

Petition for *Inter Partes* Review of
U.S. Patent No. 6,842,502

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

**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

Ex. No.	Description of Document
1201	U.S. Patent No. 6,842,502 issued to David A. Jaffray, <i>et al.</i> (“’502 patent”)
1202	Declaration of Dr. James Balter (“Balter Decl.”)
1203	U.S. Patent No. 5,207,223 issued to Adler <i>et al.</i> (“Adler”)
1204	U.S. Patent No. 5,427,097 issued to Depp (“Depp”)
1205	D.A. Jaffray <i>et al.</i> , <i>Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager</i> , SPIE, 3659:204-14 (Feb. 1999) (“Jaffray 1999 SPIE”)
1206	D.A. Jaffray <i>et al.</i> , <i>A Radiographic and Tomographic Imaging System Integrated into a Medical Linear Accelerator for Localization of Bone and Soft-Tissue Targets</i> , Int. J. Radiation Oncology Biol. Phys., 45:773-89 (Oct. 1999) (“Jaffray 1999 JRO”)
1207	D. Yan <i>et al.</i> , <i>The Use of Adaptive Radiation Therapy to Reduce Setup Error: A Prospective Clinical Study</i> , Int’l J. Radiation Oncology Biol. Phys., 41:715-20 (1998) (“Yan”)
1208	Apr. 20, 2004 Office Action
1209	Jan 23, 2004 Applicant’s Remarks
1210	Provisional Application No. 60/183,590 filed by David A. Jaffray <i>et al.</i> (“’590 Provisional”)
1211	Highlighted copy of the ’502 Patent showing matter not disclosed in the ’590 Provisional Application
1212	P. Munro, <i>Portal Imaging Technology: Past, Present, and Future</i> , Seminars in Radiation Oncology, 5:115-33 (Apr. 1995) (“Munro 1995”)
1213	Feb. 16, 2001 Application

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Ex. No.	Description of Document
1214	P.J. Biggs <i>et al.</i> , <i>A Diagnostic X Ray Field Verification Device For A 10 MV Linear Accelerator</i> , Int’l J. Radiation Oncology Biol. Phys., 11:635-43 (1985) (“Biggs 1985”)
1215	A. Ezz <i>et al.</i> , <i>Daily Monitoring and Correction of Radiation Field Placement Using a Video-Based Portal Imaging System: A Pilot Study</i> , Int’l J. Radiation Oncology Biol. Phys., 22:159-65 (1991) (“Ezz 1991”)
1216	W. De Neve <i>et al.</i> , <i>Routine clinical on-line portal imaging followed by immediate field adjustment using a tele-controlled patient couch</i> , Radiotherapy & Oncology, 24:45-54 (1992) (“De Neve 1992”)
1217	T.R. Mackie <i>et al.</i> , <i>Tomotherapy: A new concept for the delivery of dynamic conformal radiotherapy</i> , Med. Phys., 20:1709-19 (Nov./Dec. 1993) (“Mackie 1993”)
1218	L.E. Antonuk <i>et al.</i> , <i>Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging</i> , IEEE Transactions on Medical Imaging, 13:482-90 (Sept. 1994) (“Antonuk 1994”)
1219	R. Sephton <i>et al.</i> , <i>A diagnostic-quality electronic portal imaging system</i> , Radiotherapy & Oncology, 35:204-47 (1995) (“Sephton 1995”)
1220	M.C. Kirby <i>et al.</i> , <i>Clinical Applications of Composite and Realtime Megavoltage Imaging</i> , Clinical Oncology, 7:308-16 (1995) (“Kirby 1995”)
1221	J.M. Michalski <i>et al.</i> , <i>Prospective Clinical Evaluation of an Electronic Portal Imaging Device</i> , Int’l J. Radiation Oncology Biol.-Phys., 34:943-51 (1996) (“Michalski 1996”)

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Ex. No.	Description of Document
1222	D.A. Jaffray <i>et al.</i> , <i>Exploring “Target Of The Day” Strategies for A Medical Linear Accelerator With Conebeam-CT Scanning Capability</i> , Proceedings of the 12th International Conference on the Use of Computers in Radiation Therapy, Medical Physics Publishing, pp. 172-75 (1997) (“Jaffray 1997”)
1223	D. Yan <i>et al.</i> , <i>Adaptive radiation therapy</i> , Phys. Med. Biol., 42:123-32 (1997) (“Yan 1997”)
1224	M.A. Mosleh-Shirazi <i>et al.</i> , <i>A cone-beam megavoltage CT scanner for treatment verification in conformal radiotherapy</i> , Radiotherapy & Oncology, 48:319-28 (1998) (“Mosleh-Shirazi 1998”)
1225	S. Webb <i>et al.</i> , <i>Tomographic Reconstruction from Experimentally Obtained Cone-Beam Projections</i> , IEEE Transactions on Medical Imaging, MI-6:67-73 (Mar. 1987) (“Webb 1987”)
1226	P.S. Cho <i>et al.</i> , <i>Cone-beam CT for radiotherapy applications</i> , Phys. Med. Biol., 40:1863-83 (1995) (“Cho 1995”)
1227	D.A. Jaffray <i>et al.</i> , <i>Dual-Beam Imaging for Online Verification of Radiotherapy Field Placement</i> , Int’l J. Radiation Oncology Biol. Phys., 33:1273-80 (1995) (“Jaffray 1995”)
1228	S.M. Midgley <i>et al.</i> , <i>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</i> , Proceedings of the 4th Int’l Workshop of Electronic Portal Imaging, Amsterdam, 1996, Abstract No. 60 (2 pages) (1996) (“Midgley 1996”)
1229	J. Wong <i>et al.</i> , <i>Initial clinical experience with a gantry mounted dual beam imaging system for setup error localization</i> , Int’l J. Radiation Oncology Biol. Phys., 42(Suppl. 1):138 (Abstract 28) (1998) (“Wong 1998”)

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Ex. No.	Description of Document
1230	L.E. Antonuk <i>et al.</i> , <i>Demonstration of megavoltage and diagnostic x-ray imaging with hydrogenated amorphous silicon arrays</i> , Med. Phys., 19:1455-66 (Nov./Dec. 1992) (“Antonuk 1992”)
1231	L.E. Antonuk <i>et al.</i> , <i>A Real-Time, Flat-Panel, Amorphous Silicon, Digital X-ray Imager</i> , RadioGraphics, 15:993-1000 (1995) (“Antonuk 1995”)
1232	J. Chabbal <i>et al.</i> , <i>Amorphous Silicon X-ray Image Sensor</i> , Proceedings of SPIE (Society of Photographic Instrumentation Engineers), 2708:499-510 (1996) (“Chabbal 1996”)
1233	R. Ning <i>et al.</i> , <i>Selenium Flat Panel Detector-Based Volume Tomographic Angiography Imaging: Phantom Studies</i> , Proceedings of SPIE (Society of Photographic Instrumentation Engineers), 3336:316-24 (Feb. 1998) (“Ning 1998”)
1234	R. Ning <i>et al.</i> , <i>Flat panel detector-based cone beam volume CT imaging: detector evaluation</i> , Proceedings of SPIE (Society of Photographic Instrumentation Engineers), 3659:192-203 (Feb. 1999) (“Ning 1999”)
1235	U.S. Patent No. 6,041,097 issued to Roos <i>et al.</i> (“Roos 1998”)
1236	J.H. Siewerdsen <i>et al.</i> , <i>Signal, noise power spectrum, and detective quantum efficiency of indirect-detection flat-panel imagers for diagnostic radiology</i> , Med. Phys., 25:614-28 (May 1998) (“Siewerdsen 1998”)
1237	A.T. Redpath <i>et al.</i> , <i>Chapter 6: Simulator Computed Tomography</i> , pp. 169-89, in <i>The Modern Technology of Radiation Oncology</i> , J. Van Dyk (ed.) (1999) (“Redpath 1999”)

Petition for *Inter Partes* Review of
U.S. Patent No. 6,842,502

Petitioner Varian Medical Systems, Inc. (“Petitioner”) respectfully submits this Petition for *Inter Partes* Review of claims 43-46, 48-55, 57, 59, 60-66, and 68 of U.S. Patent No. 6,842,502 [Ex. 1201] (“the ’502 patent”).

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

A. Real Party-In-Interest 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 43-46, 48-55, 57, 59, 60-66, and 68, based on unique legal grounds and prior art. Petitioner is also seeking *inter partes* review of apparatus claims 1-14, 16-29, 33, and 35-38 of the ’502 patent through two additional concurrently filed petitions.

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

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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.

E. Power of Attorney

Filed concurrently in accordance with 37 C.F.R. § 42.10(b).

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

This Petition requests review of 22 claims of the '502 patent, therefore excess claim fees are required. A payment of \$26,200 is submitted herewith, which comprises a \$9,400 request fee and a post-institution fee of \$16,800. *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*

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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 with respect to 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 43-46, 48-55, 57, 59, 60-66, and 68. This Petition cites the following prior art references, submitted as Exhibits **1203** through **1207**:

Ex. No.	Description of Document
1203	U.S. Patent No. 5,207,223 issued to Adler <i>et al.</i> (“Adler”)
1204	U.S. Patent No. 5,427,097 issued to Depp (“Depp”)
1205	D.A. Jaffray <i>et al.</i> , <i>Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager</i> , SPIE, 3659:204-14 (Feb. 1999) (“Jaffray 1999 SPIE”)
1206	D.A. Jaffray <i>et al.</i> , <i>A Radiographic and Tomographic Imaging System Integrated into a Medical Linear Accelerator for Localization of Bone and Soft-Tissue Targets</i> , Int. J. Radiation Oncology Biol. Phys., 45:773-89 (Oct. 1999) (“Jaffray 1999 JRO”)
1207	D. Yan <i>et al.</i> , <i>The Use of Adaptive Radiation Therapy to Reduce Setup Error: A Prospective Clinical Study</i> , Int’l J. Radiation Oncology Biol. Phys., 41:715-20 (1998) (“Yan”)

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

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Ground	Claims	Basis for Challenge
1	43-46, 48-55, 57 & 59	Obvious over Jaffray 1999 SPIE, Jaffray 1999 JRO, and Adler/Depp (§ 103(a))
2	60-66 & 68	Obvious over Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler/Depp, and Yan (§ 103(a))

Sections VIII-C and IX-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. 1202], ¶¶ 2-5.) Dr. Balter's declaration includes additional exhibits ([Exs. 1212 - 1237]), 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 43-46, 48-55, 57, 59, 60-66, and 68 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 each challenged claim 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

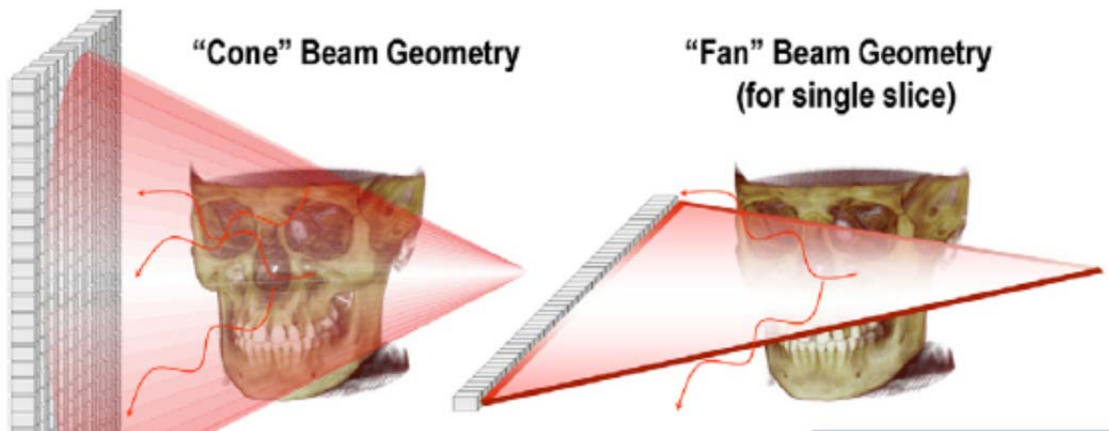
Radiation therapy or “radiotherapy” is the use of beams of radiation for the treatment of disease. Radiation therapy of internal patient lesions, such as cancerous tumors, is very old – dating back over 100 years. For decades, practitioners have known that the effectiveness of radiation therapy is increased 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. 1202, ¶ 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

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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. 1202, ¶ 131.) 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. 1202, ¶¶ 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. 1208, 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 Jaffray 1999 SPIE reference did in fact disclose the element the Examiner believed was missing from the prior art.

B. The Challenged Claims of the ’502 Patent

This Petition addresses claims 43-46, 48-55, 57, 59, 60-66, and 68. The challenged claims include two independent claims presenting methods of the use of

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a system sharing the same basic elements. The sole difference between the two method claims is that claim 43 recites controlling the path of the radiation source beam, while claim 60 recites controlling “a radiation therapy treatment plan” (an “RTTP.”) To aid in claim analysis, a table for comparison of these claims is set forth below:

Claim 43	Claim 60
A method of treating an object with radiation, comprising:	A method of treating an object with radiation, comprising:
move a radiation source about a path; direct a beam of radiation from said radiation source towards an object;	move a radiation source about a path; direct a beam of radiation from said radiation source towards an object;
emitting an x-ray beam in a cone beam form towards an object;	emitting an x-ray beam in a cone beam form towards an object;
detecting x-rays that pass through said object due to said emitting an x-ray beam with a flat-panel imager; generating an image of said object from said detected x-rays, wherein said generating comprises forming a computed tomography image of said object based on said detected x-rays,	detecting x-rays that pass through said object due to said emitting an x-ray beam with a flat-panel imager; generating an image of said object from said detected x-rays, wherein said generating comprises forming a computed tomography image of said object based on said detected x-rays,
wherein said image contains at least three dimensional information of said object based on one rotation of said x-ray source around 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 controlling said path of said radiation source based on said image.	and controlling <u>a radiation therapy treatment plan involving said radiation source</u> based on said image.

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 claims 43 and 60. 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

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

'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 based on just one rotation of the x-ray source ...” (*See* Ex. 1209, 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 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 cone beam computerized tomography acquisitions in which the object **316** is rotated through 360°.

(’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. 1202, ¶¶ 35-36.)

B. “three dimensional information”

This term appears in independent claims 43 and 60. 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. 1202, ¶ 37.)

VII. THE CLAIMS OF THE ’502 PATENT HAVE A PRIORITY DATE OF NO EARLIER THAN FEBRUARY 16, 2001

The ’502 patent seeks the benefit of provisional application 60/183,590 (“the ’590 application”), filed on February 18, 2000. (’502, 1:4-8; the ’590 provisional is submitted as Ex. 1210.) The claims of the ’502 patent, however, are not entitled to this priority date because they are wholly unsupported by the ’590 provisional.

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As noted above, the challenged claims require the claim element of controlling the path of a radiation source based on a three-dimensional image obtained through a single CBCT rotation. Independent claim 1, recites a control element: “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.” Every other challenged claim is a dependent claim that incorporates one of these independent claims.

None of the claims that were ultimately allowed are supported by the ’590 provisional. This is most clearly evidenced by the fact that the ’590 provisional contains only a fraction of the disclosure contained in the nonprovisional on which the ’502 application is based. The provisional application discloses a benchtop CBCT-FPI system, and focuses on the features of the imager and image quality. The provisional has no discussion of using the benchtop system to control a path of a radiotherapy beam, as the claims of the ’502 patent purport to cover.

The nonprovisional application filed a year later contained disclosure that is nowhere found in the provisional, including an additional 16 pages of new text, 48 new figures, and 92 new claims. The focus of these new disclosures is the installation of a CBCT-FPI system on a medical linear accelerator for use in image-guided radiotherapy. For example, every word in the specification from Column 19, line 59 to the end of the patent – over eight columns of text – is new

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matter that was not disclosed in the '590 provisional. This new disclosure is shown in Exhibit **1211**. Exhibit **1211**, is a copy of the '502 patent that shows the new matter in yellow highlight that was added to the '502 specification and absent from the '590 provisional.

As explained by Dr. Balter, the '590 provisional has no support for methods of controlling a radiation source beam based on 3-D CBCT-FPI image information. (*See* Ex. **1202**, ¶¶ 41-46.) For example, none of the teachings in the patent describing guidance of radiotherapy based on a CBCT-FPI system found in columns 19-28 of the '502 patent were presented in the '590 provisional. One of ordinary skill in the art, reviewing the '590 provisional, would not have recognized that the applicants possessed the invention they claimed. (*See* Ex. **1202**, ¶ 47.)

Because all of the claims of the '502 patent must rely on new matter added to the February 16, 2001 nonprovisional, the earliest effective filing date for the claims can be no earlier than February 16, 2001. *See, e.g., PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008); *see also Butamax Advanced Biofuels LLC v. Gevo, Inc.*, IPR2014-00402, Paper No. 11 at 5 (P.T.A.B. Aug. 8, 2014).

VIII. GROUND 1 – CLAIMS 43-46, 48-55, 57 & 59 ARE OBVIOUS OVER JAFFRAY 1999 SPIE, JAFFRAY 1999 JRO, AND ADLER/DEPP UNDER 35 U.S.C. § 103(a)

A. Prior Art and Date Qualification for Ground 1

Each limitation of claims 43-46, 48-55, 57 & 59 is disclosed or suggested by D.A. Jaffray *et al.*, *Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager*, SPIE, 3659:204-14 (February 1999) [Ex. 1205] (“**Jaffray 1999 SPIE**”), D.A. Jaffray *et al.*, *A Radiographic and Tomographic Imaging System Integrated into a Medical Linear Accelerator for Localization of Bone and Soft-Tissue Targets*, Int. J. Radiation Oncology Biol. Phys., 45:773-89 (October 1999) [Ex. 1206] (“**Jaffray 1999 JRO**”), U.S. Patent No. 5,207,223 issued to Adler *et al.*, published on May 4, 1993 [Ex. 1203] (“**Adler**”), and U.S. Patent No. 5,427,097 issued to Depp, published on June 27, 1995 [Ex. 1204] (“**Depp**”).²

The Jaffray 1999 references are § 102(b) (pre-AIA) prior art because, as noted above, the '502 patent is not entitled to seek the priority date of its provisional application, and the references published more than one year before

² 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.”

February 16, 2001, the earliest nonprovisional date of the '502 patent. And at a minimum, the Jaffray 1999 references are prior art under § 102(a) (pre-AIA) because each published before February 18, 2000, the filing date of the earliest application appearing on the face of the '502 patent. Adler/Depp 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. Adler/Depp was not before the Office during examination or considered by the Examiner prior to issuance of the patent.

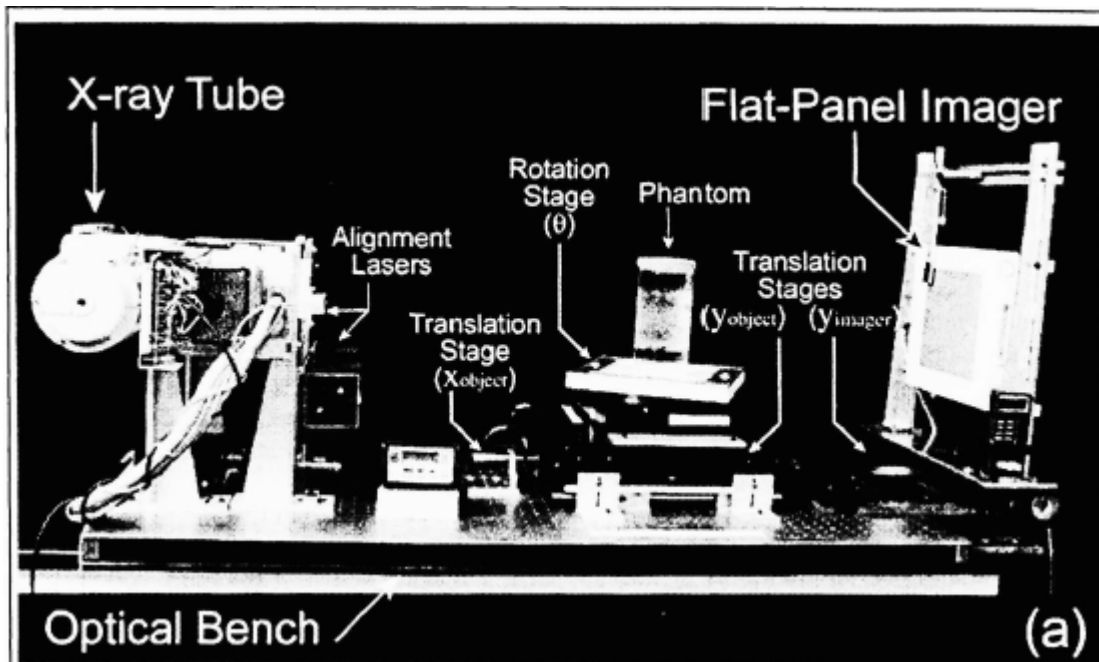
B. Brief Description of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp

Jaffray 1999 SPIE [Ex. 1205], entitled “Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager,” discloses a system for CBCT scanning to create 3-D (“volumetric”) images with flat panel imagers as detectors. As Jaffray 1999 SPIE explained:

A table-top CBCT scanner based upon an a-Si:H FPI has been constructed, and a system for CBCT image acquisition, processing, and reconstruction has been implemented. This system is capable of producing high quality volumetric images. Reconstructions were generated from 300 radiographs (100 kVp; 1 mAs per projection) obtained at 1.2° increments through 360°.

(Jaffray 1999 SPIE, at 16.) Jaffray 1999 SPIE reported the efforts as a success, concluding “The imaging performance of the prototype supports the hypothesis that FPIs can be employed in computed tomography applications.” (*Id.*)

Jaffray provided a figure summarizing the components of his system, including a CBCT system, and FPI, and a rotation stage for rotation of the x-ray beam relative to the object being imaged:



(Jaffray 1999 SPIE, at 18.) Jaffray 1999 SPIE expressly taught mounting the system on a medical linear accelerator for rotation around the patient for the purpose of image-guided radiotherapy: “The CBCT system described in this report will be adapted for implementation in our clinic for image-guidance of external beam radiotherapy. Specifically, the flat-panel imager will be mounted on a

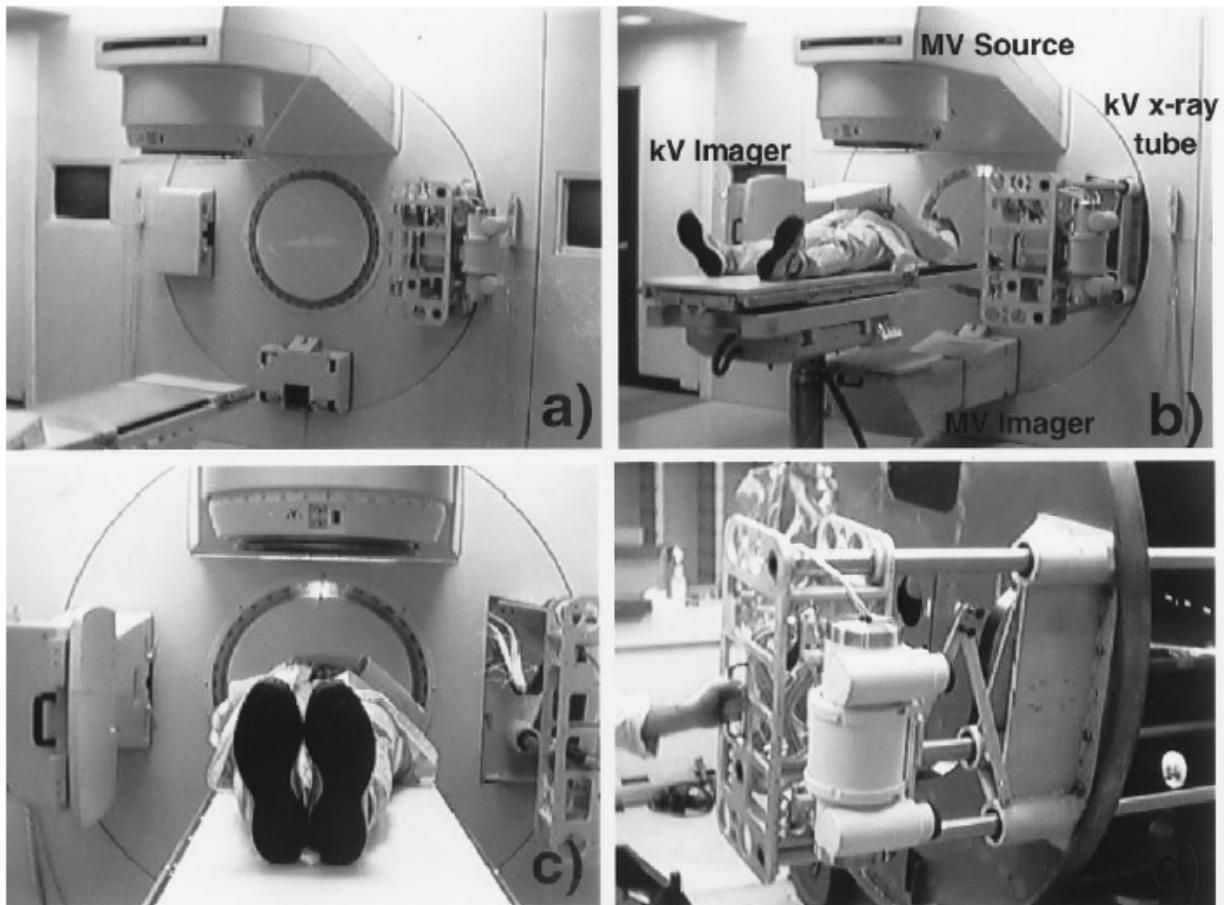
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treatment gantry opposite a kilovoltage x-ray tube in a manner previously accomplished with a CCD-based imager.” (*Id.*, at 25.)

Jaffray 1999 JRO [Ex. 1206], entitled “A Radiographic and Tomographic Imaging System Integrated into a Medical Linear Accelerator for Localization of Bone and Soft-Tissue Targets,” provides a detailed description of the realization of Jaffray’s plan to install a CBCT system onto a radiotherapy device. (Jaffray 1999 JRO, at 9.) As Jaffray explained, the system employed 120 kVp x-rays through a single complete rotation of the gantry around 360°. (*Id.*)

The dual-beam linear accelerator device of Jaffray 1999 JRO employs a CCD camera for image detection, but expressly suggests the use of a FPI in place of the CCD: “There is significant room for additional optimization of the system: investigating the impact of x-ray scatter, reducing veiling glare in the optical housing, and exploring the use of flat-panel imagers for increased detective quantum efficiency.” (*Id.*, at 15 (emphasis added).)

Jaffray 1999 JRO provides a figure showing his CBCT system installed on a linear accelerator device for rotation around the patient:



(*Id.*, at 5, stating “The dual-beam system was constructed on a Elekta SL-20 medical linear accelerator.”)

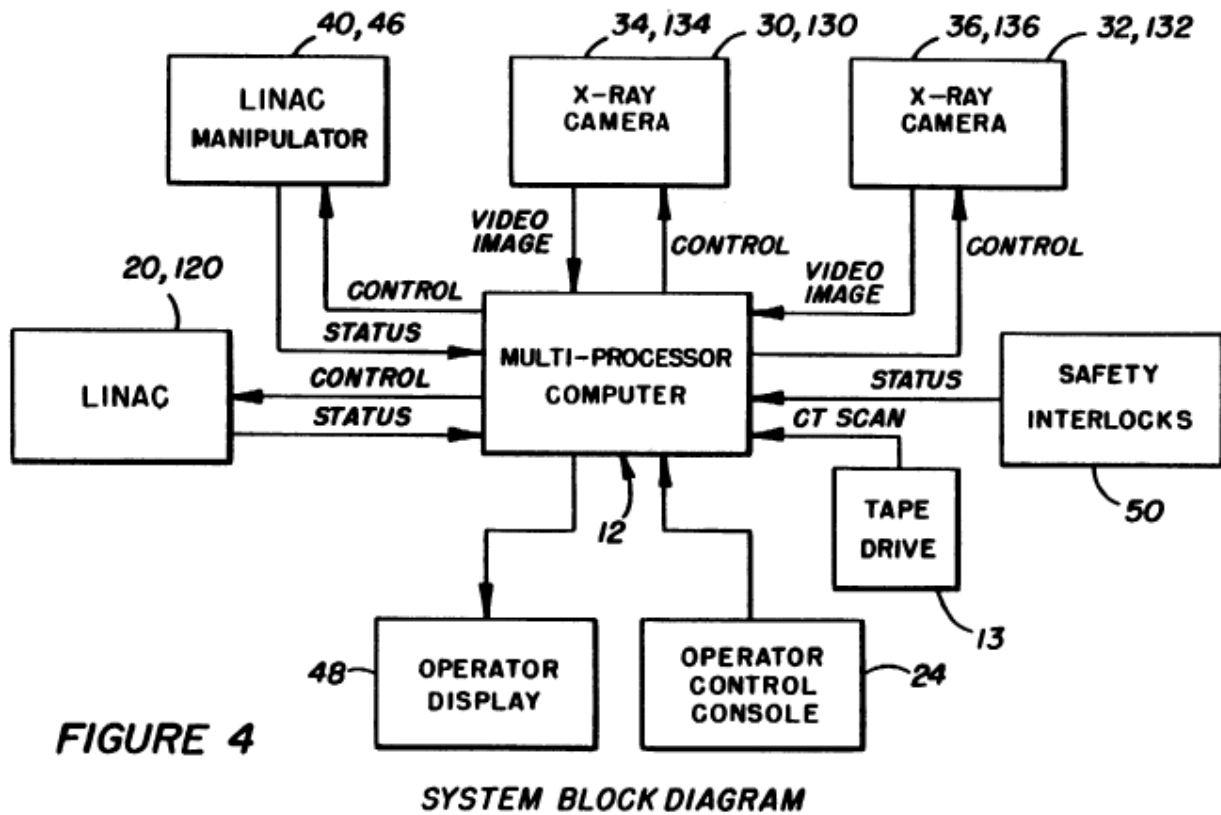
Adler [Ex. 1203], entitled “Apparatus for and Method of Performing Stereotaxic Surgery,” discloses systems for selectively irradiating a target within a patient. Adler discloses use of diagnostic x-ray imaging, 3-D image mapping of target lesions, and adjustment of the radiotherapy source if needed to 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

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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:



(*Id.*, Fig. 4.)

Depp [Ex. 1204] 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 images are used to ensure proper targeting of the treatment beam in real time.

C. Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp Disclose Each Limitation of Claims 43-46, 48-55, 57 & 59 and Were Obvious to Combine

1. Challenged Independent Claim 43

The preamble of claim 43 recites: “A method of treating an object with radiation, comprising.” Although the preamble may not be limiting under its broadest reasonable construction, Adler/Depp and Jaffray 1999 JRO disclose it.

As explained in more detail in connection with the claim limitations that follow, Adler/Depp discloses methods for radiotherapy that are 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. 1202, ¶¶ 57-59.) As shown in Figure 1 of Adler, for example, Adler/Depp disclose a system for delivering radiotherapy to a patient:

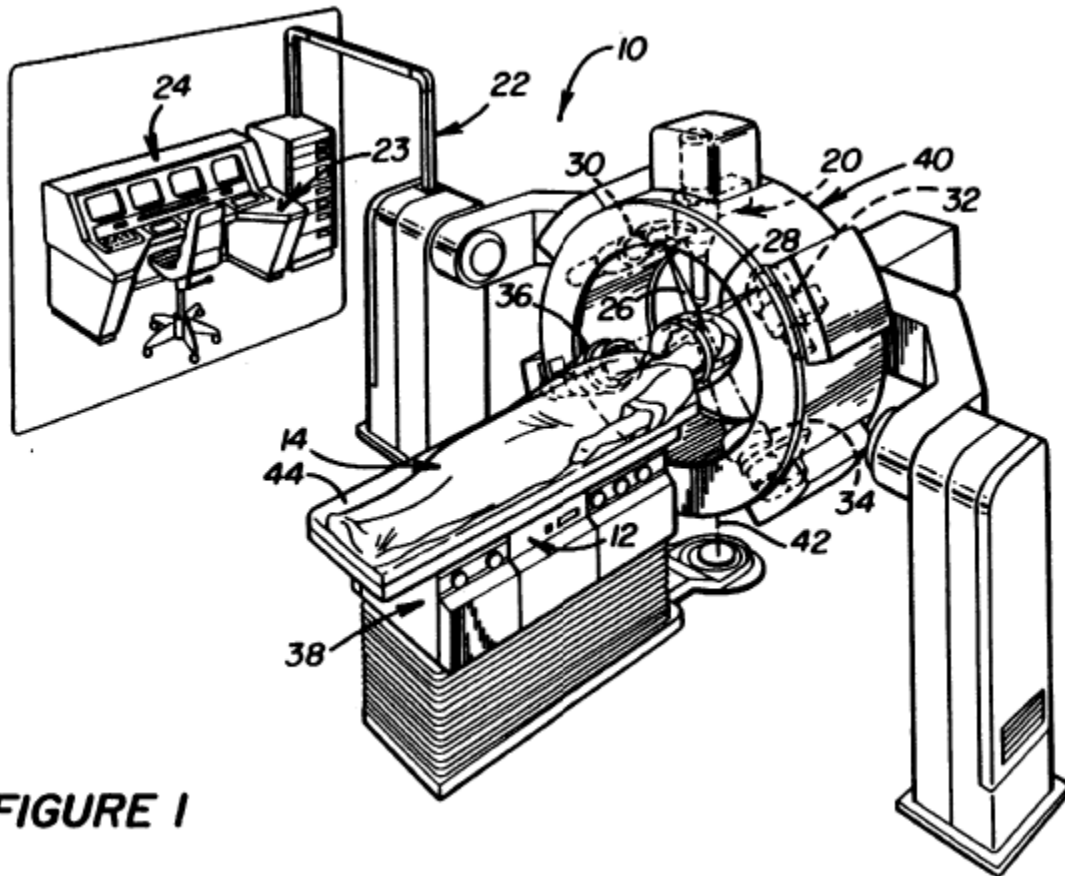


FIGURE 1

(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 VIII-B above, Jaffray 1999 JRO expressly discloses methods of radiotherapy using a medical linear accelerator device.

a. “move a radiation source about a path; direct a beam of radiation from said radiation source towards an object”

As discussed with respect to the claim preamble, 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. 1202, ¶ 60.)

Jaffray 1999 SPIE also suggests this limitation: “Ultimately, this imaging system will be installed on a conventional radiotherapy linear accelerator in our

clinic.” (Jaffray 1999 SPIE, at 17.) Such a device contains a radiation source that directs a beam of radiation at an object that it moves around. (*See* Ex. 1202, ¶ 61.) Jaffray 1999 JRO also suggests this limitation, because the CBCT system of this reference was installed on a conventional linear accelerator, which satisfies this claim limitation: “An Elekta SL-20 ... linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams.” (Jaffray 1999 JRO, at 4; *see also* Ex. 1202, ¶ 61.)

b. “emitting an x-ray beam in a cone beam form towards an object”

Jaffray 1999 SPIE expressly discloses a CBCT x-ray system that moves around the object, emitting multiple x-ray beams in cone-beam form: “The CBCT system is illustrated in Figure 1. The main components of the system are the x-ray tube, the rotation stage, and the flat-panel imager.” (Jaffray 1999 SPIE, at 17.) Jaffray explained: “A single CBCT scan is obtained by acquiring projection images at 1.2° increment rotations of the object across 360°.” (*Id.*, at 25.) As explained by Dr. Balter, this disclosure is an express disclosure of passing multiple x-ray beams in cone beam (“CB”) form through said object from different angles. (*See* Ex. 1202, ¶ 62.)

Jaffray 1999 JRO also expressly discloses this element:

To generate a CB-CT dataset, a series of radiographic exposures are acquired at regular angular intervals as the accelerator gantry is

rotated.... The control system operates the camera's shutter and read-out mechanisms in synchrony with the firing of the x-ray generator.... (Jaffray 1999 JRO, at 9.) Thus, like Jaffray 1999 SPIE, this reference expressly teaches passing multiple cone-beam x-rays through an object from multiple angles. 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. 1202, ¶ 63.)

- c. **“detecting x-rays that pass through said object due to said emitting an x-ray beam with a flat-panel imager; generating an image of said object from said detected x-rays, wherein said generating comprises forming a computed tomography image of said object based on said detected x-rays”**

Jaffray 1999 SPIE expressly teaches this element:

The CBCT system is illustrated in Figure 1. The main components of the system are the x-ray tube, the rotation stage, and the flat-panel imager.... We propose the construction of a CBCT system for radiotherapy guidance on a treatment-by-treatment basis using CT data obtained with a kV x-ray source and a large area, indirect detection flat-panel imager (FPI).

(Jaffray 1999 SPIE, at 17.) Jaffray 1999 SPIE further explained:

A single CBCT scan is obtained by acquiring projection images at 1.2° increment rotations of the object across 360°. The acquisition process – object rotation, x-ray exposure, and image acquisition — is synchronized by the host computer. Volume data sets were obtained

from the projection data using the Feldkamp algorithm for CBCT reconstruction.

(*Id.*, at 25.) Jaffray 1999 SPIE thus taught the use of an FPI to obtain 3-D image information based on a plurality of 2-D CT images that are obtained by detecting x-rays passing through the object. (*See* Ex. 1202, ¶ 64.)

Jaffray 1999 JRO also expressly suggests the use of FPI:

There is significant room for additional optimization of the system: investigating the impact of x-ray scatter, reducing veiling glare in the optical housing, and exploring the use of flat-panel imagers for increased detective quantum efficiency.

(Jaffray 1999 JRO, at 15 (emphasis added).) As explained by Dr. Balter, FPI devices function as x-ray detectors by detecting multiple x-ray beams that pass through the object being imaged, and 3-D CT images are generated from CT images based on detection of x-rays that pass through the object. Thus, this element is expressly taught by both Jaffray 1999 references. (*See* Ex. 1202, ¶¶ 64-65.)

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 Jaffray 1999 SPIE: “an entire volumetric image is acquired through a single rotation of the source and detector.” (Jaffray 1999 SPIE, at 17.) Specifically, in Jaffray 1999 SPIE, “all scans reported

in this study involved 300 projections over 360 degrees of rotation.” (*Id.*, at 19.) Jaffray 1999 SPIE reported “full 3-dimensionality of the data acquired in a single rotation.” (*Id.*, at 24.) As explained by Dr. Balter, “volumetric image” means 3-D information of the object. (*See* Ex. 1202, ¶ 66.) Jaffray 1999 SPIE thus taught the use of an FPI to obtain 3-D image information from a single rotation of the CBCT around the patient.

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. 1202, ¶ 67.)

a. “and controlling said path of said radiation source based on said image”

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.*, 7:17-23.) 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. 1202, ¶¶ 68-69.)

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.) Accordingly, this element was taught by the prior art. (*See* Ex. 1202, ¶ 70.)

2. Motivation to Combine Jaffray 1999 SPIE, Jaffray 1999 JRO, and Adler/Depp

Claim 43 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 Jaffray 1999 SPIE reference.

Adler/Depp does not disclose the use of a CBCT-FPI system for performing x-ray imaging, but it would have been obvious to obtain these elements from the Jaffray 1999 references to improve the accuracy of Adler/Depp's imaging during radiotherapy. By 1999, it was well-known that CBCT was useful for providing rapid 3-D image information about a patient in the treatment position as shown by Jaffray 1999 SPIE and Jaffray 1999 JRO, as well as other background prior art cited by Dr. Balter. (*See* Ex. 1202, ¶¶ 71-72.) 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 id.*)

As an example of the express suggestions contained in the prior art, Jaffray 1999 SPIE explains the benefit of image-guided radiotherapy:

Unfortunately, delivery of increased dose is limited by (i) the presence of adjacent normal structures and (ii) the precision of beam delivery. In some sites, the diseased target is directly adjacent to radiosensitive normal structures.... Due to uncertainties in patient positioning..., it is necessary to irradiate a larger volume to guarantee that the prostate always receives the prescribed dose. It can be demonstrated that significant dose escalation may be possible if these uncertainties could be reduced from current levels (~10 mm) to the level of 2-3 mm. This reduction can only be achieved through an on-line imaging and guidance system capable of detecting the prostate and surrounding structures with high spatial accuracy.

(Jaffray 1999 SPIE, at 16-17 (emphasis added).) Jaffray 1999 SPIE nominates CBCT-FPI as a prime candidate for this imaging system: “[a] strong candidate technology to satisfy these requirements is cone-beam computed tomography (CBCT).” (*Id.*, at 17.) Jaffray 1999 SPIE also expressly suggests use of the CBCT-FPI system for image-guided radiotherapy “[T]he CBCT system described in this report will be adapted for implementation in our clinic for image-guidance of external beam radiotherapy.” (*Id.*, at 25.)

One of skill in the art would have been motivated to combine the CBCT and FPI teachings of Jaffray 1999 SPIE with the linear accelerator radiation therapy

teachings of Jaffray 1999 JRO. First, two of the three authors of Jaffray 1999 SPIE were authors of Jaffray 1999 JRO. Second, both articles teach a system to address problems in administering radiotherapy. Specifically, both articles disclose a need to confirm the precise location of the area targeted for radiation. (Jaffray 1999 SPIE, at 16-17; Jaffray 1999 JRO, at 3-4.) Third, both articles teach implementing a CBCT system with a linear accelerator for image guidance of radiotherapy. (Jaffray 1999 SPIE, at 17, 25; Jaffray 1999 JRO, at 3-7, 18.) The primary difference between the articles is that Jaffray 1999 SPIE uses and evaluates incorporating an FPI into the CBCT system used for imaging guidance while Jaffray 1999 JRO uses a CCD-based imager mounted to a linear accelerator. Jaffray 1999 JRO teaches use of flat panel imagers as a possible substitution for the CCD-based imager, however. (Jaffray 1999 JRO, at 15.) Further, Jaffray 1999 SPIE cites directly to Jaffray 1999 JRO, teaching that a flat panel imager can be substituted for the CCD-based imager of Jaffray 1999 JRO. (Jaffray 1999 SPIE, at 25-26 (endnote 8).) As explained by Dr. Balter, one of ordinary skill in the art would have viewed this as an express suggestion to combine the teachings of these references. (*See* Ex. 1202, ¶¶ 73-74.)

It was also obvious to combine the Jaffray 1999 references with the radiotherapy system teachings of Adler/Depp. For example, Jaffray 1999 JRO expressly suggests the usefulness of its disclosure in obtaining image-guided

radiotherapy. “An on-line kV imaging system has been integrated with a medical linear accelerator for the purpose of localizing the patient and verifying beam placement.” (Jaffray 1999 JRO, at 18.) Adler/Depp likewise 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 Jaffray 1999 SPIE 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; Jaffray 1999 SPIE, at 16-17.) As explained by Dr. Balter, one of ordinary skill in the art would have viewed this as an express suggestion to combine the teachings of these references. (*See* Ex. 1202, ¶ 75.)

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 Jaffray 1999 references with Adler/Depp because all three references are in the same field of medical imaging in conjunction with radiation therapy and all three 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; Jaffray SPIE 1999, at 16-17; *see also* Ex. 1202, ¶ 76.) As explained by Dr. Balter, the combination of the CBCT-FPI methodology of the Jaffray 1999 references with the radiotherapy control apparatus of Adler and Depp, as done by the '502 applicants,

was also obvious because it combined the known methods of CBCT with an FPI to improve the diagnostic imaging and real-time adjustment of radiotherapy described in Adler and Depp. (*See* Ex. 1202, ¶ 76.) In this field, 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 Jaffray 1999 references with the radiotherapy systems of Adler/Depp. (*See id.*, ¶ 76.) Accordingly, the claimed combination was obvious. *See* MPEP § 2141 (III); *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 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 Claim – 100 kV X-rays

a. Claim 44

Claim 44 depends from claim 43 and adds the limitation “wherein x-rays within said x-ray beam have an energy of approximately 100 kV.” Jaffray 1999 SPIE expressly discloses this element: “[V]olumetric imaging is accomplished by rotating the object incrementally over 360 degrees, delivering a radiographic x-ray pulse (e.g., 100-130 kVp, ~0.1-10 mAs), and acquiring a projection image at each increment.” (Jaffray 1999 SPIE, at 16 (emphasis added).)

One of skill in the art would have been motivated to combine Adler/Depp

with Jaffray 1999 SPIE to obtain the method of claim 44 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. Indeed, as Jaffray 1999 JRO admits, “[u]sing a kV x-ray source to determine field placement is not a novel concept.” (Jaffray 1999 JRO, at 4.)

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. 1202, ¶¶ 78-80.) For example, Jaffray 1999 JRO stated: “The primary reason for the poor quality of the megavoltage portal images is the intrinsically low subject contrast of bony anatomy at megavoltage energies [W]e have taken a more direct approach: to increase the subject contrast by using a kilovoltage (kV) x-ray source to localize the placement of the field.” (Jaffray 1999 JRO, at 4.)

4. Dependent Claims – Rotation Claims

a. Claim 45

Claim 45 depends from claim 43 and adds the limitation “rotating about an axis of rotation said object relative to said x-ray source and said flat-panel imager.”

This element is expressly taught by Jaffray 1999 SPIE:

The main components of the system are the x-ray tube, the rotation stage, and the flat-panel imager. These three components are mounted rigidly to an optical bench (Fig. 1a).... A set of alignment lasers realize the axis of rotation (AOR) and the source plane (that which is

perpendicular to the axis of rotation and intersects the x-ray source); furthermore, the AOR is positioned so that it intersects the perpendicular axis between the source and detector plane.

(Jaffray 1999 SPIE, at 17.) This discloses that the stage AOR (“axis of rotation”) is relative to the x-ray source and the FPI. This reference also expressly discloses that the object rotates “volumetric imaging is accomplished by rotating the object.” (*Id.*, at 16.) Furthermore, as explained by Dr. Balter, the claim recites rotation “relative” to the x-ray source, 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 is mounted on a rotating gantry as suggested by Jaffray 1999 JRO, the object will “rotate” relative to the x-ray source as the gantry rotates around the object. (*See* Ex. 1202, ¶¶ 81-82.)

As explained by Dr. Balter, one of ordinary skill in the art would have been motivated to combine the Jaffray 1999 references and Adler/Depp to obtain the method of claim 45 because these references teach the advantages of a patient stage or table that rotates relative to the axis of rotation of the x-ray source, and Jaffray 1999 SPIE teaches 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. 1202, ¶ 83.)

b. Claim 46

Claim 46 depends from claim 45, which depends from challenged claim 43, and adds the limitation “wherein said image is formed after one rotation of said body relative to said x-ray source and said flat-panel imager.” Jaffray 1999 SPIE expressly discloses this element because it teaches the assembly of a CBCT-FPI system with an object stage that rotates through 360°: “A single CBCT scan is obtained by acquiring projection images at 1.2° increment rotations of the object across 360°.” (Jaffray 1999 SPIE, at 25.)

Furthermore, as explained by Dr. Balter, claim 46, like claim 45, recites rotation “relative” to the x-ray source, which means that rotation of the x-ray source around a stationary object accomplishes rotation of the object “relative” to the x-ray source. Thus, the rotation gantries of Jaffray 1999 JRO and Adler/Depp both encompass this limitation. (*See* Ex. 1202, ¶¶ 84-85.) One of ordinary skill in the art would have been motivated to obtain the method of claim 46 for the same reasons set forth above with respect to claim 45.

5. Dependent Claims – Flat Panel Imagers

a. Claim 48

Claim 48 depends from claim 43 and adds the limitation “wherein said flat-panel imager comprises an array of individual detector elements.” This element is expressly disclosed by Jaffray 1999 SPIE: “The FPI incorporates a 512x512 active

matrix array of a-Si:H thin-film transistors and photodiodes in combination with an overlying (133 mg/cm² Gd₂O₂S:Tb) phosphor.” (Jaffray 1999 SPIE, at 16 (emphasis added).) As explained by Dr. Balter, this statement is an express disclosure of the limitation of claim 48 because such a matrix array is made of a square of elements, 512 elements on a side. (*See also* Ex. 1202, ¶ 86.) Furthermore, one of skill in the art would have been motivated to obtain the method of claim 48 because the prior art expressly taught the advantages of FPI imagers. 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* Jaffray 1999 SPIE, at 16-17 section entitled “Introduction and Motivation”; *see also* Ex. 1202, ¶¶ 86-87.)

b. Claim 49

Claim 49 depends from claim 48 and adds the limitation “wherein said array is a two-dimensional array.” This element is also expressly taught by Jaffray 1999 SPIE because the flat panel imager array of that reference is a 2-D array, as Jaffray 1999 SPIE expressly states: “[t]his is made possible by the use of a two-dimensional (2-D) detector” (Jaffray 1999 SPIE, at 17.) As explained by Dr. Balter, an FPI array like the a-Si:H type taught in Jaffray 1999 SPIE is a 2-D array. 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. 1202, ¶ 88.)

c. Claim 50

Claim 50 depends from claim 48 and adds the limitation “wherein each of said individual detector elements comprises a-Si:H photodiode.” This element is also expressly taught by Jaffray 1999 SPIE: “The FPI incorporates a 512x512 active matrix array of a-Si:H thin-film transistors and photodiodes” (Jaffray 1999 SPIE, at 16 (emphasis added).) 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. (*See* Ex. 1202, ¶ 89.)

d. Claim 59

Claim 59 depends from claim 43 and adds the limitation of “wherein said flat-panel imager is an amorphous silicon flat-panel imager.” Jaffray 1999 SPIE expressly discloses this element. The purpose of the reference was to “characterize the performance of a cone-beam computed tomography (CBCT) imaging system based upon an indirect-detection, amorphous silicon flat-panel imager (FPI).” (Jaffray 1999 SPIE, at 16.) As the authors explained, “[r]ecent advances in amorphous silicon (a-Si:H) flat-panel technology have made large-area, efficient x-ray detectors a reality. Such imagers are well-suited to CBCT” (*Id.*, at 17.) As explained by Dr. Balter, it would have been obvious to combine the radiotherapy

systems of Adler/Depp with the CBCT-FPI apparatus, using an amorphous flat panel imager, as expressly taught by Jaffray 1999 SPIE. 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. 1202, ¶ 90.)

6. Dependent Claims – Object Imaging

a. Claim 51

Claim 51 depends from claim 43 and adds the limitation “further comprising correcting for offset and gain prior to said generating.” This element is expressly disclosed by Jaffray 1999 SPIE: “After the projections are acquired, flood and dark field images are collected to construct gain and offset images for processing of the projection images. In addition to gain and offset corrections, median filtration (3x3) is performed using a preconstructed map of unstable pixels.” (Jaffray 1999 SPIE, at 19.) As explained by Dr. Balter, these offset and gain corrections were performed prior to generation of a 3-D image. (*See* Ex. 1202, ¶ 91.) This limitation adds nothing of patentable significance because offset and gain correction were known to be appropriate steps prior to generation of a 3-D image from a plurality of 2-D projections. (*See id.*)

b. Claim 52

Claim 52 depends from claim 43 and adds the limitation “wherein said object comprises an animal.” This element is expressly disclosed by Jaffray 1999

SPIE: “The soft-tissue visibility was evaluated by comparing the visibility of the intra-abdominal structures of a laboratory rat that had been euthanized.” (Jaffray 1999 SPIE, at 24 (emphasis added).) As explained by Dr. Balter, it was obvious to use the method of claim 43 to image an animal, as the stated purpose of all of the prior art references cited herein was to improve image guided radiation therapy for use in humans. Humans are “animals” within the meaning of this claim, and furthermore it would have been obvious to apply these same methods to a non-human animal. (*See* Ex. 1202, ¶ 92.)

c. Claim 53

Claim 53 depends from claim 43 and adds the limitation “wherein said image delineates soft tissue within said animal.” This element is also expressly disclosed by Jaffray 1999 SPIE: “The soft-tissue visibility was evaluated by comparing the visibility of the intra-abdominal structures of a laboratory rat that had been euthanized.” (Jaffray 1999 SPIE, at 24 (emphasis added).) As explained by Dr. Balter, it was obvious to arrive at the method of claim 43 because the ability to delineate soft tissue within the animal being imaged is important to discern the target tumor from surrounding healthy tissues. (*See* Ex. 1202, ¶ 93.)

d. Claim 54

Claim 54 depends from claim 43 and adds the limitation “wherein said soft tissue is selected from the group consisting of fat, a muscle, a kidney, a stomach, a

bowel and a liver.” This element is also expressly disclosed by Jaffray 1999 SPIE:

The soft-tissue visibility was evaluated Examples from the resulting volumetric image data are shown in Figs. 6 and 7. Figure 6 shows axial, sagittal and coronal slices through the CBCT data set, illustrating the full 3-dimensionality of the data acquired in a single rotation. In each of the images, the white cross-hairs are centered on a kidney and indicate the location of the other planar cuts.... The two axial cuts in Fig. 7 are of the same anatomic region, containing spine, bowel and kidney.

(Jaffray 1999 SPIE, at 24 (emphasis added), *see also* Figs. 6 & 7.) As explained by Dr. Balter, claim 54 adds nothing of patentable significance because the tissue structures listed were well-known examples of soft-tissues that could be differentiated using diagnostic x-ray imaging techniques prior to 1999. (*See* Ex. 1202, ¶ 94.)

e. Claim 55

Claim 55 depends from claim 43 and adds the limitation “wherein said generated image is based solely on said detected x-rays, wherein said object is not moved by external devices during said detecting x-rays.” This element is taught by Jaffray 1999 JRO references, because it describes 3-D imaging through rotation of the CBCT system without any movement of the object being imaged. This element is also expressly suggested by Adler: “[g]enerally, it is preferable to keep the patient **14** relatively stationary and to move the gantry **40**.” (Adler, 7:59-61.)

As explained by Dr. Balter, it was obvious to obtain imaging of the patient without moving the patient to avoid causing any movement of internal structures within the patient during the imaging process. (*See* Ex. 1202, ¶ 95.)

f. Claim 57

Claim 57 depends from claim 43 and adds the limitation “wherein said object is located at a single position during said emitting and said detecting and remains at said position during said controlling.” This limitation is taught by the same disclosures discussed above for claim 55—as Adler makes clear in the section quoted above, imaging and controlling the path of the radiation source can be performed without movement of the patient. Claim 57 is thus obvious for the same reasons explained above for claim 55. (*See* Ex. 1202, ¶ 96.)

IX. GROUND 2 – CLAIMS 60-66 & 68 ARE OBVIOUS OVER JAFFRAY 1999 SPIE, JAFFRAY 1999 JRO, ADLER/DEPP, AND YAN UNDER 35 U.S.C. § 103(a)

A. Prior Art and Date Qualification for Ground 2

Yan 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.

B. Brief Description of Yan

The Jaffray 1999 references and Adler/Depp are discussed above in Section VIII-B. **Yan [Ex. 1207]**, entitled “The Use of Adaptive Radiation Therapy to Reduce Setup Error: A Prospective Clinical Study,” discloses systems and methods

for image-guided radiotherapy. Yan's authors include David Jaffray and John Wong, two of the named inventors of the '502 patent and authors of the Jaffray 1999 references. Yan expressly teaches that an RTTP can be modified based on 3-D imaging, including by making alterations to the shape of the radiation field by adjusting the MLC (multi-leaf collimator).

C. Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler/Depp and Yan Disclose Each Limitation of Claims 60-66 & 68

1. Challenged Independent Claim 60

Independent Claim 60, like claim 43, is drafted in method form. Indeed, claim 60 is identical to claim 43 except that claim 60 recites "controlling a radiation therapy treatment plan" as opposed to the "controlling said path of said radiation source" of claim 43. For comparison purposes, the claims are reproduced in the side-by-side table above in Section V-B.

The element of controlling an RTTP based on three-dimensional image information concerning the object (patient) receiving radiotherapy was expressly disclosed in the art. Yan expressly teaches:

[A] closed-loop treatment process will be used to apply the patient specific information measured during the treatment course to reevaluate and to reoptimize the treatment plan. An optimal way to implement this feedback process integrates new technologies such as a 3D treatment planning system, an on-line imaging device, and MLC [multi-leaf collimator] through an information and control network.

(Yan, at 11 (emphasis added).) Thus, as confirmed by Dr. Balter, Yan expressly teaches that the RTTP can be controlled based on 3-D imaging, including by making alterations to the shape of the radiation field by adjusting the MLC (multi-leaf collimator). This comports with the '502 specification, which states that an RTTP can be controlled by “recalculation of the RTTP” (including to “modify the planning system to generate ‘corrected’ leaf positions.”) ('502, 25:56-57, 26:65-27:2; *see also* Ex. 1202, ¶ 99.)

2. Dependent Claims – Object Imaging

a. Claims 61-64, 66, and 68

Claims 61, 62, 63, and 64 recite the same additional limitations as claims 51, 52, 53, and 54, respectively. Thus these claims add nothing of patentable significance and are invalid for the same reasons set forth for those claims in Sections VIII-C-6-a through d, respectively.

Claims 66 and 68 recite the same additional limitations as claims 55 and 57, respectively. Thus these claims add nothing of patentable significance and are invalid for the same reasons set forth for claims 55 and 57 in Sections VIII-C-6-e and f, respectively.

3. Dependent Claim – Flat Panel Imagers

a. Claim 65

Claim 65 recites the same additional limitation as claim 59. Thus this claim

adds nothing of patentable significance and is invalid for the same reasons set forth for claim 59 in Section VIII-C-5-d.

D. Motivation to Combine Jaffray 1999 SPIE, Jaffray 1999 JRO, and Adler/Depp with Yan

The motivation to combine the Jaffray 1999 references with Adler/Depp is discussed in detail in Section VIII-C-2 above. One of ordinary skill in the art would further have been motivated to combine these teachings with Yan because Yan is directed specifically at the stated purpose of the '502 patent – improving the accuracy and efficacy of radiotherapy through image-guided means. As noted above, Yan's authors include two of the named inventors of the '502 patent (and co-authors of the Jaffray 1999 references). Last, one of skill in the art would have been motivated to perform the methods of claims 60-66 and 68 based on the specific suggestions in Yan that state that use of 3-D imaging is an “optimal way” to implement the process of adjusting radiotherapy to account for patient variability, so as to more specifically target the tumor and avoid irradiation of healthy surrounding tissues. (*See* Ex. 1202, ¶ 103.)

Petition for *Inter Partes* Review of
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X. CONCLUSION

Petitioner respectfully requests institution of *inter partes* review of claims 43-46, 48-55, 57, 59, 60-66, and 68 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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Petition for *Inter Partes* Review of
U.S. Patent No. 6,842,502

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. 1201-1237**) 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
U.S. Patent No. 6,842,502

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