

Petition for *Inter Partes* Review of
U.S. Patent No. 7,471,765

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. 7,471,765
Filing Date: December 27, 2004
Issue Date: December 30, 2008

Title: CONE BEAM COMPUTED TOMOGRAPHY WITH A FLAT PANEL IMAGER

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 7,471,765**

Inter Partes Review No. 2015-____

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List of Exhibits

Ex. No.	Description of Document
1001	U.S. Patent No. 7,471,765 to David A. Jaffray, <i>et al.</i> (“’765 patent”)
1002	Declaration of Dr. James Balter (“Balter Decl.”)
1003	U.S. Patent No. 5,207,223 issued to Adler <i>et al.</i> (“Adler”)
1004	U.S. Patent No. 5,427,097 issued to Depp (“Depp”)
1005	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”)
1006	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”)
1007	Aug. 13, 2008 Notice of Allowance
1008	May 15, 2008 Applicant Remarks
1009	Provisional Application No. 60/183,590 filed by David A. Jaffray <i>et al.</i> (“’590 Provisional”)
1010	Highlighted copy of the ’765 Patent showing matter not disclosed in the ’590 Provisional Application
1011	Dec. 10, 2007 Applicant Amendment
1012	P. Munro, <i>Portal Imaging Technology: Past, Present, and Future</i> , Seminars in Radiation Oncology, 5:115-33 (Apr. 1995) (“Munro 1995”)
1013	Dec. 27, 2004 Applicant’s Preliminary Amendment
1014	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”)

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Ex. No.	Description of Document
1015	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”)
1016	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”)
1017	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”)
1018	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”)
1019	R. Sephton <i>et al.</i> , <i>A diagnostic-quality electronic portal imaging system</i> , Radiotherapy & Oncology, 35:204-47 (1995) (“Sephton 1995”)
1020	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”)
1021	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”)
1022	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”)
1023	D. Yan <i>et al.</i> , <i>Adaptive radiation therapy</i> , Phys. Med. Biol., 42:123-32 (1997) (“Yan 1997”)

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Ex. No.	Description of Document
1024	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”)
1025	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”)
1026	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”)
1027	P.S. Cho <i>et al.</i> , <i>Cone-beam CT for radiotherapy applications</i> , Phys. Med. Biol., 40:1863-83 (1995) (“Cho 1995”)
1028	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”)
1029	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”)
1030	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”)
1031	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”)

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Ex. No.	Description of Document
1032	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”)
1033	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”)
1034	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”)
1035	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”)
1036	U.S. Patent No. 6,041,097 issued to Roos <i>et al.</i> (“Roos 1998”)
1037	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”)
1038	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. 7,471,765

Petitioner Varian Medical Systems, Inc. (“Petitioner”) respectfully submits this Petition for *Inter Partes* Review of claims 1-13 & 20-31 of U.S. Patent No. 7,471,765 [Ex. 1001] (“the ’765 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 ’765 patent is the subject of a 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 ’765 patent. The Petitioner was served with a complaint in that action on September 3, 2015.

Petitioner is currently filing an additional petition for *inter partes* review of claims 1-13 & 20-31, based on unique legal grounds and prior art. Petitioner is also seeking *inter partes* review of method claims 14-19 of the ’765 patent through an additional concurrently filed petition.

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.

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

This Petition requests review of 25 claims of the '765 patent, therefore excess claim fees are required. A payment of \$28,000 is submitted herewith, comprising a \$10,000 request fee and a post-institution fee of \$18,000. *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 '765 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. Petitioner is unaware of any previous petition for *inter partes* review of the '765 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 1-13 & 20-31. This Petition cites the following prior art references, included as Exhibits **1003** through **1006**:

Ex. No.	Description of Document
1003	U.S. Patent No. 5,207,223 issued to Adler <i>et al.</i> (“Adler”)
1004	U.S. Patent No. 5,427,097 issued to Depp (“Depp”)
1005	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”)
1006	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”)

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

Ground	Claims	Basis for Challenge
1	1-13 & 20-31	Obvious over Jaffray 1999 SPIE, Jaffray 1999 JRO, and Adler/Depp (§ 103(a))

Section VIII-C below provides a detailed explanation as to why the challenged claims are unpatentable based on this ground.

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. 1002], ¶¶ 2-5.) Dr. Balter's declaration includes additional exhibits (Exs. 1012-1038), 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 1-13 & 20-31 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

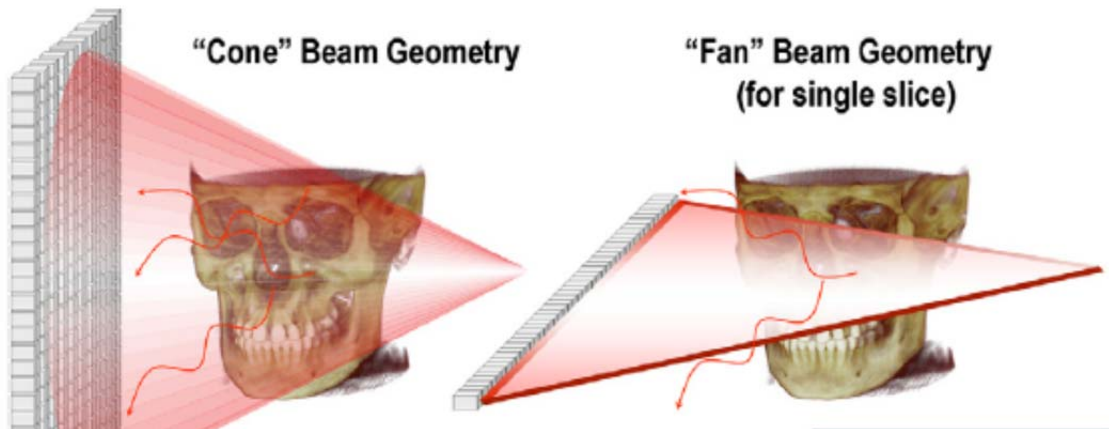
Radiation therapy or "radiotherapy" is the use of beams of radiation for the treatment of disease. Radiation therapy of internal patient lesions, such as cancerous tumors, is very old – dating back over 100 years. For decades, practitioners have known that the effectiveness of radiation therapy is increased 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. 1002, ¶ 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 '765 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 '765 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. 1002, ¶ 154.*) Thus before the ’765 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 '765 Patent Did Not Advance the Art

The '765 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 '765 patent, the patient is imaged while in position for treatment with a radiation beam. ('765, 1:16-21.) As described by the applicants, CBCT is used to obtain 3-D patient information which can be used to better guide therapeutic radiation to a target lesion such as a tumor. (*Id.*, 1:23-25; 3:41-4:2.)

The systems claimed in the '765 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 radiotherapy to use diagnostic (kV) x-rays on a radiotherapy gantry to obtain images for real-time control of a radiotherapy beam. 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 teachings 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. 1002, ¶¶ 21-22.)

In fact, the '765 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 '765 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 radiotherapy beam. Instead, the applicants claimed the obvious and well-known concept of controlling the path of a radiotherapy beam “substantially at a time” that the imaging beam is detected, and seek to exclude others from using it. This concept has long been used in radiation oncology – indeed the basic purpose of image-guided radiotherapy entails imaging as close as possible to the time of radiation delivery. The '765 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 '765 patent should not have been issued.

V. SUMMARY OF THE '765 PATENT

A. The Specification and File History of the '765 Patent

The '765 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. The specification also describes the ability to obtain 3-D images from a single rotation of the x-ray gantry around the patient as a benefit of CBCT. Finally, the specification describes an embodiment in which the radiotherapy beam is controlled “substantially at a time” when x-rays passing through the object are received by the FPI.

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

[T]he prior art discloses a radiation therapy system that comprises: a radiation source that moves about an object and directs a beam of radiation towards the object; a cone-beam computed tomography system comprising: an x-ray source that moves about the object and emits toward the object from multiple positions around the object x-ray beams in a cone-beam form; an flat-panel imager positioned to receive x-rays after at least a portion of the x-ray beams pass through

the object, the imager providing an image that contains three-dimensional information concerning the object based on a plurality of two-dimensional projection images; and a computer coupled to the computed tomography system, wherein the computer receives the three-dimensional information and based on the three-dimensional information received controls a path of the beam of radiation through the object by controlling a relative position between the radiation source and the object.

(Ex. 1007, Aug. 13, 2008 Notice of Allowance, at 6-7.)

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 radiotherapy beam control based on 3-D image information occurred “substantially at a time” that x-rays were received by the FPI. This amendment was the sole basis for Examiner Ho’s allowance of the claims:

[T]he prior art fails to disclose or fairly suggest that the receiving the x-rays by the flat-panel imager is performed substantially at a time of occurrence of the controlling the path of the beam of radiation through the object as claimed.

(*Id.* at 7.) As explained below, the prior art Adler/Depp reference, which was not considered during prosecution, did in fact expressly disclose the element that the Examiner believed was missing.

B. The Challenged Claims of the '765 Patent

This Petition addresses claims 1-13 & 20-31. Challenged independent claims 1, 7, 20, and 26 are systems claims that recite the same basic components, with minor variations and alterations. For example, claims 7 and 26 recite a support table for the patient (“object”) to be treated. As another example, claim 7 (unlike claims 1 and 20) specifies a computer that acquires data from the imager for generation of patient 3-D information.

The four independent system claims also vary in their description of the structure that controls the path of the radiation beam. Claim 1 recites “a computer,” claim 7 recites a “controller,” claim 20 recites no structure at all, and claim 26 recites that the “support table” performs the control function. To aid in claim analysis, a table for comparison of these claims is set forth below:

Claim 1	Claim 7	Claim 20	Claim 26
A radiation therapy system comprising:	A radiation therapy system comprising:	A radiation therapy system comprising:	A radiation therapy system comprising:
	a support table upon which to position an object to be treated;		a support table upon which to position an object to be treated;
a radiation source that moves about an object and directs a beam of radiation towards said object;	a radiation source which is movably mounted relative to said support table and which directs a beam of radiation toward said object;	a radiation source that moves about an object and directs a beam of radiation towards said object;	a radiation source which is movably mounted relative to said support table and which directs a beam of radiation toward said object;

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a cone-beam computed tomography system comprising:	a cone-beam computed tomography system comprising:	a cone-beam computed tomography system comprising:	a cone-beam computed tomography system comprising;
an x-ray source that moves about said object and emits toward said object from multiple positions around said object x-ray beams in a cone-beam form;	an x-ray source that emits x-rays in cone-beam form towards said object and is rotatably mounted relative to said support table;	an x-ray source that moves about said object and emits toward said object from multiple positions around said object x-ray beams in a cone-beam form;	an x-ray source that emits x-rays in cone-beam form towards said object and is rotatably mounted relative to said support table;
a flat-panel imager positioned to receive x-rays after at least a portion of said x-ray beams pass through said object,	a flat-panel imager which is rotatably mounted relative to said support table and positioned to receive x-ray beams emitted from said x-ray source and which acquires a two-dimensional projection image of said object based upon each received x-ray beam passing through said object;	a flat-panel imager positioned to receive x-rays after at least a portion of said x-ray beams pass through said object,	a flat-panel imager which is rotatably mounted relative to said support table and positioned to receive x-ray beams emitted from said x-ray source and which acquires a two-dimensional projection image of said object based upon each received x-ray beam passing through said object;
said imager providing an image that contains three-dimensional information concerning said object based on a		said imager providing an image that contains three-dimensional information concerning said object based on a	

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plurality of two-dimensional projection images;		plurality of two-dimensional projection images;	
	a computer to generate three-dimensional information concerning said object based upon multiple two-dimensional projection images of said object acquired by said flat-panel imager;		a computer to generate three-dimensional information concerning said object based upon multiple two-dimensional projection images of said object acquired by said flat-panel imager;
and a computer coupled to said cone-beam computed tomography system, wherein said computer receives said three-dimensional information and based on said three-dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object,	a controller to control a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object in response to said three-dimensional information being sent to said controller,	and wherein said radiation therapy system has a structure for controlling a path of said beam of radiation through said object based on said three-dimensional information by controlling a relative position between said radiation source and said object,	wherein said support table controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object in response to said three-dimensional information,
	wherein said object is correctly		wherein said object is correctly

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	positioned relative to said radiation beam,		positioned relative to said radiation beam and,
wherein said receiving said x-rays by said flat panel imager is performed substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.	and wherein said receiving said x-ray beams by said flat panel imager is performed substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.	wherein said receiving said x-rays by said flat-panel imager is performed substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.	wherein said receiving said x-ray beams emitted from said x-ray source by said flat-panel imager is performed substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.

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. “substantially at a time”

This term, which was added during prosecution of the claims and which appears expressly or by reference in every claim in the patent, is indefinite. The phrase “substantially at a time” is vague in itself because it is a term of degree, and no standard for determining the scope of the claimed degree is given by the patent specification, confirming the indefiniteness of the term. *See Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1387 (Fed. Cir. 2015).

Furthermore, when read in light of the prosecution history, the scope of the term becomes even more uncertain. First, the ’765 applicants frankly admitted to the Examiner that no standard for measuring this time was given in the specification: “[a]pplicants’ specification does not provide a specific time frame” (*See Ex. 1008, May 15, 2008 Applicant Remarks, at 13.*) Second, the applicants’ attempt to provide clarification merely replaced the vague claim term with another vague and undefined term of degree: “one of ordinary skill would understand that the span of time ... would be such that there would be a small

¹ Petitioner reserves the right to seek different constructions for terms of the ’765 patent claims, as appropriate, in district court litigation.

probability that there would be significant changes in the positions of objects being imaged during the span of time.” (*Id.*, at 12-14 (emphasis added).) But no standard for determining a “small probability” of movement of objects being imaged was provided in the specification. Thus one of skill in the art has no standard for ascertaining how soon in time the radiation beam must be controlled after the x-rays are detected while remaining within the scope of the claims. Indeed, such a decision would be dependent on the subjective and varied judgment of the treating physician, the kind of “unpredictable vagaries of any one person’s opinion” that render such terms of degree indefinite. (*See* Ex. 1002, ¶¶ 35-37.) *See also* *Biosig*, 783 F.3d at 1381. Thus the term is invalid for indefiniteness. *See Medshape, Inc. v. Cayenne Med., Inc.*, IPR2015-00848, Paper No. 9 at 8-10 (P.T.A.B. Sept. 14, 2015).

Nevertheless, should the Board conclude that, under the broadest reasonable construction standard, it can proceed to evaluate the scope of the claim against the prior art, the claim should be given a construction consistent with the express statements made by the applicants during prosecution. In that regard, the applicants stated that:

[T]he independent claims have been amended to clarify that the receiving or detection of x-rays by the flat-panel imager is at

substantially the same time as the controlling the path of the radiation
through the object.

(Ex. 1008, May 15, 2008 Applicant Remarks, at 13 (emphasis added).)

While still failing to properly delimit the boundaries of the claims' scope, the term "substantially at a time" in view of the file history should be construed to mean "substantially at the same time." As explained by Dr. Balter, this proposed construction comports with how one of ordinary skill in the art would interpret the term from the intrinsic record. (*See* Ex. 1002, ¶ 38.) And as explained in detail below, the prior art expressly discloses subject matter that meets this claim element despite the inability to ascertain its full scope with reasonable certainty.

B. "three-dimensional information"

This term appears in challenged independent claims 1, 7, 20, and 26. 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. ('765, 3:41-44 ("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. 1002, ¶ 39.)

- C. “a computer coupled to said cone-beam computed tomography system, wherein said computer receives said three-dimensional information and based on said three-dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object”**

This term appears in claim 1. The element generically recites a computer and the function it performs: receiving 3-D information and based on that 3-D information controlling the path of the radiation beam through the object by controlling a relative position between the radiation source and the object. 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).

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 ’765 patent was filed before September 16, 2012, the pre-AIA version of § 112(6) (now referred to as § 112(f)) applies.

There is no structure disclosed in the specification for programming the general-purpose computer to perform the recited function. *WMS Gaming Inc. v. 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 functional 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.” (’765, 4:56-61.) The flow charts (and accompanying text) likewise merely restate the claimed function of controlling the radiation path based on the 3-D image. (’765, 26:59-67, 27:16-57, 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. 1002, ¶¶ 40-42.) The absence of corresponding structure for performing the claimed function, as required by § 112(6), renders the claims of the '765 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). ('765, 4:56-61, 26:59-67, 27:16-57, Figs. 24 & 26.) Under this view, the claims are invalid as obvious because structure for performing the claimed function at the level of detail of the '765 specification was already taught in the prior art. (*See* Ex. 1002, ¶ 43.)

D. “a controller to control a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object in response to said three-dimensional information being sent to said controller”

This term appears in claim 7. The element generically recites the nonce word “controller” in place of the controlling “computer” of claim 1 discussed above. As with the computer element of claim 1, the function performed is

essentially the same: controlling the relative position between the radiation source and the object based on 3-D information from the CBCT system. And again, no structure for performing the claimed function is recited by the claim. The term is thus also governed by the means-plus-function limitations of 35 U.S.C. §112(6). *Williamson*, 792 F.3d at 1349.

For the same reason set forth above regarding the controlling “computer” of claim 1, the specification fails to disclose adequate linked structure for this function. Indeed, claim 7 specifies the requirement that the object be “correctly positioned relative to said radiation beam.” But, as with claim 1, no structure is provided that actually accomplishes the claimed function of correct positioning based on the 3-D information obtained from the CBCT system. With no disclosure of corresponding structure as required by § 112(6), claims of the ’765 patent including this element are invalid for indefiniteness. (*See also* Ex. 1002, ¶¶ 44-45.)

Nevertheless, should the Board conclude that the term is not indefinite under § 112(6), then this “controller” 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). (’765, 4:56-61, 26:59-67, 27:16-57, Figs. 24 & 26.) Under this view, the claims are invalid as obvious because structure for performing the claimed function at the level of detail of the ’765 specification was already taught

in the prior art. (*See* Ex. 1002, ¶ 46.)

E. “a structure for controlling a path of said beam of radiation through said object based on said three-dimensional information”

This term appears in claim 20. The element recites the words “a structure for” performing the claimed function of controlling, and thus is even more purely functional than the nonce words of “computer” and “controller” of claims 1 and 7. Thus, this element is a means-plus-function term under of 35 U.S.C. § 112(6). *Williamson*, 792 F.3d at 1349. And as insufficient structure is provided for performing the claimed function of beam control relative to the patient based on the 3-D information obtained from the CBCT system, the claims of the ’765 patent that include this element are invalid for indefiniteness. (*See also* Ex. 1002, ¶¶ 47-48.)

Nevertheless, should the Board conclude that the term is not indefinite under § 112(6), then this “a structure for controlling” 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). (’765, 4:56-61, 26:59-67, 27:16-57, Figs. 24 & 26.) Under this view, the claims are invalid as obvious because structure for performing the claimed function at the level of detail of the ’765 specification was already taught in the prior art. (*See* Ex. 1002, ¶ 49.)

F. “said support table controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object in response to said three-dimensional information”

This term appears in claim 26. The element recites the words “support table” for performing the claimed function of controlling based on the image, but the claim provides no further details about how the recited table structure performs that function. Under the broadest reasonable construction, it is impossible that any support table could perform the recited function other than under computer control. (See Ex. 1002, ¶¶ 50-52.) Indeed, the specification is clear that the embodiment recited by the claim is under computer control. The specification discusses “a computer-controlled treatment table **443** for correction of lesion localization errors.” (See ’765, 24:51-57 (emphasis added).) Under the broadest reasonable construction, therefore, this element requires a computer and, like the “computer” and “controller” terms of claims 1 and 7, is governed by the means-plus-function provisions of 35 U.S.C. § 112(6). *Williamson*, 792 F.3d at 1349.

Just as with the “computer,” “controller,” and “a structure for controlling” elements discussed above, the specification does not contain sufficient linked structure for performing the claimed function. (See also Ex. 1002, ¶ 52.) One of ordinary skill in the art would not find the disclosures of the patent to adequately describe an algorithm for performing the claimed function. With no disclosure of

corresponding structure as required by § 112(6), claims of the '765 patent including this element are invalid for indefiniteness.

Nevertheless, should the Board conclude that the term is not indefinite under § 112(6), then this 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). ('765, 4:56-61, 26:59-67, 27:16-57, Figs. 24 & 26.) Under this view, the claims are invalid as obvious because structure for performing the claimed function at the level of detail of the '765 specification was already taught in the prior art. (*See Ex. 1002, ¶ 53.*)

VII. THE CLAIMS OF THE '765 PATENT HAVE A PRIORITY DATE OF NO EARLIER THAN FEBRUARY 16, 2001

The '765 patent seeks the benefit of provisional application 60/183,590 (“the '590 provisional”), filed on February 18, 2000. ('765, 1:4-11; the '590 provisional is submitted as Ex. 1009.) The claims of the '765 patent, however, are not entitled to this priority date because they are wholly unsupported by the '590 provisional.

Every claim in the patent requires that the claim element of controlling the path of the radiation beam is performed “substantially at a time” when the flat panel imager receives or detects x-rays. For example, claim 1 recites the element “wherein said receiving said x-rays by said flat panel imager is performed

substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.” (’765, claim 1 (emphasis added).) Independent claims 7, 20, and 26 also contain this element, drafted in virtually identical language. And independent claims 14 and 17, drafted in method form, likewise recite a comparable limitation, claim 14 in the context of controlling a path of a radiation beam and claim 17 in the context of modifying a radiation therapy treatment plan. The remaining dependent claims of the patent, all of which are challenged in this petition, all incorporate this “substantially at a time” element by reference. As described above, this limitation is extremely significant, as it was the sole element the Examiner believed to be missing from the prior art.

None of the claims that were ultimately allowed in the ’765 patent 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 ’765 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 substantially at the same time as the x-rays are received by the FPI, as the claims of the ’765 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

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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 of the '765 patent from Column 19, line 33 to the end – over eight columns of text – is new matter that was not disclosed in the '590 provisional. This new disclosure is shown in Exhibit **1010**, a copy of the '765 patent that highlights the new matter that was added to the '765 specification and absent from the '590 provisional. (*See* Ex. 1010.)

As confirmed by Dr. Balter, the '590 provisional has no support for claims reciting controlling the relative position of the radiation beam path substantially at the same time as the x-rays are received by the FPI. None of the teachings in the patent describing guidance of radiotherapy based on a CBCT-FPI system found in columns 19-27 of the '765 patent were presented in the '590 provisional. The provisional does not even disclose control of radiotherapy based on 3-D imaging, let alone performing such control “substantially at a time” when the FPI receives the x-rays. One of ordinary skill in the art, would not have recognized that the applicants possessed the missing “substantially at a time” element based on the '590 provisional application. (*See* Ex. **1002**, ¶¶ 57-63.)

During prosecution of the '765 patent, the applicants were challenged by the Examiner to identify support in the specification for the “substantially at a time”

claim limitation. In response, the only support they identified was the phrase “the cone beam computerized tomography image is preferably acquired with the patient on the treatment table, in the treatment position, and immediately prior to treatment delivery.” (Ex. **1008**, May 15, 2008 Applicant Remarks, at 12.) This disclosure is present only in the nonprovisional (’765, 23:26-29), and was not disclosed in the ’590 provisional. (*See, e.g.*, Ex. 1010, 23:26-29.)³ One of ordinary skill in the art, reviewing the ’590 provisional, therefore would not have recognized that the applicants possessed the “substantially at a time” element in the provisional. (*See* Ex. **1002**, ¶ 64.)

Because all of the claims of the ’765 patent must rely on the new matter added to the February 16, 2001 nonprovisional (and not present in the ’590 provisional), the earliest effective filing date for the claims can be no earlier than

³ On Dec. 10, 2007, the applicants also improperly amended their specification to add new matter during prosecution, adding two sentences containing the phrase “real-time” and relating to the “substantially at a time” concept. (*See* ’765, 23:29-33, 27:53-57; *see also* Ex. **1011**, Dec. 10, 2007 Applicant Amendment, at 3.) To the extent the Patent Owner attempts to rely on these improper additions of new matter for support of the “substantially at a time” limitation of the claims, the claims are invalid for improper reliance on new matter.

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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 1-13 & 20-31 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 1-13 & 20-31 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. 1005] (“**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. 1006] (“**Jaffray 1999 JRO**”), U.S. Patent No. 5,207,223 issued to Adler *et al.*, published on May 4, 1993 [Ex. 1003] (“**Adler**”), U.S. Patent No. 5,427,097 issued to Depp, published on June 27, 1995 [Ex. 1004] (“**Depp**”).⁴

⁴ 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.”

The Jaffray 1999 references are § 102(b) (pre-AIA) prior art because, as noted above, the '765 patent is not entitled to seek the priority date of its provisional application, and the references published more than one year before February 16, 2001, the earliest nonprovisional date of the '765 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 '765 patent. Adler/Depp qualifies 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 '765 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, and Adler/Depp

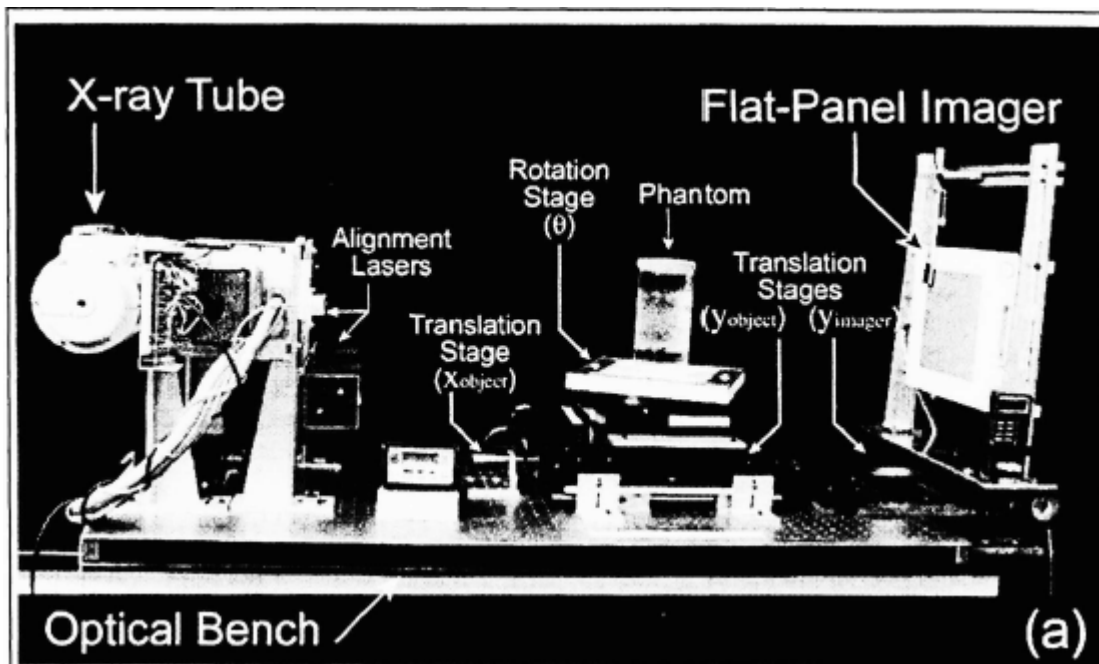
Jaffray 1999 SPIE [Ex. 1005], entitled “Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager,” discloses a system for CBCT scanning to create 3-D (“volumetric”) images with flat panel imagers as detectors. As Jaffray 1999 SPIE explained:

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

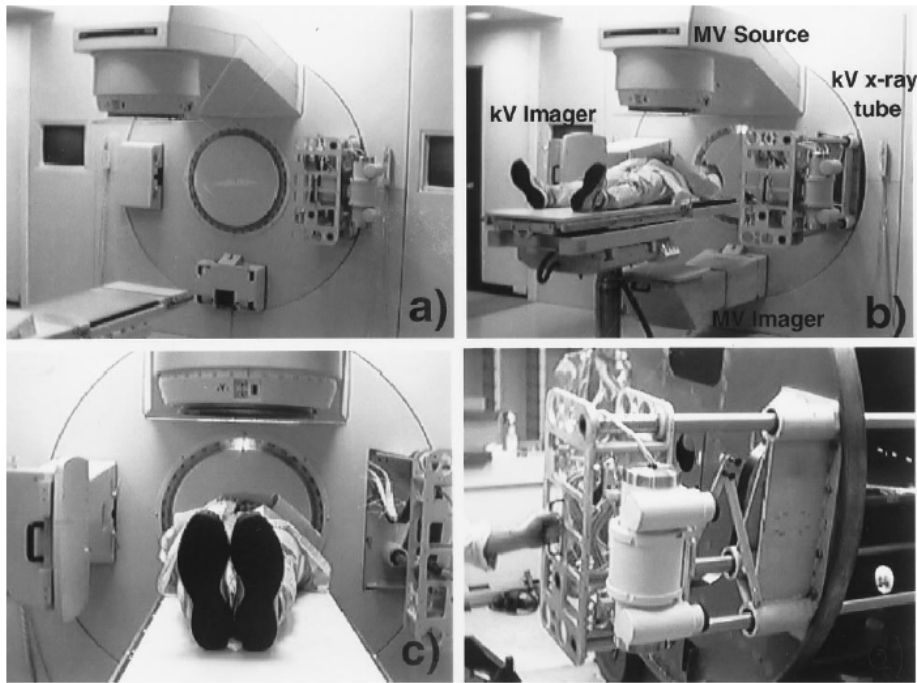
beam radiotherapy. Specifically, the flat-panel imager will be mounted on a treatment gantry opposite a kilovoltage x-ray tube in a manner previously accomplished with a CCD-based imager.” (*Id.*, at 25.)

Jaffray 1999 JRO [Ex. 1006], 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 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:

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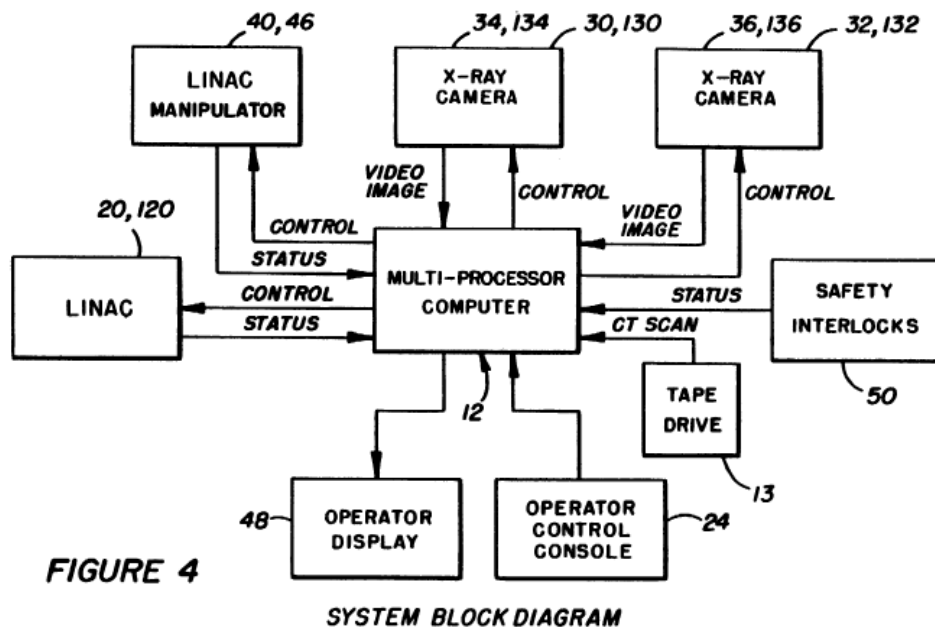


(*Id.*, at 5, stating “The dual-beam system was constructed on a Elekta SL-20 medical linear accelerator.”)

Adler [Ex. 1003], 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 beam if needed to ensure targeted delivery of the radiation dose. Like the ’765 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:



(*Id.*, Fig. 4.)

Depp [Ex. 1004] 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 radiation beam in real time.

C. Jaffray 1999 SPIE, Jaffray 1999 JRO, and Adler/Depp Disclose Each Limitation of Claims 1-13 & 20-31

1. Challenged Independent Claims 1, 7, 20, and 26

As noted above, this petition challenges all four independent systems claims in the '765 patent (claims 1, 7, 20, and 26).

a. Claim 1

The preamble of claim 1 recites: “A radiation therapy system comprising.” Although the preamble of claim 1 may not be limiting under its broadest reasonable construction, Adler/Depp and Jaffray 1999 JRO disclose it.

As explained in more detail below, Adler/Depp discloses a system for radiotherapy that is 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. 1002, ¶¶ 76-78.) As shown in Figure 1 of Adler, for example, Adler/Depp discloses a system for delivering radiotherapy to a patient:

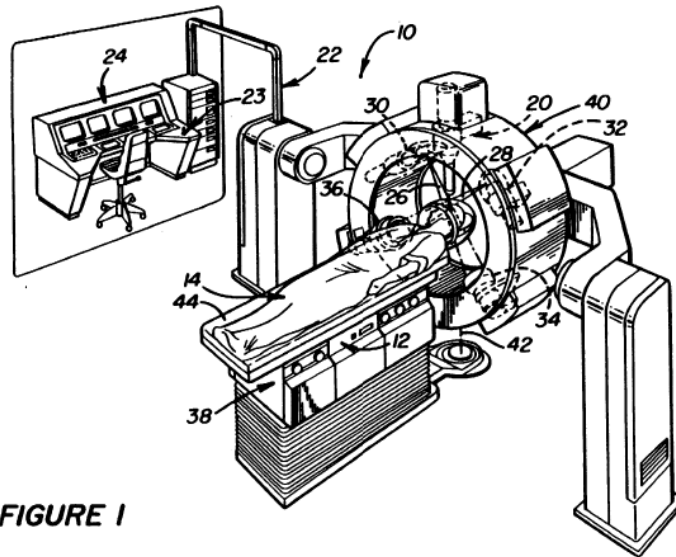


FIGURE 1

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

Adler/Depp also teaches an alternative embodiment in which the radiation beam 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 radiotherapy using a medical linear accelerator device.

- (1) **“a radiation source that moves about an object and directs a beam of radiation towards said 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. 1002, ¶¶ 79-80.) For the same reason, this claim element is also taught by both Jaffray 1999 references, which disclose medical linear accelerators that comprise this claim element. (*See id.*, ¶ 81.)

- (2) **“a cone-beam computed tomography system comprising: an x-ray source that moves about said object and emits toward said object from multiple positions around said object x-ray beams in a cone-beam form”**

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.)

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.) As confirmed 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. 1002, ¶ 82.)

- (3) **“a flat-panel imager positioned to receive x-rays after at least a portion of said x-ray beams pass through said object, said imager providing an image that contains three-dimensional information concerning said object based on a plurality of two-dimensional projection images”**

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 (emphasis added).) 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 (“volume data sets”). (*See* Ex. 1002, ¶¶ 83-84.)

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 confirmed by Dr. Balter, these FPI devices function as x-ray detectors by detecting multiple x-ray beams that pass through the object being imaged. Thus, this element is expressly taught by both Jaffray 1999 references. (*See* Ex. 1002, ¶ 86.)

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. 1002, ¶ 85.)

- (4) **“and a computer⁵ coupled to said cone-beam computed tomography system, wherein said computer receives said three-dimensional information and based on said three-dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object”**

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

⁵ 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.

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 beam based on multiple x-rays images. (*See* Ex. 1002, ¶ 87-88.)

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 also* Ex. 1002, ¶ 88.)

- (5) **“wherein said receiving said x-rays by said flat panel imager is performed substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.”**

Adler teaches controlling the path of the radiation beam at the same time as

detecting the x-rays:

Means are provided for producing electronic images from and representative of the first and second images. Means are provided for comparing the 3-dimensional mapping stored in the data storage memory with the electronic images representative of the first and second images to derive therefrom data representative of the real time location of the target region. Means are provided for adjusting the relative positions of the beaming apparatus and the living organism as needed in response to the data representative of the real time location of the target region in such a manner that the collimated beam, when activated, is continuously focused on to the target region.

(Adler, 4:39-51; *see also id.*, 5:29-39, 7:36-42, 9:4-9, and claim 1.)

The claims of the Adler patent provide further express teaching of “real time” control of a radiotherapy beam based on imaging. Claim 1 of Adler recites:

[I]n response to said real time spatial locations of said collimated beam and target region, adjusting the relative positions of the beaming apparatus and the living organism in such a manner that the collimated beam is focused onto the target region

(*Id.*, claim 1.) The same claim also recites repeating this step:

[P]eriodically repeating the comparing step at small time intervals using newly produced first and second images such that any movement of the target region relative to the focus of the collimated beam is detected in substantially real time

(*Id.*) Claim 2 continues: “wherein the repeating of the adjusting is carried out

automatically in response to the position data obtained in the comparing step.”
(*Id.*, claim 2.)

Depp also discloses this element, as noted above: “The radiosurgical beam is accurately directed into the target region in substantially real time based on this information.” (Depp, 11:58-61.) Depp discloses the real-time control nature of his invention throughout the specification. (*See id.*, Abstract, 2:48-68, 5:10-15.) As confirmed by Dr. Balter, the Adler/Depp disclosure discloses this claim element. (*See Ex. 1002*, ¶¶ 89-91.)

b. Claim 7

Independent claim 7 is very similar to claim 1. The primary differences are that it adds a limitation of a support table for the object to be treated, specifies a computer that generates the 3-D object information, and adds a “controller” to control the radiation beam path where claim 1 recites a “computer” for the same function. Each of these additional limitations were taught by the prior art.

Claim 7 is reproduced in the table below, which refers the Board to the arguments above that pertain to the elements that claim 7 shares with claim 1:

Claim 7	Citation to Argument
A radiation therapy system comprising: a support table upon which to position an object to be treated;	<i>See</i> claim 1, Section VIII-C-1-a above. This limitation was expressly taught by Adler/Depp. Referring to Figure 1, Adler teaches an “operating table 38 ” for the patient 14 . (Adler, 7:37-52.)

Claim 7	Citation to Argument
	Depp contains the same teaching. (Depp, 5:10-25.) Jaffray 1999 JRO also expressly teaches this element. The Elekta SL-20 device of the reference, shown in Fig. 1 (reproduced in Section VIII-B above) depicts the patient table.
a radiation source which is movably mounted relative to said support table and which directs a beam of radiation toward said object;	<i>See</i> claim 1, Section VIII-C-1-a-(1) above.
a cone-beam computed tomography system comprising: an x-ray source that emits x-rays in cone-beam form towards said object and is rotatably mounted relative to said support table;	<i>See</i> claim 1, Section VIII-C-1-a-(2) above.
a flat-panel imager which is rotatably mounted relative to said support table and positioned to receive x-ray beams emitted from said x-ray source and which acquires a two-dimensional projection image of said object based upon each received x-ray beam passing through said object;	<i>See</i> claim 1, Section VIII-C-1-a-(3) above.
a computer to generate three-dimensional information concerning said object based upon multiple two-dimensional projection images of said object acquired by said flat-panel imager;	This element is expressly disclosed by Jaffray 1999 SPIE: “The acquisition process – object rotation, x-ray exposure, and image acquisition — <u>is synchronized by the host computer.</u> Volume data sets were obtained from the projection data using the Feldkamp algorithm for CBCT reconstruction.” (Jaffray 1999 SPIE, at 25 (emphasis added).)

Claim 7	Citation to Argument
a controller ⁶ to control a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object in response to said three-dimensional information being sent to said controller, wherein said object is correctly positioned relative to said radiation beam,	<i>See</i> claim 1 “computer,” Section VIII-C-1-a-(4) above.
and wherein said receiving said x-ray beams by said flat panel imager is performed substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.	<i>See</i> claim 1, Section VIII-C-1-a-(5) above.

Petitioner notes that claim 7 recites “a controller to control a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object in response to said three-dimensional information being sent to said controller, wherein said object is correctly positioned relative to said radiation beam.” Under the broadest reasonable construction, this “controller” element is equivalent to the “computer” element of claim 1 that controls the path of the radiation beam. Whether styled as a

⁶ As discussed above in Section VI-D, 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.

“computer” or “controller,” the function is the same, and the element is expressly taught by Adler/Depp, as noted in the claim chart above and explained in detail in Section VIII-C-1-a-(4). (*See also* Ex. 1002, ¶¶ 92-94.)

c. Claim 20

Independent claim 20 is virtually identical to claim 1, with the sole difference being that the claim does not even employ a nonce word for its means-plus-function element, instead simply stating that the claimed system “has a structure for controlling” the path of the radiation beam.⁷

Under the broadest reasonable construction, if the Board does not determine the claim to lack corresponding structure under 35 U.S.C. § 112(6), the “structure for controlling” can be performed, for example, by the “computer” that controls the radiation beam as set forth in claim 1. Thus, claim 20 is obvious for the same reasons as claim 1, covered in Section VIII-C-1 above. (*See also* Ex. 1002, ¶ 95.)

d. Claim 26

Independent claim 26 is virtually identical to independent claim 7. The sole difference between the claims is that where claim 7 recites “a controller to control

⁷ As discussed above in Section VI-E, 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.

a path” of the radiation beam, claim 26 recites that the “support table controls a path” of the radiation beam.⁸ 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 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.

(Adler, 7:42-58 (emphasis added).) Depp contains the same express teaching. (Depp, 5:15-31.) Per Adler/Depp, such support tables can move and be used to position a patient relative to a radiotherapy beam. (*See also* Ex. 1002, ¶¶ 96-97.)

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

The claims are obvious because all elements 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

⁸ As discussed above in Section VI-F, 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.

prior art CBCT-FPI system (Roos), but believed the only element of the claims missing from the prior art was controlling the path of the radiation beam “substantially at a time” that the FPI was receiving x-ray projection images. As shown above, Adler/Depp provides this missing limitation in a radiation therapy system using x-ray imaging for real time radiation beam control.

It was known in radiotherapy to use diagnostic x-rays on a radiotherapy gantry to obtain diagnostic quality images to effect real-time control of a radiation beam (Adler/Depp). It was also known to use x-rays for cone beam imaging on a linear accelerator gantry because of its superior image quality (Jaffray 1999 JRO), and indeed it was known to use the exact type of flat panel imager used in the prior art CBCT system and the preferred embodiment of the ‘765 patent on a radiotherapy system (Jaffray 1999 SPIE). 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 would be obvious to use the prior art CBCT/FPI system to control the prior art radiotherapy system. 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.... 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.) (*See also* Ex. 1002, ¶¶ 98-100.)

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

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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).)

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.)

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

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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. 1002, ¶ 102.) As confirmed by Dr. Balter, the combination of the CBCT-FPI methodology of the Jaffray 1999 references with the radiotherapy control apparatus of Adler/Depp, as done by the '765 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/Depp. (*See* Ex. 1002, ¶ 102.) 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 beam) were the predictable work of combining the CBCT-FPI system of the Jaffray 1999 references with the radiotherapy systems of Adler/Depp. (*See* Ex. 1002, ¶¶ 98-103.) 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 Claims – Support Table Limitations

a. Claims 2 and 21

Claim 2 adds the limitation to claim 1 of “a support table upon which said object is placed while said radiation source directs said beam of radiation towards said object.” This limitation was expressly taught by Adler/Depp. Referring to Figure 1, Adler teaches an “operating table **38**” for the patient **14**. (Adler, 7:37-52.) Depp contains the same teaching. (Depp, 5:10-25.) Jaffray 1999 JRO also expressly teaches this element. The Elekta SL-20 device of the reference, shown in Fig. 1 (reproduced in Section VIII-B above) depicts the patient table.

It would have been obvious to combine the teachings of Adler/Depp, including the “operating table **38**” with the CBCT-FPI system of Jaffray 1999 SPIE. As confirmed by Dr. Balter, one of ordinary skill in the art would have been motivated to include the support table since it is standard, essential equipment for the use of a radiotherapy device. (*See* Ex. 1002, ¶¶ 105-106.)

Claim 21 depends from claim 20, and adds the identical limitation of claim 2. Claim 20 is discussed in Section VIII-C-1-c.

b. Claims 3 and 22

Claim 3 depends from claim 2 and adds the limitation “wherein said support table moves based on said three-dimensional information so as to control said path of said beam of radiation.” 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 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.

(Adler, 7:42-58 (emphasis added).) Depp contains the same express teaching. (Depp, 5:15-31.) As Adler/Depp makes clear, such support tables can move and be used to position a patient with respect to a radiotherapy beam. As confirmed by Dr. Balter, one of ordinary skill in the art would have been motivated to use the support table for this purpose. (*See* Ex. 1002, ¶ 108.)

Claim 22 depends from claim 20 and adds the identical limitation. Claim 20 is discussed in Section VIII-C-1-c.

c. Claims 11 and 30

Claim 11 is very similar to claims 3 and 22 discussed above, except it recites that the “controller controls said path of said radiation beam by controlling movement of said support table.” Claim 11 depends from claim 7, which recites the “controller” element referred to in claim 11. However, this claim is obvious for the same reasons claims 3 and 22 are, because Adler/Depp expressly disclose controlling the path of the radiation beam, based on image information about the

patient, by moving the support table. Claim 11 depends from claim 7, discussed in Section VIII-C-1-b. (*See also* Ex. 1002, ¶ 110.)

Claim 30 is much like claim 11, adding the controller of claim 7 (from which claim 11 depends): “further comprising a controller that controls said path of said radiation beam by controlling movement of said support table.” Thus, claim 30 recites the same controller element of claim 7, and like claim 11 recites that this controller controls the path of the radiation beam through support table movement. This claim is obvious for the same reason claim 11 is obvious, because Adler/Depp expressly discloses controlling the path of the radiation beam, based on image information, by moving the support table. Claim 30 depends from claim 26, discussed in Section VIII-C-1-d. (*See also* Ex. 1002, ¶ 111.)

4. Dependent Claims – kV X-rays

a. Claims 4, 8, 23, and 27

Claim 4 depends from claim 1 discussed above and adds the limitation “wherein said x-ray source comprises a kV x-ray source.” Jaffray 1999 SPIE provides express disclosure of this limitation: “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 (emphasis added).)

One of skill in the art would have been further motivated to combine

Adler/Depp with Jaffray 1999 SPIE 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. Jaffray 1999 JRO states “[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. 1002, ¶¶ 112-114.) 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.)

Claims 8, 23, and 27 all recite the identical limitation of claim 4 and depend from claims 7, 20, and 26, respectively. Those claims are discussed in Sections VIII-C-1-b, c, and d, respectively.

5. Dependent Claims – Flat Panel Imagers

a. Claims 5, 9, 24, and 28

Claim 5 depends from claim 1 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 above with claim 1 in Section VIII-C-1, 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. As confirmed by Dr. Balter, 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. 1002, ¶ 116.)

Claims 9, 24, and 28 all recite the same limitation of claim 5 and depend from claims 7, 20, and 26, respectively, discussed in Sections VIII-C-1-b, c, and d, respectively.

6. Additional Dependent Claims

a. Claims 6, 10, 25, and 29

Claim 6 depends from claim 1, adding the limitation “wherein said three-dimensional information from said object is based on one rotation of said x-ray beam 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.) It would have been obvious to combine the radiotherapy systems of Adler/Depp with the CBCT-FPI apparatus, by obtaining 3-D information from one rotational scan, as expressly taught by Jaffray 1999 SPIE. Indeed, as confirmed by Dr. Balter, one of ordinary skill in the art would have been aware from the teachings of the prior art that a benefit of CBCT methods is the ability to obtain a 3-D image of a patient from a single rotation of the CT gantry around the patient. (*See* Ex. 1002, ¶¶ 118-119.)

Claims 10, 25, and 29 recite a virtually identical limitation as claim 6 and depend from claims 7, 20, and 26, respectively. Those claims are discussed in Sections VIII-C-1-b, c, and d, respectively.

b. Claim 12

Claim 12 depends from claim 7, and specifies that the controller is a “second computer.” Under the broadest reasonable construction, this element is meant to differentiate the controller from the first “computer” element recited in claim 7, which is the computer that generates the 3-D image. The second computer element of claim 12 is expressly taught by Depp, in which a “second processor **12**” controls the radiation beam:

The electronic images are passed to the microprocessor **12** ...

whereupon comparison can take place. Signals are then generated by a second processor 12' (the controller for mechanism 46) which serves as a remote extension to multiprocessor 12 to control the positioning of the overall operation of the robotic arm mechanism including a mechanism whereby the; positioning of the beaming apparatus 120 is adjusted to assure that the collimated surgical beam which it produces is focused on the target region 18 that is to be irradiated.

(Depp, 6:18-29 (emphasis added).) Thus, the additional limitation of claim 12 was expressly taught in the prior art in Depp. As confirmed by Dr. Balter, one of ordinary skill in the art would have been motivated to include this express teaching of the prior art because it was known that computers can be used to perform the image reconstruction necessary to compile multiple 2-D CBCT scans into a 3-D image. (*See Ex. 1002, ¶¶ 121-122.*) Claim 12 depends from claim 7, which is discussed in Section VIII-C-1-b.

c. Claims 13 and 31

Claim 13 depends from claim 7, and specifies “wherein said controller automatically controls said path of said radiation beam.” The automatic control of the path of the radiation beam was expressly taught by Adler. For example, the claims of the Adler patent provide express teaching of control of radiotherapy based on imaging that is automatic (without human intervention). Claim 1 of Adler recites the element:

[I]n response to said real time spatial locations of said collimated beam and target region, adjusting the relative positions of the beaming apparatus and the living organism in such a manner that the collimated beam is focused onto the target region

(*Id.*, claim 1.) The same claim also recites repeating this step:

[P]eriodically repeating the comparing step at small time intervals using newly produced first and second images such that any movement of the target region relative to the focus of the collimated beam is detected in substantially real time

(*Id.*) Claim 2 further recites: “wherein the repeating of the adjusting is carried out automatically in response to the position data obtained in the comparing step.”

(*Id.*, claim 2.) Accordingly, the automatic control limitation of claim 13 is taught by Adler/Depp. As confirmed by Dr. Balter, one of ordinary skill in the art would have been motivated to combine these automatic control teachings with the obvious CBCT-FPI radiotherapy systems of the independent claims because the prior art expressly suggested the benefit of real-time control of the radiotherapy beam based on patient image information. (*See Ex. 1002, ¶¶ 123-124.*)

Claim 31 depends from claim 26 but adds the essentially identical limitation of claim 13, “wherein said path of said radiation beam is controlled automatically,” and is obvious for the same reason. Claim 26 is discussed in Section VIII-C-1-d.

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IX. CONCLUSION

Petitioner respectfully requests institution of *inter partes* review of claims 1-13 & 20-31 of the '765 patent, and a finding that those claims are unpatentable, based on the grounds presented in this Petition.

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Respectfully submitted,

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Petition for *Inter Partes* Review of
U.S. Patent No. 7,471,765

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. 7,471,765**, including all exhibits (**Nos. 1001-1038**) 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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DATED: November 6, 2015

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