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. 8,498,374
Case: IPR2025-00787

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,498,374

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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, *Osseo Imaging, LLC v. Planmeca USA Inc.*, 1-17-cv-01386 (D. Del. 2017).
Ex. 1010	Markman Memorandum, Dkt. 44, *Osseo Imaging, LLC v. Planmeca USA Inc.*, 1-17-cv-01386 (D. Del. 2017).
Ex. 1011	Markman Transcript, Dkt. 41, *Osseo Imaging, LLC v. Planmeca USA Inc.*, 1-17-cv-01386 (D. Del. 2017).
Ex. 1012	Summary Judgement Hearing Transcript, Dkt. 143, *Osseo Imaging, LLC v. Planmeca USA Inc.*, 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," *Journal of Computer Assisted Tomographs* 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").
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, THE ESSENTIAL PHYSICS OF MEDICAL IMAGING (Williams & Wilkins 1994) ("Bushberg").
Ex. 1022	Genant *et al.*, "Bone Densitometry: Current Assessment," *Osteoporosis International* S:91–97 (1993) ("Genant 1993").
Ex. 1023	Genant *et al.*, "Current State of Bone Densitometry for Osteoporosis," *Radiographics* 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), *available at* https://www.nobelprize.org/uploads/2018/06/hounsfield-lecture.pdf.
Ex. 1029	Grant, "TOMOSYNTHESIS: A Three-Dimensional Radiographic Imaging Technique," *IEEE Transactions on Biomedical Engineering*, BME-19(1):20–28 (Jan. 1972) ("Grant").
Ex. 1030	U.S. Patent No. 6,073,044 ("Fitzpatrick").
Ex. 1031	Hosie *et al.*, "A Gamma Ray Computed Tomography Scanner for the Quantitative Measurement of Bone Density," *Journal of Biomedical Engineering* 7:30–34 (Jan. 1985) ("Hosie").
Ex. 1032	World Health Organization, "Assessment of Fracture Risk and Its Application to Screening for Postmenopausal Osteoporosis," WHO Technical Report Series 843 (1994) ("WHO 1994").
Ex. 1033	Venkatesh *et al.*, "Cone Beam Computed Tomography: Basics and Applications in Dentistry," *Journal of Istanbul University Faculty of Dentistry*, 51(3 Suppl 1): S102-121 (December 2017) ("Venkatesh").
Ex. 1034	Summary Judgment Answering Brief in Opposition, Dkt. 131, *Osseo Imaging, LLC v. Planmeca USA Inc.*, 1-17-cv-01386 (D. Del. 2017).

Ex. 1035	Mozzo *et al.*, "A new volumetric CT machine for dental imaging based on the cone-beam technique: preliminary results," *Eur. Radiol.*, 8: 1558-64 (1998) ("Mozzo").
Ex. 1036	Noo *et al.*, "Stable and Efficient Shift-Variant Algorithm for Circle-Plus-Lines Orbits in Cone-Beam C.T.," *Institute of Electrical and Electronics Engineers,* Conference Date: Sept. 19, 1996 ("Noo").
Ex. 1037	Lindh *et al.*, "Quantitative computed tomography of trabecular bone in the mandible," *Dentomaxillofacial Radiology*, 25:146–150 (1996) ("Lindh").
Ex. 1038	Sonka, M., & Fitzpatrick, J. M. (Eds.). (2000). *Handbook of Medical Imaging, Volume 2: Medical Image Processing and Analysis.* SPIE Press. ("SPIE")

I. INTRODUCTION

Dentsply Sirona Inc. ("Dentsply" or "Petitioner") respectfully requests *inter partes* review ("IPR") of Claims 1–24 of U.S. Patent No. 8,498,374 ("the '374 patent"), Exhibit ("Ex. 1001"), 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 there was a reasonable likelihood that the claims were unpatentable. *See* IPR2020-00659. In that proceeding, the Board's Institution Decision determined that:

> ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–24 of the '374 patent on all grounds presented in the Petition, namely:
>
> (1) Claims 1, 3, 4, 7, and 9 under 35 U.S.C. § 102(e) as unpatentable over Arai;
>
> (2) Claims 1–24 under 35 U.S.C. § 103 as unpatentable over Arai alone, in combination with Cann, and/or in combination with Xu, Milestone, Pelc '080, or knowledge of one of ordinary skill in the art ;
>
> (3) Claims 1–4 and 7–10 under 35 U.S.C. § 102(e) as unpatentable over Pelc; and
>
> (4) Claims 1–24 under 35 U.S.C. § 103 as unpatentable over Pelc alone, in combination with Rothman, Cann, and/or in combination with Xu, Milestone, and in view of the knowledge of one of ordinary skill in the art;

IPR2020-00659, Paper No. 10 at 56. Petitioner here relies on the same prior art and substantially the same grounds that the Board previously agreed warranted institution, and thus the Board should likewise institute the instant IPR proceeding.[1]

The patent concedes it uses known technology to apply known methods to create a claimed system for tomographic imaging. Ex. 1001 at 5:34-8:21. It touts as an advantage that the purported invention "utilizes commercially available tomography equipment." *Id.* at 3:20-22. Yet, it admits that tomographical medical imaging was known: "Tomography or sectional radiography techniques using scanning X-ray beams have previously been employed for dental applications." *Id.* at 2:8-14. And it admits that it was known to measure bone density with "densitometry procedures" using "scanning X-ray beam techniques." *Id.* at 2:15-19.

The patent contends as a point of novelty: "Heretofore there has not been available a system or method for applying the technology of densitometry to dental and medical applications such as the detection of caries and decalcification and the monitoring of osseointegration in connection with dental and medical prostheses." *Id.* at 2:43-47; *see also id.* at 2:31-32 ("The present invention utilizes such densitometry modeling and mapping techniques for dental applications."). This

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[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.

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 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.

Therefore, the Board should determine that this IPR petition demonstrates a reasonable likelihood to prevail in rending challenged claims 1-24 unpatentable and institute this IPR proceeding.

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. 8,498,374 was previously subject to an IPR, IPR2020-00659 (the ‘659 IPR), which was Instituted on June 10, 2020. See ‘659 IPR at Paper 10. The Trial was terminated due to settlement. See ‘659 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]

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

Petitioner is represented by the following counsel:

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

Lead Counsel	Backup Counsel
James P. Murphy (Reg. No. 55,474) Polsinelli PC 1000 Louisiana Street Suite 6400 Houston, Texas 77002 Telephone: 713.374.1631 jpmurphy@polsinelli.com	Ryan Murphy (Reg. No. 66,285) Polsinelli PC 1401 I St NW Suite 800 Washington DC 20005 Telephone: 202-626-8373 rmurphy@polsinelli.com Mark Deming (Reg. No. 69,263) Polsinelli PC 150 N. Riverside Plaza Suite 3000 Chicago, IL 60606 312-873-3625 mdeming@polsinelli.com

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

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

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

James Murphy
Polsinelli PC
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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 13,965 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 '374 patent is available for *inter partes* review, and that Petitioner is not barred or estopped from requesting an *inter partes* review of the '374 Patent claims on the grounds identified in this Petition. 37 C.F.R. §42.104(a).

IV. IDENTIFICATION OF GROUNDS

In the '659 IPR, the Board Instituted Review of claims 1-24 based on the two primary references presented below, Arai and Pelc. The Board found there was a reasonable likelihood that Arai anticipated claims 1, 3, 7, and 9 of the '374 patent, and that Arai alone, or in combination with other prior art, rendered claims 1-24 obvious. ‘659 IPR at Paper 10 at 26-42. The Board also found there was a reasonable likelihood that Pelc anticipated claims 1-4 and 7-10 of the ‘374 patent and that Pelc alone, or in combination with other prior art, rendered claims 1-24 obvious. ‘659 IPR at Paper 10 at 42-55. Petitioner relies on a subset of the grounds identified by the Board in the ’659 IPR. ‘659 IPR at Paper 10 at 7-11. 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 1-24 of the ‘374 patent.[3]

Like in the ’659 IPR, Petitioner challenges claims 1–24 of the ‘374 patent and requests the claims be found unpatentable based on the following Grounds:

Arai-Based Grounds

1. Arai (Ex. 1013, U.S. Patent No. 6,118,842) anticipates claims 1, 3, 7 and 9 under 35 U.S.C. § 102.[4]

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[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 ‘374 patent issued was filed before March 16, 2013, it is subject to pre-AIA 35 U.S.C. §§ 102–103.

2. Arai renders claims 1–12 obvious under 35 U.S.C. § 103 alone or in combination with Cann (Ex. 1014, “Precise Measurement of Vertebral Mineral Content Using Computed Tomography,” *Journal of Computer Assisted Tomography* 4(4) 493–500 (August 1980)), and in further combination with:

- Ex. 1018-Pelc ‘080 (claims 4 and 10)
- Ex. 1019-Xu and/or Ex. 1020-Milestone (claims 5–6 and 11–12); and

3. Arai renders claims 13–24 obvious under 35 U.S.C. § 103 in combination with Xu and/or Milestone, or additionally in combination with Cann, and in further combination with:

- Pelc ‘080 (claims 16 and 20); and

<u>Pelc-Based Grounds</u>

4. Ex. 1015-Pelc anticipates claims 1–4 and 7–10 under 35 U.S.C. § 102.

5. Pelc renders claims 1–12 obvious under 35 U.S.C. § 103 alone, in combination with Ex. 1016-Rothman, or in combination with Rothman and Cann, and in further combination with:

- Xu and/or Milestone (claims 5–6 and 11–12); and

6. Pelc renders claims 13–24 obvious under 35 U.S.C. § 103 alone, in combination with Rothman, or in combination with Rothman and Cann, all in further combination with Xu and/or Milestone.

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

V. TECHNOLOGICAL BACKGROUND

The patent claims a system for "tomographically modeling a dental structure," *see* claims 1 and 21, or a "tomographic modeling system," *see* claim 13. Computed tomography was common as of the priority date and is the technology most relevant to this petition. 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 the area. *Id*.

Conventional X-ray imaging results in a two-dimensional projection of all of 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, they have limited usefulness. *Id*.

Computed tomography, or "CT," solves this issue by allowing physicians to view a *cross-sectional image* of the area of interest (*i.e.*, a "slice"). *Id*. at ¶¶62-85. These slices are referred to as tomographic images. *Id*. Development of CT scanners began in the 1960s, and their use in 1999 for medical imaging was commonplace. *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)[5] 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 calculates how much attenuation occurred in a small three-dimensional volume of tissue, called a "voxel." *Id*. at ¶¶68-70; 90-91. 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

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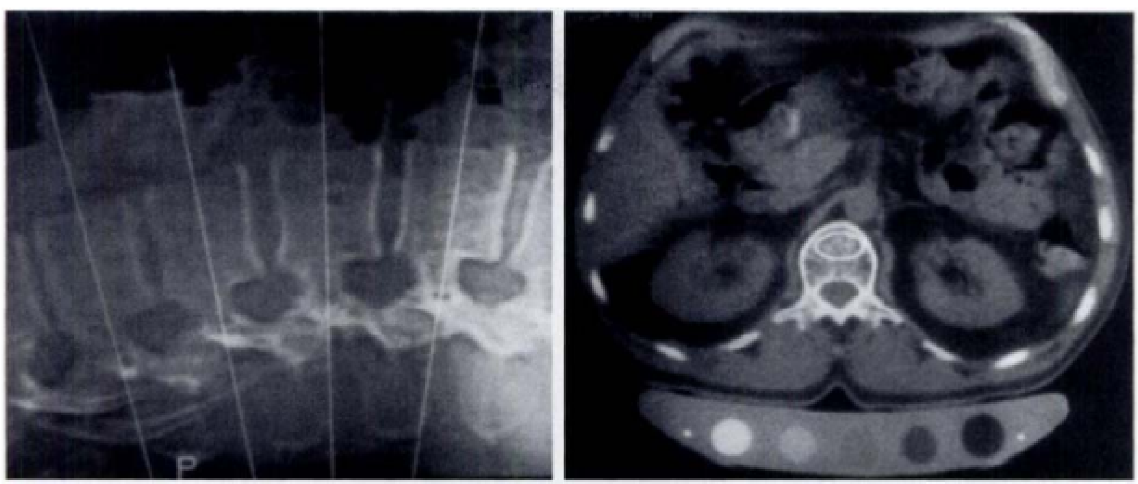
[5] Bushberg, THE ESSENTIAL PHYSICS OF MEDICAL IMAGING (Williams & Wilkins 1994) ("Bushberg"). It is prior art under 35 U.S.C. §§ 102(a) and (b).

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 the density of bone. *Id*. at ¶92. It was 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, known as "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.



a. b.

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 the 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*. CT numbers for bone range from ~300 to 3000, depending on density. Ex. 1021 (Bushberg) at 247.

VI. THE '374 PATENT AND PROSECUTION HISTORY

A. The '374 Patent Specification

The specification of the '374 patent is notably sparse, corresponding to a lack of patentable subject matter in the claims. The '374 patent states that it "relates generally to dental and orthopedic diagnosis and treatment, and in particular to a densitometry modeling system and method." Ex. 1001 at 1:25-27.

The patent doesn't assert any new tomographic modeling technology or techniques. Instead, the patent admits that its technology 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 '374 Patent Admits CT Dental Imaging Was Known.

The patent concedes, "Tomography or sectional radiography techniques using scanning X-ray beams have previously been employed for dental applications." Ex. 1001 at 2:8-10. It expressly incorporates by reference five patents in connection with this acknowledgement, including U.S. Pat. No. 5,214,686, Ex. 1024 (Webber). *Id*. at 2:11-14. Webber discloses that, "Computed tomography also has been used in dental radiography to obtain a slice through a subject's head, parallel to the plane of the subject's teeth." Ex. 1024 at 1:37-50.

The '374 patent further concedes the existence of "commercially available tomography equipment" suitable for use in the claimed invention as of the priority date. Ex. 1001 at 3:20-22; *see also id.* at 4:27-30 (incorporating prior art "examples of X-ray equipment adaptable for use with the present invention").

2. The '374 Patent Admits CT Densitometry Was Known.

The '374 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. 1001 at 2:15-17. It states that "[e]xamples are shown in U.S. Patent No. 5,533,080," among others. *Id.* at 2:17-21. The '080 patent discloses a CT system where 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 "so that the fan beam intercepts the imaged object at different angles." *Id.* at 1:42-44. "The projections at each of these different angles together form a tomographic projection set." *Id.* That information is processed to "reconstruct" a slice image according to reconstruction algorithms known in the art. *Id.* at 1:62-65.

3. The '374 Patent's Description of the Purported Invention

The patent describes a generic system for creating a tomographical model having conventional components. 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 4:2-13; (2) an input device ("such as a keyboard, …mouse…a communications link, or another computer"), *id.* at 4:14-17; (3) X-ray equipment, *id.* at 4:27-30 (listing prior art "examples of X-ray equipment adaptable for use with the present invention"); and (4) a generic output device (*e.g.*, monitor, printer, another computer), *id.*, 4:43-50.

The system's operation is likewise generic, including moving the X-ray equipment along a preprogrammed scan path controlled by the microprocessor, emitting and detecting X-ray beams, and using that information to create a tomographical densitometry model. *Id.* at 5:10-31. The patent also describes providing a "database including densitometry parameters for comparison with a patient's densitometry model" and comparing the results of a scan "to predetermined parameters unique to the patient." *Id.* at 2:55-3:3.

B. The Claims of the '374 Patent

1. Independent Claims 1, 13, and 21

Independent claims 1, 13, and 21 are system claims reciting a tomographic modeling system. Ex. 1001 at 5:34-50; 6:45-62; 7:18-8:13. The claims recite the following common features: (1) "a controller with a microprocessor and a memory device connected to the microprocessor," (2) said controller being adapted for storing computed tomographic models, (3) "an input device connected to the microprocessor," (4) "a positioning motor connected to the microprocessor and responsive to commands from said microprocessor," (5) "X-ray equipment including an X-ray source, a detector array, and a restricted beam device," (6) "a convertor for converting a signal from said detector array, said converter being connected to said detector array and to said microprocessor," (7) "an output device connected to said microprocessor and adapted for receiving a tomographic model from said microprocessor." *Id.* Claims 1, 13, and 21 are similar, with differences identified in detail below.

2. Dual-Energy: Claims 2, 8, 14, 18, 22, and 24

These dependent claims add that the X-ray equipment includes a "restricted beam device compris[ing] a dual-energy level restricted beam device." *Id*. at 5:51-53; 6:4-13; 6:62-64; 7:7-9; 8:14-16; 8:19-21.

3. 3D Tomographic Model: Claims 3 and 9

Dependent claims 3 and 9 recite a requirement that the output device receives "a 3D tomographic model." *Id*. at 5:54-56; 6:19-21.

4. X-ray Scan Path: Claims 4, 10, 16, and 20

These dependent claims require that "said x-ray source travels along a single axis" and "said x-ray source simultaneously rotates around said single axis." *Id*. at 5:57-60; 6:22-25; 7:1-4; 7:13-16.

5. Adapted to Compare: Claims 5, 6, 11, 12, 15, and 19

Dependent claims 5 and 11 add a controller (1) "adapted for storing a first tomographic model and a second tomographic model," (2) "said first tomographic model is a preexisting, commercially available standard model," (3) "said second tomographic model is a current patient model," and (4) "said controller is further adapted to compare said first tomographic model with said second tomographic model." *Id*. at 5:61-6:3; 6:26-35. Dependent claims 6, 12, 15, and 19 are similar.

6. Cone Beam: Claims 7, 17, and 23

Dependent claims 7, 17, and 23 require an "X-ray beam comprising a cone configuration." *Id*. at 6:13-14; 7:5-6; 8:17-18.

C. Prosecution History

The ‘374 patent claims priority through a lengthy chain of continuations and continuations-in-part to an initial application filed on December 1, 1999. *Id*. at [63]. Dentsply adopts that date as the priority date for purposes of this Petition.

The ‘374 patent issued from U.S. Patent App. No. 13/619,356. There was no substantive prosecution during the pendency of the ‘356 application other than the filing of a terminal disclaimer to overcome a rejection on the ground of obviousness-type double patenting. Ex. 1004 (December 17, 2012 Non-Final Rejection) at p. 235-41 and (Terminal Disclaimer) at 256-57.[6]

Two points from the prior history are relevant:

1. 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 own history is known. What applicant appears to believe is lacking is the use of such a system for

[6] 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.

dental tomographic imaging." Ex. 1005 (April 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. *See* Ex. 1005 (October 9, 2001, Response) at 48-52, 55, 57.[7] 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-

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[7] Despite applicant's argument distinguishing the prior art on the basis of the patented system allowing for a comparison, a number of claims were amended or drafted such that no comparison actually is required. For instance, claim 1 of the '301 patent, merely requires a "means for storing a pre-existing tomographical dental/orthopedic densitometry model," but not the actual performance of a comparison. *See* Ex. 1010 (Markman Memorandum) at 12-13.

existing densitometry model." Ex. 1005 (November 30, 2001 Notice of Allowability) at 67.

2. In the prosecution of U.S. Patent App. No. 10/351,567, which issued as U.S. Patent No. 6,944,262, the claims were rejected as anticipated and obvious. After an interview, the applicant amended the claims to add two limitations. First, the applicant added a limitation requiring that the densitometry model be "three-dimensional." Ex. 1006 (March 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*. These limitations are found in the '374 patent in claims 3, 9, 13, and 21 (three-dimensional models) and claims 13 and 21 (no fiducial markers).

VII. LEVEL OF SKILL IN THE ART

The person of 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); 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.[8] Ex. 1009 (Markman Corrected Order), 1010 (Markman Memorandum). Dentsply was not a party to that case but adopts those constructions for purposes of this petition.

1. "Tomographically modeling/tomographic model(s)" (Claims 1, 3, 5, 6, 9, 11, 12, 13, 15, 19 and 21)

"Merging information from multiple tomographic scans of an object to produce a representation of the subject/said representation depicting quantitative

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[8] "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).

density differences of the object scanned, which is created by the microprocessor in the controller using densitometry from at least one focal plane." Ex. 1010 at 5. With respect to the "quantitative" aspect, the Court held that a calculation of BMD (*e.g.*, bone mineral density in terms of mass/volume), while within the scope of the claim, is not required, and that any quantitative densitometric calculation would suffice. *Id.* at 7. Densitometry was defined to mean "quantitatively calculated bone density." *Id.* at 8.

2. "3D (digital) tomographic model(s)" (Claims 3, 9, 13 and 21)

The Court noted the Delaware parties' agreement that "the model is digital" and that "a three dimensional (3D) model must be constructed from two or more focal planes." *Id*. at 9-10. The Court found that no further construction was required. *Id.* This construction was not intended to differentiate from the plain meaning of "3D," in which a 3D 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 (Markman Transcript) at 60:1-62:15.

3. "A controller" (Claims 1, 5, 6, 11, 12, 13, 15, 19 and 21)

"One or more controllers." No construction was deemed necessary for the term controller. *Id*. at 11. Controller, as used by the patent, is a generic term for components having computing capability. *E.g.*, Ex. 1001 at 4:3-10.

4. "Preexisting patient model/current patient model" (Claims 6, 12, 15 and 19)

"A pair of tomographic models obtained during different imaging sessions, the earlier or preexisting model for use as a baseline for comparing with a later or then current patient model." Ex. 1009 at 3.

B. Construction of Additional Terms

1. "Fiducial marker" (Claims 13 and 21)

The '374 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. "Said controller being adapted for storing computed tomographic models of a dental structure" (Claim 1)

A POSA would understand this term in accordance with its plain meaning, *i.e.*, the controller has the capability to store tomographic models.

3. "Controller is adapted to compare" (Claims 5, 6, 11, 12, 15 and 19)

The Delaware Court held no construction of these terms was necessary. Ex. 1010 at 14. The '374 patent does not describe how the controller is adapted to compare densitometry models.[9] The background of the invention acknowledges in the BMD context that comparisons between a standard model and a patient's model were known, as were comparisons between a patient's current and historical model. Ex. 1001 at 2:22-28. This supports a construction of "comparison" in accord with its ordinary meaning: "Said controller is programmed with an algorithm that has the capability to identify differences between data sets."

IX. DETAILED EXPLANATION OF GROUNDS FOR INVALIDITY

A. Description of the Prior Art

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

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

Arai describes a dental X-ray imaging apparatus that can conduct local CT and panoramic tomographic imaging. Ex. 1013 at 2:3-5; Ex. 1007 (Sonka) ¶¶171-

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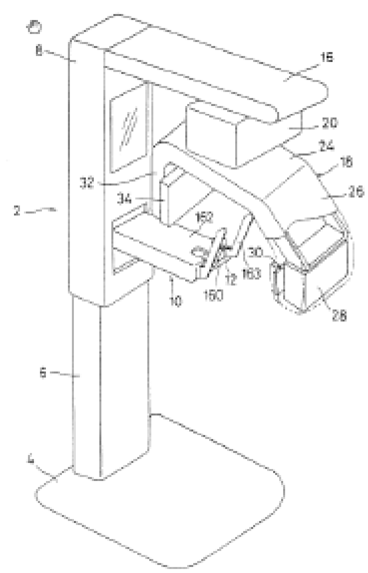
[9] Indeed, claim 9 of U.S. Patent No. 6,381,301, Ex. 1002, was held to be invalid as indefinite in the Delaware litigation. Ex. 1010 at pp. 14-16. Claim 9 of the '301 patent recites "means for comparing said pre-existing tomographical densitometry model to a current tomographical densitometry model." Ex. 1002 at 6:1-4. The Court found that "a POSA would not know with reasonable certainty what the required structure is to perform the comparing functions." Ex. 1010 at 16.

180. 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.

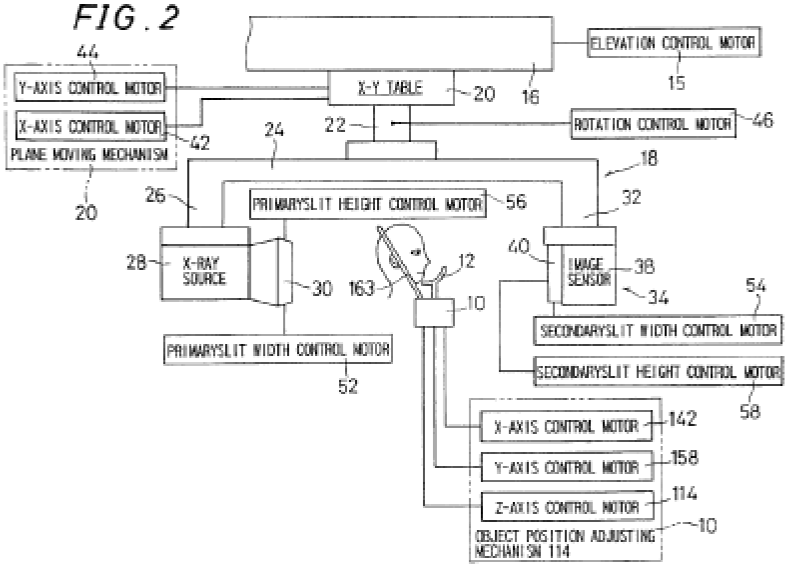
The apparatus includes a frame (2, 4, 6, and 8) with a "horizontal arm 16" and "object position adjusting mechanism 10." *Id*. at 9:49-10:40; Fig. 1. The arm holds a "moving mechanism 20" and "supporting means 18" to which an "X-ray source 28" and an "image sensor 38" are attached. *Id.* at 10:3-40.

FIG. 1



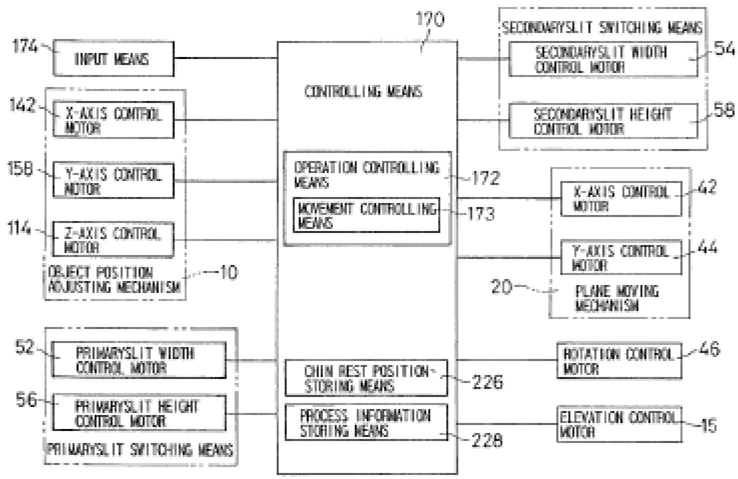
The target is positioned between the source and the sensor. *Id*. at 10:41-44; Fig. 2. The "primary slit means 30" restricts the width and height of X-rays emitted from the source. *Id*. at 10:44-47; Fig. 2.

FIG. 2



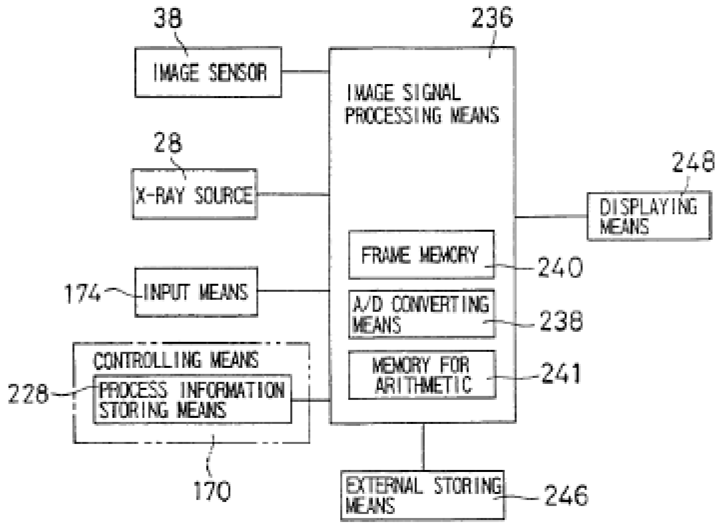
"Controlling means 170" operates motors to move the X-ray equipment in response to pre-programmed scanned paths. *See* Fig. 7. Arai discloses "x-axis control motor 42," "y-axis control motor 44," and "rotation control motor 46." *Id.* at 15:62-16:1. "The process information storing means 228 stores CT 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. 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*.

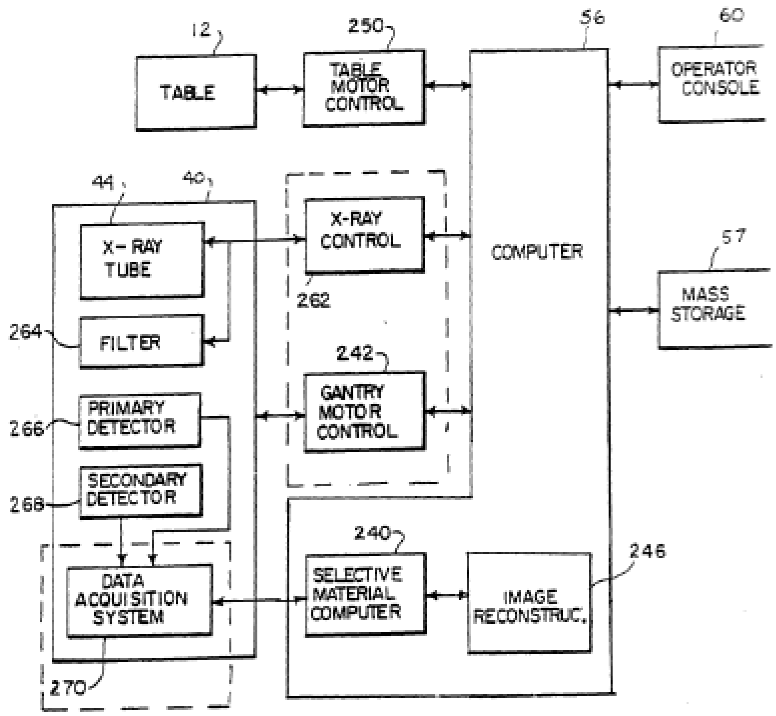
Cann describes methods of improving the accuracy and precision of quantitative CT measurements for bone density. *Id.* at 493-94; Ex. 1007 (Sonka)

¶¶181-185. 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 the calculation of the mineral equivalent density of the bone in terms of mg K_2HPO_4/mL. *Id.* at 494-96*;* Table 1 (illustrating measurements in both CT number and mineral content). 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

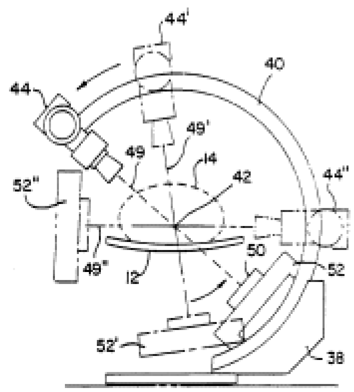


Pelc's system includes an X-ray source, an X-ray detector, and a beam-restricting device. *Id*. at 5:22-6:7; 14:24-31; Ex. 1007 (Sonka) ¶¶187-90. Pelc has a "radiation source and a detector" that are "affixed to the ends of the C-arm to provide energy attenuation measurements along an axis between those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

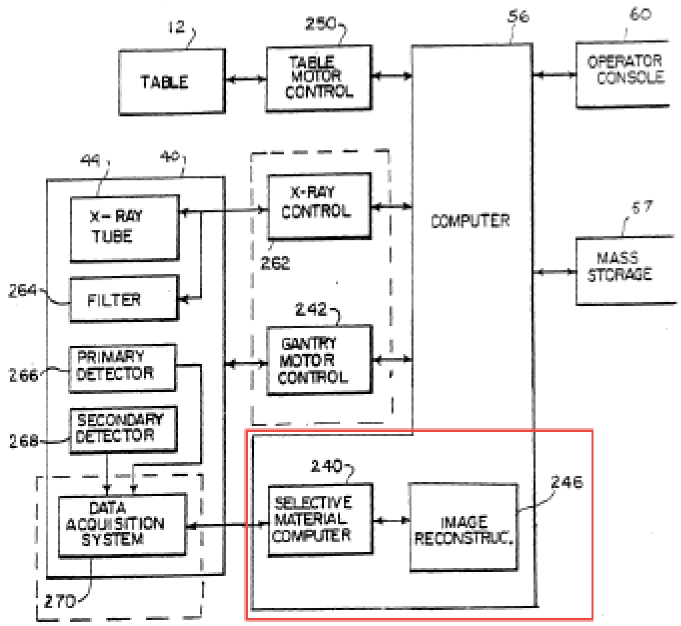
FIG. 15



An "electronic computer…controls the C-arm, the radiation source and the detector," *Id*. at 5:31-33. Pelc elsewhere 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:

FIG. 19



Pelc teaches "[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. a*t 36:1-3. The POSA would understand that "image data" in this context is referring to the digital tomographic models described above. Ex. 1007 (Sonka) ¶¶198-204.

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.

4. Rothman, DENTAL APPLICATIONS OF COMPUTERIZED TOMOGRAPHY: SURGICAL PLANNING FOR IMPLANT PLACEMENT (Ex. 1016)

The treatise "DENTAL APPLICATIONS OF COMPUTERIZED TOMOGRAPHY: SURGICAL PLANNING FOR IMPLANT PLACEMENT," by Stephen Rothman, MD ("Rothman"), was published in 1998 and is prior art under 35 U.S.C. §§ 102(a)-(b). Ex. 1016. Rothman discusses CT in the dental area. After "spinal CT became standard in the early 1980s," Rothman teaches, "it was logical to adapt the same process to dental CT." *Id.* at 13. "In the last decade, computerized tomography (CT) has become one of the most frequently used imaging modalities for the preoperative evaluation of the jaw for dental implants." *Id*. at 1; Ex. 1007 (Sonka) ¶¶205-209. Rothman also discusses non-surgical dental applications of CT. *Id.* at 153.

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

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

1. Independent Claim 1

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

a. Preamble

Claim 1 recites: "A system for tomographically modeling a dental structure, the system comprising…." Ex. 1001 at 5:34-35.

1) The Preamble Is Not Limiting

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 "for tomographically modeling a dental structure" language in the preamble is a non-limiting statement of purpose. Arai anticipates claim 1 if the preamble is non-limiting.

2) Anticipation by Arai

Even if the preamble is limiting, Arai teaches a system for tomographically modeling a dental structure. *See supra* § IX.A.1. Arai discloses a CT system. "It is an object of the invention to provide an X-ray imaging apparatus which can conduct a partial CT imaging in addition to a panoramic tomographic imaging." Ex. 1013 at 2:3-5; 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 ("Plural sets of image information stored in the frame memory 240 are stored in the image memory for arithmetic 241. A predetermined arithmetic process corresponding to the selected imaging mode is conducted on image information read out from the image memory for arithmetic 241, ***thereby generating a tomographic image*** of the selected mode.") (emphasis added); Ex. 1007 (Sonka) ¶227.

Arai discloses that these tomographic images are of dental structures. *See* Ex. 1013 at 23:8-10 ("an implant operation in the dental treatment can be easily performed while observing the partial CT image"); Fig. 18; Ex. 1007 (Sonka) ¶228.

Arai's CT system is quantitative because, as previously described, CT scanners use information from multiple scans to calculate a CT number, represented by Hounsfield units, which provides information regarding the bone density. Ex. 1007 (Sonka) ¶¶70, 92-93, 229. This is further supported by the '374 patent's reference to the CT system disclosed in Pelc '080 as disclosing densitometry procedures, Ex. 1001 at 2:15-21. Ex. 1007 (Sonka) ¶229.

3) Obviousness 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 of "tomographically modeling." That is incorrect as discussed above. Nevertheless, in the alternative, it would be obvious to combine Arai and Cann. Cann teaches use of CT for measuring bone mineral content through the use of quantitative CT imaging. Ex. 1014 at 493-95; Ex. 1007 (Sonka) ¶¶181-185, 230. 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) ¶231. 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 1:34-36. 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) ¶231. 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*.

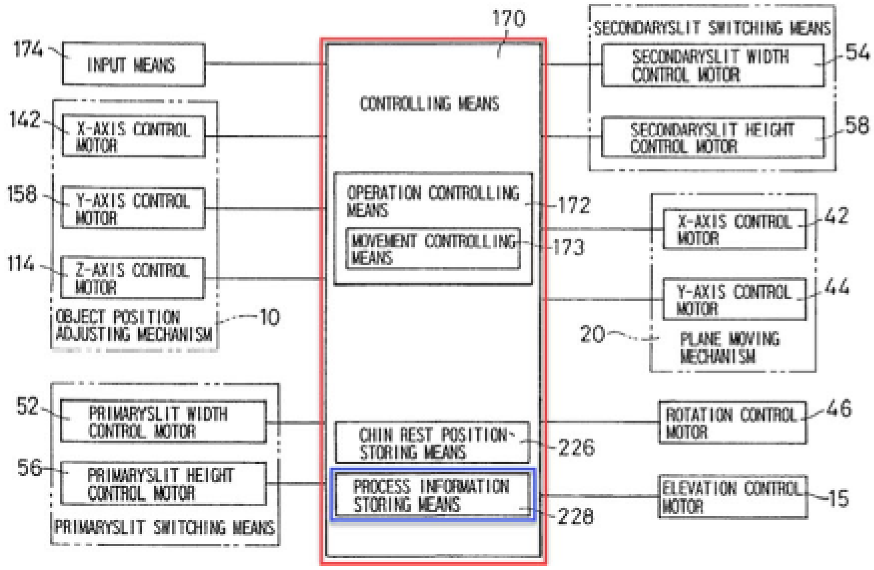
A POSA would have had a reasonable expectation of success in using the phantom quantitative process taught by Cann in combination with Arai given the minimal modifications required and the established use of CT for densitometrical purposes by the priority date (almost 20 years after Cann's publication).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

b. Controller

Claim 1 recites "a controller with a microprocessor and a memory device connected to the microprocessor." Ex. 1001 at 5:36-37. Arai discloses this limitation. It has a controller comprising "controlling means 170" and/or "image signal processing means 236." Ex. 1013 at 16:46-48; 17:30-32. (The Court's construction expressly allows one or more controllers. Ex. 1010 at 11-12.)

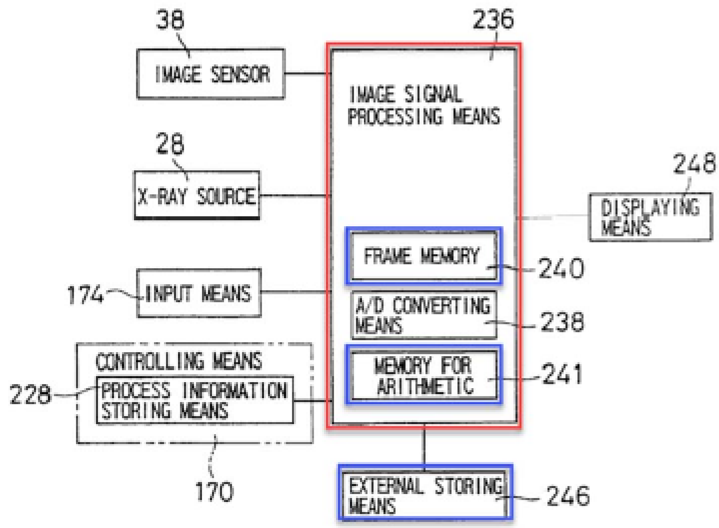
The "controlling means 170" controls motors that move the imaging equipment during a scan, and "may be configured by…a microprocessor." Ex. 1013 at 14:48-54; *see also id.* at 15:62-16:6. Figure 7 depicts "controlling means 170" (outlined in red) having a memory device, *i.e.*, "process information storing means 228" (outlined in blue). *Id*. at 16:6-10; 16:41-44. Moreover, a POSA would recognize that a microprocessor having the functions described in Arai would necessarily have memory. Ex. 1007 (Sonka) ¶232-33.

FIG. 7



Additionally, Arai's "image signal processing means 236" controls the processing of the image signals detected by "image sensor 38." Ex. 1013 at 17:29-38. Arai teaches that the "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 236" (outlined in red) has memory devices in the forms of "frame memory 240," "image memory for arithmetic 241," and "external storing means 246" for storing tomographic images (all outlined in blue). *Id.* at 17:29-48; 18:11-12; Ex. 1007 (Sonka) ¶234; *see also* '659 IPR at Paper 10 at 31-32 (relying on Arai's disclosure of controlling means 170, alone or in combination).

FIG. 9



c. Storing tomographic models of dental structure

Claim 1 further recites "said controller being adapted for storing computed tomographic models of a dental structure." Ex. 1001 at 5:37-39.

Arai discloses this limitation. Arai's "image signal processing means" stores CT models of a dental structure in the "memory for arithmetic 241" component of the "image signal processing means 236," and also separately describes "external storing means 246." 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 (describing "external storing means" as "a hard disk apparatus or magnetooptical disk"); Ex. 1007 (Sonka) ¶235; *see also* '659 IPR at Paper 10 at 31-32.

d. Input device

Claim 1 further recites "an input device connected to the microprocessor." Ex. 1001 at 5:40. The specification of the '374 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. 1001 at 4:14-16.

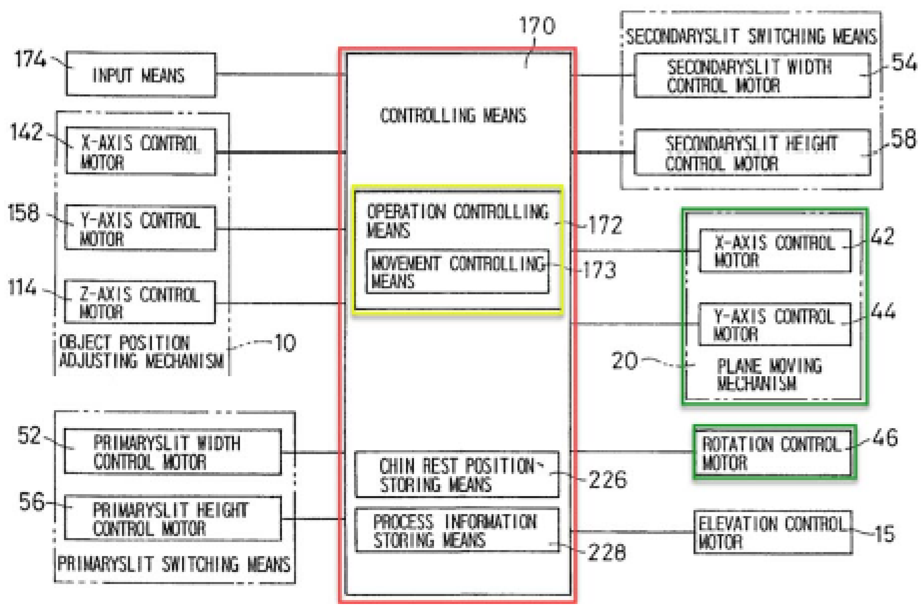
Arai discloses this limitation. Arai discloses "input means 174" and "operation panel 176," which can be used by the operator to choose the imaging mode and input information relating to the object to be imaged. Ex. 1013 at 14:51-56 ("The controlling means 170 may be configured by, for example, a microprocessor, and controls the motors on the basis of a signal supplied from input means 174, as described later. In the embodiment, the input means 174 comprises an operation panel 176 which is shown in FIG. 8."); Fig. 7-9; Ex. 1007 (Sonka) ¶236; *see also* '659 IPR at Paper 10 at 32-33 (relying on Arai's disclosure of an input means 174 and an operation panel 176, alone or in combination).

e. Positioning motor

Claim 1 further recites "a positioning motor connected to the microprocessor and responsive to commands from said microprocessor." Ex. 1001 at 5:41-42.

Arai discloses this limitation. Arai teaches "X-axis control motor 42," "Y-axis control motor 44," and "rotation control motor 46." Ex. 1013 at 11:23-26. These positioning motors (outlined in green) are responsive to commands from the controlling means' microprocessor (red) via "operation controlling means 172" and "movement controlling means 173" (yellow). *Id*. at 15:62-16:6; Figure. 7; Ex. 1007 (Sonka) ¶237; *see also* '659 IPR at Paper 10 at 33-34 (relying on Arai's disclosure of an X-axis control motor 42, Y-axis control motor 44, and rotation control motor 46, alone or in combination).

FIG. 7



f. X-ray equipment

Claim 1 further recites "X-ray equipment including an X-ray source, a detector array, and a restricted beam device." Ex. 1001 at 5:43-44. This limitation is disclosed by Arai.

The system in Arai includes an "X-ray source 28" and "image sensor 38." Ex. 1013 at 10:41-44; Fig. 2. A POSA would understand "image sensor" to be a detector array. Ex. 1007 (Sonka) ¶238.

Arai further teaches that the X-ray equipment in its imaging system includes a restricted beam device. "The primary slit means 30 restricts the width and height of X-rays emitted from the X-ray source 28, thereby preventing unnecessary X-rays from being emitted toward the object." Ex. 1013 at 10:44-47. Moreover, the U.S. Food and Drug Administration (FDA) required all X-ray imaging devices to use restricted beams well before the priority date. Ex. 1007 (Sonka) ¶¶239; Ex. 1025 (21 C.F.R. § 1020.31, April 1998) at 566; *see also* '659 IPR at Paper 10 at 34-35 (relying on Arai's disclosure of X-ray source 28 and image sensor 38, alone or in combination).

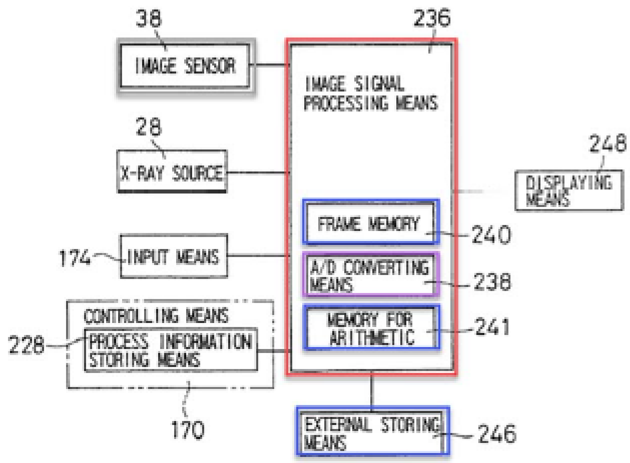
g. Converter

Claim 1 further recites "a convertor for converting a signal from said detector array, said converter being connected to said detector array and to said microprocessor." Ex. 1001 at 5:45-47.

Arai discloses this limitation. It has "A/D converting means 238" for converting an analog signal from "image sensor 38" (detector array) into a digital signal. Ex. 1013 at 17:38-42 ("The image signal supplied from the image sensor 38 to the image signal processing means 236 is converted into a digital signal by the A/D converting means 238…."). Figure 9 shows that this convertor (purple) is connected to the detector array (gray) and is a part of, and thus connected to, the microprocessor of the "image signal processing means 236" (red). Ex. 1007

(Sonka) ¶240; *see also* '659 IPR at Paper 10 at 35 (relying on Arai's disclosure of A/D converting means 238, alone or in combination).

FIG. 9



h. Output device

Claim 1 recites "an output device connected to said microprocessor and adapted for receiving a tomographic model from said microprocessor." Ex. 1001 at 5:48-50. The '374 patent describes "output device" broadly, including "a monitor, a display, a printer, a communications link, and/or another computer." *Id.* at 4:45-47.

Arai discloses this limitation. It has two output devices that are capable of receiving a tomographic model from the microprocessor of the image signal processing means: "external storing means 246" and "displaying means 248." Ex. 1013 at 18:3-15; Ex. 1007 (Sonka) ¶241; *see also* '659 IPR at Paper 10 at 35-

36 (relying on Arai's disclosure of external storing means 246 and displaying means 248, alone or in combination).

2. Dependent Claim 7

Claim 7 recites "wherein said X-ray source emits an X-ray beam comprising a cone configuration." Ex. 1001 at 6:14-15.

Arai discloses this limitation, rendering this claim anticipated by Arai, and obvious over Arai and Cann. Arai teaches an X-ray source emitting a cone beam. Ex. 1013 at 26:39-43 ("X-rays which are emitted from the X-ray source…irradiate the imaging region 262 in a cone-like shape"); 38:54-57 ("X-rays emitted from the X-ray source are irradiated in a cone-like shape…."); Ex. 1007 (Sonka) ¶243-44; *see also* '659 IPR at Paper 10 at 36.

3. Dependent Claims 2 and 8

Claims 2 and 8 recite "wherein said restricted beam device comprises a dual-energy level restricted beam device." Ex. 1001 at 5:51-53; 6:16-18. These claims are obvious over Arai in view of the admitted prior art, and over Arai in view of Cann.

The '374 patent admits that the use of dual-energy X-ray beams in medical densitometry applications was known (citing U.S. Patent No. RE 36,162 ("Bisek") (Ex. 1026)), and that "[a]s discussed therein, dual-energy densitometry can result in a more accurate patient model." Ex. 1001 at 5:18-22; *see also* Ex. 1007 (Sonka) at ¶¶246-48. A POSA would have been motivated to modify Arai to use a dual-energy source in light of its known benefits and had a reasonable expectation of success in using this established method. Ex. 1007 (Sonka) at ¶249; *see also* ‘659 IPR at Paper 10 at 37-42 (relying on Arai's disclosure, alone or in combination). Moreover, Cann discloses dual-energy CT and discusses its advantages. Ex. 1014 at 493-94. By the priority date of the ‘374 patent, a POSA would understand that the value of dual-energy scans, as discussed in Cann, was well established. Ex. 1007 (Sonka) ¶249. A POSA would have been motivated to combine Arai and Cann in light of the knowledge in the art regarding the increased accuracy of dual-energy scans. *Id*. at ¶249. A POSA would have had an expectation of success in incorporating dual-energy imaging from Cann into the system taught in Arai given the high level of experience and knowledge in the art regarding the use of such dual-energy systems. *Id*.

4. Dependent Claims 3 and 9

Claims 3 and 9 further recite a system "wherein said tomographic model received by said output device is a 3D tomographic model." Ex. 1001 at 5:54-56; 6:19-21. This limitation is inherent in Arai, rendering these claims anticipated by Arai, obvious over Arai in view of the knowledge of a POSA including admitted prior art, and obvious over Arai in view of Cann.

A POSA would understand that Arai's system generates a 3D model, *i.e.*, a dataset corresponding to multiple focal planes. *See* Ex. 1013 at 17:42-48; Ex. 1007 (Sonka) ¶252; *see also* '659 IPR at Paper 10 at 36 (relying on Arai's disclosure, alone or in combination). A POSA would also understand that the Arai CT system would use this information to generate a 3D model for display. Ex. 1007 (Sonka) ¶252. In particular, Arai discloses the use of a cone beam CT system. Ex. 1013 at 26:39-43. Use of such a system as disclosed in Arai necessarily creates a three-dimensional model, which would be sent to the output device for use by a physician. Ex. 1007 (Sonka) ¶¶79-81, 251-52.

Alternatively, 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 and most useful application of CT imaging and well within the skill of the art. *Id*. at ¶ 253. The '374 patent does not mention 3D models. Defending against arguments under 35 U.S.C. § 112 in the Delaware litigation, Osseo admitted:

> [O]ne 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.

Given the state of the art, and the known usefulness to users, a POSA would find it obvious to use Arai's system to generate 3D models. *Id*. at ¶ 252-53. A POSA would have had a reasonable expectation of success in making this combination given the advanced state of the art with respect to the creation of 3D tomographic models. *Id*. Further, it would have been obvious to a POSA that the Arai CT system would send this model to the output device in order to communicate information to the user. *Id*.

5. Dependent Claims 4 and 10

Claims 4 and 10 further recite a system "wherein: said x-ray source travels along a single axis; and said x-ray source simultaneously rotates around said single axis." Ex. 1001 at 5:57-60; 6:22-25. The '374 patent concedes that this arrangement is not novel: "Examples of X-ray equipment adaptable for use with the present invention are disclosed in U.S. Pat. No. 5,533,080 [the Pelc '080 patent, Ex. 1018]…which [is] incorporated herein by reference." *Id*. at 4:24-30. Modifying Arai's system (and the Arai and Cann combination) in a way that satisfies the limitations of these claims would be obvious in view of Pelc '080.

Pelc '080, which is prior art under 35 U.S.C. §§ 102(a)-(b), discloses a C-arm X-ray system that rotates around an axis and translates along that axis. Ex. 1018 at 9:15-28, 9:62-65, 10:47-51. This rotation and translation produces a scan path that is well-known in the art. Ex. 1021 (Bushberg) at 260-62. While current-day helical scanning typically involves a rotating X-ray source/detector and a target table that translates through the plane of the X-ray equipment, a POSA would understand the same result is achieved by rotating and translating the X-ray equipment around the target as disclosed in Pelc '080. Ex. 1007 (Sonka) at ¶¶255-58.

Claims 4 and 10, properly construed, do not require actual movement along the axis and simultaneous rotation. Arai includes mechanisms for adjusting the X-ray equipment in the vertical direction. Ex. 1013 at 9:49-59; Figs. 1, 7. Arai's X-ray source rotates around a vertical axis centered through the target. *Id.* at 2:62-65. Accordingly, the Arai system's capability satisfies the claims' limitations.

Alternatively, while Arai does not disclose simultaneous rotation while the source is moving along the axis, a POSA would have been motivated to use the Arai apparatus in such a way, as the Pelc '080 patent teaches. Ex. 1007 (Sonka) ¶258; *see also* '659 IPR at Paper 10 at 37-42 (relying on Arai's disclosure, alone or in combination). This would allow Arai to image a greater volume of the object. *Id.* Making this simple modification to the operation of Arai would have been well within the skill of a POSA, because the underlying mechanisms are already present in Arai. *Id.*

6. Dependent Claims 5 and 11

Claims 5 and 11 recite "said controller is adapted for storing a first tomographic model and a second tomographic model; said first tomographic model is a preexisting, commercially available standard model; said second tomographic model is a current patient model; and said controller is adapted to compare said first tomographic model with said second tomographic model." Ex. 1001 at 5:61-6:3; 6:26-35.

These claims, relating to a comparison of two tomographic models, are obvious over Arai (and Arai and Cann) in view of Xu and/or Milestone. The '374 patent admits that means for comparing tomographic models were known in the prior art. *Id*. at 2:26-31. Beyond that admission, the only disclosure in the specification regarding comparison is that the "array output is merged and compared to the diagnostic parameters which are stored in the computer's memory." *Id.* at 5:25-27. 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 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 comparisons of medical images, including CT images, are routinely performed for purposes of diagnosis and tracking treatment, and that a physician or other medical professional seeks out and relies on such comparisons in the regular course of medical treatment. Ex. 1007 (Sonka) at ¶¶95-97, 260-65. As admitted by the patent, such comparisons could be between a patient's current scan and standard models, or between the patient's current and prior scans. *Id.*; *see also* Ex. 1001 at 2:26-31.

As of the priority date of the '374 patent, it was well-known to a POSA that a microprocessor could be successfully programmed with software to perform these comparisons, and a POSA would be motivated to do so. Xu, which is prior art under § 102(e) for the '374 patent, teaches a method and system that uses a computer to detect changes in three-dimensional medical scans by using temporal subtraction. Ex. 1019 at 2:19-32; 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, which is prior art under 35 U.S.C. § 102(a), teaches the use of software to compare volumetric or three-dimensional rendering of internal structures. Ex. 1020 at 5:15-26. Specifically, Milestone teaches that the comparison can be between two patient scans (current and previous) as well as a patient scan and scanned/stored data representing a "normal" baseline structure. *Id.*; *see also id.* at 10:26-11:12; 13:17-22.

Arai includes memory for storing CT data (*e.g.*, "external storing means 246," "frame memory 240," and "memory for arithmetic 241."). *See supra* § IX.B.1.c. Arai further teaches that its microprocessor, "image signal processing means 236" is programmed with an algorithm, "arithmetic process," for generating tomographic images. Ex. 1013 at 17:44-48. A POSA would have been motivated to adapt the microprocessor in Arai to perform comparisons between a pre-existing commercial model and a patient's current model, as stored in Arai's system memory, and would have had a reasonable expectation of success in doing so. Ex. 1007 (Sonka) at ¶¶95-97, 261-267. A "preexisting, commercially available standard model" is, by definition, available to the POSA. A POSA could thus use commercially available comparison software, which Osseo admits was well-known, with Arai's CT system to compare a pre-existing commercial model and a patient's current model. A POSA would use existing software, which the '374 patent admits was commercially available, Ex. 1001 at 4:10-13, to program the microprocessor of Arai for such comparisons. Ex. 1007 (Sonka) ¶266. Furthermore, as evident from Xu and Milestone, such comparisons were often used in CT imaging systems for medical purposes. *Id*. at ¶267; *see also* '659 IPR at Paper 10 at 37-42 (relying on Arai's disclosure, alone or in combination).

7. Dependent Claims 6 and 12

Claims 6 and 12 are substantially identical to claims 5 and 11. The only difference is that the comparison in claims 6 and 12 is between a patient's pre-existing model (*i.e.*, a previous scan) and the patient's current model. *Id*. at ¶¶269-70. The analysis for claims 5 and 11 applies equally here, as such comparisons were known in the prior art and a POSA would be motivated to utilize them in connection with Arai for reasons of diagnosis and treatment for the reasons discussed, with a reasonable expectation of success. *Id*. These claims are thus obvious over Arai (and Arai and Cann) in view of Xu and/or Milestone for the same reasons. *Id*.

8. Independent Claims 13 and 21

Claims 13 and 21 are obvious over Arai (and Arai and Cann) in combination with Xu and/or Milestone.

Claims 13 and 21 are substantially similar to each other, and to claim 1:

Claim 13 vs. Claim 21. The only difference between claims 13 and 21 is the preamble. Claim 21's preamble recites a "dental structure," whereas claim 13 does not. For the reasons discussed above, the preamble is not limiting. *See supra* § IX.B.1. To the extent it is limiting, Petitioner has addressed those limitations with respect to claim 1. *Id.*

Claims 13 and 21 vs. Claim 1. Independent claims 13 and 21 are similar to independent claim 1. Ex. 1007 (Sonka) ¶¶1273-78. Petitioner's discussion of claim

1 is incorporated here by reference. *See supra* § IX.B.1. The limitations of claims 13 and 21 differ from claim 1 in that they recite a controller "being adapted for creating, storing, and comparing 3D digital tomographic models of an object without the use of fiducial markers of said object." This limitation is addressed below.

a. Creating, storing and comparing tomographic models

The creation of tomographic models was addressed in connection with the description of Arai and in the discussion of claim 1's preamble. *See supra* §§ IX.A.1, IX.B.1.a. The storage of tomographic models, satisfied by Arai, was addressed with respect to claim 1's "adapted for storing" limitation. *See supra* § IX.B.1.c. The comparison of tomographic models, satisfied by the combination of Arai (and Arai and Cann) with Xu and/or Milestone, was addressed with respect to claims 5, 6, 11 and 12. *See supra* §§ IX.B.6-7.

b. 3D digital tomographic models

A POSA would understand that the controller disclosed in Arai is adapted to create 3D models, or that it would be obvious to modify it to do so. *See supra* § IX.B.4 (claims 3 and 9).

c. "Without the 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) ¶278. Just as the '374 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.”). A POSA would understand that, in the absence of any disclosures teaching the use of a fiducial marker, the Arai CT imaging system creates, stores and compares tomographic models without the use of a fiducial marker. Ex. 1007 (Sonka) at ¶278. Thus, Arai discloses this limitation.

Alternatively, it would have been obvious for a POSA to use the Arai system without fiducial markers. *Id.* A POSA would be motivated to avoid fiducial markers to reduce the complexity and cost associated with the scan, and a POSA would have had a reasonable expectation of success in implementing such a system. *Id.*

9. Dependent Claims 17 and 23

Arai discloses a system "wherein said X-ray source emits an X-ray beam comprising a cone configuration," *see supra* § IX.B.2 (claim 7), rendering these claims obvious over Arai (and Arai and Cann) in combination with Xu and/or Milestone. Ex. 1007 (Sonka) ¶¶279-81.

10. Dependent Claims 14, 18, 22, and 24

Arai in combination with Xu and/or Milestone, and additionally in combination with Cann; and Arai in combination with Xu and/or Milestone, and additionally in combination with the admitted prior art, renders obvious these claims, which add the limitation "wherein said restricted beam device comprises a dual-energy level restricted beam device." *See supra* § IX.B.3 (claims 2 and 8); Ex. 1007 (Sonka) ¶¶282-84.

11. Dependent Claims 15 and 19

Arai (and Arai and Cann) in combination with Xu and/or Milestone, renders obvious these claims, which add the limitation "wherein said controller is adapted to compare a pre-existing tomographic model with a current tomographic model." *See supra* §§ IX.B.6-7 (claims 5, 6, 11 and 12); Ex. 1007 (Sonka) ¶¶285-87.

12. Dependent Claims 16 and 20

Arai (and Arai and Cann) in further view of Xu and/or Milestone, and in combination with Pelc '080, renders obvious the claims, which add the limitation "said x-ray source travels along a single axis; and said x-ray source simultaneously rotates around said single axis." *See supra* §§ IX.B.5 (claims 4 and 10); Ex. 1007 (Sonka) ¶¶288-90.

C. Grounds 4-6: Pelc-Based Anticipation and Obviousness

1. Independent Claim 1

Claim 1 is anticipated by Pelc if the preamble is not limiting. If the preamble is limiting, Claim 1 is obvious over Pelc in combination with Rothman, and alternatively obvious over Pelc and Rothman in further combination with Cann.

a. Preamble

1) The Preamble is Not Limiting

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

2) Obviousness over Pelc in View of Rothman

To the extent the preamble is limiting, Pelc in view of Rothman teaches a system for tomographic densitometry modeling of a dental structure. Ex. 1007 (Sonka) ¶¶292-96.

Pelc discloses "[a]n X-ray imaging system" that "provides both scanning radiography and ***computed tomography***…." Ex. 1015, Abstract; *see also id.* 1:13-17 (emphasis added). 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 (emphasis added).

Although the system taught by Pelc is not expressly directed to imaging dental structures, it would have been obvious to apply Pelc's teaching in the context of dental imaging. Ex. 1007 (Sonka) ¶296. The POSA would have been aware of the widespread use of CT imaging technology in dental applications, including with respect to densitometry. *Id*. As Rothman notes in 1998, "[i]n the last decade, computerized tomography (CT) has become one of the most frequently used imaging modalities for the preoperative evaluation of the jaw for dental implants." Ex. 1016 at 1; *see also id.* at 3.

The POSA would have been motivated to combine Rothman and Pelc and would have had a reasonable expectation of success in doing so. Ex. 1007 (Sonka) ¶296. Rothman extolls the benefits of using CT imaging technology for dental applications, and explicitly notes that "[m]ost commercially available CT scanners are capable of producing the high-resolution images needed for the evaluation of the jaw for dental implants." Ex. 1016 at 10. Indeed, Rothman explains how to use a CT imaging device similar to the one disclosed in Pelc—*i.e.*, in which the patient lies supine on a table while the X-ray equipment rotates around the patient to produce a tomographic model of a dental structure. *See id.* at 13-15.

Pelc's CT system, like all digital CT systems, is quantitative for the reasons discussed above. *See supra* § IX.B.1.a; Ex. 1007 (Sonka) ¶294. Also, Rothman discloses the "[q]uantitative assessment of mineral content" in the mandible using such CT imaging technology. Ex. 1016 at 57.

The Board found that Pelc's disclosure of an X-ray imaging system, alone or in view of the combinations presented, was sufficient for Institution of claim 1. '659 IPR at Paper 10 at 46.

3) Obviousness over Pelc and Rothman in Further View of Cann.

Alternatively, to the extent CT imaging is found not to be quantitative, it would have been obvious to the POSA to combine Pelc and Rothman with Cann, which teaches quantitative densitometry. Ex. 1007 (Sonka) ¶295. A POSA would have been motivated to use the calibration phantom and process disclosed Cann to obtain a more accurate model of densitometry of the tissue of interest. *Id.*; *see also* § IX.B.1.a. 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 quantitative process taught by Cann in combination with Pelc given the minimal modifications required, such as the use of a phantom and the established use of CT for densitometrical purposes by the priority date. *Id*. For the same reasons, incorporation of the quantitative CT system taught by Cann would not impact any of the combinations discussed below. *Id.*

b. Controller

Pelc discloses 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"); 18:10-12 (motor operated "under the control of computer"); 18:22-24 (same). Pelc teaches that the "computer" may be a "general purpose computer." *Id.* at 35:17-21. This computer would be understood to necessarily include memory. Ex. 1007 (Sonka) ¶¶297-98; *see also* '659 IPR at Paper 10 at 46-47 (relying on Pelc's disclosure of an electronic computer, alone or in view of the combinations presented).

c. Storing tomographic models of dental structure

The controller taught by Pelc is capable of storing CT models. *Id*. Pelc refers to "[a] mass storage device" connected to the computer that "provides a means for storing…image data for future reference by the user." Ex. 1015 at 36:1-3. The POSA would understand that "image data" in this context includes digital tomographic models. Ex. 1007 (Sonka) ¶298; *see also* '659 IPR at Paper 10 at 46-47 (relying on Pelc's disclosure of a mass storage device, alone or in view of the combinations presented).

d. Input device

Pelc teaches an input device connected to the computer. *Id*. at ¶¶299-300. 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; *see also* '659 IPR at Paper 10 at 47-48 (relying on Pelc's disclosure of computer 56, display terminal 58, and keyboard 60, alone or in view of the combinations presented).

e. Positioning motor

Pelc discloses this limitation. The Pelc system "includes a track for moving a pallet with respect to a patient along a first and second perpendicular axis. A collar is attached to the pallet and holds a C-arm which may slide through the collar so that its ends rotate to one of a plurality of angles about the patient." *Id*. at 5:24-27. The C-arm is positioned by "actuator 63," which is "driven by a stepper motor…under the control of computer 56…." *Id.* at 18:7-14; *see also id.* at 35:9-13 ("The control system of a CT imaging system suitable for use with the present invention has gantry motor controller 242…."); *id.* at 35:28-31 ("The speed and position of table 12…is communicated to and controlled by computer 56 by means of table motor controller 250."); Ex. 1007 (Sonka) ¶301; *see also* '659 IPR at Paper 10 at 48-49 (relying on Pelc's disclosure of actuator 63 and a stepper motor, alone or in view of the combinations presented).

f. X-ray equipment

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.

Pelc discloses the radiation source "includes an x-ray tube together with filter and collimator…." *Id*. at 14:24-25; *see also id.* at 22:10-11. The POSA would understand this to mean the equipment includes a restricted beam device. Ex. 1007 (Sonka) ¶¶303-305; *see* Fig. 8 (collimator 68 outlined in red, below); *see also* '659 IPR at Paper 10 at 48-49 (relying on Pelc's disclosure of a radiation source and a detector, alone or in view of the combinations presented).

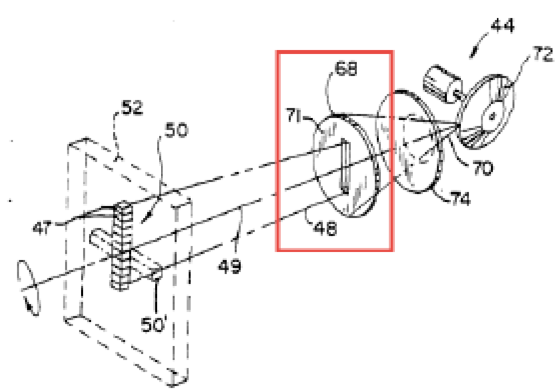


FIG. 8

Further, as of the priority date, CT devices were required to use restricted beam devices, and a POSA would understand that Pelc inherently includes a restricted beam device. Ex. 1007 (Sonka) ¶306.

g. Converter

Pelc discloses this limitation. Pelc teaches that analog-to-digital converters are necessary in digital imaging systems such as those disclosed in Pelc:

> The detector elements receiving the transmitted radiation produce electrical signals which may be **converted to digital values by an analog to digital converter** for the later development of an image or for other processing by computer equipment. The ability to quantify the measurement of the transmitted radiation, implicit in the digitization by the analog to digital converter, allows not only the formation of a radiographic 'attenuation' image but also the mathematical analysis of the composition of the attenuating material by dual energy techniques.

Ex. 1015 at 2:1-10 (emphasis added); *see also id.* at 33:34-34:16; Fig. 19. A POSA would understand that Pelc's CT system, which uses a computer to process digital data for imaging purposes, necessarily includes an analog-to-digital converter that translates the signal information from the detector array into digital format. Ex. 1007 (Sonka) ¶308; *see also* '659 IPR at Paper 10 at 50-51 (relying on Pelc's disclosure of an analog-to-digital converter, alone or in view of the combinations presented).

h. Output device

Pelc discloses this limitation. 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) ¶309; *see also* '659 IPR at Paper 10 at 51 (relying on Pelc's disclosure of a CRT display, alone or in view of the combinations presented).

2. Dependent Claim 7

Pelc discloses this limitation, and accordingly this claim is anticipated. This claim is further obvious over Pelc alone, Pelc and Rothman, or Pelc, Rothman, and Cann, all in further combination with the knowledge of a POSA. Pelc has an X-ray source that emits a "cone beam," Ex. 1015 at 22:10-14, as shown in Figure 8 (annotated with red to show relevant feature).

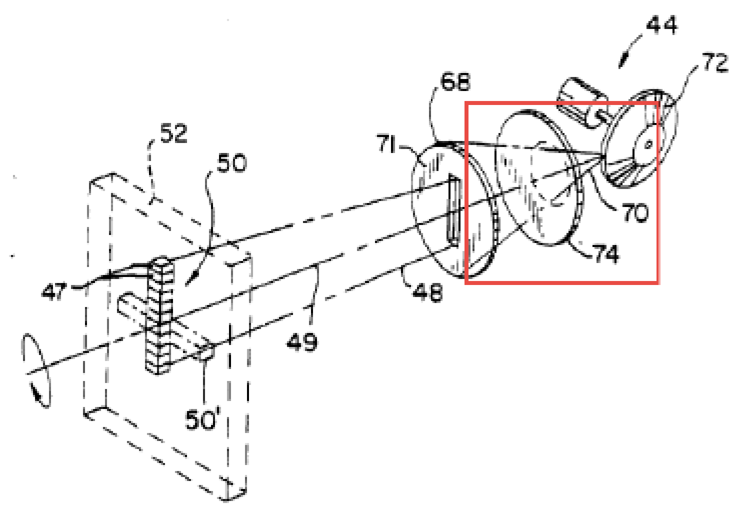


FIG. 8

Also, claim 7 of Pelc recites "an x-ray tube for producing a substantially conical beam of radiation…." *Id.* at 45:1-5; *see also* '659 IPR at Paper 10 at 52-55 (relying on Pelc's disclosure, alone or in view of the combinations).

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Alternatively, this limitation describes an obvious modification to Pelc's system in light of the knowledge of a POSA. That is, if Pelc does not expressly disclose a cone beam, it would have been obvious to a POSA to use a cone beam in connection with the Pelc system as of the priority date based on the long-standing knowledge and use of cone beam CT, and its advantages in allowing the reconstruction of many CT slices with only one rotation around the patient, limiting the radiation dose and time required for a scan. *See, e.g.*, Ex. 1021 (Bushberg) at 272-73; Ex. 1007 (Sonka) ¶¶311-14. A POSA would have had a reasonable expectation of success in integrating this known CT technology into Pelc's CT apparatus. Ex. 1007 (Sonka) ¶314.

3. Dependent Claims 2 and 8

Pelc discloses this limitation, and accordingly these claims are anticipated by Pelc. These claims are further obvious over Pelc; Pelc and Rothman; or Pelc, Rothman, and Cann. And with respect to claim 8, in further combination with the knowledge of a POSA.

Pelc discloses the use of a dual-energy restricted beam device, and identifies dual-energy scanning as one of its central features. *Id.* at ¶¶316-17. It teaches that dual energy techniques are desirable because they "quantitatively compare the attenuation of radiation at two energies to distinguish, for example, between bone and soft tissue" and "allow the measure of bone mass…." Ex. 1015 at 2:14-17; *see* *also id.* at 6:25-29 (system "may produce separate attenuation measurements indicating attenuation at two energy levels."). Sections V.C-F of Pelc describe dual-energy computed tomography in detail. *See generally id.* at 33:3-40:36; *see also* '659 IPR at Paper 10 at 52-55 (relying on Pelc's disclosure, alone or in view of the combinations).

4. Dependent Claims 3 and 9

Pelc discloses this limitation, and accordingly these claims are anticipated by Pelc. These claims are further obvious over Pelc; Pelc and Rothman; or Pelc, Rothman, and Cann. And with respect to claim 9, in further combination with the knowledge of a POSA.

Pelc teaches generating 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 25:34-26:1. Ex. 1007 (Sonka) ¶321; *see also* '659 IPR at Paper 10 at 52-55 (relying on Pelc's disclosure, alone or in view of the combinations).

Alternatively, this limitation describes an obvious modification to Pelc's system in light of the knowledge of a POSA. As discussed above, *see* § IX.B.4, Osseo has disclaimed any contention that use of a CT imaging system to generate a 3D tomographic model was inventive as of the priority date of the '374 patent. Ex. 1012 (SJ Hearing Transcript) at 21:21-22:4 ("It was known. We're not professing that that's the invention."). A POSA would have been motivated to modify Pelc to provide 3D models as of the priority date, as that was the common use of CT imaging and well within the skill of the art (as Osseo admitted). Ex. 1007 (Sonka) ¶321. For example, Rothman teaches that "with CT it is possible to generate three-dimensional images from the same data set," and describes in detail how multiple tomographic slices can be compiled to create a 3D model of the region of interest, specifically within the context of dental CT imaging. Ex. 1016 at 7.

5. Dependent Claims 4 and 10

Pelc discloses this limitation, and accordingly these claims are anticipated by Pelc. These claims are further obvious over Pelc; Pelc and Rothman; or Pelc, Rothman, and Cann. And with respect to claim 10, in further combination with the knowledge of a POSA.

Pelc discloses a system with an X-ray source that rotates around a single axis. Ex. 1007 (Sonka) ¶¶323-29. "The fan beam and detector array may be mounted to the c-arm so that the fan beam and the detector array may rotate about a fan beam axis connecting the radiation source and the detector array." Ex. 1015 at 7:9-12. Pelc further teaches that this system can simultaneously move along that axis of rotation (via "longitudinal rails…which allow the gantry pallet…to be positioned longitudinally)." *Id.* at 13:34-14:2; *see also* Figs. 1, 6, 9, 15, 18, 19; *see also* '659 IPR at Paper 10 at 52-55 (relying on Pelc's disclosure, alone or in view of the combinations).

Pelc further teaches that this movement can be simultaneous: "[t]ogether, motion of the pallet 34 and slider 36 permit a scanning by the detector 50 and radiation source 44 of the densitometer 10…." *Id.* at 14:32-34; *see also id.* at 21:18-35 (further describing the "rotation of the detector and fan beam").

6. Dependent Claims 5 and 11

Claims 5 and 11 require the controller to have the capability to compare "a preexisting, commercially available standard model" with "a current patient model." These claims are further obvious over Pelc; Pelc and Rothman; or Pelc, Rothman, and Cann, all in further view of Xu and/or Milestone. And with respect to claim 11, in further combination with the knowledge of a POSA.

As discussed above, *see* § IX.B.6, the '374 patent has a very limited disclosure of the purported comparison feature of its invention, beyond admitting that means for comparing tomographic models were known in the prior art. Ex. 1001 at 2:26-31. And Osseo has admitted that "one of skill in the art would know how to compare two sets of data in a computer," and that, as of the priority date, there existed commercially-available software that could be purchased that performs a comparison as claimed. Ex. 1012 (SJ Hearing Transcript) at 17:23-18:21.

A POSA would understand that comparisons of medical images, including CT images, are routinely performed for purposes of diagnosis and tracking treatment, and sought out by medical professionals on a regular basis. *See* Ex. 1007 (Sonka) at ¶¶95-97; 331-32. As admitted by the '374 patent, such comparisons could be between a patient's current scan and standard models, or between the patient's current and prior scans. Ex. 1001 at 2:26-31; Ex. 1007 (Sonka) at ¶332. As of the priority date of the '374 patent, it was well-known to a POSA that a microprocessor could be programmed with software to perform these comparisons, and a POSA would be motivated to do so. *See supra* § IX.B.6; *see also* Ex. 1007 (Sonka) ¶332; *see also* '659 IPR at Paper 10 at 52-55 (relying on Pelc's disclosure, alone or in view of the combinations).

A "preexisting, commercially available model" is by definition available to the POSA. A POSA would have been motivated to adapt the microprocessor in Pelc to perform comparisons between a pre-existing commercial model and a patient's current model, as stored in those memories, for the reasons discussed above, and would have had a reasonable expectation of success in doing so given the advanced state of the art as admitted by Osseo. Ex. 1007 (Sonka) ¶332.

7. Dependent Claims 6 and 12

Claims 6 and 12 are substantially identical to claims 5 and 11. The only difference is that the comparison in claims 6 and 12 is between a patient's pre-existing model (*i.e.*, a previous scan) and the patient's current model. The analysis for claims 5 and 11 applies equally here, as such comparisons were known in the prior art and a POSA would be motivated to utilize them in connection with Pelc for reasons of diagnosis and treatment for the reasons discussed. *Id*. These claims are accordingly obvious over Pelc; Pelc and Rothman; or Pelc, Rothman, and Cann, all in further view of Xu and/or Milestone. Ex. 1007 (Sonka) ¶333. And with respect to claim 12, in further combination with the knowledge of a POSA.

8. Independent Claims 13 and 21

Claims 13 and 21 are obvious over Pelc; Pelc in combination with Rothman; or Pelc, Rothman and Cann; all in further combination with Xu and/or Milestone.

Claims 13 and 21 are substantially similar to each other, and to claim 1:

<u>Claim 13 vs. Claim 21</u>. The only difference between claims 13 and 21 is the preamble. Claim 21's preamble recites a "dental structure" whereas claim 13 does not. For the reasons discussed with claim 1, the preamble is not limiting. To the extent it is limiting, Petitioner has addressed those limitations with respect to claim 1. *See supra* § IX.C.1.

Claims 13 and 21 vs. Claim 1. Independent claims 13 and 21 are similar to independent claim 1. Ex. 1007 (Sonka) ¶¶334-46. Petitioner's discussion of claim 1 is incorporated here by reference. *See supra* § IX.C.1. The limitations of claims 13 and 21 differ from claim 1 in that they recite a controller "being adapted for creating, storing, and comparing 3D digital tomographic models of an object without the use of fiducial markers of said object." This limitation is addressed below.

a. Creating, storing and comparing tomographic models

The creation of tomographic models was addressed in connection with the description of Pelc and the discussion of claim 1's preamble. *See supra* §§ IX.A.3, IX.C.1.a. The storage of tomographic models by Pelc's system was addressed with respect to claim 1's "adapted for storing" limitation. *See supra* § IX.C.1.c. The comparison of tomographic models, satisfied by Pelc, Pelc and Rothman, or Pelc, Rothman and Cann, in further combination with Xu and/or Milestone, was addressed with respect to claims 5, 6, 11, and 12. *See supra* §§ IX.C.1a, 6-7; Ex. 1007 (Sonka) ¶337.

b. 3D digital tomographic models

A POSA would understand that the controller disclosed in Pelc is adapted to create 3D models, or that it would be obvious to modify it to do so. *See supra* § IX.C.4 (claims 3 and 9); Ex. 1007 (Sonka) ¶338.

c. “Without the use of fiducial markers”

With respect to this limitation, the CT system in Pelc does not use “fiducial markers.” Ex. 1007 (Sonka) ¶339. Just as the ‘374 patent specification does not discuss the usage 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 Pelc 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 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.*

9. Dependent Claims 17 and 23

Pelc’s disclosure of a system “wherein said X-ray source emits an X-ray beam comprising a cone configuration,” *see supra* § IX.C.2 (claim 7), renders these claims obvious over Pelc; Pelc and Rothman; or Pelc, Rothman, and Cann; all in further combination with Xu and/or Milestone, and with the knowledge of a POSA. Ex. 1007 (Sonka) ¶340.

10. Dependent Claims 14, 18, 22, and 24

Pelc's disclosure that its "restricted beam device comprises a dual-energy level restricted beam device," *see supra* § IX.C.3 (claims 2 and 8), renders these claims obvious over Pelc; Pelc and Rothman; or Pelc, Rothman, and Cann; all in further combination with Xu and/or Milestone; and (with respect to claims 18, 22, and 2) further in combination with the knowledge of a POSA. Ex. 1007 (Sonka) ¶341.

11. Dependent Claims 15 and 19

These claims recite "said controller is adapted to compare a pre-existing tomographic model with a current tomographic model." They are obvious over Pelc; Pelc and Rothman; or Pelc, Rothman and Cann, all in further view of Xu and/or Milestone, as discussed above, and (with respect to claim 19) in further view of the knowledge of a POSA. *See supra* §§ IX.C.6-7 (claims 5, 6, 11 and 12); Ex. 1007 (Sonka) ¶342.

12. Dependent Claims 16 and 20

Pelc's disclosure of a system where "said x-ray source travels along a single axis; and said x-ray source simultaneously rotates around said single axis" *see supra* §§ IX.C.5 (claims 4 and 10), renders these claims obvious over Pelc; Pelc and Rothman; or Pelc, Rothman and Cann, all in further view of Xu and/or Milestone, as discussed above, and (with respect to claim 20) in further view of the knowledge of a POSA. Ex. 1007 (Sonka) ¶343.

X. CONCLUSION

With this Petition, Petitioner has established a reasonable likelihood that the challenged claims of the '374 patent will be found unpatentable. Petitioner therefore respectfully requests that *inter partes* review of the '374 patent be granted, and that Claims 1–24 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. 8,498,374 on March 26, 2025 upon the following:

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