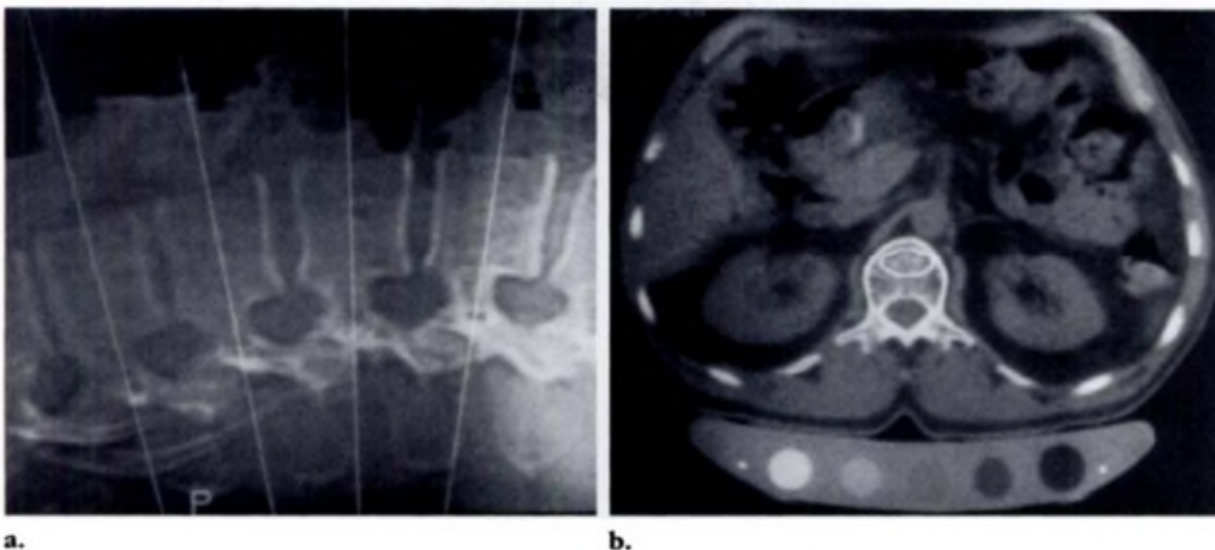


Figure 2. Evaluation of trabecular bone density with quantitative CT. **(a)** Lateral scout view provides a rapid and simple means of defining the midplane of four vertebral bodies. *P* = posterior. **(b)** A single CT scan (8-10-mm section thickness) is obtained at each level, and the classic oval region 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 (a “phantom”) is included in the scan to allow calibration of CT attenuation measurements (in Hounsfield Units) to bone-equivalent values in mg/cm^3 . *Id.*; Ex. 1021 (Bushberg) at 273. However, even without the use of 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. 1021 (Bushberg) at 246, 273; Ex. 1007 (Sonka) ¶¶93-94. That is, “[t]he CT number for a certain pixel actually corresponds to physical properties within the patient in the corresponding voxel.” *Id.* at 246. CT numbers for bone range from ~300 to 3000, depending on density. *Id.* at 247.

VI. THE ‘262 PATENT AND PROSECUTION HISTORY

A. The ‘262 Patent Specification

The ‘262 patent states that it “relates generally to dental and orthopedic diagnosis, forensics, identification, biometrics and treatment, and in particular to a densitometry modeling system and method.” Ex. 1003 at 1:15-19. The background 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 1:21-2:2, and monitoring dental implant osseointegration, *id.* at 2:31-39.

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 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 ‘262 Patent Admits CT Imaging Equipment Was Known.

The patent concedes, “Tomography or sectional radiography techniques using scanning X-ray beams have previously been employed for dental applications.” Ex. 1003 at 2:3-9. It expressly incorporates by reference five patents in connection with this acknowledgment, 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,” *id.* at 1:37-50, and describes a CT system that has many of the elements claimed in the ‘262 patent. *Id.* at 10:1011:46, Figures 7, 8.

The ‘262 patent further concedes the existence of “commercially available tomography equipment” suitable for use in the claimed invention as of the priority date. Ex. 1003 at 3:20-22; *see also id.* at 4:52-55 (incorporating prior art “examples of X-ray equipment adaptable for use with the present invention”); *id.* at 6:39-45 (“either or both of the beam source 120 and the sensor/receptor 122 can be preprogrammed for computer-controlled movement with respect to the patient 124...Such equipment is commercially available....”).

2. The ‘262 Patent Admits CT Densitometry Was Known.

The ‘262 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. 1003 at 2:10-17. The patent states that “[e]xamples are shown in U.S. Patent No. 5,533,080,” along with two other patents. *Id.* The ‘080 patent discloses a CT system in which X-rays are transmitted through bone being imaged and detected with a detector array. Ex. 1018 (Pelc ‘080) at 1:22-35. It includes a controller that rotates a dual-energy X-ray source and detector array on a gantry “so that the fan beam intercepts the

imaged object at different angles.” *Id.* at 1:43-49. “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 7:44-56.

3. The ‘262 Patent’s Description of the Purported Invention

The patent describes a generic system with conventional components for creating a tomographical model. Indeed, the patent claims as an advantage that it “utilizes commercially available tomography equipment.” Ex. 1003 at 3:20-22. The system described includes: (1) a controller with a microprocessor and a memory device connected to the microprocessor (“any of a number of suitable hardware devices which are commercially available and are suitable for this application”), *id.* at 4:25-37, 5:64-67; (2) an input device (“such as a keyboard,...mouse...a communications link, or another computer”), *id.* at 4:38-41, 5:60-63; (3) Energy sources, including (a) X-ray equipment, *see id.* at 4:52-55 (listing prior art “[e]xamples of X-ray equipment adaptable for use with the present invention”), or (b) an electron beam source/detector, *id.* at 6:10-11; and (4) a generic output device (*e.g.*, monitor, printer, another computer), *id.* at 5:3-8, 5:67-6:6.

The system’s operation is likewise generic, including moving the energy source and detector equipment along a preprogrammed scan path controlled by the

microprocessor, emitting and detecting X-ray or electron beams, and using that information to create a tomographical densitometry model. *Id.* at 5:33-53. The patent also discloses that the computer can be used to compare different models using comparison software. *Id.* at 6:6-9; 7:59-8:6.

The ‘262 patent is a continuation-in-part of the chain of applications that gave rise to the two related patents (U.S. Patent Nos. 6,381,301 and 8,498,374) that are the subject of co-pending petitions for *inter partes* review filed by Dentsply. As compared to the disclosure of those patents, there is new matter in the ‘262 patent, primarily consisting of disclosure of a “modified” densitometry modeling system using an electron beam source, *id.* at 5:56-7:17, discussed in more detail in Section IX (“Priority Date of the Challenged Claims”) below. The ‘262 patent also adds discussion regarding the process of developing a baseline database and performing comparisons between a patient’s scans, or between a patient’s scan and the model. *Id.* at 7:40-8:45; Figs. 6-7.

B. The Claims of the ‘262 Patent

Independent claim 1 recites a digital modeling system including conventional equipment, such as a computer (specified to have a memory and an input) that can create, store and compare 3D densitometry models, an energy source and sensor, and a display and associated software. Dependent claim 2

requires that the source is external, claim 4 requires that the sensor is external, and claim 6 requires the energy beam to be collimated.

C. Prosecution History

The '262 patent claims priority through a lengthy chain of continuations and continuations-in-part to an initial application (U.S. Patent App. 09/452,348) filed on December 1, 1999. Ex. 1003 at 1:8-12. Priority of the claims of the '262 patent is addressed in Section IX, below.

The '262 patent issued from U.S. Patent App. No. 10/351,567, filed January 24, 2003. During prosecution, the claims were rejected as anticipated and obvious.⁵ After an interview, the applicant amended the claims to add two limitations. First, the applicant added a limitation requiring the densitometry model be "three-dimensional." Ex. 1006 (3/1/2005, Amendment) at 96, 100. Second, the applicant added a negative limitation stating the densitometry model is created, stored and compared "without the use of fiducial markers." *Id.*

⁵ 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.

Additionally, during prosecution of U.S. Patent App. 09/452,348, which issued as U.S. Patent No. 6,381,301, the Examiner rejected all then-pending claims as obvious. The Examiner stated that “applicant 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 [sic] own history is known. What applicant appears to believe is lacking is the use of such a system for dental tomographic imaging.” Ex. 1005 (4/9/2001, Office Action) at 43. The Examiner concluded that, based on prior art not asserted here, “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.

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. The Examiner allowed the claims, stating in the reasons for allowance that, “though the prior art discloses tomographic modeling for dentistry, it 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 person of ordinary skill in the art (“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 an *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 invention.” See *Phillips v. AWH Corp.*, 415F.3d 1303, 1313 (Fed. Cir. 2005); see 37 C.F.R. § 42.100(b).

A. District Court Constructions

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.⁶ Ex. 1009, 1010. Dentsply was not a party to that case but adopts those constructions for purposes of this petition.

1. **“Densitometry” (Claim 1)**

“Quantitatively calculated bone density.” Ex. 1010 at 8.

2. **“Three-dimensional digital densitometry model” (Claim 1)**

A digital three-dimensional model, *i.e.*, a digital model constructed from two or more focal planes. *Id.* at 9-10. This construction was not intended to differentiate from the plain meaning of “three-dimensional,” in which a three-dimensional model is one that includes information for three dimensions, such as would be true for a model constructed from two or more focal planes. *See* Ex. 1011 at 60:1-62:15.

3. **“Comparing three-dimensional digital densitometry models” (Claim 1)**

The Court held that no construction was necessary. Ex. 1010 at 14.

The patent’s background section acknowledges that, in the densitometry context, comparisons between a standard model and a patient’s model were known, as were comparisons between a patient’s current and historical model. Ex. 1003 at 2:22–24. With respect to the purported invention, the patent discloses that a

⁶ “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).

computer can be loaded with “comparison software 118, which is adapted for digitally comparing baseline and patient-specific dental and orthopedic densitometry models,” *id.* at 6:6-9, and describes using that software to compare a patient model with “a corresponding baseline model,” *id.* at 7:59-63, or a prior patient model, *id.* at 7:64-8:6. This supports a construction of “comparing” digital densitometry models in accord with its ordinary meaning: “identifying differences between models.”

B. Construction of Additional Terms

1. “Fiducial marker” (Claim 1)

The ‘262 patent specification does not use or define the term “fiducial marker.” A POSA would understand this term in the context of the patent to mean: “An x-ray attenuating object on or within the structure to be imaged that serves as a reference point.”

2. “An energy source and an energy sensor” (Claim 1)

The ‘262 patent describes two types of energy sources/sensors used in the scanning apparatus: (a) X-ray equipment, Ex. 1003 at 4:52-55; and (b) electron beam equipment, *id.* at 6:10-11. Accordingly, “an energy source and an energy sensor” should be construed to include an X-ray source and sensor, and an electron beam source and sensor.

IX. PRIORITY DATE OF THE CHALLENGED CLAIMS

The ‘262 patent issued from U.S. Patent App. No. 10/351,567, filed January 24, 2003. The applicant styled the ‘567 application as a continuation-in-part application (“CIP”), claiming priority through a chain of applications to U.S. Patent App. No. 09/452,348, filed December 1, 1999. Ex. 1003 at 1:8-12.

The designation of the ‘567 application as a “continuation-in-part” is an acknowledgement that it contains new matter. *See* MPEP § 201.08. The pre-existing disclosure (*i.e.*, the disclosure in the ‘262 patent that is coextensive with the prior applications in the chain) describes only the use of **X-rays** in the purported invention. *E.g.*, Ex. 1003 at 4:21-5:19 (describing “X-ray equipment 12” comprised of “X-ray source beam 14” and “detector array 16.”). As relevant here, the new matter in the ‘262 patent includes the additional disclosure of “Modified Embodiment Densitometry Modeling Systems,” Ex. 1003 at 5:56-7:17. These newly-disclosed “modified” systems use **electron beams** in the scanning apparatus. *E.g.*, *id.* at 6:10-28 (emphasis added); Figs. 3-4 (disclosing “electron beam source”).

In a CIP application, only a claim with all of its limitations fully supported by the disclosure of the parent application is entitled to the parent’s earlier priority date. *See* MPEP § 211.05(I)(B); *Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co.*, 112 F.3d 1561, 1564 (Fed. Cir. 1997) (earlier priority date “only applies to claims that recite subject matter adequately described in an earlier application, and

does not extend to claims with subject matter outside the description in the earlier application.”). All other claims are given the CIP application’s later priority date. *Id.*

Here, the challenged claims of the ‘262 patent each broadly claim a system having “an energy source and an energy sensor.” This is a generic limitation that encompasses both the pre-existing X-ray disclosure as well as the newly-added electron beam disclosure in the patent. *See supra* § VIII.B.2. Because the prior-filed applications disclose only X-ray sources/sensors, and do not disclose “electron beam” sources/sensors, the claims of the ‘262 patent cannot obtain the benefit of those earlier applications’ filing date. A POSA would not understand the applicant to have invented or been in possession of the purported invention as broadly claimed in the ‘262 patent based on the prior applications. Ex. 1007 (Sonka) ¶¶518-20. This is clear from the contents of the prior applications, as well as applicant’s filing of a self-identified “continuation-in-part” application containing an extensive discussion of a “modified embodiment” not present in those prior applications. *Id.*; *see LizardTech v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005) (specification failed to adequately support a generic claim by description of only one particular method and no evidence existed that the specification contemplated a more generic method).

Accordingly, the challenged claims of the ‘262 patent, each of which contain the broad energy source/sensor limitations unsupported by any earlier application, are entitled to a priority date of January 24, 2003, the filing date of the ‘567 continuation-in-part application in which the new matter was added.

X. DETAILED EXPLANATION OF GROUNDS FOR INVALIDITY

A. Ground 1: The Massie Publication Anticipates and Renders Obvious the Asserted Claims.

On December 1, 2000, Applicant filed International Application No. PCT/US00/32905. The relevant substance of this PCT application is the same as the initial priority document in the chain listed in the ‘262 patent, U.S. Patent App. No. 09/452,348. The PCT application published on June 7, 2001, as WO 01/39667 (Ex. 1017, the “Massie Publication”). Because the priority date of the ‘262 patent is January 24, 2003, *see supra* Section IX, the Massie Publication is prior art under at least Sections 102(a)-(b).

The Massie Publication invalidates the claims as explained below. That the Massie Publication shares an inventor and part of its specification with the ‘262 patent is no hurdle to its status as invalidating prior art. *See In re Chu*, 66 F.3d 292, 296-97 (Fed. Cir. 1995) (holding that even though Chu’s “application claims to be a CIP of the Doyle patent,” some claims were not supported by Doyle alone, so for those claims “the Doyle patent was properly relied on as prior art”); *In re Van Langenhoven*, 458 F.2d 132, 136-37 (C.C.P.A. 1972) (allowing “appellant’s

own French patent” to be cited “to establish obviousness” of CIP claims for subject matter beyond the original disclosure).

1. Independent Claim 1

The Massie Publication anticipates claim 1 or renders it obvious, either alone or in combination with Xu and/or Milestone.

a. Preamble

Claim 1’s preamble recites “A digital modeling system for creating dental or orthopedic models of patients.” This preamble should not be construed to limit the claimed invention. “[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 perform and report scan results, the preamble is a non-limiting statement of purpose.

To the extent the preamble is limiting, the Massie Publication discloses a digital modeling system for creating dental or orthopedic densitometry models of patients. See Ex. 1017 at 5:6-9 (“providing such an application which includes a method for modeling dental and orthopedic structure using densitometry”); *id.* at 7:4-9:7; *id.* at Fig. 1; Ex. 1007 (Sonka) at ¶¶523-524, 532-533. Further, the Massie Publication’s system explicitly states that it generates a tomographical

densitometry model (*id.* at 5:7-11, 9:2-6) and it incorporates by reference prior art CT systems that it relies on as suitable for practicing the purported invention. Moreover, Osseo admitted, with respect to the U.S. counterparts having substantially the same disclosure as the Massie Publication, that “[t]hese patents...are talking about doing a calculation, quantitative calculation that represent[s] bone density.” Ex. 1012 (SJ Transcript) at 32:20-22.

The Board agreed that Massie’s disclosure of tomographic densitometry” alone or in combination, provided a reasonable likelihood of showing unpatentability of this claim feature. ‘672 IPR at Paper 10 at 18-19.

b. Computer having memory, an input and an output

Claim 1 further recites “a computer including a digital memory storing patient densitometry information, an input and an output.”

The Massie Publication discloses a computer in the form of “a controller 4 with a microprocessor 6 connected to a digital memory device 7.” Ex. 1017 at 7:6-14. The computer “is adapted to receive input from one or more input devices 8.” *Id.* at 7:15-17; Ex. 1007 (Sonka) at ¶¶525-527. The computer further has “an output device or devices 26,” such as a “monitor.” *Id.* at 8:15-19

The element reciting “storing patient densitometry information” is a non-limiting statement of intended use in the context of a system claim and has no patentable weight. *See Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d

1464, 1468 (Fed. Cir. 1990) (“[A]pparatus claims cover what a device *is*, not what a device *does*.”). However, if it is a limitation, the Massie Publication discloses it. Among the information that can be input and stored in the memory is “a patient’s dental and orthopedic records, including previous tomographical densitometry models.” *Id.* at 7:17-19; *see also id.* at 9:13-14; ‘672 IPR at Paper 10 at 19-20 (relying on Massie’s disclosure of a computer adapted to receive input from input devices and having output devices, alone or in combination).

c. Energy source and energy sensor

Claim 1 recites “a dental or orthopedic input device including an energy source and an energy sensor; said source and said sensor being placed with at least a portion of the patient’s dental or orthopedic structure therebetween.” The Massie Publication discloses an X-ray source and detector. Ex. 1017 at 8:7-12. “The source and the detector array 14, 16 are adapted for positioning on either side of a patient’s dental/orthopedic structure 18.” *Id.* at 8:10-12; Ex. 1007 (Sonka) at ¶528; *see also* ‘672 IPR at Paper 10 at 19-20 (relying on Massie’s disclosure of an X-ray source and detector adapted for positioning on either side of a patient’s dental structures, alone or in combination).

d. Sensor transferring signals

Claim 1 further recites “said sensor transferring signals to the computer input.” The Massie Publication discloses a system in which signals are transferred

from the X-ray sensor to a computer input: “Analog signals from the detector array 16 are output to an analog-to-digital (A/D) convertor 20, from which digitized signals are transmitted to a merger device 22 for merging into formats suitable for processing and analyzing by the microprocessor 6.” Ex. 1017 at 8:13-15; Ex. 1007 (Sonka) at ¶529; *see also* ‘672 IPR at Paper 10 at 20-21 (relying on Massie’s disclosure of analog signals from a detector array, alone or in combination).

e. Signals representing densitometry

Claim 1 further recites “said signals representing densitometry of the patient’s dental or orthopedic structure.” These signals transferred from the sensor to the computer input are representative of densitometry. The Massie Publication teaches that the computer uses data from the signals to create a densitometric model. *Id.* at 8:15-17 (“The microprocessor 6, using data from the merger device 22, creates a tomographical densitometry model 24 which is transmitted to an output device or devices 26.”); Ex. 1007 (Sonka) at ¶¶530; *see also* ‘672 IPR at Paper 10 at 20-21 (relying on Massie’s disclosure of analog signals from a detector array being analyzed by Massie’s microprocessor to create a densitometric model, alone or in combination).

f. Creating, storing and comparing 3D models without fiducial markers

Claim 1 recites “said computer creating, storing and comparing three-dimensional digital densitometry models without the use of fiducial markers of patient dental or orthopedic structure.”

1) Creating

The Massie Publication discloses the creation of densitometry models by the system’s computer. *See supra* § X.A.1.a; Ex. 1017 at 5:6-9.

2) Storing

Likewise, the Massie Publication discloses the storage of densitometry models. *See supra* § X.A.1.b; *see also* Ex. 1017 at 7:17-19, 9:13-14.

3) Comparing

The Massie Publication discloses the comparison of densitometry models. *See, e.g.*, Ex. 1017 at 15 (claim 18) (“inputting to said microprocessor a pre-existing tomographical densitometry model” and “comparing said patient’s current densitometry model to said pre-existing densitometry model.”); *see also* Ex. 1012 at 15:14-17:1 (Osseo admission that the common specification of the U.S. counterpart to the Massie Publication describes the comparing limitation). Alternatively, use of the system disclosed in the Massie Publication to perform comparisons would be obvious. The ‘262 patent admits that means for comparing tomographic models were known in the prior art. Ex. 1003 at 2:23-25. Moreover,

in defense of a Section 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 Transcript) at 17:23-18:21.

A POSA would understand that comparisons of medical models are routinely performed for purposes of diagnosis and tracking treatment, and that medical professionals desire such comparisons. 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. Ex. 1003 at 2:23-25; Ex. 1007 (Sonka) at ¶¶95-97, 534-36.

As of the priority date of the ‘262 patent, it was well-known to a POSA that a microprocessor could be programmed with software to perform these comparisons. Xu⁷ teaches a method and system that uses a computer to detect changes in three-dimensional medical scans by using temporal subtraction. Ex.

⁷ U.S. Patent No. 6,363,163 (“Xu”) was filed on February 23, 1998 and issued on March 26, 2002. It is prior art under Sections 102(a), (b), and (e) to the January 24, 2003, priority date. It is prior art under Section 102(e) to the December 1, 1999, priority date.

1019 at 2:19-32; 16:43-18:52 (reciting various claims covering computer algorithms to perform comparisons). The method involves obtaining the first and second scans of interest, matching the images, non-linearly warping the first image, and subtracting the first warped image from the second image. *Id.* at 2:36-44. Milestone⁸ 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. A POSA would have recognized that programming a computer to compare may help medical professionals identify small changes or abnormalities that they might otherwise miss as well as save them time. A POSA would thus have been motivated to adapt the microprocessor in the Massie Publication to perform comparisons between densitometry models 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

⁸ International Publication No. WO 98/36683 (Milestone) was filed on February 20, 1998. It is prior art under Sections 102(a), (b), and (e) to the January 24, 2003, priority date. It is prior art under Section 102(e) to the December 1, 1999, priority date.

admitted by Osseo. Ex. 1007 (Sonka) ¶¶534-36, *see also* ‘672 IPR at Paper 10 at 21-22, 25-28 (relying on Massie discloses creating, storing, and comparing three-dimensional digital densitometry models, alone or in combination).

4) Three-dimensional models

The Massie Publication discloses that the models created, stored and compared are 3D models. Osseo admitted this in defending against written description and enablement challenges in the Delaware litigation directed to the U.S. patent applications that correspond to the Massie Publication. Ex. 1012 (SJ Transcript), 21:21-22:4 (“There is disclosure, specific disclosure of the use of 3D models.”); Ex. 1034 (Osseo SJ Opp.) at 11. Additionally, the Massie Publication discloses the use of cone beam scanning technology. *E.g.*, Ex. 1017 at 8:7-9. Use of a cone beam CT system necessarily creates a three-dimensional dataset, which can then be stored and compared as described in the Massie Publication with respect to tomographical models. Ex. 1007 (Sonka) ¶¶79-81, 537-39.

Alternatively, creating, storing and comparing 3D models is obvious. Osseo admitted that:

one of ordinary skill in the art would know, at the time of the invention, how to take datasets and make 3D models out of them. It was known. We’re not professing that that’s the invention. It was known at the time, fairly well known by those of ordinary skill in the art how to make 3D models out of image datasets.

Ex. 1012 (SJ Hearing Transcript) at 21:21-22:4. A POSA would have been motivated to modify the Massie Publication's system to provide such 3D models as of the priority date, as that was a common use of CT imaging and well within the skill of the art (as Osseo admitted). A POSA would be motivated to use the Massie Publication system to create, store and compare 3D models because that was the expected use of such systems, and would have had a reasonable expectation of success in doing so. Ex. 1007 (Sonka) ¶¶79-81, 537-39; *see also* Ex. 1012 (SJ Transcript) at 17:23-18:21, 21:21-22:4.

5) Without use of fiducial markers

With respect to the fiducial marker negative limitation, the Massie Publication, like the '262 patent, does not discuss the use of "fiducial markers." Accordingly, if the '262 patent discloses this limitation, so does the Massie Publication.

Alternatively, it would be obvious to use the system disclosed in the Massie Publication to create, store and compare densitometric models without fiducial markers. While fiducial markers can help to align individual slices in a 3D tomographic model to improve the accuracy of the resulting model, a POSA would recognize that they are not necessary for the creation, storage, or comparison of tomographic models with the system disclosed in the Massie Publication. Ex. 1007 (Sonka) ¶¶91, 540-41. A POSA would be motivated not to use fiducial

markers to reduce the complexity and cost associated with the scan in using such markers, and a POSA would have had a reasonable expectation of success in implementing such a system. *Id.*

g. Output device, imaging software and display

Claim 1 further requires “an output device connected to said computer output and communicating densitometry model comparison information; imaging software associated with said computer; and a display associated with said output device and displaying information pertaining to said densitometry model.” The Massie Publication discloses that the “controller 4 can be programmed in any suitable manner utilizing any of a variety of commercially available programming languages and software development systems.” Ex. 1017 at 7:12-14. Further, the Massie Publication discloses an output device. *E.g.*, Ex. 1017 at 10:9-12 (“...output, for example to a monitor or printer for converting the model to a visual image.”); *see also id.* at 8:15-19; ‘672 IPR at Paper 10 at 22-23 (relying on Massie’s disclosure of a monitor and printer for converting a densitometry model to a visual image, alone or in combination).

The claim element that the information communicated is “densitometry model comparison information” is a non-limiting statement of intended use in the context of a system claim and has no patentable weight. *See Hewlett-Packard Co.*, 909 F.2d at 1468. To the extent it is limiting, the Massie Publication teaches

communication of comparison information, or it would have been obvious to use the system for that purpose. As discussed above, *see supra* § X.A.1.f.3, performing comparisons between two or more models is commonplace in medicine for purposes of diagnosis or monitoring treatment. Ex. 1007 (Sonka) ¶¶95-97. For such information to be useful to physicians, it needs to be transmitted to them. The system of the Massie Publication includes a monitor and displaying tomographic information for those purposes. *E.g.*, Ex. 1017 at 3:17-18 (“the present invention has applications in monitoring osseointegration”); 9:2-3 (same); 10:9-12 (describing converting model to image and outputting to monitor). For those reasons, a POSA would understand that the “densitometry [] tomographically modeled and output” as described in the Massie Publication would include densitometry comparison information. Ex. 1007, (Sonka) ¶¶542-45. Alternatively, a POSA would find it obvious to use the Massie Publication’s system to display comparison model information developed by that system for the purposes stated in the patent. *Id.* A POSA would reasonably expect to be able to successfully display the comparison model with the Massie Publication system in the same manner as displaying a present patient model.

2. Dependent Claim 2

Claim 2 recites “said source is external.” The Massie Publication anticipates claim 2 or renders it obvious, either alone or in combination with Xu and/or Milestone, and in further combination with the knowledge of the POSA.

The Massie Publication discloses “positioning a patient and positioning the X-ray equipment relative to the patient, *i.e.* with the patient’s dental/orthopedic structure to be examined located between the X-ray source 14 and the detector array 16.” Ex. 1017 at 9:10-12. Given this disclosure and the state of the art as of the priority date, a POSA would understand the Massie Publication to disclose an external X-ray source. Ex. 1007 (Sonka) ¶548; *see also* ‘672 IPR at Paper 10 at 24, 29 (relying on Massie’s disclosure of X-ray equipment positioned relative to a patient’s dental structures, alone or in combination). Additionally, the Massie Publication incorporates by reference U.S. Patent No. 5,533,080 (Pelc ‘080) stating that it provides an “[e]xample of X-ray equipment adaptable for use with the present invention.” Ex. 1017 at 8:5-7. Pelc ‘080 discloses an external source. *See* Ex. 1018 at Figs. 1, 5.

Alternatively, a POSA would understand that an external source is one of a finite number of known and predictable solutions regarding source placement—internal or external—and that an external source placement was the most common and accepted placement with respect to X-ray sources in CT machines like that

disclosed in the Massie Publication, and would have every expectation of success in using an external source. Ex. 1007 (Sonka) ¶549.

3. **Dependent Claim 4**

Claim 4 recites “said sensor is external.” The Massie Publication anticipates claim 4 or renders it obvious, either alone or in combination with Xu and/or Milestone, and in further combination with the knowledge of the POSA.

The Massie Publication discloses “positioning a patient and positioning the X-ray equipment relative to the patient, *i.e.* with the patient’s dental/orthopedic structure to be examined located between the X-ray source 14 and the detector array 16.” Ex. 1017 at 9:10-12. Given this disclosure and the state of the art as of the priority date, a POSA would understand the Massie Publication to disclose an external X-ray sensor. Ex. 1007 (Sonka) ¶552. Additionally, the Massie Publication incorporates Pelc ‘080 by reference, stating that it provides an “[e]xample of X-ray equipment adaptable for use with the present invention.” Ex. 1017 at 8:5-7. Pelc ‘080 discloses an external sensor. Ex. 1018 at Figs. 1, 5.

Alternatively, a POSA would understand that an external sensor is one of a finite number of known and predictable solutions regarding sensor placement—internal or external—and that an external sensor placement was the most common and accepted placement with respect to X-ray sources in CT machines like that disclosed in the Massie Publication, and would have every expectation of success

in using an external sensor. Ex. 1007 (Sonka) ¶552. Accordingly, the limitation is anticipated and obvious.

4. Dependent Claim 6

Claim 6 recites “said energy being collimated.” The Massie Publication discloses a collimated X-ray energy source. The Massie Publication therefore anticipates claim 6 or renders it obvious, either alone or in combination with Xu and/or Milestone. “The X-ray beam can suitably [be] collimated to assume any suitable configuration, such as fan, pencil, cone, etc.” Ex. 1017 at 8:8-9; Ex. 1007 (Sonka) ¶¶554-55; *see also* ‘672 IPR at Paper 10 at 24-25, 29 (relying on Massie’s disclosure of an X-ray beam that can be collimated, alone or in combination). Accordingly, claim 6 is anticipated and obvious.

B. Detailed Description of Prior Art for Grounds 2-3

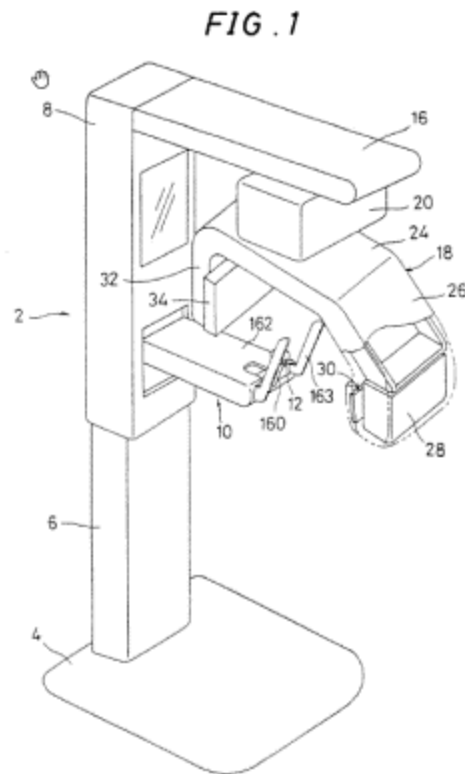
1. Arai, U.S. Patent No. 6,118,842 (Ex. 1013)

Arai was filed on December 9, 1997, and issued on September 12, 2000. *See* Ex. 1013 at [22], [45]. For a January 24, 2003, priority date, Arai is prior art under (pre-AIA) 35 U.S.C. §§ 102(a)-(b). For a December 1, 1999, priority date, Arai is prior art under (pre-AIA) 35 U.S.C. § 102(e).

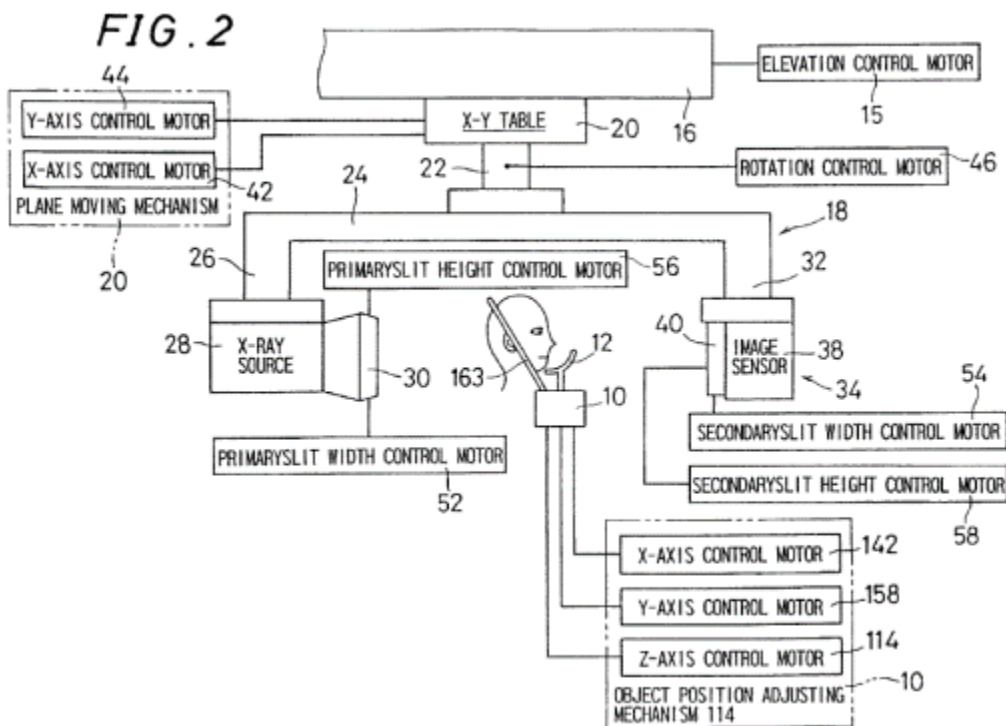
Arai describes a dental X-ray imaging apparatus that can conduct local CT and panoramic tomographic imaging. Ex. 1013 at 2:3-5; Ex. 1007 (Sonka) at ¶¶172-73. But Arai also teaches that its apparatus may be used solely for CT imaging: “[I]t is also possible to construct a dedicated partial X-ray CT imaging

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.

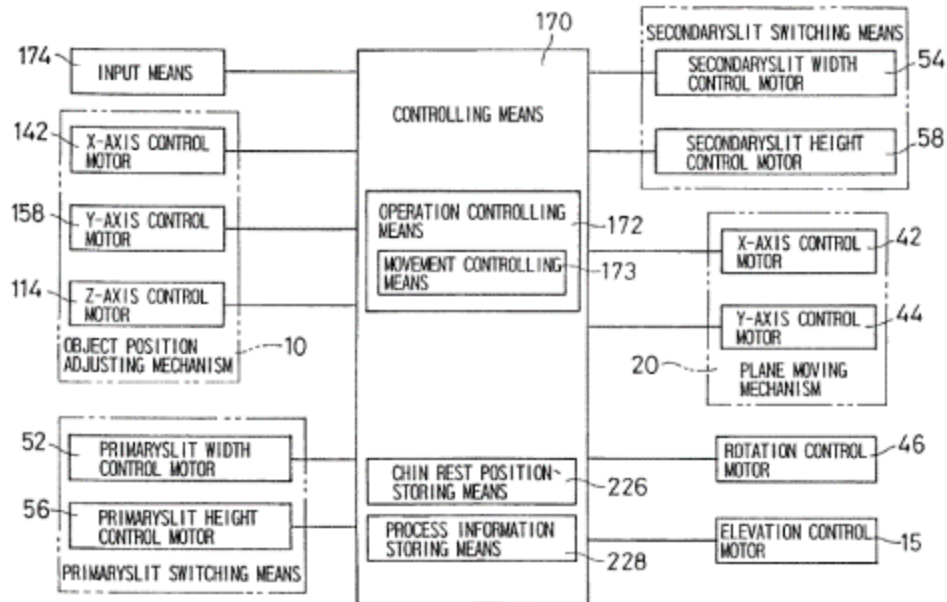


The target is positioned between the source and the sensor. *Id.* at 10:41-44; Fig. 2. The “primary slit means 30” restricts the width and height of X-rays emitted from the source. *Id.* at 10:44-47; Fig. 2.



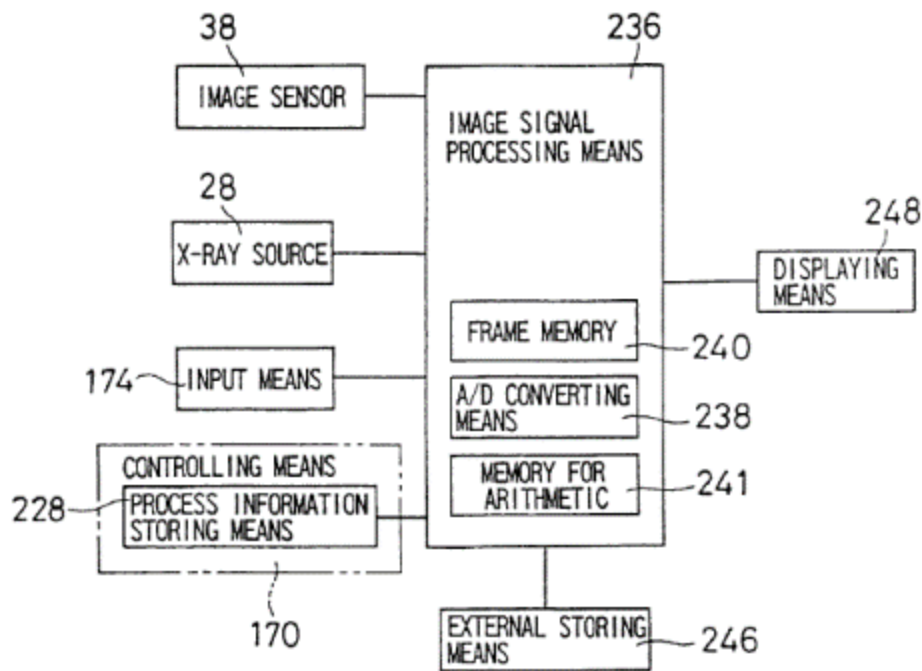
“Controlling means 170” operates motors to move the X-ray equipment in response to pre-programmed scanned paths. See Fig. 7. Arai discloses “x-axis control motor 42,” “y-axis control motor 44,” and “rotation control motor 46.” *Id.* at 15:62-16:1; Ex. 1007 (Sonka) at ¶¶175-77. “The process information 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).

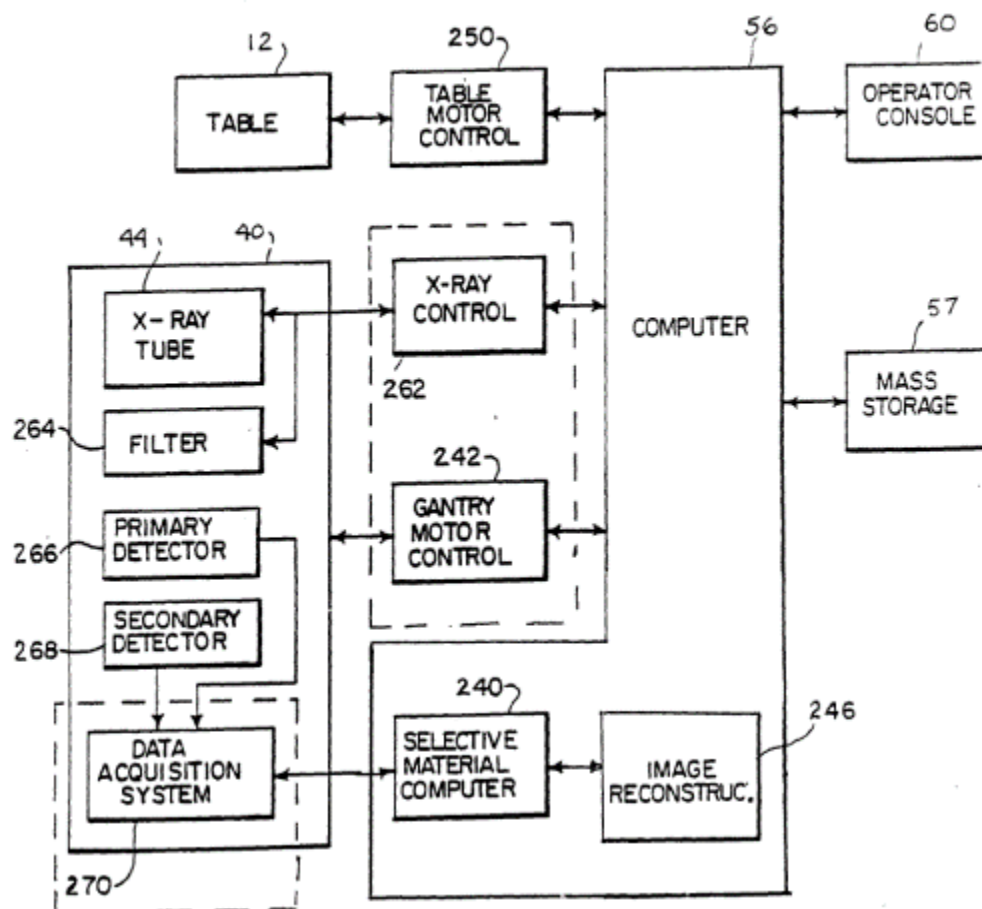
Cann discloses that, as of the 1980s, “[q]uantitative bone mass measurements [were] widely used in the assessment of skeletal status in metabolic bone disease,” including “X-ray computed tomography (CT).” *Id.* at 493. “The usefulness of CT for measuring bone mineral in the vertebrae lies in its ability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

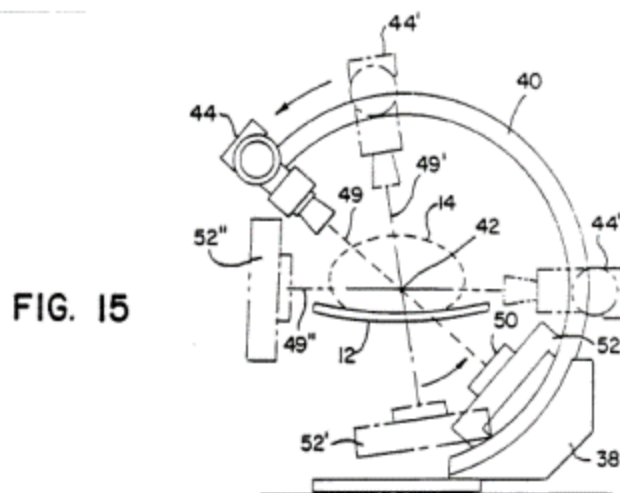


Pelc's system includes an X-ray source, an X-ray detector, and a beam-restricting device. *Id.* at 5:22-6:7; 14:24-31; Ex. 1007 (Sonka) ¶¶187-90. The source and detector are "affixed to the ends of the C-arm to provide energy attenuation measurements along an axis between those ends at the plurality 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.

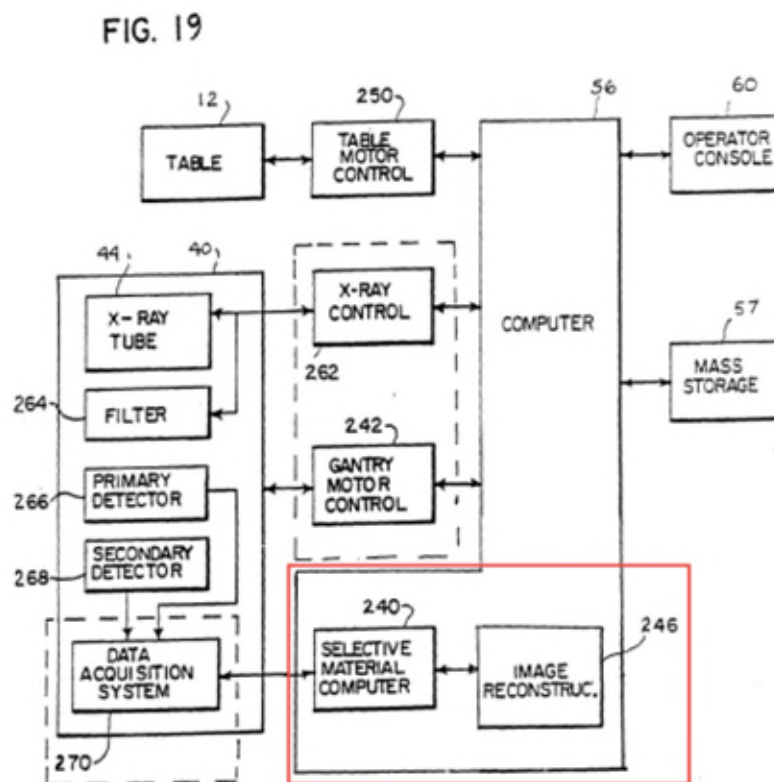
These positioning motors generate the movement required to obtain data for generating the tomographic model. Ex. 1007 (Sonka) ¶¶191-97; Ex. 1015 at 7:9-12. Pelc teaches the X-ray equipment simultaneously rotates and moves longitudinally along that axis of rotation via rails. *Id.* at 13:34-14:2; *see 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 is referring to digital tomographic models. Ex. 1007 (Sonka) ¶¶198-202.

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 (Field of the Invention). 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.

C. Ground 2: Arai Renders Obvious the Challenged Claims.

Arai renders each of challenged claims 1, 2, 4 and 6 obvious in view of Xu and/or Milestone and alternatively further in view of Cann.

1. Independent Claim 1

a. Preamble

Claim 1’s preamble recites “A digital modeling system for creating dental or orthopedic models of patients.” This preamble should not be construed to limit the claimed invention. *See supra* § X.A.1.a.

To the extent it is limiting, Arai discloses a system for creating a dental model of a patient. *Id.* 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; Figures. 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 (“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....”); Ex. 1007(Sonka) ¶¶559-60.

Arai discloses that these tomographic images are of dental structures. *See* Ex. 1013 at 23:8-11; Fig. 18; Ex. 1007(Sonka) ¶560.

To the extent the preamble requires quantitative modeling, Arai’s CT system is quantitative because, as previously described, CT scanners provide information regarding bone density. Ex. 1007(Sonka) ¶561; *see also* Ex. 1001 at 2:15-21(referencing CT system of Pelc ‘080 as disclosing densitometry procedures); ‘672 IPR at Paper 10 at 33-34 (relying Arai’s disclosure of an X-ray imaging apparatus, alone or in combination).

Alternatively, the preamble would be obvious over Arai in view of Cann. In the Delaware litigation, Osseo has argued that CT imaging does not satisfy the

quantitative aspect of the Court’s construction. That is incorrect as discussed above. See §V. Nevertheless, as an alternative ground, it would be obvious to combine Arai and Cann. Cann teaches the use of CT for measuring bone mineral content through quantitative CT imaging. Ex. 1014 at 493-95; Ex. 1007 (Sonka) ¶¶181-185, 562-63. Because both Arai and Cann involve CT imaging systems, it would have been obvious to a skilled artisan to use the quantitative CT system taught in Arai for the densitometry measurements disclosed in Cann. Ex. 1007 (Sonka) ¶563. A POSA would have been motivated to do so in order 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 1:3436. A POSA would understand that density of the relevant portion of jawbone would likewise be helpful to know pre-implantation to further assess the integrity of the bone to ensure that it can successfully support the implant. Ex. 1007 (Sonka) ¶563. He or she would thus be motivated to use the system of Arai for that purpose in light of Cann. *Id.* Adding a quantitative densitometrical function as described in Cann (*e.g.*, using a phantom containing bone equivalent matter to enable scan 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.*

Nothing in the description of the system taught in Arai suggests that it could not be used for densitometry purposes. Rather, 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 phantom quantitative process taught by Cann in combination with Arai given the minimal modifications required 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.*

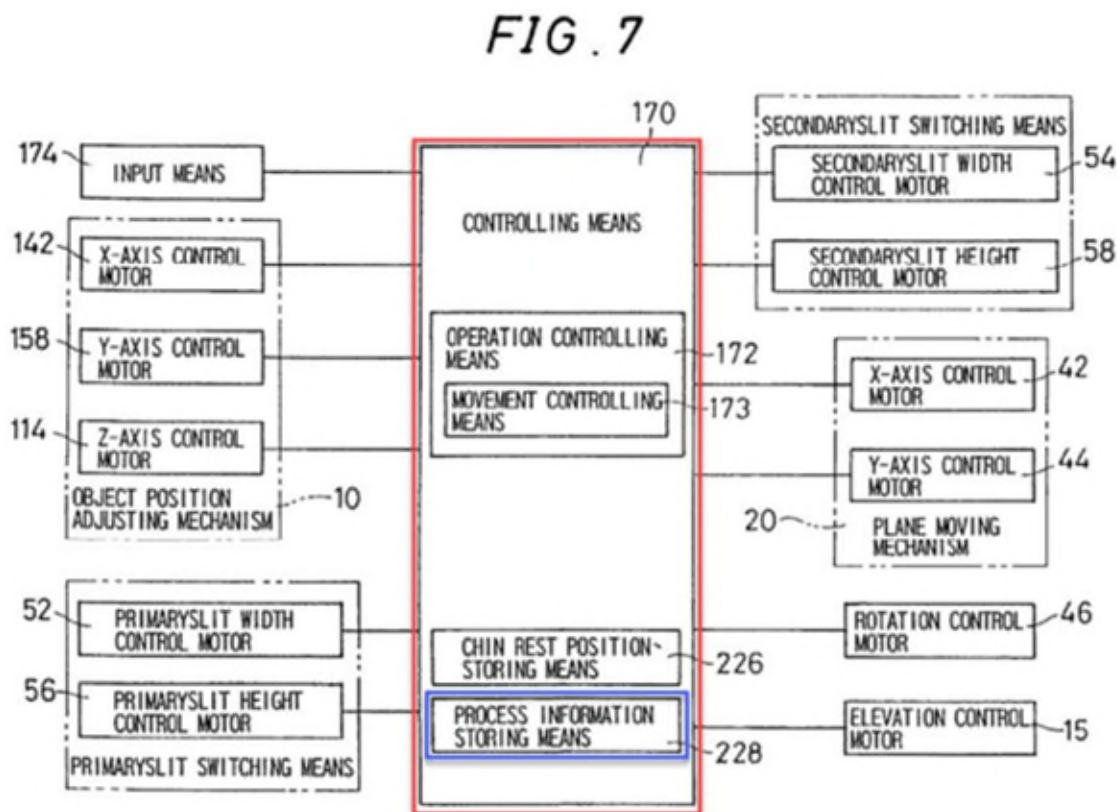
b. Computer having memory, and an input and an output

Claim 1 further recites “a computer including a digital memory storing patient densitometry information, an input and an output.” The ‘262 patent discloses that the system may employ “various programmable logic devices (PLDs) and special-purpose microprocessors” as well as “general purpose, commercially available personal computers.” Ex. 1003 at 4:27-34.

1) Computer

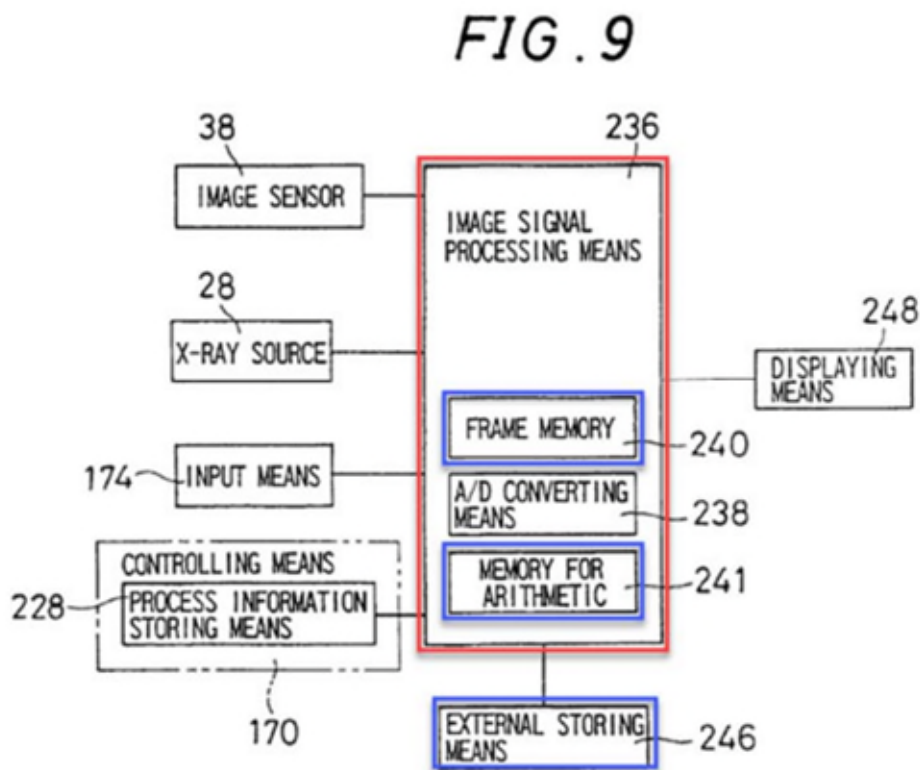
Arai discloses this limitation. It includes a computer comprising “controlling means” and “image signal processing means.” The controlling means “may be configured by...a microprocessor.” Ex. 1013 at 14:48-54; *see also id.* at

15:62-16:6. Figure 7 depicts “controlling means” (outlined in red) having a memory device, *i.e.*, “process information storing means” (outlined in blue). *Id.* At 16:6-10; 16:41-44. Moreover, a POSA would recognize that a microprocessor with the functions described in Arai would necessarily have memory. Ex. 1007 (Sonka) ¶¶564-65.



Arai’s “image signal processing means” controls the processing of the image signals detected by “image sensor.” Ex. 1013 at 17:29-38. Arai teaches that “image signal processing means 236 may be configured by, for example, a microprocessor for image processing.” *Id.* at 17:32-34. And as shown in Fig. 9, “image signal processing means” (outlined in red) has memory devices in the

forms of “frame image,” “image memory for arithmetic,” and “external storing means” for storing tomographic images (all outlined in blue). *Id.* at 17:29-48; 18:11-12; Ex. 1007 (Sonka) ¶566.



2) Memory

As discussed above, Arai’s computer has a digital memory. The element reciting “storing patient densitometry information” is a statement of intended use that bears no patentable weight. *See supra* § X.A.1.b. To the extent it is limiting, Arai’s “image signal processing means” stores patient densitometry information in the course of use of the Arai system. For example, CT models of a dental structure are stored in the “memory for arithmetic” component of the “image signal

processing means,” and patient densitometry information also would be stored in Arai’s “external storing means.” Ex. 1013 at 17:42-44 (“Plural sets of image information stored in the frame memory 240 are stored in the image memory for arithmetic 241.”); *see also id.* at 18:11-15; X.C.1.a. (describing quantitative CT as disclosed in Arai and Arai in view Cann); Ex. 1007 (Sonka) ¶¶567-69.

3) Input

The specification of the ‘262 patent describes “input device” broadly to include one or more input devices, “such as a keyboard, a pointing device (*e.g.*, a mouse), a communications link, or another computer.” Ex. 1003 at 4:38-41. 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; Fig. 7-9; Ex. 1007 (Sonka) ¶570.

4) Output

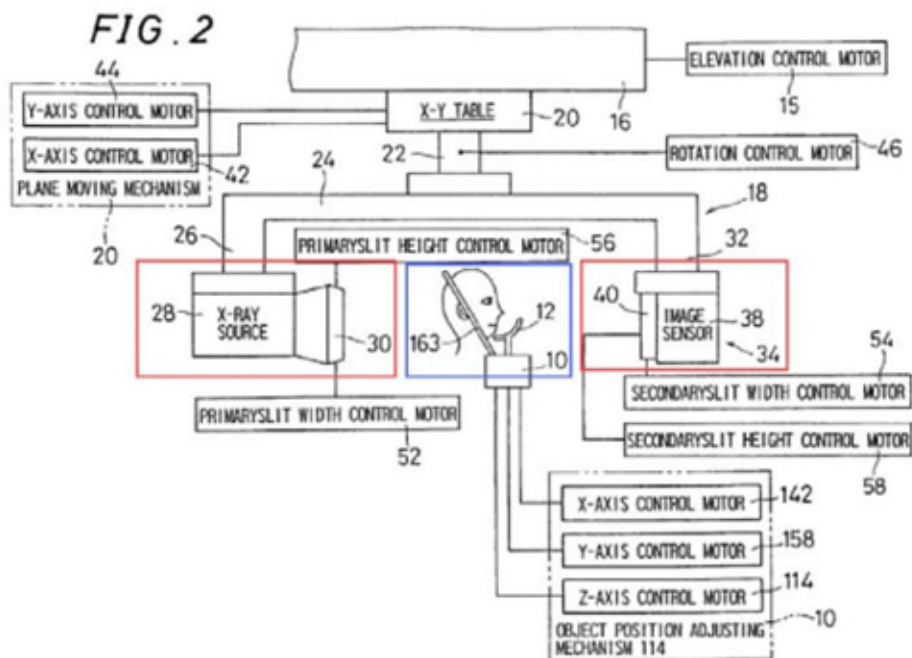
The ‘262 patent describes “output device” broadly, including “a monitor, a display, a printer, a communications link, and/or another computer.” Ex. 1003 at 5:3-5. Arai teaches two output devices adapted for receiving a tomographic model from the “image signal processing means”: “external storing means 246” and “displaying means 248.” Ex. 1013 at 18:3-8; 18:11-15; Ex. 1007 (Sonka) ¶571; *see also* ‘672 IPR at Paper 10 at 34 (relying on Arai’s disclosure of input means, an

operation panel, display means, external storing means, and X-ray source and image sense, alone or in combination).

c. Energy source and energy sensor

Claim 1 recites “a dental or orthopedic input device including an energy source and an energy sensor; said source and said sensor being placed with at least a portion of the patient’s dental or orthopedic structure therebetween.”

Arai discloses this limitation. The system in Arai includes an “X-ray source” and “image sensor.” Ex. 1013 at 2:15-18; Fig. 2. A POSA would understand “image sensor” to be an energy sensor. Ex. 1007 (Sonka) ¶572; *see also* ‘672 IPR at Paper 10 at 19-20 (relying on Arai’s disclosure of input means, an operation panel, display means, external storing means, and X-ray source and image sensor, alone or in combination). Further, as Figure 2 illustrates, Arai teaches that the patient’s dental or orthopedic structure (outlined in blue) is placed between its energy source and energy sensor (outlined in red).



d. Sensor transferring signals

Claim 1 further recites “said sensor transferring signals to the computer input.” Arai’s system includes “image sensor 38,” which receives the X-rays after passing through the target tissue. This “image sensor 38” then transfers these signals to the “imaging signal processing means 236,” which can be configured by a microprocessor. Ex. 1013 at 17:30-34; Ex. 1007 (Sonka) ¶573; *see also* ‘672 IPR at Paper 10 at 19-20 (relying on Arai’s disclosure of input means, an operation panel, display means, external storing means, and X-ray source and image sensor, alone or in combination).

e. Signals representing densitometry

Claim 1 further recites “said signals representing densitometry of the patient’s dental or orthopedic structure.” The signals that pass from “image sensor

38” to “image signal processing means 236” represent densitometry of the patient’s dental or orthopedic structure because X-ray attenuation is dependent on density, among other things. *See supra* § V.B; *see also* X.C.1.a. (describing quantitative CT as disclosed in Arai and Arai in view Cann); Ex. 1007 (Sonka) ¶¶574-75. The sensor provides a signal to the “image signal processing means 236,” where the analog-to-digital converter converts it into a digital signal. Ex. 1013 at 17:3042. This information is stored in “frame memory 240.” *See id.* The “memory for arithmetic 241” then takes the plural sets of image information stored in “frame memory 240” and uses a predetermined algorithm to generate a tomographic model of the dental structure. *Id.* at 17:42-48.

f. Creating, storing and comparing 3D models without fiducial markers

Claim 1 recites “said computer creating, storing and comparing three-dimensional digital densitometry models without the use of fiducial markers of patient dental or orthopedic structure.”

1) Creating

Arai, or Arai in view of Cann, discloses the creation of densitometry models by the system’s computer. *See supra* §§ X.B.1, X.C.1.a; *see* Ex. 1013 at 2:3-5, 17:42-48.

2) Storing

Likewise, Arai discloses the storing of densitometry models. *See supra* § X.C.1.b.2; *see* Ex. 1013 at 17:42-44, 18:11-15.

3) Comparing

This limitation is obvious over Arai in view of Xu and/or Milestone. The ‘262 patent admits that means for comparing tomographic models were known in the prior art. Ex. 1003 at 2:23-25. Moreover, Osseo admitted, as of December 1, 1999, “one of skill in the art would know how to compare two sets of data in a computer,” and that there existed commercially-available software that could be purchased that was capable of producing a comparison as claimed. Ex. 1012 (SJ Hearing Transcript) at 17:23-18:21.

A POSA would understand that, as of or before December 1, 1999, comparisons of medical images, including CT images, are routinely performed for purposes of diagnosis and tracking treatment. 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. Ex. 1003 at 2:23-25; Ex. 1007 (Sonka) at ¶¶579-81.

As of the priority date of the ‘262 patent, it was well-known to a POSA that a microprocessor could be programmed with software to perform these comparisons. Xu teaches a method and system that uses a computer to detect changes in three-dimensional medical scans by using temporal subtraction. Ex.

1019 at 2:19-32; 16:43-18:52 (reciting various claims covering computer algorithms to perform comparisons). The method involves obtaining the first and second scans of interest, matching the images, non-linearly warping the first image, and subtracting the first warped image from the second image. *Id.* at 2:36-44. Milestone teaches the use of software to compare volumetric or three-dimensional renderings 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” baseline structure. *Id.*; *see also id.* at 10:26-11:12; 13:17-22.

A POSA would have been motivated to program the microprocessor in Arai to perform comparisons between a patient’s models or between a patient’s current model and a baseline normal model, as stored in Arai’s system memory, 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) ¶¶210-21, 579-81.

4) 3D Models

Arai discloses the use of cone beam scanning technology. *E.g.*, Ex. 1017 at 8:7-9. Use of a cone beam CT system as disclosed creates a three-dimensional dataset. Ex. 1007 (Sonka) ¶¶79-81, 582-83.

Alternatively, creating, storing and comparing 3D models is obvious. Osseo admitted that “one of ordinary skill in the art would know, at the time of the invention, how to take datasets and make 3D models out of them. It was known. We’re not professing that that’s the invention. It was known at the time, fairly well known by those of ordinary skill in the art how to make 3D models out of image datasets.” Ex. 1012 (SJ Hearing Transcript) at 21:21-22:4. A POSA would have been motivated to modify Arai’s system to provide such 3D models as of the priority date, as that was a common use of CT imaging and well within the skill of the art (as Osseo admitted). A POSA would be motivated to use Arai to create, store and compare 3D models because that was the expected use of such systems, and would have had a reasonable expectation of success in doing so. Ex. 1007 (Sonka) ¶¶79-81, 582-83; *see also* Ex. 1012 (SJ Hearing Transcript) at 17:2318:21, 21:21-22:4.

5) Without use of fiducial markers

With respect to the fiducial marker negative limitation, the CT system in Arai does not use “fiducial markers.” Ex. 1007 (Sonka) ¶¶584-85. Just as the ‘262 patent specification does not discuss use of a “fiducial marker,” the system of Arai does not discuss or require use of a “fiducial marker.” *Id.* While fiducial markers can help to align individual slices in a 3D tomographic model to improve the accuracy of the resulting model, a POSA would recognize that they are not

necessary for the creation, storage, or comparison of tomographic models with the system disclosed in Arai. *Id.*

A later issued Arai patent on a similar CT scanning apparatus, U.S. Patent No. 6,243,439, explicitly discloses the use of a “position marker” or “fiducial marker” to improve accuracy of the CT measurements. *Id.*; Ex. 1027 (“Arai 439”) at 2:5-10, 2:29-32 (“From the position of the image of the position marker in the obtained two-dimensional X-ray image, it is possible to calculate error data regarding the image pickup system in each X-ray image.”). A POSA would understand that, in the absence of any disclosures teaching the use of a fiducial marker, the Arai CT imaging system can create, store and compare tomographic models without use of a fiducial marker. Ex. 1007 (Sonka) at ¶¶584-85; *see also* ‘672 IPR at Paper 10 at 35-36 (relying on Arai’s disclosure of creating and storing three-dimensional digital densitometry models, alone or in combination).

Alternatively, it would be obvious to use the system disclosed in Arai to create, store and compare densitometric models without fiducial markers. While fiducial markers can help to align individual slices in a 3D tomographic model to improve the accuracy of the resulting model, a POSA would recognize that they are not necessary for the creation, storage, or comparison of tomographic models with the system disclosed in Arai. *Id.* A POSA would be motivated not to use fiducial markers to reduce the complexity and cost associated with the scan in

using such markers, and a POSA would have had a reasonable expectation of success in implementing such a system. *Id.*

g. Output device, imaging software and display.

Claim 1 further requires “an output device connected to said computer output and communicating densitometry model comparison information; imaging software associated with said computer; and a display associated with said output device and displaying information pertaining to said densitometry model.”

Arai teaches that data from “image sensor 38” is supplied to the “image signal processing means 236.” Ex. 1013 at 17:29-42. That information is used to mathematically generate a tomographic model. *Id.* at 17:42-61. “The signal of the tomographic image...generated by the image signal processing means 236 is supplied to displaying means 248...for example, a display device, and the tomographic image signal is displayed...as tomographic image information.” *Id.* at 18:3-9. A POSA would understand the generation of tomographic images in Arai to include software. Ex. 1007 (Sonka) at ¶588-89; *see also* ‘672 IPR at Paper 10 at 36 (relying on Arai’s disclosure of display means that displays tomographic models, alone or in combination).

The claim element that the information communicated is “densitometry model comparison information” is a non-limiting statement of intended use in the context of a system claim. *See supra* § X.A.1.g. To the extent it is a limitation, it

would be obvious to communicate such comparison information with the Arai system. As discussed above, *see supra* § X.C.1.f.3, performing comparisons between two or more models is commonplace in medicine for purposes of diagnosis or monitoring treatment, among others. Ex. 1007 (Sonka) ¶¶95-97. For such information to be useful to a physician, it needs to be transmitted to them. The system of Arai is described as including a monitor and displaying tomographic information for medical use. Ex. 1013 at 18:3-9. A POSA would find it obvious to use Arai’s system, programmed with comparison software as described above, to display comparison model information developed by that system for medical purposes. Ex. 1007 (Sonka) ¶¶586-87. A POSA would reasonably expect to be able to successfully display the comparison model with the Arai system in the same manner as displaying a present patient model.

2. Dependent Claim 2

Claim 2 recites “said source is external.” Arai discloses an external source. *See, e.g.*, Ex. 1013 at Figs. 1, 2, 26; Ex. 1007 (Sonka) ¶¶591-92; *see also* ‘672 IPR at Paper 10 at 37-38.

3. Dependent Claim 4

Claim 4 recites “said sensor is external.” Arai discloses an external sensor. *See, e.g.*, Ex. 1013 at Figs. 1, 2, 26; Ex. 1007 (Sonka) ¶¶594-95; *see also* ‘672 IPR at Paper 10 at 37-38.

4. Dependent Claim 6

Claim 6 recites “said energy being collimated.” Arai discloses a collimated X-ray energy source: “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; *see also* ‘672 IPR at Paper 10 at 38. 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) ¶¶596-99; Ex. 1025 (21 C.F.R. § 1020.31, April 1998) at 566.

D. Ground 3: Pelc Renders Obvious the Challenged Claims.

Pelc renders each of challenged claims 1, 2, 4 and 6 obvious in combination with Xu and/or Milestone, and alternatively in further combination with Cann. This is true whether the priority date is January 24, 2003, or December 1, 1999.

1. Independent Claim 1

a. Preamble

The preamble should not be construed to limit the claimed invention. *See supra* § X.A.1.a.

To the extent it is limiting, Pelc discloses a system for creating an orthopedic model of a patient. Ex. 1007 (Sonka) ¶¶601-04. Pelc, a “tomographic bone scanning system,” discloses “[a]n X-ray imaging system” that “provides both

scanning radiography and computed tomography....” Ex. 1015, Title, Abstract; *see also id.* 1:13-17.

To the extent quantitative modeling is required, Pelc teaches quantitative densitometric modeling; Pelc refers to “tomographic scanning of a patient for evaluation of bone density and bone morphology.” *Id.* at 1:13-17. Pelc’s CT system, like all digital CT systems, is quantitative for the reasons discussed above. *See supra* § V.B; Ex. 1007 (Sonka) ¶603; *see also* ‘672 IPR at Paper 10 at 40-41 (relying on Pelc’s disclosure of an X-ray imaging system, alone or in combination).

Alternatively, to the extent CT imaging is found to not be quantitative, it would have been obvious to the POSA to combine Pelc with Cann, which teaches quantitative densitometry. Ex. 1007 (Sonka) ¶604. A POSA would have been motivated to use the calibration phantom and process disclosed Cann in order to obtain a more accurate model of densitometry of the tissue of interest. *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 1:13-17. 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) ¶604. For the same reasons, incorporation of the quantitative CT system taught by Cann would not impact any of the combinations discussed below. *Id.*

b. Computer having memory, and an input and an output

1) Computer

Pelc discloses an “electronic computer” that “controls the C-arm, the radiation source, and the detector,” Ex. 1015 at 5:31-32; *see also* Fig. 1, 9:34-10:2 (“a controlling computer”); 16:18-22 (computer controls radiation source and collects attenuation data); 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 necessarily to include memory. Ex. 1007 (Sonka) ¶605; *see also* ‘672 IPR at Paper 10 at 41 (relying on Pelc’s disclosure of an electronic computer with memory for storing image data, keyboard, and CRT display, alone or in combination).

2) Memory

The computer taught by Pelc has a memory. Ex. 1015 at 5:31-35 (computer “store[s] the attenuation measurements” from a plurality of angles.) Pelc further refers to “[a] mass storage device” connected to the computer that “provides a means for storing...image data for future reference by the user.” *Id.* at 36:1-3. The element reciting “storing patient densitometry information” is a statement of

intended use that bears no patentable weight. *See supra* § X.A.1.b. To the extent it is a limitation, the POSA would understand that “attenuation measurements” and “image data” discussed in Pelc include patient densitometry information because CT by nature is quantitative, and Pelc specifically teaches densitometry. *See also* X.D.1.a (describing quantitative CT as disclosed in Pelc and Pelc in view Cann); Ex. 1007 (Sonka) ¶¶606-608.

3) Input

Pelc teaches an input device connected to the computer. *Id.* at ¶609. Pelc refers to “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 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* Fig. 1; Fig. 19.

4) Output

Pelc’s system 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; Ex. 1007 (Sonka) ¶609.

c. Energy source and energy sensor

Pelc discloses “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 id.* at 16:23-36. The target tissue to be measured is placed in between the source and detector. *Id.* at Figs. 1, 6, 18. Ex. 1007 (Sonka) ¶610; *see also* ‘672 IPR at Paper 10 at 41 (relying on Pelc’s disclosure of an electronic computer with memory for storing image data and a radiation source and detector affixed to a C-arm, alone or in combination).

d. Sensor transferring signals

Claim 1 further recites “said sensor transferring signals to the computer input.” Pelc discloses this limitation: “A radiation source and a detector...provide energy attenuation measurements...such measurements being received by an electronic computer.” Ex. 1015 at 5:27-31; *see also id.* at 35:3-8 (“After passing through the patient 14, the radiation is received by detector array 50 comprised of a number of detector elements 47 which together receive and detect radiation...to produce separate signals...for each detector element and for each energy of radiation.”); Ex. 1007 (Sonka) ¶611; *see also* ‘672 IPR at Paper 10 at 41 (relying on Pelc’s disclosure of an electronic computer with memory for storing image data and a radiation source and detector, alone or in combination).

e. Signals representing densitometry

Claim 1 further recites “said signals representing densitometry of the patient’s dental or orthopedic structure.” Because X-ray attenuation is dependent on density, among other things, these signals represent densitometry of the patient’s orthopedic structure. *See supra* § V.B; *see also* § X.D.1.a (describing quantitative CT as disclosed in Pelc and Pelc in view Cann); Ex. 1007 (Sonka) ¶¶612-13; *see also* ‘672 IPR at Paper 10 at 41 (relying on Pelc’s disclosure of an electronic computer with memory for storing image data and a radiation source and detector, alone or in combination).

f. Creating, storing and comparing 3D models without fiducial markers

Claim 1 recites “said computer creating, storing and comparing three-dimensional digital densitometry models without the use of fiducial markers of patient dental or orthopedic structure.” Ex. 1007 (Sonka) ¶¶614-24.

1) Creating

Pelc, or Pelc in view of Cann, discloses the creation of densitometry models by the system’s computer. *See supra* §§ X.B.3, X.D.1.a; *see* Ex. 1015 at 5:22-6:1.

2) Storing

Likewise, Pelc discloses the storing of densitometry models. *See supra* § X.D.1.b.2; *see* Ex. 1015 at 36:1-3.

3) Comparing

This limitation is obvious over Pelc in view of Xu and/or Milestone. The ‘262 patent admits that means for comparing tomographic models were known in the prior art. Ex. 1003 at 2:23-25. Moreover, Osseo admitted, as of December 1, 1999, “one of skill in the art would know how to compare two sets of data in a computer,” and that there existed commercially-available software that could be purchased that was capable of producing a comparison as claimed. Ex. 1012 (SJ Hearing Transcript) at 17:23-18:21.

A POSA would understand that, as of or before December 1, 1999, comparisons of medical images, including CT images, are routinely performed for purposes of diagnosis and tracking treatment. 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. Ex. 1003 at 2:23-25; Ex. 1007 (Sonka) at ¶617; *see also* ‘672 IPR at Paper 10 at 42 (relying on Pelc’s disclosure of an electronic computer with memory for storing image data and a radiation source and detector, alone or in combination).

As of the priority date of the ‘262 patent, it was well-known to a POSA that a microprocessor could be programmed with software to perform these comparisons. Xu teaches a method and system that uses a computer to detect changes in three-dimensional medical scans by using temporal subtraction. Ex. 1019 at 2:19-32; 16:43-18:52 (reciting various claims covering computer

algorithms to perform comparisons). The method involves obtaining the first and second scans of interest, matching the images, non-linearly warping the first image, and subtracting the first warped image from the second image. *Id.* at 2:36-44. Milestone 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” baseline structure. *Id.*; *see also id.* at 10:26-11:12; 13:17-22. Ex. 1007(Sonka) at ¶¶619.

A POSA would have been motivated to program Pelc’s computer to perform comparisons between a patient’s models or between a patient’s current model and a baseline normal model 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) ¶¶618.

4) 3D Models

Pelc teaches creating a model having at least two focal planes, *i.e.*, a 3D model. Pelc teaches generating a model having at least two focal planes, and accordingly is a 3D model as required by claims 3 and 9. Pelc describes acquiring images from multiple angles as the X-ray equipment moves axially with respect to the patient and using that information to create a tomographic model. *E.g.*, Ex.

1015 at 5:22-6:1. Pelc further teaches acquiring “images obtained at any two gantry angles having sufficient separation to provide the necessary third dimensions of information.” Ex. 1015 at 25:35-26:1. Ex. 1007(Sonka) ¶620; *see also* ‘672 IPR at Paper 10 at 42 (relying on Pelc’s disclosure of an electronic computer with memory for storing image data and a radiation source and detector, alone or in combination).

Alternatively, creating, storing and comparing 3D models is obvious. Osseo admitted that “one of ordinary skill in the art would know, at the time of the invention, how to take datasets and make 3D models out of them. It was known. We’re not professing that that’s the invention.” Ex. 1012 (SJ Hearing Transcript) at 21:21-22:4. A POSA would have been motivated to modify Pelc’s system to provide such 3D models as of the priority date, as that was a common use of CT imaging and well within the skill of the art (as Osseo admitted). A POSA would be motivated to use Pelc to create, store and compare 3D models because that was the expected use of such systems, and would have had a reasonable expectation of success in doing so. Ex. 1007 (Sonka) ¶¶621-22; *see also* Ex. 1012 (SJ Hearing Transcript) at 17:23-18:21, 21:21-22:4.

5) Without use of fiducial markers

With respect to the fiducial marker negative limitation, the CT system in Pelc does not use “fiducial markers.” Ex. 1007 (Sonka) ¶¶623-24. Just as the ‘262

patent specification does not discuss use of a “fiducial marker,” the system of Pelc does not discuss or require use of a “fiducial marker.” *Id.*

Alternatively, it would be obvious to use the system disclosed in Pelc to create, store and compare densitometric models without fiducial markers. While fiducial markers can help to align individual slices in a 3D tomographic model to improve the accuracy of the resulting model, a POSA would recognize that they are not necessary for the creation, storage, or comparison of tomographic models with the system disclosed in Pelc. *Id.* A POSA would be motivated not to use fiducial markers to reduce the complexity and cost associated with the scan in using such markers, and a POSA would have had a reasonable expectation of success in implementing such a system. *Id.*

g. Output device, imaging software and display

Claim 1 further recites “imaging software associated with said computer; and a display associated with said output device and displaying information pertaining to said densitometry model.”

Pelc’s system 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) ¶¶625-28; *see also* ‘672

IPR at Paper 10 at 42 (relying on Pelc’s disclosure of an electronic computer with memory for storing image data and a radiation source and detector, alone or in combination).

The claim element that the information communicated is “densitometry model comparison information” is a non-limiting statement of intended use in the context of a system claim. *See supra* § X.A.1.g. To the extent it is a limitation, it would be obvious to communicate such comparison information with the Pelc system. As discussed above, *see supra* § X.D.1.f.3, performing comparisons between two or more models is commonplace in medicine for purposes of diagnosis or monitoring treatment, among others. For such information to be of use to a physician, it needs to be transmitted to them. Pelc’s system is designed to assist evaluation of patient bone density and morphology. Ex. 1015 at 1:13-17. A POSA would find it obvious to use Pelc’s system, programmed with comparison software as described above, to display comparison model information developed by that system for medical purposes. Ex. 1007 (Sonka) ¶¶625-28. A POSA would reasonably expect to be able to successfully display the comparison model with the Pelc system in the same manner as displaying a present patient model.

2. Dependent Claim 2

Claim 2 recites “said source is external.” Pelc discloses an external source. *See, e.g.*, Ex. 1015 at Figs. 1, 6, 15, and 18; Ex. 1007 (Sonka) ¶¶630-31; *see also* ‘672 IPR at Paper 10 at 43-44.

3. Dependent Claim 4

Claim 4 recites “said sensor is external.” Pelc discloses an external sensor. *See, e.g.*, Ex. 1015 at Figs. 1, 6, 15, and 18; Ex. 1007 (Sonka) ¶¶633-34; *see also* ‘672 IPR at Paper 10 at 43-44.

4. Dependent Claim 6

Claim 6 recites “said energy being collimated.” Pelc discloses the radiation source “includes an x-ray tube together with filter and collimator...” Ex. 1015 at 14:24-25; *see also id.* at 22:10-11; ‘672 IPR at Paper 10 at 43-44. Moreover, the FDA required all X-ray imaging devices to use restricted beams well before the priority date. Ex. 1007 (Sonka) ¶¶636-37; Ex. 1025 (21 C.F.R. § 1020.31, April 1998) at 566.

XI. CONCLUSION

Petitioner has established a reasonable likelihood that the challenged claims of the ‘262 patent will be found unpatentable. Therefore, *inter partes* review of the ‘262 patent be granted, and that Claims 1, 2, 4 and 6 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. 6,944,262 on March 26, 2025 upon the following:

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