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**
1101	U.S. Patent No. 7,471,765 issued to David A. Jaffray, *et al.* ("'765 patent")
1102	Declaration of Dr. James Balter ("Balter Decl.")
1103	U.S. Patent No. 5,207,223 issued to Adler *et al.* ("Adler")
1104	U.S. Patent No. 5,427,097 issued to Depp ("Depp")
1105	P.S. Cho *et al.*, *Cone-beam CT for radiotherapy applications*, Phys. Med. Biol., 40:1863-83 (1995) ("Cho")
1106	L.E. Antonuk *et al.*, *Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging*, IEEE Transactions on Medical Imaging, 13:482-90 (1994) ("Antonuk")
1107	D.A. Jaffray *et al.*, *Exploring "Target Of The Day" Strategies for A Medical Linear Accelerator With Conebeam-CT Scanning Capability*, Proceedings of the 12th International Conference on the Use of Computers in Radiation Therapy, Medical Physics Publishing, pp. 172-75 (1997) ("Jaffray 1997")
1108	Aug. 13, 2008 Notice of Allowance
1109	May 15, 2008 Applicant Remarks
1110	Exhibit Not Used
1111	Dec. 10, 2007 Applicant Amendment
1112	P. Munro, *Portal Imaging Technology: Past, Present, and Future*, Seminars in Radiation Oncology, 5:115-33 (Apr. 1995) ("Munro 1995")
1113	Dec. 27, 2004 Applicant's Preliminary Amendment

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Ex. No.	Description of Document
1114	P.J. Biggs *et al.*, *A Diagnostic X Ray Field Verification Device For A 10 MV Linear Accelerator*, Int'l J. Radiation Oncology Biol. Phys., 11:635-43 (1985) ("Biggs 1985")
1115	A. Ezz *et al.*, *Daily Monitoring and Correction of Radiation Field Placement Using a Video-Based Portal Imaging System: A Pilot Study*, Int'l J. Radiation Oncology Biol. Phys., 22:159-65 (1991) ("Ezz 1991")
1116	W. De Neve *et al.*, *Routine clinical on-line portal imaging followed by immediate field adjustment using a tele-controlled patient couch*, Radiotherapy & Oncology, 24:45-54 (1992) ("De Neve 1992")
1117	T.R. Mackie *et al.*, *Tomotherapy: A new concept for the delivery of dynamic conformal radiotherapy*, Med. Phys., 20:1709-19 (Nov./Dec. 1993) ("Mackie 1993")
1118	R. Sephton *et al.*, *A diagnostic-quality electronic portal imaging system*, Radiotherapy & Oncology, 35:204-47 (1995) ("Sephton 1995")
1119	M.C. Kirby *et al.*, *Clinical Applications of Composite and Realtime Megavoltage Imaging*, Clinical Oncology, 7:308-16 (1995) ("Kirby 1995")
1120	J.M. Michalski *et al.*, *Prospective Clinical Evaluation of an Electronic Portal Imaging Device*, Int'l J. Radiation Oncology Biol. Phys., 34:943-51 (1996) ("Michalski 1996")
1121	D. Yan *et al.*, *Adaptive radiation therapy*, Phys. Med. Biol., 42:123-32 (1997) ("Yan 1997")
1122	D. Yan *et al.*, *The Use of Adaptive Radiation Therapy to Reduce Setup Error: A Prospective Clinical Study*, Int'l J. Radiation Oncology Biol. Phys., 41:715-20 (1998) ("Yan")

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Ex. No.	Description of Document
1123	M.A. Mosleh-Shirazi *et al.*, *A cone-beam megavoltage CT scanner for treatment verification in conformal radiotherapy*, Radiotherapy & Oncology, 48:319-28 (1998) ("Mosleh-Shirazi 1998")
1124	S. Webb *et al.*, *Tomographic Reconstruction from Experimentally Obtained Cone-Beam Projections*, IEEE Transactions on Medical Imaging, MI-6:67-73 (Mar. 1987) ("Webb 1987")
1125	D.A. Jaffray *et al.*, *Dual-Beam Imaging for Online Verification of Radiotherapy Field Placement*, Int'l J. Radiation Oncology Biol. Phys., 33:1273-80 (1995) ("Jaffray 1995")
1126	S.M. Midgley *et al.*, *A Feasibility Study For The Use Of Megavoltage Photons And A Commercial Electronic Portal Imaging Area Detector For Beam Geometry CT Scanning To Obtain 3D Tomographic Data Sets Of Radiotherapy Patients In The Treatment Position*, Proceedings of the 4th Int'l Workshop of Electronic Portal Imaging, Amsterdam, 1996, Abstract No. 60 (2 pages) (1996) ("Midgley 1996")
1127	J. Wong *et al.*, *Initial clinical experience with a gantry mounted dual beam imaging system for setup error localization*, Int'l J. Radiation Oncology Biol. Phys., 42(Suppl. 1):138 (Abstract 28) (1998) ("Wong 1998")
1128	L.E. Antonuk *et al.*, *Demonstration of megavoltage and diagnostic x-ray imaging with hydrogenated amorphous silicon arrays*, Med. Phys., 19:1455-66 (Nov./Dec. 1992) ("Antonuk 1992")
1129	L.E. Antonuk *et al.*, *A Real-Time, Flat-Panel, Amorphous Silicon, Digital X-ray Imager*, RadioGraphics, 15:993-1000 (1995) ("Antonuk 1995")
1130	J. Chabbal *et al.*, *Amorphous Silicon X-ray Image Sensor*, Proceedings of SPIE (Society of Photographic Instrumentation Engineers), 2708:499-510 (1996) ("Chabbal 1996")

List of Exhibits

Ex. No.	Description of Document
1131	R. Ning *et al.*, *Selenium Flat Panel Detector-Based Volume Tomographic Angiography Imaging: Phantom Studies*, Proceedings of SPIE (Society of Photographic Instrumentation Engineers), 3336:316-24 (Feb. 1998) ("Ning 1998")
1132	R. Ning *et al.*, *Flat panel detector-based cone beam volume CT imaging: detector evaluation*, Proceedings of SPIE (Society of Photographic Instrumentation Engineers), 3659:192-203 (Feb. 1999) ("Ning 1999")
1133	U.S. Patent No. 6,041,097 issued to Roos *et al.* ("Roos 1998")
1134	J.H. Siewerdsen *et al.*, *Signal, noise power spectrum, and detective quantum efficiency of indirect-detection flat-panel imagers for diagnostic radiology*, Med. Phys., 25:614-28 (May 1998) ("Siewerdsen 1998")
1135	A.T. Redpath *et al.*, *Chapter 6: Simulator Computed Tomography*, pp. 169-89, in *The Modern Technology of Radiation Oncology*, J. Van Dyk (ed.) (1999) ("Redpath 1999")

Petitioner Varian Medical Systems, Inc. ("Petitioner") respectfully submits this Petition for *Inter Partes* Review of claims 1-13 & 20-31 of U.S. Patent No. 7,471,765 **[Ex. 1101]** ("the '765 patent").

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

A. Real Party-ln-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 concurrently 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.

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 **1103** through **1007**:

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

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 Cho, Antonuk, Jaffray 1997, and Adler/Depp (§ 103(a))

Section VII-D 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. 1102]**, ¶¶ 2-5.) Dr. Balter's declaration includes additional exhibits (Exs. 1112-1135), 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.

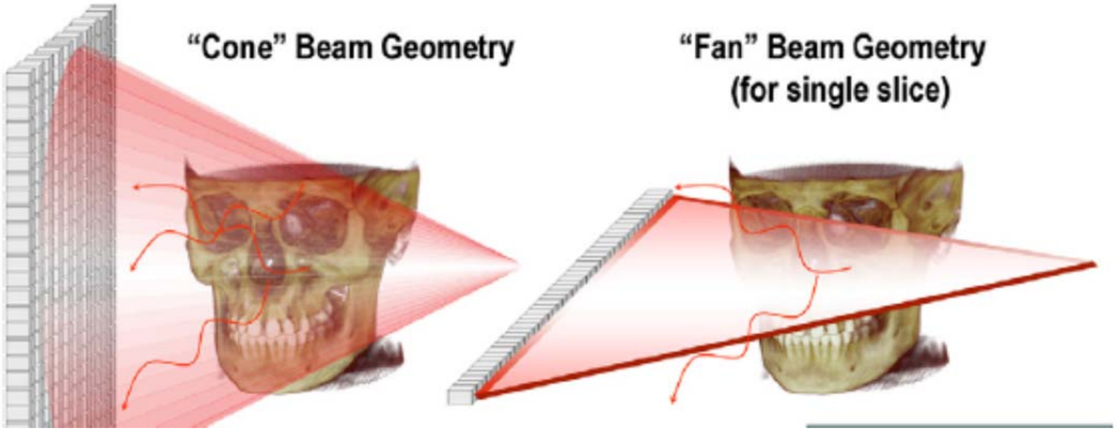
IV. BRIEF BACKGROUND OF THE UNDERLYING TECHNOLOGY

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. 1102, ¶ 14.) Indeed, the first known instance of using x-ray imaging to improve the accuracy of radiation therapy dates back to the 1940s. (*Id.*, ¶¶ 15-16.) The corollary concept that imaging should be done close in time to when the radiation is delivered is likewise very old. As explained by Dr. Balter, the field of radiation therapy has consistently maintained its focus on combining imaging with radiation therapy, and the ’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 machine emitting a “fan” shaped beam around a patient and then progressively translating the patient through the scanner. By the mid-1990s, however, systems were available that obtained 3-D images in a single rotation using a technology called “cone-beam” CT (“CBCT”). As the name suggests, CBCT works by using a large x-ray field shaped in a cone rather than a thin “fan-beam.” The figure below contrasts the fan-beam and cone-beam approaches to CT that were well established by 1999:



Central to the utility of this cone-beam approach were detectors that could receive x-ray cone-beam projection data. By the mid 1990s, the field of large flat-panel detector arrays had developed to meet this need. The art was unequivocal that such flat panel imagers were an obvious choice for large field x-ray imaging, stating in 1994 that "[t]he recent development of large-area, flat-panel a-Si:H imaging arrays is generally expected to lead to realtime diagnostic and megavoltage x-ray projection imagers." (*See* Ex. 1102, ¶ 58.) Thus before the '765 applicants began their work, it was already known that CBCT imaging could be improved by the use of a large FPI to facilitate rapid acquisition of 3-D CT 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. 1102, ¶¶ 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 radiotherapy. 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 form 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. 1108, 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;
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	an x-ray source that emits x-rays in cone-beam form	an x-ray source that moves about said object and	an x-ray source that emits x-rays in cone-beam form

emits toward said object from multiple positions around said object x-ray beams in a cone-beam form;	towards said object and is rotatably mounted relative to said support table;	emits toward said object from multiple positions around said object x-ray beams in a 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 plurality of two-dimensional projection images;		said imager providing an image that contains three-dimensional information concerning said object based on a plurality of two-dimensional projection images;	
	a computer to generate three-dimensional information concerning said		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;		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 positioned relative to said radiation beam,		wherein said object is correctly positioned relative to said radiation beam and,
wherein said receiving said x-rays by said flat panel imager is performed	and wherein said receiving said x-ray beams by said flat panel imager is performed	wherein said receiving said x-rays by said flat-panel imager is performed	wherein said receiving said x-ray beams emitted from said x-ray source by said flat-

substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.	substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.	substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.	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.

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

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. 1109, 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 <u>small probability</u> that there would be significant changes in the positions of objects being imaged during the span of time.” (*Id.*, at 13-14 (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. 1102, ¶¶ 35-37.) *See also Biosig,* 783 F.3d at 1381. Thus the term is invalid for indefiniteness. *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 <u>substantially the same time</u> as the controlling the path of the radiation through the object.

(Ex. 1109, 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. 1102, ¶ 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. 1102, ¶ 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 independent claim 1. The element generically recites a computer and the function it performs: receiving 3-D information and based on that 3-D information 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).

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

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[2] Section 112 was amended and subsections were renamed by the America Invents Act ("AIA"), Pub. L. No. 112-29, § 4(c), 125 Stat. 284, 296 (2011). Because the application that led to the '765 patent was filed before September 16, 2012, the pre-AIA version of § 112(6) (now referred to as § 112(f)) applies.

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. 1102, ¶¶ 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. 1102, ¶¶ 40-43.)

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 independent 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. 1102, ¶¶ 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. 1102, ¶ 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 independent 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 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. 1102, ¶¶ 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. 1102, ¶ 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 independent 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. 1102, ¶ 41.) Indeed, the specification is clear that the embodiment recited by the claim is under computer control. The specification discusses "a <u>computer-controlled</u> treatment table **443** for correction of lesion localization errors." (*See* '765, 24:52-54 (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. 1102, ¶¶ 50-52.) 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.

1102, ¶ 53.)

VII. GROUND 1 – CLAIMS 1-13 & 20-31 ARE OBVIOUS OVER CHO, ANTONUK, JAFFRAY 1997, AND ADLER/DEPP UNDER 35 U.S.C. § 103(a)

A. Introductory Comments

As noted, above, Petitioner has concurrently submitted another petition challenging claims 1-13 & 20-31 based on different prior art, asserting that the claims are not entitled to the ’590 provisional that is claimed on the cover of the ’765 patent. However, there is a theoretical possibility that Patent Owner is able to establish that it is entitled to priority based on the ’590 provisional – which Petitioner denies as explained in its concurrent petition. In light of this theoretical possibility, however, Petitioner submits the grounds in this petition, relying only on references that qualify as § 102(b) art regardless of which priority date is accorded to the challenged claims. Petitioner respectfully requests institution of *inter partes* review of the challenged claims based on all the grounds in both petitions because each ground presents unique, non-redundant issues central to the patentability of the challenged claims.

B. Prior Art and Date Qualification for Ground 1

Each limitation of claims 1-13 & 20-31 is disclosed or suggested by P.S. Cho *et al.*, *Cone-beam CT for radiotherapy applications*, Physics in Medicine and Biology, 40:1863-83 (1995) **[Ex. 1105] (“Cho”)**, L.E. Antonuk *et al.*, *Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging*, IEEE

Transactions on Medical Imaging, 13:482-90 (1994) **[Ex. 1106] ("Antonuk"),** D.A. Jaffray *et al.*, *Exploring "Target Of The Day" Strategies for A Medical Linear Accelerator With Conebeam-CT Scanning Capability*, Proceedings of the 12th International Conference on the Use of Computers in Radiation Therapy, Medical Physics Publishing, pp. 172-75 (1997) **[Ex. 1107] ("Jaffray 1997")**, U.S. Patent No. 5,207,223 issued to Adler *et al.*, published on May 4, 1993 **[Ex. 1103] ("Adler")**, U.S. Patent No. 5,427,097 issued to Depp, published on June 27, 1995 **[Ex. 1104] ("Depp")**.[3] Each of these references qualify as prior art under at least § 102(b) (pre-AIA) because they were published more than one year before February 18, 2000, the filing date of the earliest application appearing on the face of the '765 patent. Cho, Antonuk and Adler/Depp were not before the Office during examination or considered by the Examiner prior to issuance of the patent.

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

Cho [Ex. 1105], entitled "Cone-beam CT for radiotherapy applications," discloses the use of cone beam CT for patient imaging in the treatment position on

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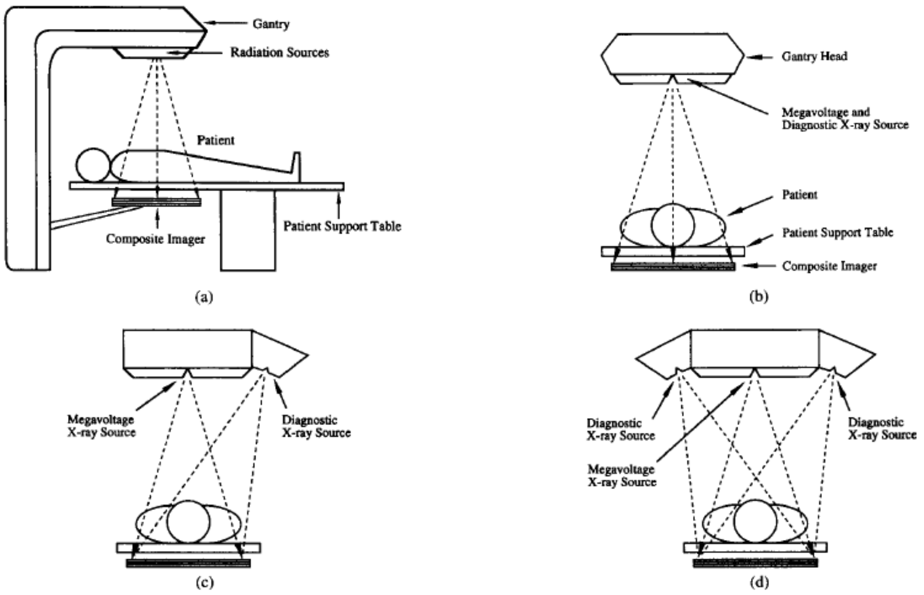
[3] As discussed below, Adler and Depp are treated as a single reference for this petition because Depp expressly incorporates Adler by reference and describes itself as an improvement of Adler's disclosure. The disclosures are collectively referred to herein as "Adler/Depp."

a radiotherapy simulator. Cho notes that detector size was an existing limitation in 1995 for the clinical implementation of CBCT. (*See* Cho, at 5.) Cho discloses the use of the same Feldkamp algorithm referenced in the ’765 patent for 3-D image reconstruction from a plurality of 2-D cone-beam projection images. (*See id.*, at 6; *see also* ’765, 10:66-11:11.) Cho also reported the benefits of using kV CBCT for differentiation of soft tissue. (*See id.*, at 22.) Cho also expressly suggested the use of amorphous silicon FPIs for the problem of detector size for rapid acquisition of 3-D images using CBCT, citing to **Antonuk**. (*See id.*, at 24.)

Antonuk [Ex. 1106], entitled “Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging,” describes the development of amorphous silicon flat panel imagers for use in diagnostic imaging in the radiotherapy setting. Specifically, Antonuk teaches the dual use of kV and MV “real-time flat panel composite imagers” “helping to resolve the patient localization and verification problem in megavoltage radiography.” (Antonuk, at 3.) Antonuk taught that radiotherapy could be improved by reduction of uncertainty about the location of the tumor within the patient’s healthy surrounding anatomy, and that “[I]t is widely perceived that part of the solution is to obtain imaging information with the portal beam immediately prior to and/or during the treatment.” (*Id.*, at 5.) As Antonuk recognized, the state of the art in 1994 included use of megavoltage imaging devices to obtain patient location verification. (*Id.*) Antonuk explained, however, that "[a] major limitation in the general approach of using only the megavoltage images is the limited spatial and contrast resolution of the resulting images…. In comparison, diagnostic x-ray images offer excellent spatial and contrast resolution due to the dominance of photoelectric interactions." (*Id.*) As explained elsewhere in Antonuk, "diagnostic x-ray images" refers to images obtained using x-ray beams of kV rather than MV energy. (*See id.*, at 3 (defining diagnostic quality x-rays as having energies of 20 to 150 kVp); *see also* Ex. 1102, ¶ 58.)

Antonuk proposed several configurations for use of his dual kV and MV flat panel approach, including mounting a kV imager on an MV radiotherapy device and using a single dual-energy detector to capture both kV and MV images:



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

Jaffray 1997 [Ex. 1107], entitled "Exploring 'Target Of The Day' Strategies for A Medical Linear Accelerator With Conebeam-CT Scanning Capability," discloses the use of CBCT on a medical linear accelerator. (Jaffray 1997, at 4.) Jaffray 1997 suggests that radiotherapy could be improved by imaging systems coordinated with radiotherapy: "A solution to the dose limits imposed by margins is to locate the clinical target and surrounding normal structures on a fraction-by-fraction basis." (*Id.*) Indeed, Jaffray 1997 recognized that this suggestion was not new: "Other investigators have recognized the potential advantages of integrating a volumetric imaging system with the radiation delivery system." (*Id.*) Jaffray 1997 described the addition of a cone-beam system to a radiotherapy device: "To this end, we are developing a [CBCT] scanner for installation on our medical linear accelerator." (*Id.*) The authors expected the integration of CBCT onto a medical linear accelerator to be successful: "Current imaging technology should allow the construction of a conebeam computed tomography imaging system which is capable of providing image quality comparable to conventional CT at a modestly higher dose." (*Id.*) The authors disclosed the integration of a CBCT imaging system into a medical linear accelerator system, all mounted on a gantry that would obtain three-dimensional image data by rotating around the patient:

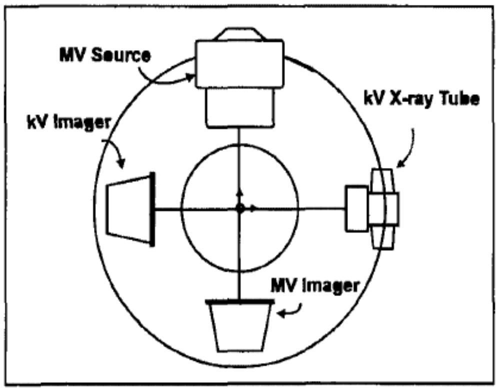
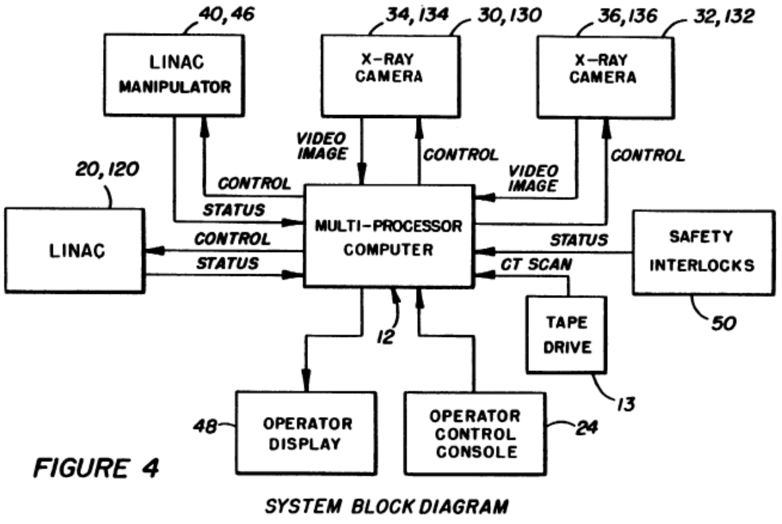


Figure 1: Schematic of dual-beam system to be used for conebeam computed tomography (CBCT). The kV x-ray beam is orthogonal to the treatment beam.

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

Adler [Ex. 1103], entitled "Apparatus for and Method of Performing Stereotaxic Surgery," discloses systems for selectively irradiating a target within a patient. Adler discloses use of diagnostic x-ray imaging, 3-D image mapping of target lesions, and adjustment of the radiotherapy 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. 1104] shares a similar title and the same assignee as Adler and describes itself as describing improvements to the method and apparatus disclosed in Adler, which Depp incorporates by reference. (Depp, 1:12-17.) Among other improvements, Depp describes "a unique temporal procedure for operating the radiosurgical beam and the diagnostic target locating beams in order to continuously locate the target region in substantially real time." (*Id.*, 7:42-45.) Thus, Depp expressly teaches a device in which diagnostic images are used to ensure proper targeting of the radiation beam in real time.

D. Cho, Antonuk, Jaffray 1997, 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, Antonuk, and Jaffray 1997 disclose it.

As explained in more detail in connection with the claim limitations that follow, 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. 1102, ¶¶ 64-65.) As shown in Figure 1 of Adler, Adler/Depp discloses a system for delivering radiotherapy to a patient:

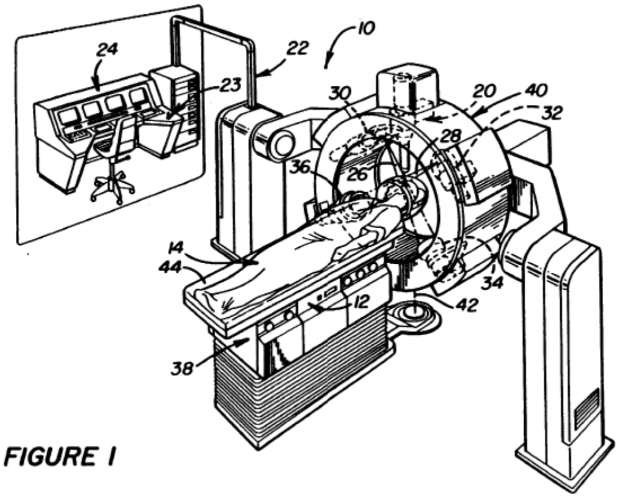


FIGURE I

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

Adler/Depp also teaches an alternative embodiment in which the radiation 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 VII-C above, Antonuk and Jaffray 1997 both expressly disclose radiotherapy systems using a medical linear accelerator device. (*See also* Ex. 1102, ¶ 66.)

(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.) (*See* Ex. 1102, ¶ 67.)

Jaffray 1997 expressly teaches the use of radiation source as recited in this limitation: "we have begun to pursue the construction of a conebeam CT (CBCT) scanner for integration with a medical linear accelerator." (Jaffray 1997, at 4.)

Antonuk likewise discussed the use of FPIs for diagnostic imaging on a medical linear accelerator comprising a radiation source that moves around a patient, directing a radiation beam towards the patient. (*See* Section VII-C; *see also* Ex. 1102, ¶¶ 68-69.)

(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"

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

(Cho, at 5.) The publication details the construction of a CBCT system for generating a 3-D image by rotating an x-ray source around an object. "The projection data were obtained by rotating the gantry over 360° at approximately 1° increments." (*Id.*, at 15.) As explained by Dr. Balter, this disclosure is an express disclosure of passing multiple x-ray beams in cone beam ("CB") form through said object from different angles. (*See* Ex. 1102, ¶ 70.)

Jaffray 1997 also discloses 3-D imaging using a cone beam CT apparatus mounted to a linear accelerator: "[w]e are developing a conebeam-computed tomography (CB-CT) scanner for installation on our medical linear accelerator." (Jaffray 1997, at 4.) Jaffray 1997 discussed the mounting of this system on an Elekta SL-20 linear accelerator, and provided an image of the arrangement (reproduced above in Section VII-C). (*See id.*, at 5 (Fig. 1).) Jaffray 1997 also teaches obtaining 3-D information from a plurality of 2-D projection images obtained by rotating the gantry around the patient. (*Id.*) Thus, like Cho, this reference expressly teaches passing multiple cone-beam x-rays through an object from multiple angles. (*See* Ex. 1102, ¶ 71.)

As explained by Dr. Balter, the Antonuk reference also teaches the use of cone-beam x-ray CT imaging, because the x-ray source of Antonuk emits x-rays in a cone beam form for detection on a large 2-D array in the form of an FPI. Indeed, as explained by Dr. Balter, any x-ray source emits beams in cone-beam geometry, unless that x-ray source further comprises a collimator to shape the beam into a fan shape or other geometry. Thus, as Dr. Balter explains, the x-ray beam paths shown in Figure 5 of Antonuk expressly shows x-rays being emitted in a cone-beam shape. (*See* Ex. 1102, ¶ 72.)

(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”

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

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

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

Antonuk provides detailed disclosures of flat panel imagers for use as diagnostic x-ray detectors mounted on a linear accelerator for imaging during radiotherapy. (Antonuk, at 3.) As explained by Dr. Balter, these FPI devices function as x-ray detectors by detecting multiple x-ray beams that pass through the object being imaged, for example as shown in Figure 5 of Antonuk. (*See* Ex. 1102, ¶¶ 73-74.)

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

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

(Antonuk, at 3 (citations omitted).) Antonuk also expressly discloses a flat panel imager receiving a plurality of 2-D x-rays in the geometry of a positron emission tomography machine: "Several a-Si:H x-ray detectors rotate with an x-ray tube collecting conebeam projection data inside the bore of a PET machine …." (*Id.*, at 8.) As confirmed by Dr. Balter, one of ordinary skill in the art would understand these teachings as disclosures of the use of an FPI to receive x-rays passing through an object for providing an image of the object. (*See* Ex. 1102, ¶ 58.)

Adler/Depp teaches the use of three-dimensional information about the object based on a plurality of 2-D projection images, because Adler/Depp teaches obtaining two x-ray images ("diagnostic beams **26** and **28**") at a "known non-zero angle relative to one another." (Adler, 7:6-12.) These beams are received by "[i]mage receivers **34** and **36**" and the resulting signals are passed to the "microprocessor **12**." (*Id.*, 7:17-23.) As confirmed by Dr. Balter, these images provide three-dimensional information. (*See* Ex. 1102, ¶ 75.)

(4) "and a computer[4] 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 ("diagnosic 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

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

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

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

(Adler, 7:42-58.) Finally, Adler/Depp notes that “FIG. 4 illustrates, in system block diagram form, operation of the logic by which the apparatus of FIG. 1 … can be controlled.” (Adler, 8:32-34.) As Adler/Depp explains, “[s]ignals from the image receivers **34**,**134** and **36**,**136** are passed to the processor **12**.” (Adler, 8:36-38.) Then, “[s]ignals from the processor **12** are passed to … the gimbal **40** thus controlling its positioning ….” (*Id.*, 8:43-47.) As confirmed by Dr. Balter, these teachings would have been recognized by one of ordinary skill in the art as an express disclosure of a system comprising a computer connected to a moveable radiation source and a diagnostic x-ray imaging system, controlling the position of the radiation beam based on multiple x-rays images. (*See* Ex. 1102, ¶¶ 76 -77.)

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

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

(Depp, 11:46-61.) Accordingly, this element was taught by the prior art. (*See* Ex. 1102, ¶ 78.)

(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 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.)

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 provides detailed teachings of this claim element. (*See* Ex. 1102, ¶¶ 79-80.)

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	Argument
A radiation therapy system comprising:	*See* claim 1, Section VII-D-1 above.
a support table upon which to position an object to be treated;	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.) Antonuk and Jaffray 1997 also expressly teach this element. As explained by Dr. Balter, the Philips SL-20 device of Jaffray 1997 comprises a support table that the patient is positioned on during radiation therapy. (*See* Ex. 1102, ¶ 82.)
a radiation source which is movably mounted relative to said support table and which directs a beam of radiation toward said object;	*See* claim 1, Section VII-D-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;	*See* claim 1, Section VII-D-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;	*See* claim 1, Section VII-D-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 Cho: "[p]reprocessing and reconstruction algorithms were coded in C and executed on an HP-735 workstation …." (Cho, at 17.) "[T]he algorithm was able to provide

Claim 7	Argument
	volumetric CT images with clearly delineated gross inhomogeneities (soft tissue, lung, bone, and air) from which contours can be extracted for the purpose of treatment planning." (Cho, at 22.)
a controller[5] 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,	*See* claim 1 "computer," Section VII-D-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.	*See* claim 1, Section VII-D-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

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[5] 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.

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 "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 VII-D-1-a-(4). (*See also* Ex. 1102, ¶¶ 81-83.)

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.[6]

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 path of the radiation beam as set forth in claim 1. Therefore, claim 20 is obvious for the same reasons as claim 1, as explained in Section VII-D above. (*See also*

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[6] 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.

Ex. 1102, ¶ 84.)

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 a path" of the radiation beam, claim 26 recites that the "support table controls a path" of the radiation beam.[7] 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.) Jaffrey 1997 also teaches the same thing, because, as explained by Dr. Balter, the SL-20 medical linear accelerator comprise a table on which the patient is placed during radiotherapy treatment. (*See* Ex. 1102, ¶ 85.)

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[7] 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

Antonuk likewise expressly discloses that imaging information obtained "immediately prior to and/or during the treatment" would facilitate "(a) localization of the patient relative to the treatment unit prior to irradiation; and (b) verification of the correct alignment of the patient anatomy with respect to the treatment field edges throughout the irradiation." (*See* Antonuk, at 5.) Antonuk further teaches performing these methods on a radiotherapy system that is shown to comprise a table for the patient in Figure 5. As explained by Dr. Balter, one of ordinary skill in the art would have recognized this as teaching the system of claim 26 in which a moveable stage is used to control patient position relative to the radiation beam. (*See* Ex. 1102, ¶ 85.)

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

The claims are obvious because all elements of the claim were taught by the prior art, as explained above, and because one of ordinary skill in the art would have been motivated to combine them. As discussed above, during prosecution the Examiner was readily able to combine a prior art radiation therapy system (Swerdloff) with a prior art CBCT-FPI system (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. Adler/Depp (which was not before the Examiner) provides this missing limitation in a radiation therapy system using x-ray imaging for real time control.

It was known in radiotherapy to use diagnostic (kV) x-rays on a radiotherapy gantry to obtain diagnostic quality images to effect real-time control of a radiation beam (Adler/Depp). It was also known to use cone beam imaging because of its superiority for 3-D imaging based on single rotation scanning (Cho and Jaffray 1997), and indeed it was known to use the exact type of flat panel imager used in the preferred embodiment of the ’765 patent (Cho/Antonuk). Because of the known benefits of CBCT, the known benefits of image-guided radiotherapy, and the express teaching in the prior art to use the same flat panel imager of the prior art CBCT system on a radiotherapy gantry, it was obvious to use the prior art CBCT/FPI system with the prior art radiotherapy control system of Adler/Depp because of the known benefits of improved imaging. CBCT-FPI was one of only a finite number of choices the artisan had to provide an obvious improvement on the radiotherapy control systems of Adler/Depp, and indeed the art specifically suggested this assembly. (*See* Ex. 1102, ¶¶ 86-88.)

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

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

> Other investigators have recognized the potential advantages of integrating a volumetric imaging system with the radiation delivery system. In this article, a discussion of a 'Target of the Day' approach is presented with respect to the development of a medical linear accelerator with conebeam CT scanning capability…. Current imaging technology should allow the construction of a conebeam computed tomography imaging system which is capable of providing image quality comparable to conventional CT at a modestly higher dose…. For these reasons, we have begun to pursue the construction of a conebeam CT (CBCT) scanner for integration with a medical linear accelerator.

(Jaffray 1997, at 4 (citations omitted).) (*See* Ex. 1102, ¶¶ 89-90.) Antonuk provides a similar express suggestion: "It is widely perceived that part of the solution is to obtain imaging information with the portal beam immediately prior to and/or during the treatment." (Antonuk, at 5.) Finally, Adler/Depp teaches that improved x-ray image based targeting, in real-time, of internal lesions such as tumors is desirable to avoid irradiation of healthy surrounding tissues, and Cho provides an improved method for acquiring volumetric (3-D) CT image data using CBCT and an FPI. (*See* Adler, 2:49-53, 3:34-42, 5:40-54; Depp, Abstract, 1:55-65, 2:48-53, 11:54-61; Cho, at 24.)

Adler and Depp should be treated as a single reference because Depp states that it is an improvement of Adler, and incorporates it by reference. (*See* Depp, 5:35-55, 7:31-47.) One of skill in the art would be motivated to combine the Cho, Antonuk, and Jaffray 1997 references with Adler/Depp because all the references are in the same field of medical imaging in conjunction with radiation therapy and all are concerned with the problem of obtaining accurate 3-D information about the internal structure of objects like patients. (*See* Adler, 1:6-18; Depp, 1:6-18; Cho, at 5; Antonuk, at 3, 5; Jaffray 1997, at 4; *see also* Ex. 1102, ¶ 91.) As explained by Dr. Balter, the results obtained by the inventors (obtaining 3-D image information concerning target lesions in patients for the purpose of targeting the radiation beam) were the predictable work of combining the CBCT-FPI system of the Cho and Antonuk references with the radiotherapy systems of Adler/Depp. (*See* Ex. 1102, ¶¶ 86-91.) Accordingly, the claimed combination was obvious. *See* MPEP § 2141 (III); *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1742 (2007); *see also*

Toshiba Samsung Storage Tech Korea Corp. v. LG Elec., 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.) Antonuk and Jaffray 1997 also expressly teach this element. As explained by Dr. Balter, the Philips SL-20 device of Jaffray 1997 comprises a support table that the patient is positioned on during radiation therapy. (*See* Ex. 1102, ¶ 93.)

It would have been obvious to combine the teachings of Adler/Depp, including the "operating table **38**" with the CBCT-FPI system of Cho and Antonuk (and with the CBCT system of Jaffray 1997). 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. 1102, ¶¶ 93-94.)

Claim 21 depends from claim 20, and adds the identical limitation. Claim 20 is discussed in Section VII-D-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 <u>along with conventional apparatus for lowering and raising the operating table **38** and for rotating it about an axis **42** and for tilting the top **44** of the operating table 38 about a longitudinally extending axis</u>, all as illustrated by arrows in FIG. 2.

(Adler, 7:42-58 (emphasis added).) Depp contains the same express teaching. (Depp, 5:15-31.) (*See* Ex. 1102, ¶ 96.)

Antonuk likewise expressly discloses that imaging information obtained "immediately prior to and/or during the treatment" would facilitate "(a) localization of the patient relative to the treatment unit prior to irradiation; and (b) verification of the correct alignment of the patient anatomy with respect to the treatment field edges throughout the irradiation." (*See* Antonuk, at 5.) Antonuk further teaches performing these methods on a radiotherapy system that is shown to comprise a table for the patient in Figure 5. As explained by Dr. Balter, one of ordinary skill in the art would have recognized this as teaching the system of claim

3 in which a moveable stage is used to control patient position relative to the radiation beam. (*See* Ex. 1102, ¶ 119.)

Claim 22 depends from claim 20 and adds the identical limitation. Claim 20 is discussed in Section VII-D-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 VII-D-1-b. (*See also* Ex. 1102, ¶ 98.)

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 about the patient, by moving the support table. Claim 30 depends from claim 26, discussed in Section VII-D-1-d. (*See also* Ex. 1102, ¶ 99.)

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 1997 provides express disclosure of this limitation: "Two fluoroscopic imaging systems are attached to a Philips SL-20 medical linear accelerator; one detects the megavoltage image, the other <u>a kV image produced with a kV beam</u> projected at 90° to the treatment beam axis." (Jaffray 1997, at 4 (emphasis added).) Cho also provides express disclosure of a kV beam source: "The scans were performed using 100 kV x-rays except for the chest scan in which case 120 kV was used." (Cho, at 16.)

Antonuk also provides express disclosure of this limitation: "An array detects the incident radiation indirectly by means of an x-ray converter placed on or over the surface of the array. For diagnostic quality X rays (20 to 150 kVp), the converter may be a phosphor screen, a channelled-light scintillator such as CsI(TI) or fiber-optic scintillator, or some other suitable scintillator." (Antonuk, at 3.) Antonuk further expressly discloses the mounting of such a diagnostic x-ray system (defined as 20 to 150 kVp) on a megavoltage radiotherapy device: "a composite diagnostic-megavoltage imager consisting of a pair of flat-panel imagers would be a relatively compact device much better suited to the space constraints of this application. In particular, it could be used to correlate details of the patient anatomy, obtained from the diagnostic images, with the portal field." (*Id.*, at 5.) As Antonuk explains, "[t]he x-ray source could be (1) an x-ray tube positioned in a retractable position in the head of the gantry; (2) an x-ray tube (or tubes) attached to the side(s) of the gantry…. illustrated schematically in Fig. 5." (*Id.*, at 6 (citations omitted).) (*See also* Ex. 1102, ¶¶ 100-01.)

One of skill in the art would have been further motivated to combine Adler/Depp with the CBCT-FPI kV diagnostic imaging teachings of Cho, Antonuk, and Jaffray 1997 because it was well-known by those of ordinary skill in the art that kV energy x-ray beams are superior to megavolt energy beams for imaging. As explained by Dr. Balter, the published work in the field clearly disclosed the superiority of kV beams over MV beams for imaging. (*See* Ex. 1102, ¶ 102.) For example, Antonuk expressly suggests the combination:

> A major limitation in the general approach of using only the megavoltage images is the limited spatial and contrast resolution of the resulting images…. <u>In comparison, diagnostic x-ray images offer excellent spatial and contrast resolution</u> due to the dominance of photoelectric interactions. Thus, in principle, the addition of diagnostic imaging information concerning the patient position immediately prior to treatment, in combination with the megavoltage

> portal images showing the relationship of the field edges to the treated volume, should greatly facilitate the goal of better patient localization and verification.

(Antonuk, at 5 (emphasis added).)

Claims 8, 23, and 27 all recite the identical limitation, and depend from claims 7, 20, and 26, respectively. Those claims are discussed in Sections VII-D-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." Cho expressly discloses this element: "Further increase in volume of reconstruction can be accomplished by … using a larger detector. The <u>flat panel detector based on amorphous silicon (a-Si:H) technology</u> is being developed as a potential real-time diagnostic x-ray imager (Antonuk *et al* 1994)." (Cho, at 24 (emphasis added).)

Antonuk, cited by Cho as shown above, provides detailed disclosures of flat panel imagers for use as diagnostic x-ray detectors mounted on a linear accelerator for imaging during radiotherapy. (Antonuk, at 3.) Antonuk explains that "[t]he arrays consist of a regular two-dimensional matrix of imaging pixels, illustrated schematically in Fig. 2. Each pixel consists of a thin-film transistor (TFT) coupled to an a-Si:H [amorphous silicon] n-i-p or p-i-n photodiode." (*Id*.) As explained above with claim 1 in Section VII-D-1, it would have been obvious to combine the radiotherapy systems of Adler/Depp with the CBCT apparatus of Jaffray 1997, using an amorphous flat panel imager, as expressly taught by Cho and Antonuk. One of ordinary skill in the art would have been motivated by this express suggestion and by the known benefits of FPI detectors that were disclosed in the prior art. (*See* Ex. 1102, ¶¶ 104-06.)

Claims 9, 24, and 28 all recite the identical limitation, and depend from claims 7, 20, and 26, respectively. Those claims are discussed in Sections VII-D-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 Cho: "The projection data were obtained by rotating the gantry over 360° at approximately 1° increments." (Cho, at 15; *see also id.*, at 22 ("For our method, data were available through a full 360° rotation …."").) Cho thus taught obtaining 3-D information about an object based on a single full rotation of the x-ray source gantry relative to the object. It would have been obvious to combine the radiotherapy systems of Adler/Depp with the CBCT-FPI apparatus discussed above for obtaining 3-D information from one rotation, as expressly taught by Cho. Indeed, as explained by Dr. Balter, one of ordinary skill in the art understood from the teachings of the art that a benefit of CBCT 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. 1102, ¶¶ 108-09.)

Claims 10, 25, and 29 recite a virtually identical limitation, and depend from claims 7, 20, and 26, respectively. Those claims are discussed in Sections VII-D-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 <u>second processor **12'**</u> (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. 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. 1102, ¶ 111.) Claim 12 depends from claim 7, which is discussed in Section VII-D-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 taught by Adler. For example, the claims of the Adler patent teach 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. 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. 1102, ¶¶ 112-13.)

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." Claim 26 is discussed in Section VII-D-1-d.

VIII. 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.

Dated: November 6, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify, pursuant to 37 C.F.R. Sections 42.6 and 42.105, that a complete copy of the attached **PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 7,471,765**, including all exhibits (**Nos. 1101-1135**) 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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