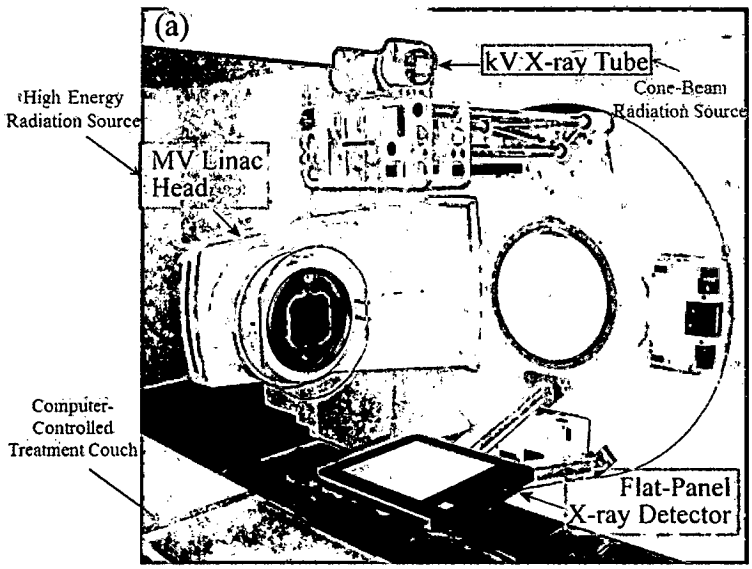
through his association with William Beaumont Hospital includes an Elekta SL-20 linear accelerator, which has a high energy treatment radiation source and a computer-controlled treatment couch, as well a cone beam radiation source and a flat panel imager added by Dr. Jaffray:



RX-0262 (*Jaffray 2001*) at Fig. 4(a) (annotations added).

Jaffray 2001 inherently includes the features of the well-known SL-20, which are explained in several publications. *See Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992). One such paper was authored by R. Anderson, titled "Software system for automatic parameter logging on Philips SL-20 linear accelerator," and dated March 1995 ("Anderson"). RX-430; RX-501C at 0011. Another such paper, titled "Premarket Notification (510k) for the SL Series Linear Accelerator," provides details about the communications structure in the SL-20. RX-491C at 9008; RX-0501C (Brown RWS) at Q50-53.

As explained below, *Jaffray 2001*, like *Jaffray WIPO*, includes all the limitations of the asserted claims.

Element-by-Element Analysis

- **Claims 1, 15: "An apparatus, comprising"**

Jaffray 2001 discloses this uncontested limitation by showing and discussing "a medical linear accelerator." RX-0262 (*Jaffray 2001*) at 800; Fig. 4(a); *see also* RX-0433C (Papanikolaou WS) at Q211-12.

- **Claims 1, 15: "a [clinical] radiation treatment system capable of implementing a treatment plan, the system comprising"**

Jaffray 2001 satisifies this limitation by disclosing a new system for "image-guided radiation therapy" that is adapted to a known SL-20 "medical linear accelerator" to enable "intra-therapeutic guidance," as shown above. RX-0262 (*Jaffray 2001*) at 800; Fig. 4(a); RX-0433C (Papanikolaou WS) at Q213-16. One skilled in the art would understand that Dr. Jaffray's modified system was "capable of implementing a treatment plan" because an SL-20 was a linear accelerator that was routinely used for that purpose. RX-0433C (Papanikolaou WS) at Q139, 140, 142, 143, 213-16.

To overcome the inherent disclosure of this claim limitation, Varian seeks to read into the claims a requirement that Dr. Jaffray's modified system must be "commissioned" to meet this claim limitation. Resps. Br. at 40 (citing CX-3879C (Mutic RWS) at Q93). However, as Dr. Papanikolaou explained, there is a difference between commissioning a machine for use with patients and creating a system "capable" of implementing a treatment plan. RX-0433C (Papanikolaou WS) at Q143. A machine could be capable of implementing a treatment plan even if it is not licensed, approved, or otherwise validated

by governmental authorities for use with cancer patients. The addition of the image guidance components to the SL-20 gantry did not change the essence of the unit's ability to perform a treatment plan. *Id.*

- **Claims 1, 15: "a frame"**

Jaffray 2001 discloses this undisputed claim limitation: "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." RX-0262 (*Jaffray 2001*) at 804. Further, the linear accelerator in *Jaffray 2001* was an Elekta SL-20, which inherently included a structure to support the gantry that can be considered a frame. RX-0433C (Papanikolaou WS) at 0041; RX-0435C (Brown WS) at 0004.

- **Claims 1, 15: "a rotatable gantry coupled to the frame"**

Jaffray 2001 discloses this undisputed claim limitation: "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." RX-0262 (*Jaffray 2001*) at 804. *Jaffray 2001* also states that "[m]ultiple radiographs of a 0.8 cm steel ball-bearing (BB) placed near isocenter are acquired as the gantry rotates through 360°." *Id.* Further, the linear accelerator in *Jaffray 2001* was an Elekta SL-20, which inherently meets this claim limitation. RX-0433C (Papanikolaou WS) at Q217-22; RX-0435C (Brown WS) at Q18, 19.

- **Claims 1, 15: "a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation"**

Jaffray 2001 discloses this undisputed limitation: "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." RX-0262 (*Jaffray 2001*) at 804. Fig. 4(a) illustrates the high energy source. RX-0262 (*Jaffray 2001*) at Fig. 4(a); *see also* RX-0433C (Papanikolaou WS) at Q223-24.

- **Claims 1, 15: "a cone-beam radiation source coupled to the rotatable gantry to radiate a patient"**

Jaffray 2001 discloses this undisputed limitation: "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." RX-0262 (*Jaffray 2001*) at 804; Fig. 4(a); *see also* RX-0433C (Papanikolaou WS) at Q225-26. Table II discloses a "cone angle" that defines the kV imaging geometry. RX-0262 (*Jaffray 2001*) at Table II.

- **Claims 1, 15: "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"**

Jaffray 2001 discloses this undisputed limitation: "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." RX-0262 (*Jaffray 2001*) at 805; Fig. 5. *See also, Id.* at 804; Fig. 4(a). "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 dimension with the cone-beam approach." *Id.* at 806. *Jaffray 2001* also discloses "[an] 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; *see also* RX-0433C (Papanikolaou WS) at Q227-28.

- **Claim 1: "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 2001 discloses this limitation. In the claim construction section, the administrative law judge determined that the claim term "communications network" should be given its plain and ordinary meaning, *i.e.*, "a system of computers interconnected by telephone wires or other means in order to share information."

As discussed above, *Jaffray 2001* discloses "[an] 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. *Jaffray 2001* further discloses that "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)." RX-0262 (*Jaffray 2001*) at 801. Further, as with *Jaffray WIPO* discussed above, *Jaffray 2001* discloses a centralized computer control scheme in which "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.

- **Claim 15: "a translatable treatment couch coupled to the rotatable gantry via a communications network"**

In the claim construction section, the administrative law judge determined that the claim term "communications network" should be given its plain and ordinary meaning, *i.e.*, "a system of computers interconnected by telephone wires or other means in order to share information." *Jaffray 2001* discloses this limitation, noting that "[w]ith 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 360°." RX-0262 (*Jaffray 2001*) at 805 (emphasis added); Fig. 4(a) (showing the treatment couch rotated partially out of view in the bottom left of the figure). The linear accelerator depicted in *Jaffray 2001* is the Elekta SL20, which had a couch that moved under motor control to place the patient laying on the couch in the appropriate position for treatment. RX-0435C (Brown WS) at Q20, 21, 25-27; RX-0433C (Papanikolaou WS) at Q255-57.

- **Claim 15: "the translatable treatment couch is capable of movement in three planes plus angulation"**

Jaffray 2001 discloses this undisputed limitation of claim 15. As explained, the linear accelerator depicted in *Jaffray 2000* is the Elekta SL20, which had a treatment couch translatable in three planes and capable of angulation and coupled to the gantry via a communications network. RX-0433C (Papanikolaou) at Q258-60; RX-0501C (Brown RWS) at Q46; RX-0435C (Brown WS) at Q23-27. Thus, this limitation is inherently satisfied. 976 F.2d at 1565. Indeed, the PTAB recently found that "[p]etitioner made an adequate showing that *Jaffray 2001* discloses … the translatable treatment couch is capable of movement in three planes plus angulation (claims 15 [])." RX-429 at 0017-18. Thus, there is little question that *Jaffray 2001* discloses this limitation. *See also* RX-0433C (Papanikolaou WS) at Q258-60.

- **Claim 4: "the computing unit generates a three-dimensional image of a target volume based on the captured image projection data"**

Jaffray 2001 meets this limitation by disclosing that "[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." RX-0262 (*Jaffray 2001*) at 8055; Fig. 5; *see also* RX-0433C (Papanikolaou WS) at Q235-37.

Varian is incorrect that *Jaffray 2001* does not meet this limitation because the Shapiro inventors allegedly "taught a separate cone-beam reconstruction computer." Resps. Br. at 47 (citng CX-3879C (Mutic RWS) at Q81). Claim 4 does not require a

separate computer for reconstruction and another for system control, as discussed above with respect to *Jaffray WIPO*.

- **Claim 9: "the cone-beam source and high-energy radiation source are different from one another, and the cone-beam source comprises a KV source and wherein the high-energy radiation source comprises a MV source coupled to the rotatable gantry to radiate a patient with therapeutic radiation"**

Jaffray 2001 discloses this undisputed limitation: "Flat-panel imagers [are] employed in the investigations of kV cone-beam CT." RX-0262 (*Jaffray 2001*) at 801. *Jaffray 2001* further discloses that 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." *Id.* at 804; Fig. 4(a); *see also* RX-0433C (Papanikolaou WS) at Q251-53.

* * *

Accordingly, respondents have shown by clear and convincing evidence that *Jaffray 2001* anticipates the asserted claims of the '021 patent.

c. *Jeffray 2000*

Overview

Dr. Jaffray's work is also memorialized in a third printed publication titled, "Cone-Beam Computed Tomography on a Medical Linear Accelerator Using a Flat-Panel Imager," published more than 1 year before the '021 patent was filed. RX-0275 ("*Jaffray*

2000"). Like *Jaffray 2001*, *Jaffray 2000* publicizes Dr. Jaffray's work modifying the Elekta SL-20 to include online image guidance capabilities. *Id. Jaffray 2000* incorporates by reference two prior articles describing Dr. Jaffray's system. *Id.* at 558. The first is a printed publication titled "A Radiographic and Tomographic Imaging System Integrated Into a Medical Linear Accelerator for Localization Of Bone and Soft-Tissue Targets," published in 1999. *See* RX-0264 (David A. Jaffray *et al.*, *A Radiographic and Tomographic Imaging System Integrated Into a Medical Linear Accelerator for Localization Of Bone and Soft-Tissue Targets*, Int. J. Radiation Oncology Biol. Phys., Vol. 45, No. 3, 773-789) (1999) (hereinafter, "Jaffray JRO 1999"). The second is a printed publication titled "Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager," published in February 1999. *See* RX-0261 (D.A. Jaffray *et al.*, *Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager*, SPIE Vol. 3659, 204-214 (1999) (hereinafter, "*Jaffray SPIE 1999*").

As explained by respondents in a tabular form, *Jaffray 2000* (incorporating *Jaffray JRO 1999* and *Jaffray SPIE 1999*), like *Jaffray WIPO* and *Jaffray 2001*, includes all the limitations of the asserted claims, when properly construed. *See* Resps. Br. at 49-51. The table providing an element-by-element analysis is replicated below.

Element-by-Element Analysis

'021 Claim Elements	***Jaffray 2000***
1, 15. An apparatus, comprising A [clinical] radiation treatment system capable of implementing a treatment plan, the system comprising:	*Jaffray 2000* describes Fig. 3 as a "[p]hotograph of the prototype FPI-based CBCT system implemented on a medical linear accelerator (Elekta SL-20)". RX-0275 (*Jaffray 2000*) at 559. *Jaffray 2000* also describes imaging "preferably with the patient in treatment position" and use of a "treatment machine." *Id.*

'021 Claim Elements	*Jaffray 2000*
	at 558
a frame;	*Jaffray 2000* discloses use of a "SL20 accelerator," shown in Fig. 3, which inherently included a structure to support the gantry that can be considered a frame. RX-0433C (Papanikolaou WS) at 0041; RX-0435C (Brown WS) at 0004; RX-0275 (*Jaffray 2000*) at 559.
a rotatable gantry coupled to the frame;	The SL-20 inherently included a structure coupled to the gantry, which can be considered a frame, to support the rotating gantry on the SL-20. RX-0433C (Papanikolaou WS) at 0041; RX-0435C (Brown WS) at 0004.
a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;	Fig. 3 shows a "medical linear accelerator (Elekta SL-20)." RX-0275 (*Jaffray 2000*) at 559 (emphasis added). And *Jaffray JRO 1999* discloses that the gantry of the SL-20 included a high energy treatment source. RX-0264 at 774; *see also* RX-0433C (Papanikolaou WS) at 0054-55.
a cone-beam radiation source coupled to the rotatable gantry to radiate the patient;	*Jaffray 2000* disclosed use of "cone-beam CT (CBCT) ... to acquire on-line volumetric CT images in the reference frame of the treatment machine." RX-0275 (*Jaffray 2000*) at 558; Fig. 3; *see also* RX-0433C (Papanikolaou WS) at 0055.
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	*Jaffray 2000* discloses that "cone-beam CT (CBCT) is employed to acquire on-line volumetric CT images in the reference frame of the treatment machine" and use of "flat-panel imager" integrated inot a linear accelerator. RX-0275 (*Jaffray 2000*) at 558; 559.
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 2000* discloses that flat panel imager pixel "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." RX-0261 at 205. Based on these disclosures, the PTAB recently

'021 Claim Elements	*Jaffray 2000*
	found that that *Jaffray 2000* meets this limitation. RX-0429 at 0020. Also, the commercial SL-20 linac used in *Jaffray 2000* inherently satisfies Varian's narrow construction of "communications network."
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.	The caption of FIG. 5 discusses that the "image was reconstructed" from "427 projections." RX-0275 (*Jaffray 2000*) at caption of Fig. 5; 560. *See also* RX-261 at 212; RX-0433C (Papanikolaou WS) at 0057-58.
9. The apparatus of claim 1, wherein the cone-beam source and high-energy radiation source are different from one another, and the cone-beam source comprises a KV source and wherein the high-energy radiation source comprises a MV source coupled to the rotatable gantry to radiate a patient with therapeutic radiation.	*Jaffray 2000* discloses a system that includes both a "kV imaging system" and a MV source from the "medical linear accelerator." RX-0275 (*Jaffray 2000*) at 558; Fig. 3; *see also* RX-0264 at 774; RX-0433C (Papanikolaou WS) at 0060-61.
15. a translatable treatment couch coupled to the rotatable gantry via a communications network.	*Jaffray 2000* inherently discloses this limitation by disclosing the use of a commercial Elekta SL-20." RX-0275 (*Jaffray 2000*) at 559; RX-0433C (Papanikolaou WS) at 0061-62; RX-0435C (Brown WS) at 0004. Indeed, the PTO recently confirmed that this limitation is disclosed by *Jaffray 2000*. RX-0429 at 0020.
15. The apparatus of claim 14, wherein the translatable treatment couch is capable of movement in three planes plus angulation.	As explained with respect to *Jaffray 2001*, the Elekta SL-20 disclosed in *Jaffray 2000* had a couch translatable in three planes and capable of angulation.

* * *

Accordingly, respondents have shown by clear and convincing evidence that *Jaffray 2000* anticipates the asserted claims of the '021 patent.

3. Obviousness

Elekta argues that *Jaffray 2001* renders obvious claims 1, 4, 9, and 15 of the '021 patent. *See* Resps. Br. at 51-54. Elekta also argues that the combination of *Jaffray 2000*, Jaffray JRO 1999 and Jaffray SPIE 1999 renders obvious claims 1, 4, 9, and 15 of the '021 patent. *See id.* at 54-55.

Varian argues that Elekta's obviousness arguments are insufficient because Elekta did not conduct a complete *Graham* analysis. *See* Compls. Br. at 95-96. The "factual predicates underlying an obviousness analysis" includes the scope and content of the prior art, differences between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, and any secondary considerations of non-obviousness, such as commercial success, long felt but unsolved needs, and failure of others. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

The Staff argues that "Elekta has made a *prima facie* showing that the claims of the '021 patent are obvious," but that it "agrees with Varian that Elekta has not shown the claims to be obvious because it has not weighed all four Graham factors." Staff Br. at 54.

For the reasons discussed below, as the Staff argued, Elekta has made a *prima facie* showing that the asserted claims of the '021 patent are obvious. However, as Varian and the Staff argued, Elekta has not shown the claims to be obvious because it has not weighed all four *Graham* factors. *See* Compls. Br. at 98 and Staff Br. at 54 (citing RX-0433C (Papanikolaou WS) at Q416; Resps. Br. at 51-55 (no briefing of *Graham* factors); *see also Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d 1356, 1365-67 (2013) (vacating determination of obviousness that was otherwise supported by substantial evidence for failure to consider secondary considerations).

a. *Jaffray 2001*

Jaffray 2001 (RX-0262) discloses all of the limitations of claims 1, 4, 9, and 15, as discussed in detail above. However, to the extent *Jaffray 2001* (RX-0262) is found not to provide an anticipatory teaching of the "computing unit, coupled to the rotatable gantry via a communications network, to store image projection data captured by the flat-panel imager," this element would have been obvious to one of ordinary skill in the art at the time the '021 patent was filed. The linear accelerator depicted in *Jaffray 2001* (RX-0262) is the Elekta SL-20, which is a conventional linear accelerator equipped with a flat panel imager to generate image projection data used to create volumetric cone beam CT images. It would have been obvious to one of skill in the art at the time of the '021 patent that in order to process the image projection data to generate volumetric images, it is necessary to store the image projection data in the computer that will process the data. RX-0433C (Papanikolaou WS) at Q419-20. Providing a coupling via a communications network was known to be a standard means of connecting the gantry to the computer. *Id.*

Under the correct claim construction of "communications network,"[28] by 1981, it was standard to couple components to the gantry of a linear accelerator via a communications network, as shown for example by an article (titled "A Primer on Theory and Operation of Linear Accelerators in Radiation Therapy") written by C.J. Karzmark. RX-0290 ("*Karzmark*") at 35; RX-0433C (Papanikolaou WS) at Q351, 421-25.

Likewise, to the extent *Jaffray 2001* is found not to provide an express or inherent

[28] The administrative law judge determined that the claim term "communications network" should be given its plain and ordinary meaning, *i.e.*, "a system of computers interconnected by telephone wires or other means in order to share information."

disclosure of the "translatable treatment couch coupled to the rotatable gantry via a communications network" under the ordinary meaning of "communications network," this element would have been obvious to one of ordinary skill in the art at the time the '021 patent was filed because, by 1981, it was standard to use a translatable treatment couch coupled to the gantry via a communications network on a linear accelerator. *See* RX-0433C (Papanikolaou WS) at Q431.

For instance, *Karzmark* shows this arrangement in Figure 41, and explains that "[a] number of auxiliary systems are essential for operation, control, and monitoring of the linac treatment unit." *See* RX-0290 (*Karzmark*) at 35 (Fig. 41 (Block diagram of a high energy bent-beam medical linac. Major components, auxiliary systems and interconnections are identified.)). *Karzmark* also discloses that "[f]ast and slow speeds or variable speed motor control are provided for the couch, together with control of gantry rotation." *Id.* at 12. A person of ordinary skill in the art would have applied this common knowledge to *Jaffray 2001* and would have been motivated to do so because it was one of a relatively small number of communications options. *See* RX-0433C (Papanikolaou WS) at Q430-31. A combination resulting from a "finite number of identified, predictable solutions" is likely obvious. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Moreover, the linear accelerator depicted in *Jaffray 2001* is the Elekta SL-20. RX-0433C (Papanikolaou WS) at Q430-31. Even if not expressly or inherently disclosed, it would have been obvious to use the SL-20 treatment couch with the *Jaffray 2001* system inasumuch as the entire system was based on the SL-20 linac. *See* RX-0433C (Papanikolaou WS) at Q430-31.

Accordingly, to the extent that *Jaffray 2001* is not anticipatory, the evidence has shown that *Jaffray 2001* renders claims 1, 4, 9, and 15 of the '021 patent *prima facie* obvious. As noted above, however, Elekta has not performed a complete *Graham* analysis.

b. *Jaffray 2000* in View of *Jaffray JRO 1999* and *Jaffray SPIE 1999*

Jaffray 2000 discloses all of the limitations of claims 1, 4, 9, and 15 of the '021 patent, as discussed in detail above. However, to the extent *Jaffray 2000* is found not to provide an anticipatory teaching of the "computing unit, coupled to the rotatable gantry via a communications network, to store image projection data captured by the flat-panel imager" in claim 1, this claim element would have been obvious to one of ordinary skill in the art at the time the '021 patent was filed, as discussed above with respect to the same element for *Jaffray 2001*. *See* RX-0433C (Papanikolaou WS) at Q426-31. The same reasoning applies here with respect to the modification of *Jaffray 2000*.

Likewise, to the extent *Jaffray 2000* is found not to provide an anticipatory teaching of the "translatable treatment couch coupled to the rotatable gantry via a communications network," that claim element would have been obvious to one of ordinary skill in the art at the time the '021 patent was filed, as discussed in detail above with respect to the obviousness of these features in view of *Jaffray 2001*.

Accordingly, to the extent that *Jaffray 2000* is not anticipatory, the evidence has shown that *Jaffray 2000* in combination with *Jaffray JRO 1999*[29] and *Jaffray SPIE*

[29] *See* RX-0264 (David A. Jaffray *et al.*, *A Radiographic and Tomographic Imaging System Integrated Into a Medical Linear Accelerator for Localization Of Bone and Soft-Tissue Targets*, Int. J. Radiation Oncology Biol. Phys., Vol. 45, No. 3, 773-789) (1999)

1999[30] renders claims 1, 4, 9, and 15 of the '021 patent *prima facie* obvious. However, as noted above, Elekta has not performed a complete *Graham* analysis.

V. U.S. Patent No. 8,116,430

United States Patent No. 8,116,430 ("the '430 patent"), entitled "Multi-mode cone beam CT radiotherapy simulator and treatment machine with a flat panel imager," issued on February 14, 2012, to named inventors Edward G. Shapiro, Edward J. Seppi, John M. Pavkovich, Peter Munro, Stanley W. Johnsen, and Richard E. Colbeth. JX-0002 ('430 Patent). The '430 patent issued from Application No. 11/891,505, filed on August 10, 2007, a continuation of Application No. 10/324,227 (which led to the '021 patent). *Id.* The '430 patent generally relates to "therapeutic radiology," and in particular, "involves imaging devices." JX-0002 at col. 1, lns. 14-16. The '430 patent has a total of 20 claims.

Complainants allege infringement of dependent apparatus claim 6 (which depends from independent claim 1) and independent method claim 18 of the '430 patent. *See* Compls. Br. at 114-29. Complainants argue that they have a domestic industry based on claim 6. *See* Compls. Br. at 129-32.

As noted, complainants assert dependent apparatus claim 6 (which depends from claim 1) and independent method claim 18. Those claims read as follows:

> **1**. An apparatus, comprising:
>
> logic configured to modify a treatment plan for a target volume, the logic comprising at least one of hardwired logic and a programmable computer component;

("Jaffray JRO 1999").

[30] *See* RX-0261 (D.A. Jaffray *et al.*, *Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager*, SPIE Vol. 3659, 204-214 (1999) ("Jaffray SPIE 1999").

a rotatable gantry;

a cone-beam radiation source coupled to the rotatable gantry; and

a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data to generate cone-beam computed tomography (CT) volumetric image data capable of being used by the logic to modify a treatment plan for a target volume.

6. The apparatus of claim **1**, 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.

18. A method to perform a clinical treatment, comprising:

using a clinical simulator machine to capture image projection data from a flat-panel imager for generating cone-beam computed tomography (CT) volumetric image data capable of being used by logic of the clinical simulator machine configured to modify a treatment plan for a clinical treatment machine;

emitting a cone-beam from a radiation source;

transmitting at least a portion of the cone-beam through a target volume;

providing a treatment plan;

modifying said treatment plan using said logic;

continuing to rotate a gantry on which the imager is mounted while capturing image projection data; and

one of capturing radiation at non-uniformly spaced angles with respect to a rotation, and changing the speed of rotation of the gantry during a rotation.

JX-0002 ('430 Patent) at col. 8, ln. 63 – col. 9, ln. 8; col. 9, lns. 27-30; col. 10, lns. 44-60.

A. Claim Construction

1. Applicable Law

Claim construction begins with the plain language of the claim.[31] Claims should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art, viewing the claim terms in the context of the entire patent.[32] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006).

In some instances, claim terms do not have particular meaning in a field of art, and claim construction involves little more than the application of the widely accepted meaning of commonly understood words. *Phillips*, 415 F.3d at 1314. "In such circumstances, general purpose dictionaries may be helpful." *Id.*

In many cases, claim terms have a specialized meaning, and it is necessary to determine what a person of skill in the art would have understood the disputed claim language to mean. "Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to

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[31] Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vanderlande Indus. Nederland BV v. Int'l Trade Comm.*, 366 F.3d 1311, 1323 (Fed. Cir. 2004); *Vivid Tech., Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

[32] Factors that may be considered when determining the level of ordinary skill in the art include: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

mean.'" *Phillips*, 415 F.3d at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). The public sources identified in *Phillips* include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* (quoting *Innova*, 381 F.3d at 1116).

In cases in which the meaning of a claim term is uncertain, the specification usually is the best guide to the meaning of the term. *Phillips*, 415 F.3d at 1315. As a general rule, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). The specification is, however, always highly relevant to the claim construction analysis, and is usually dispositive. *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Moreover, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316.

Claims are not necessarily, and are not usually, limited in scope to the preferred embodiment. *RF Delaware, Inc. v. Pacific Keystone Techs., Inc.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003); *Decisioning.com, Inc. v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1314 (Fed. Cir. 2008) ("[The] description of a preferred embodiment, in the absence of a clear intention to limit claim scope, is an insufficient basis on which to narrow the claims."). Nevertheless, claim constructions that exclude the preferred embodiment are "rarely, if ever, correct and require highly persuasive evidentiary support." *Vitronics*, 90

F.3d at 1583. Such a conclusion can be mandated in rare instances by clear intrinsic evidence, such as unambiguous claim language or a clear disclaimer by the patentees during patent prosecution. *Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc.*, 214 F.3d 1302, 1308 (Fed. Cir. 2000); *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319 (Fed. Cir. 2002).

If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence consists of all evidence external to the patent and the prosecution history, and includes inventor testimony, expert testimony, and learned treatises. *Phillips*, 415 F.3d at 1317. Inventor testimony can be useful to shed light on the relevant art. In evaluating expert testimony, a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent. *Id.* at 1318. Extrinsic evidence may be considered if a court deems it helpful in determining the true meaning of language used in the patent claims. *Id.*

2. A Person of Ordinary Skill in the Art

Complainants argue:

> In the context of the Shapiro patents, a person of ordinary skill in the art as of December 2002 would be a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field, and two or more years of experience in radiation oncology physics and image processing/computer programming related to radiation oncology applications. Alternatively, one of ordinary skill in the art might have an M.D. degree and two or more years of practical experience with image processing/computer programming related to medical applications.

Compls. Br. at 31 (citations omitted).

Respondents argue:

> A person of ordinary skill in the art relevant to the Shapiro patents would be a person with a graduate degree (MS or Ph.D.) in medical physics or a related field (e.g. Physics or Engineering) and three years of work in radiation oncology beyond the completion date of their degree.

Resps. Br. at 15 (citations omitted).

The Staff argues:

> The same definition of a person of ordinary skill should apply to the '430 patent as the '021 patent. As described above with regard to the '021 patent, the Staff agrees with Varian's first definition: a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field, and two or more years of experience in radiation oncology physics and image processing/computer programming related to radiation oncology applications. However, the differences in the proposed levels of skill do not affect the substantive issues of the investigation.

Staff Br. at 57.

For the reasons explained by the Staff, the Staff's proposed level of ordinary skill is most persuasive. Thus, as proposed by the Staff, the administrative law judge finds that a person of ordinary skill in the art with respect to the Shapiro patents as of December 2002 would be a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field, and two or more years of experience in radiation oncology physics and image processing/computer programming related to radiation oncology applications.

3. "communications network" (Claim 6)

Below is a chart showing the parties' proposed claim constructions.

"communications network"		
Complainants' Construction	**Respondents' Construction**	**Staff's Construction**
plain and ordinary meaning	plain and ordinary meaning	plain and ordinary meaning

See Compls. Br. at 45; Resps. Br. at 17; Staff Br. at 58.

As discussed above in the claim construction section for the '021 patent, all parties agree that the claim term "communications network" should be given its plain and ordinary meaning. *See* Compls. Br. at 45 ("This term appears in all asserted claims of the '021 patent and claim 6 of the '430 patent, but was not identified by either party as needing construction by the ALJ. All parties agree the term should be given its plain and ordinary meaning to one of ordinary skill in the art."); Resps. Br. at 17 ("Because the parties opted not to identify this term as requiring construction, they have conceded it should be given its ordinary, lay meaning."); Staff Br. at 25, 29, 58 ("The term 'communications network' appears in claim 6 of the '430 patent. The term was not offered for construction by any party during the parties' claim construction exchange process. For the reasons given for the '021 patent, the evidence has shown that the plain and ordinary meaning of 'communications network' is correct.") (citations omitted).

For the reasons discussed in the claim construction section for the '021 patent, the administrative law judge has determined that the claim term "communications network" recited in claim 6 of the '430 patent should be given its plain and ordinary meaning, *i.e.*, "a system of computers interconnected by telephone wires or other means in order to share information."

4. "Logic"

Below is a chart showing the parties' proposed claim constructions.

"Logic"		
Complainants' Construction	**Respondents' Construction**	**Staff's Construction**
"a hardware or software programmable computer component"	"software and/or hardware that performs a logical operation"	"a hardware or software programmable computer component"

See Compls. Br. at 102-03; Resps. Br. at 79-82; Staff Br. at 58.

Varian and the Staff propose that the correct construction for the disputed claim term "logic" is "a hardware or software programmable computer component." This proposed construction is supported by the express teachings of the patent specification. The specification discloses "machine-executable instructions (e.g. software)" or "hardware components that contain hardwired logic for performing the operations" to carry out the function. *See* JX-0002 at col. 8, lns. 5-23; *see also* CX-0848C (Mutic WS) at Q26.

Respondents' proposed construction does not appear to be markedly different from Varian and the Staff's. However, unlike the construction proposed by Varian and the Staff, respondents' proposed construction is circular, using the word "logical" to define "logic" in the term. *See* CX-3879C (Mutic RWS) at Q36.

Accordingly, the administrative law judge has determined that the claim term "logic" should be construed to mean "a hardware or software programmable computer component."

5. "logic configured to modify a treatment plan for a target volume"

Below is a chart showing the parties' proposed claim constructions.

"logic configured to modify a treatment plan for a target volume"	
Complainants' and Staff's Construction	**Respondents' Construction**
Subject to 35 U.S.C. §112(6) Function: to modify a treatment plan for a target volume. Structure: a hardwired logic or programmable computer component with software as described at 5:37-42, 7:29-34, 8:5-32, 5:53-58, Fig. 4 (525)[33] and structural equivalents thereof.	Subject to 35 U.S.C. § 112(6). Function: modify a treatment plan for a target volume. Structure: no adequate disclosure of corresponding structure; therefore, claim is indefinite.

See Compls. Br. at 103-07; Resps. Br. at 82-91; Staff Br. at 60.

For the reasons discussed below, the administrative law judge has determined that the claim term "logic configured to modify a treatment plan for a target volume" should be construed as proposed by complainants.

All parties agree that the claim term "logic configured to modify a treatment plan for a target volume" is a means-plus-function term governed by § 112(6), and all parties

[33] The Staff argues: "However, the Staff is no longer of the view that 5:53-58 and Figure 4 at element 525 are corresponding structure. The parties have agreed that the 'treatment plan' in the asserted claims is 'the set of instructions used by the radiation treatment system to deliver radiation to a target volume.' And 5:53-58 and Figure 4 at element 525 describe 'repositioning' the patient to match the treatment plan, not modifying the treatment plan itself." Staff Br. at 62. The Staff argues: "Despite this slight difference, the Staff submits that corresponding structure exists for the limitation 'logic configured to modify a treatment plan for a target volume.'" *Id.*

agree that the function covered by the term is "to modify a treatment plan for a target volume." *See* Compls. Br. at 103-07; Resps. Br. at 82-91; Staff Br. at 60. All parties also agree that a "treatment plan" is "the set of instructions used by the radiation treatment system to deliver radiation to a target volume." The patent expressly teaches that "the treatment plan may provide initial targeting information about the target volume." JX-0002, col. 5, lns. 49-50. As Dr. Mutic testified, when a departure is made from the initial targeting information given in the treatment plan, such as by repositioning the patient based on registering the captured CBCT image data with a reference image to determine any repositioning required before treatment (as taught by the '430 patent at col. 5, lns. 55-58), the repositioning constitutes a modification of the treatment plan for a target volume. *See* CX-0848C (Mutic WS) at Q27; *see also* Mutic Tr. 487.

Tumors move within a patient's anatomy. Repositioning a patient after the tumor has moved constitutes a modification of the original treatment plan, inasmuch as it requires moving the treatment machine into *new* coordinates to apply the radiation beams to the *new* tumor position. As Dr. Mutic testified, "between the treatment plan and the tumor, there is a very specific relationship. One tumor position, one treatment plan." Mutic Tr. 508. Dr. Mutic further explained during the hearing that a treatment plan is for "a specific tumor volume" and "the treatment plan has two components. It has what the machine does and what a patient is. They go one to one, and there is specific information about [the] patient and where that radiation is within the patient." Mutic Tr. 488. When a tumor moves, the radiation is applied to a different location within the patient.

Dr. Mutic further explained that the "geometry of the patient, the numbers that are in the treatment plan, they are very specific numbers that define where the patient is and

what the relationship of [the] beam is to the patient." Mutic Tr. 487. He then explained how repositioning a patient when a tumor has moved within the patient's anatomy constitutes a modification to the treatment plan that arises from the changed relative position of the tumor:

> So if the tumor has moved, then I'm going to position the patient to a different location within the patient. The numbers that are in the treatment plan, ***there are specific numbers that define where this beam should enter the patient***, what is the distance from the radiation source to the entry point in the patient and where this location is. ***Those pieces change***. So that would be [a] modification of a treatment plan because I'm ***changing parameters***.

Mutic Tr. 488 (emphasis added); *see also* Mutic Tr. 507-508 ("I can modify where a patient is . . . the moment that this changes, the numbers that are in the treatment plan is going to change, they're not going to be the same."). Dr. Mutic also identified specific numbers in the treatment plan that change as a result of repositioning the patient, which included the isocenter position and the source-to-skin distance (SSD). *See* Mutic Tr. 488-489. Thus, one of ordinary skill in the art understands that repositioning a patient, when there has been a movement of the tumor within the patient, prior to applying treatment constitutes a modification of the treatment plan for a target volume.

The understanding of one of ordinary skill in the art of the function of "modifying a treatment plan for a target volume" is further supported by the specification. The specification discloses how such modifications can be performed: "cone-beam CT image data can then be used to tailor a dose of therapeutic radiation based on at least the generated pre-defined treatment plan." JX-0002 at col. 5, lns. 41-44. The specification also teaches that the disclosed inventions "may use the kV cone-beam CT image data to make any necessary adjustments to the treatment plan based on identified movement of

the target volume or to determine the amount of patient repositioning required by the treatment couch 418 or collimator movements." JX-0002 at col. 7, lns. 29-34.

Dr. Papanikolaou acknowledges that the term "treatment plan" is a well-known to those in his field. Papanikolaou Tr. 900-901. He also agrees that the term "treatment plan" is broad, encompassing: "the set of instructions used by the radiation treatment system to deliver radiation to a target volume." *See* RX-0494 (Papanikolaou RWS) at Q93. He acknowledges that "the treatment plan include[s] a prescribed *relative position* at the time of treatment between the target volume to be treated and the therapeutic beam or beams used to treat the target volume." RX-0494 (Papanikolaou RWS) at Q95 (emphasis in original).

Nonetheless, Dr. Papanikolaou opines that the specification excludes adjustment to the treatment plan that occurs through patient repositioning (even if the tumor has moved), and changes in the collimator movements. *See* RX-0494 (Papanikolaou RWS) at Q99. However, during cross examination, Dr. Papanikolaou gutted this notion when he agreed that modifications to the collimator movements would be one way that the patent teaches how to modify a treatment plan. *See* Papanikolaou Tr. 901-902 ("Q And, Doctor, in your opinion, moving the collimator from the positions prescribed in the treatment plan would be changing the treatment plan, correct? . . . A Correct.").

Elekta and Dr. Papanikolaou essentially argue that the inventors disclaimed or disavowed that patient repositioning and changes in the collimator movements can constitute modification of a treatment plan. Yet, the specification provides no lexicography defining "modify[ing] a treatment plan for a target volume" to exclude modifications that occur when a tumor has moved within a patient and the patient is

therefore repositioned, even though treatment of the target volume would then occur in a position within the patient different from the position of the original treatment plan. *See Thorner*, 669 F.3d at 1365. There is nothing in the intrinsic or extrinsic record to justify limiting the plain and ordinary meaning of the term in this manner.

In addition, the parties' differences on the issue of corresponding structure stems from their differences in the application of the claimed function. Respondents do not dispute that there is corresponding structure for "logic to modify a treatment plan" when a treatment plan is modified by repositioning a patient. Rather, respondents argue that changes to the position of a patient can never be a modification of a treatment plan. However, as noted, one of skill in the art would understand that any change in the parameters of a treatment plan constitutes a modification of a treatment plan and this includes changes imparted by repositioning. *See* Mutic Tr. 507-508. Both claim 6 and 18 of the '430 patent further recite limitations associated with capturing image data using a flat-panel imager that further require the "logic to modify a treatment plan for a target volume" to be capable of using CBCT volumetric image data generated from image projection data captured by the flat panel imager. Thus, the claim language discloses CBCT volumetric image data as input data for the "logic to modify a treatment plan."

The '430 patent discloses "logic" in the form of "machine-executable instructions (*e.g.* software)" and "hardware components that contain hardwired logic for performing the operations" to carry out the function. JX-0002 ('430 Patent) at col. 8, lns. 5-32. The specification further describes an algorithm that performs the function of modifying a treatment plan for a target volume. *See, e.g.*, JX-0002 ('430 Patent) at col. 5, lns. 37-42, 53-58; col. 7, lns. 29-34; Figure 4 (525). These sections of the specification provide a

step-by-step procedure for use of volumetric cone-beam CT images collected on a target volume to modify a treatment plan. *See id.* at col. 5, lns. 41-44 ("cone-beam CT image data can then be used to tailor a dose of therapeutic radiation based on at least the generated pre-defined treatment plan"); col. 7, lns. 29-34. For example, the specification teaches comparing/registering the collected cone-beam CT images of the target volume against "reference images to determine the patient repositioning required, if any, before treatment." *See id.* at col. 5, lns. 53-58; Fig. 4 (525). One of ordinary skill in the art would thus find corresponding structure to practice the function claimed by "logic . . . configured to modify a treatment plan."

6. "clinical simulator machine" (claim 18)

Below is a chart showing the parties' proposed claim constructions.

"clinical simulator machine"		
Complainants' Construction	**Respondents' Construction**	**Staff's Construction**
"a system for acquiring imaging of a target volume with a patient setup that replicates a setup of a radiation treatment system"	"a system for acquiring pretreatment imaging of a target volume with a patient setup that replicates a setup of the radiation treatment system"	"a system for acquiring pretreatment imaging of a target volume with a patient setup that replicates a setup of the radiation treatment system"

See Compls. Br. at 107-14; Resps. Br. at 91-98; Staff Br. at 62.

For the reasons discussed below, the administrative law judge has determined that the claim term "clinical simulator machine" should be construed to mean "a system for acquiring pretreatment imaging of a target volume with a patient setup that replicates a setup of the radiation treatment system."

The parties' constructions of the term "clinical simulator machine" are identical except that the Staff and Elekta propose that is it is "a system for acquiring pretreatment imaging," whereas Varian omits the "pretreatment" requirement. *See* Compls. Br. at 107-14; Resps. Br. at 91-98; Staff Br. at 62.

Claim 18 is a method claim, and the term "clinical simulator machine" appears twice in the following step:

> *using a **clinical simulator machine** to capture image projection data from a flat-panel imager for generating cone-beam computed tomography (CT) volumetric image data capable of being used by logic of the **clinical simulator machine** configured to modify a treatment plan for a clinical treatment machine;*

JX-0002 ('430 Patent) at col. 10, lns. 45-50 (emphasis added).

The crux of the dispute is that Elekta argues that the machine that does the treatment "simulation" cannot physically be on the same device as the machine that does the therapeutic treatment itself. *See* Resps. Br. at 92 ("Turning first the claim language itself, it is immediately apparent that there are *two different machines* described in the claim—i.e., a 'clinical simulator machine' and a 'clinical treatment machine.'") (emphasis in original). In this regard, Elekta argues that "[o]bviously, a machine cannot 'replicate' its own setup; thus, the term 'replicate' in Elekta's construction (and in Varian's) necessarily requires two separate machines—one that 'replicates' another." *See* Resps. Br. at 93. This is incorrect. A machine can replicate its own setup in the sense that it can perform pretreatment imaging before exposing the patient to the high-dose radiation treatment. The '430 patent discloses one embodiment where both the MV (high-energy radiation source used for treatment) and the kV (lower-energy radiation

source used for imaging) are mounted on the same gantry. *See* JX-0002 ('430 Patent) at col. 7, lns. 17-25.

In addition, the title and the abstract of the '430 patent refer to a "Multi-mode Cone Beam CT Radiotherapy Simulator ***and*** Treatment Machine with a Flat Panel Imager." *See* JX-0002 ('430 Patent) (emphasis added). While the '430 patent discloses embodiments where the simulator and treatment machines are shown on different devices (*e.g.*, Figures 1 and 3), the '430 patent does not require that they be separated, as opposed to merely using different figures to highlight different functionality that could be combined on one machine.

"Pretreatment," which Elekta and the Staff have included in their proposed construction is a requirement of this limitation, in order to distinguish it from actual treatment with a therapeutic radiation beam. The '430 patent states that "[r]adiotherapy simulator machines have been used to perform the pre-treatment analysis of the target volume ***before*** a radiotherapy treatment machine applies the therapeutic radiation." *See* JX-0002 ('430 Patent) at col. 1, lns. 7-40 (emphasis added); *see also id.* at col. 5, lns. 55-58 ("At block 525, the captured image data can be compared/registered with the simulator or other reference images to determine the patient repositioning required, if any, ***before treatment***.") (emphasis added); *id.* at col. 8, lns. 36-39 ("In this way, the generation of the treatment plan via the clinical simulation machine ***prior to the application of therapeutic radiation***, increases the accuracy of treating the tumor target.") (emphasis added).

B. Infringement Analysis of the '430 Patent

As discussed above, complainants allege infringement of dependent apparatus claim 6 (which depends from independent claim 1) and independent method claim 18 of the '430 patent. *See* Compls. Br. at 114-29.

Respondents argue that the accused products do not infringe the asserted claims. *See* Resps. Br. at 124-36.

The Staff argues that the Accused Linacs infringe claim 6 but not do not infringe claim 18. *See* Staff Br. at 66-70.

1. Applicable Law

Under 35 U.S.C. §271(a), direct infringement consists of making, using, offering to sell, or selling a patented invention without consent of the patent owner. The complainant in a section 337 investigation bears the burden of proving infringement of the asserted patent claims by a "preponderance of the evidence." *Certain Flooring Products*, Inv. No. 337-TA-443, Comm'n Notice of Final Determination of No Violation of Section 337, 2002 WL 448690, at *59, (Mar. 22, 2002); *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376 (Fed. Cir. 1998).

Literal infringement of a claim occurs when every limitation recited in the claim appears in the accused device, *i.e.*, when the properly construed claim reads on the accused device exactly.[34] *Amhil Enters., Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1562 (Fed. Cir. 1996); *Southwall Tech. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed Cir. 1995).

[34] Each patent claim element or limitation is considered material and essential. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). If an accused device lacks a limitation of an independent claim, the device cannot infringe a dependent claim. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).

2. Accused Products

Complainants argue that "Elekta's Accused Linacs infringe claim 6, which is dependent on claim 1, and independent claim 18 of the '430 patent." Compls. Br. at 114, 114-29.

3. Infringement of Accused Linacs

Complainants argue that "Elekta's Accused Linacs infringe claim 6, which is dependent on claim 1, and independent claim 18 of the '430 patent as shown by the evidence produced in this case, deposition testimony of Elekta's witnesses, and Dr. Mutic." Compls. Br. at 114, 114-29.

Respondents disagree. *See* Resps. Br. at 124-36.

The Staff argues that the Accused Linacs infringe claim 6 but not do not infringe claim 18. *See* Staff Br. at 66-70.

a. Claim 6

Complainants argue: "Claim 6 of the '430 patent depends on independent apparatus claim 1. All limitations of claim 6 are met by Elekta's Accused Linacs." Compls. Br. at 114. Respondents argue that the accused products do not infringe claim 6. *See* Resps. Br. at 124-30. The Staff argues that "the evidence has shown that the Accused Linacs infringe claim 6." Staff Br. at 67.

As noted, complainants assert dependent apparatus claim 6, which depends from claim 1. Those claims read as follows:

> **1**. An apparatus, comprising:
>
> logic configured to modify a treatment plan for a target volume, the logic comprising at least one of hardwired logic and a programmable computer component;

a rotatable gantry;

a cone-beam radiation source coupled to the rotatable gantry; and

a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data to generate cone-beam computed tomography (CT) volumetric image data capable of being used by the logic to modify a treatment plan for a target volume.

6. The apparatus of claim **1**, 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.

18. A method to perform a clinical treatment, comprising:

using a clinical simulator machine to capture image projection data from a flat-panel imager for generating cone-beam computed tomography (CT) volumetric image data capable of being used by logic of the clinical simulator machine configured to modify a treatment plan for a clinical treatment machine;

emitting a cone-beam from a radiation source;

transmitting at least a portion of the cone-beam through a target volume;

providing a treatment plan;

modifying said treatment plan using said logic;

continuing to rotate a gantry on which the imager is mounted while capturing image projection data; and

one of capturing radiation at non-uniformly spaced angles with respect to a rotation, and changing the speed of rotation of the gantry during a rotation.

JX-0002 ('430 Patent) at col. 8, ln. 63 – col. 9, ln. 8; col. 9, lns. 27-30.

For the reasons discussed below, the evidence shows that claim 6 is infringed by Elekta's Accused Linacs.

"An apparatus, comprising" (claim 1)

Claim 1 of the '430 patent recites: "An apparatus comprising." This preamble is not limiting. Elekta does not dispute this preamble is limiting or that it is met by the Accused Linacs. As discussed above with respect to claim 1 of the '021 patent, the Accused Linacs nonetheless satisfy this preamble language.

"logic configured to modify a treatment plan for a target volume, the logic comprising at least one of hardwired logic and a programmable computer component" (claim 1)

The Accused Linacs have "logic configured to modify a treatment plan for a target volume, the logic comprising at least one of hardwired logic and a programmable computer component." *See* CX-0848C (Mutic WS) at Q139-42. The construction for treatment plan is "the set of instructions used by the radiation treatment system to deliver radiation to a target volume." CX-3693 (Joint Submission Regarding Constructions of Disputed and Undisputed Claim Terms) at 1-2. As discussed above in the claim construction section, whenever there is any change to the set of instructions for the treatment plan prior to delivering radiation to a target volume, there has been a modification of the treatment plan.

As Dr. Mutic testified, the Accused Linacs modify a treatment plan for a target volume when the [

]. *Id.*; CX-0235.58C ([ ]). For example, the Accused Linacs use [

]." *Id.* (emphasis added); *see* CX-0211.12 ([

]).

That Elekta's own internal documents further refer to "[

]" also indicates that a change to patient's position prior to treatment is recognized to be a modification to the treatment plan. Otherwise there would be no need to [

]. These statements are consistent with the specification's teaching that "the treatment plan may provide initial targeting information," which may be modified if patient repositioning is required. If no repositioning from the initial targeting information of the treatment plan is required, then the treatment plan can be delivered without modification.

This limitation requires hardwired logic or a programmable computer component with software as described in the '430 patent (at col. 5, lns. 37-42; col. 5, lns. 53-58; col. 7, lns. 29-34; col. 8, lns. 5-32; Figure 4 (525); or structural equivalents thereof), that perform the function of modifying a treatment plan. As Dr. Mutic explained, [

]." *See* CX-0848C (Mutic WS) at at Q141; CX-0233.38C ([

]). VolumeView software, "[d]uring registration," "shows the difference in position of the reference data and the acquired VolumeView." *See* CX-0848C (Mutic WS) at at Q141; CX-0233.251C. "[

]." *See* CX-0848C (Mutic WS) at at Q141; CX-0235.87C ([ ]). These satisfy both the structures and algorithms identified in Complainants and Staff's agreed upon construction for the term.

The corresponding structure in the '430 patent (at col. 5, lns. 53-58) identifies modification of the treatment plan by capturing image data to generate images of the target volume, followed by registering generated images of the target volume with reference images to determining the patient repositioning required, if any, before treatment. This is how the [ ] modifies a treatment plan by repositioning the patient in a manner different from the initial targeting information in the treatment plan. *See* CX-0848C (Mutic WS) at Q141.

The [ ] likewise has "at least one of hardwired logic and a programmable computer component." It consists of [

]. *Id.* at Q142. This hardware and software is used, for example, to "[

]...." JX-0002 at col. 5, lns. 55-58.

"a rotatable gantry; a cone-beam radiation source coupled to the rotatable gantry; and a flat-panel imager coupled to the rotatable gantry, wherein" (claim 1)

Claim 1 of the '430 patent recites the limitations of "a rotatable gantry," "a cone-beam radiation source coupled to the rotatable gantry," and "a flat-panel imager coupled to the rotatable gantry." Elekta does not dispute these recited limitations. As discussed above with respect to claim 1 of the '021 patent, the Accused Linacs meet the limitations.

"the flat-panel imager is operable to capture image projection data to generate cone-beam computed tomography (CT) volumetric image data capable of being used by the logic to modify a treatment plan for a target volume." (claim 1)

As Dr. Mutic testified, Elekta's Accused Linacs satisfy this limitation. *See* CX-0848C (Mutic WS) at Q146-148. First, the [ ] "is operable to capture image projection data to generate cone-beam computed tomography (CT) volumetric image data," as described above with respect to claim 1 of the '021 patent. Second, the [ ] is "capable of being used by the logic to modify a treatment plan for a target volume." For example, the [

]. *See, e.g.*, CX-0235.58C ([ ]); CX-0211.12 ([ ]). Elekta does not dispute this limitation.

"The apparatus of claim 1, 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." (claim 6)

As discussed above with respect to claim 15 of the '021 patent, the Accused

Linacs have "a translatable treatment couch coupled to the rotatable gantry via a communications network." Dependent claim 6 recites the further limitation of "the translatable treatment couch is capable of movement in three planes plus angulation." Elekta does not to dispute this dependent limitation. As discussed above with respect to claim 15 of the '021 patent, the [ ] of the Accused Linacs constitute a treatment couch that is translatable in three planes plus angulation.

b. Claim 18

Complainants argue:

> Claim 18 of the '430 patent is an independent method claim that Elekta infringes directly and by inducement by performing all of the recited steps itself, by performing all of the recited steps jointly with customers, and by inducing its customers to perform all of the steps using the Accused Linacs. Dr. Mutic has provided extensive testimony based on Elekta's documents and its belated disclosure regarding training that proves Elekta and/or its customers directly infringe claim 18 when using the Accused Linacs in a workflow that includes [
>
>].

Compls. Br. at 118 (citations omitted), 118-29.

Respondents argue that the accused products do not infringe claim 18. *See* Resps. Br. at 130-36. The Staff argues that "the evidence has not shown that claim 18 has been infringed by Elekta customers." Staff Br. at 70.

As noted, complainants assert independent method claim 18, which reads as follows:

> **18**. A method to perform a clinical treatment, comprising:
>
> using a clinical simulator machine to capture image projection data from a flat-panel imager for generating cone-beam computed tomography (CT) volumetric image data capable of being used by logic of the

> clinical simulator machine configured to modify a treatment plan for a clinical treatment machine;
>
> emitting a cone-beam from a radiation source;
>
> transmitting at least a portion of the cone-beam through a target volume;
>
> providing a treatment plan;
>
> modifying said treatment plan using said logic;
>
> continuing to rotate a gantry on which the imager is mounted while capturing image projection data; and
>
> one of capturing radiation at non-uniformly spaced angles with respect to a rotation, and changing the speed of rotation of the gantry during a rotation.

JX-0002 ('430 Patent) at col. 10, lns. 44-60.

For the reasons discussed below, asserted claim 18 is not infringed by Elekta's Accused Linacs.

Asserted claim 18 is a method claim. Varian alleges that the Elekta uses the Accused Linacs to directly infringe claim 18 by performing all of the recited steps itself and indirectly infringes by inducing its customers to perform all of the steps of claim 18. *See* Compls. Br. at 118-29.

Elekta argues that the Accused Linacs do not meet three limitations of claim 18. *See* Resps. Br. at 131-36. First, Elekta argues that the Accused Linacs do not meet the "using a clinical simulator machine to capture image projection data . . ." because the Accused Linacs are "not clinical simulator machines; they are clinical treatment machines" (the [ ], for example, has a linear accelerator attached to it). *See id.* at 136 (emphasis in original). Under the correct claim construction of "clinical simulator machine," which does not require that the simulator and treatment machines be on different devices, the evidence shows that the Accused Linacs meet this limitation. *See*

Compls. Br. at 108-11 (providing thorough analysis regarding whether the simulator and treatment machines must be on different devices).

Second, Elekta argues that the Accused Linacs do not meet the "modifying said treatment plan using said logic" limitation for the same reasons the Accused Linacs allegedly do not meet this limitation in claim 6. *See* Resps. Br. at 133. For the same reasons given above with regard to claim 6, the evidence shows that the Accused Linacs meet this limitation.

Third, Elekta argues that the Accused Linacs do not meet the "one of capturing radiation at non-uniformly spaced angles with respect to a rotation, and changing the speed of a rotation of the gantry during a rotation" limitation. *See* Resps. Br. at 133-36. This claim limitation is phrased as a Markush group, and thus the limitation can be fulfilled by either capturing radiation at non-uniformly spaced angles with respect to a rotation, or by changing the speed of a rotation of the gantry during a rotation. *See Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925).

Varian argues that this limitation is satisfied because [

]," the speed of rotation of the gantry during a rotation is changed on the Accused Linacs. *See* Compls. Br. at 126-29. However, Varian has not shown that an infringing act of [ ] has occurred.

Infringement of Method Claims Under *Electronic Devices*

As the Staff noted, the Commission has previously determined that performance of a claimed method directly by a respondent is not proof of a violation under section 337. *See Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, 337-TA-724, Comm'n Op. at 14, 17-19 (Nov. 21,

2011) ("*Electronic Devices*").

The Commission's opinion in *Electronic Devices* holds that the practice of an asserted method claim within the United States after importation cannot serve as the basis for an exclusion order. *Electronic Devices*, Comm'n Op. at 17. As discussed in *Electronic Devices*, section 337 prohibits:

> (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that –
>
> (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17; or
>
> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337(a)(1)(B).

The statute is violated only by the importation, sale for importation, or sale after importation of articles that either infringe a valid U.S. patent claim or are made by a method covered by a valid U.S. patent claim. An article, standing alone, cannot directly infringe a method claim. *Electronic Devices*, Comm'n Op. at 17; *see also Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 576 F.3d 1348, 1364 (Fed. Cir. 2009). A method claim is infringed only where someone performs all of the claimed method steps. *See NTP v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) ("[T]he use of a [claimed] process necessarily involves doing or performing each of the steps recited."); *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) ("A method claim is directly infringed only by one practicing the patented method.").

In *Electronic Devices*, the Commission ruled that complainant did not have a legally cognizable claim that respondent violated the statute by using articles within the United States when infringement allegedly occurred by virtue of that use. *Electronic Devices*, Comm'n Op. at 19 ("domestic use of such a method, without more, is not a sufficient basis for a violation of Section 337(a)(1)(B)(i)"). Relying expressly on the statutory language of section 337 and applicable Federal Circuit law, the Commission ruled that the act of importation "is not an act that practices the steps of the asserted method claim," and "[m]erely importing a device that may be used to perform a patented method does not constitute direct infringement of a claim to that method." *Id.* at 17-18 (citing *Cardiac Pacemakers*, 576 F.3d at 1364; *NTP*, 418 F.3d at 1319; *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1335 (Fed. Cir. 2008) ("[A] party that sells or offers to sell software containing instructions to perform a patented method does not infringe the patent under § 271(a)."); *Joy Techs.*, 6 F.3d at 773 ("The law is unequivocal that the sale of equipment to perform a process is not a sale of the process within the meaning of section 271(a).")).

The Commission stated:

> [S]ection 337(a)(1)(B)(i) covers imported articles that directly or indirectly infringe when it refers to "articles that – infringe." We also interpret the phrase "articles that – infringe" to reference the status of the articles at the time of importation. Thus, infringement, direct or indirect, must be based on the articles as imported to satisfy the requirements of section 337.

Electronic Devices, Comm'n Op. at 13-14. The Commission determined that the importation requirement was not met in that case by the respondent's post-importation performance of a claimed method. *Id.* at 18. Nevertheless, the Commission stated that

the complainant "might have proved a violation of section 337 if it had proved indirect infringement" of the method claim. *Id.* The Commission cited, as an example, *Certain Chemiluminescent Compositions, and Components Thereof and Methods of Using, and Products Incorporating the Same*, Inv. No. 337-TA-285, USITC Pub. No. 2370, Order No. 25 (Initial Determination) at 38 n.12 (March 1991), in which "the ALJ found that the 'importation and sale' of the accused articles constituted contributory and induced infringement of the method claim at issue in that investigation." *Electronic Devices*, Comm'n Op. at 18 n.11.

Indirect Infringement

With respect to indirect infringement, the evidence shows that Elekta instructs its customers to use its Accused Linacs in accordance with the documentation and training it provides. However, Elekta argues that both of its customers that Varian deposed in this investigation, [

]. *See* Resps. Br. at 134-35. Indeed, both [

]. *See* JX-0023C ([ ] Dep. Tr.) at 99-106, 136-137; JX-0034C ([ ] Dep. Tr.) at 125, 149, 152.

In addition, hearing testimony does not support a finding that Eletka's hospital customers have performed intra-fractional imaging. *See* Tr. 24-25, 1207-1208 (citing CX-3892C ([ ] Declaration); CX-3895C ([ ] Declaration); CX-3896C ([ ]); CX-3898C ([ ] Declaration)). Also, these statements were not subject to

cross-examination to determine the exact meaning of "[ ]" as used by the declarants. Thus, Varian has not shown a violation of section 337 with respect to method claim 18, although the accused products are capable of practicing the claim.

Elekta argues that Varian has failed to carry its burden of proof with regard to the intent elements of induced and contributory infringement. *See* Resps. Br. at 136. The evidence shows that Elekta provided testing and training materials to its customers, and has the requisite intent to contribute to infringement, at least since the filing of Varian's original complaint.

Elekta's documents and witnesses confirm that Elekta instructs and trains its customers to use its instruments in accordance with the documentation and training it provides, and its [

]. *See* CX-3779C ([

]); *see also, e.g.*, CX-0277.36C ("[

]"); CX-0233.38C (same); CX-3780.36C (same); CX-3779.9C; JX-0025C (Brown Dep. Tr.) at 101-102; JX-0031C (Hedges Dep. Tr.) at 60, 93-94; JX-0060C (Symons II Dep. Tr.) at 69-72; JX-0023C ([

]) Dep. Tr.) at 80-83, 85-86.

C. Domestic Industry (Technical Prong)

Complainants argue that their "TrueBeam radiotherapy system and Edge radiosurgery system practice claim 6 of the '430 patent." Compls. Br. at 129, 129-32.

The Staff agrees with complainants and concludes that "Varian's domestic industry products practice claim 6 of the '430 patent." Staff Br. at 72.

Respondents argue: "Varian's sole argument for technical domestic industry for the '430 patent is that its TrueBeam product allegedly practices claim 6. Varian has not established that TrueBeam has 'logic configured to modify a treatment plan,' as required by this claim. Accordingly, it has not shown a domestic industry in the '430 patent." *See* Resps. Br. at 137.

For the reasons discussed below, the TrueBeam and Edge systems meet each limitation of claim 6 of the '430 patent and therefore practices that claim.

Varian's domestic industry products include the Clinac iX and Trilogy linac systems when used with the On-Board Imager system, and the TrueBeam and Edge linac systems. *See, e.g.*, CX-0848C (Mutic WS) at Q289. Varian's linacs are integrated and networked computer-controlled systems used to perform imaging and implement radiotherapy treatments, such as treatment plans generated by Varian's RapidArc VMAT planning software. *See, e.g.*, CX-0848C (Mutic WS) at 289; CX-3835C (Bergeron WS) at Q11. They all function similarly and their basic configuration is the same: a rotatable gantry with a high-energy MV source and opposing MV flat-panel imager and an orthogonal kV source and opposing kV flat-panel imager coupled to the gantry. *See, e.g.*, CX-3835C (Bergeron WS). The Clinac iX and Trilogy systems optionally include the "On-Board Imager," a kV imaging system used with the linacs. *See, e.g.*, CX-0848C (Mutic WS) at 298-300, 312-14. The integrated kV imaging system of the TrueBeam and Edge systems is called the "X-Ray Imaging System." *See, e.g.*, CX-0848C (Mutic WS) at 331-33, 366-67, 377-79.

As noted, respondents only dispute that Varian's TrueBeam products practice the limitation "logic configured to modify a treatment plan" of claim 1 of the '430 patent.

Respondents argue that repositioning a patient is not modifying a treatment plan. Resps. Br. at 137.

The TrueBeam and Edge function similarly, and practice the '430 patent in the same way, as evidenced by their shared technical manuals. *See, e.g.*, CX-0420C; CX-1020C; CX-1021C. Hence, "TrueBeam" refers collectively to the TrueBeam and Edge systems.

Claim 1 of the '430 patent (which claim 6 depends on) recites: "An apparatus, comprising ...." This is a preamble and as such is not limiting. To the extent it is limiting, the TrueBeam is an apparatus. *See* CX-0848C (Mutic WS) at Q361.

Claim 1 recites: [an apparatus comprising] "logic configured to modify a treatment plan for a target volume, the logic comprising at least one of hardwired logic and a programmable computer component ...." The term "treatment plan" means "the set of instructions used by the radiation treatment system to deliver radiation to a target volume." The term "logic configured to modify a treatment plan for a target volume" specifies the function "to modify a treatment plan for a target volume" and a corresponding structure of a hardwired logic or programmable computer component with software, including an algorithm that performs that function. The specification of the '430 patent describes an algorithm that performs the function of modifying a treatment plan for a target volume, disclosing step-by-step use of volumetric cone-beam CT images collected on a target volume to modify a treatment plan by, for example, comparing/registering the collected cone-beam CT images of the target volume against "reference images to determine the amount of patient repositioning required, if any, before treatment." *See, e.g.*, CX-0848C (Mutic WS) at Q362.

The TrueBeam performs the function of modifying the set of instructions used by the radiation treatment system to deliver radiation to a target volume. The TrueBeam uses acquired kV images to verify the correct patient position. *See, e.g.*, CX-0848C (Mutic WS) at Q363; CX-0420.187C (TrueBeam Instructions for Use). If the target tumor has moved, the patient is moved requiring a change to a specific patient geometry or specific machine setting resulting in a modification of the treatment plan. *Id.*; Papanikolaou Tr. 901-902. The TrueBeam performs this function using a hardwired logic or programmable computer component with software. The TrueBeam Workstation is used to verify and correct the patient setup based on images acquired by the TBX system, *see* CX-0420.187C (TrueBeam Instructions for Use), and the TrueBeam Workstation is made up of a hardwired logic or a programmable computer component with software. The TrueBeam also uses an algorithm that compares/registers the collected cone-beam CT images of the target volume against "reference images to determine the amount of patient repositioning required, if any, before treatment," as disclosed in the '430 patent specification. *See, e.g.*, CX-0848C (Mutic WS) at Q364.

Claim 1 recites: [an apparatus comprising] "a rotatable gantry; a cone-beam radiation source coupled to the rotatable gantry; a flat-panel imager coupled to the rotatable gantry …." The TrueBeam meets these limitations. CX-0848C (Mutic WS) at Q365-67. The TrueBeam has a rotatable gantry, and a cone-beam radiation source coupled to the gantry. *See, e.g.*, CX-1021.17-18, 27-28C (TrueBeam Technical Reference Guide – Volume 2: Imaging). The TrueBeam has a flat-panel imager that is coupled to the gantry. *See, e.g.*, CX-1021.17-18C.

Claim 1 recites: "wherein the flat-panel imager is operable to capture image projection data to generate cone-beam computed tomography (CT) volumetric image data capable of being used by the logic to modify a treatment plan for a target volume." The TrueBeam meets this limitation. CX-0848C (Mutic WS) at Q368-69. The TBX system's flat-panel imager captures image projection data which is used to generate cone-beam CT volumetric image data of the patient. *See, e.g.*, CX-1021.22C. This cone-beam CT volumetric data is capable of being used by the TrueBeam's logic to modify a treatment plan for a target volume, for example, the cone-beam CT volumetric data is used to correct the patient's position. *See, e.g.*, CX-0420.130C.

In addition to the limitations of claim 1, claim 6 claims "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." The TrueBeam meets this limitation. CX-0848C (Mutic WS) at Q370. The TrueBeam has a translatable treatment couch that is capable of movement in three planes as well as angulation. *See, e.g.*, CX-1020.24C (TrueBeam Technical Reference Guide – Volume 1). The [

]. *See, e.g.*, CX-1020.25-28C.

Accordingly, the TrueBeam meets each limitation of claim 6 of the '430 patent, and therefore practices that claim.

D. Validity of the '430 Patent

Elekta argues: (1) claim 6 of the '430 patent is anticipated by Jaffray WIPO[35] and that both claims 6 and 18 are anticipated by Jaffray MICCAI 2001;[36] (2) Jaffray MICCAI 2001 renders claim 6 obvious; (3) the combination of Jaffray WIPO, Mosleh-Shirazi3,[37] and Jaffray JRO 1999[38] renders claim 18 obvious; (4) Jaffray MICCAI 2001 renders claim 18 obvious in view of Mosleh-Shirazi3, Jaffray JRO 1999, and Mallik;[39] (5) claims 6 and 18 are invalid under Section 112, ¶ 1; and (6) claims 6 and 18 are invalid under Section 112, ¶ 2. *See* Resps. Br. at 99-124.

Complainants and the Staff disagree. *See* Compls. Br. at 132-39. The Staff argues that claim 6 is anticipated, but otherwise disagrees with respondents that the asserted claims are invalid. *See* Staff Br. at 73-79.

1. Applicable Law

One cannot be held liable for practicing an invalid patent claim. *See Pandrol USA, LP v. AirBoss Railway Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003).

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[35] *See* RX-0270 (WIPO Publication No. WO 01/60236) ("Jaffray WIPO").

[36] *See* RX-0272 (David Jaffray *et al.*, *Image Guided Radiotherapy of the Prostate*, MICCAI 2001, LNCS 2208, 1075-1080) (2001) (hereinafter, "Jaffray MICCAI 2001").

[37] *See* RX-0225 (Mohammad Amin Mosleh-Shirazi *et al.*, *A Cone-Beam Megavoltage CT Scanner for Treatment Verification in Conformal Radiotherapy*, Radiotherapy and Oncology 48, 319-328 (1998) (hereinafter, "Mosleh-Shirazi3").

[38] *See* RX-0264 (David A. Jaffray *et al.*, *A Radiographic and Tomographic Imaging System Integrated Into a Medical Linear Accelerator for Localization Of Bone and Soft-Tissue Targets*, Int. J. Radiation Oncology Biol. Phys., Vol. 45, No. 3, 773-789) (1999) ("Jaffray JRO 1999").

[39] *See* RX-0274 (Raj Mallik *et al.*, *Simulator Based CT: 4 Years of Experience at the Royal North Shore Hospital, Sydney, Australia*, 3-D Radiation Treatment Planning and Conformal Therapy, Proceedings of an International Symposium, Apr. 21-23, 1993, 177-185 (Purdy & Emami, eds.) (hereinafter, "Mallik").

Nevertheless, each claim of a patent is presumed to be valid, even if it depends from a claim found to be invalid. 35 U.S.C. § 282; *DMI Inc. v. Deere & Co.*, 802 F.2d 421 (Fed. Cir. 1986).

A respondent that has raised patent invalidity as an affirmative defense must overcome the presumption by "clear and convincing" evidence of invalidity. *Checkpoint Systems, Inc. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995).

a. Anticipation

Anticipation under 35 U.S.C. § 102 is a question of fact. *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1347 (Fed. Cir. 2007). Section 102 provides that, depending on the circumstances, a claimed invention may be anticipated by variety of prior art, including publications, earlier-sold products, and patents. *See* 35 U.S.C. § 102 (*e.g.*, section 102(b) provides that one is not entitled to a patent if the claimed invention "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States").

The general law of anticipation may be summarized, as follows:

> A reference is anticipatory under § 102(b) when it satisfies particular requirements. First, the reference must disclose each and every element of the claimed invention, whether it does so explicitly or inherently. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed.Cir.2006). While those elements must be "arranged or combined in the same way as in the claim," *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1370 (Fed.Cir.2008), the reference need not satisfy an *ipsissimis verbis* test, *In re Bond*, 910 F.2d 831, 832-33 (Fed.Cir.1990). Second, the reference must "enable one of ordinary skill in the art to make the invention without undue experimentation." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed.Cir.2008); *see In re LeGrice*, 49 C.C.P.A. 1124, 301 F.2d 929, 940-44 (1962). As

> long as the reference discloses all of the claim limitations and enables the "subject matter that falls within the scope of the claims at issue," the reference anticipates -- no "actual creation or reduction to practice" is required. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1380-81 (Fed.Cir.2003); *see In re Donohue*, 766 F.2d 531, 533 (Fed.Cir.1985). This is so despite the fact that the description provided in the anticipating reference might not otherwise entitle its author to a patent. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed.Cir.1991) (discussing the "distinction between a written description adequate to support a claim under § 112 and a written description sufficient to anticipate its subject matter under § 102(b)").

In re Gleave, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

b. Obviousness

Under section 103 of the Patent Act, a patent claim is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[40] 35 U.S.C. § 103. While the ultimate determination of whether an invention would have been obvious is a legal conclusion, it is based on "underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness." *Eli Lilly and Co. v. Teva Pharmaceuticals USA, Inc.*, 619 F.3d 1329 (Fed. Cir. 2010).

The objective evidence, also known as "secondary considerations," includes commercial success, long felt need, and failure of others. *Graham v. John Deere Co.*,

[40] The standard for determining whether a patent or publication is prior art under section 103 is the same as under 35 U.S.C. § 102, which is a legal question. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987).

383 U.S. 1, 13-17 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006). "[E]vidence arising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). Secondary considerations, such as commercial success, will not always dislodge a determination of obviousness based on analysis of the prior art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007) (commercial success did not alter conclusion of obviousness).

"One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *KSR*, 550 U.S. at 419-20. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.*

Specific teachings, suggestions, or motivations to combine prior art may provide helpful insights into the state of the art at the time of the alleged invention. *Id.* at 420. Nevertheless, "an obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way." *Id.* "Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* A "person of ordinary skill is also a person of ordinary creativity." *Id.* at 421.

Nevertheless, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); *see KSR*, 550 U.S. at 416 (a combination of elements must do more than yield a predictable result; combining elements that work together in an "unexpected and fruitful manner" would not have been obvious).[41]

c. Written Description

The issue of whether a patent is invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1 is a question of fact. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 670 F.3d 1171, 1188 (Fed. Cir. 2012). A patent's written description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. The test for sufficiency of a written description is "whether the disclosure of the application relied upon reasonable conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*)).

[41] Further, "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 550 U.S. at 416 (citing *United States v. Adams*, 383 U.S. 39, 52 (1966)).

d. Indefiniteness

The definiteness requirement of 35 U.S.C. § 112 ensures that the patent claims particularly point out and distinctly claim the subject matter that the patentee regards to be the invention. *See* 35 U.S.C. § 112, ¶ 2; *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366 (Fed. Cir. 2004). If a claim's legal scope is not clear enough so that a person of ordinary skill in the art could determine whether or not a particular product infringes, the claim is indefinite, and is, therefore, invalid. *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003).[42]

Thus, it has been found that:

> When a proposed construction requires that an artisan make a separate infringement determination for every set of circumstances in which the composition may be used, and when such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not), that construction is likely to be indefinite.

Halliburton Energy Servs. v. M-I LLC, 514 F.3d 1244, 1255 (Fed. Cir. 2008).

The Supreme Court addressed the issue of indefiniteness, and stated that a finding of indefiniteness should not be found if the claims, "viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014).

A patent is not indefinite if the claims, "viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124

[42] Indefiniteness is a question of law. *IGT v. Bally Gaming Int'l, Inc.*, 659 F.3d 1109 (Fed. Cir. 2011).

(2014). "If, after a review of the intrinsic and extrinsic evidence, a claim term remains ambiguous, the claim should be construed so as to maintain its validity." *Certain Consumer Electronics And Display Devices With Graphics Processing And Graphics Processing Units Therein*, Inv. No. 337-TA-932, Order No. 20 (Apr. 2, 2015) (quoting *Phillips*, 415 F.3d at 1327).

The burden is on the accused infringer to come forward with clear and convincing evidence to prove invalidity. *See Young v. Lumenis, Inc.*, 492 F.3d 1336, 1344 (Fed. Cir. 2007) ("A determination that a patent claim is invalid for failing to meet the definiteness requirement in 35 U.S.C. § 112, ¶ 2 is a legal question reviewed de novo.").

2. Anticipation

Respondents argue:

> The evidence shows that claims 6 and 18 of the '430 patent are invalid as anticipated by the printed publication titled "Image Guided Radiotherapy of the Prostate" ("*Jaffray MICCAI 2001*") and that claim 6 of the '430 patent is also invalid as anticipated by WIPO Publication No. WO 01/60236 ("*Jaffray WIPO*").

Resps. Br. at 98-99.

As noted, complainants assert dependent apparatus claim 6 (which depends from claim 1) and independent method claim 18. Those claims read as follows:

> **1**. An apparatus, comprising:
>
> logic configured to modify a treatment plan for a target volume, the logic comprising at least one of hardwired logic and a programmable computer component;
>
> a rotatable gantry;
>
> a cone-beam radiation source coupled to the rotatable gantry; and
>
> a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture

image projection data to generate cone-beam computed tomography (CT) volumetric image data capable of being used by the logic to modify a treatment plan for a target volume.

6. The apparatus of claim **1**, 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.

18. A method to perform a clinical treatment, comprising:

using a clinical simulator machine to capture image projection data from a flat-panel imager for generating cone-beam computed tomography (CT) volumetric image data capable of being used by logic of the clinical simulator machine configured to modify a treatment plan for a clinical treatment machine;

emitting a cone-beam from a radiation source;

transmitting at least a portion of the cone-beam through a target volume;

providing a treatment plan;

modifying said treatment plan using said logic;

continuing to rotate a gantry on which the imager is mounted while capturing image projection data; and

one of capturing radiation at non-uniformly spaced angles with respect to a rotation, and changing the speed of rotation of the gantry during a rotation.

JX-0002 ('430 Patent) at col. 8, ln. 63 – col. 9, ln. 8; col. 9, lns. 27-30; col. 10, lns. 44-60.

a. Jaffray MICCAI 2001 (Claim 6)

Overview

As discussed below, the evidence shows that *Jaffray MICCAI 2001* anticipates claim 6 of the '430 patent because it discloses each and every element of the claim. *Jaffray MICCAI 2001* is a printed publication that was published in October 2001 and lists Dr. David Jaffray et al. as the authors. RX-0272. All parties agree it is prior art

against the '430 patent under 35 U.S.C. § 102 (a) and (b). Resps. Br. at 99 (citing Mutic Tr. 971-972). *Jaffray MICCAI 2001* anticipates claims 6 and 18 of the '430 patent because it discloses each and every element of the claims. It discloses a medical linear accelerator, and SL-20, equipped with an integrated cone-beam CT imaging system comprising a flat-panel imager for use in image guided radiotherapy, treatment planning, treatment modification, and treatment implementation. Mutic Tr. 972.

Varian and its expert Dr. Mutic does not dispute that *Jaffray MICCAI 2001* discloses each and every element of claim 1, from which claim 6 depends. He disputes only that Jaffray MICCAI discloses the "treatment couch" limitation of claim 6. Mutic Tr. 994-995.

Independent apparatus claim 1 and asserted dependent claim 6 read as follows:

> **1**. An apparatus, comprising:
>
> logic configured to modify a treatment plan for a target volume, the logic comprising at least one of hardwired logic and a programmable computer component;
>
> a rotatable gantry;
>
> a cone-beam radiation source coupled to the rotatable gantry; and
>
> a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data to generate cone-beam computed tomography (CT) volumetric image data capable of being used by the logic to modify a treatment plan for a target volume.
>
> **6**. The apparatus of claim **1**, 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.

JX-0002 ('430 Patent) at col. 8, ln. 63 – col. 9, ln. 8; col. 9, lns. 27-30.

Element-by-Element Analysis

Claim 1: "An apparatus"

There is no dispute that *Jaffray MICCAI 2001* discloses "[a] prototype of an integrated system for cone-beam CT guided radiotherapy of prostate cancer." RX-0272 at 0001-0002; Fig. 1.

Claim 1: "logic configured to modify a treatment plan for a target volume, the logic comprising at least one of hardwired logic and a programmable computer component"

In the claim construction section above, the administrative law judge determined that the claim term "logic configured to modify a treatment plan for a target volume" should be construed as proposed by complainants. Under this claim construction, *Jaffray MICCAI 2001* discloses this undisputed limitation. The parties agree that "logic…configured to modify a treatment plan for a target volume" is a means-plus-function limitation and the structure includes the algorithm for performing the recited function. RX-0465 at 0006. The parties also agree that a treatment plan is "the set of instructions used by the radiation treatment system to deliver radiation to a target volume." *Id.* at 0005. The set of instructions includes things like "the energy or potency of the treatment beam, angles for the collimator gantry, and positions of the radiation limiting jaws for the collimator" and "a prescribed relative position at the time of treatment between the target volume to be treated and the therapeutic beam or beams used to treat the target volume." RX-494C (Papanikolaou RWS) at Q94-95. The parties agree that modification of the treatment plan occurs when these "instructions" are changed. *Jaffray MICCAI 2001* discloses "logic configured to modify a treatment plan for a target volume."

Jaffray MICCAI 2001 discloses that cone beam CT is acquired and the "...3D CT data set is analyzed automatically to localize the prostate and the treatment prescription is adapted to match the actual position and orientation of the prostate" prior to delivering the treatment prescription. RX-0272 at 0002 (emphasis added). It discloses modifying the treatment plan using multiple algorithms including: an "analysis algorithm," a "chamfer matching algorithm," and a "registration algorithm." *Id.* at 0003. Specifically, it discloses the "analysis algorithm" utilizes the "chamfer matching algorithm" to register bony anatomy of the on-line CT with the planning CT scan. *Id.* at 0003. The "registration algorithm" measures "...the displacement of the prostate relative to the pelvis..." *Id.* at 0003. *Jaffray MICCAI 2001* then defines prostate contours and aligns the "planned prostate shape" with the "on-line CT." *See id.* at 0003. The algorithm for "on-line prostate localization [is] shown in Figs. 3a-d" and illustrates that the algorithm uses cone-beam CT imaging during planning. *Id.* at 0004-0005. Jaffray MICCAI also discloses that "a best fitting treatment plan is selected from the set of pre-defined treatment plans to account for prostate rotation" to "minimize the on-line planning time." *Id.* at 0003. Finally, *Jaffray MICCAI 2001* discloses cone beam acquisition after treatment delivery for the purpose of "re-planning based on the pre- and post-treatment CT images...to determine the cumulative radiation dose delivered." *Id.* at 0003. These scans are used to increase safety because "possible deficiencies of each fraction can be rectified on later fractions." *Id.*

The above process and steps constitute modification of a treatment plan under Varian's proposed construction (adopted by the administrative law judge), as shown below:

Varian's Citations to corresponding Structure in the '430 patent (JX-0002)	Disclosure in *Jaffray MICCAI 2001* (RX-0272)
5:37-42	*Jaffray MICCAI 2001* discloses a gantry that can rotate about an isocenter to place the cone-beam CT radiation source and imager at any position 360 degrees around the target volume. The resulting image data can then be used to tailor a dose of therapeutic radiation based on at least the generated pre-defined treatment plan. *Id.* at 0002.
5:53-58	*Jaffray MICCAI 2001* discloses capturing cone beam radiation from the radiation source to generate images of the target volume. The captured image data can be compared/registered with reference images to determine the patient repositioning required, if any, before treatment. *Id.* at 0003-0005.
7:29-34	*Jaffray MICCAI 2001* discloses that the clinical treatment machine may use the kV cone-beam CT image data to make any necessary adjustments to the treatment plan based on identified movement of the target volume or to determine the amount of patient repositioning required by the treatment couch 418 or collimator movements. *Id.* at 0003-0005.
8:5-32	*Jaffray MICCAI 2001* discloses that these functions can be accomplished by software running on a general purpose computer. *Id.* at 0003.
Fig. 4 (525)	*Jaffray MICCAI 2001* discloses registering treatment image data with simulator/reference image data and repositioning the patient. *Id.* at 0003-0005.

Jaffray MICCAI 2001 also discloses "logic comprising at least one of hardwired logic and a programmable computer component" under the correct claim construction of the claim term "logic."[43] On page 0003, it discloses that "[p]rototypes of the hardware

[43] As discussed above, as proposed by complainants and the Staff, the administrative law judge determined that the claim term "logic" should be construed to mean "a hardware or

and software of the system have been constructed," which satisfies the correct claim construction of 'logic.'" RX-0272 at 0003.

Claim 1: "a rotatable gantry"

This undisputed limitation is met because *Jaffray MICCAI 2001* acquires images "...over 360 degrees of rotation in a single gantry rotation." RX-0272 at 0002; *see also* RX-0433C (Papanikolaou WS) at Q513-514.

Claim 1: "a cone-beam radiation source coupled to the rotatable gantry"

Jaffray MICCAI 2001 discloses this undisputed limitation because it discloses using "...a kilovoltage cone-beam CT system that is integrated on the gantry of an Elekta SL-20 linear accelerator[4]" to acquire images. RX-0272 at 0002. Fig. 1 illustrates a "[p]rototype cone beam CT scanner" where "[a] diagnostic X-ray tube (right) and a flat panel imager (left) have been added" to a linac. *Id.*; *see also* RX-433C at Q515-516.

Claim 1: "a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data to generate cone-beam computed tomography (CT) volumetric image data capable of being used by the logic to modify a treatment plan for a target volume"

Jaffray MICCAI 2001 discloses coupling "a flat-panel imager" to "the rotatable gantry" in Fig. 1. It discloses a "[p]rototype cone beam CT scanner mounted on the gantry of a commercial medical linear accelerator" with "...a flat panel imager (left)...added." RX-0272 at 0002. During image acquisition the "flat-panel imager" makes "... half field images...over 360 degrees of rotation in a single gantry rotation." *Id.*

Jaffray MICCAI 2001 further describes that "[a] cone beam CT scan will be

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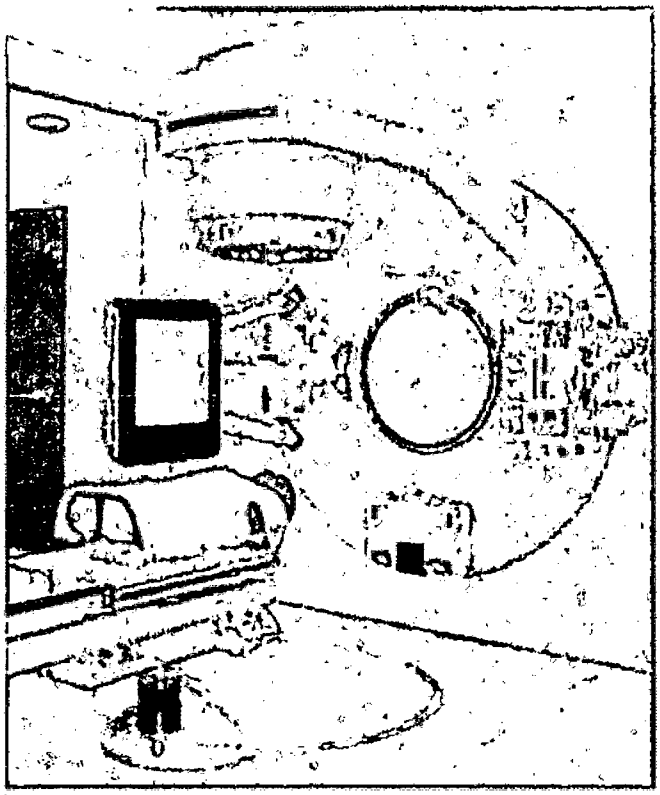
software programmable computer component."

acquired on the treatment machine for each treatment fraction (Fig. 1)." RX-0272 at 0002. The scan is "[a] three-dimensional image of the patient, which is obtained by cone beam reconstruction using the Feldkamp algorithm for limited cone reconstruction [2]." RX-0272 at 0002. *Jaffray MICCAI 2001* uses the "image data" to "modify a treatment plan for a target volume" as explained above. *See also* RX-433C at Q517-518.

Claim 6: "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."

As discussed above in the claim construction section, the administrative law judge determined that the claim term "communications network" should be given its plain and ordinary meaning, *i.e.*, "a system of computers interconnected by telephone wires or other means in order to share information." Under this claim construction, *Jaffray MICCAI 2001* discloses this limitation.

Jaffray MICCAI 2001 discloses a system with "...a kilovoltage cone-beam CT system that is integrated on the gantry of an Elekta SL-20 linear accelerator [4]." RX-0272 at 0002. *Jaffray MICCAI 2001* expressly discloses and illustrates a translatable treatment couch as seen in Fig. 1, which is a standard component of an Elekta SL-20 linac.



RX-0272 at 0002. As Mr. Brown testified, the treatment couch in an SL-20 can "move in three directions, e.g., forward and backward, left and right, and up and down" and can rotate. RX-0435C (Brown WS) at Q23. The general rule explained by the Federal Circuit is that "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). Inasmuch as *Jaffray MICCAI 2001* includes an SL-20 linac, it inherently includes all the features of the SL-20 such as the "communications network." As explained by Anderson and acknowledged by Dr. Mutic at the hearing, in an Elekta SL-20, "[c]ommunication between the control processor and the accelerator, gantry and patient couch is handled by a pair of high-speed serial links." RX-0430 at 0001; Mutic

Tr. 973. The high-speed serial links meet the ordinary meaning of communications network because they consist of two or more computers or devices that share information with each other. The control processor and patient couch communicate over the serial links and therefore *Jaffray MICCAI 2001* inherently discloses this limitation under the ordinary meaning of "communications network."

b. Jaffray WIPO (Claim 6)

Overview

As discussed below, the evidence shows that *Jaffray WIPO*[44] anticipates claim 6 of the '430 patent because it discloses each and every element of the claim. Varian does not dispute that *Jaffray WIPO* discloses each and every element of claim 1; only the additional element recited in claim 6 is disputed. *See* Compls. Br. at 132-35.

Independent apparatus claim 1 and asserted dependent claim 6 read as follows:

> **1**. An apparatus, comprising:
>
> logic configured to modify a treatment plan for a target volume, the logic comprising at least one of hardwired logic and a programmable computer component;
>
> a rotatable gantry;
>
> a cone-beam radiation source coupled to the rotatable gantry; and
>
> a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data to generate cone-beam computed tomography (CT) volumetric image data capable of being used by the logic to modify a treatment plan for a target volume.
>
> **6**. The apparatus of claim **1**, further comprising a translatable treatment couch coupled to the rotatable gantry via a communications network, wherein the translatable

[44] *See* RX-0270 (WIPO Publication No. WO 01/60236) ("Jaffray WIPO").

> treatment couch is capable of movement in three planes plus angulation.

JX-0002 ('430 Patent) at col. 8, ln. 63 – col. 9, ln. 8; col. 9, lns. 27-30.

Element-by-Element Analysis

Claim 1: "An apparatus"

Jaffray WIPO discloses that "system 400 may be retrofitted onto an existing or new radiation therapy system 700...." RX-0270 at 0034. This system constitutes "an apparatus."

Claim 1: "logic configured to modify a treatment plan for a target volume, the logic comprising at least one of hardwired logic and a programmable computer component"

In the claim construction section above, the administrative law judge determined that the claim term "logic configured to modify a treatment plan for a target volume" should be construed as proposed by complainants. Under this claim construction, *Jaffray WIPO* discloses the claim element.

Jaffray WIPO discloses that "...[t]he present invention provides an apparatus and method for improving the precision of radiation therapy by incorporating a cone beam computerized tomography imaging system in the treatment room, the 3-D images from which are used to modify current and subsequent treatment plans." RX-0270 at 0009. "The preferred embodiment includes a mechanism (reconstruction engine) for high-speed cone beam computerized tomography image reconstruction" where "[t]he cone beam computerized tomography image is then made available to a system for on-line treatment planning." *Id.* at 0042 (emphasis added). The system of *Jaffray WIPO* can also modify

subsequent treatment sessions using cone beam computerized tomography images acquired before, during or after treatment. *Id.* at 0047.

Jaffray WIPO discloses "logic" in the form of various methods that are capable of modifying the treatment plan including "...recalculation of the RTTP, selection of a modified RTTP from a previously calculated set of plans, and/or translation, rotation, and/or angulation of the patient." RX-0270 at 0045. It further describes that "[t]he preferred embodiment entails a streamlined process for rapid lesion localization, selection of an appropriate RTTP, dosimetry review, and transfer of the prescription to the radiation therapy delivery system." *Id.* at 0046 (emphasis added). *Jaffray WIPO* also discloses a "computer-controlled treatment table" that can correct the location of a lesion by translating the patient. *Id.* at 0047. Jaffray further discloses a computer that "...is connected to the radiation source and the cone beam computerized tomography system, wherein the computer receives the image of the object and...sends a signal to the radiation source that controls the path of the radiation source." *Id.* at 0008. Finally, the flat panel imager can communicate with a computer "...via an RS-422 bus." *Id.* at 0014. The various components in *Jaffray WIPO* described above disclose "logic" under the correct claim construction.

The above process and steps constitute modification of a treatment plan under the correct claim construction,[45] as shown below:

[45] The administrative law judge determined that the claim term "logic configured to modify a treatment plan for a target volume" should be construed as proposed by complainants.

Varian's Citations to corresponding Structure in the '430 patent (JX-0002)	Disclosure in *Jaffray WIPO* (RX-0270)
5:37-42	*Jaffray WIPO* discloses a gantry that can rotate about an isocenter to place the cone-beam CT radiation source and imager at any position 360 degrees around the target volume. The resulting image data can then be used to tailor a dose of therapeutic radiation based on at least the generated pre-defined treatment plan. RX-0270 at 0042 and 0045-0047.
5:53-58	*Jaffray WIPO* discloses capturing cone beam radiation from the radiation source to generate images of the target volume. The captured image data can be compared/registered with reference images to determine the patient repositioning required, if any, before treatment. *Id.* at 0042 and 0045-0047.
7:29-34	*Jaffray WIPO* discloses that the clinical treatment machine may use the kV cone-beam CT image data to make any necessary adjustments to the treatment plan based on identified movement of the target volume or to determine the amount of patient repositioning required by the treatment couch 418 or collimator movements. *Id.* at 0042 and 0045-0047.
8:5-32	*Jaffray WIPO* discloses that these functions can be accomplished by software running on a general purpose computer. *Id.* at 0008 and 0014.
Fig. 4 (525)	*Jaffray WIPO* discloses registering treatment image data with simulator/reference image data and repositioning the patient. *Id.* at 0042 and 0045-0047.

Claim 1: "a rotatable gantry"; "a cone-beam radiation source coupled to the rotatable gantry"; "a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data to generate cone-beam computed tomography (CT) volumetric image data capable of being used by the logic to modify a treatment plan for a target volume"

Jaffray WIPO discloses these limitations for the same reasons discussed above for claim 1 of the '021 patent. *See* RX-0433C (Papanikolaou WS) at Q491-497; RX-0270 at 0006, 0034-0035, 0040, 0042, 0045, 0047.

c. Jaffray MICCAI 2001 (Claim 18)

Elekta argues that claim 18 of the '430 patent is anticipated by *Jaffray MICCAI 2001*;[46] *See* Resps. Br. at 99-112.

Asserted independent method claim 18 reads as follows:

> **18.** A method to perform a clinical treatment, comprising:
>
> using a clinical simulator machine to capture image projection data from a flat-panel imager for generating cone-beam computed tomography (CT) volumetric image data capable of being used by logic of the clinical simulator machine configured to modify a treatment plan for a clinical treatment machine;
>
> emitting a cone-beam from a radiation source;
>
> transmitting at least a portion of the cone-beam through a target volume;
>
> providing a treatment plan;
>
> modifying said treatment plan using said logic;
>
> continuing to rotate a gantry on which the imager is mounted while capturing image projection data; and
>
> one of capturing radiation at non-uniformly spaced angles with respect to a rotation, and changing the speed of rotation of the gantry during a rotation.

[46] *See* RX-0272 (David Jaffray *et al.*, *Image Guided Radiotherapy of the Prostate*, MICCAI 2001, LNCS 2208, 1075-1080) (2001).

JX-0002 ('430 Patent) at col. 10, lns. 44-60.

For the reasons discussed below, respondents have not shown by clear and convincing evidence that *Jaffray MICCAI 2001* anticipates the asserted claim 18.

As noted and explained by Dr. Mutic, Dr. Papanikolaou admits that not all the limitations of the method of claim 18 are disclosed by *Jaffray MICCAI 2001*, stating that "Jaffray MICCAI does not explicitly disclose" the limitation of "one of capturing radiation at non-uniformly spaced angles . . .." *See* CX-3879C (Mutic RWS) at Q196, 198; RDX-053.013; *see also* CX-3899C. Instead, Dr. Papanikolaou refers to a separate reference by a different group of authors, "Mosleh-Shirazi3." *See id.* Dr. Papanikolaou thus admits that a single reference does not disclose all the elements of claim 18.

As explained by Dr. Mutic, Mosleh-Shirazi3 does not disclose the limitation or show inherent disclosure of the limitation within *Jaffray MICCAI 2001* as Dr. Papanikolaou opines. At most the reference discloses the incidental fact that the gantry system utilized in the reference had mechanical characteristics that caused some incidental variation in gantry speed despite the intent of the system to be run at a constant speed. *See* CX-3879C (Mutic RWS) at Q198. That is not a disclosure of the affirmative method step of "changing the speed of rotation of the gantry during a rotation." Further, Mosleh-Shirazi3 does not teach this method step in combination with another of the steps of claim 18, "continuing to rotate a gantry on which the imager is mounted while capturing image projection data." *See* Mutic Tr. 1051.

Moreover, Dr. Papanikolaou's inherency opinion is misplaced because at most he opines that incidental non-uniformities in angle or changes in gantry speed may sometimes occur in some undisclosed class of linear accelerators. Such occurrences,

even if common or probable, are not sufficient to show inherent anticipation, which requires that one of skill in the art appreciate that the limitation is "necessarily" present in the primary reference. *See Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) ("a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference"); *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002) ("[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation.") (emphasis in original). Thus, respondents cannot meet their burden of proving anticipation by clear and convincing evidence.

3. Obviousness

Elekta argues: (1) Jaffray MICCAI 2001 renders claim 6 of the '430 patent obvious; (2) the combination of Jaffray WIPO, Mosleh-Shirazi3, and Jaffray JRO 1999 renders claim 18 obvious; (3) and Jaffray MICCAI 2001 renders claim 18 obvious in view of Mosleh-Shirazi3, Jaffray JRO 1999, and Mallik. *See* Resps. Br. at 115-21.

a. Jaffray MICCAI 2001 (Claim 6)

Elekta argues that to the extent that *Jaffray MICCAI 2001* does not anticipate claim 6, it renders claim 6 obvious. *See* Resps. Br. at 115-17. For the same reasons as described previously with regard to anticipation, the evidence shows that *Jaffray MICCAI 2001* renders claim 6 *prima facie* obvious. However, Elekta has not shown the claims to be obvious because it has not weighed all four *Graham* factors. *See* Compls. Br. at 98 and Staff Br. at 75 (citing RX-0433C (Papanikolaou WS) at Q416; Resps. Br. at 115-21 (no briefing of *Graham* factors); *see also Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d

1356, 1365-67 (2013) (vacating determination of obviousness that was otherwise supported by substantial evidence for failure to consider secondary considerations).

b. Jaffray WIPO, Mosleh-Shirazi3, and Jaffray JRO 1999 (Claim 18)

Elekta argues that the combination of *Jaffray WIPO*, *Mosleh-Shirazi3*,[47] and *Jaffray JRO 1999* renders claim 18 invalid as obvious. *See* Resps. Br. at 120-21. However, none of these references disclose the limitation of claim 18 "one of capturing radiation at non-uniformly spaced angles with respect to a rotation, and changing the speed of rotation of the gantry during a rotation." *See* Compls. Br. at 135-37.

In addition, Elekta provides no analysis of the motivation to combine these references, or an analysis of all four *Graham* factors. *See* RX-0433C (Papanikolaou WS); *see also Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d 1356, 1365-67 (2013) (vacating determination of obviousness that was otherwise supported by substantial evidence for failure to consider secondary considerations).

Accordingly, the evidence does not show that this combination renders claim 18 obvious.

c. *Jaffray MICCAI*, *Mosleh-Shirazi3*, *Jaffray JRO 1999*, and *Mallik* (Claim 18)

Elekta argues that *Jaffray MICCAI 2001*renders claim 18 of the '430 patent obvious in view of *Mosleh-Shirazi3*, *Jaffray JRO 1999*, and *Mallik*.[48] *See* Resps. Br. at

[47] *See* RX-0225 (Mohammad Amin Mosleh-Shirazi *et al.*, *A Cone-Beam Megavoltage CT Scanner for Treatment Verification in Conformal Radiotherapy*, Radiotherapy and Oncology 48, 319-328 (1998) ("Mosleh-Shirazi3").

[48] *See* RX-0274 (Raj Mallik *et al.*, *Simulator Based CT: 4 Years of Experience at the Royal North Shore Hospital, Sydney, Australia*, 3-D Radiation Treatment Planning and

117-20. In particular, Elekta argues that any of the three supplemental references discloses "one of capturing radiation at non-uniformly spaced angles with respect to a rotation, and changing the speed of rotation of the gantry during a rotation," which Varian argues is not disclosed by Jaffray MICCAI. *See id.*

As discussed above, *Mosleh-Shirazi3* merely discloses that gantries speed up and slow down at the beginning and end of an arc, and thus do not have uniform speed—not by design, but because of the difficulty of swinging a one-ton object in an arc.

Jaffray JRO 1999 does not disclose "one of capturing radiation at non-uniformly spaced angles with respect to a rotation, and changing the speed of rotation of the gantry during a rotation." Instead, it teaches that the "speed of tomographic acquisition" is a factor, which could refer to the total amount of time that the imaging takes, rather than changing the speed of rotation during a rotation. Thus, this disclosure is not clear and convincing evidence that *Jaffray JRO 1999* teaches this limitation.

Elekta does not identify where in *Mallik* the "one of capturing radiation at non-uniformly spaced angles with respect to a rotation, and changing the speed of rotation of the gantry during a rotation" is disclosed. *See* Resps. Br. at 117-20; RX-0433C (Papanikolaou WS) at Q586-90.

In addition, Elekta has not weighed all four *Graham* factors. *See* Compls. Br. at 98 and Staff Br. at 75 (citing RX-0433C (Papanikolaou WS) at Q416; Resps. Br. at 115-21 (no briefing of *Graham* factors); *see also Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d 1356, 1365-67 (2013). Finally, Elekta has not presented clear and convincing evidence

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Conformal Therapy, Proceedings of an International Symposium, Apr. 21-23, 1993, 177-185 (Purdy & Emami, eds.) ("Mallik").

of a motivation to combine these four references. *See* Compls. Br. at 135-37; Staff Br. at 117-20.

Accordingly, the evidence does not show that claim 18 is obvious.

4. 35 U.S.C. § 112

Elekta argues: (1) claims 6 and 18 are invalid under Section 112, ¶ 1; and (2) claims 6 and 18 are invalid under Section 112, ¶ 2. *See* Resps. Br. at 121-24.

As noted, complainants assert dependent apparatus claim 6 (which depends from claim 1) and independent method claim 18. Those claims read as follows:

> **1**. An apparatus, comprising:
>
> logic configured to modify a treatment plan for a target volume, the logic comprising at least one of hardwired logic and a programmable computer component;
>
> a rotatable gantry;
>
> a cone-beam radiation source coupled to the rotatable gantry; and
>
> a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data to generate cone-beam computed tomography (CT) volumetric image data capable of being used by the logic to modify a treatment plan for a target volume.
>
> **6**. The apparatus of claim **1**, 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.
>
> **18**. A method to perform a clinical treatment, comprising:
>
> using a clinical simulator machine to capture image projection data from a flat-panel imager for generating cone-beam computed tomography (CT) volumetric image data capable of being used by logic of the clinical simulator machine configured to modify a treatment plan for a clinical treatment machine;

> emitting a cone-beam from a radiation source;
>
> transmitting at least a portion of the cone-beam through a target volume;
>
> providing a treatment plan;
>
> modifying said treatment plan using said logic;
>
> continuing to rotate a gantry on which the imager is mounted while capturing image projection data; and
>
> one of capturing radiation at non-uniformly spaced angles with respect to a rotation, and changing the speed of rotation of the gantry during a rotation.

JX-0002 ('430 Patent) at col. 8, ln. 63 – col. 9, ln. 8; col. 9, lns. 27-30; col. 10, lns. 44-60.

§ 112, ¶ 2 (Claims 6 and 18): claim terms "logic configured to modify a treatment plan"

Respondents argue that claims 6 and 18 violate the definiteness requirement of § 112, ¶ 2 because of an alleged lack of corresponding algorithmic structure of the means plus function claim element of a " logic configured to modify a treatment plan." *See* Resps. Br. at 121-22. The express written disclosures of the specification, including its drawings, show otherwise. The algorithm identified as corresponding structure for a means-plus-function element may be expressed as a flow chart, in prose, or in any other manner that provides sufficient structure for performing the claimed function. *See, e.g.*, *Typhoon Touch Techs., Inc. v. Dell, Inc.*, 659 F.3d 1376, 1386 (Fed. Cir. 2011). Dr. Papanikolaou opines that the specification does not disclose "circuit diagrams," (RX-0433C (Papanikolaou WS) at Q115). It is not, however, necessary that computer code or "a highly detailed description of the algorithm" be disclosed. *Typhoon Touch Techs.*, 659 F.3d at 1385-86. Rather, "[a] description of the function in words may 'disclose, at least to the satisfaction of one of ordinary skill in the art, enough of an algorithm to provide the

necessary structure under § 112, ¶ 6.'" *Id.* at 1386 (quoting *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008)).

Here, the recited function of modifying a treatment plan is supported by the corresponding structure in the specification that teaches the use of volumetric cone-beam CT images collected on a target volume to modify a treatment plan as disclosed at JX-0002, col. 5, lns. 37-42 and col. 7, lns. 29-34, by comparing/registering the collected cone-beam CT images of the target volume against "reference images to determine the patient repositioning required, if any, before treatment," as disclosed at JX-0002, col. 5, lns. 53-58 and Fig. 4 (**525**). As explained by Dr. Mutic, these teachings, including the flow chart provided in Fig. 4, explain how to modify the treatment plan, such as, for example, by making necessary adjustments to the treatment plan by patient repositioning or collimator movements. *See* CX-3879C (Mutic RWS) at Q243.

§ 112, ¶ 1: claim terms "hardwired logic" (claim 6) and "logic of the clinical simulator machine configured to modify a treatment plan" (claim 18)

Respondents argue that the claim terms "hardwired logic" (claim 6) and "logic of the clinical simulator machine configured to modify a treatment plan" (claim 18) lack written description. *See* Resps. Br. at 122-24.

The specification provides express support for the "hardwired logic" limitation: "The instructions can be used to cause a general-purpose or special-purpose processor that is programmed with the instructions to perform the operations described. Alternatively, the operations might be performed by specific hardware components that contain hardwired logic for performing the operations, or by any combination of programmed computer components and custom hardware components." JX-0001 ('021

Patent) at col. 7, ln. 67 – col. 8, ln. 6. Thus, as explained by Dr. Mutic, one of ordinary skill in the art would understand that in the context of the disclosed inventions, the term "logic" is referring to the hardwired or software components of the system used to control the components and implement the functions of the described instruments and methods. As discussed above, these methods include modification of a treatment plan as recited in claim 18. *See* CX-3879C (Mutic RWS) at Q243. Accordingly, claim 6 is supported by adequate written description.

Respondents argue that there is a lack of written description for the use of a "clinical simulator machine" in the context of the steps recited in claim 18 of the '430 patent which include a "logic … configured to modify a treatment plan." However, as discussed above and explained by Dr. Mutic, the specification expressly discloses such logic, and one of skill in the art would understand that such logic would be for use in a clinical simulator machine that obtains image projection data relating to a target volume. *See* CX-3879C (Mutic RWS) at Q250.

VI. U.S. Patent No. 8,867,703

United States Patent No. 8,867,703 ("the '703 patent"), entitled "Multi-mode cone beam CT radiotherapy simulator and treatment machine with a flat panel imager," issued on October 21, 2014, to named inventors Edward G. Shapiro, Edward J. Seppi, John M. Pavkovich, Peter Munro, Stanley W. Johnsen, and Richard E. Colbeth. JX-0003 ('703 Patent). The '703 patent issued from Application No. 13/352,222, filed on January 17, 2012, which is a continuation of Application No. 11/891,505 (now the '430 patent), which is a continuation of Application No. 10/324,227 (now the '021 patent). *Id.* The

'703 patent generally relates to "therapeutic radiology," and in particular, "involves imaging devices." JX-0003 at col. 1, lns. 17-19. The '703 patent has a total of 21 claims.

Complainants allege infringement of, and a domestic industry based on, independent apparatus claim 1 of the '703 patent. *See* Compls. Br. at 146-62.

As discussed below, the evidence shows that asserted claim 1 is not infringed; that complainants do not satisfy the technical prong of the domestic industry requirement; and that claim 1 is not invalid.

Asserted independent apparatus claim 1 reads as follows:

> **1**. A radiation treatment system, comprising:
>
> a rotatable gantry;
>
> a treatment source;
>
> a cone-beam radiation source coupled to the rotatable gantry;
>
> a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data of a patient;
>
> a first logic that reconstructs a cone-beam computer tomography (CT) volumetric image data based on the image projection data;
>
> a patient support to support the patient; and
>
> a second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data.

JX-0003 ('703 Patent) at col. 8, ln. 65 – col. 9, ln. 13.

A. Claim Construction

1. Applicable Law

Claim construction begins with the plain language of the claim.[49] Claims should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art, viewing the claim terms in the context of the entire patent.[50] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006).

In some instances, claim terms do not have particular meaning in a field of art, and claim construction involves little more than the application of the widely accepted meaning of commonly understood words. *Phillips*, 415 F.3d at 1314. "In such circumstances, general purpose dictionaries may be helpful." *Id.*

In many cases, claim terms have a specialized meaning, and it is necessary to determine what a person of skill in the art would have understood the disputed claim language to mean. "Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to

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[49] Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vanderlande Indus. Nederland BV v. Int'l Trade Comm.*, 366 F.3d 1311, 1323 (Fed. Cir. 2004); *Vivid Tech., Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

[50] Factors that may be considered when determining the level of ordinary skill in the art include: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

mean.'" *Phillips*, 415 F.3d at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). The public sources identified in *Phillips* include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* (quoting *Innova*, 381 F.3d at 1116).

In cases in which the meaning of a claim term is uncertain, the specification usually is the best guide to the meaning of the term. *Phillips*, 415 F.3d at 1315. As a general rule, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). The specification is, however, always highly relevant to the claim construction analysis, and is usually dispositive. *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Moreover, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316.

Claims are not necessarily, and are not usually, limited in scope to the preferred embodiment. *RF Delaware, Inc. v. Pacific Keystone Techs., Inc.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003); *Decisioning.com, Inc. v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1314 (Fed. Cir. 2008) ("[The] description of a preferred embodiment, in the absence of a clear intention to limit claim scope, is an insufficient basis on which to narrow the claims."). Nevertheless, claim constructions that exclude the preferred embodiment are "rarely, if ever, correct and require highly persuasive evidentiary support." *Vitronics*, 90

F.3d at 1583. Such a conclusion can be mandated in rare instances by clear intrinsic evidence, such as unambiguous claim language or a clear disclaimer by the patentees during patent prosecution. *Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc.*, 214 F.3d 1302, 1308 (Fed. Cir. 2000); *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319 (Fed. Cir. 2002).

If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence consists of all evidence external to the patent and the prosecution history, and includes inventor testimony, expert testimony, and learned treatises. *Phillips*, 415 F.3d at 1317. Inventor testimony can be useful to shed light on the relevant art. In evaluating expert testimony, a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent. *Id.* at 1318. Extrinsic evidence may be considered if a court deems it helpful in determining the true meaning of language used in the patent claims. *Id.*

2. A Person of Ordinary Skill in the Art

Complainants argue:

> In the context of the Shapiro patents, a person of ordinary skill in the art as of December 2002 would be a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field, and two or more years of experience in radiation oncology physics and image processing/computer programming related to radiation oncology applications. Alternatively, one of ordinary skill in the art might have an M.D. degree and two or more years of practical experience with image processing/computer programming related to medical applications.

Compls. Br. at 31 (citations omitted).

Respondents argue:

> A person of ordinary skill in the art relevant to the Shapiro patents would be a person with a graduate degree (MS or Ph.D.) in medical physics or a related field (e.g. Physics or Engineering) and three years of work in radiation oncology beyond the completion date of their degree.

Resps. Br. at 15 (citations omitted).

The Staff argues:

> The same definition of a person of ordinary skill should apply to the '703 patent as to the '021 and '430 patents. As described above with regard to the '021 patent, the Staff adopts Varian's first definition: a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field, and two or more years of experience in radiation oncology physics and image processing/computer programming related to radiation oncology applications. Again, however, the differences between the parties' positions do not affect the substantive issues in this investigation.

Staff Br. at 79-80.

For the reasons explained by the Staff, the Staff's proposed level of ordinary skill is most persuasive. Thus, as proposed by the Staff, the administrative law judge finds that a person of ordinary skill in the art with respect to the Shapiro patents as of December 2002 would be a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field, and two or more years of experience in radiation oncology physics and image processing/computer programming related to radiation oncology applications.

3. "first logic that reconstructs a cone-beam computer tomography (CT) volumetric image data based on the image projection data"

Below is a chart showing the parties' proposed claim constructions.

"first logic that reconstructs a cone-beam computer tomography (CT) volumetric image data based on the image projection data"	
Complainants' and Staff's Construction	**Respondents' Construction**
Subject to 35 U.S.C. §112(6) Function: to reconstruct a cone-beam computer tomography (CT) volumetric image data based on the image projection data. Structure: a hardwired logic or a programmable computer component with software for reconstructing a cone-beam computer tomography (CT) volumetric image data based on the image projection data as described at 4:34-5:10, 7:19-32, 8:7-55, Fig. 1 (221), Fig. 3 (421), and structural equivalents thereof.	Subject to 35 U.S.C. § 112(6) Function: reconstructs a conebeam computer tomography (CT) volumetric image data based on the image projection data. Structure: the general purpose computer described at 8:7-16 and 28-34 and configured as described at col. 5:1-6, and structural equivalents thereof.

See Compls. Br. at 139-41; Resps. Br. at 138-39; Staff Br. at 80.

For the reasons discussed below, the administrative law judge has determined that the claim term "first logic that reconstructs a cone-beam computer tomography (CT) volumetric image data based on the image projection data" should be construed as proposed by complainants and the Staff.

The parties agree that the function of this limitation is to reconstruct a cone-beam computer tomography (CT) volumetric image data based on the image projection data, and also agree on at least a portion of the corresponding structure (disclosed at col. 8, lns. 7-16, 28-34). *See* Compls. Br. at 139-41; Resps. Br. at 138-39; Staff Br. at 80. The essence of the dispute is that Elekta argues that the only corresponding structure disclosed by the '703 patent is the well-known "Feldkamp cone-beam reconstruction technique" algorithm referenced at column 5, lines 1-6 and a general purpose computer.

See Resps. Br. at 138-39. Elekta argues that the balance of the corresponding structure cited by Varian and the Staff is "unnecessary." *See id.*

As Varian and the Staff noted, Elekta's corresponding structure is overly narrow. The specification discloses the hardware more broadly and describes the "first logic" and associated hardware more generally than Elekta argues. The specification discloses "***a general-purpose computer or special-purpose processor*** that is programmed with the instructions to perform the operations described. Alternatively, the operations might be performed by specific hardware components that contain hardwired logic for performing the operations, or ***by any combination of programmed computer components and custom hardware components***." JX-0003, col. 8, lns. 10-17 (emphasis added). Respondents' proposal to limit the structure to only the general-purpose computer embodiment of the specification specifically reads out covered structure.

Further, all parties agree that the structure of the "first logic" further includes the disclosure at column 5, lines 1-6, which discloses the use of image data that is reconstructed using a "cone beam reconstruction algorithm well known to those of ordinary skill in the art, such as, for example, the Feldkamp cone beam reconstruction technique." JX-0003 ('703 Patent) at col. 5, lns. 1-6. This portion of the specification further teaches how to perform both partial cone-beam and full cone-beam reconstruction using the Feldkamp algorithm. *Id.* Yet, respondents discount the disclosures within the specification of additional structure associated with this "first logic." *See id.* at col. 4, ln. 34 – col. 5, ln. 10; col. 7, lns. 19-32; col. 8, lns. 7-55; Fig. 1 (221), Fig. 3 (421).

4. "second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the conebeam CT volumetric image data or the image projection data"

Below is a chart showing the parties' proposed claim constructions.

"second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the conebeam CT volumetric image data or the image projection data"	
Complainants' and Staff's Construction	**Respondents' Construction**
Subject to 35 U.S.C. § 112(6) Function: to control the patient support and place the patient in an operative position to begin a treatment based on the conebeam CT volumetric image data or the image projection data. Structure: a hardwired logic or a programmable computer component with software for controlling the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data as described at 5:33-39, 5:51-59, 7:32-41 ("The clinical treatment machine 400 may use the kV cone-beam CT image data [deleted portion] to determine the amount of patient repositioning required by the treatment couch 418 [deleted portion]. In this way, the kV cone-beam CT radiation source and flat panel imager share a common axis of rotation with the MV cone-beam CT radiation source 404 and provide additional information for aligning the patient to the generated simulation treatment plan."), 8:7-34, Fig. 4 (520, 525, 530), and structural equivalents thereof.	Subject to 35 U.S.C. § 112(6) Function: control the patient support and place the patient in an operative position to begin a treatment based on the conebeam CT volumetric image data or the image projection data. Structure: the general purpose computer described at 8:7-16 and 28-34 and configured as described 5:33-39, 5:51-59, 7:32-41 ("The clinical treatment machine 400 may use the kV cone-beam CT image data [deleted portion] to determine the amount of patient repositioning required by the treatment couch 418 [deleted portion]. In this way, the kV cone-beam CT radiation source and flat panel imager share a common axis of rotation with the MV conebeam CT radiation source 404 and provide additional information for aligning the patient to the generated simulation treatment plan."), 8:7-34, Fig. 4 (520, 525, 530), and structural equivalents thereof.

See Compls. Br. at 141-46; Resps. Br. at 139-43; Staff Br. at 81.

For the reasons discussed below, the administrative law judge has determined that the claim term "second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the conebeam CT volumetric image data or the image projection data" should be construed as proposed by complainants and the Staff.

Claim 1 of the '703 patent recites a "second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data." All parties agree the term should be construed as a means-plus-function term and have identified the same recited function and, with the exception of the physical form of the claimed "second logic," the structure from within the specification for performing the recited function.

However, respondents misapply the agreed upon function and corresponding structure from the specification in a manner that is inconsistent with the claim language itself, the intrinsic record, and how one of ordinary skill in the art would interpret the claim.

The claimed function of the "second logic"

All parties agree the function of the "second logic" is "to control the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data." *See* Compls. Br. at 141-46; Resps. Br. at 139-43; Staff Br. at 81. Dr. Papanikolaou confirmed that the CBCT image or image projection data must be obtained in order to perform the function of placing the patient into an operative position to begin a treatment. *See* Papanikolaou Tr. 890-891. Thus, there is no dispute that the claimed function requires "CBCT volumetric

image or image projection data" as a predicate for performing the claimed function "to control the patient support and place the patient in an operative position to begin a treatment."

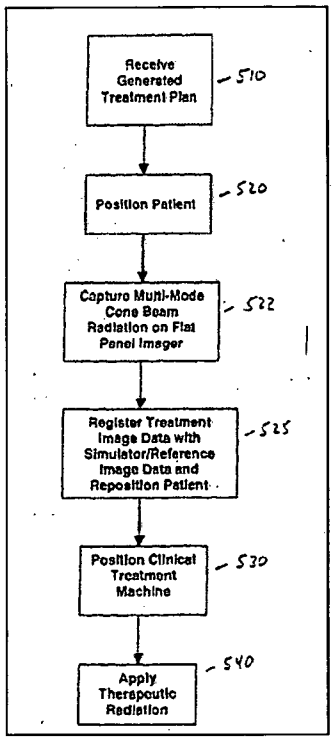
The corresponding structure for the "second logic"

The parties largely identify the same structure for construction of this means-plus-function term. However, respondents limit the identified structure to a "general purpose computer." As with the "first logic" term, there is no basis in the specification for respondents' narrow identification of the hardware that performs the claimed function of the "second logic" to a general purpose computer. The specification discloses that logic-based functions that perform the programmed instructions of the claimed "second logic" can include a hardwired logic or a programmable computer component with software:

> The instructions can be used to cause a general-purpose or special-purpose processor that is programmed with the instructions to perform the operations described. Alternatively, the operations might be performed by specific hardware components that contain hardwired logic for performing the operations, or by any combination of programmed computer components and custom hardware components.

See JX-0003 at col. 8, lns. 7-34; CX-0848C (Mutic WS) at Q26. As noted by Dr. Mutic during the hearing, in the context of the structural requirements of the claim, the steps of the identified algorithm for the "second logic" are performed by logic, either hardwired logic or software logic. Mutic Tr. 420.

In addition, although the parties have identified steps 520, 525, and 530 of Figure 4 (depicted) as algorithm for performing the claimed function of the "second logic," Elekta misreads what is required in step 520. JX-0003, Fig. 4; *see also* CX-0848C (Mutic WS) at Q35. While there are two "positioning steps," steps 520 and 525, associated with the algorithm for the "second logic," only one of those steps, step 525, is "based on the cone-beam CT image." *See* Mutic Tr. 421, 429-430 ("step 520 is a positioning step that is done before you've acquired any CBCT data"). Thus, the claimed function of the algorithm is performed at step 525, which uses images from step 522 to register and reposition the patient.



Step 520, in contrast, is labeled "Position Patient" and occurs before any image data is collected. Step 520 only requires that a patient be present on the treatment couch before the system collects images of the patient for use in step 525. The initial positioning of the patient to obtain images for step 525 can be done in any manner (*i.e.*, manually or automatically). All that is required to perform the claimed function is that the initial couch coordinates from step 520 be provided to step 525. In other words, the patient must be initially positioned on the treatment couch before the steps of the claimed function are performed, that is, performing CBCT imaging and placing the patient in an operative position for treatment based on that CBCT imaging.

As Dr. Mutic testified, step 520 "is there for context" because "[i]f I don't know where the patient was before, ***where the treatment couch is before***, I can't do the subsequent steps" of the algorithm. Mutic Tr. 1009-1010 (emphasis added). As Dr.

Mutic explained, step "520 provides a context for the 525. If I don't have a patient position, ***if I don't have couch coordinates, I cannot perform 525***." Mutic Tr. 422 (emphasis added); *see also* Mutic Tr. 429 ("525 goes with the context of 520. Take the couch coordinates from 520, we need to know where the couch coordinates are."). Dr. Mutic also summarized the proper interpretation of the entire identified algorithm:

> So those three steps, the 525 is the logic, which is based on the cone-beam CT. 520 provides me the initial coordinates, so the input into the logic, the input into the algorithm, into the mathematical function. And then 530 provides the context of what is the output of the logic 525 that's performed based on the cone-beam CT.

Mutic Tr. 422. Based on Dr. Mutic's testimony, the algorithm is: (1) providing the input couch coordinates for the initial positioning the patient prior to the capturing of the CBCT image data (step 522); (2a) registering the image data against reference data and (2b) repositioning the patient (step 525) to new couch coordinates; and (3) positioning the clinical treatment machine (step 530).

B. Infringement Analysis of the '703 Patent

Complainants allege infringement of independent apparatus claim 1 of the '703 patent. *See* Compls. Br. at 146-56.

Respondents argue that the Accused Linacs do not infringe claim 1 of the '703 patent. *See* Resps. Br. at 163-70.

The Staff argues that the evidence does not show that the Accused Linacs infringe claim 1. *See* Staff Br. at 83-84.

1. Applicable Law

Under 35 U.S.C. §271(a), direct infringement consists of making, using, offering

to sell, or selling a patented invention without consent of the patent owner. The complainant in a section 337 investigation bears the burden of proving infringement of the asserted patent claims by a "preponderance of the evidence." *Certain Flooring Products*, Inv. No. 337-TA-443, Comm'n Notice of Final Determination of No Violation of Section 337, 2002 WL 448690, at *59, (Mar. 22, 2002); *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376 (Fed. Cir. 1998).

Literal infringement of a claim occurs when every limitation recited in the claim appears in the accused device, *i.e.*, when the properly construed claim reads on the accused device exactly.[51] *Amhil Enters., Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1562 (Fed. Cir. 1996); *Southwall Tech. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed Cir. 1995).

If the accused product does not literally infringe the patent claim, infringement might be found under the doctrine of equivalents. "Under this doctrine, a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 21 (1997) (citing *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 609 (1950)). "The determination of equivalence should be applied as an objective inquiry on an element-by-element basis."[52] *Id.* at 40.

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[51] Each patent claim element or limitation is considered material and essential. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). If an accused device lacks a limitation of an independent claim, the device cannot infringe a dependent claim. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).

[52] "Infringement, whether literal or under the doctrine of equivalents, is a question of fact." *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1130 (Fed. Cir.

"An element in the accused product is equivalent to a claim limitation if the differences between the two are insubstantial. The analysis focuses on whether the element in the accused device 'performs substantially the same function in substantially the same way to obtain the same result' as the claim limitation." *AquaTex Indus. v. Techniche Solutions*, 419 F.3d 1374, 1382 (Fed. Cir. 2005) (quoting *Graver Tank*, 339 U.S. at 608); *accord Absolute Software*, 659 F.3d at 1139-40.[53]

Prosecution history estoppel can prevent a patentee from relying on the doctrine of equivalents when the patentee relinquished subject matter during the prosecution of the patent, either by amendment or argument. *AquaTex*, 419 F.3d at 1382. In particular, "[t]he doctrine of prosecution history estoppel limits the doctrine of equivalents when an applicant makes a narrowing amendment for purposes of patentability, or clearly and unmistakably surrenders subject matter by arguments made to an examiner." *Id.* (quoting *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1344 (Fed. Cir. 2005)).

2. Accused Products

Complainants argue that "the evidence demonstrates that Elekta's Accused Linacs infringe apparatus claim 1 of the '703 patent." Compls. Br. at 146. Complainants argue that "the evidence proves that Elekta's Icon Product infringes apparatus claim 1 of the '703 patent." *Id.* at 153.

2011).

[53] "The known interchangeability of substitutes for an element of a patent is one of the express objective factors noted by *Graver Tank* as bearing upon whether the accused device is substantially the same as the patented invention. Independent experimentation by the alleged infringer would not always reflect upon the objective question whether a person skilled in the art would have known of the interchangeability between two elements, but in many cases it would likely be probative of such knowledge." *Warner-Jenkinson*, 520 U.S. at 36.

3. Infringement of Accused Linacs – Claim 1

Complainants argue:

> Elekta only disputes that a single claim element—the "second logic" element of claim 1—is not met by the Accused Linacs. Specifically, Elekta contends that under its flawed claim construction the Accused Linacs [
>
>]." As demonstrated below, the evidence demonstrates that Elekta's Accused Linacs infringe apparatus claim 1 of the '703 patent, including the disputed "second logic" element, when the claim is properly construed.

Compls. Br. at 146, 146-53 (citations omitted).

Respondents argue that the Accused Linacs do not infringe claim 1 of the '703 patent. *See* Resps. Br. at 163-70.

The Staff argues that the evidence does not show that the Accused Linacs infringe claim 1. *See* Staff Br. at 83-84.

Elekta argues that the Accused Linacs do not infringe this claim because they do not meet the "second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the conebeam CT volumetric image data or the image projection data" limitation of claim 1. *See* Resps. Br. at 163-70. While the parties did not offer the phrase "an operative position" within this limitation for construction, it is now at the center of their dispute. *See* Compls. Br. at 146-53.

Varian argues that "operative position" means "a treatment position prior to beginning treatment." *See id.* at 148-49 Elekta does not dispute this interpretation, but rather argues that in the representative Accused Linac Versa HD, [

]." *See See* Resps. Br. at 164-65; RX-0494C (Papanikolaou RWS) at Q134; RX-501C (Brown WS) at Q20-25.

At the hearing, Elekta witness Kevin Brown testified that there are [

]. *See* Brown Tr. 630, 647-648. However, even if the [

]." JX-0003 ('703 Patent) at col. 9, lns. 10-12. Regardless of how the therapist chooses to manipulate the table, the [

]. *See* Resps. Br. at 164-65 (citing RX-0494C (Papanikolaou RWS) at Q134; RX-501C (Brown WS) at Q20-25; Mutic Tr. 425-426; RX-0406C. Varian does not dispute that even if a "logic" [

]. *See, e.g.,* Mutic Tr. 419-420.

Thus, the evidence does not show that the Accused Linacs infringe claim 1.

4. Infringement of Gamma Knife Icon – Claim 1

Complainants argue:

> As with the Accused Linacs, Elekta only disputes that a single claim element—the "second logic" element of claim 1—is not met by the Icon Product. As demonstrated below, the evidence proves that Elekta's Icon Product infringes apparatus claim 1 of the '703 patent, including the disputed "second logic" element, when the claim is properly construed.

Compls. Br. at 153, 153-56 (citations omitted).

Respondents argue that the Gamma Knife Icon products do not infringe claim 1 of the '703 patent. *See* Resps. Br. at 171-75.

The Staff argues: "For the same reasons given above with regard to the Accused Linacs, the evidence therefore has not shown that the Gamma Knife Icon infringes claim 1." Staff Br. at 84.

Varian accuses Elekta's Gamma Knife Icon of infringing claim 1 of the '703 patent. *See* Compls. Br. at 153-56. Elekta argues that the Gamma Knife Icon does not infringe this claim because it does not meet the "second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the conebeam CT volumetric image data or the image projection data" limitation of claim 1. *See* Resps. Br. at 171-75. Elekta argues that, similar to the Accused Linacs, the step of "Position Patient" (520) [

]. *See* Resps. Br. at 172-73 (citing RX-0494C (Papanikolaou RWS) at Q224; RX-409C at 75-89). Thus, for the same reasons given above with respect to the Accused Linacs, the evidence has not shown that the Gamma Knife Icon infringes claim 1.

C. Domestic Industry (Technical Prong)

Complainants argue:

> Varian's Clinac iX, Trilogy, TrueBeam, and Edge systems practice the '703 patent. Varian's expert, Dr. Mutic, testified how these systems meet each limitation of claim 1. Respondents dispute only a single

limitation: "a second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data." Respondents' position is contrary to the record evidence.

See Compls. Br. at 156, 156-62.

Respondents argue:

> Varian argues that its Clinac and TrueBeam products practice claim 1 of the '703 patent, and this is its sole basis for its technical domestic industry case for this patent. But Varian has not established that either product meets the "second logic" limitation of claim 1. Therefore, it has not carried its burden to prove the technical prong of the domestic industry requirement.
>
> Again, both parties agreed on the portions of the specification where corresponding structure is disclosed, which included step 520 of Figure 4. According to the proper construction, the "second logic" limitation of claim 1 requires logic (e.g., software) for placing the patient on the treatment couch and positioning the couch relative to the clinical treatment machine *before* any cone-beam radiation is captured to generate images of the target volume (i.e., step 520 of Fig. 4). But Varian has failed to show that either the Clinac or TrueBeam has software for placing the patient on the couch and positioning the patient before capturing images.

See Resps. Br. at 175-76, 175-79.

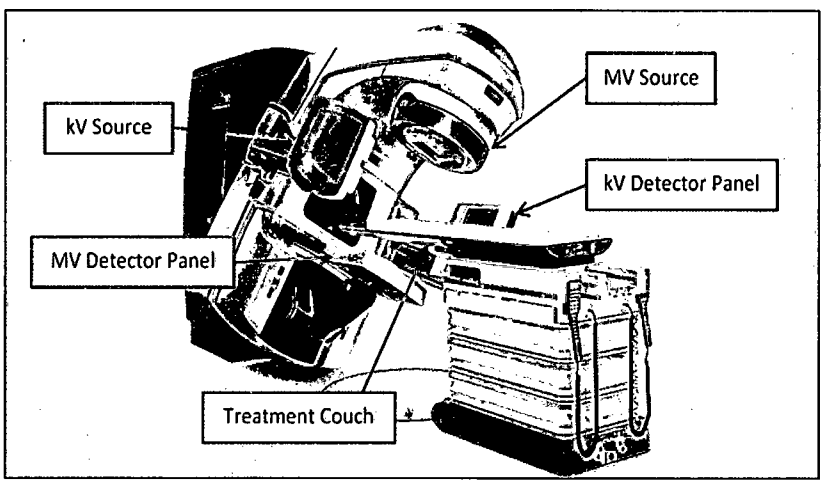
The Staff argues:

> The evidence has not shown that the domestic industry products are configured to control the patient support to place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data. Varian summarily argues that this is accomplished on the TrueBeam by the TrueBeam Workstation, which is made up of a hardwired logic or a programmable computer component with software. But the evidence shows that, as with the accused products, the relevant steps are performed by the therapist, not directly by any software or hardwired logic.

See Staff Br. at 85-86 (citations omitted).

Varian's Clinac iX and TrueBeam Linacs

Varian's domestic industry products include the Clinac iX and Trilogy linac systems when used with the On-Board Imager system, and the TrueBeam and Edge linac systems. *See, e.g.*, CX-0848C (Mutic WS) at Q289. Varian's linacs are integrated and networked computer-controlled systems used to perform imaging and implement radiotherapy treatments, such as treatment plans generated by Varian's RapidArc VMAT planning software. *See, e.g.*, CX-0848C (Mutic WS) at 289; CX-3835C (Bergeron WS) at Q11. They all function similarly and their basic configuration is the same: a rotatable gantry with a high-energy MV source and opposing MV flat-panel imager and an orthogonal kV source and opposing kV flat-panel imager coupled to the gantry, as shown with respect to the Clinac iX. *See, e.g.*, CX-3835C (Bergeron WS).



The Clinac iX and Trilogy systems optionally include the "On-Board Imager," a kV imaging system used with the linacs. *See, e.g.*, CX-0848C (Mutic WS) at 298-300, 312-14. The integrated kV imaging system of the TrueBeam and Edge systems is called the "X-Ray Imaging System." *See, e.g.*, CX-0848C (Mutic WS) at 331-33, 366-67, 377-

79.

Varian's RapidArc

RapidArc is a VMAT treatment technology sold by Varian. It includes both treatment planning and treatment delivery components. For treatment planning, it consists of optimization algorithms used within Eclipse for developing VMAT treatment plans. For treatment delivery, it consists of hardware modifications to TrueBeam (including Edge) and Clinac (including Clinac iX and Trilogy) treatment delivery platforms to enable delivery of VMAT treatment plans. During these VMAT treatments, the delivering linac varies both the dose rate and beam shape while moving in a trajectory around the patient and delivering radiation. *See* CX-3835C (Bergeron WS) at Q224.

For the reasons discussed below, the evidence shows that Varian's domestic industry products practice the '703 patent.

The Trilogy is a configuration of the Clinac iX, as a result the Trilogy practices the '703 patent in the same way as the Clinac iX. *See, e.g.*, CX-0848C (Mutic WS) at Q306-307. This is shown by the shared technical manuals of the systems, such as their common Instructions for Use. *See* CX-0964C. Hereinafter, "Clinac" refers collectively to the Clinac iX and Trilogy.

Asserted independent apparatus claim 1 reads as follows:

> **1**. A radiation treatment system, comprising:
>
> a rotatable gantry;
>
> a treatment source;
>
> a cone-beam radiation source coupled to the rotatable gantry;

> a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data of a patient;
>
> a first logic that reconstructs a cone-beam computer tomography (CT) volumetric image data based on the image projection data;
>
> a patient support to support the patient; and
>
> a second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data.

JX-0003 ('703 Patent) at col. 8, ln. 65 – col. 9, ln. 13.

Clinac: Undisputed Elements

Claim 1 of the '703 patent begins: "A radiation treatment system, comprising …." This is a preamble and as such is not limiting. To the extent it is limiting, the Clinac is a radiation treatment system. *See, e.g.*, CX-0848C (Mutic WS) at Q309.

Claim 1 recites: [the system comprising] "a rotatable gantry; a treatment source …." The Clinac has a rotatable gantry and a treatment source. CX-0848C (Mutic WS) at Q310–311, *see also* CX-0964.21–22C.

Claim 1 recites: [the system comprising] "a cone-beam radiation source coupled to the rotatable gantry …." The Clinac has a cone-beam radiation source, which is part of the On-Board Imager, and it is coupled to the rotatable gantry. CX-0848C (Mutic WS) at Q312; *see also* CX-0424.50, 62C.

Claim 1 recites: [the system comprising] "a flat-panel imager coupled to the rotatable gantry …." The Clinac has a flat-panel imager, which is part of the On-Board Imager, and it is coupled to the rotatable gantry. CX-0848C (Mutic WS) at Q313; *see also* CX-0424.62, 66C.

Claim 1 recites: "wherein the flat-panel imager is operable to capture image projection data of a patient ...." The On-Board Imager's flat-panel imager is operable to capture image projection data of a patient. CX-0848C (Mutic WS) at Q314; *see also* CX-0964.127C.

Claim 1 recites: [the system comprising] "a first logic that reconstructs a cone-beam computer tomography (CT) volumetric image data based on the image projection data ...." This element specifies a function and a corresponding structure, the function being "to reconstruct a cone-beam computed tomography (CT) volumetric image data based on the image projection data," and the corresponding structure being a hardwired logic or programmable computer component with software for reconstructing a cone-beam CT volumetric image data based on the image projection data. The specification describes an algorithm that performs the function.

The Clinac satisfies this limitation. CX-0848C (Mutic WS) at Q315-16. The Clinac's CBCT application is a software application located on a programmable computer component. *See, e.g.*, CX-0424.54–57C. The CBCT application reconstructs cone-beam CT volumetric image data based on image projection data. *See, e.g.*, CX-0424.147C.

Claim 1 recites: [the system comprising] "a patient support to support the patient ...." Clinac has a patient support that supports the patient. *See* CX-0848C (Mutic WS) at Q317.

Clinac: Disputed "second logic"

Claim 1 recites: [the system comprising] "a second logic configured to control the patient support and place the patient in an operative position to begin a treatment based