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. 7,826,592
Filing Date: November 21, 2008
Issue Date: November 2, 2010

Title: CONE-BEAM COMPUTED TOMOGRAPHY WITH A FLAT-PANEL IMAGER

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,826,592

Inter Partes Review No. _____

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EXHIBITS

Ex. No.	Title of Document
1001	U.S. Patent No. 7,826,592 issued to David A. Jaffray *et al.* ("'592 patent")
1002	Excerpts from the Prosecution History of U.S. Patent No. 7,826,592 issued to David A. Jaffray *et al.*
1003	Declaration of Dr. James J. Balter ("Balter Decl.")
1004	D.A. Jaffray and J.W. Wong, *Exploring "Target of the Day" Strategies for a Medical Linear Accelerator With Conebeam-CT Scanning Capability*, PROCEEDINGS OF THE XIITH INTERNATIONAL CONFERENCE ON THE USE OF COMPUTERS IN RADIATION THERAPY, MEDICAL PHYSICS PUBLISHING, pp. 172-75 (May 27-30, 1997) ("Jaffray '97")
1005	U.S. Patent No. 4,459,485 issued to Span ("Span")
1006	U.S. Patent No. 5,262,649 issued to Antonuk *et al.* ("Antonuk")
1007	U.S. Patent No. 3,784,837 issued to Holmström ("Holmström")
1008	PCT International Publication No. WO 91/06876 issued to Lim *et al.* ("Lim")
1009	J. Thariat *et al.*, *Past, Present, and Future of Radiotherapy for the Benefit of Patients*, NATURE REVIEW CLINICAL ONCOLOGY, 10:52-60 (Jan. 2013) ("Thariat")
1010	L. Xing *et al.*, *Overview of Image-Guided Radiation Therapy*, MEDICAL DOSIMETRY, 31:91-112 (2006) ("Xing")
1011	W. Scarfe et al., *What is Cone-Beam CT and How Does it Work?*, DENT. CLIN. N. AM., 52:707-30 (2009) ("Scarfe")

Ex. No.	Title of Document
1012	http://search.newport.com/?x2=sku&q2=AX95 (last visited Sept. 25, 2015) ("Guy Pivot Support")
1013	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 IJR")
1014	P. Munro, *Portal Imaging Technology: Past, Present, and Future*, Seminars in Radiation Oncology, 5:115-33 (Apr. 1995) ("Munro 1995")
1015	U.S. Patent No. 6,288,398 issued to Stark ("Stark")
1016	P.S. Cho *et al.*, *Cone-beam CT for radiotherapy applications*, Phys. Med. Biol., 40:1863-83 (1995) ("Cho 1995")
1017	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")
1018	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 1994")
1019	L.E. Antonuk *et al.*, *A Real-Time, Flat-Panel, Amorphous Silicon, Digital X-ray Imager*, RadioGraphics, 15:993-1000 (1995) ("Antonuk 1995")
1020	J. Chabbal *et al.*, *Amorphous Silicon X-ray Image Sensor*, Proceedings of SPIE (Society of Photographic Instrumentation Engineers), 2708:499-510 (1996) ("Chabbal 1996")

Varian Medical Systems, Inc. ("Petitioner" or "Varian") hereby petitions for *inter partes* review under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 of claims 25-29 and 35-42 of U.S. Patent No. 7,826,592 **[Ex. 1001]** ("the '592 patent").

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

A. Real Party-In-Interest under 37 C.F.R. § 42.8(b)(1)

In addition to petitioner Varian Medical Systems, Inc., VMS International AG is a real party-in-interest. VMS International AG has two Dutch parent companies, VMS Nederland Holdings BV and VMS Nederland BV, which are also real parties-in-interest.

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

The '592 patent is the subject of one pending litigation involving the Petitioner: *Elekta Ltd. v. Varian Medical Systems, Inc.*, Case No. 2:15-cv-12169-AC-MKM (E.D. Mich. June 15, 2015), in which the patent owner contends that the Petitioner infringes the '592 patent. The Petitioner was served with a complaint in that action on September 3, 2015.

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

Petitioner provides the following designation of counsel.

LEAD COUNSEL	BACK-UP COUNSEL
Heidi L. Keefe (Reg. No. 40,673) hkeefe@cooley.com zpatdcdocketing@cooley.com COOLEY LLP ATTN: Patent Group	Scott A. Cole (Reg. No. 60.619) scole@cooley.com zpatdcdocketing@cooley.com COOLEY LLP ATTN: Patent Group

1299 Pennsylvania Ave., NW, Suite 700 Washington, DC 20004 Tel: (650) 843-5001 Fax: (650) 849-7400	1299 Pennsylvania Ave., NW, Suite 700 Washington, DC 20004 Tel: (703) 456-8032 Fax: (703) 456-8001

D. Service Information

As identified in the attached Certificate of Service, a copy of the present petition, in its entirety, including all Exhibits and a power of attorney, is being served by Federal Express to the address of the attorney or agent of record for the owner of record of the '592 patent, William Beaumont Hospital. Varian may be served at the lead counsel address provided in Section I.C. Varian consents to electronic service by e-mail at the e-mail addresses provided above, which include both individual e-mail addresses and a general docketing e-mail address.

E. Power of Attorney

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

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

This petition requests review of 13 claims of the '592 patent and is accompanied by a payment of $23,000 for 13 claims. *See* 37 C.F.R. § 42.15(a). This Petition therefore meets the fee requirements under 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)

Petitioner certifies that the '592 patent is eligible for *inter partes* review and that the Petitioner is not barred or otherwise estopped from requesting *inter partes*

review challenging the identified claims on the grounds identified herein. The Petitioner is unaware of any previous petition for *inter partes* review with respect to the '592 patent.

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

Petitioner respectfully requests that the Board initiate *inter partes* review of claims 25-29 and 35-42 of the '592 patent, and find them unpatentable based on the grounds set forth herein. The prior art references upon which the invalidity challenge in this Petition is based are listed below:

Ex. No.	Prior Art Document
1004	D.A. Jaffray and J.W. Wong, *Exploring "Target of the Day" Strategies for a Medical Linear Accelerator With Conebeam-CT Scanning Capability*, PROCEEDINGS OF THE XIITH INTERNATIONAL CONFERENCE ON THE USE OF COMPUTERS IN RADIATION THERAPY, MEDICAL PHYSICS PUBLISHING, pp. 172-75 (May 27-30, 1997) ("Jaffray '97")
1005	U.S. Patent No. 4,459,485 issued to Span ("Span")
1006	U.S. Patent No. 5,262,649 issued to Antonuk *et al.* ("Antonuk")
1007	U.S. Patent No. 3,784,837 issued to Holmström ("Holmström")
1008	PCT International Publication No. WO 91/06876 issued to Lim *et al.* ("Lim")

This Petition cites additional prior art materials for purposes of providing a technology background and describing the state of the art at the time of the alleged

invention, which are provided as Exhibits 1009 to 1020. These materials are also cited and discussed in the accompanying Declaration of Dr. James Balter **[Ex. 1003]** ("Balter Decl."), an expert with more than 20 years of experience in the field of radiation oncology and medical physics. The specific grounds for IPR are identified in the following table:

Ground No.	**Claim(s) Affected**	**Proposed Ground for *Inter Partes* Review**
1	25-28	Obvious over Jaffray '97 and Span (§ 103(a))
2	29	Obvious over Jaffray '97, Span , and Antonuk (§ 103(a))
3	25-28	Obvious over Jaffray '97 and Holmström (§ 103(a))
4	29	Obvious over Jaffray '97, Holmström, and Antonuk (§ 103(a))
5	35, 40-42	Anticipated by Jaffray '97 (§ 102)
6	36-39	Obvious over Jaffray '97 and Lim (§ 103(a))

Each of the references relied upon above qualifies as prior art to the '592 patent under at least 35 U.S.C. § 102(b) (pre-AIA). A specific explanation of each of the grounds listed above is set forth in Part VII below.

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

The Board should institute *inter partes* review of claims 25-29 and 35-42 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 claim challenged herein is disclosed and/or suggested by the prior art, as explained below

in Section VII.

IV. TECHNOLOGY BACKGROUND RELEVANT TO THE '592 PATENT

The '592 patent, entitled "Cone-Beam Computed Tomography With A Flat-Panel Imager," generally relates to systems and methods for providing image guidance to reduce errors in radiation treatment resulting from organ motion. (Ex. 1001 at 5:18-28.) The accompanying declaration of Dr. James Balter describes the state of the art at the time of the alleged invention. (*See* Balter Decl. ¶¶ 15-27.) This section provides an overview of that description.

A. Early History of Radiotherapy

The discovery of x-rays by Wilhelm Röntgen in 1895 ushered in a new era in the fight against cancer. (J. Thariat *et al.*, *Past, present, and future of radiotherapy for the benefit of patients*, NATURE REVIEWS, CLINICAL ONCOLOGY, 10:52-60 (Jan. 2013) **[Ex. 1009]** at 1.) As the 20th century dawned, radiotherapy—the delivery of tumorcidal doses of radiation to a target volume—became commonplace. (*Id*.; Ex. 1001 at 1:36-38.) Early radiotherapy systems were capable of generating energy only in low voltages (kilovolts), making them ineffective against deep-seated tumors. (Ex. 1009 at 1.) By the 1950s, however, alternative sources of higher energy radiation production were discovered, enabling the construction of the first megavoltage linear acceleration x-ray machine and more effective targeting of internal tumors. (*Id*. at 2.)

B. Computer Aided Radiotherapy

As was clear from the earliest days of radiotherapy, although large doses of radiation are effective at killing cancerous cells, they are also effective at killing healthy cells and tissue. Therefore, the goal of radiologists has always been to maximize the desired doses of radiation to the targeted cells while minimizing the doses applied to the surrounding cells and tissue. (Ex. 1009 at 1.)

The advent of computers in the latter half of the twentieth century played a pivotal role in advancing this goal. (*Id*. at 3.) With the advent of computed tomography ("CT") scanning in the 1970s-1980s, 3-dimensional pictures of internal organs could be generated. (*Id*.) This provided a more precise understanding of the boundaries between healthy and unhealthy tissues, providing a much clearer picture to define the targeted area.

C. Image-Guided Radiotherapy

Though CT scanning provided a major breakthrough in the targeting of tumors, uncertainties remained. In particular, CT scanning is typically performed prior to treatment. Thus, at the time of treatment, the precise location of the tumor is not known as a result of inter- and intra-organ movement resulting from even such innocuous motions of the patient as breathing. (L. Xing *et al.*, *Overview of Image-Guided Radiation Therapy*, MEDICAL DOSIMETRY, 31:91-112 (2006) **[Ex. 1010]** at 2-3, 6.) Absent additional information, oncologists were required to

reduce radiation doses and increase radiation sessions (referred to as fractions) to remain within safety margins. (*See id*. at 6.)

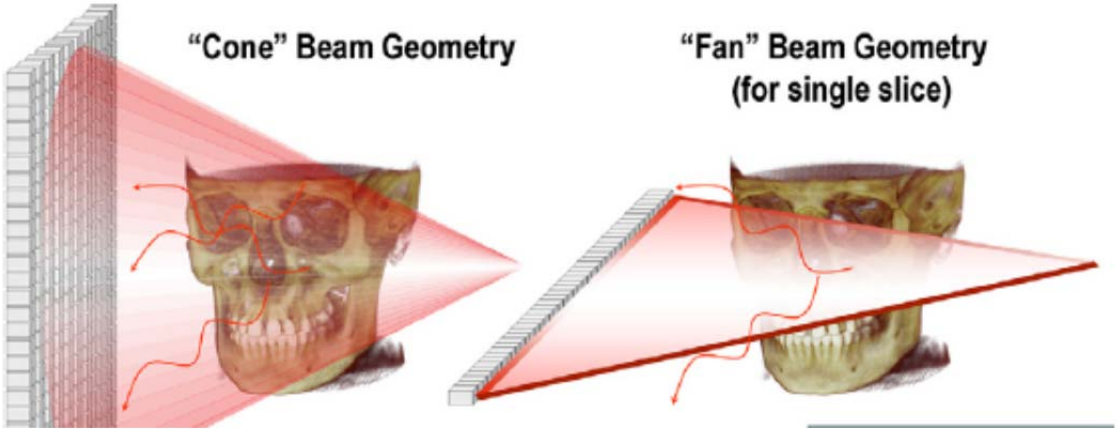
Image-Guided Radiation Therapy ("IGRT") is a term of art that loosely refers to different approaches for addressing these concerns through radiation planning, patient setup, delivery procedures integrating image-based tumor definition methods, patient positioning devices, and radiation delivery guiding tools. (*Id*. at 2-3.) One such approach is to actively monitor the tumor position using an on-board imaging system. (*Id*. at 3, 12.)

D. Cone-Beam Computerized Tomography ("CBCT")

Active monitoring of tumor position, of course, requires frequent scanning. This presents a problem, as conventional CT scans can be lengthy. This is due to the fact that traditional CT scanning utilizes a flat, fan-shaped beam that results in the projection of a one-dimensional slice. Generation of a series of these one-dimensional slice images is repeated through multiple rotations of the beam generator around the target area of a patient to generate a three-dimensional image. (W. Scarfe *et al.*, *What is Cone-Beam CT and How Does it Work?*, DENT. CLIN. N. AM., 52:707-30 (2009) **[Ex. 1011]** at 2.)

However, a much faster image-generation time is achieved through the use of Cone-Beam Computerized Tomography. In contrast to traditional CT scans, CBCT uses a cone shaped beam that results in the projection of a two-dimensional

image that includes a greater amount of information regarding the scanned structures, enabling reconstruction of a three-dimensional image in a single rotation. (*Id*.) The shorter image acquisition time makes CBCT an ideal approach for on-line imaging applications. (*Id*.)



The availability of CBCT for on-line imaging applications was also aided by the advent of amorphous silicon flat panel image detectors. (Ex. 1011 at 3.) Prior to the advent of flat panel imagers, CBCT was typically performed using detectors that employed larger and bulkier image intensifiers that commonly had restricted fields of view for receiving signals from the cone beam, diminishing overall image quality and efficiency. The flat geometry and larger surface area of flat panel detectors provides a greater range of detection with reduced peripheral distortion, increasing the value of CBCT-generated images.

E. The '592 Patent Did Not Advance the Art

The '592 patent generally relates to an imaging system that employs x-rays

detected by an imager on a radiotherapy system. In the embodiments described by the '592 patent, the patient is imaged while in position for treatment with a beam of radiation. (Ex. 1001 at 1:29-34.) As described by the applicants, CBCT (as opposed to other forms of medical imaging such as traditional x-ray or magnetic resonance) is used to obtain three-dimensional patient information which can be used to better guide therapeutic radiation to a target lesion such as a tumor. (*Id.* at 1:36-38; 3:56-4:17.)

The systems claimed in the '592 patent were nothing more than the combination of known elements, with each element performing its well-known function. The applicants' assembly of old elements provided results just as would be expected by one of skill in the art. As described fully herein, it was known in the field of radiotherapy to use diagnostic (kV) x-rays on a radiotherapy gantry to obtain images for real-time control of a radiation source. It was also known to use kV x-rays for cone beam imaging on a linear accelerator gantry because of its superior image quality. Because of the known benefits of CBCT, the known benefits of image-guided radiotherapy, and the express teaching in the prior art to use of flat panel imagers, it was obvious to mount such an imager on a rotating drum support structure because of the known benefits of improved imaging.

In fact, the '592 patent does not claim any inventive elements in assembling these old components. Nor does it disclose the invention of the use of x-ray

images as a means for guiding a radiation source. Instead, the applicants claimed the means of mounting an imager to a support structure, and seek to exclude others from using it. But the claimed mounting techniques have also long been known in the field of diagnostic imaging. The '592 patent does nothing more than assemble known components to achieve an expected result. Thus the assembly was obvious, and the claims of the '592 patent should not have been issued.

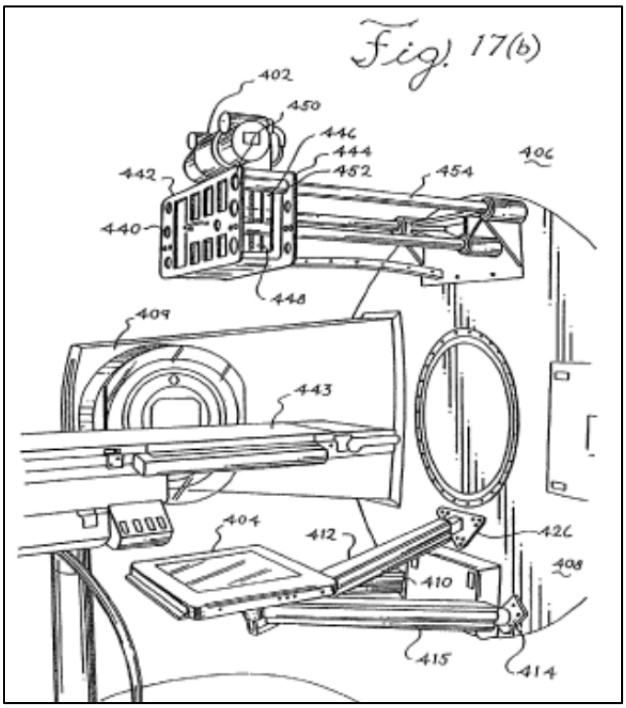
V. SUMMARY OF THE CLAIMED SUBJECT MATTER

A. The Specification of the '592 Patent

The radiation therapy and x-ray imaging techniques and components described in Section IV above were known to persons of ordinary skill in the art well in advance of the earliest possible priority date listed on the face of the '592 patent. Although the '592 patent specification expends considerable space detailing the operation, benefits, and difficulties associated with the use of cone beam computerized tomography in radiation therapy, as well as the roles of radiation sources, x-ray sources, and amorphous silicon flat-panel imagers in that technique, it ultimately acknowledges that the technique and its constituent components were already known in the art. (*See* Ex. 1001 at 3:38-41 ("Another example of a known on-line imaging system . . . is an X-ray cone-beam computerized tomography system."), 4:31-39 ("Another example of a known auxiliary cone beam computerized tomography imaging system is shown in FIG. 2.

. . . [T]he imaging system 200 consists of a kilovoltage x-ray tube 202 and a flat panel imager 204 having an array of amorphous silicon detectors . . . ."), 3:22-29 (indicating that "typical radiation therapy" involves "irradiation of a lesion 112 located within a target volume with a radiation beam 114 . . . .").)

The remainder of the specification describes various embodiments addressing the configuration and mounting techniques for these known components. One such embodiment is depicted in Figure 17(b), which is reproduced below.

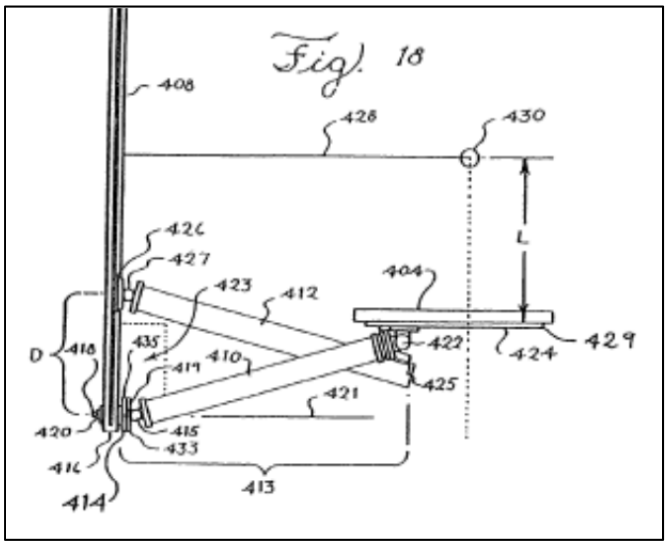


Ex. 1001, '592 Patent: Figure 17(b)

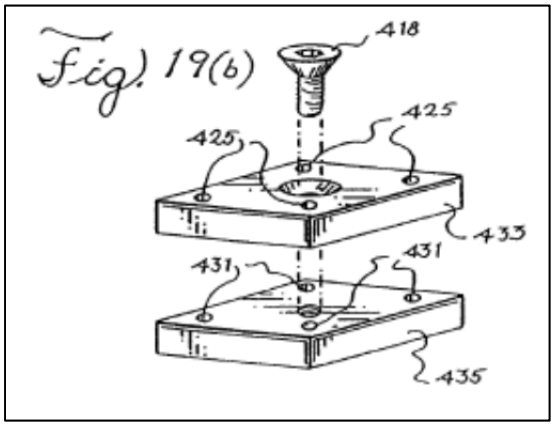
Figure 17(b) depicts "a wall-mounted cone beam computerized tomography system 400." (Ex. 1001 at 19:53-55.) It consists of an imaging system that includes x-ray source 402 and flat-panel imager 404 constructed from an array of

amorphous silicon detectors. (*Id*. at 19:56-62.) The x-ray source 402 and flat-panel imager 404 may be mounted opposite one another on a rotating drum 408 using a support structure. (*Id*. at 20:11-33, 21:17-31.)

The imager support structure described in the specification includes standard hardware, such as arms, pivots, plates, bolts, and nuts. Specifically, the imager is mounted to the drum using a tripod structure constructed of three arms (410, 412, and 415). (*Id*. at 20:17-19.) The specification explains that side arms 410 and 415 "have ends attached to a Ax95 Guy pivot 417 which in turn is attached to a mounting 414 by screws that are threaded through aligned threaded holes of the pivot 417 and threaded holes 425 and 431 of plates 433 and 435, respectively . . . ." (*Id*. at 20:19-25; *see* Figs. 18 and 19(b) (reproduced below).) The specification further explains that "[e]ach mounting 414 is attached to an end portion 416 of the drum 408 by inserting a threaded male member 418 through an opening 437 formed through the drum 408. Once inserted, the male member 418 is attached to the drum 408 by tightening a nut 420 onto the threaded male member 418." (*Id*. at 20:34-39.)



Ex. 1001, Figure 18



Ex. 1001, Figure 19(b)

Further, "[t]he other ends of the arms 410 and 415 are attached to Ax95 Guy pivots 422 attached to the back of an 3/8 inch thick Aluminum square plate 424 is attached [sic] to the rear of the flat-panel imager 404 via bolts . . . ." (*Id*. at 20:39-43.) The specification indicates that the center arm 412 is connected to the drum and flat-panel imager in much the same way except that it "has one end attached to Ax95 Guy pivot 427 that is in turn attached to a tapped, triangular-shaped, reinforcing plate 426 formed on the drum 408 . . . ." (*Id*. at 20:54-58.)

The specification explains that the imaging system may be retrofitted to a new or existing radiation therapy system consisting of a radiation therapy source, such as linear source 409. (*Id*. at 19:63-67.) The linear source 409 is also mounted to the rotating drum 408, such that the imaging system is orthogonal to the treatment beam created by the linear source. (*Id*. at 20:11-16.)

In this configuration, a patient may be interposed between the x-ray source

and the imager, for example, on treatment table 443. (*Id*. at 25:11-14.) The x-ray source will emit an energy beam that passes through the patient, the intensity of the x-rays emerging from the patient are detected by the imager, and the collected intensity data is used to form a projection of the targeted area. (*Id*. at 19:67-20:10.)

B. Summary of the Relevant Prosecution History

During prosecution, claims 25-28 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,157,707 to Ohlson.[1] (Ex. 1002 at 36-37.[2]) Claim 29 was also rejected under 35 U.S.C. § 103(a) as obvious over Ohlson in view of U.S. Patent No. 5,877,501 to Ivan. (*Id.* at 38.) In response, the patent owner amended claim 25, rewriting it in independent form and adding limitations "to clarify that the imaging system has a rotating drum and the x-ray source is attached to the rotating drum." (Ex. 1002 at 60, 52.) In support of patentability, the patent owner argued that prior art of record did "not disclose an x-ray source attached to a rotating drum." (Ex. 1002 at 60.) Claims 26-29 were also amended to depend

[1] Claims 25-28 were prosecuted as claims 51-54 before renumbering after the claims were allowed. Claim 29 was similarly prosecuted as claim 55.

[2] Exhibit 1002 includes excerpts of the file history of the '592 patent. Consecutive pagination has been added for clarity. Citations to Exhibit 1002 in this Petition refer to these added page numbers rather than the page numbers of the original documents.

from claim 25 and the patent owner justified their patentability on the same reasoning. (*Id*. at 60-62.)

Although the Examiner subsequently allowed claims 25-29, the basis for the allowance did not coincide with the patent owner's justification. Instead, the Examiner concluded that the prior art:

> [D]iscloses an imaging system that comprises: a rotating drum (102); an x-ray source (105) that emits x-rays toward an object, wherein the x-ray source is attached to the rotating drum; an imager (106) that receives x-rays from the object based on the emitted x-rays and forms an image of the object; and an imager support system that attaches the imager to the rotating drum. However, the prior art fails to disclose or fairly suggest a pivot arm that has one end pivotably attached to the rotating drum and another end pivotably attached to the imager.

(Ex. 1002 at 71.) Thus, the sole distinction of claims 25-29 over the prior art considered by the Examiner involved the manner of attaching the imager to the rotating drum using a pivot arm.

Claims 35-42 were provided as part of the original prosecution.[3] As with claims 25-29, however, the Examiner found only a single limitation not present in the prior art:

[T]he prior art (U.S. Patent No. 6,285,739 B1) discloses a method that

[3] Claims 35-42 were prosecuted as claims 81-88 before renumbering after the claims were allowed.

> comprises providing an existing radiation therapy system that comprises a radiation source (20) that is supported on a support structure; and attaching an imager (30) that does not directly face the radiation source (Figs. 1B and 1E). However, the prior art fails to disclose or fairly suggest a method that comprises attaching an imager that does not directly face the radiation source to the support structure as claimed.

(Ex. 1002 at 39.) In other words, the sole distinguishing basis of claims 35-42, in the eyes of the Examiner, was that the prior art reviewed lacked attachment of the imager to the support structure.

C. The Claims of the '592 Patent

Independent claim 25 recites an imaging system. Claim 25 recites in full:

> 25. An imaging system comprising:
> **[a]** a rotating drum;
> **[b]** an x-ray source that emits x-rays towards an object, wherein said x-ray source is attached to said rotating drum;
> **[c]** an imager that receives x-rays from said object based on said emitted x-rays and forms an image of said object;
> **[d]** an imager support system that attaches said imager to said rotating drum, wherein said imager support system comprises: a pivoting arm that has one end pivotably attached to said rotating drum and another end pivotably attached to said imager.

(Ex. 1001 at 29:34-45 (claim 25) (bracketed notations (e.g., "[a]," "[b]," etc.) added to facilitate easier identification of the specific claim limitations in this

Petition).) Claims 26-29 depend from claim 25 and add nothing of patentable significance, as shown in Part VII below.

The other independent claim addressed in this Petition, claim 35, recites a method of adding an auxiliary imaging system to an existing radiation therapy system. Claim 35 recites in full:

> 35. A method of adding an auxiliary imaging system to an existing radiation therapy system, said method comprising:
>
> **[a]** providing an existing radiation therapy system that comprises a radiation source that is supported on a support structure; and
>
> **[b]** attaching an imager that does not directly face said radiation source to said support structure.

Claims 36-42 depend from claim 35 and add nothing of patentable significance, as shown in Part VII below.

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

A claim subject to *inter partes* review must be given its "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). As the Federal Circuit has recognized, the "broadest reasonable" construction standard is different from the manner in which the scope of a claim is determined in litigation.[4] *See In re Swanson*, 540 F.3d 1368, 1377-78

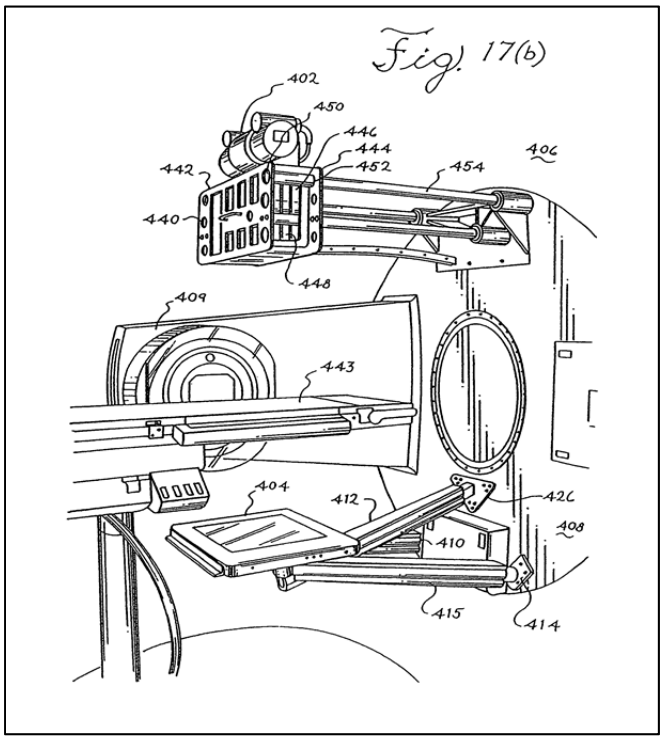
[4] Petitioner's proposed constructions in Section VI are based on the broadest reasonable construction in light of the specification. *See* 37 C.F.R. § 42.100(b);

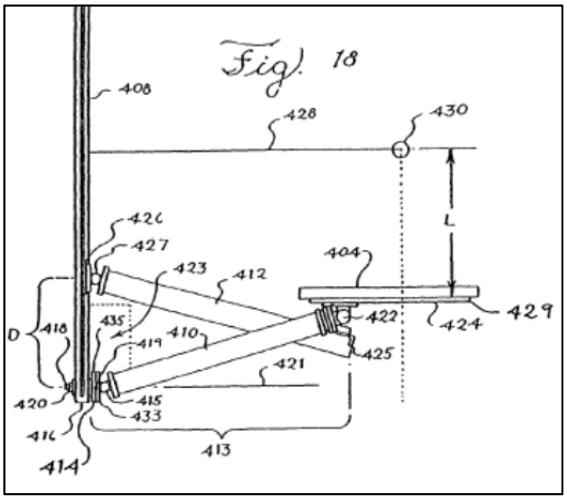
(Fed. Cir. 2008). Petitioner accordingly requests that the Board adopt the broadest reasonable construction of each challenged claim. For claim terms not addressed below, Petitioner has applied the plain and ordinary meaning of those terms.

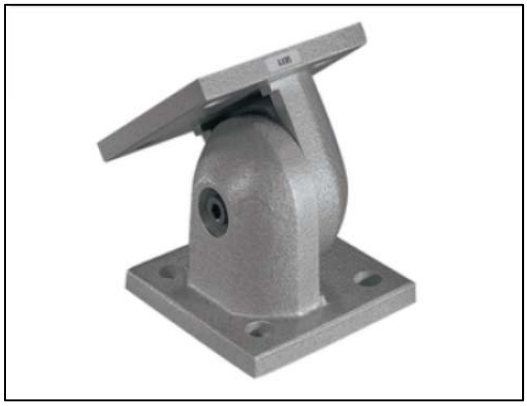
A. "Pivotably Attached"

The term "pivotably attached" is recited in independent claim 25 to describe the manner of attaching ends of a pivoting arm to a rotating drum and an imager. With respect to the attachment of the pivoting arm to the imager, the '592 specification explains that "arms 410 and 415 are attached to Ax95 Guy pivots 422 attached to the back of an 3/8 inch thick Aluminum square plate 424 [which] is attached to the rear of the flat-panel imager 404 via bolts (not shown)." (Ex. 1001 at 20:39-43; Figs. 17(b) and 18 (reproduced below).)

M.P.E.P. § 2111. Petitioner reserves the right to seek different constructions for terms of the '592 patent claims, as appropriate, in district court litigation. *See In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).







Ex. 1012, Figure 1

Accordingly, under the broadest reasonable construction, one of ordinary skill in the art would understand "pivotably attached" to mean "connected in such a way as to enable relative rotation between the connected objects."

VII. CLAIMS 25-29 AND 35-42 OF THE '529 PATENT ARE UNPATENTABLE

A. Ground 1: Claims 25-28 Are Obvious over Jaffray '97 in view of Span

Ground 1 combines a 1997 Proceedings of the XIIth International Conference on the Use of Computers in Radiation Therapy publication by D.A.

Jaffray *et al.*, entitled, "Exploring 'Target of the Day' Strategies for a Medical Linear Accelerator With Conebeam-CT Scanning Capability" **[Ex. 1004]** ("Jaffray '97") with U.S. Patent No. 4,459,485 to Francis Span **[Ex. 1005]** ("Span"). Jaffray '97 qualifies as prior art under at least 35 U.S.C. § 102(b) (pre-AIA) because it was published no later than May 30, 1997, more than a year before the earliest possible priority date listed on the face of the '592 patent. Span qualifies as prior art to the '592 patent under at least 35 U.S.C. § 102(b) (pre-AIA) because it was patented on July 10, 1984, more than one year before the earliest possible priority date listed on the face of the '592 patent.

Jaffray '97 [Ex. 1004]: Jaffray '97 discloses an investigation and results of integrating an on-line cone-beam x-ray imaging system with a medical linear accelerator for the purpose of locating "the clinical target and surrounding normal structures on a fraction-by-fraction basis." (Ex. 1004 at 4.) The system consists of a Philips SL-20 medical linear accelerator comprising a Megavoltage x-ray treatment source and an imaging device. (*Id*. at 4-5, Fig. 1.) Supplementing this treatment system is a kilovoltage x-ray source capable of cone-beam computerized tomography and a second imager mounted opposite the kilovoltage source, the combination mounted orthogonally to the beam path of the MV source. (*Id*.)

Span [Ex. 1005]: Span discloses a suspension system for diagnostic equipment, such as a paired x-ray source and detector or gamma camera. (Ex.

1005 at 2:29-34, 4:3-14.) The specification explains that, due to the claimed suspension system, equipment "can be very easily moved by rotation of the arm 14 about the pivot 24 . . . ." (*Id*. at 2:59-63 (emphasis added).) The specification addresses this need, in part, by pivotably attaching a detector to a support arm, which in turn is pivotably attached to a rotating supporting ring. (*Id*. at 2:45-3:6.)

Ground 1 relies on Jaffray '97 for the majority of the claim limitations in independent claim 25, and all limitations in dependent claims 26-28, but cites Span for certain aspects of one claim element in independent claim 25 relating to the imager support system. Jaffray '97 and Span render claims 25-28 obvious as explained below. A specific description of the motivation for combining Jaffray '97 and Span is provided below in connection with the claim limitations in which Span is cited.

1. Jaffray '97 and Span Render Claim 25 Obvious

The preamble of claim 25 recites "[a]n imaging system." Although the preamble may not be a claim limitation, under the broadest reasonable construction, Jaffray '97 discloses it. Jaffray '97 discloses that "[t]wo fluoroscopic imaging systems are attached to a Philips SL-20 medical linear accelerator; one detects the megavoltage image, the other a kV image produced with a kV beam projected at 90° to the treatment beam axis." (Ex. 1004 at 4-5, Fig. 1.) Accordingly, Jaffray '97 teaches an imaging system.

a. Claim 25[a]: "a rotating drum"

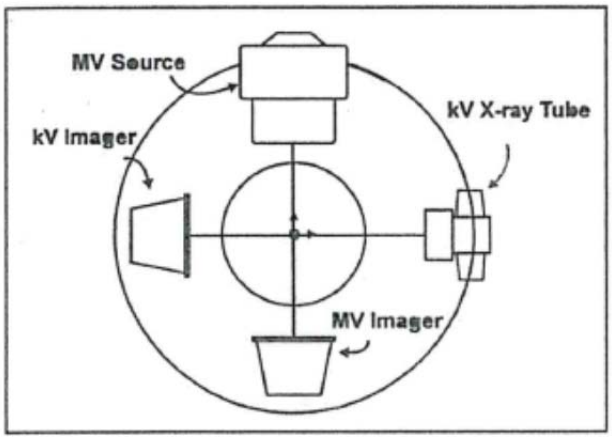
The first limitation of claim 25 following the preamble recites "a rotating drum." Jaffray '97 discloses this limitation. Specifically, Jaffray '97 teaches that "[t]wo fluoroscopic imaging systems are attached to a Philips SL-20 medical linear accelerator." (Ex. 1004 at 4.) One of ordinary skill in the art would understand that the Philips SL-20 medical linear accelerator includes a rotating drum.[5] (Balter Decl. ¶ 60.) Jaffray '97 adds: "[t]he gantry is **rotated** continuously at approximately 4°/sec . . . ." (Ex. 1004 at 5 (emphasis added).) Moreover, the rotating drum is clearly depicted in Figure 1. (*Id*. at Fig. 1; Balter Decl. ¶ 61.) Thus, Jaffray '97 teaches the claimed rotating drum. (Balter Decl. ¶¶ 60-62.)

b. Claim 25[b]: "an x-ray source that emits x-rays towards an object, wherein said x-ray source is attached to said rotating drum"

Claim 25[b] next recites "an x-ray source that emits x-rays towards an object, wherein said x-ray source is attached to said rotating drum." Jaffray '97 discloses an x-ray source attached to a rotating drum. In particular, Jaffray '97 teaches: "a 600,000 HU [heating unit] x-ray tube mounted on a retractable arm." (Ex. 1004 at 4 (emphasis added).) Jaffray '97 further explains that this system is

[5] Indeed, a subsequent publication by Jaffray employing the same SL-20 medical linear accelerator explicitly notes that "[t]he SL-20 is a drum-based accelerator" which is "rotated through 360°." (Ex. 1013 at 2, 4.)

"for integration with a medical linear accelerator." (*Id.*) Jaffray '97 further warns that "[c]areful mapping of the motion of each component with gantry angle must be performed before the patient's anatomy can be accurately localized in the treatment reference frame[,]" indicating to the skilled artisan that the x-ray tubes move when the drum rotates. (*Id*. at 5; Balter Decl. ¶ 63.) In combination with the depiction of Figure 1, one of ordinary skill would understand that the integrated x-ray source is attached to the rotating drum. (Balter Decl. ¶ 63.)



Ex. 1004, Jaffray '97 Figure 1

Moreover, as one of ordinary skill would understand, such an x-ray imaging system operates by the x-ray source emitting x-rays toward an object, with the imager receiving the residual x-rays thereafter. (Balter Decl. ¶ 64.) Indeed, Jaffray '97 confirms this understanding in the context of prostate imaging, noting that "[a]t a fixed angular increment, the x-ray generator delivers a short 30 ms exposure (100mA). The total dose required to locate the prostate-fat boundary is estimated

to be ~4 cGy for a 5mm slice thickness." (Ex. 1004 at 5.) Accordingly, Jaffray '97 teaches this claim limitation as well. (Balter Decl. ¶¶ 63-65.)

c. Claim 25[c]: "an imager that receives x-rays from said object based on said emitted x-rays and forms an image of said object"

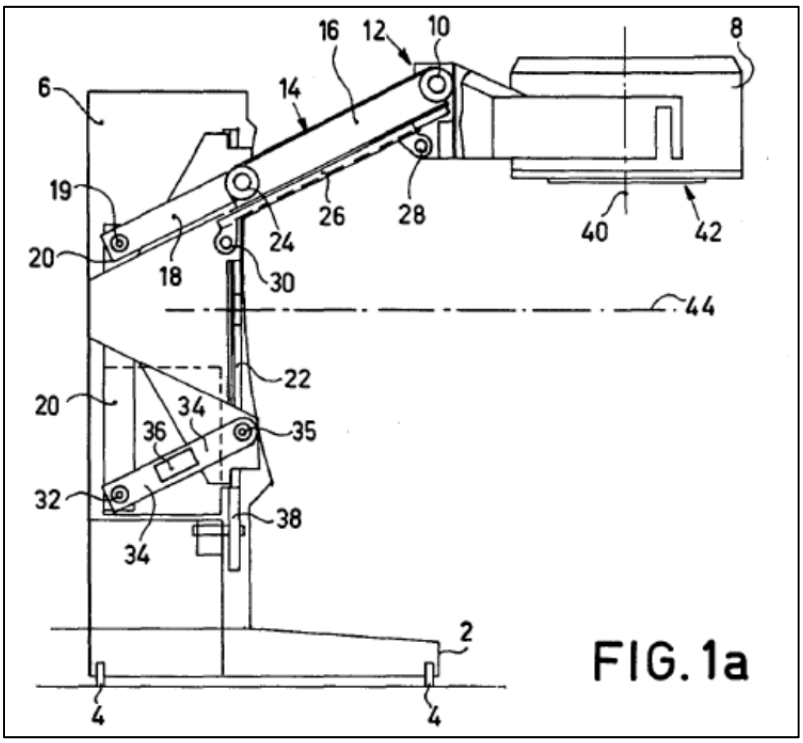
Claim 25[c] requires "an imager that receives x-rays from said object based on said emitted x-rays and forms an image of said object." Jaffray '97 also discloses this limitation. (Balter Decl. ¶¶ 66-68.) In particular, Figure 1 of Jaffray '97 shows that the imager receives x-rays based on the energy emitted by the x-ray source. (Ex. 1004 at Fig. 1 (reproduced above).) Further, Jaffray '97 teaches that the image formed is that of a particular object: "[a] fundamental requirement of the imaging system is the visualization of the target and surrounding normal structures." (*Id*. at 5.)

d. Claim 25[d]: "an imager support system that attaches said imager to said rotating drum, wherein said imager support system comprises: a pivoting arm that has one end pivotably attached to said rotating drum and another end pivotably attached to said imager"

Claim 25[d] recites "an imager support system that attaches said imager to said rotating drum, wherein said imager support system comprises: a pivoting arm that has one end pivotably attached to said rotating drum and another end pivotably attached to said imager." Jaffray '97 teaches mounting the imaging system on the rotating drum. (Ex. 1004 at 5; Balter Decl. ¶ 69.) Jaffray '97 further indicates that

"the heavy clinical load carried on the medical linear accelerators would require the imaging system be well integrated with the accelerator." (*Id*. at 6.) However, Jaffray '97 does not disclose any details of the imager support system that would achieve such integration.

Span teaches an imager support system:



Ex. 1005, Span Figure 1(a)

As described in one embodiment, Span discloses: "a suspension system for a gamma camera 8." (Ex. 1005 at 2:29-34, Fig. 1(a).) Span also teaches a rotating drum in the form of rotating ring 22, which "bears rotatably on, for example, two guide wheels 38 connected to the housing." (*Id*. at 2:55-3:2; Fig. 1(b).) This support system of Span attaches the imager (in one embodiment, a gamma camera

8) to the rotating ring 22: "Supporting device 12 comprises a first arm 14 which consists of two sections. A first arm section 16 of the arm 14 extends outside of the housing 6 and supports the gamma camera 8 via the pivot 10. . . . A pivot 24 which is mounted on a supporting ring 22 interconnects the two sections of arm 14." (Ex. 1005 at 2:35-44 (emphasis added), Fig. 1(a); Balter Decl. ¶ 70.)

This passage also demonstrates that Span discloses a pivoting arm that has one end pivotably attached to the rotating drum and another end pivotably attached to the imager. Specifically, Span teaches that: "arm section 16 of the arm 14 extends outside of the housing 6 and supports the gamma camera 8 via the pivot 10." (Ex. 1005 at 2:35-44 (emphasis added); Fig. 1(a).) On the other end of arm section 16, the specification indicates, "[a] pivot 24 which is mounted on a supporting ring 22 interconnects the two sections [arm section 16 and arm section 18] of arm 14." (Ex. 1005 at 2:35-44 (emphasis added).) Thus, arm section 16 is attached to both the camera [i.e., imager] and the supporting ring (i.e., rotating drum) through pivoting connections. (Balter Decl. ¶ 71.)

Although the imaging device highlighted in the primary embodiment described in Span is a gamma camera (*id*. at 2:29-34), Span explicitly states that the support structure disclosed is applicable to "a source and a detector, for example, X-ray image intensifier tube [that] have to be moved in a fixed mutual relationship with respect to the patient, such as in X-ray equipment . . . ." (*Id*. at

4:3-7.) Indeed, the '592 patent itself recognizes that "[c]one-beam computed tomography has been a topic of active research and development for over a decade in areas such as nuclear medicine . . . ." (Ex. 1001 at 19:33-37; *see* Balter Decl. ¶¶ 72-73 (noting that it is common to use gamma cameras in nuclear medical imaging).)

Motivation to Combine Jaffray '97 and Span

One of ordinary skill in the art would have been motivated to combine the imaging support structure of Span with the x-ray tomography system of Jaffray '97. In both settings, heavy diagnostic equipment is commonly mounted on a gantry to facilitate movement of the equipment and therefore both settings present similar mounting difficulties. (Balter Decl. ¶ 73.) Although Jaffray '97 teaches mounting one or more detectors to the drum, it does not teach an imager support system pivotably mounted to the drum or the imager. (Ex. 1004 at Fig. 1.) However, Jaffray '97 does suggest that "important characteristics [of the imaging system] include . . . (iii) flexibility of use . . . and, (v) convenience." (*Id*. at 5.) Span addresses this flexibility and convenience, explaining that, with the disclosed support structure, equipment "can be very easily moved by rotation of the arm 14 about the pivot 24 . . . ." (Ex. 1005 at 2:59-63.) Thus, it would have been obvious to the skilled artisan to apply the known mounting technique of Span to the known x-ray source and imaging techniques of Jaffray '97 with no change in their

respective functions and with a reasonable expectation of success. (Balter Decl. ¶¶ 74-75.)

2. Claim 26: "[t]he imaging system of claim 25, wherein said x-ray source translates in a direction that is parallel to an axis of rotation of said drum"

Claim 26 depends from claim 25 and further requires "[t]he imaging system of claim 25, wherein said x-ray source translates in a direction that is parallel to an axis of rotation of said drum." Jaffray '97 discloses this limitation, identifying an "x-ray tube mounted on a retractable arm." (Ex. 1004 at 4.) Because the x-ray tube is mounted on the face of the drum, as shown in Figure 1, one of ordinary skill in the art would understand that the retraction of the x-ray source into the drum would be parallel to the axis of rotation of the drum about its center. (Balter Decl. ¶¶ 76-77.)

3. Claim 27: "[t]he imaging system of claim 25, further comprising a radiation source attached to said rotating drum"

Claim 27 depends from claim 25 and further specifies "[t]he imaging system of claim 25, further comprising a radiation source attached to said rotating drum." Jaffray '97 discloses this limitation. Specifically, Jaffray '97 teaches that "[t]wo fluoroscopic imaging systems are attached to a Philips SL-20 medical linear accelerator; one detects the megavoltage image, the other a kV image produced with a kV beam projected at 90° to the treatment beam axis." (Ex. 1004 at 4

(emphasis added).) Figure 1 also depicts a radiation source (i.e., "MV Source") attached to the circular drum. (*Id*. at Fig. 1; Balter Decl. ¶ 78.) Accordingly, Jaffray '97 previously disclosed this claim limitation. (Balter Decl. ¶¶ 78-79.)

4. Claim 28: "[t]he imaging system-of claim 25, wherein said x-rays emitted from said x-ray source are emitted in a cone beam form"

Claim 28 depends from claim 25 and further claims "[t]he imaging system-of claim 25, wherein said x-rays emitted from said x-ray source are emitted in a cone beam form." Jaffray '97 discloses this limitation. Specifically, Jaffray '97 teaches that "[i]n 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." (Ex. 1004 at 4.) In the context of discussing the kV system (and thus the kV x-ray source rather than the MV radiation source), Jaffray '97 further explains that "[t]he conebeam imaging sequence consists of ~100 exposures over 194° of rotation." (*Id*. at 5.) Accordingly, Jaffray '97 previously disclosed this claim limitation. (Balter Decl. ¶¶ 80-81.)

B. Ground 2: Claim 29 Is Obvious Over Jaffray '97 in View of Span Further in View of Antonuk

Ground 2 combines Jaffray '97 with Span and U.S. Patent No. 5,262,649 to Antonuk [Ex. 1006] ("Antonuk"). Jaffray '97 and Span qualify as prior art for the reasons set forth above in Section VII.A. Antonuk qualifies as prior art to the '592 patent under at least 35 U.S.C. § 102(b) (pre-AIA) because it issued on November

16, 1993, more than a year before the earliest possible priority date identified on the face of the '592 patent.

Antonuk [Exhibit 1006]: Antonuk discloses an amorphous silicon flat-panel imager for use in diagnostic imaging. (Ex. 1006 at Abstract, 9:13-36.) Antonuk explains that some of the advantages of the disclosed imager over existing diagnostic fluoroscopic imaging systems utilizing an intensifier tube include a reduction in size, overcoming a common hindrance to certain clinical procedures, and improved image quality. (*Id*. at 4:31-55, 6:23-32.)

Claim 29: "[t]he imaging system of claim 25, wherein said imager comprises an amorphous silicon flat-panel imager"

Claim 29 depends from claim 25 and further requires "[t]he imaging system of claim 25, wherein said imager comprises an amorphous silicon flat-panel imager." Jaffray '97 discloses an imager in the form of a phosphor screen that emits light which is focused on a charge coupled device ("CCD"). (Ex. 1004 at 4.) However, it does not disclose an amorphous silicon flat-panel imager.

Antonuk does disclose an amorphous silicon flat-panel imager. In particular, Antonuk teaches "[a] thin-film, flat-panel, pixelated detector array serving as a real-time digital imager and dosimeter for diagnostic or megavoltage X rays or gamma rays, including a plurality of photodiodes made of hydrogenated amorphous silicon arrayed in columns and rows upon a glass substrate." (Ex. 1006 at Abstract.) Thus, Antonuk discloses this claim limitation. (Balter Decl. ¶ 84.)

Motivation to Combine Jaffray '97, Span, and Antonuk

One of ordinary skill in the art would have been motivated to combine the amorphous silicon flat-panel imager of Antonuk with the drum-mounted x-ray tomography system of Jaffray '97. Both references address the use of medical diagnostic imaging on a rotating support structure. (Balter Decl. ¶ 85.) Indeed, Antonuk explains that the disclosed amorphous silicon flat-panel imager "[i]n the case of diagnostic x-ray imaging, as in localization imaging, the goal is to produce a high quality image with a minimum of radiation. The present invention allows images to be produced in real-time both for fluoroscopic and radiographic modes of operation whether the radiation is megavoltage or diagnostic x-ray." (Ex. 1006 at 18:31-36.) Although Jaffray '97 teaches the use of a phosphor screen with a CCD, it emphasized that important characteristics of the imaging system included "flexibility of use" and "convenience." (Ex. 1004 at 5.) Moreover, Jaffray '97 explains that "[t]he flexibility to image any treatment site will depend upon: imager field-of-view (FOV), and collision of the imaging system with other structures . . . ." (*Id*. at 6.)

Antonuk directly addresses these concerns. In fact, Antonuk also recognizes that imagers employing a CCD for fluoroscopic imaging "are relatively bulky" and notes that "[t]his is a definite hindrance in various clinical procedures." (Ex. 1006 at 4:31-52.) The amorphous silicon flat-panel imager of Antonuk is "far more

compact than an image-intensifier fluoroscopic unit" and thus overcomes this problem. (*Id*. at 6:23-27.) Accordingly, one of ordinary skill in the art would have been motivated to replace the bulky phosphor screen and CCD of Jaffray '97 with the more compact amorphous flat-panel imager of Antonuk with no change in their respective functions and with a reasonable expectation of success. (Balter Decl. ¶¶ 83-95.)

C. Ground 3: Claims 25-28 Are Obvious over Jaffray '97 in view of Holmström

Claim 25 is an independent claim from which claims 26-28 depend. Ground 3 combines Jaffray '97 and U.S. Patent No. 3,784,837 to Holmström **[Ex. 1007]** ("Holmström"). Jaffray '97 qualifies as prior art for the reasons previously explained in Section VII.A. Holmström qualifies as prior art to the '592 patent under at least 35 U.S.C. § 102(b) (pre-AIA) because it issued on January 8, 1974, well over one year before the earliest possible priority date listed on the face of the '592 patent.

Holmström [Ex. 1007]: Holmström discloses an x-ray device having a rotating bracket supporting an x-ray tube and corresponding x-ray amplifier. (Ex. 1007 at Abstract; 2:30-44; Fig. 1 (reproduced below).) Further, the x-ray tube and x-ray amplifier of Holmström are attached to the bracket by pivoting carrying arms in order to provide "the greatest possible freedom in the selection of the direction of illumination." (*Id*. at Fig. 1; 1:8-11.)

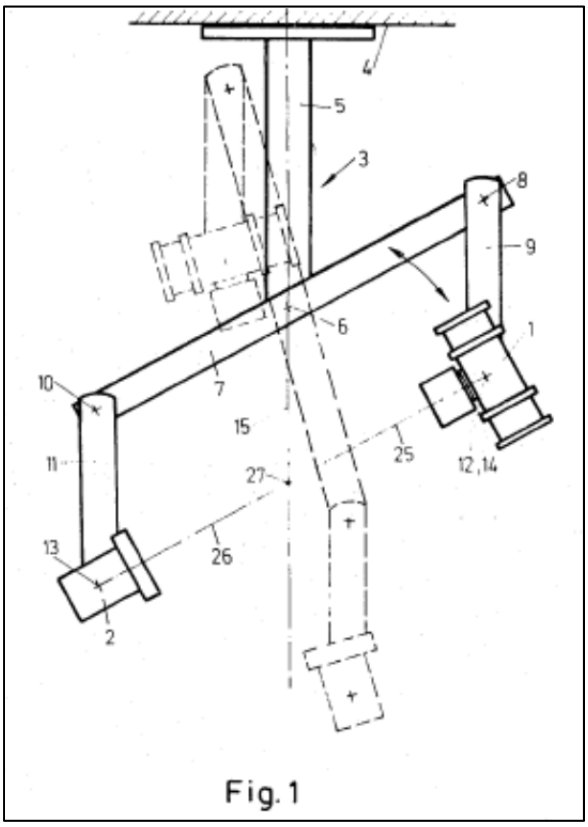


Fig. 1

Ground 3 relies on Jaffray '97 for the majority of the claim limitations in independent claim 25, and all elements of dependent claims 26 - 28, but cites Holmström for certain aspects of one claim element in independent claim 25 relating to the imager support system. Jaffray '97 and Holmström render claims 25-28 obvious as explained below. A specific description of the motivation for combining Jaffray '97 and Holmström is provided below in connection with the claim limitations in which Holmström is cited.

1. Jaffray '97 and Holmström Render Claim 25 Obvious

The preamble of claim 25 recites "[a]n imaging system." Although the preamble may not be a claim limitation, under the broadest reasonable

construction, Jaffray '97 discloses it. Jaffray '97 discloses this limitation for the reasons set forth above in Section VII.A.1, which is incorporated here by reference.

a. Claim 25[a]: "a rotating drum"

The first limitation of claim 25 following the preamble recites "a rotating drum." Jaffray '97 discloses this limitation for the reasons set forth above in Section VII.A.1.a, which is incorporated here by reference.

b. Claim 25[b]: "an x-ray source that emits x-rays towards an object, wherein said x-ray source is attached to said rotating drum"

Claim 25[b] next recites "an x-ray source that emits x-rays towards an object, wherein said x-ray source is attached to said rotating drum." Jaffray '97 discloses this limitation for the reasons set forth above in Section VII.A.1.b, which is incorporated here by reference.

c. Claim 25[c]: "an imager that receives x-rays from said object based on said emitted x-rays and forms an image of said object"

Claim 25[c] requires "an imager that receives x-rays from said object based on said emitted x-rays and forms an image of said object." Jaffray '97 also discloses this limitation for the reasons set forth above in Section VII.A.1.c, which is incorporated here by reference.

d. Claim 25[d]: "an imager support system that attaches said imager to said rotating drum, wherein said imager support system comprises: a pivoting arm that has one end pivotably attached to said rotating drum and another end pivotably attached to said imager."

Claim 25[d] recites "an imager support system that attaches said imager to said rotating drum, wherein said imager support system comprises: a pivoting arm that has one end pivotably attached to said rotating drum and another end pivotably attached to said imager." Jaffray '97 teaches mounting the imaging system on the rotating drum. (Ex. 1004 at 4; Balter Decl. ¶ 99.) Jaffray '97 further indicates that "the heavy clinical load carried on the medical linear accelerators would require that the imaging system be well integrated with the accelerator." (*Id*. at 6.) However, Jaffray '97 does not disclose any details of the imager support system that would achieve such integration.

Holmström teaches an imager support system. (Balter Decl. ¶ 100.) In particular Holmström describes "a carrying arm 11 for the X-ray image amplifier 2 which is located at the other end of the bracket 7 and is swingable about a horizontal axle 10 also extending parallel to the axle 6. The X-ray tube and the X-ray image amplifier are swingable about horizontal axles 12 and 13, respectively, which are also parallel to the axle 6." (Ex. 1007 at 2:30-44; Fig. 1 (reproduced above in § VII.C).) Holmström further explains that "X-ray image amplifier 2 can be replaced by any other image carrier adapted to receive slides, roll films and/or a

screen and fixed to the carrying arm 11." (*Id*. at 3:47-49.)

Thus, one of ordinary skill would understand that image amplifier 2 of Holmström satisfies the imager limitation of claim 25[d][6] and that the carrying arm 11 satisfies the imager support system limitation of claim 25[d]. (Balter Decl. ¶ 101.) The skilled artisan would also recognize that, because carrying arm 11 can rotate with respect to bracket 7 around horizontal axle 10, the carrying arm 11 is pivotably attached to one end of that supporting bracket. (*Id*.) Similarly, the skilled artisan would understand that, because image amplifier 2 can rotate with respect to carrying arm 11 around horizontal axis 13, the image amplifier 2 is pivotably attached to the other end of carrying arm 11. (*Id*.) Accordingly, Jaffray '97 in view of Holmström discloses all the elements of claim 25[d]. (*Id*.)

[6] The term "imager" appears in claims 25, 29, and 35-36. No particular type of imager is specified in claims 25 and 35-36. However, the imager described in claim 29 derives antecedent basis from the imager of claim 25 and further requires that "said imager comprises an amorphous silicon flat-panel imager." Thus, the doctrine of claim differentiation creates the presumption that the imager of claim 25 is not limited to an amorphous silicon flat-panel imager, since claim 29 would be rendered superfluous otherwise. *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998).

Motivation to Combine Jaffray '97 and Holmström

One of ordinary skill in the art would have been motivated to combine the imaging support structure of Holmström with the drum-mounted x-ray tomography system of Jaffray '97. Both references address the use of medical diagnostic imaging on a rotating support structure. (Balter Decl. ¶ 102.) Indeed, Holmström explains that the disclosed invention "is equally suitable for use in X-ray therapy and X-ray diagnosis." (Ex. 1007 at 1:35-37.) Although Jaffray '97 teaches mounting one or more detectors to a drum, it does not teach an imager support system pivotably mounted to the drum or the imager. (Ex. 1004 at 4-5, Fig. 1.) However, Jaffray '97 does suggest that "important characteristics [of the imaging system] include . . . (iii) flexibility of use . . . and, (v) convenience." (*Id*. at 5.) Holmström addresses this concern, explaining that "in X-ray therapy it is sometimes necessary to be able to move the ray source as freely as possible around the patient." (Ex. 1007 at 1:6-8; Balter Decl. ¶ 102.) Moreover, one of ordinary skill in the art would have recognized that bracket 7 in Holmström, which itself rotates, serves the same function as the rotating drum of Jaffray '97. (Balter Decl. ¶ 102.) As such, it would have been obvious to a skilled artisan to incorporate the pivotably mounted imager and support system of Holmström to the known x-ray source and imaging techniques of Jaffray '97 with no change in their respective functions and with a reasonable expectation of success. (Balter Decl. ¶¶ 102-103.)

2. Claim 26: "[t]he imaging system of claim 25, wherein said x-ray source translates in a direction that is parallel to an axis of rotation of said drum."

Claim 26 depends from claim 25 and further requires "[t]he imaging system of claim 25, wherein said x-ray source translates in a direction that is parallel to an axis of rotation of said drum." Jaffray '97 teaches this limitation for the reasons set forth above in Section VII.A.2, which is incorporated here by reference.

3. Claim 27: "[t]he imaging system of claim 25, further comprising a radiation source attached to said rotating drum."

Claim 27 depends from claim 25 and further specifies "[t]he imaging system of claim 25, further comprising a radiation source attached to said rotating drum." Jaffray '97 discloses this limitation for the reasons set forth above in Section VII.A.3, which is incorporated here by reference.

4. Claim 28: "[t]he imaging system-of claim 25, wherein said x-rays emitted from said x-ray source are emitted in a cone beam form."

Claim 28 depends from claim 25 and further claims "[t]he imaging system-of claim 25, wherein said x-rays emitted from said x-ray source are emitted in a cone beam form." Jaffray '97 discloses this limitation for the reasons set forth above in Section VII.A.4, which is incorporated here by reference.

D. Ground 4: Claim 29 Is Obvious Over Jaffray '97 in View of Holmström Further in View of Antonuk

Ground 4 combines Jaffray '97 with Holmström and Antonuk. Jaffray '97

and Holmström qualify as prior art for the reasons set forth above in Section VII.A. Antonuk qualifies as prior art for the reasons set forth above in Section VII.B.

Claim 29: "[t]he imaging system of claim 25, wherein said imager comprises an amorphous silicon flat-panel imager"

Claim 29 depends from claim 25 and further requires "[t]he imaging system of claim 25, wherein said imager comprises an amorphous silicon flat-panel imager." Jaffray '97 discloses an imager in the form of a phosphor screen that emits light which is focused on a charge coupled device ("CCD"). (Ex. 1004 at 4.) However, it does not disclose an amorphous silicon flat-panel imager.

Antonuk does disclose an amorphous silicon flat-panel imager. In particular, Antonuk teaches "[a] thin-film, flat-panel, pixelated detector array serving as a real-time digital imager and dosimeter for diagnostic or megavoltage X rays or gamma rays, including a plurality of photodiodes made of hydrogenated amorphous silicon arrayed in columns and rows upon a glass substrate." (Ex. 1006 at Abstract.) Thus, Antonuk discloses this claim limitation. (Balter Decl. ¶ 104, 83-95.)

Motivation to Combine Jaffray '97, Holmström, and Antonuk

One of ordinary skill in the art would have been motivated to combine the amorphous silicon flat-panel imager of Antonuk with the drum-mounted x-ray tomography system of Jaffray '97. Both references address the use of medical diagnostic imaging in a radiation treatment system. (Ex. 1006 at 1:26-29, 7:14-19;

Balter Decl. ¶ 104, 85.) Indeed, Antonuk explains that the disclosed amorphous silicon flat-panel imager "[i]n the case of diagnostic x-ray imaging, as in localization imaging, the goal is to produce a high quality image with a minimum of radiation. The present invention allows images to be produced in real-time both for fluoroscopic and radiographic modes of operation whether the radiation is megavoltage or diagnostic x-ray." (Ex. 1006 at 18:31-36.) Although Jaffray '97 teaches the use of a phosphor screen with a charge coupled device, it emphasized that important characteristics of the imaging system included "flexibility of use" and "convenience." (Ex. 1004 at 5.) Moreover, Jaffray '97 explains that "[t]he flexibility to image any treatment site will depend upon: imager field-of-view (FOV), and collision of the imaging system with other structures . . . ." (*Id*. at 6.)

Antonuk directly addresses these concerns. In fact, Antonuk also recognizes that imagers employing a CCD for fluoroscopic imaging "are relatively bulky" and notes that "[t]his is a definite hindrance in various clinical procedures." (Ex. 1006 at 4:31-52.) The amorphous silicon flat-panel imager of Antonuk is "far more compact than an image-intensifier fluoroscopic unit" and thus overcomes this problem. (*Id*. at 6:23-27.) Accordingly, one of ordinary skill in the art would have been motivated to replace the bulky phosphor screen and CCD of Jaffray '97 with the more compact amorphous flat-panel imager of Antonuk with no change in their respective functions and with a reasonable expectation of success. (Balter Decl. ¶¶

104, 83-95.)

E. Ground 5: Jaffray '97 Anticipates Claims 35 and 40-42

As explained above in Section VII.A, Jaffray '97 qualifies as prior art under at least 35 U.S.C. § 102(b). Jaffray '97 discloses all of the limitations of claims 35 and 40-42, and thus anticipates those claims.

1. Claim 35: "A method of adding an auxiliary imaging system to an existing radiation therapy system"

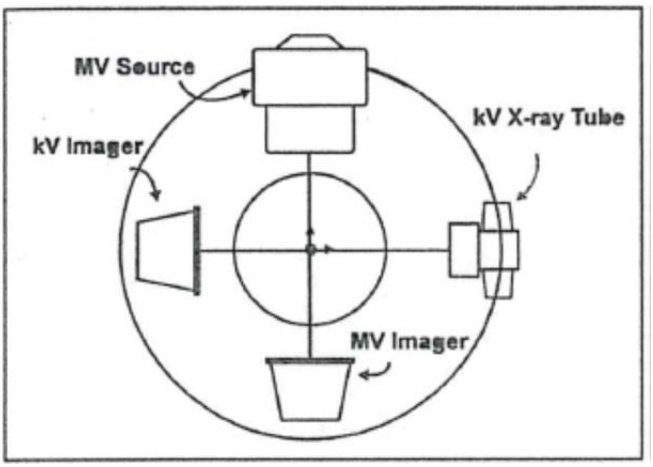
The preamble of claim 35 recites: "A method of adding an auxiliary imaging system to an existing radiation therapy system." Although the preamble may not be a claim limitation, under the broadest reasonable construction, Jaffray '97 discloses it. Jaffray '97 discloses that "we are developing a conebeam-computed tomography (CB-CT) scanner for installation on our medical linear accelerator." (Ex. 1004 at 4.) In particular, Jaffray '97 describes "[t]wo fluoroscopic imaging systems are attached to a Philips SL-20 medical linear accelerator . . . ." (*Id*.)

According to Jaffray '97, and as would be recognized by one skilled in the art, the medical linear accelerator is a radiation therapy system. (Balter Decl. ¶ 107.) Jaffray '97 explains that "[c]urrent practice [of delivering radiation therapy] has evolved under a variety of constraints, forcing the radiation oncologist to make compromises between the ideal and what is deliverable over many fractions." (Ex. 1004 at 4.) Jaffray '97 explains that these compromises are due to variances in the target position, which introduces the possibility that treatment will irradiate not

only the target, but also nearby healthy tissue, requiring the use of a lesser dosage per fraction. (*Id*.) Jaffray '97 explains that "[a] solution to the dose limits imposed by margins is to locate the clinical target and surrounding normal structure on a fraction-by-fraction basis" using the system described in the reference. (*Id*.) Thus, the medical linear accelerator and imaging system of Jaffray '97 constitute a radiation therapy system. (Balter Decl. ¶¶ 105-108.)

a. Claim 35[a]: "providing an existing radiation therapy system that comprises a radiation source that is supported on a support structure."

Claim 35[a] recites: "providing an existing radiation therapy system that comprises a radiation source that is supported on a support structure." Jaffray '97 discloses this limitation. Specifically, Jaffray '97 teaches that "[t]wo fluoroscopic imaging systems are attached to a Philips SL-20 medical linear accelerator; one detects the megavoltage image, the other a kV image produced with a kV beam projected at 90° to the treatment beam axis." (Ex. 1004 at 4 (emphasis added).) Figure 1 (above) also depicts a radiation source (i.e., "MV Source") attached to the circular drum. (*Id*. at Fig. 1; Balter Decl. ¶ 109.)



Ex. 1004, Jaffray '97 Figure 1

Accordingly, Jaffray '97 discloses this claim limitation. (Balter Decl. ¶¶ 109-111.)

b. Claim 35[b]: "and attaching an imager that does not directly face said radiation source to said support structure"

Claim 35[b] recites: "and attaching an imager that does not directly face said radiation source to said support structure." Jaffray '97 discloses a kV imager for "installation on our medical linear accelerator." (Ex. 1004 at 4.) The kV imager of Jaffray '97 does not directly face the MV radiation treatment source: "Two fluoroscopic imaging systems are attached to a Philips SL-20 medical linear accelerator; one detects the megavoltage image, the other a kV image produced with a kV beam projected at 90° to the treatment beam axis." (*Id*. (emphasis added).) This arrangement is confirmed by the picture of the system in Figure 1, which shows the kV imager mounted to the rotating drum such that it does not

directly face the MV radiation treatment source. (*See id.* at Fig. 1; Balter Decl. ¶ 112.) Accordingly, Jaffray '97 teaches attaching an imager that does not directly face said radiation source to said support structure.[7] (Balter Decl. ¶¶ 112-114.)

2. Claim 40: "[t]he method of claim 35, wherein said support structure comprises a rotating drum."

Claim 40 depends from claim 35 and further requires: "[t]he method of claim 35, wherein said support structure comprises a rotating drum." As demonstrated in the analysis of claim 35, Jaffray '97 discloses that the support structure for the MV radiation source and the kV imager is a rotating drum. (Ex. 1004 at 5, Fig. 1; Balter Decl. ¶¶ 115-117; Ex. 1013 at Fig. 1(b).)

3. Claim 41: "[t]he method of claim 40, further comprising attaching an x-ray source to said rotating drum"

Claim 41 depends from claim 40 and further requires: "[t]he method of claim 40, further comprising attaching an x-ray source to said rotating drum." Jaffray '97 discloses an x-ray source attached to a rotating drum. In particular,

[7] As explained in Section V.B, during prosecution of this claim, the Examiner found that the sole deficiency in the prior art was attaching an imager, which does not face the radiation source, to a support structure. As noted above, however, Jaffray '97 plainly describes and shows the kV imager, which does not face the MV radiation treatment source, mounted to the rotating drum. Accordingly, Jaffray '97 overcomes this isolated deficiency in the prior art. (Balter Decl. ¶ 114.)

Jaffray '97 teaches: "a 600,000 HU [heating unit] x-ray tube mounted on a retractable arm." (Ex. 1004 at 4 (emphasis added).) Jaffray '97 further explains that this system is "for integration with a medical linear accelerator." (*Id.*) Jaffray '97 further warns that "[c]areful mapping of the motion of each component with gantry angle must be performed before the patient's anatomy can be accurately localized in the treatment reference frame[,]" indicating to the skilled artisan that the x-ray tubes move when the drum rotates. (*Id*. at 5; Balter Decl. ¶ 118.) In combination with the depiction of Figure 1, one of ordinary skill would understand that the integrated x-ray source is attached to the rotating drum. (Balter Decl. ¶ 118.) Accordingly, Jaffray '97 anticipates claim 41. (Balter Decl. ¶¶ 118-119.)

4. Claim 42: "[t]he method of claim 35, further comprising attaching an x-ray source to said support structure"

Claim 42 depends from claim 35 and further recites: "[t]he method of claim 35, further comprising attaching an x-ray source to said support structure." Jaffray '97 teaches this claim limitation for the same reasons set forth in the analysis of claim 41 above. Although claim 41 addresses the rotating drum of Jaffray '97, that same drum satisfies the support structure limitation of claim 42. (Balter Decl. ¶¶ 120-121.)

F. Ground 6: Claims 36-39 Are Obvious over Jaffray '97 in view of Lim

Ground 6 combines Jaffray '97 and PCT Application No. WO 91/06876

issued to Lim *et al.* **[Ex. 1008]** ("Lim"). The qualifications of Jaffray '97 as prior art were previously addressed in Section VII.A. Lim qualifies as prior art to the '592 patent under at least 35 U.S.C. § 102(b) (pre-AIA), since it was published on May 16, 1991, well over one year before the earliest possible priority date listed on the face of the '592 patent.

Lim [Ex. 1008]: Lim discloses a gantry and pallet assembly that includes two scintillation cameras mounted opposite one another on a rotation ring in order to perform whole body and single photon emission computed tomography scans. (Ex. 1008 at Abstract.) Lim discloses a mechanical arrangement of components enabling the gantry to translate laterally so that it can then be "stopped at any point along the axis of the patient's body to conduct the appropriate scan." (Ex. 1008 at 11.)[8] Lim further teaches that the gantry bears a rotation ring, which itself supports radially translatable detectors. (*Id.* at 12.) This arrangement results in "dual action movement," permitting independent movement of the rotating ring and translatable detectors. (*Id.*)

Ground 6 relies on Jaffray '97 for the claim limitations of independent claim 35, from which claims 36-39 depend. Ground 6 relies on Lim for its imager

[8] Page numbers have been added to Exhibit 1008 (Lim) for clarity. Citations to Exhibit 1008 in this Petition refer to these page numbers, rather than the original pagination of the reference.

support system and its disclosure of the mounting of diagnostic equipment to a rotating element. Jaffray '97 and Lim render claims 36-39 obvious as explained below. A specific description of the motivation for combining Jaffray '97 and Lim is provided below in connection with the claim limitations in which Jaffray '97 and Lim are cited.

1. Jaffray '97 and Lim Render Claim 36 Obvious

Claim 36 depends from claim 35. Jaffray '97's disclosure of the limitations of independent claim 35 was fully explained in Ground 5 above. *See* Section VII.E. The analysis of the remaining limitations of claim 36 is set forth below.

a. Claim 36[a]: "[t]he method of claim 35, wherein said attaching comprises: attaching said imager to an imager support system"

Claim 36[a] requires "[t]he method of claim 35, wherein said attaching comprises: attaching said imager to an imager support system." Lim discloses an imager attached to an imager support system. (Balter Decl. ¶ 124.) In particular, Lim teaches that a back plate 32 and mounting block 42 provide support for detector 46. (Ex. 1008 at 12; Fig. 6 (reproduced below).)

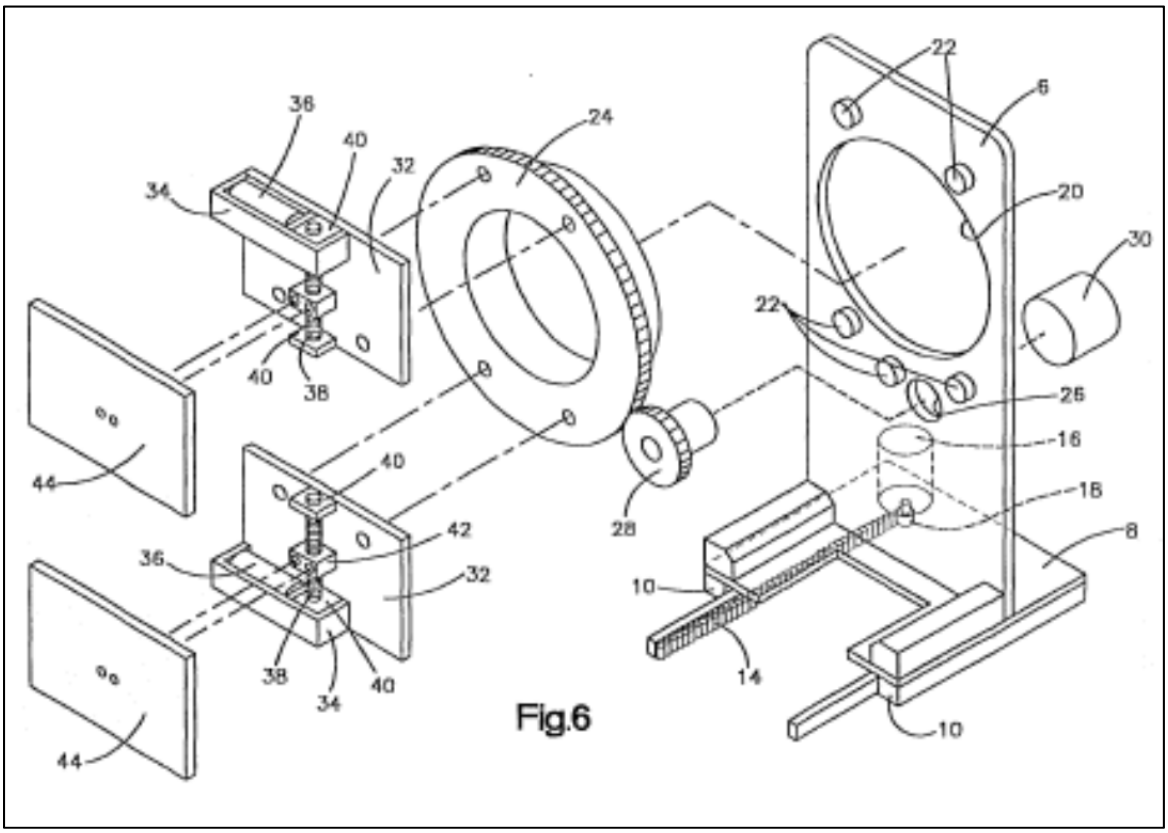


Fig.6

The Lim specification further indicates that one use of the detectors is to scan parts of a person's body using SPECT scanning to generate images. (*Id*. at 4.) Thus, a skilled artisan would recognize detector 46 as an imager and would also recognize back plate 32 and mounting block 42 as an imager support system. (Balter Decl. ¶ 124.) Accordingly, Lim teaches this claim limitation. (*Id*.)

Motivation to Combine Jaffray '97 and Lim

One of ordinary skill in the art would have been motivated to combine Lim's disclosure of an imager support system with the x-ray tomography system of Jaffray '97. Both references address the use of medical diagnostic imaging on a rotating drum. (Balter Decl. ¶ 125.) Further, as previously noted, Jaffray '97

teaches a need for increased flexibility and convenience in imaging systems: "important characteristics [of the imaging system] include . . . (iii) flexibility of use . . . and, (v) convenience." (Ex. 1004 at 5.) Thus, one of ordinary skill in the art would have recognized that flexibility and convenience of the imaging system would require movement of the imager independent of the drum. (Balter Decl. ¶ 125.) But Jaffray '97 does not disclose how such an imaging system would be mounted.

Lim, however, does address the mounting of a detector to a drum with independent movement capability, as described above. (*See also* Ex. 1008 at Fig. 6.) Thus, it would have been obvious to apply the known mounting technique of Lim to the known x-ray tomography apparatus of Jaffray '97 with no change in their respective functions and with a reasonable expectation of success. (Balter Decl. ¶¶ 124-126.)

b. Claim 36[b]: "forming an opening in said support structure"

Claim 36[b] requires: "forming an opening in said support structure." The support structure identified in this claim limitation refers back to the support structure of claim 35, on which the radiation source and imager are supported. Lim teaches the use of a rotation ring 24 mounted on a gantry plate 6. (Ex. 1008 at 11.) According to Lim, "[t]he rotation ring 24 has two radial back plates 32 rigidly connected thereto." (*Id*. at 12.) Each back plate 32 supports a detector 46, which

are coupled by a mounting block 42. (*Id*.) Thus, the rotation ring 24 acts as a support structure to each of these elements. (*Id.*; Balter Decl. ¶ 127.) As shown in Figure 6 of Lim, openings are formed in the rotation ring 24. (*Id*. at Fig. 6 (reproduced above in Section VII.F.1.a).) Therefore, Lim discloses this claim limitation. (Balter Decl. ¶ 127.)

One of ordinary skill in the art would have been motivated to combine Lim's disclosure of mounting techniques with the x-ray tomography system of Jaffray '97 for precisely the same reasons discussed above in relation to claim 36[a]. Thus, it would have been obvious to apply the known mounting technique of Lim to the known x-ray tomography apparatus of Jaffray '97 with no change in their respective functions and with a reasonable expectation of success. (Balter Decl. ¶¶ 127-128.)

c. Claim 36[c]: "inserting a male member through an opening formed in said imager support system and said opening formed in said support structure"

Claim 36[c] requires: "inserting a male member through an opening formed in said imager support system and said opening formed in said support structure." As explained in the prior claim limitation analysis, the imager support system of Lim consists of back plate 32 and mounting block 42. As shown in Fig. 6 (reproduced above), openings are formed in the top left and top right corners of back plate 32. (Ex. 1008 at Fig. 6.) Figure 6 further depicts that these openings

are aligned with the opening formed in the rotation ring 24 (i.e., the support structure). (*Id*.) Lim explains that "[t]he back plates 32 can be connected to the rotation ring 24 in a known manner, such as nuts and bolts . . . ." (*Id*. at 12.) One of ordinary skill would understand that a bolt is a "male member" and that the alignment of openings described in Figure 6 is designed for the insertion of those bolts through the openings to connect them. (Balter Decl. ¶ 129.) Thus, Lim teaches one of ordinary skill this claim limitation. (*Id*.)

One of ordinary skill in the art would have been motivated to combine Lim's disclosure of mounting techniques with the x-ray tomography system of Jaffray '97 for precisely the same reasons discussed above in relation to claim 36[a]. (Balter Decl. ¶ 130.) Thus, it would have been obvious to apply the known mounting technique of Lim to the known x-ray tomography apparatus of Jaffray '97 with no change in their respective functions and with a reasonable expectation of success. (Balter Decl. ¶¶ 130. 125-126.)

d. Claim 36[d]: "and attaching said inserted male member to said support structure and said imager support system"

Claim 36[d] requires: "and attaching said inserted male member to said support structure and said imager support system." As explained above in relation to claim 36[c], Lim teaches one of ordinary skill to attach the support structure (i.e., the rotation ring 24) and the imager support system (i.e., back plate 32 and

mounting block 42) to the male member (i.e., bolts) with nuts. (Ex. 1008 at 12; Balter Decl. ¶ 131.) Thus, Lim teaches one of ordinary skill this claim limitation. (*Id*.)

One of ordinary skill in the art would have been motivated to combine Lim's disclosure of mounting techniques with the x-ray tomography system of Jaffray '97 for precisely the same reasons discussed above in relation to claim 36[a]. (Balter Decl. ¶¶ 132, 125-126.) Thus, it would have been obvious to apply the known mounting technique of Lim to the known x-ray tomography apparatus of Jaffray '97 with no change in their respective functions and with a reasonable expectation of success. (Balter Decl. ¶¶ 131-132.)

2. Claim 37: "[t]he method of claim 36, wherein said attaching said inserted male member comprises tightening a nut onto said male member"

Claim 37 depends from claim 36 and further specifies: "[t]he method of claim 36, wherein said attaching said inserted male member comprises tightening a nut onto said male member." Lim discloses that the attachment of the imager support system and the support structure using nuts and bolts. It would have been obvious to one of ordinary skill in the art that such a process would involve tightening the nut onto the bolt. (Balter Decl. ¶ 133.) Thus, Lim teaches one of ordinary skill this claim limitation. (*Id*.)

One of ordinary skill in the art would have been motivated to combine Lim's

disclosure of mounting techniques with the x-ray tomography system of Jaffray '97 for precisely the same reasons discussed above in relation to claim 36[a]. Thus, it would have been obvious to apply the known mounting technique of Lim to the known x-ray tomography apparatus of Jaffray '97 with no change in their respective functions and with a reasonable expectation of success. (Balter Decl. ¶¶ 133-134.)

3. Claim 38: "[t]he method of claim 36, wherein said support structure comprises a rotating drum."

Claim 38 depends from claim 36 and adds: "[t]he method of claim 36, wherein said support structure comprises a rotating drum." Both Jaffray '97 and Lim disclose this limitation. Jaffray '97 teaches that the structure supporting the imager and radiation source is a rotation drum, as more fully explained in Section VII.E.1.a. (*See* Ex. 1004 at 4-5, Fig. 1.) Similarly, Lim teaches that the support structure (i.e., rotation ring 24) cooperates with spur gear 28 and drive motor 30 "in a conventional manner so that when the drive motor 30 is activated the rotation of spur gear 28 causes the rotation ring 24 to rotate." (Ex. 1008 at 11-12.) Accordingly, both Jaffray '97 and Lim teach this claim limitation. (Balter Decl. ¶¶ 135-136.)

4. Claim 39: "[t]he method of claim 38, further comprising attaching an x-ray source to said rotating drum"

Claim 39 depends from claim 38 and further specifies: "[t]he method of

claim 38, further comprising attaching an x-ray source to said rotating drum." Jaffray '97 discloses this claim limitation. In particular, Jaffray '97 teaches: "a 600,000 HU [heating unit] x-ray tube mounted on a retractable arm." (Ex. 1004 at 4 (emphasis added).) Jaffray '97 further explains that this system is "for integration with a medical linear accelerator." Jaffray '97 further warns that "[c]areful mapping of the motion of each component with gantry angle must be performed before the patient's anatomy can be accurately localized in the treatment reference frame[,]" indicating to the skilled artisan that the x-ray tubes move when the drum rotates. (*Id*. at 5; Balter Decl. ¶ 137.) In combination with the depiction of Figure 1, one of ordinary skill would understand that the integrated x-ray source is attached to the rotating drum. (Balter Decl. ¶ 137.) Thus, Jaffray '97 teaches this claim limitation. (Balter Decl. ¶¶ 137-138.)

VIII. CONCLUSION

The prior art references identified in this Petition contain pertinent technological teachings, either explicitly or inherently disclosed, that were not previously considered in the manner presented herein or applied during original examination of the '592 patent. At least by virtue of disclosing the limitations that served as the basis for the allowance of the claims at issue, the references relied upon herein should be considered important in determining patentability. In sum, these references provide new, non-cumulative technological teachings not

previously considered and relied upon on the record, and establish a reasonable likelihood of success as to Petitioner's assertions that claims 25-29 and 35-42 of the '592 patent are invalid pursuant to the grounds presented in this Petition.

Accordingly, Petitioner respectfully requests institution of *inter partes* review for claims 25-29 and 35-42 of the '592 patent for each of the grounds presented herein.

Dated: November 11, 2015

Respectfully submitted,
COOLEY LLP

COOLEY LLP
ATTN: Patent Group
1299 Pennsylvania Ave., NW, Suite 700
Washington, DC 20004
Tel: (650) 843-5001
Fax: (650) 849-7400

By: / Heidi L. Keefe/
Heidi L. Keefe
Reg. No. 40,673
Lead Counsel for Petitioner

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. 7,826,592**, including all exhibits (**Nos. 1001-1020**) and related documents, are being served by Federal Express on the 11th 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:

Jonathan P. O'Brien, Ph.D.
Honigman Miller Schwartz & Cohn LLP
350 East Michigan Avenue, Suite 300
Kalamazoo, MI 49007

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:

J. Michael Huget
Deborah J. Swedlow
Sarah E. Waidelich
Honigman Miller Schwartz & Cohn LLP
315 East Eisenhower Parkway, Suite 100
Ann Arbor, MI 48108

Theresa M. Gillis
Brian A. Rosenthal
B. Clayton McCraw
Mayer Brown LLP
1221 Avenue of the Americas
New York, NY 10020

///

///

Andrew S. Rosenman
Amanda K. Streff
Mayer Brown LLP
71 South Wacker Drive
Chicago, IL 60606

DATED: November 11, 2015

/ Heidi L. Keefe/
Heidi L. Keefe
Reg. No. 40,673

COOLEY LLP
ATTN: Heidi L. Keefe
Patent Docketing
1299 Pennsylvania Ave. NW, Suite 700
Washington, D.C. 20004
Tel: (650) 843-5001
Fax: (650) 849-7400