UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELEKTA INC.
Petitioner

v.

VARIAN MEDICAL SYSTEMS, INC.
Patent Owner

Case: IPR2015-01401

Patent 7,945,021

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,945,021

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

PETITIONER'S EXHIBIT LIST

Description	Exhibit #
U.S. Patent No. 7,945,021	1001
Prosecution History of U.S. Patent No. 7,945,021	1002
D.A. Jaffray et al., A Volumetric Cone-Beam CT System Based on a 41x41 cm^2 Flat-Panel Imager, Medical Imaging (June 28, 2001) ("Jaffray 2001")	1003
SPIE, Volume 4320, Medical Imaging 2001: Physics of Medical Imaging, Table of Contents	1004
Jaffray et al., Cone-beam computed tomography on a medical linear accelerator using a flat-panel imager, 2000 ("Jaffray 2000")	1005
ICCR 2000 Index	1006
Jaffray et al., A Radiographic and tomographic imaging system integrated into a medical linear accelerator for localization of bone and soft-tissue targets, 1999 ("Jaffray JRO 1999")	1007
Jaffray et al., Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager, February 1999 ("Jaffray SPIE 1999)	1008
Jaffray et al., Cone-beam computer tomography with a flat-panel imager: Initial performance characterization, June 2000 ("Jaffray June 2000")	1009
C.J Karzmark, A Primer on Theory and Operation of Linear Accelerators in Radiation Therapy, Radiological Health, (Dec. 1981)	1010
U.S. Patent 5,661,773	1011
U.S. Patent 6,041,097	1012
Siewerdsen et al., A Ghost Story Spatio-temporal Response Characteristics of an Indirect-Detection Flat-Panel Image, Medical Physic, 26(8):1624-1641 (1999)	1013

Siewerdsen et al., Cone-beam Computed Tomography With a Flat-panel Imager: Effects of Image Lag, Medical Physics, 26(12):2635-2647 (1999)	1014
Anderson, Software System for Automatic Parameter Logging on Philips SL20 Linear Accelerator, Medical & Biological Engineering & Computing, 33:20-222 (1995)	1015
Declaration of Dr. Russell J. Hamilton, PHD	1016

Pursuant to 35 U.S.C. § 311, Petitioner hereby respectfully requests *inter partes* review of claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 of U.S. Patent No. 7,945,021 ("the '021 Patent") (Ex. 1001), which issued on May 17, 2011. The challenged claims are unpatentable under 35 U.S.C. §§ 102 and 103 over the prior art publications in this petition (the "Petition").

I. MANDATORY NOTICES PURSUANT TO 37 C.F.R. §42.8

A. Real Parties-In-Interest. Elekta Ltd. and Elekta AB are real parties-in-interest with Petitioner Elekta Inc.

B. Related Matters. Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner submits that the '021 Patent is related to U.S. Patent Nos. 8,116,430, 8,867,703, Application No. 14/486,819, and WIPO Publication No. WO 2004/060137, which claim priority to the '021 Patent.

C. Lead and Back-up Counsel.

Theresa M. Gillis (lead) Registration No. 28,078 Mayer Brown LLP 1221 Avenue of the Americas New York, NY 10020-1001 Telephone: 212-506-2553 Facsimile: 212-849-5553 tgillis@mayerbrown.com	**Amanda K. Streff (back-up)** Registration No. 65,224 MAYER BROWN LLP 71 S. Wacker Drive Chicago, IL 60606 Telephone: 312-701-8645 Facsimile: 312-701-7711 astreff@mayerbrown.com

D. Service Information. Pursuant to 37 C.F.R. §42.8(b)(4), please direct all correspondence to lead counsel at the address identified above. Petitioner consents to electronic service by email to tgillis@mayerbrown.com and astreff@mayerbrown.com, with a courtesy copy to ElektaIPR@mayerbrown.com.

II. PAYMENT OF FEES

Pursuant to 37 C.F.R. § 42.103, $23,000 is being paid at the time of filing this petition, charged to Deposit Account **130019**. Should any further fees be required by the present Petition, the Patent Trial and Appeal Board ("the Board") is hereby authorized to charge the above-referenced Deposit Account.

III. STANDING

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the patent for which review is sought, the '021 Patent, is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review of the '021 Patent.

IV. REQUEST FOR *INTER PARTES* REVIEW

Pursuant to 37 C.F.R. § 42.104(b), Petitioner requests that the Board find claims 1, 4, 5, 6, 7, 14, 15, 53, 60 and 61 of the '021 Patent unpatentable.

A. Technology Background

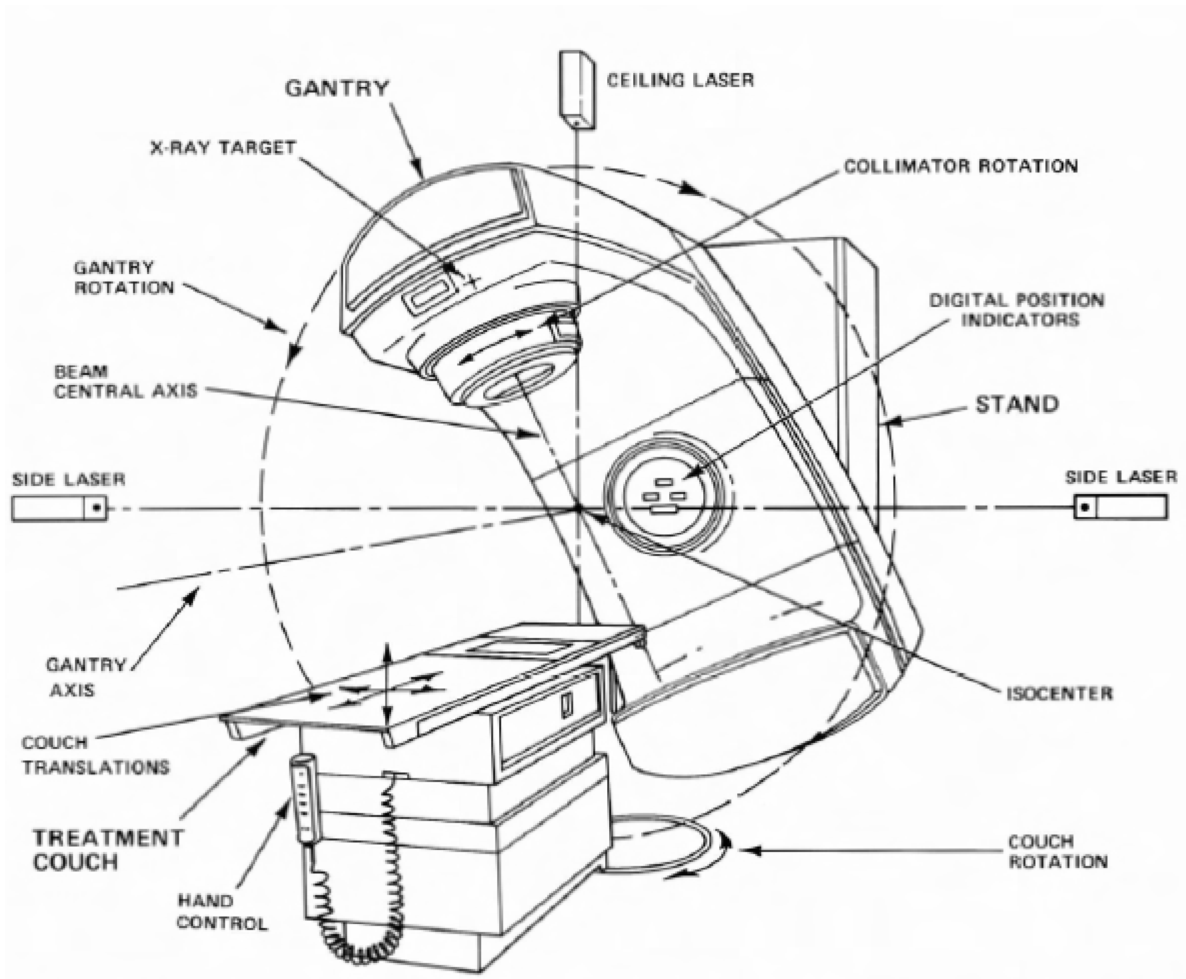
The claims at issue relate to therapeutic radiation treatment systems, more specifically to linear accelerators. Ex. 1016 at ¶100. Linear accelerators have been used to treat patients with radiation therapy for many years. *Id*. at ¶33.

A linear accelerator delivers therapeutic radiation from a high energy radiation source in the form of radiation beams. *Id*. at ¶34. The radiation source rotates around the patient, and beams are delivered toward the patient from various points. *Id*. at ¶¶34-35. The beams intersect at the "isocenter" of the linear accelerator. *Id*. at ¶81. Because every beam passes through the isocenter, the cumulative amount of radiation delivered to the isocenter is greater than that delivered elsewhere along each individual beam's path. *Id*.

A patient must be carefully positioned in the linear accelerator so that the target (tumor) is at the isocenter and receives this cumulative radiation dose. *Id*. at ¶¶66, 82. In order to position the target at the isocenter of the linear accelerator, the patient is positioned on a couch or table, which can be adjusted in three planes and angulated. *Id*. at ¶36.

Standard linear accelerators have had the same basic components since at least the early 1980s. Ex.1010 at 1-3; Ex. 1016 at ¶¶37-38. Depicted below is a diagrammatic figure from a 1981 primer on linear accelerators.

As shown in this figure, a linear accelerator has a gantry which is supported on a frame and is rotatable about a treatment couch. The couch is translatable in three planes and can rotate. Ex. 1010 at 1, 12; Ex. 1016 at ¶37. The treatment beam is delivered from the gantry in a straight line toward the isocenter of the linear accelerator. Ex. 1010 at 1, 3; Ex. 1016 at ¶¶33, 35.



Ex. 1010 at 2, Fig. 2

In order to correctly position the target at the linear accelerator's isocenter, a therapist obtains treatment planning images (x-rays, CT, etc.). Ex. 1016 at ¶¶52-54. Treatment planning is typically done days or more in advance of treatment. *Id*. at ¶89. In addition, radiation treatment is generally delivered in fractions over a period of days or even months. *Id*. at ¶66. Between the time of treatment planning and each treatment fraction, the target may shift. *Id*. at ¶85.

To ensure that the target is located at the isocenter during each fraction of the treatment, various methods had been developed by 2001 to re-image the patient once in position on the treatment couch. *Id*. at ¶¶55-63. Electronic imaging while the patient is in position for treatment is often referred to as on-line portal imaging. *Id*. at ¶62. A comparison of the target position in these images relative to its position in the images used for treatment planning allows the therapist to adjust the treatment couch to correctly position the target at the isocenter based on the target's location at the time of treatment. *Id*. at ¶93.

The '021 Patent relates to a specific type of imaging system that can be used on a linear accelerator, a "cone beam CT" or "CBCT" imaging system.

B. Alleged Invention Of The '021 Patent

The '021 Patent generally relates to patient imaging systems used either during therapeutic radiation sessions or during treatment planning simulations. Ex. 1001 at 1:9-11. Specifically, the '021 Patent relates to using a cone-beam CT imager integrated into a linear accelerator (which the patent refers to as a "radiation treatment system") or into a simulator. Ex. 1001 at 1:46-53, 2:17-31.

Like a typical linear accelerator the claimed "radiation treatment system" includes a rotatable gantry to which the high energy radiation source used to treat the target volume (tumor) is coupled. *Id*. at 2:25-40. The specific imaging system used in the claimed system includes a cone-beam radiation source and a flat-panel imager each of which is coupled to the gantry. *Id*. at claim 1. The imager is able to capture image data when the cone-beam source irradiates the patient. *Id*. Using conventional cone beam processing techniques this image data can be processed to produce 3D images of the target area of the patient. *Id*. at 1:46-53, 2:17-31, 2:44-46. The cone-beam imager radiation source can be the same source as the high energy radiation source used to treat the target or it can be a second radiation source.

The ’021 Patent discloses that the images may be used “to tailor a dose of therapeutic radiation to a target volume” by verifying that the target volume is properly located or for positioning and re-positioning the patient [] and therefore the target volume.” *Id*. at 2:36-49, 5:48-61.

C. The Prosecution History Of The ’021 Patent

During the prosecution of the ’021 Patent, the Examiner rejected most of the claims based on U.S. Pub. No. 2003/0007601 (the “Jaffray Application”) (U.S. Appl. No. 09/788,335, U.S. Patent No. 6,842,502). *See, e.g.*, Ex. 1002 at Elekta_000000226-228; *see also* Ex. 1016 at ¶¶105-106. The applicant was never able to persuade the Examiner that the Jaffray Application did not make the claims unpatentable. *See* Ex. 1016 at ¶107. Instead, the Examiner withdrew his rejections over the Jaffray Application when the applicant filed Rule 131 Declarations arguing that it had experiments that antedated Jaffray’s filing date of February 12, 2000. *See, e.g.*, *id*. at Elekta_000000286, Elekta_000000289-362; *see also* Ex. 1016 at ¶107.

Subsequently, the Examiner made rejections based on Roos *et al.* (U. S. Patent No. 6,041,097) (Ex. 1011) alone or Swerdloff *et al.* (U. S. Patent No. 5,661,773) (Ex. 1012) in view of Roos. *See, e.g.*, Ex. 1002 at Elekta_000000426-446; *see also* Ex. 1016 at ¶¶108-112. Here, however, the Examiner was not relying solely on patents in the radiation treatment field, but rather was combining the Roos patent from the imaging field with references from the radiation treatment field. *See* Ex. 1016 at ¶109.

In the Notice of Allowance on January 24, 2011, the Examiner found that the prior art taught most of the features of each claim. *See* Ex. 1002 at Elekta_000001322. Allowance of some of the claims here at issue was based on the Examiner's conclusion that the prior art did not disclose a flat panel cone beam imaging system in the context of a linear accelerator. Ex. 1002 at Elekta_000001327.

> [T]he prior art fails to disclose or fairly suggests [*sic*] that the [radiation treatment system] further comprises: a cone-beam radiation source coupled to the rotatable gantry to radiation [*sic*] the patient; and a flat-panel image [*sic*] coupled to the rotatable gantry.

Id. Contrary to this conclusion, each of the five prior art references relied upon in this petition discloses or suggests use of a cone beam source and a flat panel imager on a linear accelerator.

Other claims at issue in this proceeding were allowed based on additional limitations in the claims requiring that the claimed system have conventional linear accelerator features, such as a computer to store the image data or a translatable couch. *Id*. at Elekta_000001322-1323; *see also* Ex. 1016 at ¶¶111-112. These conventional features are also disclosed in the prior art relied upon in this petition.

V. CLAIM CONSTRUCTION

Petitioner submits that, for purposes of this Petition only[1], the terms of the ’021 Patent are generally clear on their face, and should be given their broadest reasonable construction in light of the specification of the ’021 Patent except for those terms discussed specifically below. 37 C.F.R. § 42.100(b).

A. “a high energy radiation source coupled to the rotatable gantry” and “a cone-beam radiation source coupled to the rotatable gantry”

Independent claims 1, 14, and 53 all require “a high energy radiation source

[1] Petitioner notes that the standard for claim construction applied in this proceeding is different than the standard applied in district court litigation. Petitioner expressly reserves the right to submit constructions for the claims in any related district court litigation, under the legal standard applicable in that proceeding, including how a person of ordinary skill in the art would understand the claims in light of relevant intrinsic and extrinsic evidence

coupled to the rotatable gantry" and "a cone-beam radiation source coupled to the rotatable gantry." Based on the specification, dependent claims, and the prosecution history, these limitations should be construed to cover both two separate sources coupled to the gantry or a single source coupled to the gantry with two different functions.

First, the specification of the '021 Patent discloses an embodiment in which the kV cone-beam CT radiation source coupled to the gantry is a separate source. Ex. 1001 at 7:9-14; *see also* Ex. 1016 at ¶115. Second, claim 9, which depends from claim 1, recites that "the cone-beam source and high energy radiation source are different from one another." *Id*. at 9:28-30. Therefore, claim 1, from which claim 9 depends, should be construed to be broader than systems where the radiation sources are different; it must also cover systems where the two sources are not different. *See* Ex. 1016 at ¶116. Third, the Applicant argued during prosecution that the claims cover both a single source with a dual function or a system with two separate sources. *See id*. at ¶117. In response to an Office Action, the Applicant amended Fig. 3 noting that it "previously omitted different cone beam source coupled to the same gantry as the high energy source." Ex. 1002 at Elekta_000000600. The Applicant also argued that "current independent claims 1 and 45 do not require that the cone beam source is necessarily different from the high energy source claimed." *Id*. at Elekta_000000615. Therefore, the Applicant admitted during prosecution that the claims cover systems where the cone beam source is different from the high energy source and systems where they are not different. *See* Ex. 1016 at ¶117.

Accordingly, the broadest reasonable interpretation of the limitations "a high energy radiation source coupled to the rotatable gantry" and "a cone-beam radiation source coupled to the rotatable gantry" in claims 1, 14, and 53 covers both two separate sources coupled to the gantry or a single source coupled to the gantry with two different functions.

B. "frame"

Independent claims 1, 14, and 53 all require "a frame." Based on the specification and the claim language, the broadest reasonable construction of "a frame" is "the structure that supports the gantry." The claim language requires "a rotatable gantry coupled to the frame." *See* Ex. 1016 at ¶119. The specification never discusses "a frame." *See id*. at ¶119. Instead, it explains that the gantry is coupled to a structure called a "drive stand," which is the structure that supports the gantry. *See id*. at ¶120. Specifically, the '021 Patent discloses that "[t]he clinical treatment machine 400 includes a rotatable gantry pivotably attached to a drive stand 403," which can be seen in Fig. 3. Ex. 1001 at 5:19-20. Therefore, "frame" as used in the claims refers to the "the structure that supports the gantry."

VI. JAFFRAY INVENTION

As mentioned above, the ’021 Patent was rejected under § 102(e) as anticipated by the Jaffray Application because the Jaffray Application, like the claims of the ’021 Patent, discloses a radiation therapy system having a flat panel cone beam CT system. *See* Ex. 1016 at ¶¶104-106. As also mentioned above, the § 102 rejection over the Jaffray Application was overcome by filing Rule 131 Affidavits purporting to show an invention date earlier than the Jaffray Application filing date, not by distinguishing the ’021 Patent claims from the radiation therapy system described in the Jaffray Application. *Id.* at ¶107.

The § 102 grounds for unpatentability in this Petition rest on publications by Jaffray, which, like the Jaffray Application, describe Jaffray’s radiation therapy system equipped with a flat panel cone beam CT imaging system. *See* Ex. 1016 at ¶¶123-129. These Jaffray publications are § 102(b) prior art which constitute an absolute bar to patentability. Therefore, unlike the § 102(e) rejection over the Jaffray Application, these publications cannot be avoided by Rule 131 Affidavits.[2]

[2] Petitioner does not agree that the Rule 131 Affidavits were effective to antedate the Jaffray Application. However, because the grounds for unpatentability raised in this petition rest on Jaffray’s § 102(b) publications, the inadequacy of the Rule 131 Affidavits offered during prosecution to purportedly

These § 102(b) Jaffray publications were not cited during prosecution.

VII. SUMMARY OF PRIOR ART TO THE ’021 PATENT FORMING THE BASES FOR THIS PETITION

A. D.A. Jaffray et al., A Volumetric Cone-Beam CT System Based on a 41x41 cm^2 Flat-Panel Imager, Medical Imaging (Feb. 17, 2001) (“Jaffray 2001”)

Jaffray 2001 (Ex. 1003) describes and depicts a flat panel cone beam imaging system on a linear accelerator. Jaffray 2001 was published at least as of June 28, 2001 more than one year before the December 18, 2002 filing date of the ’021 Patent and is prior art to the ’021 Patent at least under pre-AIA 35 U.S.C. § 102(b). Ex. 1004 at Elekta_000001407; *see also* Ex. 1016 at ¶130. Jaffray 2001 was not cited or considered by the examiner during the prosecution of the application that led to the ’021 Patent.

B. Jaffray et al., Cone-beam computed tomography on a medical linear accelerator using a flat-panel imager, 2000 (“Jaffray 2000”)

As its title indicates, Jaffray 2000 (Ex. 1005) describes and depicts a cone beam flat panel imager on a linear accelerator. Jaffray 2000 was published at least as of May 25, 2000 more than one year before the December 18, 2002 filing date of the ’021 Patent and is prior art to the ’021 Patent at least under pre-AIA 35 U.S.C. § 102(b). *See* Ex. 1006 at Elekta_000001433; *see also* Ex. 1016 at ¶208.

---

overcome the Jaffray Application under § 102(e) need not be addressed in this proceeding.

Jaffray 2000 was not cited or considered by the examiner during the prosecution of the application that led to the ’021 Patent.

C. Jaffray et al., A Radiographic and tomographic imaging system integrated into a medical linear accelerator for localization of bone and soft-tissue targets, 1999 (“Jaffray JRO 1999”)

Jaffray JRO 1999 (Ex. 1007) discloses details of the linear accelerator used in Jaffray 2001, Jaffray 2000, and Jaffray June 2000. Jaffray JRO 1999 was published at least as of 1999 more than one year before the December 18, 2002 filing date of the ’021 Patent and is prior art to the ’021 Patent at least under pre-AIA 35 U.S.C. § 102(b). Ex. 1007 at 773. Jaffray JRO 1999 is listed on the face of the ’021 Patent but it was not cited or considered by the Examiner during prosecution of the application that led to the ’021 Patent.

D. Jaffray et al., Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager, February 1999 (“Jaffray SPIE 1999)

Jaffray SPIE 1999 (Ex. 1008) describes the details of the flat panel imager used in Jaffray 2001, Jaffray 2000, and Jaffray June 2000. Jaffray SPIE 1999 was published at least as of February 1999 more than one year before the December 18, 2002 filing date of the ’021 Patent and is prior art to the ’021 Patent at least under pre-AIA 35 U.S.C. § 102(b). Ex. 1008 at 204. During prosecution, the Examiner noted Jaffray SPIE 1999 as “prior art made of record and not relied upon” and as such, the Examiner never cited this reference as a basis for an Office Action. Ex. 1002 at Elekta_000000527.

E. Jaffray et al., Cone-beam computer tomography with a flat-panel imager: Initial performance characterization, June 2000 ("Jaffray June 2000")

Jaffray June 2000 (Ex. 1009) teaches that a cone beam flat panel imager can be integrated with a linear accelerator. Jaffray June 2000 was published at least as of June 2000 more than one year before the December 18, 2002 filing date of the '021 Patent and is prior art to the '021 Patent at least under pre-AIA 35 U.S.C. § 102(b). Ex. 1009 at 1311; *see also* Ex. 1016 at ¶293. Jaffray June 2000 is listed on the face of the '021 Patent but it was not cited or considered by the Examiner during prosecution of the application that led to the '021 Patent.

VIII. GROUNDS FOR UNPATENTABILITY FOR EACH CLAIM

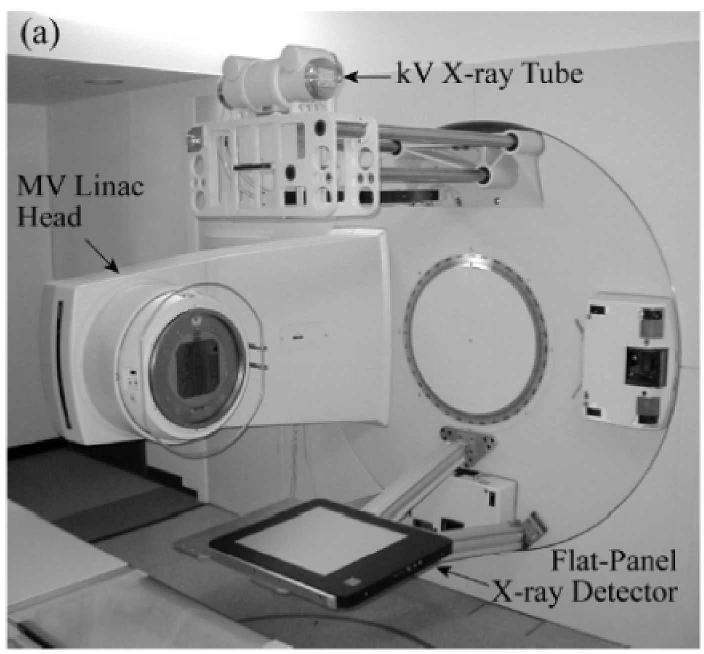
In light of the disclosures detailed below, the '021 Patent is unpatentable for at least the reasons in the following chart and discussed in more detail herein.

No.	Ground	Prior Art	Exhibit Nos.	Claims
1	102(b)	Jaffray 2001	Ex. 1003	1, 4, 5, 6, 7, 14, 15, 53, 60, and 61
2	103(a)	Jaffray 2001	Ex. 1003	1, 4, 5, 6, 7, 14, 15, 53, 60, and 61
3	102(b)	Jaffray 2000	Ex. 1005	1, 4, 5, 6, 7, 14, 15, 53, 60, and 61
4	103(a)	Jaffray 2000 and Jaffray JRO 1999 and Jaffray SPIE 1999	Ex. 1005 and Ex. 1007 and Ex. 1008	1, 4, 5, 6, 7, 14, 15, 53, 60, and 61
5	103(a)	Jaffray June 2000 and Jaffray JRO 1999	Ex. 1009 and Ex. 1007	1, 4, 5, 6, 7, 14, 15, 53, 60, and 61

The challenged claims of the '021 Patent have significant overlapping limitations. For example, in many cases the claims are identical but for one additional limitation. For these reasons, the identical limitations will be discussed together.

A. Ground 1: Jaffray 2001 Anticipates Claims 1, 4, 5, 6, 7, 14, 15, 53, 60 and 61

Jaffray 2001 anticipates claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 because Jaffray 2001 discloses a system embodying all of the elements of these claims. Specifically, all the claims at issue require a conventional linear accelerator equipped with a rotatable gantry coupled to a frame, a high energy treatment radiation source, a cone beam radiation source, and a flat panel imager to generate image data used to create volumetric cone beam CT images.



Jaffray 2001 discloses such a linear accelerator as reflected in his Figure 4(a) shown here. Ex. 1003 at 805, Fig. 4a. As depicted, the linear accelerator has a rotatable gantry supported on a frame, a high energy (MV) radiation source, a kV cone beam radiation source, and a flat panel imager as required by claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61. *See* Ex.

1016 at ¶¶134-141. Further, as explained in Jaffray 2001, the kV radiation source and the flat panel imager were used to create cone beam CT images (*see* Ex. 1003 at 806, Fig. 5 caption). *See* Ex. 1016 at ¶142. Moreover, as required by claims 1, 4, 14, and 53, the images created are 3D volumetric cone beam images created based on the captured image projection data. "A low-resolution volume (341×341×341 voxels at 0.75 mm voxel pitch) [was] . . . reconstructed for presentation . . . . The volumetric surface rendering of the reconstruction [Fig. 5(a)] illustrates the large FOV achieved with a single rotation of the gantry in the cone-beam approach." Ex. 1003 at 805 (emphasis added).

Claims 14, 15, and 60 additionally require a conventional translatable treatment couch coupled to the gantry via a communications network that can be angulated and moved in three planes. The linear accelerator used in Jaffray 2001 is an Elekta SL-20 which, like any standard linear accelerator, has a translatable couch coupled to the gantry via a communications network and capable of movement in three planes plus angulation. *See* Ex. 1003 at Fig. 4; Ex. 1010 at 1, 2, 12, 39-48; Ex. 1015 at 220; Ex. 1016 at ¶¶127-128. It can be seen rotated partially out of view in the lower right hand corner of the figure above.

Claim 1 also requires that the image data generated by the system is communicated via a communications network to a computer for storage. Jaffray 2001 discloses this feature noting that his system allows "image acquisition, processing and reconstruction in an integrated Windows NT-based application" and that the software "collects the resulting projections in host memory." Ex. 1003 at 801, 804; *see also* Ex. 1016 at ¶¶145-146.

Claim 5 requires a kilovoltage cone beam radiation source and a megavoltage radiation source and claim 7 requires a megavoltage source to radiate a target volume. The figure above shows both the kV cone beam and MV source are present in the Jaffray 2001 system. Ex. 1003 at Fig. 4; *see also* Ex. 1016 at ¶¶155-156, 165-166. Additionally, Jaffray 2001 refers to the MV source as the treatment beam thus the MV source is used to radiate a target volume with radiation. Ex. 1003 at 804; *see also* Ex. 1016 at ¶165.

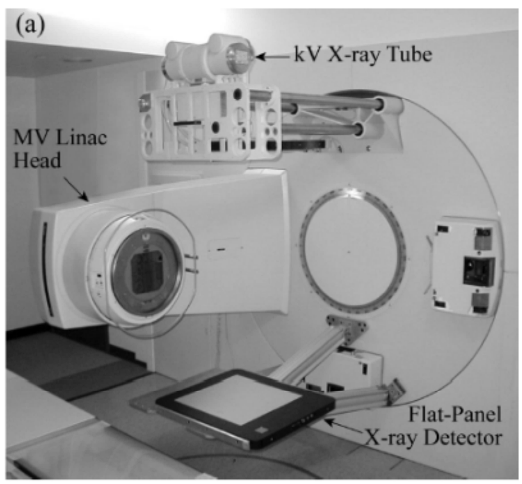
Claim 6 requires that the gantry rotate 360 degrees and claim 61 additionally requires that the rotation be capable of capturing image projection data while continuously rotating about a target volume. The Elekta SL-20 is capable of continuous 360 degree rotation and Jaffray 2001 expressly noted that it could do so while collecting image data: "<u>Multiple radiographs</u> of a 0.8 cm steel ball-bearing (BB) placed near isocenter are <u>acquired as the</u> <u>gantry rotates through 360°</u>." Ex. 1003 at 804 (emphases added). The rotation of the gantry is also continuous, although the speed of rotation can vary, "[t]he angular velocity was found to vary from 1.5˚/sec to 3.0˚/sec through 360˚, excluding periods of accelerations/deceleration at the start and stop of acquisition." *Id*. at 804. *See also*

Ex. 1016 at ¶¶160-161.

The claim chart below shows a detailed analysis of how each of claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 of the '021 Patent is anticipated by Jaffray 2001. For all these reasons, claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 are unpatentable in view of Jaffray 2001 and thus, Petitioner has a reasonable likelihood of prevailing with respect to at least one claim.

'021 Claim Elements	**Jaffray 2001 (Ex. 1003)[3]**
1. An apparatus, comprising [1.a] a radiation treatment system capable of implementing a treatment plan, the system comprising:	"The adaptation of this system to a medical <u>linear accelerator</u> for on-line image-guided radiation therapy demonstrates the suitability of this technology for intra-therapeutic guidance." Ex. 1003 at 800. *See also* Ex. 1016, Hamilton Decl. at ¶¶134-135.
[1.b] a frame;	"The large-area flat-panel imager has been adapted to an isocentric medical <u>linear accelerator</u> equipped with a 600 kHU x-ray tube [Fig. 4(a)]. The x-ray tube is mounted to <u>the drum structure</u> of the accelerator on a retractable arm that extends ~130 cm from the gantry face, allowing the focal spot of the tube to reach the plane occupied by the MV treatment source." Ex. 1003 at 804. *See also* Ex. 1016, Hamilton Decl. at ¶136.
[1.c] a rotatable gantry coupled to the frame;	"The large-area flat-panel imager has been adapted to an isocentric medical linear accelerator equipped with a 600 kHU x-ray tube [Fig. 4(a)]. The x-ray tube is mounted to <u>the drum structure</u> of the accelerator on a

[3] All underlining in the claim charts represents emphasis added.

’021 Claim Elements	Jaffray 2001 (Ex. 1003)[3]
	retractable arm that extends ~130 cm from the gantry face, allowing the focal spot of the tube to reach the plane occupied by the MV treatment source.” Ex. 1003 at 804. “Multiple radiographs of a 0.8 cm steel ball-bearing (BB) placed near isocenter are acquired as the gantry rotates through 360°.” *Id*. *See also* Ex. 1016, Hamilton Decl. at ¶137.
[1.d] a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;	“The x-ray tube is mounted to the drum structure of the accelerator on a retractable arm that extends ~130 cm from the gantry face, allowing the focal spot of the tube to reach the plane occupied by the MV treatment source.” Ex. 1003 at 804.  *Id*. at Fig. 4. *See also* Ex. 1016, Hamilton Decl. at ¶138.
[1.e] a cone-beam radiation source coupled to the rotatable gantry to radiate the patient;	“The large-area flat-panel imager has been adapted to an isocentric medical linear accelerator equipped with a 600 kHU x-ray tube [Fig. 4(a)]. The x-ray tube is mounted to the drum structure of the accelerator on a retractable arm that extends ~130 cm from the gantry face, allowing the focal spot of the tube to reach the plane occupied by the MV treatment source.” Ex. 1003 at 804; *see also* Fig. 4 above.

<table>
<tr><th>’021 Claim Elements</th><th>Jaffray 2001 (Ex. 1003)[3]</th></tr>
<tr><td></td><td>
<table>
<tr><th>kV Imaging Geometry</th><th>Bench Top System</th><th>Gantry-based System</th></tr>
<tr><td>Focal Spot – Isocenter Distance (nominal)</td><td>100.2 cm</td><td>100 cm</td></tr>
<tr><td>Focal Spot – Detector Distance (nominal)</td><td>159.4 cm</td><td>155 cm</td></tr>
<tr><td>Cone Angle</td><td>14.4°</td><td>14.8°</td></tr>
</table>

Id. at 803 (Table II).

See also Ex. 1016, Hamilton Decl. at ¶139.
</td></tr>
<tr><td>[1.f] a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data of the patient from the cone-beam radiation source to generate cone-beam computed tomography (CT) volumetric image data of the patient; and</td><td>
“The large-area flat-panel imager has been adapted to an isocentric medical linear accelerator equipped with a 600 kHU x-ray tube [Fig. 4(a)]. The x-ray tube is mounted to the drum structure of the accelerator on a retractable arm that extends ~130 cm from the gantry face, allowing the focal spot of the tube to reach the plane occupied by the MV treatment source.” Ex. 1003 at 804; see also Fig. 4.

“The adaptation of this system to a medical linear accelerator for on-line image-guided radiation therapy demonstrates the suitability of this technology for intra-therapeutic guidance.” Id. at 800.

“A low-resolution volume (341×341×341 voxels at 0.75 mm voxel pitch) and high-resolution sagittal slice (1024×1024 voxels at 0.25 mm voxel pitch) were reconstructed for presentation and are shown in Fig. 5. The volumetric surface rendering of the reconstruction [Fig. 5(a)] illustrates the large FOV achieved with a single rotation of the gantry in the cone-beam approach.” Id. at 805.

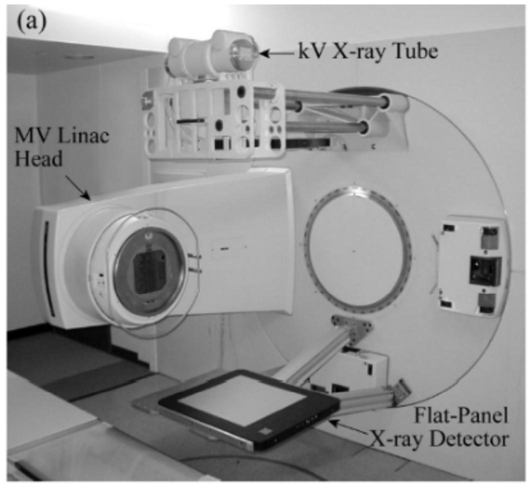
Id. at Fig. 5.

“Cone-beam CT images acquired on the medical linear accelerator. (a) Volumetric rendering of an anthropomorphic head phantom reconstructed [389×389×389 voxels at (0.75 mm)3] from 330 projections acquired over 360° . (b) A single sagittal slice [1×1024×1024 at (0.25mm)3] illustrates the high spatial resolution that can be achieved in the axial
</td></tr>
</table>

'021 Claim Elements	**Jaffray 2001 (Ex. 1003)[3]**
	dimension with the cone-beam approach. The spatial resolution of the system is demonstrated in the magnified sagittal views shown in (c) and (d). It is important to emphasize that the resolution demonstrated here has been achieved on the medical linear accelerator-based system in the presence of geometric non-idealities." *Id*. at 806. *See also* Ex. 1016, Hamilton Decl. at ¶¶141-144.
[1.g]a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager.	"The adaptation of this system to a medical linear accelerator for on-line image-guided radiation therapy demonstrates the suitability of this technology for intra-therapeutic guidance." Ex. 1003 at 800. "In addition to improvements in the detector, the control system has also been improved to allow geometric calibration, image acquisition, processing and reconstruction in an integrated Windows NT-based application. The software runs on a 500 MHz Pentium Xeon processor equipped with 1GB of RAM. A modified Feldkamp cone-beam CT reconstruction algorithm has been implemented that permits reconstruction from projections acquired on nonideal circular trajectories (see Table II)." *Id*. at 801. "X-ray exposure, detector read-out and gantry motion is coordinated using the same Windows-NT based software application as described in Section 3.1. The software application monitors gantry angle through a precision potentiometer, directs x-ray exposure, and collects the resulting projections in host memory." *Id*. at 804. *See also* Ex. 1016, Hamilton Decl. at ¶¶145-146.
4. The apparatus of claim 1, wherein the computing unit generates a three-	"A low-resolution volume (341×341×341 voxels at 0.75 mm voxel pitch) and high-resolution sagittal slice (1024×1024 voxels at 0.25 mm voxel pitch) were reconstructed for presentation and are shown in Fig. 5.

’021 Claim Elements	Jaffray 2001 (Ex. 1003)[3]
dimensional image of a target volume based on the captured image projection data.	The volumetric surface rendering of the reconstruction [Fig. 5(a)] illustrates the large FOV achieved with a single rotation of the gantry in the cone-beam approach.” Ex. 1003 at 805; *see also* Fig. 5. *See also* Ex. 1016, Hamilton Decl. at ¶¶150-151.
5. The apparatus of claim 1, wherein the cone-beam CT radiation source is a kilovoltage radiation source and the high-energy radiation source is a megavoltage radiation source.	“The large-area flat-panel imager has been adapted to an isocentric medical linear accelerator equipped with a <u>600 kHU x-ray tube</u> [Fig. 4(a)]. The x-ray tube is mounted to the drum structure of the accelerator on a retractable arm that extends ~130 cm from the gantry face, allowing the focal spot of the tube to reach the plane occupied by the <u>MV treatment source</u>.” Ex. 1003 at 804. *See also* Ex. 1016, Hamilton Decl. at ¶¶155-156.
6. The apparatus of claim 1, wherein the rotatable gantry is capable of 360 degree rotation.	“Multiple radiographs of a 0.8 cm steel ball-bearing (BB) placed near isocenter are acquired as the <u>gantry rotates through 360°.”</u> Ex. 1003 at 804. “With the head of the phantom suspended off the end of the treatment couch, 321 projections (120 kVp, 25 mA, 0.025 s) were acquired over 183 seconds as the <u>gantry rotated through 360º</u>.” *Id*. at 805. *See also* Ex. 1016, Hamilton Decl. at ¶¶160-161.
7. The apparatus of claim 1, wherein the high-energy source comprises a megavoltage radiation source to radiate a target volume with radiation.	“The large-area flat-panel imager has been adapted to an isocentric medical linear accelerator equipped with a 600 kHU x-ray tube [Fig. 4(a)]. The x-ray tube is mounted to the drum structure of the accelerator on a retractable arm that extends ~130 cm from the gantry face, allowing the focal spot of the tube to reach the plane occupied by the <u>MV treatment source</u>.” Ex. 1003 at 804. *See also* Ex. 1016, Hamilton Decl. at ¶¶165-166.
14. An apparatus, comprising	*See* citations to claim element 1.a above.

'021 Claim Elements	**Jaffray 2001 (Ex. 1003)**[3]
[14.a] a radiation treatment system capable of implementing a treatment plan, the system comprising:	
[14.b] a frame;	*See* citations to claim element 1.b above.
[14.c] a rotatable gantry coupled to the frame;	*See* citations to claim element 1.c above.
[14.d] a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;	*See* citations to claim element 1.d above.
[14.e] a cone-beam radiation source coupled to the rotatable gantry to radiate the patient;	*See* citations to claim element 1.e above.
[14.f] a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data of the patient from the cone-beam radiation source to generate cone-beam computed tomography (CT) volumetric image data of the patient; and	*See* citations to claim element 1.f above.
[14.g] a translatable treatment couch coupled	"With the head of the phantom suspended off the end of the treatment couch, 321 projections (120 kVp, 25

’021 Claim Elements	**Jaffray 2001 (Ex. 1003)**[3]
to the rotatable gantry via a communications network.	mA, 0.025 s) were acquired over 183 seconds as the gantry rotated through 360º.” Ex. 1003 at 805.  *Id*. at Fig. 4. *See also* Ex. 1016, Hamilton Decl. at ¶¶127-128, 176-177.
15. The apparatus of claim 14, wherein the translatable treatment couch is capable of movement in three planes plus angulation.	“With the head of the phantom suspended off the end of the treatment couch, 321 projections (120 kVp, 25 mA, 0.025 s) were acquired over 183 seconds as the gantry rotated through 360º.” Ex. 1003 at 805; *see also* Fig. 4. *See also* Ex. 1016, Hamilton Decl. at ¶¶181-182.
53. An apparatus, comprising [53.a] a clinical radiation treatment system capable of implementing a treatment plan, the system comprising:	*See* citations to claim element 1.a above.
[53.b] a frame;	*See* citations to claim element 1.b above.
[53.c] a rotatable gantry coupled to the frame;	*See* citations to claim element 1.c above.

’021 Claim Elements	**Jaffray 2001 (Ex. 1003)**[3]
[53.d] a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;	*See* citations to claim element 1.d above.
[53.e] a cone-beam radiation source coupled to the rotatable gantry to radiate the patient; and	*See* citations to claim element 1.e above.
[53.f] a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager captures fluoroscopic or cone-beam CT imaging image projection data of the patient from the cone-beam radiation source to generate fluoroscopic or cone-beam computed tomography (CT) volumetric image data of the patient.	*See* citations to claim element 1.f above.
60. The apparatus of claim 53, further comprising a translatable treatment couch coupled to the rotatable gantry via a communications network, wherein the translatable treatment couch is capable of movement in three	“With the head of the phantom suspended off the end of the treatment couch, 321 projections (120 kVp, 25 mA, 0.025 s) were acquired over 183 seconds as the gantry rotated through 360º.” Ex. 1003 at 805; *see also* Fig. 4. *See also* Ex. 1016, Hamilton Decl. at ¶¶127-128, 195-197.

’021 Claim Elements	Jaffray 2001 (Ex. 1003)[3]
planes plus angulation.	
61. The apparatus of claim 53, wherein the rotatable gantry is capable of 360 degree rotation and the imager is capable of capturing image projection data while continuously rotating about a target volume.	“Multiple radiographs of a 0.8 cm steel ball-bearing (BB) placed near isocenter are acquired as the gantry rotates through 360°.” Ex. 1003 at 804. “With the head of the phantom suspended off the end of the treatment couch, 321 projections (120 kVp, 25 mA, 0.025 s) were acquired over 183 seconds as the gantry rotated through 360º.” *Id*. at 805. “Unfortunately, the control system for gantry rotation does not fully compensate for the mechanical imbalance, resulting in substantial variations in angular velocity with gantry angle. The angular velocity was found to vary from 1.5˚/sec to 3.0˚/sec through 360˚, excluding periods of accelerations/deceleration at the start and stop of acquisition.” *Id*. at 804. *See also* Ex. 1016, Hamilton Decl. at ¶¶200-202.

B. Ground 2: Jaffray 2001 Renders Obvious Claims 1, 4, 5, 6, 7, 14, 15, 53, 60 and 61

Jaffray 2001 discloses all of the limitations of claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 as discussed above in Ground 1 and as shown in the claim chart therein. To the extent it is argued that Jaffray 2001 does not explicitly or inherently disclose a translatable treatment couch moveable in three planes plus angulation and coupled to the gantry via a communications network, it would have been obvious to one of skill in the art at the time of the ’021 Patent because, by 1981, it was standard to use a translatable treatment couch moveable in three planes plus angulation and coupled to the gantry via a communications network on a linear accelerator. *See* Ex. 1016 at ¶36; *see also* Ex. 1015 at 220; Ex. 1010 at 1, 2, 12, 39-48. And, the linear accelerator depicted in Jaffray 2001 is the Elekta SL20, which had a couch translatable in three planes and capable of angulation and coupled to the gantry via a communications network. *Id*. at ¶128. Furthermore, nothing in Jaffray 2001 suggests using a non-standard couch. *Id*. Accordingly, it would have been obvious to use a treatment couch that is capable of movement in three directions plus angulation and coupled to the gantry via a communications network in the linear accelerator system of Jaffray 2001. *Id*. at ¶¶205-206.

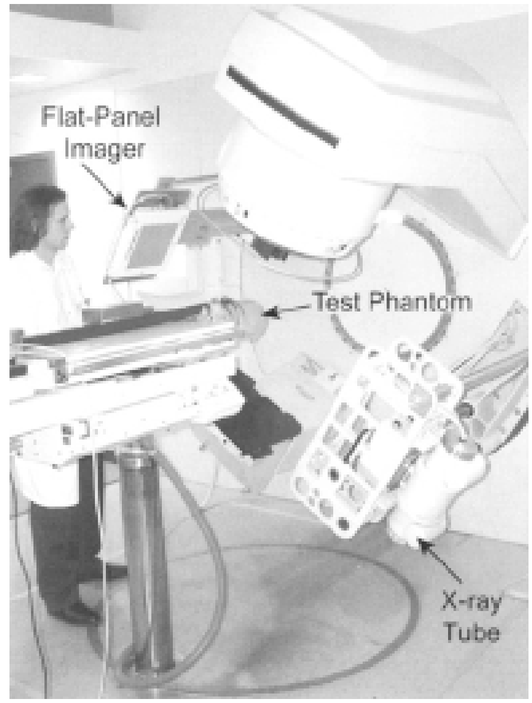
To the extent it is argued that Jaffray 2001 does not explicitly or inherently disclose a computing unit to capture and store the image projection data, it would have been obvious to one of skill in the art at the time of the ’021 Patent. *Id*. at ¶207. In order to process the image projection data to generate volumetric images, it is necessary to store the image projection data in the computer which will process the data. *Id*. at ¶207.

Therefore, claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 would have been obvious to a person of ordinary skill in the art in view of Jaffray 2001.

C. Ground 3: Jaffray 2000 Anticipates Claims 1, 4, 5, 6, 7, 14, 15, 53, 60 and 61

Jaffray 2000 anticipates claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 because Jaffray 2000 discloses a system embodying all of the elements of these claims.

As reflected in its title, Jaffray 2000 describes a linear accelerator to which a flat panel imager and a kV radiation source have been added in order to do cone-beam CT imaging on the linear accelerator. Ex. 1005 at 558. This can be seen in the figure on the right. Ex. 1005 at 559, Fig. 3. Fig. 3 is described as a "[p]hotograph of the prototype FPI-based CBCT system implemented on a medical linear accelerator (Elekta SL-20)." *Id*. at 559, Fig. 3 caption.



As required by claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61, the linear accelerator used by Jaffray 2000 was the Elekta SL-20, which has a gantry rotatably mounted on a frame, has a treatment couch that can be angulated and translated in three planes, and a computing unit coupled to the gantry via a communications network. Ex. 1005 at 558, 559, Fig. 3 caption; *see also* Ex. 1016 at ¶128. The flat panel imager is the one described in Jaffray SPIE 1999, which was incorporated by reference in Jaffray 2000 for its description of the flat panel imager. Ex. 1005 at 558 (citing reference [2], Ex. 1008). "[T]<u>the transfer of the flat-panel imager to a medical linear accelerator for CBCT is described</u>. . . . A system was constructed to measure the CT imaging performance that could be achieved with a detector based upon flat-panel imaging technology. This system is described in detail elsewhere.[2]" Ex. 1005 at 558 (emphases added).

Further, as explained in Jaffray 2000, the kV radiation source and the flat panel imager were used to create cone beam CT images. *See* Ex. 1005 at 558, 560, Fig. 5; *see also* Ex. 1016 at ¶226. Moreover, as required by claims 1, 4, 14, and 53, the images created are 3D volumetric cone beam images created based on the captured image projection data:

> CBCT image of the contrast phantom as acquired on the kV imaging system implemented on the medical linear accelerator. This image was reconstructed using the estimates for mechanical flex acquired with scans of the reference BB, as described above. The voxels in this image are 0.25 x 0.25 x 3 mm3 . The image was produced from 427 projections (100 kVp, 204 mAs of total charge,—1300 mR in-air on the axis of rotation) over 360°. . . .

Ex. 1005 at 560 (Fig. 5 caption) (emphasis added). *See also* Ex. 1016 at ¶¶232-234.

Claims 14, 15, and 60 additionally require a conventional translatable treatment couch coupled to the gantry via a communications network that can be angulated and moved in three planes. The linear accelerator used in Jaffray 2000 is an Elekta SL-20 which, like any standard linear accelerator has a translatable couch coupled to the gantry via a communications network and capable of movement in three planes plus angulation. *See* Ex. 1005 at Fig. 3; Ex. 1010 at 1, 2, 12, 39-48; Ex. 1015at 220; Ex. 1016 at ¶¶127-128, 259-260.

Claim 1 also requires a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager. Jaffray SPIE 1999 explains this feature of the imaging system noting that the "[r]adiographic exposures used in the scanning procedure are produced under computer control" and that "[t]he values are transferred via an RS-422 bus to a hardware buffer in the host computer. The processor on the host computer is interrupted when a complete frame is ready for transfer to host memory." Ex. 1008 at 205; *see also* Ex. 1016 at ¶227. Transferring image data via an RS-422 bus, a technical standard for a communication network, is a transfer over a communications network. *Id*.

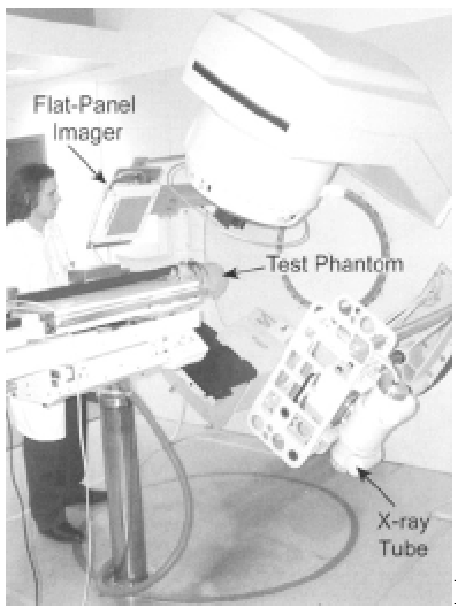
Claim 5 requires a kilovoltage cone beam radiation source and a megavoltage radiation source and claim 7 requires a megavoltage source to radiate a target volume. The figure above shows both the kV cone beam and MV source are present in the Jaffray 2000 system—the kV source is labeled as the "X-ray tube" and the MV source is the treatment beam of the linear accelerator. Ex. 1005 at Fig. 3; *see also* Ex. 1016 at ¶¶238-239. Additionally, Jaffray JRO 1999, incorporated by reference into Jaffray 2000 for its description of the linear accelerator (Ex. 1005 at 558 (citing reference [1])), refers to the MV source as the treatment beam. Thus, the MV source is used to radiate a target volume with radiation. Ex. 1007 at 774; *see also* Ex. 1016 at ¶¶220-221, 248.

Claim 6 requires that the gantry rotate 360 degrees and claim 61 additionally requires that the rotation be capable of capturing image projection data while continuously rotating about a target volume. The Elekta SL-20 is capable of continuous 360 degree rotation and Jaffray 2000 expressly noted that it could do so while collecting image data: "A total of 500 projection images were acquired over a 360° rotation at 100 kVp (0.625 mAs per projection)." Ex. 1005 at 558 (emphases added). The rotation of the gantry is also continuous: "The accelerator gantry rotates continuously at a relatively low speed (~30°/min) with the control system monitoring the gantry angle." Ex. 1007 at 779.

The claim chart below shows a detailed analysis of how each of claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 of the '021 Patent is anticipated by Jaffray 2000. For all these reasons, claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 are unpatentable in view of Jaffray 2000 and thus, Petitioner has a reasonable likelihood of prevailing with respect to at least one claim.

'021 Claim Elements	**Ex. 1005 and Ex. 1007 and Ex. 1008**
1. An apparatus, comprising [1.a] a radiation treatment system	"Figure 3. Photograph of the prototype FPI-based CBCT system implemented on a medical linear accelerator (Elekta SL-20)." Ex. 1005 at 559.

'021 Claim Elements	**Ex. 1005 and Ex. 1007 and Ex. 1008**
capable of implementing a treatment plan, the system comprising:	"Furthermore, such a system must also be capable of producing multiple images over the course of treatment — preferably with the patient in treatment position. In this report, an approach based upon cone-beam CT (CBCT) is employed to acquire on-line volumetric CT images in the reference frame of the treatment machine. In previous reports, the development of the cone-beam method has been described for a CCD-based kV imaging system integrated onto a <u>medical linear accelerator</u>.[1] Subsequent investigation were performed using a more efficient detector based-upon an amorphous silicon flat-panel imager. These investigations were performed on a test-bed and demonstrate the CT imaging performance that can be achieved with these detectors. [2] In this article, recent results of our investigations using the test-bed are reported and the transfer of the flat-panel imager to a medical linear accelerator for CBCT is described" Ex. 1005 at 558. "Gantry rotation can be performed either by hand-pendant from behind a shield or through the assisted motion features of the <u>SL20 accelerator</u>." *Id*. at 559. "Photograph of the prototype FPI-based CBCT systems implemented on a medical linear accelerator (Elekta SL-20)." *Id*. at 559 (Fig. 3 caption). **<u>Ex. 1007</u>** "Two fluoroscopic imager assemblies are attached to the accelerator; one detects the megavoltage (MV) treatment beam, the other detects the kV beam projected at 90° to the treatment beam axis. An <u>Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator</u> forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based

'021 Claim Elements	**Ex. 1005 and Ex. 1007 and Ex. 1008**
	accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d)." Ex. 1007 at 774. *See also* Ex. 1016, Hamilton Decl. at ¶215.
[1.b] a frame;	"Gantry rotation can be performed either by hand-pendant from behind a shield or through the assisted motion features of the <u>SL20 accelerator</u>." Ex. 1005 at 559. Ex. 1005 at Fig. 3. *See also* Ex. 1016, Hamilton Decl. at ¶217.
[1.c] a rotatable gantry coupled to the frame;	"<u>Gantry rotation</u> can be performed either by hand-pendant from behind a shield or through the assisted motion features of the <u>SL20 accelerator</u>." Ex. 1005 at 559. *See also* Ex. 1016, Hamilton Decl. at ¶219.
[1.d] a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;	"Figure 3. Photograph of the prototype FPI-based CBCT system implemented on a medical linear accelerator (Elekta SL-20)." Ex. 1005 at 559. **<u>Ex. 1007</u>** "Two fluoroscopic imager assemblies are attached to the accelerator; one detects <u>the megavoltage (MV) treatment beam</u>, the other detects the kV beam

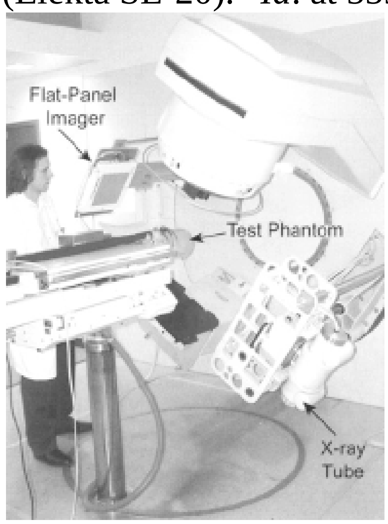
'021 Claim Elements	**Ex. 1005 and Ex. 1007 and Ex. 1008**
	projected at 90° to the treatment beam axis. An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d)." Ex. 1007 at 774. *See also* Ex. 1016, Hamilton Decl. at ¶220.
[1.e] a cone-beam radiation source coupled to the rotatable gantry to radiate the patient;	"In this report, an approach based upon cone-beam CT (CBCT) is employed to acquire on-line volumetric CT images in the reference frame of the treatment machine. In previous reports, the development of the cone-beam method has been described for a CCD-based kV imaging system integrated onto a medical linear accelerator.[1] . . . In this article, recent results of our investigations using the test-bed are reported and the transfer of the flat-panel imager to a medical linear accelerator for CBCT is described." Ex. 1005 at 558; *see also* Fig. 3. *See also* Ex. 1016, Hamilton Decl. at ¶222.
[1.f] a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data of the patient from the cone-beam radiation source to generate cone-beam computed tomography (CT) volumetric image data of the patient; and	"In this report, an approach based upon cone-beam CT (CBCT) is employed to acquire on-line volumetric CT images in the reference frame of the treatment machine. In previous reports, the development of the cone-beam method has been described for a CCD-based kV imaging system integrated onto a medical linear accelerator.[1] Subsequent investigation were performed using a more efficient detector based-upon an amorphous silicon flat-panel imager. . . . In this article, recent reports of our investigations using the test-bed are reported and the transfer of the flat-panel imager to a medical linear accelerator for CBCT is described." Ex. 1005 at 558. "The flat- panel imager employed in the investigations

’021 Claim Elements	**Ex. 1005 and Ex. 1007 and Ex. 1008**
	described above was transferred to an Elekta SL20 that is equipped with a kilovoltage x-ray source (Figure 3).” *Id*. at 559. *See also*, Ex. 1005 Fig. 3 above. *See also* Ex. 1016, Hamilton Decl. at ¶¶224-225.
[1.g]a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager.	“A system was constructed to measure the CT imaging performance that could be achieved with a detector based upon flat-panel imaging technology. This system is described in detail elsewhere.[2]” Ex. 1005 at 558. **<u>Ex. 1008</u>** “Radiographic exposures used in the scanning procedure are produced under <u>computer control</u> with a 300 kHU x-ray tube (General Electric Maxi-ray 75) and a 100 kW generator (General Electric MSI-800). The tube has a total minimum Radiographic exposures used in the scanning procedure are produced under computer control with a 300 ki-IU x-ray tube (General Electric Maxi-ray 75) and a 100 kW generator (General Electric MSI-800). The tube has a total minimum.” Ex. 1008 at 205. “The FPI used in these investigations was manufactured by EG&G Heimann (RID 512-400 A0) and is comprised of a 512 x 512 array of a-Si:H photodiodes and thin-film transistors. The electro-mechanical characteristics of the imager are shown in Table I. The array is read out at one of eight preset frame rates (up to 5 frames per second) and operates asynchronously of the host computer. The analog signal from each pixel is integrated by ASIC amplifiers featuring correlated double-sampling noise reduction circuitry. Digitization is performed at 16 bit resolution. <u>The values are transferred via an RS-422 bus to a hardware buffer in the host computer. The processor on the host computer is interrupted when a complete frame is ready for transfer to host memory</u>.”

'021 Claim Elements	**Ex. 1005 and Ex. 1007 and Ex. 1008**
	Id. *See also* Ex. 1016, Hamilton Decl. at ¶227.
4. The apparatus of claim 1, wherein the computing unit generates a three-dimensional image of a target volume based on the captured image projection data.	"Figure 5. CBCT image of the contrast phantom as acquired on the kV imaging system implemented on the medical linear accelerator. This image was reconstructed using the estimates for mechanical flex acquired with scans of the reference BB, as described above. The voxels in this image are 0.25 x 0.25 x 3 mm3 . The image was produced from 427 projections (100 kVp, 204 mAs of total charge,—1300 mR in-air on the axis of rotation) over 360°. . . ." Ex. 1005 at 560 (Fig. 5 caption) "A system was constructed to measure the CT imaging performance that could be achieved with a detector based upon flat-panel imaging technology. This system is described in detail elsewhere.[2]" *Id*. at 558. **Ex. 1008** "The visibility of soft-tissue structures in CBCT images is illustrated in images of a rat. (a) Axial, (h) coronal, and (c) sagittal slices of the image data set, with the kidney indicated in each case by an arrow (d) Volume rendering of the fully three-dimensional data set, with the skeleton rendered above a portion of the volume." Ex. 1008 at 212 (Fig. 6 caption). *Id*. at Fig. 6. *See also* Ex. 1016, Hamilton Decl. at ¶232-234.
5. The apparatus of claim 1, wherein the cone-beam CT radiation source is a kilovoltage radiation source and the high-energy radiation source is a megavoltage radiation source.	"In previous reports, the development of the cone-beam method has been described for a CCD-based kV imaging system integrated onto a medical linear accelerator.[1]." Ex. 1005 at 558. "The flat-panel imager employed in the investigations described above was transferred to an Elekta SL20 that is equipped with a kilovoltage x-ray source (Figure

’021 Claim Elements	**Ex. 1005 and Ex. 1007 and Ex. 1008**
	3).” *Id*. at 559. **Ex. 1007** “Two fluoroscopic imager assemblies are attached to the accelerator; one detects the megavoltage (MV) treatment beam, the other detects the kV beam projected at 90° to the treatment beam axis. An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d).” Ex. 1007 at 774. *See also* Ex. 1016, Hamilton Decl. at ¶238.
6. The apparatus of claim 1, wherein the rotatable gantry is capable of 360 degree rotation.	“A total of 500 projection images were acquired over a 360° rotation at 100 kVp (0.625 mAs per projection).” Ex. 1005 at 559. *See also* Ex. 1016, Hamilton Decl. at ¶243.
7. The apparatus of claim 1, wherein the high-energy source comprises a megavoltage radiation source to radiate a target volume with radiation.	“Figure 3. Photograph of the prototype FPI-based CBCT system implemented on a medical linear accelerator (Elekta SL-20).” Ex. 1005 at 559. “In previous reports, the development of the cone-beam method has been described for a CCD-based kV imaging system integrated onto a medical linear accelerator.[1].” Ex. 1005 at 558. **Ex. 1007** “Two fluoroscopic imager assemblies are attached to the accelerator; one detects the megavoltage (MV) treatment beam, the other detects the kV beam projected at 90° to the treatment beam axis. An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and

’021 Claim Elements	Ex. 1005 and Ex. 1007 and Ex. 1008
	18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d).” Ex. 1007 at 774. *See also* Ex. 1016, Hamilton Decl. at ¶248.
14. An apparatus, comprising [14.a] a radiation treatment system capable of implementing a treatment plan, the system comprising:	*See* citations to claim element 1.a above.
[14.b] a frame;	*See* citations to claim element 1.b above.
[14.c] a rotatable gantry coupled to the frame;	*See* citations to claim element 1.c above.
[14.d] a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;	*See* citations to claim element 1.d above.
[14.e] a cone-beam radiation source coupled to the rotatable gantry to radiate the patient;	*See* citations to claim element 1.e above.
[14.f] a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data of the patient from the cone-beam radiation source	*See* citations to claim element 1.f above.

'021 Claim Elements	**Ex. 1005 and Ex. 1007 and Ex. 1008**
to generate cone-beam computed tomography (CT) volumetric image data of the patient; and	
[14.g] a translatable treatment couch coupled to the rotatable gantry via a communications network.	"In previous reports, the development of the cone-beam method has been described for a CCD-based kV imaging system integrated onto a medical linear accelerator.[1] Subsequent investigation were performed using a more efficient detector based-upon an amorphous silicon flat-panel imager." Ex. 1005 at 558. "Gantry rotation can be performed either by hand-pendant from behind a shield or through the assisted motion features of the SL20 accelerator." *Id*. at 559. "Photograph of the prototype FPI-based CBCT systems implemented on a medical linear accelerator (Elekta SL-20)." *Id*. at 559 (Fig. 3 caption).  *Id*. at Fig. 3. *See also* Ex. 1016, Hamilton Decl. at ¶¶259-260.
15. The apparatus of claim 14, wherein the translatable treatment couch is capable of movement in three	"In previous reports, the development of the cone-beam method has been described for a CCD-based kV imaging system integrated onto a medical linear accelerator.[1] Subsequent investigation were performed using a more efficient detector based-upon

’021 Claim Elements	Ex. 1005 and Ex. 1007 and Ex. 1008
planes plus angulation.	an amorphous silicon flat-panel imager.” Ex. 1005 at 558. “Gantry rotation can be performed either by hand-pendant from behind a shield or through the assisted motion features of the SL20 accelerator.” *Id*. at 559. “Photograph of the prototype FPI-based CBCT systems implemented on a medical linear accelerator (Elekta SL-20).” *Id*. at 559 (Fig. 3 caption); *see also* Fig. 3. *See also* Ex. 1016, Hamilton Decl. at ¶265.
53. An apparatus, comprising [53.a] a clinical radiation treatment system capable of implementing a treatment plan, the system comprising:	*See* citations to claim element 1.a above.
[53.b] a frame;	*See* citations to claim element 1.b above.
[53.c] a rotatable gantry coupled to the frame;	*See* citations to claim element 1.c above.
[53.d] a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;	*See* citations to claim element 1.d above.
[53.e] a cone-beam radiation source coupled to the rotatable gantry to radiate the patient; and	*See* citations to claim element 1.e above.
[53.f] a flat-panel imager coupled to the rotatable gantry,	*See* citations to claim element 1.f above.

’021 Claim Elements	**Ex. 1005 and Ex. 1007 and Ex. 1008**
wherein the flat-panel imager captures fluoroscopic or cone-beam CT imaging image projection data of the patient from the cone-beam radiation source to generate fluoroscopic or cone-beam computed tomography (CT) volumetric image data of the patient.	
60. The apparatus of claim 53, further comprising a translatable treatment couch coupled to the rotatable gantry via a communications network, wherein the translatable treatment couch is capable of movement in three planes plus angulation.	“In previous reports, the development of the cone-beam method has been described for a CCD-based <u>kV imaging system</u> <u>integrated onto a medical linear accelerator.[1]</u> Subsequent investigation were performed using a more efficient detector based-upon an amorphous silicon flat-panel imager.” Ex. 1005 at 558. “Gantry rotation can be performed either by hand-pendant from behind a shield or through the assisted motion features of the <u>SL20 accelerator</u>.” *Id*. at 559. “Photograph of the prototype FPI-based CBCT systems implemented on a medical linear accelerator (Elekta SL-20).” *Id*. at 559 (Fig. 3 caption); *see also* Fig. 3. *See also* Ex. 1016, Hamilton Decl. at ¶¶279-281.
61. The apparatus of claim 53, wherein the rotatable gantry is capable of 360 degree rotation and the imager is capable of capturing image projection data while continuously	“A total of 500 projection images were acquired over a <u>360° rotation</u> at 100 kVp (0.625 mAs per projection).” Ex. 1005 at 559. **<u>Ex. 1007</u>** “To generate a CB-CT dataset, a series of radiographic exposures are acquired at regular angular intervals as the <u>accelerator gantry is rotated through a specified</u>

’021 Claim Elements	Ex. 1005 and Ex. 1007 and Ex. 1008
rotating about a target volume.	range (typically 180° or 360°). The control system operates the camera’s shutter and read-out mechanisms in synchrony with the firing of the x-ray generator; these operations are slaved to the accelerator’s gantry angle.” Ex. 1007 at 779. “The accelerator gantry rotates continuously at a relatively low speed (~30°/min) with the control system monitoring the gantry angle.” *Id*. *See also* Ex. 1016, Hamilton Decl. at ¶¶285-286.

D. Ground 4: Jaffray 2000 In View of Jaffray JRO 1999 And Jaffray SPIE 1999 Renders Obvious Claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61

Jaffray 2000 discloses all of the limitations of claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 as discussed above in Ground 3 and as shown in the claim chart therein. To the extent it is argued that Jaffray JRO 1999 and Jaffray SPIE 1999 are not expressly incorporated by reference, it would have been obvious to one of ordinary skill in the art to combine Jaffray 2000 with Jaffray JRO 1999 and Jaffray SPIE 1999. *See* Ex. 1016 at ¶¶289-292. To a person of ordinary skill in the art, the series of Jaffray articles is describing the evolution of a single system. *Id*. at ¶289. While one article may focus on operation of a specific aspect of that system, the person of skill in the art would understand that the teachings in other articles concerning other aspects of the system remain part of the system. Indeed, Jaffray 2000 directly provides a motivation to combine teachings of his articles by stating that details of the flat-panel imaging system are described in reference 2, which is

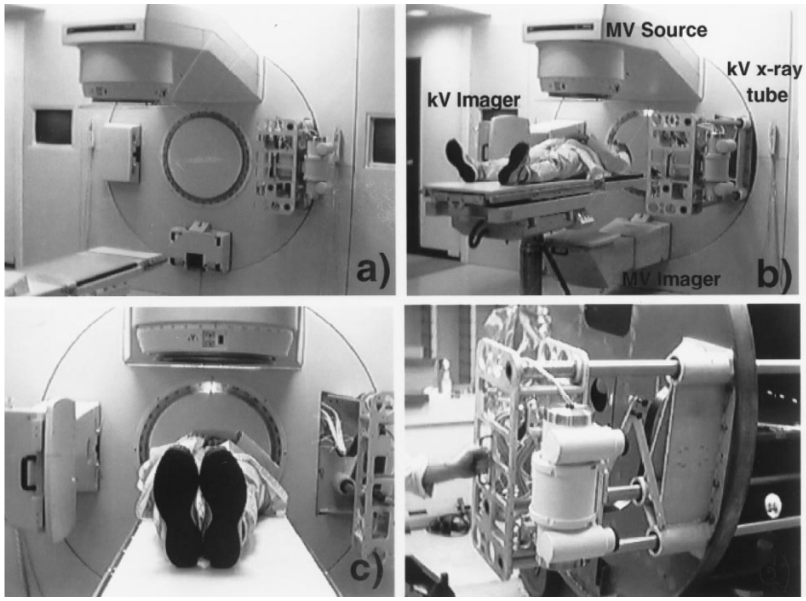
Jaffray SPIE 1999, and by teaching that he is transferring that imager to the Elekta SL-20 linear accelerator system used in prior work with a CCD imager described in reference 1, which is Jaffray JRO 1999. Ex. 1005 at 558; *see also* Ex. 1016 at ¶289.

In addition, the references in Jaffray 2000 to linear accelerators generally, and to the Elekta SL-20 specifically, disclose to a person of skill in the art the standard features of a linear accelerator, including its rotatable gantry on a frame, megavoltage treatment source, treatment couch capable of translatable movement and angulation and operation via communications network. Ex. 1005 at 558, 559, Fig. 3; *see also* Ex. 1015 at 220; Ex. 1016 at ¶¶290-291. It would therefore be obvious to a person of skill in the art that the system disclosed in Jaffray 2000 has these standard features.

E. Ground 5: Jaffray June 2000 In View of Jaffray JRO 1999 Renders Obvious Claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61

Claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 are obvious over Jaffray June 2000 in view of Jaffray JRO 1999. As discussed above in Section IV.C, the Examiner's §103 rejections did not rely solely on patents in the radiation treatment field, but rather involved combinations from the imaging field with references from the radiation treatment field. Ex. 1016 at ¶¶108-110. While references disclosing using flat panel cone-beam CT in the radiation treatment field were of record in the '021 prosecution, the Examiner never considered such a combination. Below is such a combination where Jaffray teaches implementing a flat panel cone beam imager system on the linear accelerator disclosed in one of his prior publications.

Jaffray June 2000 involves investigation of a flat panel imaging system "for use in the guidance of radiation therapy on a medical linear accelerator." Ex. 1009 at 1321. According to Jaffray June 2000 "the development of a kV cone-beam CT imaging system for on-line tomographic guidance was reported. [8] The system consisted of a kV x-ray tube and a radiographic detector mounted on the gantry of a medical linear accelerator." Ex. 1009 at 1311. Jaffray June 2000 states that flat panel imaging offers "an ideal replacement for the CCD-based imager" in the prior system. *Id*. at 1312. Reference [8], which Jaffray June 2000 indicates describes the CCD-based prior system, is Jaffray JRO 1999. Jaffray JRO 1999 expressly states that the linear accelerator he discloses is the Elekta SL20. Ex. 1007 at 774. The Elekta SL20, which is depicted in Fig. 1 below has a rotatable gantry supported on a frame, a high energy (MV) radiation source, and a kV cone beam radiation source as required by claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61. Ex. 1007 at Fig. 1; see also Ex. 1015; Ex. 1016 at ¶¶127-128.



Jaffray June 2000 also teaches integrating a flat panel imager on the Elekta SL20: "an imaging system based on this technology will be installed on a conventional radiotherapy linear accelerator in our clinic for application to image-guided radiation therapy." Ex. 1009 at 1312. Therefore, it would have been obvious to one of ordinary skill in the art to implement a flat panel imager and kV radiation source on the Elekta SL20 medical linear accelerator disclosed in Jaffray JRO 1999 for cone beam CT. One of skill in the art would understand that the flat panel imager disclosed in Jaffray June 2000 is the imaging technology that Jaffray June 2000 states will be installed into the conventional radiotherapy linear accelerator, the SL20 described in Jaffray JRO 1999. Ex. 1016 at ¶¶294-298. Finally, Jaffray June 2000 explains the motivation for incorporating the flat panel imaging technology into the Elekta SL20 linear accelerator. *See* Ex. 1009 at 1322

("The results of the investigation suggest that this is significant potential for use of these detectors in CBCT systems for radiotherapy . . . ."); Ex. 1016 at ¶299.

Further, as explained in Jaffray June 2000, the kV radiation source and the flat panel imager were used to create cone beam CT images. *See* Ex. 1009 at 1319, Fig. 9 caption. Moreover, as required by claims 1, 4, 14, and 53, the images created are 3D volumetric cone beam images created based on the captured image projection data because Jaffray June 2000 notes that "[v]oxel size in each case is 0.25X0.25X0.25 mm3, and the vertical scale in the images shows 1 cm spacing." *See* Ex. 1009 at 1319, Fig. 9 caption (emphasis added).

Claims 14, 15, and 60 additionally require a conventional translatable treatment couch coupled to the gantry via a communications network that can be angulated and moved in three planes. The linear accelerator incorporated into Jaffray June 2000 is an Elekta SL-20 which, like any standard linear accelerator has a translatable couch coupled to the gantry via a communications network and capable of movement in three planes plus angulation. *See* Ex. 1007 at Fig. 1; Ex. 1010 at 1, 2, 12, 39-48; Ex. 1016 at ¶¶127-128, 356-359.

Claim 1 also requires that the image data generated by the system is communicated via a communications network to a computer for storage. Jaffray June 2000 discloses this feature noting that in his system "[t]he values are transferred via an RS-422 bus to a hardware buffer in the host computer. The processor on the host computer is interrupted when a complete frame is ready for transfer to host memory" and that "[e]ach projection image is written to hard disk between frame transfer and motor rotation." Ex. 1009 at 1313, 1314 (emphases added); *see also* Ex. 1016 at ¶¶320-321. Transferring image data via an RS-422 bus, a technical standard for a communication network, is a transfer over a communications network. *Id*.

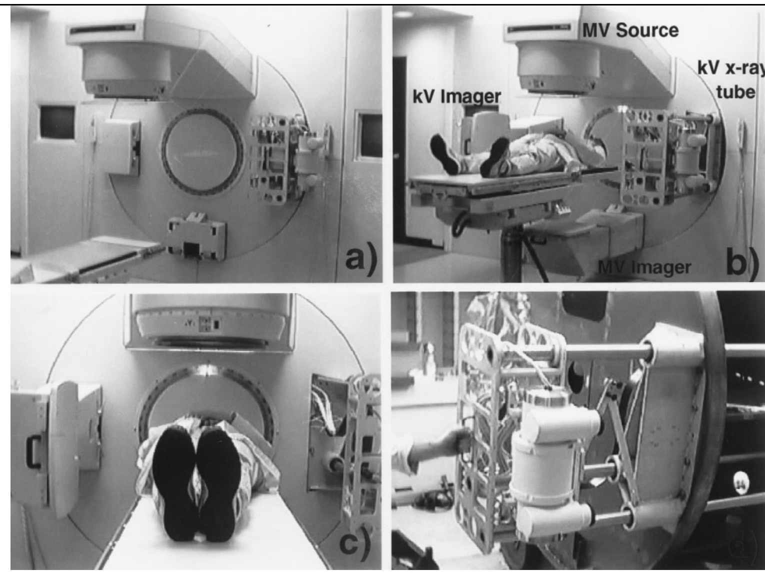
Claim 5 requires a kilovoltage cone beam radiation source and a megavoltage radiation source and claim 7 requires a megavoltage source to radiate a target volume. Figure 1 above shows both the kV cone beam and MV source are present in the Jaffray June 2000 system. Ex. 1007 at Fig. 1; Ex. 1009 at 1311, 1313 (table I); *see also* Ex. 1016 at ¶¶333-336. Additionally, Jaffray JRO 1999 refers to the MV source as the treatment beam thus the MV source is used to radiate a target volume with radiation. Ex. 1007 at 774; *see also* Ex. 1016 at ¶335.

Claim 6 requires that the gantry rotate 360 degrees and claim 61 additionally requires that the rotation be capable of capturing image projection data while continuously rotating about a target volume. The Elekta SL-20 is capable of continuous 360 degree rotation and Jaffray JRO 1999 expressly noted that it could do so while collecting image data: "To generate a CB-CT dataset, a series of radiographic exposures are acquired at regular angular intervals as the accelerator gantry is rotated through a specified range (typically 180° or 360°).." Ex. 1007 at

779 (emphases added). The rotation of the gantry is also continuous: "The accelerator gantry rotates continuously at a relatively low speed (~30°/min) with the control system monitoring the gantry angle." Ex. 1007 at 779 (emphasis added).

The claim chart below shows a detailed analysis of how each of claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 of the '021 Patent is made obvious by Jaffray June 2000. For all these reasons, claims 1, 4, 5, 6, 7, 14, 15, 53, 60, and 61 are unpatentable in view of Jaffray June 2000 and thus, Petitioner has a reasonable likelihood of prevailing with respect to at least one claim.

'021 Claim Elements	**Ex. 1009 and Ex. 1007**
1. An apparatus, comprising [1.a] a radiation treatment system capable of implementing a treatment plan, the system comprising:	"In a previous article, the development of a kV cone-beam CT imaging system for on-line tomographic guidance was reported.[8] The system consisted of a kV x-ray tube and a radiographic detector mounted on the gantry of a medical linear accelerator." Ex. 1009 at 1311. "Ultimately, an imaging system based on this technology will be installed on a conventional radiotherapy linear accelerator." *Id*. at 1312. **Ex. 1007** "An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d)." Ex. 1007 at 774.

’021 Claim Elements	Ex. 1009 and Ex. 1007
	 *See also* Ex. 1016, Hamilton Decl. at ¶302.
[1.b] a frame;	“In a previous article, the development of a kV cone-beam CT imaging system for on-line tomographic guidance was reported. [8] The system consisted of a kV x-ray tube and a radiographic detector mounted on the gantry of a medical linear accelerator.” Ex. 1009 at 1311. **Ex. 1007** “An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d).” Ex. 1007 at 774; *see also* Fig. 1 above. *See also* Ex. 1016, Hamilton Decl. at ¶¶303-305.
[1.c] a rotatable gantry coupled to the frame;	“In a previous article, the development of a kV cone-beam CT imaging system for on-line tomographic guidance was reported. [8] The system consisted of a kV x-ray tube and a radiographic detector mounted on the gantry of a medical linear accelerator.” Ex. 1009 at 1311.

’021 Claim Elements	**Ex. 1009 and Ex. 1007**
	Ex. 1007 “An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d).” Ex. 1007 at 774; *see also* Fig. 1 above. *See also* Ex. 1016, Hamilton Decl. at ¶306.
[1.d] a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;	“In a previous article, the development of a kV cone-beam CT imaging system for on-line tomographic guidance was reported. [8] The system consisted of a kV x-ray tube and a radiographic detector mounted on the gantry of a medical linear accelerator.” Ex. 1009 at 1311. **Ex. 1007** “Two fluoroscopic imager assemblies are attached to the accelerator; one detects the megavoltage (MV) treatment beam, the other detects the kV beam projected at 90° to the treatment beam axis. An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d).” Ex. 1007 at 774. *See also* Ex. 1016, Hamilton Decl. at ¶¶308-309.
[1.e] a cone-beam radiation source coupled to the rotatable gantry to radiate the patient;	“cone angle 7.1°” Ex. 1009 at 1313 (Table I). “In a previous article, the development of a kV cone-beam CT imaging system for on-line tomographic guidance was reported. [8] The system consisted of a kV x-ray tube and a radiographic detector mounted on

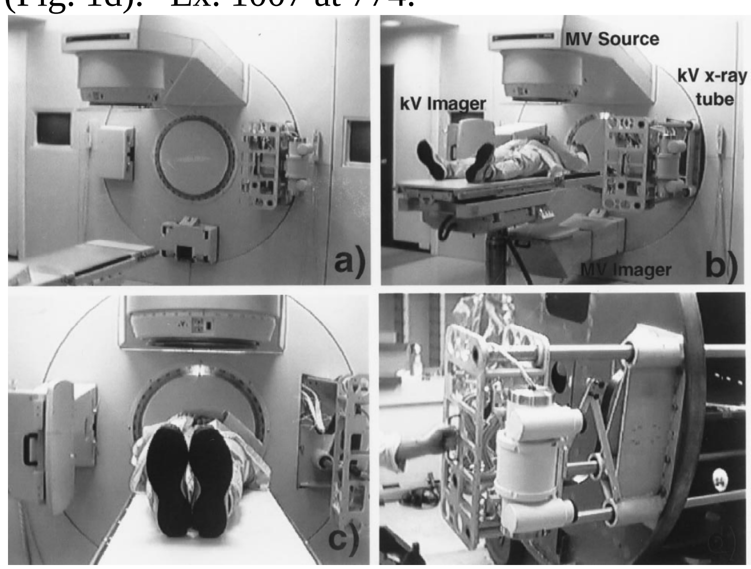
'021 Claim Elements	**Ex. 1009 and Ex. 1007**
	the gantry of a medical linear accelerator." Ex. 1009 at 1311. **Ex. 1007** "An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d)." Ex. 1007 at 774; *see also* Fig. 1 above. *See also* Ex. 1016, Hamilton Decl. at ¶¶310-311.
[1.f] a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data of the patient from the cone-beam radiation source to generate cone-beam computed tomography (CT) volumetric image data of the patient; and	"Recently developed flat-panel imaging technology offers an ideal replacement for the CCD-based imager. This technology is based upon thin-film hydrogenated amorphous silicon (a-Si:H) electronics fabricated on large area panels (e.g., —40X40 cm2). A two-dimensional matrix of a-Si:H thin-film transistors (TFTs) and optically sensitive photodiodes collect the image emitted from the phosphor screen. Such panels demonstrate excellent optical coupling efficiency (>50%) and possess high tolerance to radiation damage (> —2X 104 Gy). Their spatial resolution and noise characteristics are compatible with computed tomography, and the devices appear overall well-suited to CBCT." Ex. 1009 at 1312. "Ultimately, an imaging system based on this technology will be installed on a conventional radiotherapy linear accelerator." *Id*. at 1312. "It is interesting to note that all the data presented in Figs. 9 and 10 were obtained from a single acquisition performed in a single rotation." *Id*. at 1320. "It should be kept in mind that this level of detail was produced on a CBCT bench-top system that operates on a scale that mimics the geometry of the linear

’021 Claim Elements	**Ex. 1009 and Ex. 1007**
	accelerator; therefore, this level of detail would be expected in the clinical implementation of the device, given accurate correction of mechanical flex.” *Id*. “FIG. 9. CBCT images of a euthanized rat in regions of (a,b,c) the lungs, (d,e,f) the kidney, and (g,h,i) the lower spine. The window and level settings were varied in each image to allow visualization of the structures of interest. Axial (a,d,g), corona] (b,e,h), and sagittal (c,f,i) slices qualitatively demonstrate isotropic spatial resolution, with excellent soft-tissue contrast in each case. Bronchial tructure within the lungs is clearly identifiable, the kidney is well delineated from surrounding muscle and fat, and fine detail in the vertebrae and intervertebral spaces is demonstrated. Voxel size in each case is 0.25X0.25X0.25 mm3, and the vertical scale in the images shows 1 cm spacing.” *Id*. at 1319. *Id*. at Fig. 9. *See also* Ex. 1016, Hamilton Decl. at ¶¶312-319.
[1.g]a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager.	“The FPI used in these investigations was manufactured by EG&G Heimann Optoelectronics (RID 512-400 A0) and incorporates a 512x512 array of a-Si:H photodiodes and thinfilm transistors. The electromechanical characteristics of the imager are shown in Table I. The array is read out at one of eight present frame rates (up to 5 frames per second) and operates asynchronously of the host computer. The analog signal from each pixel is integrated by ASIC amplifiers featuring correlated double-sampling noise reduction circuitry. Digitization is performed at 16 bit resolution. The values are transferred via an RS-422 bus to a hardware buffer in the host computer. The processor on the host computer is interrupted when a complete frame is ready for transfer to host memory.” Ex. 1009 at 1313. “Each projection image is written to hard disk

'021 Claim Elements	**Ex. 1009 and Ex. 1007**
	between frame transfer and motor rotation; all scans reported in this study involved 300 projections over 360° of rotation." *Id*. at 1314. *See also* Ex. 1016, Hamilton Decl. at ¶¶320-322.
4. The apparatus of claim 1, wherein the computing unit generates a three-dimensional image of a target volume based on the captured image projection data.	"Ultimately, an imaging system based on this technology will be installed on a conventional radiotherapy linear accelerator." Ex. 1009 at 1312. "It is interesting to note that all the data presented in Figs. 9 and 10 were obtained from a single acquisition performed in a single rotation." *Id*. at 1320. "It should be kept in mind that this level of detail was produced on a CBCT bench-top system that operates on a scale that mimics the geometry of the linear accelerator; therefore, this level of detail would be expected in the clinical implementation of the device, given accurate correction of mechanical flex." *Id*. "FIG. 9. CBCT images of a euthanized rat in regions of (a,b,c) the lungs, (d,e,f) the kidney, and (g,h,i) the lower spine. The window and level settings were varied in each image to allow visualization of the structures of interest. Axial (a,d,g), corona] (b,e,h), and sagittal (c,f,i) slices qualitatively demonstrate isotropic spatial resolution, with excellent soft-tissue contrast in each case. Bronchial structure within the lungs is clearly identifiable, the kidney is well delineated from surrounding muscle and fat, and fine detail in the vertebrae and intervertebral spaces is demonstrated. Voxel size in each case is 0.25X0.25X0.25 mm3, and the vertical scale in the images shows 1 cm spacing." *Id*. at 1319. *See also* Ex. 1016, Hamilton Decl. at ¶¶326-329.
5. The apparatus of claim 1, wherein the cone-beam CT radiation source is a kilovoltage radiation source and the	"Beam energy 100kVp." Ex. 1009 at 1313 (Table I). "A strong candidate technology to satisfy these requirements is kilovoltage (kV) cone-beam computed tomography (CBCT). CBCT operates on

'021 Claim Elements	**Ex. 1009 and Ex. 1007**
high-energy radiation source is a megavoltage radiation source.	the same principle as conventional CT, with the exception that an entire volumetric image is acquired through a single rotation of the source and detector." *Id*. 1311. **Ex. 1007** "Two fluoroscopic imager assemblies are attached to the accelerator; one detects the megavoltage (MV) treatment beam, the other detects the kV beam projected at 90° to the treatment beam axis. An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d)." Ex. 1007 at 774. *See also* Ex. 1016, Hamilton Decl. at ¶¶333-336.
6. The apparatus of claim 1, wherein the rotatable gantry is capable of 360 degree rotation.	**Ex. 1007** "The gantry was then rotated through 360˚ and the relative movement between the end of the couch and the drum face was recorded." Ex. 1007 at 776-777. *See also* Ex. 1016, Hamilton Decl. at ¶¶339-341.
7. The apparatus of claim 1, wherein the high-energy source comprises a megavoltage radiation source to radiate a target volume with radiation.	**Ex. 1007** "Two fluoroscopic imager assemblies are attached to the accelerator; one detects the megavoltage (MV) treatment beam, the other detects the kV beam projected at 90° to the treatment beam axis. An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d)." Ex. 1007 at 774. *See also* Ex. 1016, Hamilton Decl. at ¶¶345-346.

’021 Claim Elements	Ex. 1009 and Ex. 1007
14. An apparatus, comprising [14.a] a radiation treatment system capable of implementing a treatment plan, the system comprising:	*See* citations to claim element 1.a above.
[14.b] a frame;	*See* citations to claim element 1.b above.
[14.c] a rotatable gantry coupled to the frame;	*See* citations to claim element 1.c above.
[14.d] a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;	*See* citations to claim element 1.d above.
[14.e] a cone-beam radiation source coupled to the rotatable gantry to radiate the patient;	*See* citations to claim element 1.e above.
[14.f] a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data of the patient from the cone-beam radiation source to generate cone-beam computed tomography (CT) volumetric image data of the patient; and	*See* citations to claim element 1.f above.
[14.g] a translatable treatment couch	“In a previous article, the development of a kV cone-beam CT imaging system for on-line tomographic

’021 Claim Elements	Ex. 1009 and Ex. 1007
coupled to the rotatable gantry via a communications network.	guidance was reported.[8] The system consisted of a kV x-ray tube and a radiographic detector mounted on the gantry of a medical linear accelerator.” Ex. 1009 at 1311. “Ultimately, an imaging system based on this technology will be installed on a conventional radiotherapy linear accelerator.” *Id*. at 1312. **Ex. 1007** “An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d).” Ex. 1007 at 774.  *Id*. at Fig. 1. *See also* Ex. 1016, Hamilton Decl. at ¶¶127-128, 356-359.
15. The apparatus of claim 14, wherein the translatable treatment couch is capable of	“In a previous article, the development of a kV cone-beam CT imaging system for on-line tomographic guidance was reported.[8] The system consisted of a kV x-ray tube and a radiographic detector mounted on

’021 Claim Elements	Ex. 1009 and Ex. 1007
movement in three planes plus angulation.	the gantry of a medical linear accelerator.” Ex. 1009 at 1311. “Ultimately, an imaging system based on this technology will be installed on a conventional radiotherapy linear accelerator.” *Id*. at 1312. **Ex. 1007** “An Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d).” Ex. 1007 at 774; *see also* Fig. 1 above. *See also* Ex. 1016, Hamilton Decl. at ¶¶127-128, 356-359.
53. An apparatus, comprising [53.a] a clinical radiation treatment system capable of implementing a treatment plan, the system comprising:	*See* citations to claim element 1.a above.
[53.b] a frame;	*See* citations to claim element 1.b above.
[53.c] a rotatable gantry coupled to the frame;	*See* citations to claim element 1.c above.
[53.d] a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;	*See* citations to claim element 1.d above.
[53.e] a cone-beam radiation source coupled to the rotatable	*See* citations to claim element 1.e above.

’021 Claim Elements	**Ex. 1009 and Ex. 1007**
gantry to radiate the patient; and	
[53.f] a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager captures fluoroscopic or cone-beam CT imaging image projection data of the patient from the cone-beam radiation source to generate fluoroscopic or cone-beam computed tomography (CT) volumetric image data of the patient.	*See* citations to claim element 1.f above and the below. “Furthermore, these improvements are largely driven by other forces in digital imaging that anticipate use of FPIs in place of conventional image-intensifier systems for interventional <u>fluoroscopy</u>.” Ex. 1009 at 1322. *See also* Ex. 1016, Hamilton Decl. at ¶¶374-376.
60. The apparatus of claim 53, further comprising a translatable treatment couch coupled to the rotatable gantry via a communications network, wherein the translatable treatment couch is capable of movement in three planes plus angulation.	In a previous article, the development of a kV cone-beam CT imaging system for on-line tomographic guidance was reported.[8] The system consisted of a kV x-ray tube and a radiographic detector mounted on the gantry of a <u>medical linear accelerator</u>.” Ex. 1009 at 1311. “Ultimately, an imaging system based on this technology will be installed on a <u>conventional radiotherapy linear accelerator</u>.” *Id*. at 1312. **<u>Ex. 1007</u>** “An <u>Elekta SL-20 (Elekta Oncology Systems, Crawley, UK) linear accelerator</u> forms the basis of the system. This accelerator is computer controlled and produces 6 and 18 MV photon beams. Field shaping is performed with an 80 leaf collimator. The SL-20 is a drum-based accelerator, making the installation of a retractable kV x-ray source relatively straightforward (Fig. 1d).” Ex. 1007 at 774; *see also* Fig. 1 above. *See also* Ex. 1016, Hamilton Decl. at ¶¶127-128, 356-

’021 Claim Elements	**Ex. 1009 and Ex. 1007**
	359.
61. The apparatus of claim 53, wherein the rotatable gantry is capable of 360 degree rotation and the imager is capable of capturing image projection data while continuously rotating about a target volume.	**Ex. 1007** “To generate a CB-CT dataset, a series of radiographic exposures are acquired at regular angular intervals as the accelerator gantry is rotated through a specified range (typically 180° or 360°). The control system operates the camera’s shutter and read-out mechanisms in synchrony with the firing of the x-ray generator; these operations are slaved to the accelerator’s gantry angle.” Ex. 1007 at 779. “The accelerator gantry rotates continuously at a relatively low speed (~30°/min) with the control system monitoring the gantry angle.” *Id*. at 779. *See also* Ex. 1016, Hamilton Decl. at ¶¶127-128, 356-359.

IX. CONCLUSION

The references above teach and suggest the claimed subject matter of the ’021 Patent in such a manner that the Petitioner is likely to prevail in showing that the alleged inventions in the challenged claims of the ’021 Patent were described in printed publications more than one year prior to the effective filing date of the ’021 Patent. Accordingly, the Petitioner respectfully requests that the Board grant this petition for *inter partes* review.

Dated: June 15, 2015 Respectfully submitted,

/Theresa M Gillis Reg No 28078/
Theresa M. Gillis
Registration No. 28,078
Mayer Brown LLP

1221 Avenue of the Americas
New York, NY 10020-1001
Telephone: 212-506-2553
Facsimile: 212-849-5553
tgillis@mayerbrown.com

Amanda K. Streff
Registration No. 65,224
Mayer Brown LLP
71 S. Wacker Drive
Chicago, IL 60606
Telephone: 312-701-8645
Facsimile: 312-701-7711
astreff@mayerbrown.com

CERTIFICATE OF SERVICE

I hereby certify that on June 15, 2015, a copy of the attached PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,945,021, together with all exhibits, the power of attorney, and all other papers filed therewith were served by UPS on the attorneys of record for the patent owner at the following addresses:

Attorney of Record for Patent Owner

BLAKELY SOKOLOFF TAYLOR & ZAFMAN LLP
1279 OAKMEAD PARKWAY
SUNNYVALE CA 94085-4040

Date: June 15, 2015

Respectfully submitted,

By:/Theresa M Gillis Reg No 28078 /

Theresa M. Gillis
Registration No. 28,078
Mayer Brown LLP
1221 Avenue of the Americas
New York, NY 10020-1001
Telephone: 212-506-2553
Facsimile: 212-849-5553
tgillis@mayerbrown.com

Amanda K. Streff
Registration No. 65,224
Mayer Brown LLP
71 S. Wacker Drive
Chicago, IL 60606
Telephone: 312-701-8645
Facsimile: 312-701-7711
astreff@mayerbrown.com
Counsel for Elekta AB