UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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VARIAN MEDICAL SYSTEMS, INC.
Petitioner

v.

WILLIAM BEAUMONT HOSPITAL
Patent Owner

U.S. Patent No. 6,842,502
Filing Date: February 16, 2001
Issue Date: January 11, 2005

Title: CONE BEAM COMPUTED TOMOGRAPHY WITH A FLAT PANEL IMAGER

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PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,842,502

Inter Partes Review No. 2015-___

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List of Exhibits

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1102	Declaration of Dr. James Balter ("Balter Decl.")
1103	U.S. Patent No. 5,207,223 issued to Adler *et al.* ("Adler")
1104	U.S. Patent No. 5,427,097 issued to Depp ("Depp")
1105	P.S. Cho *et al.*, *Cone-beam CT for radiotherapy applications*, Phys. Med. Biol., 40:1863-83 (1995) ("Cho")
1106	L.E. Antonuk *et al.*, *Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging*, IEEE Transactions on Medical Imaging, 13:482-90 (1994) ("Antonuk")
1107	D.A. Jaffray *et al.*, *Exploring "Target Of The Day" Strategies for A Medical Linear Accelerator With Conebeam-CT Scanning Capability*, Proceedings of the 12th International Conference on the Use of Computers in Radiation Therapy, Medical Physics Publishing, pp. 172-75 (1997) ("Jaffray 1997")
1108	A.L. Boyer, *Laser "cross-hair" sidelight*, Med. Phys., 5:58-60 (1978) ("Boyer")
1109	Apr. 20, 2004 Office Action
1110	Jan. 23, 2004 Applicant's Remarks
1111	P. Munro, *Portal Imaging Technology: Past, Present, and Future*, Seminars in Radiation Oncology, 5:115-33 (Apr. 1995) ("Munro 1995")
1112	Feb. 16, 2001 Application
1113	P.J. Biggs *et al.*, *A Diagnostic X Ray Field Verification Device For A 10 MV Linear Accelerator*, Int'l J. Radiation Oncology Biol. Phys., 11:635-43 (1985) ("Biggs 1985")

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1114	A. Ezz *et al.*, *Daily Monitoring and Correction of Radiation Field Placement Using a Video-Based Portal Imaging System: A Pilot Study*, Int'l J. Radiation Oncology Biol. Phys., 22:159-65 (1991) ("Ezz 1991")
1115	W. De Neve *et al.*, *Routine clinical on-line portal imaging followed by immediate field adjustment using a tele-controlled patient couch*, Radiotherapy & Oncology, 24:45-54 (1992) ("De Neve 1992")
1116	T.R. Mackie *et al.*, *Tomotherapy: A new concept for the delivery of dynamic conformal radiotherapy*, Med. Phys., 20:1709-19 (Nov./Dec. 1993) ("Mackie 1993")
1117	R. Sephton *et al.*, *A diagnostic-quality electronic portal imaging system*, Radiotherapy & Oncology, 35:204-47 (1995) ("Sephton 1995")
1118	M.C. Kirby *et al.*, *Clinical Applications of Composite and Realtime Megavoltage Imaging*, Clinical Oncology, 7:308-16 (1995) ("Kirby 1995")
1119	J.M. Michalski *et al.*, *Prospective Clinical Evaluation of an Electronic Portal Imaging Device*, Int'l J. Radiation Oncology Biol. Phys., 34:943-51 (1996) ("Michalski 1996")
1120	D. Yan *et al.*, *Adaptive radiation therapy*, Phys. Med. Biol., 42:123-32 (1997) ("Yan 1997")
1121	D. Yan *et al.*, *The Use of Adaptive Radiation Therapy to Reduce Setup Error: A Prospective Clinical Study*, Int'l J. Radiation Oncology Biol. Phys., 41:715-20 (1998) ("Yan")
1122	M.A. Mosleh-Shirazi *et al.*, *A cone-beam megavoltage CT scanner for treatment verification in conformal radiotherapy*, Radiotherapy & Oncology, 48:319-28 (1998) ("Mosleh-Shirazi 1998")

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Ex. No.	Description of Document
1123	S. Webb *et al.*, *Tomographic Reconstruction from Experimentally Obtained Cone-Beam Projections*, IEEE Transactions on Medical Imaging, MI-6:67-73 (Mar. 1987) ("Webb 1987")
1124	D.A. Jaffray *et al.*, *Dual-Beam Imaging for Online Verification of Radiotherapy Field Placement*, Int'l J. Radiation Oncology Biol. Phys., 33:1273-80 (1995) ("Jaffray 1995")
1125	S.M. Midgley *et al.*, *A Feasibility Study For The Use Of Megavoltage Photons And A Commercial Electronic Portal Imaging Area Detector For Beam Geometry CT Scanning To Obtain 3D Tomographic Data Sets Of Radiotherapy Patients In The Treatment Position*, Proceedings of the 4th Int'l Workshop of Electronic Portal Imaging, Amsterdam, 1996, Abstract No. 60 (2 pages) (1996) ("Midgley 1996")
1126	J. Wong *et al.*, *Initial clinical experience with a gantry mounted dual beam imaging system for setup error localization*, Int'l J. Radiation Oncology Biol. Phys., 42(Suppl. 1):138 (Abstract 28) (1998) ("Wong 1998")
1127	L.E. Antonuk *et al.*, *Demonstration of megavoltage and diagnostic x-ray imaging with hydrogenated amorphous silicon arrays*, Med. Phys., 19:1455-66 (Nov./Dec. 1992) ("Antonuk 1992")
1128	L.E. Antonuk *et al.*, *A Real-Time, Flat-Panel, Amorphous Silicon, Digital X-ray Imager*, RadioGraphics, 15:993-1000 (1995) ("Antonuk 1995")
1129	J. Chabbal *et al.*, *Amorphous Silicon X-ray Image Sensor*, Proceedings of SPIE (Society of Photographic Instrumentation Engineers), 2708:499-510 (1996) ("Chabbal 1996")
1130	R. Ning *et al.*, *Selenium Flat Panel Detector-Based Volume Tomographic Angiography Imaging: Phantom Studies*, Proceedings of SPIE (Society of Photographic Instrumentation Engineers), 3336:316-24 (Feb. 1998) ("Ning 1998")

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1131	R. Ning *et al.*, *Flat panel detector-based cone beam volume CT imaging: detector evaluation*, Proceedings of SPIE (Society of Photographic Instrumentation Engineers), 3659:192-203 (Feb. 1999) ("Ning 1999")
1132	U.S. Patent No. 6,041,097 issued to Roos *et al.* ("Roos 1998")
1133	J.H. Siewerdsen *et al.*, *Signal, noise power spectrum, and detective quantum efficiency of indirect-detection flat-panel imagers for diagnostic radiology*, Med. Phys., 25:614-28 (May 1998) ("Siewerdsen 1998")
1134	A.T. Redpath *et al.*, *Chapter 6: Simulator Computed Tomography*, pp. 169-89, in *The Modern Technology of Radiation Oncology*, J. Van Dyk (ed.) (1999) ("Redpath 1999")

Petitioner Varian Medical Systems, Inc. ("Petitioner") respectfully submits this Petition for *Inter Partes* Review of claims 1-14, 16-29, 33, and 35-38 of U.S. Patent No. 6,842,502 **[Ex. 1101]** ("the '502 patent").

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

A. Real Party-ln-lnterest Under 37 C.F.R. § 42.8(b)(1)

In addition to petitioner Varian Medical Systems, Inc., VMS International AG and its two Dutch parent companies, VMS Nederland Holdings BV and VMS Nederland BV, are real parties-in-interest.

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

The '502 patent is the subject of one pending litigation involving the Petitioner: *Elekta Ltd. v. Varian Medical Systems, Inc.*, Case No. 2:15-cv-12169-AC-MKM (E.D. Mich. June 15, 2015), in which the patent owner contends that the Petitioner infringes the '502 patent. The Petitioner was served with a complaint in that action on September 3, 2015.

Petitioner is concurrently filing an additional petition for *inter partes* review of claims 1-14, 16-29, 33, and 35-38, based on unique legal grounds and prior art. Petitioner is also seeking *inter partes* review of method claims 43-46, 48-55, 57, 59, 60-66, and 68 of the '502 patent through two additional concurrentaly filed petitions.

C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Heidi L. Keefe (Reg. No. 40,673) (lead) hkeefe@cooley.com zpatdcdocketing@cooley.com COOLEY LLP ATTN: Patent Group 1299 Pennsylvania Ave., NW, Suite 700 Washington, DC 20004 Tel: (650) 843-5001 Fax: (650) 849-7400	Daniel J. Knauss (Reg. No. 56,393) dknauss@cooley.com zpatdcdocketing@cooley.com COOLEY LLP ATTN: Patent Group 1299 Pennsylvania Ave., NW, Suite 700 Washington, DC 20004 Tel: (650) 843-5287 Fax: (650) 849-7400

D. Service Information

The Petitioner may be served at the address provided above in Part I.C for lead and back-up counsel, and consents to electronic service at those addresses.

II. PAYMENT OF FEES - 37 C.F.R. § 42.103

This Petition requests review of 33 claims of the ’502 patent, therefore excess claim fees are required. A payment of $32,800 is submitted herewith, which comprises a $11,600 request fee and a post-institution fee of $21,200. *See* 37 C.F.R. § 42.15(a). This Petition meets the requirements of 35 U.S.C. § 312(a)(1).

III. REQUIREMENTS FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. §§ 42.104 AND 42.108

A. Grounds for Standing under 37 C.F.R. § 42.104(a)

The Petitioner certifies that the ’502 patent is available for *inter partes* review, and that the Petitioner is not barred or otherwise estopped from requesting *inter partes* review on the grounds identified in the present Petition. The Petitioner is unaware of any previous petition for *inter partes* review of the ’502 patent.

B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Statement of Precise Relief Requested

The Petitioner respectfully requests that the Board initiate *inter partes* review of claims 1-14, 16-29, 33, and 35-38. This Petition cites the following prior art references, submitted as Exhibits **1103** through **1108**:

Ex. No.	Description of Document
1103	U.S. Patent No. 5,207,223 issued to Adler *et al.* ("Adler")
1104	U.S. Patent No. 5,427,097 issued to Depp ("Depp")
1105	P.S. Cho *et al.*, *Cone-beam CT for radiotherapy applications*, Phys. Med. Biol., 40:1863-83 (1995) ("Cho")
1106	L.E. Antonuk *et al.*, *Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging*, IEEE Transactions on Medical Imaging, 13:482-90 (1994) ("Antonuk")
1107	D.A. Jaffray *et al.*, *Exploring "Target Of The Day" Strategies for A Medical Linear Accelerator With Conebeam-CT Scanning Capability*, Proceedings of the 12th International Conference on the Use of Computers in Radiation Therapy, Medical Physics Publishing, pp. 172-75 (1997) ("Jaffray 1997")
1108	A.L. Boyer, *Laser "cross-hair" sidelight*, Med. Phys., 5:58-60 (1978) ("Boyer")

The grounds on which this Petition is based are listed in the table below.

Ground	Claim(s)	Basis for Challenge
1	1-8, 10-14, 16-29, 33, and 35-38	Obvious over Cho, Antonuk, Jaffray 1997, and Adler/Depp (§ 103(a))
2	9	Obvious over Cho, Antonuk, Jaffray 1997, Boyer, and Adler/Depp (§ 103(a))

Sections **VII-D** and **VIII-C** below provide a detailed explanation as to why the challenged claims are unpatentable based on these grounds.

This Petition also submits the accompanying Declaration of Dr. James Balter, an expert with over 20 years of experience in the fields of radiation oncology and medical physics. (*See* Balter Decl., **[Ex. 1102]**, ¶¶ 2-5.) Dr. Balter's declaration includes additional exhibits (Exs. 1111-1134), relied on by Dr. Balter as providing further information regarding the relevant technology and the state of the art at the relevant time.

C. Requirements for *Inter Partes* Review 37 C.F.R. § 42.108(c)

The Board should institute *inter partes* review of claims 1-14, 16-29, 33, and 35-38 because this Petition establishes a reasonable likelihood of prevailing with respect to each challenged claim. *See* 35 U.S.C. § 314(a). Each limitation of these claims is disclosed and/or suggested by the prior art, as explained in detail below.

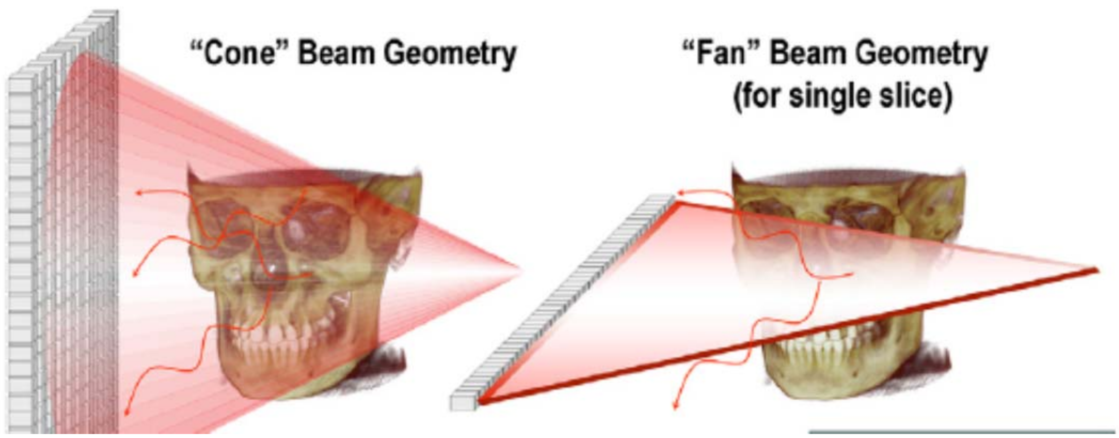
IV. BRIEF BACKGROUND OF THE UNDERLYING TECHNOLOGY

A. Radiotherapy and Image Guidance

Radiation therapy or "radiotherapy" is the use of beams of radiation for the treatment of disease. Radiation therapy of internal patient lesions, such as cancerous tumors, is very old – dating back over 100 years. For decades, practitioners have known that the effectiveness of radiation therapy is increased when imaging is used to ensure that the radiation therapy beam is applied as narrowly as possible to a tumor while minimizing exposure to surrounding healthy tissues. (*See* Ex. 1102, ¶ 14.) Indeed, the first known instance of using x-ray imaging to improve the accuracy of radiation therapy dates back to the 1940s. (*Id.*, ¶¶ 15-16.) The corollary concept that imaging should be done close in time to when the radiation is delivered is likewise very old. As explained by Dr. Balter, the field of radiation therapy has consistently maintained its focus on combining imaging with radiation therapy, and the ’502 patent did nothing to shift the direction of the field. (*Id.*, ¶¶ 14-17.)

B. 3-D Computed Tomography with Flat Panel Imagers

The field of 3-D computed tomography (“CT”) imaging using x-rays was fully developed well in advance of the earliest possible priority date listed on the face of the ’502 patent. By this time it was already well known that high quality 3-D images of patient internal structures could be obtained using x-ray technology and computer imaging systems. (*Id.*, ¶¶ 18-20.) In brief, these prior art systems used an x-ray source and imager to collect a multitude of x-ray projection images at different angles around the patient. Initially, these CT systems worked through a “stack-of-slices” approach in which several 2-D images were stacked on top of each other to form a 3-D image. The underlying 2-D CT images were obtained one at a time by rotating an x-ray source emitting a “fan” shaped beam around a patient and then progressively translating the patient through the scanner. By the mid-1990s, however, systems were available that obtained 3-D images in a single rotation using a technology called "cone-beam" CT ("CBCT"). As the name suggests, CBCT works by using a large x-ray field shaped in a cone rather than a thin "fan-beam." The figure below contrasts the fan-beam and cone-beam approaches to CT that were well established by 1999:



Central to the utility of this cone-beam approach were detectors that could receive x-ray cone-beam projection data. By the mid 1990s, the field of large flat-panel detector arrays had developed to meet this need. The art was unequivocal that such flat panel imagers were an obvious choice for large field x-ray imaging, stating in 1994 that "[t]he recent development of large-area, flat-panel a-Si:H imaging arrays is generally expected to lead to realtime diagnostic and megavoltage x-ray projection imagers …." (*See* Ex. 1102, ¶ 46.) Thus before the '502 applicants began their work, it was already known that CBCT imaging could be improved by the use of a large flat panel image detector to facilitate rapid acquisition of 3-D CT image data obtained from a single rotation of the imaging system around the patient.

C. The ’502 Patent Did Not Advance the Art

The ’502 patent generally relates to a cone-beam computed tomography (“CBCT”) imaging system that employs x-rays detected by a flat-panel imager (“FPI”) on a radiotherapy system. In the systems described by the ’502 patent, the patient is imaged while in position for treatment with a beam of radiation. (’502, 1:12-18.) As described by the applicants, CBCT (as opposed to other forms of medical imaging such as traditional x-ray or magnetic resonance) is used to obtain three-dimensional patient information which can be used to better guide therapeutic radiation to a target lesion such as a tumor. (*Id.*, 1:20-22; 3:40-4:2.)

The systems claimed in the ’502 patent were nothing more than the combination of known elements, with each element performing its well-known function. The applicants’ assembly of old elements provided results just as would be expected by one of skill in the art. As described fully herein, it was known in the field of radiotherapy to use diagnostic (kV) x-rays on a radiotherapy gantry to obtain images for real-time control of a radiation source. It was also known to use kV x-rays for cone beam imaging on a linear accelerator gantry because of its superior image quality. A combined CBCT/FPI system was also known, and indeed it was known to use the exact type of flat panel imager used in this prior art

CBCT system on a radiotherapy system. Because of the known benefits of CBCT, the known benefits of image-guided radiotherapy, and the express teaching in the prior art to use the same flat panel imager of the prior art CBCT system on a radiotherapy gantry, it was obvious to apply the prior art CBCT/FPI system to control the prior art radiotherapy system because of the known benefits of improved imaging. (*See also* Ex. 1102, ¶¶ 21-22.)

In fact, the ’502 patent does not claim any inventive elements in assembling these old components. The claims merely recite systems employing a CBCT-FPI in combination with a radiotherapy device, but the ’502 applicants did not invent the use of CBCT with an FPI to obtain 3-D images of a patient. Nor did they invent the use of x-ray images as a means for guiding a radiation source. Instead, the applicants claimed the concept of performing image guided radiotherapy “based on one rotation” of the x-ray source around the object, and seek to exclude others from using it. This concept has also long been known in the field of computed tomography and radiation oncology. The ’502 patent does nothing more than assemble known components to achieve an expected result. Thus the assembly (and the claimed methods of using it) were obvious, and the claims of the ’502 patent should not have been issued.

V. SUMMARY OF THE ’502 PATENT

A. The Specification and File History of the ’502 Patent

The ’502 patent is entitled “Cone Beam Computed Tomography with a Flat Panel Imager.” It describes a radiotherapy system with a cone-beam x-ray source coupled to an FPI for providing 3-D images of a patient, all under computer control, and methods of using the same for patient radiotherapy. The specification describes embodiments of this basic system employing aspects such as a motorized table for movement of the patient, the use of kV x-rays, and the use of amorphous silicon imagers as an FPI. The specification also describes a benefit of CBCT in the ability to obtain 3-D images from a single rotation of the x-ray gantry around the patient. Finally, the specification describes an embodiment in which the radiotherapy source is controlled based on the CBCT scan of the patient.

During prosecution, applicants originally sought broad claims to radiotherapy systems with a radiation source, cone-beam x-ray source and FPI, and computerized control of the radiation source based on the CBCT image. But as Examiner Ho noted, every one of these limitations were already known in the prior art “Swerdloff,” “Hu,” and “Roos” references:

> [T]he prior art discloses a radiation therapy system comprising a radiation source, a con-beam [sic] computed tomography system comprising an x-ray source and a flat-panel imager receiving x-rays after they pass through the object, the imager providing an image of

> the object, and a computer controls the path of the radiation source based on the image ….

(Ex. 1109, Apr. 20, 2004 Office Action, at 6.)

In response to rejections based on these prior art image-guided radiotherapy systems combined with CBCT-FPI systems, the applicants amended their claims to specify that the image "contains at least three dimensional information of said object based on one rotation of said x-ray source around said object." This amendment was the sole basis for Examiner Ho's allowance of the claims:

> [T]he prior art fails to teach or fairly suggest that the image contains at least three-dimensional information of the object based on one rotation of the x-ray source around the object as claimed.

(*Id*.) As explained below, the prior art Cho reference, which was not considered by the Examiner, did in fact disclose the element the Examiner believed was missing.

B. The Challenged Claims of the '502 Patent

This Petition addresses claims 1-14, 16-29, 33, and 35-38. The challenged claims include one independent claim and 32 dependent claims directly or indirectly depending from claim 1. Claim 1 is reproduced below:

Claim 1
A radiation therapy system comprising:
a radiation source that moves about a path and directs a beam of radiation towards an object;
a cone-beam computed tomography system comprising: an x-ray source that emits an x-ray beam in a cone-beam form towards said object,

Claim 1
a flat-panel imager receiving x-rays after they pass through the object, said imager providing an image of said object,
wherein said image contains at least three dimensional information of said object based on one rotation of said x-ray source around said object;
and a computer connected to said radiation source and said cone beam computed tomography system, wherein said computer receives said image of said object and based on said image sends a signal to said radiation source that controls said path of said radiation source.

The remaining challenged claims are all dependent claims that incorporate the above limitations by reference, but add nothing of patentable significance. The specific arguments of invalidity of all challenged claims are set forth in detail in the specific grounds below.

VI. CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(b)(3)

A claim subject to *inter partes* review must be given its "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). As the Federal Circuit has recognized, the "broadest reasonable" construction standard is fundamentally different from the manner in which the scope of a claim is determined in litigation. *See In re Swanson*, 540 F.3d 1368, 1377-78 (Fed. Cir. 2008). Accordingly, the constructions proposed in this Petition represent the broadest reasonable interpretation that one of ordinary skill in the art would assign to the terms below, and not necessarily the construction that would be appropriate in litigation.[1] For claim terms not addressed below, Petitioner has applied the plain and ordinary meaning of those terms.

A. "based on one rotation"

This term appears in independent claim 1. The proper construction of this term is "based on a single complete, 360° degree rotation." The term was added during prosecution to differentiate the prior art references. Specifically, the '502 applicants argued that the prior art cited by the Examiner did not render the claims obvious because they could not form a usable 3-D image based on a single complete rotation of the CBCT-FPI system around the object. Instead, applicants argued, these prior art systems required multiple rotations around the object in a helical or spiral scan approach in order to generate a 3-D image. For example, the applicants stated that the prior art x-ray device "could not form a usable image <u>based on just one rotation</u> of the x-ray source …." (*See* Ex. 1110, Jan. 23, 2004 Applicant Remarks, at 37 (emphasis added).)

The claims of the patent reciting this element, therefore, should be construed such that a single full rotation (through 360°) around the object being imaged is required. This construction comports with the express teachings of the

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[1] Petitioner reserves the right to seek different constructions for terms of the '502 patent claims, as appropriate, in district court litigation.

specification. For example, in the "Preferred Embodiments," the specification refers to the CBCT system of Figure 3 and states:

> The flat plane [sic] imager **326** is positioned such that the piercing point (i.e., the intersection of the central ray and the image plane) is centered on the imaging array (i.e., between columns #**256** and #**257**, ±0.01 mm), with a quarter-pixel offset applied to give improved view sampling for <u>cone beam computerized tomography acquisitions in which the object **316** is rotated through 360°</u>.

('502, 7:64-8:4 (emphasis added).) Thus, one of skill in the art would understand that the "based on one rotation" element of the claims means that the CBCT system necessarily requires a single complete, 360° rotation around the object to obtain its 3-D image (*See* Ex. 1102, ¶¶ 35-36.)

B. "three dimensional information"

This term appears in independent claim 1. The term should be construed as "information concerning three dimensions of an object (such as length, width, and depth)." This construction is confirmed by the specification, which states that three-dimensional information is obtained from a plurality of 2-D images obtained from different angles. ('502, 3:40-43 ("a cone beam computerized tomography system reconstructs three-dimensional (3-D) images from a plurality of two-dimensional (2-D) projection images acquired at various angles about the subject.").) One of ordinary skill in the art would understand "three-dimensional information" as "information concerning three dimensions of an object (such as length, width, and depth)." (*See* Ex. 1102, ¶ 37.)

C. "a computer connected to said radiation source and said cone beam computed tomography system, wherein said computer receives said image of said object and based on said image sends a signal to said radiation source that controls said path of said radiation source"

This term appears in independent claim 1. The element generically recites a computer and the function it performs: receiving 3-D information and based on that 3-D information sending a signal that controls the path of the radiation source. This purely functional computer term is not a description of structure, and no structure for performing the claimed function is recited elsewhere in the claim. Accordingly, the term is governed by the means-plus-function limitations of 35 U.S.C. §112(6).[2] *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (en banc).

There is no structure disclosed in the specification for programming the general-purpose computer to perform the recited function. *WMS Gaming Inc. v.*

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[2] Section 112 was amended and subsections were renamed by the America Invents Act ("AIA"), Pub. L. No. 112-29, § 4(c), 125 Stat. 284, 296 (2011). Because the application that led to the '502 patent was filed before September 16, 2012, the pre-AIA version of § 112(6) (now referred to as § 112(f)) applies.

Int'l Game Tech., 184 F.3d 1339, 1349 (Fed. Cir. 1999) ("In a means-plus-function claim in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm."). What meager structural description is linked to the recited function in the specification is not a sufficient algorithm to comply with the requirements of § 112(6) for computer-implemented claims. The specification states broadly that the control function can be performed by "[a] computer … connected to the radiation source and the [CBCT] system, wherein the computer receives the image of the object and based on the image sends a signal to the radiation source that controls the path of the radiation source." ('502, 4:57-62.) The flow charts (and accompanying text) likewise merely restate the claimed function of controlling the radiation path based on the 3-D image. ('502, 27:15-23, 27:40-28:19, Figs. 24 & 26.) This disclosure is insufficient to comply with the algorithm requirements of § 112(6). *Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1317 (Fed. Cir. 2012) ("purely functional language, which simply restates the function associated with the means-plus-function limitation, is insufficient to provide the required corresponding structure.").

As explained by Dr. Balter, the specification's disclosure is insufficient algorithm structure because it contains no description of *how* to reposition the object based on the 3-D information obtained from the CBCT system to obtain the claimed control. (*See* Ex. 1102, ¶¶ 38-40.) The absence of corresponding structure for performing the claimed function, as required by § 112(6), renders the claims of the ’502 patent that include this element invalid for indefiniteness.

Nevertheless, should the Board conclude that the term is not indefinite under § 112(6), then this claim element should be construed as a means-plus-function element, whose structure includes an algorithm based on the meager functional restatements provided in the specification (and equivalents thereof) as required by § 112(6). (’502, 4:57-62, 27:15-23, 27:40-28:19, Figs. 24 & 26.) Under this view, the claims are invalid as obvious because structure for performing the claimed function, at least at the level of detail of the ’502 specification, was already taught in the prior art. (*See* Ex. 1102, ¶ 41.)

VII. GROUND 1 – CLAIMS 1-8, 10-14, 16-29, 33, AND 35-38 ARE OBVIOUS OVER CHO, ANTONUK, JAFFRAY 1997, AND ADLER/DEPP UNDER 35 U.S.C. § 103(a)

A. Introductory Comments

As noted, above, Petitioner has concurrently submitted another petition challenging the same claims based on different prior art, asserting that the claims are not entitled to the ’590 provisional claimed on the cover of the ’502 patent. However, there is a theoretical possibility that Patent Owner can establish that it is entitled to priority based on the ’590 provisional – which Petitioner denies as explained in its concurrent petition. In light of this theoretical possibility, however, Petitioner submits the grounds in this petition, relying only on references that qualify as § 102(b) art regardless of which priority date is accorded to the claims. Petitioner respectfully requests institution of *inter partes* review of the challenged claims based on the grounds in both petitions because each presents unique, non-redundant issues central to the patentability of the challenged claims.

B. Prior Art and Date Qualification for Ground 1

Each limitation of claims 1-8, 10-14, 16-29, 33, and 35-38 is disclosed or suggested by P.S. Cho *et al.*, *Cone-beam CT for radiotherapy applications*, Physics in Medicine and Biology, 40:1863-83 (1995) **[Ex. 1105] ("Cho")**, L.E. Antonuk *et al.*, *Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging*, IEEE Transactions on Medical Imaging, 13:482-90 (1994) **[Ex. 1106] ("Antonuk"),** D.A. Jaffray *et al.*, *Exploring "Target Of The Day" Strategies for A Medical Linear Accelerator With Conebeam-CT Scanning Capability*, Proceedings of the 12th International Conference on the Use of Computers in Radiation Therapy, Medical Physics Publishing, pp. 172-75 (1997) **[Ex. 1107] ("Jaffray 1997")**, U.S. Patent No. 5,207,223 issued to Adler *et al.*, published on May 4, 1993 **[Ex. 1103] ("Adler")**, U.S. Patent No. 5,427,097 issued to Depp, published on June 27, 1995 **[Ex. 1104] ("Depp")**.[3] Each of these references qualify as prior art under at least § 102(b) (pre-AIA) because they were published more than one year before February 18, 2000, the filing date of the earliest application appearing on the face of the ’502 patent. Cho, Antonuk and Adler/Depp were not considered by the Examiner prior to issuance of the patent.

C. Brief Description of Cho, Antonuk, Jaffray 1997, and Adler/Depp

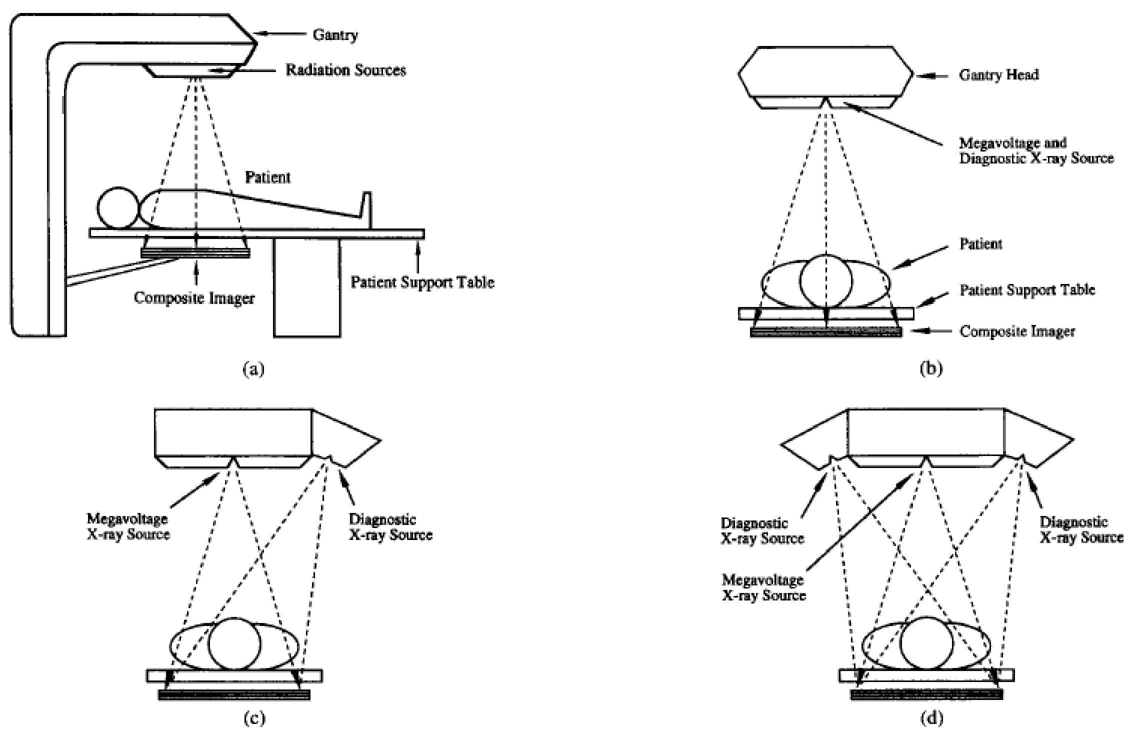
Cho [Ex. 1105], entitled "Cone-beam CT for radiotherapy applications," discloses the use of cone beam CT for patient imaging in the treatment position on a radiotherapy simulator. Cho notes that detector size was an existing limitation in 1995 for the clinical implementation of CBCT. (*See* Cho, at 5.) Cho discloses the use of the same Feldkamp algorithm referenced in the ’502 patent for 3-D image reconstruction from a plurality of 2-D cone-beam projection images. (*See* ’502, 11:9-21.) Also like the ’502 applicants, Cho obtained 3-D image date by rotating the gantry through 360°, using diagnostic x-rays of approximately 100 kV. (*See* Cho, at 15-16.) Cho also reported the benefits of using kV CBCT for

[3] As discussed below, Adler and Depp are treated as a single reference for this petition because Depp expressly incorporates Adler by reference and describes itself as an improvement of Adler's disclosure. The disclosures are collectively referred to herein as "Adler/Depp."

differentiation of soft tissue. (*See id.*, at 22.) Cho also expressly suggested the use of amorphous silicon FPIs to solve the problem of detector size for rapid acquisition of 3-D images using CBCT, citing to **Antonuk**. (*See id.*, at 24.)

Antonuk [Ex. 1106], entitled "Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging," describes the development of amorphous silicon FPIs for use in diagnostic imaging in the radiotherapy setting. Specifically, Antonuk teaches the dual use of kV and MV "real-time flat panel composite imagers" "helping to resolve the patient localization and verification problem in megavoltage radiography." (Antonuk, at 3.) Antonuk taught that radiotherapy could be improved by reduction of uncertainty about the location of the tumor within the patient's healthy surrounding anatomy, and that "[I]t is widely perceived that part of the solution is to obtain imaging information with the portal beam immediately prior to and/or during the treatment." (*Id.*, at 5.) As Antonuk recognized, the state of the art in 1994 included use of megavoltage imaging devices to obtain patient location verification. (*Id.*) Antonuk explained, however, that "[a] major limitation in the general approach of using only the megavoltage images is the limited spatial and contrast resolution of the resulting images…. In comparison, diagnostic x-ray images offer excellent spatial and contrast resolution due to the dominance of photoelectric interactions." (*Id.*) As explained elsewhere in Antonuk, "diagnostic x-ray images" refers to images obtained using x-ray beams of kV rather than MV energy. (*See id.*, at 3 (defining diagnostic quality x-rays as having energies of 20 to 150 kVp); *see also* Ex. 1102, ¶ 46.)

Antonuk proposed mounting a kV imager on an MV radiotherapy device and using a single dual-energy detector to capture both kV and MV images:



(Antonuk, at 7 (Fig. 5).) The flat panel imager of Antonuk "would be attached to the gantry of the therapy machine thereby rotating with it in the same fashion as present real-time megavoltage imagers." (*Id.*, at 6.) Antonuk disclosed the use of FPI detectors for realtime patient imaging. (*Id.*, at 3.) Antonuk also taught using kV x-rays in cone-beam form with image detection by a flat panel. (*See id.*, at 8.)

Jaffray 1997 [Ex. 1107], entitled "Exploring 'Target Of The Day' Strategies for A Medical Linear Accelerator with Conebeam-CT Scanning

Capability," discloses the use of CBCT on a medical linear accelerator. (Jaffray 1997, at 4.) Jaffray 1997 suggests that radiotherapy could be improved by imaging systems coordinated with radiotherapy: "A solution to the dose limits imposed by margins is to locate the clinical target and surrounding normal structures on a fraction-by-fraction basis." (*Id.*) Indeed, Jaffray 1997 recognized that this suggestion was not new: "Other investigators have recognized the potential advantages of integrating a volumetric imaging system with the radiation delivery system." (*Id.*) Jaffray 1997 described the addition of a cone-beam system to a radiotherapy device: "To this end, we are developing a [CBCT] scanner for installation on our medical linear accelerator." (*Id.*) The authors expected the integration of CBCT onto a medical linear accelerator to be successful: "Current imaging technology should allow the construction of a conebeam computed tomography imaging system which is capable of providing image quality comparable to conventional CT at a modestly higher dose." (*Id.*) The authors disclosed the integration of a CBCT imaging system into a medical linear accelerator system, all mounted on a gantry that would obtain three-dimensional image data by rotating around the patient:

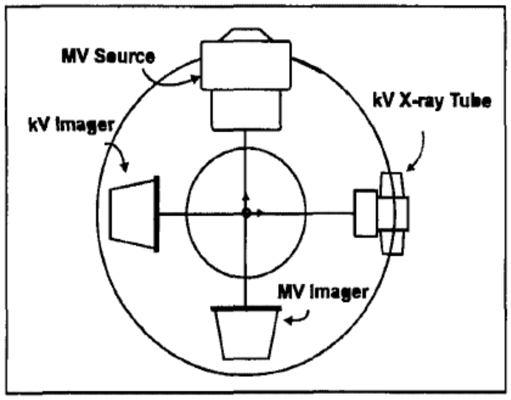


Figure 1: Schematic of dual-beam system to be used for conebeam computed tomography (CBCT). The kV x-ray beam is orthogonal to the treatment beam.

(*Id.*, at 5 (Fig. 1).) The authors employed a CCD-camera for the purpose of obtaining an image from the x-ray source. (*Id.*, at 4.)

Adler [Ex. 1103], entitled "Apparatus for and Method of Performing Stereotaxic Surgery," discloses systems for selectively irradiating a target within a patient. Adler discloses use of diagnostic x-ray imaging, 3-D image mapping of target lesions, and adjustment of the radiotherapy source if needed to ensure targeted delivery of the radiation dose. Like the '502 applicants, Adler recognized the benefit of accurately targeting high doses of radiation to a tumor while avoiding unnecessary irradiation of surrounding healthy tissues. (Adler, 3:34-52.) To solve the problem of prior localization of tumor targets within a patient, Adler provides a system in which a 3-D "map" of the patient is compared against diagnostic x-ray scans, to obtain "the real time location of the target region" within the patient. (*Id.*, 5:10-39.) Based on this real-time information, the relative position of the radiosurgical apparatus and the patient can be adjusted to ensure proper aim at the target region. (*Id.*)

As shown in Figure 4 of Adler, the process is under computer control, in which x-ray image information is processed and control signals are sent to the "linac manipulator" which controls the therapeutic beam:

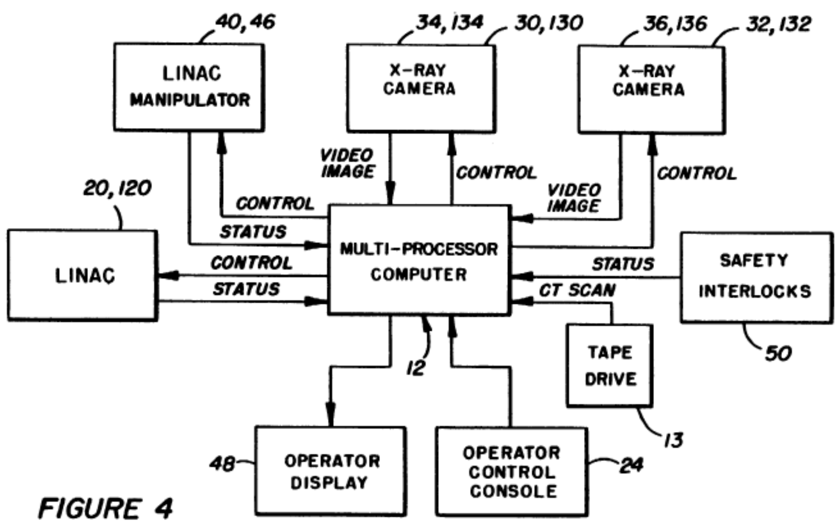


FIGURE 4

SYSTEM BLOCK DIAGRAM

(*Id.*, Fig. 4.)

Depp [Ex. 1104] shares a similar title and the same assignee as Adler and describes itself as describing improvements to the method and apparatus disclosed in Adler, which Depp incorporates by reference. (Depp, 1:12-17.) Among other improvements, Depp describes "a unique temporal procedure for operating the radiosurgical beam and the diagnostic target locating beams in order to continuously locate the target region in substantially real time." (*Id.*, 7:42-45.)

Thus, Depp expressly teaches a device in which diagnostic patient images are used to ensure proper targeting of the radiation source in real time.

D. Cho, Antonuk, Jaffray 1997, and Adler/Depp Disclose Each Limitation of Claims 1-8, 10-14, 16-29, 33, and 35-38 and Were Obvious to Combine

1. Challenged Independent Claim 1

The preamble of claim 1 recites: "A radiation therapy system comprising." Although the preamble may not be limiting under its broadest reasonable construction, Adler/Depp, Antonuk, and Jaffray 1997 disclose it. Adler/Depp discloses a radiotherapy system configured for selectively irradiating a target within a patient. (*See* Adler, Abstract, 3:62-68; Depp, Abstract, 1:6-12, 1:18-26; *see also* Ex. 1102, ¶¶ 51-52.) As shown in Figure 1 of Adler, for example, Adler/Depp disclose a system for delivering radiotherapy to a patient:

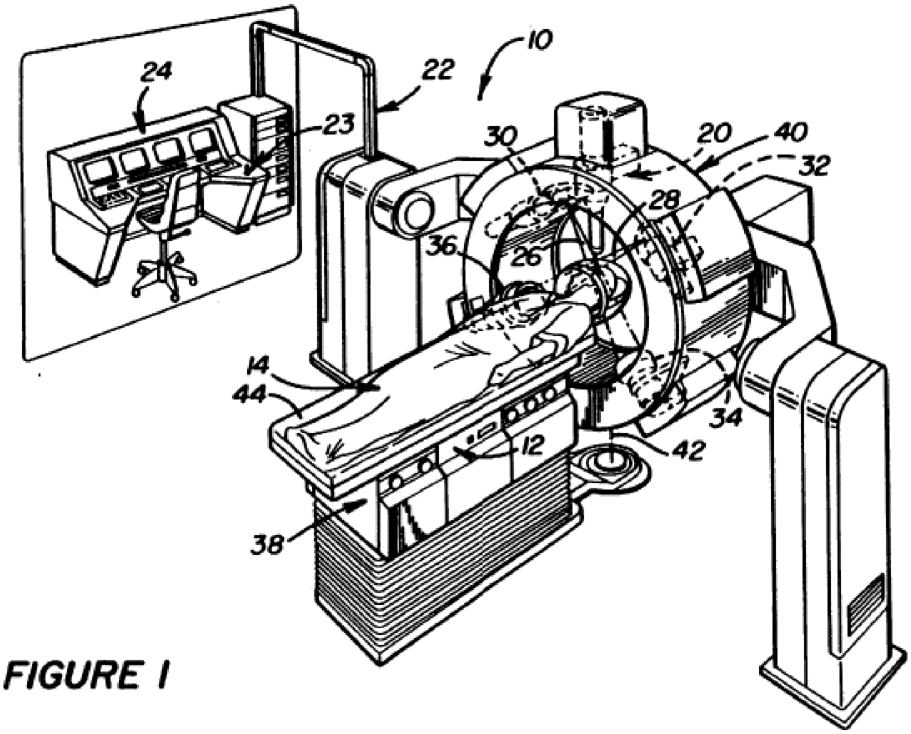


FIGURE I

(Adler, Fig. 1; *see also* Depp, Fig. 1.)

Adler/Depp also teaches an alternative embodiment in which the radiation source is contained in a mechanism having six degrees of movement freedom (as opposed to being within the gantry **40** shown in Adler's Figure 1). (*See* Adler, Fig. 3; *see also* Depp, Fig. 3.) Finally, as discussed in Section VII-C above, Antonuk and Jaffray 1997 also expressly disclose a radiotherapy system using a medical linear accelerator device.

a. "a radiation source that moves about a path and directs a beam of radiation towards an object"

As discussed in the preceding section, Adler/Depp teaches systems with a radiation source that moves with respect to the patient (the "object") and directs a beam of radiation toward that object: "A beaming apparatus **20** is provided which, when activated, emits a collimated surgical ionizing beam of a strength sufficient to cause the target region **18** to become necrotic." (Adler, 6:44-47; *see also* Depp, 4:19-22.) As explained by Adler/Depp, their radiation source moves:

> The broad range of adjustment of the relative positions of the gantry **40** and the patient **14** allows the collimated beam to be continuously focused on the target region while the healthy tissue through which the collimated beam passes is changed, as by rotating the beaming apparatus **20** through as much as 360° about the patient.

(Adler, 7:52-58; *see also* Depp, 5:25-31.) As explained by Dr. Balter, the reference to a medical linear accelerator would have been understood by one of ordinary skill in the art as a teaching of a system comprising a radiation source that moves about a path and directs a beam of radiation toward an object (usually a radiotherapy patient). (*See* Ex. 1102, ¶¶ 54-55.) For the same reason, this claim element is also taught by Antonuk and Jaffray 1997, both of which disclose medical linear accelerators that possess this claim element. (*See id.*)

b. "a cone-beam computed tomography system comprising: an x-ray source that emits an x-ray beam in a cone-beam form towards said object"

Cho and Jaffray 1997 both expressly disclose a CBCT x-ray system that moves around the object, emitting multiple x-ray beams in cone-beam form. Cho describes "development of a cone-beam CT system for radiotherapy applications."

(Cho, at 5.) The publication details the construction of a CBCT system for generating a 3-D image by rotating an x-ray source around an object. "The projection data were obtained by rotating the gantry over 360° at approximately 1° increments." (*Id.*, at 15.) "The scans were performed using 100 kV x-rays except for the chest scan in which case 120 kV was used." (*Id.*, at 16.) Cho notes that their system used an "SLS simulator," which was an Elekta product. As explained by Dr. Balter, this disclosure is an express teaching of passing multiple x-ray beams in cone beam ("CB") form through said object from different angles. (*See* Ex. 1102, ¶ 56.)

Jaffray 1997 also discloses 3-D imaging using a cone beam CT apparatus mounted to a linear accelerator: "[w]e are developing a conebeam-computed tomography (CB-CT) scanner for installation on our medical linear accelerator." (Jaffray 1997, at 4.) Jaffray 1997 discussed the mounting of this system on an Elekta SL-20 linear accelerator, and provided an image of the arrangement (reproduced above in Section VII-C). (*See id.*, at 5 (Fig. 1).) Jaffray 1997 also teaches obtaining 3-D information from a plurality of 2-D projection images obtained by rotating the gantry around the patient. (*Id.*) Thus, like Cho, this reference expressly teaches passing multiple cone-beam x-rays through an object from multiple angles. (*See* Ex. 1102, ¶ 57.)

As explained by Dr. Balter, the Antonuk reference also teaches the use of cone-beam x-ray CT imaging, because the x-ray source of Antonuk emits x-rays in a cone beam form for detection on a large 2-D array in the form of an FPI. Indeed, as explained by Dr. Balter, any x-ray source emits beams in cone-beam geometry, unless that x-ray source further comprises a collimator to shape the beam into a fan shape or other geometry. Thus, as Dr. Balter explains, the x-ray beam paths shown in Figure 5 of Antonuk expressly show x-rays being emitted in a cone-beam shape. (*See* Ex. 1102, ¶ 58.)

c. "a flat-panel imager receiving x-rays after they pass through the object, said imager providing an image of said object"

Cho expressly teaches the use of an amorphous silicon flat panel imager to detect the cone-beam x-ray projection images. According to Cho, flat panel imagers would be advantageous for solving the problem of detector size in large-area 3-D CT imaging:

> Further increase in volume of reconstruction can be accomplished by … using a larger detector. The flat panel detector based on amorphous silicon (a-Si:H) technology is being developed as a potential real-time diagnostic x-ray imager (Antonuk *et al* 1994).

(Cho, at 24.) As noted above, Cho specially refers to Antonuk for its FPI.

Antonuk provides detailed disclosures of flat panel imagers for use as diagnostic x-ray detectors mounted on a linear accelerator for imaging during radiotherapy. (Antonuk, at 3.) As explained by Dr. Balter, these FPI devices function as x-ray detectors by detecting multiple x-ray beams that pass through the object being imaged, for example as shown in Figure 5 of Antonuk. (*See* Ex. 1102, ¶¶ 59-60.)

Antonuk also provides an overview of the structure and operation of flat panel imager technology.

> The rapidly emerging technologies of thin-film transistors and photodiodes, under intense development for active matrix liquid crystal displays, solar cells, scanners, and copiers, have, over the last few years, been adapted to create the first two-dimensional, self-scanning amorphous silicon (a-Si:H) imaging arrays. Recently, the first high-quality, diagnostic and megavoltage x-ray images of low-contrast anatomical detail have been demonstrated using this new technology.

(Antonuk, at 3 (citations omitted).) Antonuk also separately discloses a flat panel imager receiving a plurality of 2-D x-rays in the geometry of a positron emission tomography machine: "Several a-Si:H x-ray detectors rotate with an x-ray tube collecting <u>conebeam</u> projection data inside the bore of a PET machine …." (*Id.*, at 8 (emphasis added).) As confirmed by Dr. Balter, one of ordinary skill in the art would understand these teachings as disclosures of the use of an FPI to receive x-rays passing through an object for providing an image of the object. (*See* Ex. 1102, ¶ 60.)

d. "wherein said image contains at least three dimensional information of said object based on one rotation of said x-ray source around said object"

This limitation was expressly taught by Cho: "The projection data were obtained by rotating the gantry over 360° at approximately 1° increments." (Cho, at 15; *see also id.*, at 22 ("For our method, data were available through a full 360° rotation ….").) Cho thus taught obtaining 3-D information about an object based on a single full rotation of the x-ray source gantry relative to the object. Cho further discloses this element by teaching a computer-assisted system to create 3-D image based on a plurality of 2-D projection images from the cone-beam x-ray. Cho is directed to generating 3-D images based on 2-D CBCT scans using a modified Feldkamp algorithm. (*See* Cho, at 15-16 (discussing the scanning of CT phantom models using this approach); *id.*, at 17 (discussing image processing and use of reconstruction algorithms on a computer).) As explained by Dr. Balter, one of skill in the art would recognize Cho as teaching creation of a 3-D image based on one rotation of the CBCT system. (*See* Ex. 1102, ¶ 61.) Furthermore, the image reconstruction methodology employed by Cho, such as the Feldkamp algorithm, was well-known and in standard use for this purpose before 1999. (*See id*.)

Adler/Depp teaches the use of three-dimensional information about the object based on a plurality of 2-D projection images, because Adler/Depp teaches obtaining two x-ray images ("diagnostic beams **26** and **28**") at a "known non-zero angle relative to one another." (Adler, 7:6-12.) These beams are received by "[i]mage receivers **34** and **36**" and the resulting signals are passed to the "microprocessor **12**." (*Id.*, 7:17-23.) As confirmed by Dr. Balter, these images provide three-dimensional information. (*See* Ex. 1102, ¶ 62.)

e. "and a computer[4] connected to said radiation source and said cone beam computed tomography system, wherein said computer receives said image of said object and based on said image sends a signal to said radiation source that controls said path of said radiation source"

Adler teaches a computer ("the processor **12**") that is coupled to the x-ray imaging system, receives image information, and based on the image information, sends a signal to the radiation source to control its path. Adler teaches obtaining two x-rays ("diagnostic beams **26** and **28**") at a "known non-zero angle relative to one another." (Adler, 7:6-12.) These beams are received by "[i]mage receivers **34** and **36**" and the resulting signals are passed to the "microprocessor **12**." (*Id.*, 7:17-

[4] As discussed above in Section VI-C, this means-plus-function claim element is invalid for indefiniteness. Nevertheless, to the extent that its scope can be understood, Petitioner has shown it is disclosed in the prior art.

23.) Adler/Depp then teaches control of positioning based on this image: "[m]eans are provided for adjusting the relative position of the beaming apparatus **20** and the patient **14** as needed in response to data which is representative of the real time location of the target region **18** …." (*Id.*, 7:37-40.) Adler/Depp teaches that this adjusting may be done by moving the radiation source in the gantry or by moving the patient table:

> In the particular embodiment illustrated in FIG. 1 the means for adjusting the relative positions of the beaming apparatus and the patient comprises a gantry **40** to which the beaming apparatus **20**, the diagnostic x-ray generators **30** and **32** and the image receivers **34** and **36** are mounted along with conventional apparatus for lowering and raising the operating table **38** and for rotating it about an axis **42** and for tilting the top **44** of the operating table **38** about a longitudinally extending axis, all as illustrated by arrows in FIG. 2. The broad range of adjustment of the relative positions of the gantry **40** and the patient **14** allows the collimated beam to be continuously focused on the target region while the healthy tissue through which the collimated beam passes is changed, as by rotating the beaming apparatus **20** through as much as 360° about the patient.

(Adler, 7:42-58.) Finally, Adler/Depp notes that "FIG. 4 illustrates, in system block diagram form, operation of the logic by which the apparatus of FIG. 1 … can be controlled." (Adler, 8:32-34.) As Adler/Depp explains, "[s]ignals from the image receivers **34**,**134** and **36**,**136** are passed to the processor **12**." (Adler, 8:36-

38.) Then, "[s]ignals from the processor **12** are passed to … the gimbal **40** thus controlling its positioning …." (*Id.*, 8:43-47.) As confirmed by Dr. Balter, these teachings would have been recognized by one of ordinary skill in the art as an express disclosure of a system comprising a computer connected to a moveable radiation source and a diagnostic x-ray imaging system, controlling the position of the radiation source based on multiple x-rays images. (*See* Ex. 1102, ¶¶ 63-64.)

Depp also teaches this element. Depp contains similar disclosures as Adler. (Depp, 6:13-40.) Depp further teaches that:

> The apparatus also utilizes a pair of [] diagnostic beams of radiation or target locating beams…. These beams are passed through the surrounding area containing the target region and reference points and, after passing through the surrounding area, contain data indicating the positions of the reference points within the surrounding area. This position data is collected by cooperating detectors, as described previously, and delivered to the multiprocessor computer where the latter compares it with previously obtained reference data for determining the position of the target region with respect to each of the reference points during each such comparison. The radiosurgical beam is accurately directed into the target region in substantially real time based on this information.

(Depp, 11:46-61.) As confirmed by Dr. Balter, one of skill in the art would recognize in these teachings an express disclosure of this claim element. (*See* Ex. 1102, ¶ 65.)

2. Motivation to Combine Cho, Antonuk, Jaffray 1997, and Adler/Depp

Claim 1 is obvious because all elements of the claim were taught by the prior art, as explained above, and because one of ordinary skill in the art would have been motivated to combine them. As discussed above, during prosecution the Examiner was readily able to combine a prior art radiation therapy system (Swerdloff) with a prior art CBCT-FPI system (Hu and Roos), but believed the only element of the claims missing from the prior art was obtaining a 3-D image based on one rotation of the x-ray source around the object. However, as shown above, this element was shown expressly in the Cho reference, which was not before the Examiner.

It was known in radiotherapy to use diagnostic (kV) x-rays on a radiotherapy gantry to obtain diagnostic quality images to effect real-time control of a radiation source (Adler/Depp). It was also known to use cone beam imaging because of its superiority for 3-D imaging based on single rotation scanning (Cho and Jaffray 1997), and indeed it was known to use the exact type of flat panel imager used in the preferred embodiment of the ’502 patent (Cho and Antonuk). Because of the known benefits of CBCT, the known benefits of image-guided radiotherapy, and the express teaching in the prior art to use the same flat panel imager of the prior art CBCT system on a radiotherapy gantry, it was obvious to use the prior art

CBCT/FPI system to control the prior art radiotherapy system because of the known benefits of improved imaging. Adler/Depp does not disclose the use of a CBCT-FPI system for performing this x-ray imaging, but it would have been obvious to obtain these elements from the Cho and Antonuk references to improve the accuracy of Adler/Depp's imaging during radiotherapy. As explained by Dr. Balter, CBCT-FPI was one of only a finite number of choices the artisan had in order to provide an obvious improvement on the radiation therapy control systems of Adler/Depp, and indeed the art specifically suggested this assembly. (*See* Ex. 1102, ¶¶ 66-68.)

One of skill in the art would have been motivated to combine the CBCT and FPI teachings of Cho with Jaffray 1997. Both articles teach a system to address problems in administering radiotherapy. While Jaffray 1997 discloses a need to confirm the precise location of the area targeted for radiation with CBCT, (*see* Jaffray 1997, at 4), Cho specifically states that its CBCT method can be used "for the purpose of treatment planning" in radiotherapy. (*See* Cho, at 22.) Cho further expressly suggests the use of an FPI as an x-ray detector, and cites the Antonuk reference, which provides detailed disclosures of flat panel imagers for use as diagnostic x-ray detectors mounted on a linear accelerator for imaging during radiotherapy.

It was also obvious to combine these teachings of Cho, Antonuk, and Jaffray

1997 with the radiotherapy system teachings of Adler/Depp. For example, Jaffray 1997 expressly suggests the usefulness of its disclosure in obtaining image-guided radiotherapy, and suggests the use of a cone beam x-ray system for this purpose:

> A solution to the dose limits imposed by margins is to locate the clinical target and surrounding normal structures on a fraction-by-fraction basis. Allowing complete elimination of margins for beam placement discrepancies and target motion. Other investigators have recognized the potential advantages of integrating a volumetric imaging system with the radiation delivery system. In this article, a discussion of a 'Target of the Day' approach is presented with respect to the development of a medical linear accelerator with conebeam CT scanning capability…. Current imaging technology should allow the construction of a conebeam computed tomography imaging system which is capable of providing image quality comparable to conventional CT at a modestly higher dose…. For these reasons, we have begun to pursue the construction of a conebeam CT (CBCT) scanner for integration with a medical linear accelerator.

(Jaffray 1997, at 4 (citations omitted).) Antonuk provides a similar express suggestion: "It is widely perceived that part of the solution is to obtain imaging information with the portal beam immediately prior to and/or during the treatment." (Antonuk, at 5.) Finally, Adler/Depp teaches that improved x-ray image based targeting, in real-time, of internal lesions such as tumors is desirable to avoid irradiation of healthy surrounding tissues, and Cho provides an improved method for acquiring volumetric (3-D) CT image data using CBCT and an FPI. (*See* Adler, 2:49-53, 3:34-42, 5:40-54; Depp, Abstract, 1:55-65, 2:48-53, 11:54-61; Cho, at 24.)

Adler and Depp should be treated as a single reference because Depp states that it is an improvement of Adler, and incorporates it by reference. (*See* Depp, 5:35-55, 7:31-47.) One of skill in the art would be motivated to combine the Cho, Antonuk, and Jaffray 1997 references with Adler/Depp because all the references are in the same field of medical imaging in conjunction with radiation therapy and all are concerned with the problem of obtaining accurate 3-D information about the internal structure of objects like patients. (*See* Adler, 1:6-18; Depp, 1:6-18; Cho, at 5; Antonuk, at 3, 5; Jaffray 1997, at 4.) As explained by Dr. Balter, the results obtained by the inventors (obtaining 3-D image information concerning target lesions in patients for the purpose of targeting the radiation source) were the predictable work of combining the CBCT-FPI system of the Cho and Antonuk references with the radiotherapy systems of Adler/Depp. (*See* Ex. 1102, ¶¶ 69-71.) Accordingly, the claimed combination was obvious. *See* MPEP § 2141 (III); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 298, 419-20 (2007); *see also Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.*, IPR2014-00204, Paper No. 31 at 29 (P.T.A.B. Mar. 31, 2015).

3. Dependent Claims – kV X-rays

a. Claim 2

Claim 2 depends from claim 1 and adds the limitation "wherein said x-ray source comprises a kV x-ray source." Cho provides express disclosure of a kV beam source: "The scans were performed using 100 kV x-rays except for the chest scan in which case 120 kV was used." (Cho, at 16.)

Antonuk also provides express disclosure of this limitation: "An array detects the incident radiation indirectly by means of an x-ray converter placed on or over the surface of the array. For diagnostic quality X rays (20 to 150 kVp), the converter may be a phosphor screen, a channelled-light scintillator such as CsI(TI) or fiber-optic scintillator, or some other suitable scintillator." (Antonuk, at 3.) Antonuk further expressly discloses the mounting of such a diagnostic x-ray system (defined as 20 to 150 kVp) on a megavoltage radiotherapy device: "a composite diagnostic-megavoltage imager consisting of a pair of flat-panel imagers would be a relatively compact device much better suited to the space constraints of this application. In particular, it could be used to correlate details of the patient anatomy, obtained from the diagnostic images, with the portal field." (*Id.*, at 5.) As Antonuk explains, "[t]he x-ray source could be (1) an x-ray tube positioned in a retractable position in the head of the gantry; (2) an x-ray tube (or tubes) attached to the side(s) of the gantry; or (3) derived from the treatment beam itself through controlled removal of the flattening filter. These various configurations are illustrated schematically in Fig. 5." (*Id.*, at 6 (citations omitted).) As confirmed by Dr. Balter, one of ordinary skill in the art would have recognized in these teachings an express disclosure of using a kV x-ray as the x-ray source of claim 1.

Jaffray 1997 also provides express disclosure of using kV x-rays: "Two fluoroscopic imaging systems are attached to a Philips SL-20 medical linear accelerator; one detects the megavoltage image, the other a kV image produced with a kV beam projected at 90° to the treatment beam axis." (Jaffray 1997, at 4 (emphasis added).)

One of skill in the art would have been motivated to combine Adler/Depp with the CBCT-FPI kV diagnostic imaging teachings of Jaffray 1997 because it was well-known by those of ordinary skill in the art that kV energy x-ray beams are superior to megavolt energy beams for imaging. As explained by Dr. Balter, the published work in the field clearly disclosed the superiority of kV beams over MV beams for imaging. (*See* Ex. 1102, ¶¶ 73-75.) For example, Antonuk expressly suggests the use of kV x-ray sources:

> A major limitation in the general approach of using only the megavoltage images is the limited spatial and contrast resolution of the resulting images. This is largely due to the dominance of Compton interactions at these energies. In comparison, diagnostic x-ray images offer excellent spatial and contrast resolution due to the dominance of

> photoelectric interactions. Thus, in principle, the addition of diagnostic imaging information concerning the patient position immediately prior to treatment, in combination with the megavoltage portal images showing the relationship of the field edges to the treated volume, should greatly facilitate the goal of better patient localization and verification.

(Antonuk, at 5 (emphasis added).) As noted above and confirmed by Dr. Balter, it was known before 1999 that kV x-ray sources are superior for obtaining diagnostic quality images. (*See* Ex. 1102, ¶ 76.)

b. Claim 5

Claim 5 depends from claim 1 and recites the additional limitation "wherein said x-ray source emits x-rays with energies of approximately 100 kV." Cho, Antonuk, and Jaffray 1997 expressly disclose this element. Cho expressly discloses the additional element of using beams of approximately 100 keV: "The scans were performed using 100 kV x-rays except for the chest scan in which case 120 kV was used." (Cho, at 16.) Antonuk's system as described in the reference employs approximately 100 kV energy x-rays: "An array detects the incident radiation indirectly by means of an x-ray converter placed on or over the surface of the array. For diagnostic quality X rays (<u>20 to 150 kVp</u>), the converter may be a phosphor screen, a channelled-light scintillator such as CsI(TI) or fiber-optic scintillator, or some other suitable scintillator." (Antonuk, at 3 (emphasis added).)

As confirmed by Dr. Balter, this teaching is an express disclosure of the use of cone-beam x-rays with an energy of approximately 100 keV, as recited in the claim. (*See* Ex. 1102, ¶ 77.) Jaffray 1997 also expressly discloses that its "kv image produced with a kV beam" is provided by a generator that can "produce up to 140 kVp x-ray exposures at 300 mA." (Jaffray 1997, at 4.) One of skill in the art would have been motivated to combine Adler/Depp with Cho, Antonuk, and Jaffray 1997 to obtain the method of claim 5 for the same reasons set forth for claim 2.

4. Dependent Claims – Object Stage and Rotation

a. Claims 3, 7, and 10

Claim 3 depends from claim 2 and adds the limitation "further comprising a stage that moves said object relative to said x-ray source and said flat-panel imager." This limitation adds nothing of patentable significance. This element was expressly taught by Adler/ Depp:

> [M]eans for adjusting the relative positions of the beaming apparatus and the patient comprises a gantry **40** to which the beaming apparatus **20**, the diagnostic x-ray generators **30** and **32** and the image receivers **34** and **36** are mounted <u>along with conventional apparatus for lowering and raising the operating table **38** and for rotating it about an axis **42** and for tilting the top **44** of the operating table 38 about a longitudinally extending axis</u>, all as illustrated by arrows in FIG. 2.

(Adler, 7:42-58 (emphasis added).) Depp contains the same express teaching.

(Depp, 5:15-31.)

Antonuk likewise expressly discloses that imaging information obtained "immediately prior to and/or during the treatment" would facilitate "(a) localization of the patient relative to the treatment unit prior to irradiation; and (b) verification of the correct alignment of the patient anatomy with respect to the treatment field edges throughout the irradiation." (*See* Antonuk, at 5 (emphasis added).) Antonuk further teaches performing these methods on a radiotherapy system that is shown to comprise a table for the patient in Figure 5. As explained by Dr. Balter, one of ordinary skill in the art would have recognized in these teachings an express disclosure of the system of claim 3 in which a moveable stage is used to control patient position relative to the radiation source. (*See* Ex. 1102, ¶¶ 78-79.)

Claims 7 and 10 recite the identical limitation. Claim 7 depends from claim 6 and claim 10 depends from claim 1. Claims 6 and 1 are discussed in Sections VII-D-8-a and VII-D-1, respectively.

b. Claims 4, 8 and 11

Claims 4 depends from claim 3 and adds the limitation "wherein said stage rotates about an axis of rotation relative to said x-ray source and said flat-panel imager." Cho expressly discloses this element: "The projection data were obtained by rotating the gantry…." (Cho, at 15; *see also id.*, at 22 ("For our method, data were available through a full 360° rotation ….”).)

As explained by Dr. Balter, the claim recites rotation "relative" to the x-ray source and FPI, which under the broadest reasonable construction means that either the object or the x-ray source must rotate. Thus, from the point of view of the x-ray source, if the x-ray source are mounted on a rotating gantry as suggested by Cho, Antonuk, and Jaffray 1997, the object will "rotate" relative to the x-ray source as the gantry rotates around the object. (*See* Ex. 1102, ¶ 80.)

Adler/Depp also discloses a stage that rotates the object being imaged relative to the x-ray source:

> [T]he means for adjusting the relative positions of the beaming apparatus and the patient comprises a gantry **40** to which the beaming apparatus **20**, the diagnostic x-ray generators **30** and **32** and the image receivers **34** and **36** are mounted along with conventional apparatus for lowering and raising the operating table **38** and for <u>rotating it about an axis **42**</u> and for tilting the top **44** of the operating table **38** about a longitudinally extending axis ….

(Adler, 7:43-52 (emphasis added).) Thus, Adler expressly discloses a stage (operating table **38**) that rotates about an axis (**42**) relative to the x-ray source and FPI.

As explained by Dr. Balter, one of ordinary skill in the art would have been motivated to obtain the method of claim 4 because of the known advantages of a patient stage or table that rotates relative to the axis of rotation of the x-ray source and FPI, and that one of the known benefits of cone-beam CT is the ability to obtain 3-D image information about an object based on a single rotation of the x-ray source relative to the object. (*See* Ex. 1102, ¶¶ 80-82.)

Claims 8 and 11 recite the identical limitation as claim 4. Claim 8 depends from claim 7, and claim 11 depends from claim 10. The invalidity of claims 7 and 10 is explained in Section VII-D-4-a.

c. Claim 13

Claim 13 depends from claim 11 and adds the limitation "wherein said stage translates along said axis of rotation." Adler expressly discloses this limitation because the patient table translates along the same axis of rotation of the gantry in order for the patient to be moved into scanning and treatment position. (*See* Adler, Fig. 1.) Furthermore, as explained by Dr. Balter, linear accelerators such as the ones depicted in Fig. 1 of Adler and Fig. 5 of Antonuk comprise operating tables with the ability to translate, rotate, raise/lower, and tilt so as to properly orient the patient for radiotherapy. (*See* Ex. 1102, ¶ 84.) Indeed, as explained by Dr. Balter, it was a mandatory requirement of standard linear accelerators or CT scanners to use a translating stage for the purpose of positioning the patient during scanning or radiation therapy beam delivery. (*See id*.)

d. Claim 14

Claim 14 depends from claim 13 and adds the limitation "wherein said stage rotates about a second axis of rotation that is perpendicular to said axis of rotation." This element is expressly disclosed by Adler/Depp's teaching of a moveable table supporting the object being imaged. Adler discloses:

> [T]he means for adjusting the relative positions of the beaming apparatus and the patient comprises a gantry **40** to which the beaming apparatus **20**, the diagnostic x-ray generators **30** and **32** and the image receivers **34** and **36** are mounted along with conventional apparatus for lowering and raising the operating table **38** and for <u>rotating it about an axis **42** and for tilting the top **44** of the operating table **38** about a longitudinally extending axis</u> ....

(Adler, 7:43-51 (emphasis added).) Thus, Adler expressly discloses a stage (operating table **38**) that rotates about an axis **42** <u>and</u> rotates about a second, perpendicular axis that is longitudinal relative to the first axis of rotation. Depp contains the same express disclosure. (Depp, 5:16-24.) As explained by Dr. Balter, one of skill in the art would be motivated to use a table with additional flexibility in degrees of rotational freedom to better facilitate patient positioning. (*See* Ex. 1102, ¶¶ 85-86.)

5. Dependent Claims – Flat Panel Imagers

a. Claim 17

Claim 17 depends from claim 1 and adds the limitation "wherein said flat-panel imager comprises an array of individual detector elements." This element is expressly disclosed by Antonuk (which is cited by Cho). Antonuk provides a schematic of the FPI of the system, expressly disclosing the operating configuration of multiple detector elements arranged in an array:

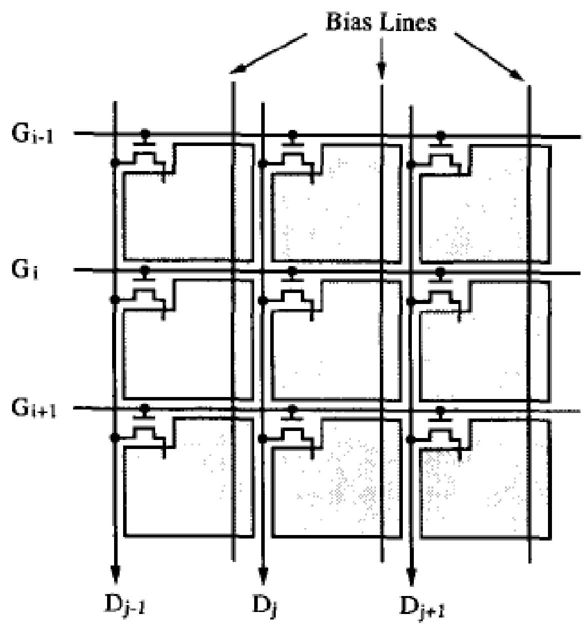


Fig. 2. Schematic diagram of the organization of a portion of a self-scanning, flat-panel a-Si:H imaging array. The sensing elements (shaded rectangular regions) are photodiodes which are coupled to field effect transistors (FETs). The FET control (GATE) lines and DATA lines are designated by symbols $G_{i\pm1}$ and $D_{j\pm1}$, respectively.

(Antonuk, at 4 (Fig. 2).) As Antonuk notes, "[t]he arrays consist of a regular two-dimensional matrix of imaging pixels, illustrated schematically in Fig. 2." (*Id.*, at 3.) As explained by Dr. Balter, this disclosure expressly teaches an array of detector elements (called "sensing elements" in the figure above). As this arrangement is a standard characteristic of an FPI, one of ordinary skill in the art would have been motivated to employ it. (*See* Ex. 1102, ¶¶ 87-88.)

b. Claim 18

Claim 18 depends from claim 17 and adds the limitation "wherein said array is a two-dimensional array." This element is also expressly taught by the same Antonuk disclosure discussed for claim 17 above, which expressly identifies the FPI as a two-dimensional matrix. (*See* Antonuk, at 3.) Indeed, a key part of the motivation to use an FPI is its 2-D array status, which makes it appropriate for detection of the large 2-D projections obtained by using a cone-beam x-ray source. (*See* Ex. 1102, ¶ 89.)

c. Claim 19

Claim 19 depends from claim 17 and adds the limitation "wherein each of said individual detector elements further comprises a-Si:H photodiode." This element is also expressly taught by the same Antonuk 1994 disclosure discussed for claim 17 above. As stated in the legend to Figure 2 reproduced above, the detector element comprises an a-Si:H photodiode. As explained by Dr. Balter, this limitation adds nothing of patentable significance, because the prior art expressly taught the use of FPIs comprising a-Si:H photodiodes, and one of ordinary skill in the art would have been motivated to employ this standard component. (*See* Ex. 1102, ¶ 90.)

d. Claim 20

Claim 20 depends from claim 19 and adds the limitation "wherein each of said individual detector elements further comprises a transistor coupled to said Si:H photodiode." This element is also expressly taught by the same Antonuk disclosure discussed above for claims 17-19. As stated in the legend to Figure 2 reproduced above in Section VII-D-5-a, the detector comprises transistors coupled to the a-Si:H photodiodes ("photodiodes which are coupled to field effect transistors"). As explained by Dr. Balter, this teaching is an express disclosure of transistors coupled to photodiodes. The limitation adds nothing of patentable significance, because the prior art expressly taught the use of FPIs comprising transistors coupled to a-Si:H photodiodes, and one of ordinary skill in the art would have been motivated to use this standard format known for an FPI. (*See* Ex. 1102, ¶ 91.)

e. Claim 38

Claim 38 depends from claim 1 and adds the limitation of "wherein said flat-panel imager is an amorphous silicon flat-panel imager." Cho expressly discloses this element: "Further increase in volume of reconstruction can be accomplished by … using a larger detector. The <u>flat panel detector based on amorphous silicon (a-Si:H) technology</u> is being developed as a potential real-time diagnostic x-ray imager (Antonuk *et al* 1994)." (Cho, at 24 (emphasis added).)

Antonuk, cited by Cho as shown above, provides detailed disclosures of flat panel imagers for use as diagnostic x-ray detectors mounted on a linear accelerator for imaging during radiotherapy. (Antonuk, at 3.) Antonuk explains that "[t]he arrays consist of a regular two-dimensional matrix of imaging pixels, illustrated schematically in Fig. 2. Each pixel consists of a thin-film transistor (TFT) coupled to an a-Si:H [amorphous silicon] n-i-p or p-i-n photodiode." (*Id*.) As explained by Dr. Balter, it would have been obvious to combine the radiotherapy systems of Adler/Depp with the CBCT apparatus of Jaffray 1997, using an amorphous flat panel imager, as expressly taught by Cho and Antonuk. One of ordinary skill in the art would have been motivated by this express suggestion and by the known benefits of FPI detectors that were disclosed in the prior art. (*See* Ex. 1102, ¶¶ 92-93.)

6. Dependent Claims – Object Imaging

a. Claims 12 and 16

Claim 12 depends from claim 11 and adds the limitation "wherein said x-rays from said x-ray source are emitted along a source plane that is perpendicular to said axis of rotation." Claim 16 adds the similar, broader limitation of "wherein said x-rays from said x-ray source are emitted along a source plane." Jaffray 1997 expressly discloses this element in disclosing an x-ray source that casts beams toward the patient for reception by an x-ray detector on the opposite side of the patient, with these beams running along a source plane that is perpendicular to the rotating gantry containing the CBCT system. A figure from Jaffray 1997 depicting this apparatus is shown in Section VII-C above. As explained by Dr. Balter, this is a disclosure of x-rays on a source plane, perpendicular to the axis of rotation of the object relative to the x-ray source. Furthermore, one of skill in the art would be motivated to provide x-rays along a source plane perpendicular to the relative axis of rotation of the object to obtain the obvious benefit of obtaining information about the entire object volume through a single rotation. (*See* Ex. 1102, ¶¶ 94.)

b. Claim 21

Claim 21 depends from claim 1 and adds the limitation "wherein said computer receives said image from said flat-panel imager and generates a computed tomography image of said object based on said received image." Cho expressly discloses this element by teaching a computer-assisted system to create 3-D image based on a plurality of 2-D projection images from the cone-beam x-ray. Cho is directed to generating 3-D images based on 2-D CBCT scans using a modified Feldkamp algorithm. (*See* Cho, at 15-16 (discussing the scanning of CT phantom models using this approach); *id.*, at 17 (discussing image processing and use of reconstruction algorithms on a computer).) Thus the system of Cho teaches a computer that receives the image information from the FPI and creates a CT image based on that image. As explained by Dr. Balter, this limitation adds nothing of patentable significance because the prior art is explicit about the use of computers to perform storage and processing of the 2-D projection images and image reconstruction using known algorithms for that purpose. (*See* Ex. 1102, ¶¶ 95, 128.) Furthermore, the image reconstruction methodology employed by Cho, such as the Feldkamp algorithm, was well-known and in standard use for this purpose before 1999. (*See id*.)

c. Claim 22

Claim 22 depends from claim 1 and adds the limitation "wherein said image is a two dimensional projection image." This element is taught by the disclosure of Cho discussed above for claim 21, which describes reconstruction of 2-D projections into 3-D images. As explained by Dr. Balter, a cone-beam x-ray detected by a 2-D detector like an FPI is a 2-D projection image. (*See* Ex. 1102, ¶ 96.)

d. Claim 23

Claim 23 depends from claim 22 and adds the limitation "wherein said computer receives said two dimensional projection image from said flat-panel imager and generates a computed tomography image of said object based on said two dimensional projection image." This element is, again expressly taught by Cho as noted for claims 21-22 above. As explained by Dr. Balter, this claim is obvious for the same reason as claims 21 and 22. (*See* Ex. 1102, ¶ 97.)

7. Dependent Claims – Gantry Limitations

a. Claim 24

Claim 24 depends from claim 1 and adds the limitation "further comprising a gantry with a first arm and a second arm, wherein said x-ray source is attached to said first arm and said flat-panel imager is attached to said second arm." This element is expressly taught by Jaffray 1997, which shows in Figure 1 that the x-ray source and detector are attached to the rotating gantry. (*See* Jaffray 1997, at 5, Fig. 1, discussing rotation of "gantry".) Jaffray 1997 also states that the x-ray source is mounted on "a retractable arm" attached to the gantry of the machine. (*See id.*, at 4.)

This element is also expressly taught by Antonuk, which teaches in Figure 5, panel (a), a gantry system with two arms, one for the x-ray source and another for the detector. Figure 5 of Antonuk is reproduced in Section VII-C above. As explained by Dr. Balter, the configuration of claim 24 is obvious because one of ordinary skill in the art would be motivated to use the commonly known gantry arrangements of the prior art for the x-ray source and FPI, and would have been motivated to perform the known substitution of an FPI for the CCD detector used in Jaffray 1997 to create the system of claim 24. (*See* Ex. 1102, ¶¶ 98-99.)

b. Claim 25

Claim 25 depends from claim 24 and adds the limitation "wherein said gantry rotates about an axis of rotation." As with claim 24, Antonuk and Jaffray 1997 expressly disclose this. Antonuk discloses a rotating gantry system in Figure 5, as discussed above: "This composite imager would be positioned behind the patient in the middle of the megavoltage radiation field during imaging. It would be attached to the gantry of the therapy machine <u>thereby rotating with it</u> in the same fashion as present real-time megavoltage imagers." (Antonuk, at 6 (emphasis added).) Jaffray 1997 also teaches rotation of the imaging (and radiotherapy) gantry around the patient on an axis of rotation. (*See* Jaffray 1997, at 5.) As explained by Dr. Balter, it is obvious that the gantry supporting the x-ray system should rotate to obtain the multiple 2-D projection images that are required for obtaining 3-D information about an object. (*See* Ex. 1102, ¶ 100.)

c. Claims 26 and 27

Claim 26 depends from claim 24 and adds the limitation "wherein said radiation source operates at a power level higher than that of said x-ray source, wherein said radiation is of an intensity and energy that is effective for radiation treatment of an area of said object." Antonuk expressly discloses the use of a dual-system with both kV and MV imaging for diagnostic imaging and treatment, respectively. For example, Antonuk discloses use of his system on a Varian Clinac 1800, which provides a 6 MV beam. (*See* Antonuk, at 6.) As explained by Dr. Balter, this MV energy was well known to be effective for radiation therapy. (*See*

Ex. 1102, ¶ 101.) Jaffray 1997 also expressly discloses the use of a dual-system with both kV and MV imaging for diagnostic imaging and treatment, respectively. For example, Jaffray 1997 discloses use of their system on a Philips/Elekta SL-20, which provides an MV beam. (*See* Jaffray 1997, at 4.)

Claim 27 depends from claim 1 and recites the identical limitation. The invalidity of claim 1 is explained in Section VII-D-1.

8. Dependent Claims – Structural Additions

a. Claim 6

Claim 6 depends from claim 1 and adds the limitation "wherein said radiation source comprises a linear accelerator." Adler expressly discloses a linear accelerator as the radiation source:

> A beaming apparatus **20** is provided which, when activated, emits a collimated surgical ionizing beam of a strength sufficient to cause the target region **18** to become necrotic. One beaming apparatus which can be utilized is in the nature of a <u>linear accelerator</u>, preferably an x-ray linear accelerator, although other ionizing radiation sources could be used as can other ionizing radiations. Such x-ray apparatus is available commercially.

(Adler, 6:44-52 (emphasis added).) Antonuk and Jaffray 1997 also expressly disclosed a linear accelerator as a radiation source. (*See* Antonuk, at Fig. 5; Jaffray 1997, at Fig. 1.) As explained by Dr. Balter, one of skill in the art would have been motivated to use the common system of a linear accelerator as the radiation source for the system of claim 1. (*See* Ex. 1102, ¶ 103.)

b. Claim 28

Claim 28 depends from claim 1 and adds the limitation "wherein said x-ray source rotates about an axis that is coincident with an axis of rotation of said radiation source." This element is expressly taught by Antonuk, which expressly shows in Figure 5 the x-ray source mounted to the same gantry head as the radiotherapy source, thus both sources rotate around the same (coincident) axes of rotation. This element is also expressly taught by Jaffray 1997, which shows in Figure 1 the x-ray source mounted to the same gantry head as the radiotherapy source, thus both sources rotate around the same (coincident) axes of rotation. As explained by Dr. Balter, by maintenance of the same isocenter in an offset beam, the x-ray and radiation source axes are coincident as recited in the claim, and this configuration would provide the obvious benefit of performing a scanning geometry on the same axis as the radiation source. (*See* Ex. 1102, ¶ 104.)

c. Claim 29

Claim 29 depends from claim 1 and adds the limitation "wherein said x-ray source is displaced relative to said radiation source." Antonuk expressly discloses the use of an x-ray source mounted near, but displaced from, the MV radiation source in the linear accelerator. This is shown in Figure 5, reproduced in Section VII-C above. Likewise, Jaffray 1997 expressly discloses the use of an x-ray source mounted in displaced fashion from the MV radiation source in the linear accelerator. This is shown in Figure 1, reproduced in Section VII-C above. This element is also expressly taught by Adler/Depp, who expressly disclosed an x-ray source displaced from said radiation source. As shown in Figures 1 and 3 of Adler/Depp, the imaging radiation source is not in the same location, and is hence displaced, from the treatment radiation source. Figure 1 of Adler/Depp are reproduced above in Section VII-D-1. As explained by Dr. Balter, being offset by 90°, the x-ray source is displaced relative to the radiation source, and this configuration offers the known benefit of facilitating simple construction of a device comprising separate diagnostic and radiotherapy treatment radiation sources (as was done in Antonuk and Jaffray 1997). (*See* Ex. 1102, ¶ 105.)

d. Claim 33

Claim 33 depends from claim 1 and adds the limitation "further comprising an imaging device positioned opposite said radiation source and generating an image of said object based on radiation from said radiation source that passes through said object." This is expressly disclosed by Antonuk, which teaches the use of a FPI opposite the MV radiation source for use in imaging. This is also suggested by Jaffray 1997, which teaches the use of a CCD imager opposite the MV radiation source for use in imaging. As with claim 29, this is specifically shown in Figure 1, reproduced in Section VII-C above. Claim 33 does not limit the type of imager positioned opposite the radiation source, thus the CCD-camera based MV imager disclosed by Jaffray 1997 satisfies this claim element. As explained by Dr. Balter, "portal imaging" using MV image detectors in radiation therapy was very well known before 1999, and one of skill in the art would have been motivated to include this known imaging capability in assembling the system of claim 1. (*See* Ex. 1102, ¶ 106.)

e. Claims 35, 36, and 37

Claims 35, 36, and 37 are highly similar. All depend from claim 1 and add similar language about "no enclosed opening is formed from a structure that supports said radiation source and said cone-beam computed tomography system." For comparison, the claims are reproduced in the table below:

Claim 35	Claim 36	Claim 37
35. The radiation therapy system of claim 1, wherein no enclosed opening is formed from a structure that supports said radiation source and said cone-beam computed tomography system into which said object is inserted for the purpose of being treated by said radiation source or imaged by said cone-beam computed tomography system within such an enclosed	36. The radiation therapy system of claim 1, wherein no enclosed opening is formed from a structure that supports said radiation source into which said object is inserted for the purpose of being treated by said radiation source within such an enclosed opening.	37. The radiation therapy system of claim 1, wherein no enclosed opening is formed from a structure that supports said cone-beam computed tomography system into which said object is inserted for the purpose of being imaged by said cone-beam computed tomography system within such an enclosed opening.

opening.		

The element of no enclosed opening is apparently meant to distinguish prior art "ring" devices. But this limitation does not avoid the prior art. This is expressly shown, again, in Figure 5 of Antonuk, which employs a system of gantry arms that does not form an enclosed opening around the object being imaged. Figure 5 is reproduced above in Section VII-C. As can be seen in the figure, no enclosed opening around the object (patient) is formed by the CBCT or radiation source systems. This is also expressly shown in Figure 1 of Jaffray 1997, which employs a system of gantry arms that does not form an enclosed opening around the object being imaged. Figure 1 is reproduced above in Section VII-C. As Jaffray 1997 expressly notes, the x-ray source is mounted on a "retractable arm," thus teaching that the patient may be accessed. (*See* Jaffray 1997, at 4.) As explained by Dr. Balter, this combination provides the obvious benefit of facilitating access to the patient on the treatment table. (*See* Ex. 1102, ¶¶ 107-08.)

VIII. GROUND 2 – CLAIM 9 IS OBVIOUS OVER CHO, ANTONUK, JAFFRAY 1997, AND ADLER/DEPP IN COMBINATION WITH BOYER UNDER 35 U.S.C. § 103(a)

A. Prior Art and Date Qualification for Ground 2

Each limitation of claim 9 is disclosed by Cho, Antonuk, Jaffray 1997, and Adler/Depp in combination with A.L. Boyer, *Laser "cross-hair" sidelight*, Medical Physics, 5:58-60 (1978) **[Ex. 1108] ("Boyer")**. Boyer qualifies as prior art under at least § 102(b) (pre-AIA) because it was published more than one year before February 18, 2000, the filing date of the earliest application appearing on the face of the '502 patent. Boyer was not before the Office during examination or considered by the Examiner prior to issuance of the patent.

B. Brief Description of Boyer

Cho, Antonuk, Jaffray 1997, and Adler/Depp are discussed in Section VII-C.

Boyer [Ex. 1108], entitled "Laser 'cross-hair' sidelight," discloses a laser system for patient alignment during radiation therapy.

C. Cho, Antonuk, Jaffray 1997, and Adler/Depp in Combination with Boyer Disclose Each Limitation of Claim 9 and Were Obvious to Combine

1. Claim 9

Claim 9 depends from claim 8, and adds the limitation "further comprising an alignment laser that allows visualization of said axis of rotation." Boyer expressly discloses this element: "a laser sidelight [] has been designed and built at this institution. The sidelight projects a cross-hair image which can be aligned to a therapy-machine isocenter." (Boyer, at 4.) Boyer's alignment laser visualizes the axis of rotation: "Two sidelights are mounted on the walls of a therapy room such that their beams are coaxial and horizontal, and pass through the therapy-machine isocenter in a direction perpendicular to the therapy machine's gantry-rotation axis." (*Id.*; *see also* Ex. 1102, ¶¶ 112-13.)) According to Boyer, a benefit of this system was that it allowed "the inclination of the patient relative to the gantry-axis rotation can be determined in at least two directions." (Boyer, at 4.)

As explained by Dr. Balter, the use of "room lasers" for visualizing the axis of rotation of radiotherapy gantries was very well known in the art. As stated by Boyer, "[s]idelights have become an accepted means of aligning patients repeatably for fractionated radiotherapy." (Boyer, at 4.) Such systems provide the obvious benefit of assisting in proper patient alignment. As explained by Dr. Balter, one faced with a need for visual aids for patient alignment had a finite number of solutions, and laser systems as in claim 9 were the most commonly used and well known for solving this problem. (*See* Ex. 1102, ¶¶ 112-13.)

IX. CONCLUSION

Petitioner respectfully requests institution of *inter partes* review of claims 1-14, 16-29, 33, and 35-38 of the '502 patent, and a finding that those claims are unpatentable, based on the grounds presented in this Petition.

Dated: November 6, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify, pursuant to 37 C.F.R. Sections 42.6 and 42.105, that a complete copy of the attached **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,842,502**, including all exhibits (**Nos. 1101-1134**) and related documents, are being served via Federal Express on the 6th day of November, 2015, the same day as the filing of the above-identified document in the United States Patent and Trademark Office/Patent Trial and Appeal Board, upon the Patent Owner by serving the correspondence address of record with the USPTO as follows:

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and upon counsel of record for the Patent Owner in the litigation pending before the U.S. District Court for the Eastern District of Michigan entitled *Elekta Ltd. and William Beaumont Hospital v. Varian Medical Systems, Inc.*, Case No. 2:15-cv-12169-AC-MKM, as follows:

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Petition for *Inter Partes* Review of
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