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

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1201	U.S. Patent No. 7,471,765 issued to David A. Jaffray, *et al.* ("'765 patent")
1202	Declaration of Dr. James Balter ("Balter Decl.")
1203	U.S. Patent No. 5,207,223 issued to Adler *et al.* ("Adler")
1204	U.S. Patent No. 5,427,097 issued to Depp ("Depp")
1205	D.A. Jaffray *et al.*, *Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager*, SPIE, 3659:204-14 (Feb. 1999) ("Jaffray 1999 SPIE")
1206	D.A. Jaffray *et al.*, *A Radiographic and Tomographic Imaging System Integrated into a Medical Linear Accelerator for Localization of Bone and Soft-Tissue Targets*, Int'l J. Radiation Oncology Biol. Phys., 45:773-89 (Oct. 1999) ("Jaffray 1999 JRO")
1207	P.S. Cho *et al.*, *Cone-beam CT for radiotherapy applications*, Phys. Med. Biol., 40:1863-83 (1995) ("Cho")
1208	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")
1209	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")
1210	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")
1211	Aug. 13, 2008 Notice of Allowance
1212	May 15, 2008 Applicant Remarks

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Ex. No.	Description of Document
1213	Provisional Application No. 60/183,590 filed by David A. Jaffray *et al.* ("'590 Provisional")
1214	Highlighted copy of the '765 Patent showing matter not disclosed in the '590 Provisional Application
1215	Dec. 10, 2007 Applicant Amendment
1216	P. Munro, *Portal Imaging Technology: Past, Present, and Future*, Seminars in Radiation Oncology, 5:115-33 (Apr. 1995) ("Munro 1995")
1217	Dec. 27, 2004 Applicant's Preliminary Amendment
1218	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")
1219	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")
1220	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")
1221	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")
1222	R. Sephton *et al.*, *A diagnostic-quality electronic portal imaging system*, Radiotherapy & Oncology, 35:204-47 (1995) ("Sephton 1995")
1223	M.C. Kirby *et al.*, *Clinical Applications of Composite and Realtime Megavoltage Imaging*, Clinical Oncology, 7:308-16 (1995) ("Kirby 1995")

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1224	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")
1225	D. Yan *et al.*, *Adaptive radiation therapy*, Phys. Med. Biol., 42:123-32 (1997) ("Yan 1997")
1226	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")
1227	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")
1228	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")
1229	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")
1230	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")
1231	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")

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Ex. No.	Description of Document
1232	L.E. Antonuk *et al.*, *A Real-Time, Flat-Panel, Amorphous Silicon, Digital X-ray Imager*, RadioGraphics, 15:993-1000 (1995) ("Antonuk 1995")
1233	J. Chabbal *et al.*, *Amorphous Silicon X-ray Image Sensor*, Proceedings of SPIE (Society of Photographic Instrumentation Engineers), 2708:499-510 (1996) ("Chabbal 1996")
1234	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")
1235	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")
1236	U.S. Patent No. 6,041,097 issued to Roos *et al.* ("Roos 1998")
1237	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")
1238	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 14-19 of U.S. Patent No. 7,471,765 **[Ex. 1201]** ("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 also seeking *inter partes* review of apparatus claims 1-13 and 20-31 of the '765 patent through two additional concurrently filed petitions.

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

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D. Service Information

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

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

This Petition requests review of six claims of the ’765 patent, therefore no excess claim fees are required. A payment of $23,000 is submitted herewith, comprising a $9,000 request fee and a post-institution fee of $14,000. *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 14-19. This Petition cites the following prior art references, included as Exhibits **1203** through **1210**:

Ex. No.	Description of Document
1203	U.S. Patent No. 5,207,223 issued to Adler *et al.* ("Adler")
1204	U.S. Patent No. 5,427,097 issued to Depp ("Depp")
1205	D.A. Jaffray *et al.*, *Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager*, SPIE, 3659:204-14 (Feb. 1999) ("Jaffray 1999 SPIE")
1206	D.A. Jaffray *et al.*, *A Radiographic and Tomographic Imaging System Integrated into a Medical Linear Accelerator for Localization of Bone and Soft-Tissue Targets*, Int. J. Radiation Oncology Biol. Phys., 45:773-89 (Oct. 1999) ("Jaffray 1999 JRO")
1207	P.S. Cho *et al.*, *Cone-beam CT for radiotherapy applications*, Physics in Medicine and Biology, 40:1863-83 (1995) ("Cho")
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1209	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")
1210	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")

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

Ground	Claims	Basis for Challenge
1	14-16	Obvious over Jaffray 1999 SPIE, Jaffray 1999 JRO, and Adler/Depp (§ 103(a))

Ground	**Claims**	**Basis for Challenge**
2	17-19	Obvious over Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler/Depp, and Yan (§ 103(a))
3	14-16	Obvious over Cho, Antonuk, Jaffray 1997, and Adler/Depp (§ 103(a))
4	17-19	Obvious over Cho, Antonuk, Jaffray 1997, Adler/Depp, and Yan (§ 103(a))

This Petition also submits the accompanying Declaration of Dr. James Balter, an expert with over 20 years of experience in the fields of radiation oncology and medical physics. (*See* Balter Decl., **[Ex. 1202]**, ¶¶ 2-5.) Dr. Balter's declaration includes additional exhibits (Exs. 1216 - 1238), 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 14-19 because this Petition establishes a reasonable likelihood of prevailing with respect to each challenged claim. *See* 35 U.S.C. § 314(a). Each limitation of each challenged claim is disclosed and/or suggested by the prior art, as explained in detail below.

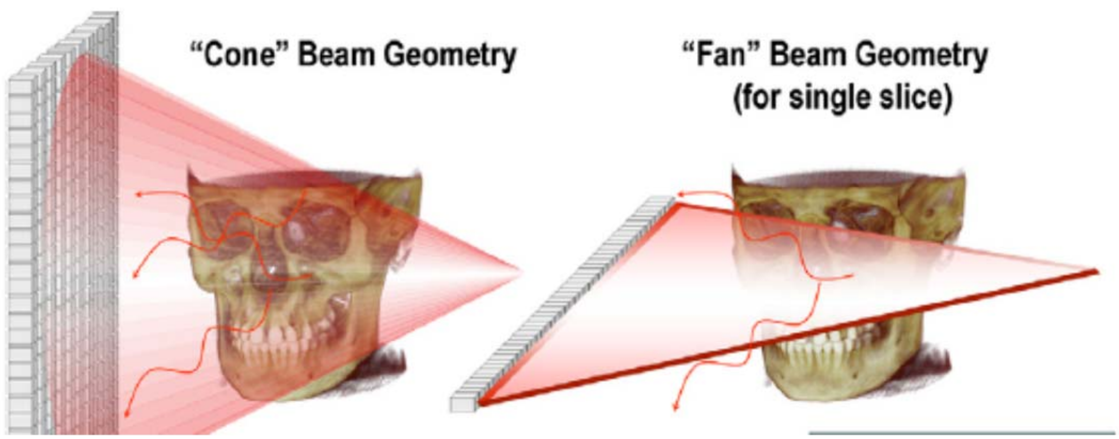
IV. BRIEF BACKGROUND OF THE UNDERLYING TECHNOLOGY

A. Radiotherapy and Image Guidance

Radiation therapy or "radiotherapy" is the use of beams of radiation for the treatment of disease. Radiation therapy of internal patient lesions, such as cancerous tumors, is very old – dating back over 100 years. For decades, practitioners have known that the effectiveness of radiation therapy is increased when imaging is used to ensure that the radiation therapy beam is applied as narrowly as possible to a tumor while minimizing exposure to surrounding healthy tissues. (*See* Ex. 1202, ¶ 14.) Indeed, the first known instance of using x-ray imaging to improve the accuracy of radiation therapy dates back to the 1940s. (*Id.*, ¶¶ 15-16.) The corollary concept that imaging should be done close in time to when the radiation is delivered is likewise very old. As explained by Dr. Balter, the field of radiation therapy has consistently maintained its focus on combining imaging with radiation therapy, and the ’765 patent did nothing to shift the direction of the field. (*Id.*, ¶¶ 14-17.)

B. 3-D Computed Tomography with Flat Panel Imagers

The field of 3-D computed tomography (“CT”) imaging using x-rays was fully developed well in advance of the earliest possible priority date listed on the face of the ’765 patent. By this time it was already well known that high quality 3-D images of patient internal structures could be obtained using x-ray technology and computer imaging systems. (*Id.*, ¶¶ 18-20.) In brief, these prior art systems used an x-ray source and imager to collect a multitude of x-ray projection images at different angles around the patient. Initially, these CT systems worked through a “stack-of-slices” approach in which several 2-D images were stacked on top of each other to form a 3-D image. The underlying 2-D CT images were obtained one at a time by rotating an x-ray source emitting a "fan" shaped beam around a patient and then progressively translating the patient through the scanner. By the mid-1990s, however, systems were available that obtained 3-D images in a single rotation using a technology called "cone-beam" CT ("CBCT"). As the name suggests, CBCT works by using a large x-ray field shaped in a cone rather than a thin "fan-beam." The figure below contrasts the fan-beam and cone-beam approaches to CT that were well established by 1999:



Central to the utility of this cone-beam approach were detectors that could receive x-ray cone-beam projection data. By the mid 1990s, the field of large flat-panel detector arrays had developed to meet this need. The art was unequivocal that such flat panel imagers were an obvious choice for large field x-ray imaging, stating in 1994 that "[t]he recent development of large-area, flat-panel a-Si:H imaging arrays is generally expected to lead to realtime diagnostic and megavoltage x-ray projection imagers." (*See* Ex. 1202, ¶ 98.) Thus before the '765 applicants began their work, it was already known that CBCT imaging could be improved by the use of a large flat panel image detector to facilitate rapid acquisition of 3-D CT image data obtained from a single rotation of the imaging system around the patient.

C. The '765 Patent Did Not Advance the Art

The '765 patent generally relates to a cone-beam computed tomography ("CBCT") imaging system that employs x-rays detected by a flat-panel imager ("FPI") on a radiotherapy system. In the systems described by the '765 patent, the patient is imaged while in position for treatment with a radiation beam. ('765, 1:16-21.) As described by the applicants, CBCT is used to obtain 3-D patient information which can be used to better guide therapeutic radiation to a target lesion such as a tumor. (*Id.*, 1:23-25; 3:41-4:2.)

The systems claimed in the '765 patent were nothing more than the combination of known elements, with each element performing its well-known function. The applicants' assembly of old elements provided results just as would be expected by one of skill in the art. As described fully herein, it was known in radiotherapy to use diagnostic (kV) x-rays on a radiotherapy gantry to obtain images for real-time control of a radiotherapy beam. It was also known to use kV x-rays for cone beam imaging on a linear accelerator gantry because of its superior image quality. A combined CBCT/FPI system was also known, and indeed it was known to use the exact type of flat panel imager used in this prior art CBCT system on a radiotherapy system. Because of the known benefits of CBCT, the known benefits of image-guided radiotherapy, and the express teachings in the prior art to use the same flat panel imager of the prior art CBCT system on a radiotherapy gantry, it was obvious to apply the prior art CBCT/FPI system to control the prior art radiotherapy system because of the known benefits of improved imaging. (*See also* Ex. 1202, ¶¶ 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. 1211, 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 14-19. Claims 14 and 17 comprise two independent method claims, each with two dependent claims. These independent claims describe method steps of using CBCT-FPI to generate 3-D image information about an object on a support table. Claim 14 recites controlling a path of a radiation beam based on the 3-D information, while claim 17 recites modification of a radiation therapy treatment plan (an "RTTP") based on the 3-D information. Both claims further recite that the controlling or modifying step is done "substantially at a time when" detecting the cone-beam x-rays by the FPI is performed. To aid in claim analysis, a table for comparison of these claims is set forth below:

Claim 14	Claim 17
A method of treating an object with radiation, comprising:	A method of planning a treatment of an object with radiation, comprising:
positioning said object on a support table;	positioning said object on a support table;
generating three-dimensional information concerning said object by: passing multiple x-ray beams in a cone	generating three-dimensional information concerning said object by: passing multiple x-ray beams in a cone

beam form through said object from different angles;	beam form from an x-ray source through said object from different angles;
creating a two-dimensional projection image of said object based on each of said multiple x-ray beams passing through said object by using a flat-panel imager to detect portions of said multiple x-ray beams passing through said object; generating an image containing three-dimensional information concerning said object,	acquiring a two-dimensional projection image of said object based on each of said multiple x-ray beams passing through said object by using a flat-panel imager to detect portions of said multiple x-ray beams passing through said object; generating an image containing three-dimensional information concerning said object
wherein said three-dimensional information concerning said object is based on a plurality of two-dimensional projection images;	based on said acquired two-dimensional projection image and other two-dimensional projection images acquired by said flat panel imager;
and controlling a path of a radiation beam through said object by controlling a relative position between said radiation beam and said object based on said three-dimensional information	
	and modifying a radiation therapy treatment plan based on said three-dimensional information
substantially at a time when said detecting portions of said multiple x-ray beams passing through said object is performed.	substantially at a time when said detecting portions of said multiple x-ray beams passing through said object is performed.

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

A claim subject to *inter partes* review must be given its "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). As the Federal Circuit has recognized, the "broadest reasonable" construction standard is fundamentally different from the manner in which the scope of a claim is determined in litigation. *See In re Swanson*, 540 F.3d

1368, 1377-78 (Fed. Cir. 2008). Accordingly, the constructions proposed in this Petition represent the broadest reasonable interpretation that one of ordinary skill in the art would assign to the terms below, and not necessarily the construction that would be appropriate in litigation.[1] For claim terms not addressed below, Petitioner has applied the plain and ordinary meaning of those terms.

A. "substantially at a time"

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

Furthermore, when read in light of the prosecution history, the scope of the term becomes even more uncertain. First, the '765 applicants frankly admitted to the Examiner that no standard for measuring this time was given in the specification: "[a]pplicants' specification does not provide a specific time frame …." (*See* Ex. 1212, May 15, 2008 Applicant Remarks, at 13.) Second, the

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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.

applicants' attempt to provide clarification merely replaced the vague claim term with another vague and undefined term of degree: "one of ordinary skill would understand that the span of time … would be such that there would be a small probability 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 (or the RTTP must be modified) 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. 1202, ¶¶ 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. 1212, 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. 1202, ¶ 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 14 and 17. 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. 1202, ¶ 39.)

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

The '765 patent seeks the benefit of provisional application 60/183,590 ("the '590 provisional"), filed on February 18, 2000. ('765, 1:4-11; the '590 provisional is submitted as Ex. 1213.) The claims of the '765 patent, however, are not entitled to this priority date because they are wholly unsupported by the '590 provisional.

As noted above, the challenged claims require that the claim element of controlling the path of the radiation beam (or modifying the RTTP) is performed "substantially at a time" when the flat panel imager receives or detects x-rays. The remaining challenged dependent claims of the patent all incorporate this "substantially at a time" element by reference. There is also no disclosure of control of the path of the radiation beam, or modification of the RTTP, based on 3D information. As described above, this limitation is extremely significant, as it was the sole element the Examiner believed to be missing from the prior art.

None of the claims that were ultimately allowed in the '765 patent are supported by the '590 provisional. This is most clearly evidenced by the fact that the '590 provisional contains only a fraction of the disclosure contained in the nonprovisional on which the '765 application is based. The provisional application discloses a benchtop CBCT-FPI system and focuses on the features of the imager and image quality. The provisional has no discussion of using the benchtop system to control a path of a radiotherapy beam substantially at the same time as the x-rays are received by the FPI, as the claims of the ’765 patent purport to cover.

The nonprovisional application filed a year later contained disclosure that is nowhere found in the provisional, including an additional 16 pages of new text, 48 new figures, and 92 new claims. The focus of these new disclosures is the installation of a CBCT-FPI system on a medical linear accelerator for use in image-guided radiotherapy. For example, every word in the specification of the ’765 patent from Column 19, line 33 to the end – over eight columns of text – is new matter that was not disclosed in the ’590 provisional. This new disclosure is shown in Exhibit **1214**. Exhibit **1214**, is a copy of the ’765 patent that shows the new matter in yellow highlight that was added to the ’765 specification and absent from the ’590 provisional.

As confirmed by Dr. Balter, the ’590 provisional has no support for claims reciting controlling the relative position of the radiation beam path substantially at the same time as the x-rays are received by the FPI. None of the teachings in the patent describing guidance of radiotherapy based on a CBCT-FPI system found in columns 19-27 of the ’765 patent were presented in the ’590 provisional. The provisional does not even disclose control of radiotherapy based on 3-D imaging, let alone performing such control "substantially at a time" when the FPI receives the x-rays. One of ordinary skill in the art, would not have recognized that the applicants possessed the missing "substantially at a time" element based on the '590 provisional application. (*See* Ex. 1202, ¶¶ 43-50.)

During prosecution of the '765 patent, the applicants were challenged by the Examiner to identify support in the specification for the "substantially at a time" claim limitation. In response, the only support they identified was the phrase "the cone beam computerized tomography image is preferably acquired with the patient on the treatment table, in the treatment position, and immediately prior to treatment delivery." (Ex. **1212**, May 15, 2008 Applicant Remarks, at 13.) This disclosure is present only in the nonprovisional ('765, 23:26-29), and was not disclosed in the '590 provisional. (*See, e.g.*, Ex. 1214, 23:26-29.)[2] One of ordinary skill in the art,

[2] On December 10, 2007, the applicants also improperly amended their specification to add new matter during prosecution, adding two sentences containing the phrase "real-time" and relating to the "substantially at a time" concept. (*See* '765, 23:29-33, 27:53-57; *see also* Ex. **1215**, Dec. 10, 2007 Applicant Amendment, at 3.) To the extent the Patent Owner attempts to rely on these improper additions of new matter for support of the "substantially at a time"

reviewing the '590 provisional, therefore would not have recognized that the applicants possessed the "substantially at a time" element when the '590 provisional was filed. (*See* Ex. 1202, ¶¶ 50-52.)

Because the challenged claims of the '765 patent must rely on the new matter added to the February 16, 2001 nonprovisional (and not present in the '590 provisional), the earliest effective filing date for these claims can be no earlier than Feb. 16, 2001. *See, e.g.*, *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008); *see also Butamax Advanced Biofuels LLC v. Gevo, Inc.*, IPR2014-00402, Paper No. 11 at 5 (P.T.A.B. Aug. 8, 2014).

VIII. GROUND 1 – CLAIMS 14-16 ARE OBVIOUS OVER JAFFRAY 1999 SPIE, JAFFRAY 1999 JRO, AND ADLER/DEPP UNDER 35 U.S.C. § 103(a)

A. Prior Art and Date Qualification for Ground 1

Each limitation of claims 14-16 is disclosed or suggested by D.A. Jaffray *et al.*, *Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager*, SPIE, 3659:204-14 (February 1999) **[Ex. 1205] ("Jaffray 1999 SPIE")**, D.A. Jaffray *et al.*, *A Radiographic and Tomographic Imaging System Integrated into a Medical Linear Accelerator for Localization of Bone and Soft-Tissue Targets*, Int.

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limitation of the challenged claims, the claims are invalid for improper reliance on new matter.

J. Radiation Oncology Biol. Phys., 45:773-89 (October 1999) **[Ex. 1206] ("Jaffray 1999 JRO")**, U.S. Patent No. 5,207,223 issued to Adler *et al.*, published on May 4, 1993 **[Ex. 1203] ("Adler")**, U.S. Patent No. 5,427,097 issued to Depp, published on June 27, 1995 **[Ex. 1204] ("Depp")**.[3]

The Jaffray 1999 references are § 102(b) (pre-AIA) prior art because, as noted above, the '765 patent is not entitled to seek the priority date of its provisional application, and the references published more than one year before February 16, 2001, the earliest nonprovisional date of the '765 patent. And at a minimum, the Jaffray 1999 references are prior art under § 102(a) (pre-AIA) because each published before February 18, 2000, the filing date of the earliest application appearing on the face of the '765 patent. Adler/Depp qualifies as prior art under at least § 102(b) (pre-AIA) because it was published more than one year before February 18, 2000, the filing date of the earliest application appearing on the face of the '765 patent. Adler/Depp was not before the Office during examination or considered by the Examiner prior to issuance of the patent.

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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."

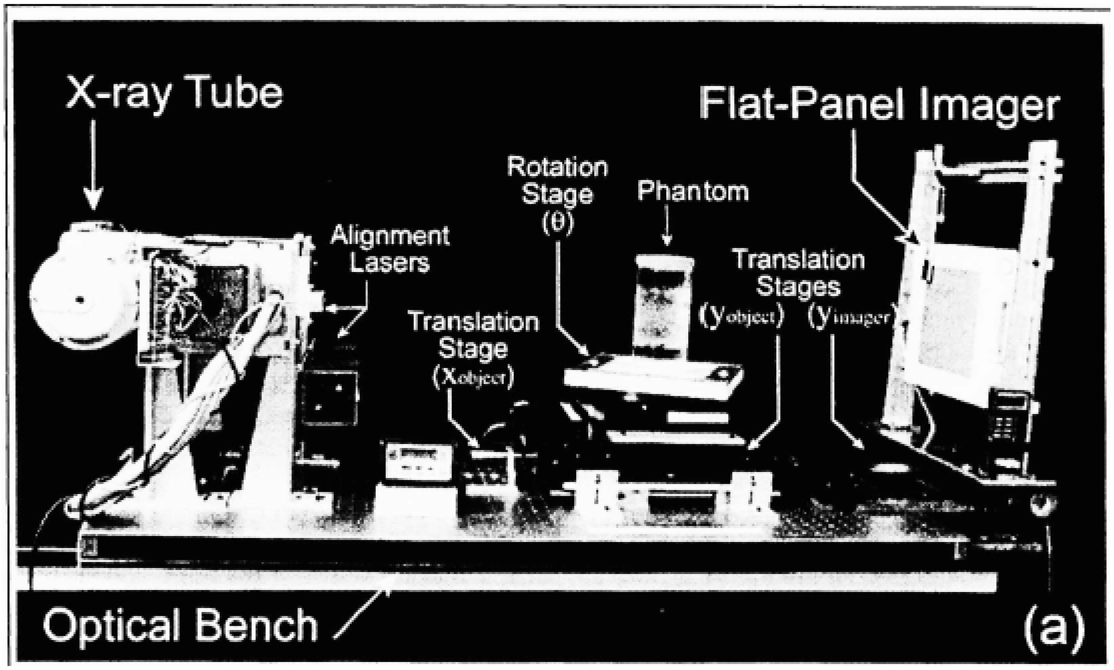
B. Brief Description of Jaffray 1999 SPIE, Jaffray 1999 JRO, and Adler/Depp

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

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

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

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



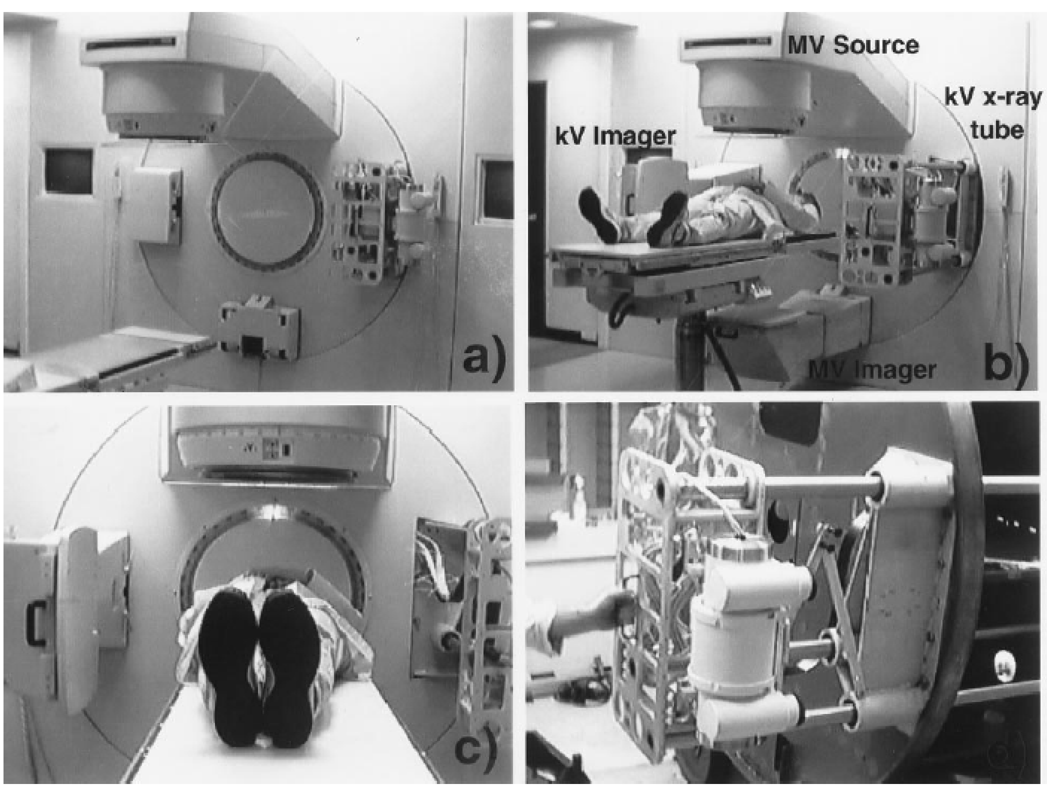
(Jaffray 1999 SPIE, at 18.) Jaffray 1999 SPIE expressly taught mounting the system on a medical linear accelerator for rotation around the patient for the purpose of image-guided radiotherapy: "The CBCT system described in this report will be adapted for implementation in our clinic for image-guidance of external beam radiotherapy. Specifically, the flat-panel imager will be mounted on a treatment gantry opposite a kilovoltage x-ray tube in a manner previously accomplished with a CCD-based imager." (*Id.*, at 25.)

Jaffray 1999 JRO [Ex. 1206], entitled "A Radiographic and Tomographic Imaging System Integrated into a Medical Linear Accelerator for Localization of Bone and Soft-Tissue Targets," provides a detailed description of the realization of Jaffray's plan to install a CBCT system onto a radiotherapy device. (Jaffray 1999

JRO, at 9.) As Jaffray explained, the system employed 120 kVp x-rays through a single complete rotation of the gantry around 360°. (*Id*.)

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

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



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

Adler [Ex. 1203], entitled "Apparatus for and Method of Performing Stereotaxic Surgery," discloses systems for selectively irradiating a target within a patient. Adler discloses use of diagnostic x-ray imaging, 3-D image mapping of target lesions, and adjustment of the radiotherapy 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 multiple diagnostic x-ray scans, to obtain "the real time location of the target region" within the patient. (*Id.*, 5:10-39.) Based on this real-time information, the relative position of the radiosurgical apparatus and the patient can be adjusted to ensure proper aim at the target region. (*Id.*)

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

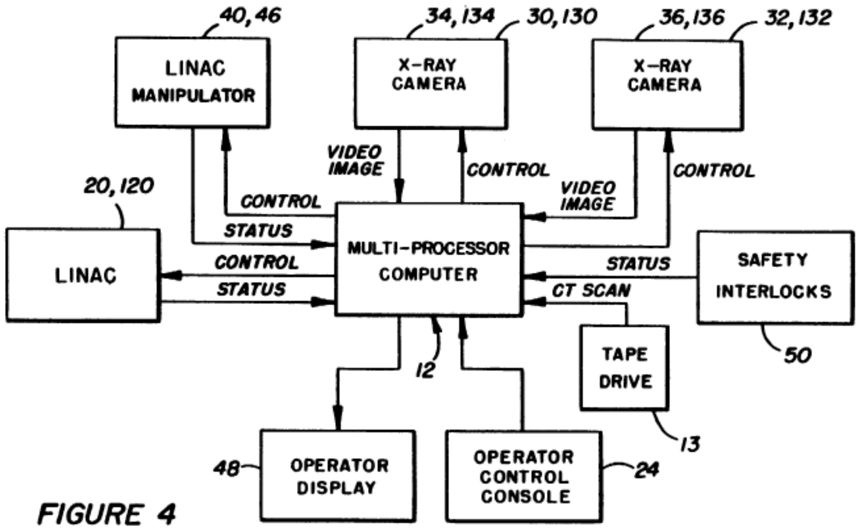


FIGURE 4

SYSTEM BLOCK DIAGRAM

(*Id.*, Fig. 4.)

Depp [Ex. 1204] shares a similar title and the same assignee as Adler and describes itself as describing improvements to the method and apparatus disclosed in Adler, which Depp incorporates by reference. (Depp, 1:12-17.) Among other improvements, Depp describes "a unique temporal procedure for operating the radiosurgical beam and the diagnostic target locating beams in order to continuously locate the target region in substantially real time." (*Id.*, 7:42-45.) Thus, Depp expressly teaches a device in which diagnostic images are used to ensure proper targeting of the radiation beam in real time.

C. Jaffray 1999 SPIE, Jaffray 1999 JRO, and Adler/Depp Disclose Each Limitation of Claims 14-16

1. Claim 14

The preamble of claim 14 recites: "A method of treating an object with radiation ….” Although the preamble of claim 14 may not be limiting under its broadest reasonable construction, Adler/Depp and Jaffray 1999 JRO disclose it.

As explained in more detail below, Adler/Depp discloses methods for radiotherapy that are configured for selectively irradiating a target within a patient. (*See* Adler, Abstract, 3:62-68; Depp, Abstract, 1:6-12, 1:18-26; *see also* Ex. 1202, ¶¶ 61-62.) As shown in Figure 1 of Adler, for example, Adler/Depp disclose a system for delivering radiotherapy to a patient:

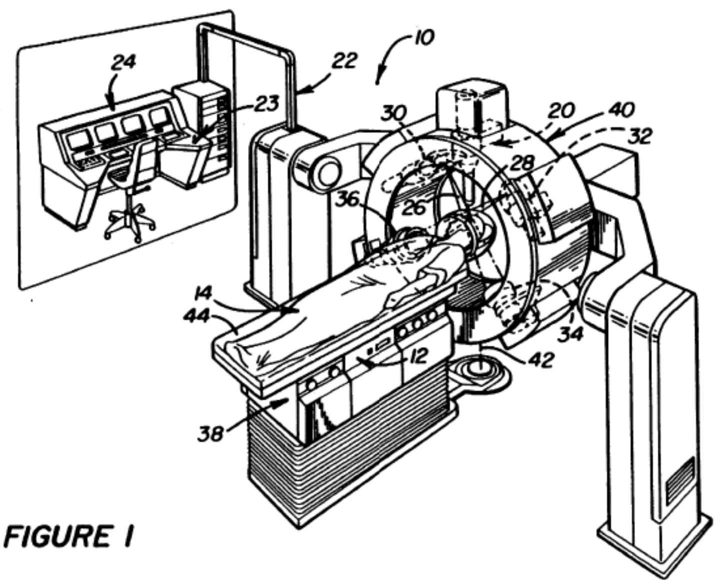


FIGURE I

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

Adler/Depp also teaches an alternative embodiment in which the radiation beam is contained in a mechanism having six degrees of movement freedom (as opposed to being within the gantry **40** shown in Adler's Figure 1). (*See* Adler, Fig. 3; *see also* Depp, Fig. 3.) Finally, as discussed in Section VIII-B above, Jaffray

1999 JRO expressly discloses methods of radiotherapy using a medical linear accelerator device. (*See also* Ex. 1202, ¶ 63.)

a. "positioning said object on a support table"

This limitation was expressly taught by Adler/Depp. Referring to Figure 1, Adler teaches an "operating table **38**" for the patient **14**. (Adler, 7:37-52.) Depp contains the same teaching. (Depp, 5:10-25.) Jaffray 1999 JRO also expressly teaches this element. The Elekta SL-20 device of the reference, shown in Fig. 1, depicts the patient table. (*See* Section VIII-B; *see also* Ex. 1202, ¶¶ 64-65.)

b. "generating three-dimensional information concerning said object by: passing multiple x-ray beams in a cone beam form through said object from different angles"

Jaffray 1999 SPIE expressly discloses a CBCT x-ray system that moves around the object, emitting multiple x-ray beams in cone-beam form: "The CBCT system is illustrated in Figure 1. The main components of the system are the x-ray tube, the rotation stage, and the flat-panel imager." (Jaffray 1999 SPIE, at 17.) Jaffray explained: "A single CBCT scan is obtained by acquiring projection images at 1.2° increment rotations of the object across 360°." (*Id.*, at 25.) As confirmed by Dr. Balter, this disclosure is an express disclosure of passing multiple x-ray beams in cone beam ("CB") form through said object from different angles. (*See* Ex. 1202, ¶ 66.)

Jaffray 1999 JRO also expressly discloses this element:

> To generate a CB-CT dataset, a series of radiographic exposures are acquired at regular angular intervals as the accelerator gantry is rotated…. The control system operates the camera's shutter and read-out mechanisms in synchrony with the firing of the x-ray generator ....

(Jaffray 1999 JRO, at 9.) Thus, like Jaffray 1999 SPIE, this reference expressly teaches passing multiple cone-beam x-rays through an object from multiple angles. (*See also* Ex. 1202, ¶ 67.)

c. "creating a two-dimensional projection image of said object based on each of said multiple x-ray beams passing through said object by using a flat-panel imager to detect portions of said multiple x-ray beams passing through said object"

Jaffray 1999 SPIE expressly teaches this element:

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

(Jaffray 1999 SPIE, at 17 (emphasis added).) Jaffray 1999 JRO also expressly suggests the use of FPI:

> There is significant room for additional optimization of the system: investigating the impact of x-ray scatter, reducing veiling glare in the

> optical housing, and exploring the use of flat-panel imagers for increased detective quantum efficiency.

(Jaffray 1999 JRO, at 15 (emphasis added).) As confirmed by Dr. Balter, these FPI devices function as x-ray detectors by detecting multiple x-ray beams that pass through the object being imaged. Thus, this element is expressly taught by both Jaffray 1999 references. (*See* Ex. 1202, ¶¶ 68-69.)

d. "generating an image containing three-dimensional information concerning said object, wherein said three-dimensional information concerning said object is based on a plurality of two-dimensional projection images"

Jaffray 1999 SPIE discloses this element. The reference explained:

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

(*Id.*, at 25 (emphasis added).) Jaffray 1999 SPIE thus taught the use of an FPI to obtain 3-D image information ("volume data sets") based on a plurality of 2-D projection images. (*See* Ex. 1202, ¶ 70.) Accordingly, this element was expressly taught in the prior art.

Adler/Depp teaches the use of three-dimensional information about the object based on a plurality of 2-D projection images, because Adler/Depp teaches obtaining two x-ray images ("diagnostic beams **26** and **28**") at a "known non-zero angle relative to one another." (Adler, 7:6-12.) These beams are received by "[i]mage receivers **34** and **36**" and the resulting signals are passed to the "microprocessor **12**." (*Id.*, 7:17-23.) As confirmed by Dr. Balter, these images provide three-dimensional information. (*See* Ex. 1202, ¶ 71.)

e. "and controlling a path of a radiation beam through said object by controlling a relative position between said radiation beam and said object based on said three-dimensional information"

As discussed with respect to the claim preamble, Adler/Depp also 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.)

Adler/Depp also teaches the "control" aspect of this element. Adler teaches a computer ("the processor **12**") that is coupled to the x-ray imaging system, receives image information, and based on the image information, sends a signal to the radiation source to control its path. Adler teaches obtaining two x-rays ("diagnostic beams **26** and **28**") at a "known non-zero angle relative to one another." (Adler, 7:6-12.) These beams are received by "[i]mage receivers **34** and **36**" and the resulting signals are passed to the "microprocessor **12**." (*Id.*, 7:17-23.) Adler/Depp then teaches control of positioning based on this image: "[m]eans are provided for adjusting the relative position of the beaming apparatus **20** and the patient **14** as needed in response to data which is representative of the real time location of the target region **18** …." (*Id.*, 7:37-40.) Adler/Depp teaches that this adjusting may be done by moving the radiation source in the gantry or by moving the patient table:

> In the particular embodiment illustrated in FIG. 1 the means for adjusting the relative positions of the beaming apparatus and the patient comprises a gantry **40** to which the beaming apparatus **20**, the diagnostic x-ray generators **30** and **32** and the image receivers **34** and **36** are mounted along with conventional apparatus for lowering and

> raising the operating table **38** and for rotating it about an axis **42** and for tilting the top **44** of the operating table **38** about a longitudinally extending axis, all as illustrated by arrows in FIG. 2. The broad range of adjustment of the relative positions of the gantry **40** and the patient **14** allows the collimated beam to be continuously focused on the target region while the healthy tissue through which the collimated beam passes is changed, as by rotating the beaming apparatus **20** through as much as 360° about the patient.

(Adler, 7:42-58.) Finally, Adler/Depp notes that "FIG. 4 illustrates, in system block diagram form, operation of the logic by which the apparatus of FIG. 1 … can be controlled." (Adler, 8:32-34.) As Adler/Depp explains, "[s]ignals from the image receivers **34**,**134** and **36**,**136** are passed to the processor **12**." (Adler, 8:36-38.) Then, "[s]ignals from the processor **12** are passed to … the gimbal **40** thus controlling its positioning …." (*Id.*, 8:43-47.) As confirmed by Dr. Balter, these teachings would have been recognized by one of ordinary skill in the art as an express disclosure of a system comprising a computer connected to a moveable radiation source and a diagnostic x-ray imaging system, controlling the position of the radiation beam based on multiple x-rays images. (*See* Ex. 1202, ¶¶ 72-74.)

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

> The apparatus also utilizes a pair of [] diagnostic beams of radiation or target locating beams…. These beams are passed through the

> surrounding area containing the target region and reference points and, after passing through the surrounding area, contain data indicating the positions of the reference points within the surrounding area. This position data is collected by cooperating detectors, as described previously, and delivered to the multiprocessor computer where the latter compares it with previously obtained reference data for determining the position of the target region with respect to each of the reference points during each such comparison. The radiosurgical beam is accurately directed into the target region in substantially real time based on this information.

(Depp, 11:46-61.) As confirmed by Dr. Balter, one of ordinary skill in the art would have recognized in these teachings an express disclosure of this claim element. (*See* Ex. 1202, ¶ 75.)

f. "substantially at a time when said detecting portions of said multiple x-ray beams passing through said object is performed."

Adler teaches controlling the path of the radiation beam at the same time as detecting 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. 1202, ¶ 76.)

2. Claim 15

Claim 15 depends from claim 14 and adds the limitation "wherein said path of said radiation beam through said object is controlled by moving said support table." This adds nothing of patentable significance, because it was expressly taught by Adler/Depp. Adler taught:

> [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 also* Ex. 1202, ¶ 77.) As confirmed by Dr. Balter, all elements of claim 15 are disclosed in the prior art. (*See* Ex. 1202, ¶ 77.)

3. Claim 16

Claim 16 depends from claim 14 and adds the limitation "wherein each of said multiple x-ray beams has an energy of approximately 100 keV." This limitation adds nothing of patentable significance. Jaffray 1999 SPIE expressly discloses the additional element of using beams of approximately 100 keV:

"[V]olumetric imaging is accomplished by rotating the object incrementally over 360 degrees, delivering a radiographic x-ray pulse (e.g., 100-130 kVp, ~0.1-10 mAs), and acquiring a projection image at each increment." (Jaffray 1999 SPIE, at 16 (emphasis added).) Thus all elements of claim 16 are disclosed in the prior art. (*See also* Ex. 1202, ¶¶ 78-79.)

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

Claims 14-16 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 these prior art elements. 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.

Adler/Depp does not disclose the use of a CBCT-FPI system for performing this x-ray imaging, but it would have been obvious to obtain these elements from the Jaffray 1999 references to improve the accuracy of Adler/Depp's imaging during radiotherapy. By 1999, it was well-known that CBCT was useful for providing rapid 3-D image information about a patient in the treatment position as shown by Jaffray 1999 SPIE and Jaffray 1999 JRO, as well as other background prior art cited by Dr. Balter. (*See* Ex. 1202, ¶ 82.) As explained by Dr. Balter, CBCT-FPI was one of only a finite number of choices the artisan had in order to provide an obvious improvement on the radiation therapy control systems of Adler/Depp, and indeed the art specifically suggested this assembly. (*See id.*, ¶¶ 81-86.)

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

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

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

One of skill in the art would have been motivated to combine the CBCT and FPI teachings of Jaffray 1999 SPIE with the linear accelerator radiation therapy teachings of Jaffray 1999 JRO. First, two of the three authors of Jaffray 1999 SPIE were authors of Jaffray 1999 JRO. Second, both articles teach a system to address problems in administering radiotherapy. Specifically, both articles disclose a need to confirm the precise location of the area targeted for radiation. (Jaffray 1999 SPIE, at 16-17; Jaffray 1999 JRO, at 3-4.) Third, both articles teach implementing a CBCT system with a linear accelerator for image guidance of radiotherapy. (Jaffray 1999 SPIE, at 17, 25; Jaffray 1999 JRO, at 3-4, 18.) The primary difference between the articles is that Jaffray 1999 SPIE uses and evaluates incorporating an FPI into the CBCT system used for imaging guidance while Jaffray 1999 JRO uses a CCD-based imager mounted to a linear accelerator. Jaffray 1999 JRO teaches use of flat panel imagers as a possible substitution for the CCD-based imager, however. (Jaffray 1999 JRO, at 15.) Further, Jaffray 1999 SPIE cites directly to Jaffray 1999 JRO, teaching that a flat panel imager can be substituted for the CCD-based imager of Jaffray 1999 JRO. (Jaffray 1999 SPIE, at 25-26 (endnote 8).) As explained by Dr. Balter, one of ordinary skill in the art would have viewed this as an express suggestion to combine the teachings of these references. (*See* Ex. 1202, ¶ 84.)

It was also obvious to combine the Jaffray 1999 references with the radiotherapy system teachings of Adler/Depp. For example, Jaffray 1999 JRO expressly suggests the usefulness of its disclosure in obtaining image-guided radiotherapy. "An on-line kV imaging system has been integrated with a medical linear accelerator for the purpose of localizing the patient and verifying beam placement." (Jaffray 1999 JRO, at 18.) Adler/Depp likewise teaches that improved x-ray image based targeting, in real-time, of internal lesions such as tumors is desirable to avoid irradiation of healthy surrounding tissues, and Jaffray 1999 SPIE provides an improved method for acquiring volumetric (3-D) CT image data using CBCT and an FPI. (*See* Adler, 2:49-53, 3:34-42, 5:40-54; Depp, Abstract, 1:55-65, 2:48-53, 11:54-61; Jaffray 1999 SPIE, at 16-17.) As explained by Dr. Balter, one of ordinary skill in the art would have viewed this as an express suggestion to combine the teachings of these references. (*See* Ex. 1202, ¶ 85.)

Adler and Depp should be treated as a single reference because Depp states that it is an improvement of Adler, and incorporates it by reference. (*See* Depp, 5:35-55, 7:31-47.) One of skill in the art would be motivated to combine the

Jaffray 1999 references with Adler/Depp because all three references are in the same field of medical imaging in conjunction with radiation therapy and all three are concerned with the problem of obtaining accurate 3-D information about the internal structure of objects like patients. (*See* Adler, 1:6-18; Depp, 1:6-18; Jaffray SPIE 1999, at 16-17; *see also* Ex. 1202, ¶ 86.) As explained by Dr. Balter, the combination of the CBCT-FPI methodology of the Jaffray 1999 references with the radiotherapy control apparatus of Adler/Depp, as done by the ’765 applicants, was also obvious because it combined the known methods of CBCT with an FPI to improve the diagnostic imaging and real-time adjustment of radiotherapy described in Adler/Depp. (*See* Ex. 1202, ¶¶ 81-86.) In this field, the results obtained by the inventors (obtaining 3-D image information concerning target lesions in patients for the purpose of targeting the radiation beam) were the predictable work of combining the CBCT-FPI system of the Jaffray 1999 references with the radiotherapy systems of Adler/Depp. Accordingly, the claimed combination was obvious. *See* MPEP § 2141 (III); *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 419-20 (2007); *see also Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.*, IPR2014-00204, Paper No. 31 at 29 (P.T.A.B. Mar. 31, 2015).

IX. Ground 2 – Claims 17-19 Are Obvious Over Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler/Depp, and Yan Under 35 U.S.C. § 103(a)

A. Prior Art and Date Qualification for Ground 2

Yan qualifies as prior art under at least § 102(b) (pre-AIA) because it was published more than one year before February 18, 2000, the filing date of the earliest application appearing on the face of the ’765 patent.

B. Brief Description of Yan

The Jaffray 1999 references and Adler/Depp are discussed above in Section VIII-B. **Yan [Ex. 1210]**, entitled “The Use of Adaptive Radiation Therapy to Reduce Setup Error: A Prospective Clinical Study,” discloses systems and methods for image-guided radiotherapy. Yan’s authors include David Jaffray and John Wong, the named inventors of the ’765 patent (and co-authors of the Jaffray 1999 references). Yan expressly teaches an RTTP can be modified based on imaging, including by making alterations to the shape of the radiation field by adjusting the MLC (multi-leaf collimator).

C. Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler/Depp and Yan Disclose Each Limitation of Claims 17-19

1. Claim 17

As noted above, Claim 17 is an independent method claim like claim 14 discussed in ground 1, but claim 17 recites a method of modifying an RTTP that employs the same system as claim 14. The only material difference from a patentability standpoint between claim 14 and claim 17 is that claim 17 contains the step of modifying the RTTP instead of the step of controlling the path of the radiation beam recited in claim 14.

This difference is not of patentable significance, however, because the element of modifying an RTTP based on three-dimensional image information concerning the object (patient) receiving radiotherapy was expressly disclosed in the art. Yan expressly teaches:

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

(Yan, at 11 (emphasis added).) Thus, as confirmed by Dr. Balter, Yan expressly teaches that the RTTP can be modified based on 3-D imaging, including by making alterations to the shape of the radiation field by adjusting the MLC (multi-leaf collimator). This comports with the ’765 patent, which states an RTTP can be modified by "recalculation of the RTTP" (including to "modify the planning system to generate 'corrected' leaf positions."). (’765, 25:30-31, 26:37-42.) Thus, all elements of claim 17 were known in the art. (*See also* Ex. 1202, ¶ 90.)

2. Claim 18

Claim 18 is a dependent claim from claim 17. The additional limitation, however, is identical to the limitation of claim 16. As discussed above in Section VIII-C-3, this limitation added nothing of patentable significance, thus claim 18 is obvious for the same reasons. (*See* Ex. 1202, ¶ 91.)

3. Claim 19

Claim 19 depends from claim 17, adding the limitation "wherein said three-dimensional information concerning said object is based on one rotation of said x-ray source around said object." This limitation was expressly taught by Jaffray 1999 SPIE: "an entire volumetric image is acquired through a single rotation of the source and detector." (Jaffray 1999 SPIE, at 17.) Specifically, in Jaffray 1999 SPIE, "all scans reported in this study involved 300 projections over 360 degrees of rotation." (*Id.*, at 19.) Jaffray 1999 SPIE reported "full 3-dimensionality of the data acquired in a single rotation." (*Id.*, at 24.) As confirmed by Dr. Balter, this limitation adds nothing of patentable significance, because it would have been obvious to combine the image guided radiotherapy systems of Adler/Depp with a CBCT-FPI apparatus, by obtaining 3-D information from one rotational scan, as expressly taught by Jaffray 1999 SPIE. (*See* Ex. 1202, ¶ 92.)

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

The motivation to combine the Jaffray 1999 references with Adler/Depp is discussed in detail in Section VIII-D above. One of ordinary skill in the art would further have been motivated to combine these teachings with Yan because Yan is directed specifically at the stated purpose of the ’765 patent – improving the accuracy and efficacy of radiotherapy through image-guided means. As noted above, Yan’s authors include the two named inventors of the ’765 patent, and two of the named authors of the Jaffray 1999 references. Last, one of skill in the art would have been motivated to perform the methods of claims 17-19 based on the specific suggestions in Yan stating that use of 3-D imaging is an “optimal way” to implement the process of adjusting radiotherapy to account for patient variability, so as to more specifically target the tumor and avoid irradiation of healthy surrounding tissues. (*See* Yan, at 11; *see also* Ex. 1202, ¶ 93.)

X. GROUND 3 – CLAIMS 14-16 ARE OBVIOUS OVER CHO, ANTONUK, JAFFRAY 1997, AND ADLER/DEPP UNDER 35 U.S.C. § 103(a)

A. Introductory Comments

Petitioner submits that strong evidence supports the institution of *inter partes* review of the challenged claims based on Grounds 1 and 2 above. 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 Section VII above. In light of this theoretical possibility, however, Petitioner submits additional Grounds 3 and 4, 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 of Grounds 1-4 because each presents unique, non-redundant issues central to the patentability of the challenged claims.

B. Prior Art and Date Qualification for Ground 3

Each limitation of claims 14-16 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. 1207] ("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. 1208] ("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. 1209] ("Jaffray 1997")**, and the Adler/Depp disclosures discussed above. Cho, Antonuk, and Jaffray 1997 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 and Antonuk (like Adler/Depp) were not before the Office during examination or considered by the Examiner prior to issuance of the patent.

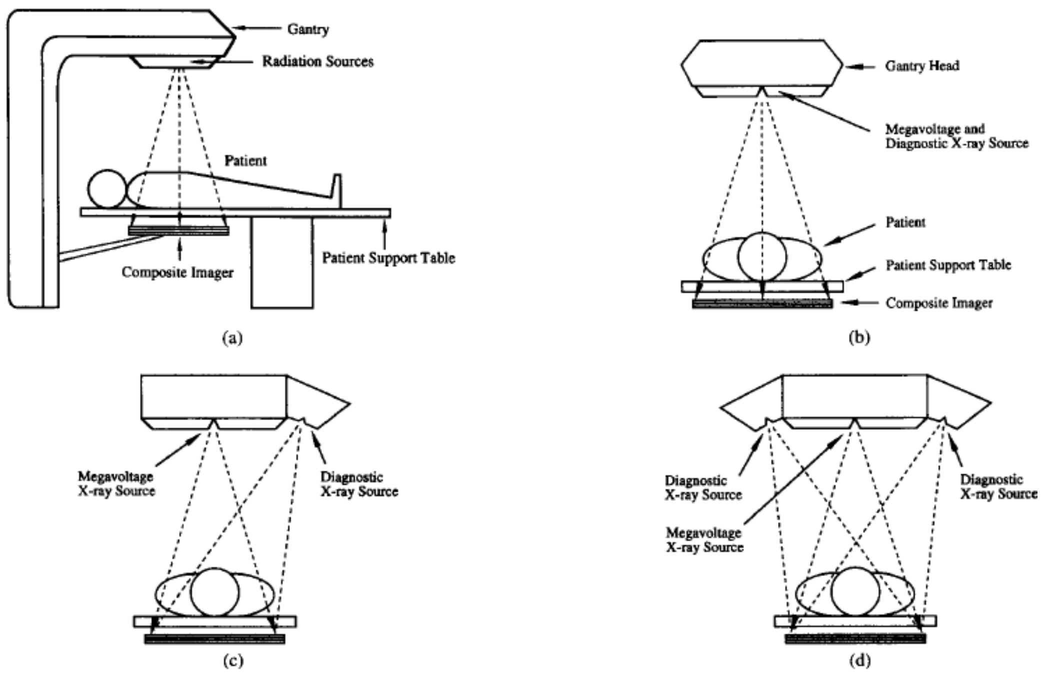
C. Brief Description of Cho, Antonuk, Jaffray 1997, and Adler/Depp

Adler/Depp is discussed in detail for Ground 1 above.

Cho [Ex. 1207], entitled "Cone-beam CT for radiotherapy applications," discloses the use of cone beam CT for patient imaging in the treatment position on a radiotherapy simulator. Cho notes that detector size was an existing limitation in 1995 for the clinical implementation of CBCT. (*See* Cho, at 5.) Cho discloses the use of a modified version 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 expressly suggested the use of amorphous silicon flat panel imagers to solve the problem of detector size for rapid acquisition of 3-D images using CBCT, citing to the 1994 Antonuk reference discussed below. (*See id.*, at 24.)

Antonuk [Ex. 1208], 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. 1202, ¶ 98.)

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 a flat panel. (*See id.*, at 8.)

Jaffray 1997 [Ex. 1209], 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:

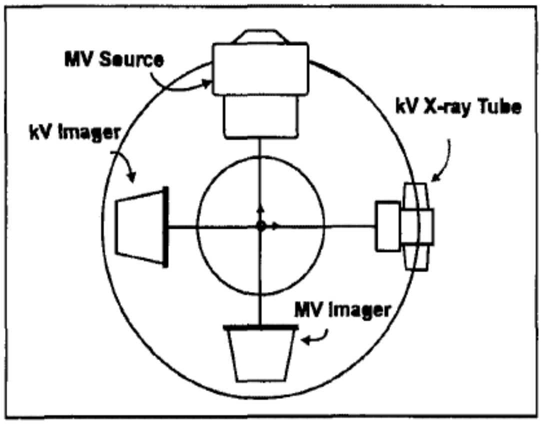


Figure 1: Schematic of dual-beam system to be used for conebeam computed tomography (CBCT). The kV x-ray beam is orthogonal to the treatment beam.

(*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.)

D. Cho, Antonuk, Jaffray 1997, and Adler/Depp Disclose Each Limitation of Claims 14-16

1. Claim 14

As noted in Ground 1 above, the preamble of claim 14 may not be a claim limitation, but if it is, Adler/Depp discloses it. (*See* Section VIII-C-1.) Antonuk and Jaffray 1997 also expressly disclose methods of radiotherapy using a medical linear accelerator device. (*See id;* Ex. 1202, ¶ 100.)

a. "positioning said object on a support table"

This limitation was expressly taught by Adler/Depp, as shown for Ground 1 above. (*See* Section VIII-C-1-a.) Antonuk depicts a support table as is standard for radiation therapy. Jaffray 1997 also teaches this element. As confirmed by Dr. Balter, the Phillips SL-20 device of Jaffray 1997, expressly referred to on page 4, comprises a patient table for use in radiotherapy. (*See* Ex. 1202, ¶ 101.)

b. "generating three-dimensional information concerning said object by: passing multiple x-ray beams in a cone beam form through said object from different angles"

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 confirmed by Dr. Balter, this disclosure is an express disclosure of passing multiple x-ray beams in cone beam ("CB") form through said object from different angles. (*See* Ex. 1202, ¶ 102.)

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 VIII-B). (*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. 1202, ¶ 103.)

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. 1202, ¶ 104.)

c. "creating a two-dimensional projection image of said object based on each of said multiple x-ray beams passing through said object by using a flat-panel imager to detect portions of said multiple x-ray beams passing through said object"

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

> Further increase in volume of reconstruction can be accomplished by … using a larger detector. The flat panel detector based on amorphous

> silicon (a-Si:H) technology is being developed as a potential real-time diagnostic x-ray imager (Antonuk *et al* 1994).

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

Antonuk provides detailed disclosures of flat panel imagers for use as diagnostic x-ray detectors mounted on a linear accelerator for imaging during radiotherapy. (Antonuk, at 3.) As explained by Dr. Balter, these FPI devices function as x-ray detectors by detecting multiple x-ray beams that pass through the object being imaged. (*See* Ex. 1202, ¶¶ 105-106.)

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 … 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. 1202, ¶ 106.)

d. "generating an image containing three-dimensional information concerning said object, wherein said three-dimensional information concerning said object is based on a plurality of two-dimensional projection images"

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 further discloses this element by teaching a computer-assisted system to create 3-D image based on a plurality of 2-D projection images from the cone-beam x-ray. Cho is directed to generating 3-D images based on 2-D CBCT scans using a modified Feldkamp algorithm. (*See* Cho, at 15-16 (discussing the scanning of CT phantom models using this approach); *id*. at 17 (discussing image processing and use of reconstruction algorithms on a computer).) As explained by Dr. Balter, one of skill in the art would recognize Cho as teaching creation of a 3-D image based on one rotation of the CBCT system. (*See* Ex. 1202, ¶ 107.) Furthermore, the image reconstruction methodology employed by Cho, such as the Feldkamp algorithm, was well-known and in standard use for this purpose before 1999. (*See id*.)

Adler/Depp teaches the use of three-dimensional information about the object based on a plurality of 2-D projection images, because Adler/Depp teaches obtaining two x-ray images ("diagnostic beams **26** and **28**") at a "known non-zero angle relative to one another." (Adler, 7:6-12.) These beams are received by "[i]mage receivers **34** and **36**" and the resulting signals are passed to the "microprocessor **12**." (*Id.*, 7:17-23.) As confirmed by Dr. Balter, these images provide three-dimensional information. (*See* Ex. 1202, ¶ 108.)

e. "and controlling a path of a radiation beam through said object by controlling a relative position between said radiation beam and said object based on said three-dimensional information"

As discussed in detail for Ground 1, Adler/Depp teaches systems with a radiation source that moves with respect to the object and controls a beam of radiation toward the object based on image guidance. (*See* Section VIII-C-1-e.) (*See* Ex. 1202, ¶ 109.)

f. "substantially at a time when said detecting portions of said multiple x-ray beams passing through said object is performed."

As discussed in detail for Ground 1, Adler/Depp teaches control of the radiation beam at substantially the same time as detecting the x-rays. (*See* Section VIII-C-1-f; Ex. 1202, ¶ 110.)

2. Claim 15

Claim 15 depends from claim 14 and adds the limitation "wherein said path of said radiation beam through said object is controlled by moving said support table." This adds nothing of patentable significance, because it was expressly taught by Adler/Depp as discussed above in Section VIII-C-2. Thus all elements of claim 15 are disclosed in the prior art. (*See also* Ex. 1202, ¶ 111.)

3. Claim 16

Claim 16 depends from claim 14 and adds the limitation "wherein each of said multiple x-ray beams has an energy of approximately 100 keV." This limitation adds nothing of patentable significance. Cho expressly discloses the additional element of using beams of approximately 100 keV: "The scans were performed using 100 kV x-rays except for the chest scan in which case 120 kV was used." (Cho, at 16.) Jaffray 1997 also expressly discloses that its "kv image produced with a kV beam" is provided by a generator that can "produce up to 140 kVp x-ray exposures at 300 mA." (Jaffray 1997, at 4.) Thus all elements of claim 16 are disclosed in the prior art. (*See also* Ex. 1202, ¶ 112.)

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

Claims 14-16 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 these prior art elements. As noted for Ground 1, Adler/Depp discloses the use of x-ray imaging to control the path of a radiation therapy beam in a radiation therapy system "substantially at a time" that the x-ray images are received. Adler/Depp thus provides the limitation the Examiner believed was absent from the prior art.

Adler/Depp does not disclose the use of a CBCT-FPI system for performing this x-ray imaging, but it would have been obvious to obtain these elements from the Cho, Antonuk, and Jaffray 1997 references to improve the accuracy of Adler/Depp's imaging during radiotherapy. As explained by Dr. Balter, CBCT-FPI was one of only a finite number of choices the artisan had to provide an obvious improvement on the radiation therapy control systems of Adler/Depp, and indeed the art specifically suggested this assembly. (*See* Ex. 1202, ¶¶ 114-115.)

As an example of the express suggestions contained in the prior art, 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 (citation omitted).) (*See* Ex. 1202, ¶ 116.)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 also 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.)

As noted above for Ground 1, one of ordinary skill in the art (as of the earliest filing date) faced with the problem of 3-D patient imaging in combination with radiation beam control had a finite number of identified and predictable solutions, among them CBCT-FPI. (*See* Ex. 1202, ¶¶ 114-116.) Accordingly, the claimed combination was obvious. *See* MPEP § 2141 (III); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419-20 (2007) ; *see also Toshiba Samsung Storage Tech Korea Corp. v. LG Elec., Inc.*, IPR2014-00204, Paper 31 at 29 (P.T.A.B. Mar. 31, 2015).

XI. GROUND 4 – CLAIMS 17-19 ARE OBVIOUS OVER CHO, ANTONUK, JAFFRAY 1997, ADLER/DEPP, AND YAN UNDER 35 U.S.C. § 103(a)

A. Prior Art and Date Qualification for Ground 4

Yan qualifies as prior art, as already explained in Section IX-A.

B. Brief Description of Yan

Yan is described in Section IX-B.

C. Cho, Antonuk, Jaffray 1997, Adler/Depp and Yan Disclose Each Limitation of Claims 17-19

1. Claim 17

As noted in Ground 2 above, claim 17 differs from claim 14 only in that it recites a method of modifying an RTTP that employs the same system as claim 14. As explained in Ground 2, Yan discloses this element. (*See* Section IX-C-1.)

2. Claim 18

Claim 18 adds nothing of patentable significance, as explained above in Ground 2. (*See* Section IX-C-2.)

3. Claim 19

As noted in Ground 2 above, Claim 19 adds the limitation "wherein said three-dimensional information concerning said object is based on one rotation of said x-ray source around said object." This limitation was expressly taught by Cho: "The projection data were obtained by rotating the gantry over 360° at approximately 1° increments." (Cho, at 15; *see also id.*, at 22 ("For our method, data were available through a full 360° rotation ….").) As confirmed by Dr.

Balter, this limitation adds nothing of patentable significance, because it would have been obvious to combine the image guided radiotherapy systems of Adler/Depp with the CBCT-FPI apparatus of Cho, by obtaining 3-D information from one rotational scan, as expressly taught by Cho. (*See* Ex. 1202, ¶ 121.)

D. Motivation to Combine Cho, Antonuk, Jaffray 1997, and Adler/Depp with Yan

The motivation to combine the Cho, Antonuk, and Jaffray 1997 references with Adler/Depp is discussed in detail in Section X-D above. The motivation to add the teachings of Yan with these disclosures is the same as the motivation to combine Yan with the teachings of the Jaffray 1999 references and Adler/Depp, discussed in Section IX-D above. (*See* Ex. 1202, ¶ 122.)

XII. CONCLUSION

Petitioner respectfully requests institution of *inter partes* review of claims 14-19 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. 1201-1238**) 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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