PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436

In the Matter of	
CERTAIN RADIOTHERAPY SYSTEMS AND TREATMENT PLANNING SOFTWARE, AND COMPONENTS THEREOF	Inv. No. 337-TA-968

FINAL INITIAL DETERMINATION

Administrative Law Judge David P. Shaw

Pursuant to the notice of investigation, 80 Fed. Reg. 66934 (2015), this is the Initial Determination in *Certain Radiotherapy Systems and Treatment Planning Software, and Components Thereof*, United States International Trade Commission Investigation No. 337-TA-968.

It is held that a violation of section 337 (19 U.S.C. § 1337) has occurred with respect to certain claims of U.S. Patent No. 7,880,154; U.S. Patent No. 7,906,770; and U.S. Patent No. 8,696,538.

PUBLIC VERSION

TABLE OF CONTENTS

I. Background 1

A. Institution of the Investigation; Procedural History 1

B. The Parties 3

C. The Accused Products 4

D. The Domestic Industry Products 9

E. Technological Background 11

II. Jurisdiction and Importation 16

III. General Principles of Applicable Law 18

IV. United States Patent No. 7,945,021 38

A. Claim Construction 40

B. Infringement 55

C. Domestic Industry (Technical Prong) 79

D. Validity 80

V. United States Patent No. 8,116,430 110

A. Claim Construction 112

B. Infringement 126

C. Domestic Industry (Technical Prong) 139

D. Validity 144

VI. United States Patent No. 8,867,703 171

A. Claim Construction 173

B. Infringement 183

C. Domestic Industry (Technical Prong) 188

D. Validity 198

E. Inequitable Conduct 207

VII. United States Patent No. 7,880,154 217

A. Claim Construction 218

B. Infringement 224

C. Domestic Industry (Technical Prong) 266

D. Validity 273

VIII. United States Patent No. 8,696,538 290

A. Claim Construction 293

B. Infringement 306

C. Domestic Industry (Technical Prong) 333

D. Validity 345

IX. United States Patent No. 7,906,770 365

A. Claim Construction 368

B. Infringement 377

C. Domestic Industry (Technical Prong) 400

D. Validity 405

X. Domestic Industry (Economic Prong) 420

XI. Public Interest 431

XII. Remedy and Bonding 451

XIII. Conclusions of Law 462

XIV. Initial Determination and Order 463

The following abbreviations may be used in this Initial Determination:

ALJ	-	Administrative Law Judge
CDX	-	Complainants' Demonstrative Exhibit
CPX	-	Complainants' Physical Exhibit
CX	-	Complainants' Exhibit
Dep.	-	Deposition
EDIS	-	Electronic Document Imaging System
JPX	-	Joint Physical Exhibit
JX	-	Joint Exhibit
P.H.	-	Prehearing
RDX	-	Respondents' Demonstrative Exhibit
RPX	-	Respondents' Physical Exhibit
RWS	-	Rebuttal Witness Statement
RX	-	Respondents' Exhibit
Tr.	-	Transcript
WS	-	Witness Statement

I. Background

A. Institution of the Investigation; Procedural History

By publication of a notice in the *Federal Register* on October 30, 2015, pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, the Commission instituted this investigation to determine:

> [W]hether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain radiotherapy systems and treatment planning software, and components thereof by reason of infringement of one or more of claims 1, 2, 4–9, 11–16, 53–56, and 58–62 of the '021 patent [U.S. Patent No. 7,945,021]; claims 1–4, 6–10, 12, 18, and 19 of the '430 patent [U.S. Patent No. 8,116,430]; claims 1–10, 12–15, and 17–21 of the '703 patent [U.S. Patent No. 8,867,703]; claims 19–28 and 33–36 of the '154 patent [U.S. Patent No. 7,880,154]; claims 61–63, 65, and 67–70 of the '770 patent [U.S. Patent No. 7,906,770]; and claims 23, 25, 26, 39–42, 45, and 50 of the '538 patent [U.S. Patent No. 8,696,538], and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

80 Fed. Reg. 66934 (2015).

Additionally, pursuant to Commission Rule 210.50(b)(1), the Commission ordered that:

> [T]he presiding administrative law judge shall take evidence or other information and hear arguments from the parties and other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1).

Id.

The complainants are Varian Medical Systems, Inc. of Palo Alto, California; and Varian Medical Systems International AG of ZG, Switzerland. The respondents are Elekta AB of Stockholm, Sweden; Elekta Ltd. of Crawley, United Kingdom; Elekta GmbH of Hamburg, Germany; Elekta Inc. of Atlanta, Georgia; IMPAC Medical Systems, Inc. of Sunnyvale, California; Elekta Instrument (Shanghai) Limited of Shanghai, China; and Elekta Beijing Medical Systems Co. Ltd. of Beijing, China. The Office of Unfair Import Investigations is also a party to this investigation. *Id.*

Initially, the target date for completion of this investigation was set at approximately fifteen and one-half months, *i.e.*, February 14, 2017. *See* Order No. 5 (Nov. 10, 2015). Thereafter, the administrative law judge set a new target date of February 27, 2017, and thus the due date for the Final Initial Determination on violation is October 27, 2016. *See* Order No. 35 (Oct. 12, 2016).

On April 4, 2016, the Commission determined not to review an initial determination granting a motion to amend the complaint and notice of investigation. Order No. 12 (Mar. 9, 2016), *aff'd*, Notice of Commission Determination Not to Review an Initial Determination Granting a Motion to Amend the Complaint and Notice of Investigation (Apr. 4, 2016).

A prehearing conference was held on June 23, 2016, with the evidentiary hearing in this investigation commencing immediately thereafter. The hearing concluded on June 29, 2016. *See* Order No. 8 (Nov. 25, 2016); P.H. Tr. 1-34; Tr. 1-1,310. The parties were requested to file post-hearing briefs not to exceed 400 pages in length, and to file reply briefs not to exceed 150 pages in length. P.H. Tr. 13. On July 15, 2016, the parties filed

a joint outline of the issues to be decided in the Final Initial Determination. *See* Joint Outline of the Issues to Be Decided ("Joint Outline") (EDIS Doc. ID No. 585975).

B. The Parties

The complainants are Varian Medical Systems, Inc. of Palo Alto, California; and Varian Medical Systems International AG of ZG, Switzerland (collectively, "complainants" or "Varian"). *See* 80 Fed. Reg. 66934 (2015). Varian Medical Systems, Inc. is the owner of the "Shapiro patents"[1] and the exclusive licensee of the "Otto patents."[2] *See* Amended Complaint, ¶ 10. Complainant Varian Medical Systems International AG is a wholly-owned indirect subsidiary of Varian Medical Systems, Inc. *See id.*, ¶ 11. Varian Medical Systems International AG is the owner of the Otto Patents. *See id.*

The respondents are Elekta AB of Stockholm, Sweden; Elekta Ltd. of Crawley, United Kingdom; Elekta GmbH of Hamburg, Germany; Elekta Inc. of Atlanta, Georgia; IMPAC Medical Systems, Inc. of Sunnyvale, California; Elekta Instrument (Shanghai) Limited of Shanghai, China; and Elekta Beijing Medical Systems Co. Ltd. of Beijing, China (collectively, "respondents" or "Elekta"). *See* 80 Fed. Reg. 66934 (2015). IMPAC Medical Systems, Inc. develops and manufactures Elekta treatment planning software within the United States. *See* Response to Complaint, ¶ 21. Elekta Instrument (Shanghai) Limited is a subsidiary of Elekta AB. *See id.*, ¶ 22.

The Office of Unfair Import Investigations is also a party to this investigation. *See* 80 Fed. Reg. 66934 (2015).

---

[1] The "Shapiro patents" are U.S. Patent Nos. 7,945,021; 8,116,430; and 8,867,703.

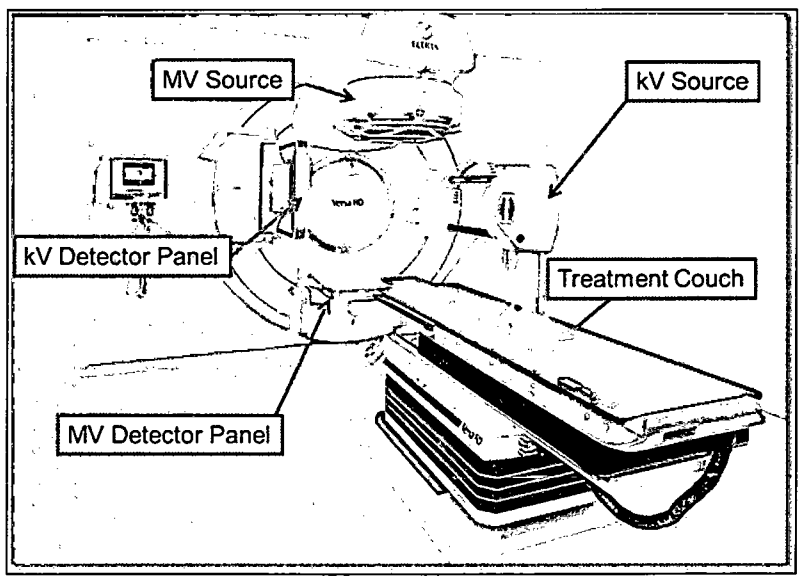
[2] The "Otto patents" are U.S. Patent Nos. 7,880,154; 7,906,770; and 8,696,538.

C. The Accused Products

The accused Elekta products include Elekta's Versa HD, Infinity, Axesse, and Synergy/Synergy S linac systems with integrated imaging and control systems (the "Accused Linacs"), as well as Elekta's Monaco treatment planning software and Active Breathing Coordinator. The parties have agreed that for purposes of this investigation, the functionality of Elekta's Versa HD is representative of the functionality of Infinity, Axesse, and Synergy/Synergy S with respect to XVI (which includes VolumeView when purchased as a licensed component of XVI), iViewGT, VMAT, and Integrity, when Infinity, Axesse, and Synergy/Synergy S include those components. *See* CX-3835C (Bergeron WS) at Q67; CX-0848C (Mutic WS) at Q38; CX-3632 (Stipulation Regarding Representative Accused Products) at 3-4.

Elekta's Accused Linacs

Elekta's Accused Linacs are integrated computer-controlled systems used to perform imaging and deliver radiotherapy treatments. The core of each Accused Linac contains a linear accelerator that focuses and accelerates a beam of electrons toward a metal target. *See* CX-3835C (Bergeron WS) at Q67; CX-0848C (Mutic WS) at Q38; CX-3632 (Stipulation Regarding Representative Accused Products) at 3-4. Upon striking the target, therapeutic radiation is produced, and a radiation beam is emitted



"primarily in the forward direction." Verhey Tr. 1113-1114. A multileaf collimator consisting of two banks of metal beams "then reduces and shapes the size of the radiation beam coming out of the machine before it enters the patient." Verhey Tr. 1114.

The Accused Linacs each share the same features and components, including the Integrity Treatment Control System (TCS), the MOSAIQ record and verify system, the Agility multi-leaf collimator, the Response MV Beam Gating system, the XVI kV cone-beam imaging system, and the Precise Treatment Table couch (that may include an adjustable couch top referred to as HexaPod). *See* CX-3835C (Bergeron WS) at Q11, 75; CX-0848C (Mutic WS) at Q38-51. Each of the Accused Linacs is the same, having 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 (Versa HD depicted). *See* CX-0848C (Mutic WS) at Q39.

Integrity Treatment Control System (TCS)

Elekta's Integrity or "TCS" provides interface and control software for Elekta's Accused Linacs. It is a program that runs on computers in a treatment control cabinet or "TCC" and provides a user interface for all of the clinical functions of the Accused Linacs. The Integrity TCS can be used to perform a number of different delivery techniques, including VMAT delivery. During a VMAT delivery, the TCS is capable of controlling at least the gantry speed, dose rate, and multileaf collimator movements, speed, and rotations as a function of the delivery. *See Mutic,* CX-0848C at Q41-42.

MOSAIQ

MOSAIQ is a record and verify software system that stores information about the

patient. It connects the different systems used for planning and delivering radiotherapy treatments. As one example, MOSAIQ receives generated treatment plans from the treatment planning system, stores them, and then transfers them to Integrity for delivery. *See* CX-3835C (Bergeron WS) at Q80, 138. As another example, MOSAIQ can be used during a treatment fraction workflow using the HexaPOD system to pre-positioning a patient using the couch move assistant (CMA) in the MOSAIQ Sequencer. *See* Brown Tr. 627-629; CX-0232.47C.

Agility

Agility is a multi-leaf collimator used in the Accused Linacs to shape the treatment radiation beam output from the linear accelerator. Agility can rotate so that its two banks of metal leaves have a different orientation with respect to the patient. *See* CX-3835C (Bergeron WS) at Q75, 442.

Response MV Beam Gating

Response MV is a beam gating system that can turn the MV treatment beam on and off in response to external stimuli, such as movement of the patient detected by another system. *See* CX-3835C (Bergeron WS) at Q11, 512; CX-0251C (Linac Overall Navigation Document at 4.

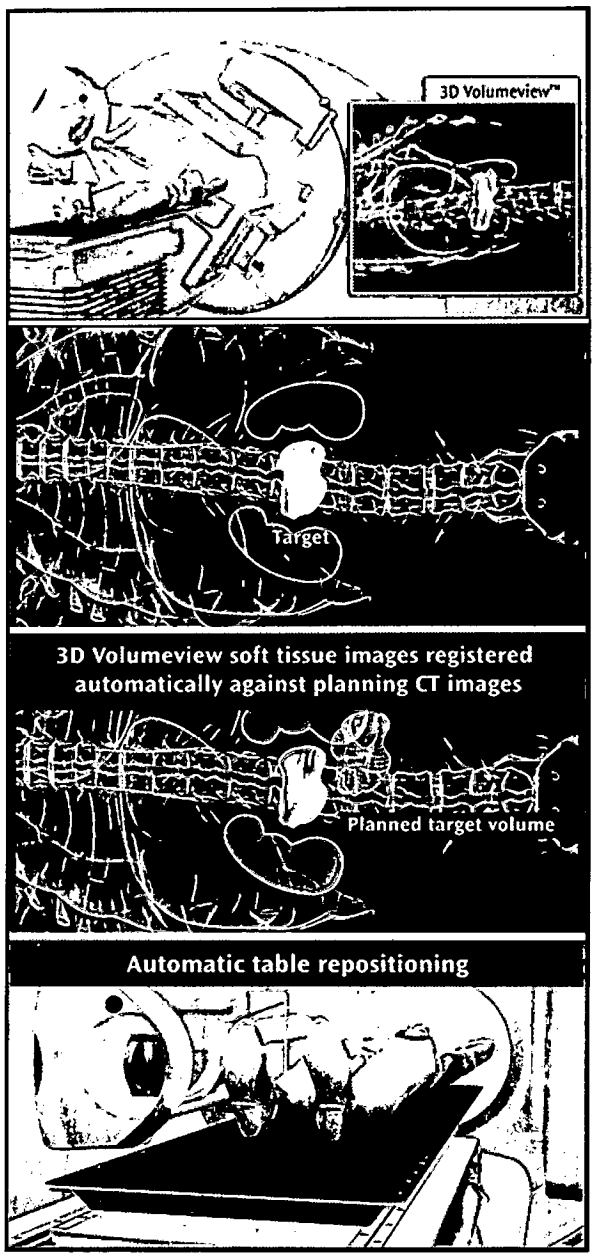
XVI

XVI is the kilovoltage (kV) X-Ray Volume Imaging system integrated within the Accused Linacs. It has a computer control system that controls the kV source arm and the kV flat-panel imager coupled to the rotatable gantry, as well as image acquisition, processing, and storage. XVI can be used to collect images before, during, and after

treatment delivery. *See* CX-0848C (Mutic WS) at Q43.

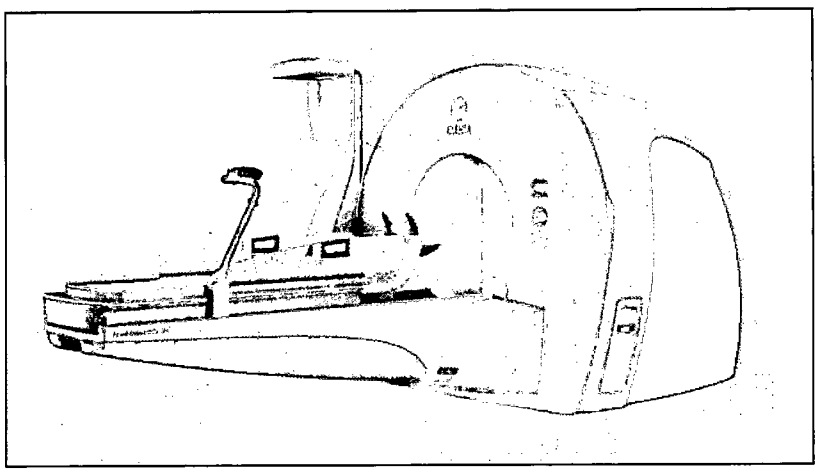
VolumeView

VolumeView is one of the image acquisition modes of the XVI system that can be used to perform CBCT volumetric imaging. During VolumeView image acquisition, XVI acquires a sequence of two-dimensional x-ray images during rotation of the gantry that can be reconstructed into a three-dimensional volumetric image. *See* CX-0848C (Mutic WS) at Q43-51. The XVI system uses the reconstructed 3-D image of the patient's anatomy to register the position of the 3D target volume against a reference image of the patient's treatment plan. The registration process determines any adjustments that have to be made to the treatment couch based on the offset between the actual and planned target volume, which is then used to perform an automatic table repositioning of the patient. *See* CX-0848C (Mutic WS) at Q43-51; CPX-0009; *see also* CPX-0008.



Gamma Knife Icon

The Leksell Gamma Knife® Icon™ is a radiosurgery system offered by Elekta. The Icon is used to perform radiosurgery by radiating targeted intra-cranial structures with a plurality of radiation beams emitted from radioactive sources housed within the Icon. *See* CX-0237.17C. By design, the Icon is limited to treating targets in the head and upper neck area. The Icon is the latest iteration of Elekta's Gamma Knife line of products with the main point of distinction being addition of a kV CBCT imaging subsystem for imaging prior to treatment. *See* CX-0848C (Mutic WS) at Q185-86.



Monaco

Monaco is a treatment planning software sold by Elekta. It provides users the ability to generate different types of radiation treatment plans for delivery on Elekta or Varian linacs. As advertised by Elekta, Monaco is specifically designed to generate Volumetric Modulated Arc Therapy ("VMAT") treatment plans. VMAT treatment plans generated by Monaco instruct the linac delivering the plan to vary the dose rate and shape of the beam (among other parameters) while the gantry rotates around the patient and while the radiation is being delivered. Monaco creates a VMAT plan that varies the dose rate and achieves a variable MU per degree through a two-stage optimization process. In the first stage, Monaco [

]. In the second stage, Monaco

[

].

See CX-3835C (Bergeron WS) at Q73-74, 78-80; CX-3620C.219.

Active Breathing Coordinator

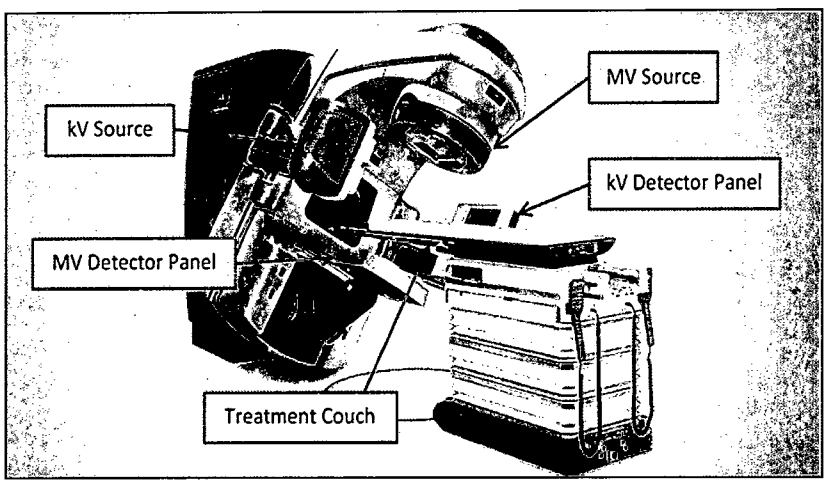
Active Breathing Coordinator is a patient position monitoring system that detects the breathing patterns of a patient. It uses a device inside of the patient's mouth to digitally monitor when the patient holds and releases his or her breath. When used in combination with Response MV Beam Gating, it can ensure that the Accused Linacs only deliver radiation during the optimal part of the patient's breathing cycle to avoid excess delivery of radiation to healthy tissue. *See* CX-3835C (Bergeron WS) at Q513; CX-3869C.1.

D. The Domestic Industry Products

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.

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.

E. Technological Background

1. Technology at Issue

On November 24, 2015, the private parties and the Staff filed a "Joint Stipulation Regarding Technology at Issue." *See* Joint Stipulation Regarding Technology at Issue ("Technology Stipulation") (EDIS Doc. ID No. 569832). The parties stipulated regarding the technology concerning radiation therapy including image-guided radiation therapy as discussed below.

Radiation Therapy

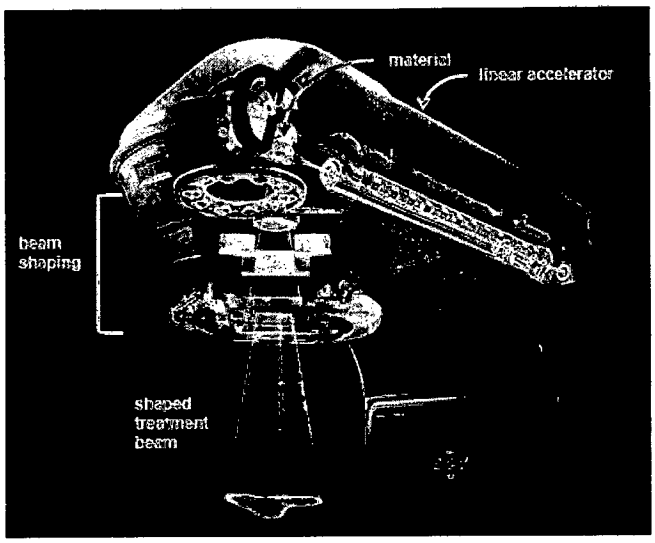
The technology at issue generally relates to radiation treatment, including radiation therapy (or "radiotherapy") technology to treat cancer, including apparatuses and methods for planning and carrying out treatment. Radiotherapy works by directing certain types of focused energy (i.e., radiation) to kill cancer cells and shrink tumors. The clinical goal in treating cancer with radiation is to deliver a prescribed dose of radiation to kill the cancerous cells of a tumor while minimizing radiation exposure to surrounding healthy tissue so that complications, side effects, and secondary effects of the radiation are minimized.

One method of generating the radiation used in radiotherapy is the use of a linear accelerator, which is frequently referred to in shorthand as a "linac."

A linear accelerator utilizes high-power electric fields to accelerate charged particles in the form of electrons to extremely high velocities. The accelerated electrons can have voltages on the order of several millions of volts (referred to as megavolts or MV). The path of the high-energy electrons from the linear accelerator is typically manipulated by magnets into a focused beam that is directed onto a material, usually made of tungsten or copper. When the accelerated electrons strike the material, high-energy x-rays are produced.

In some radiotherapy systems, a beam-shaping assembly including collimators and filters is used to shape the high-energy x-rays emitted from the material into a beam having a defined shape. The shaped beam is then directed toward a patient to image and/or treat the patient with the generated x-rays. Radiotherapy instruments are often designed such that the path of the shaped high-energy x-ray beam is capable of being adjusted in order to efficiently irradiate a tumor.

Radiotherapy systems typically have a treatment couch to support the patient and move the patient. The x-ray source may also be mounted on a mechanism that rotates around the patient in order to rotate and move the path of the emitted beam around the patient. A representative illustration of a linear accelerator treatment beam assembly on a radiotherapy instrument is as follows:



In other methods, radioactive materials such as Cobalt-60 are used.

Stereotactic radiosurgery is another method for treating tumors. It utilizes multiple radiation beams directed to and intersecting at a single point. Treatment occurs when a tumor located at the point of intersection receives the cumulative radiation from each of the multiple beams of radiation, whereas surrounding tissue that is outside the point of intersection is exposed to a lower intensity of radiation. *See* Technology Stipulation at 1-3.

Image-Guided Radiation Therapy

The clinical success of radiotherapy is enhanced when the shape and location of cancerous tumors are precisely identified prior to treatment. Clinical success may also be improved when radiation is delivered by optimizing the radiation directed to the tumor while minimizing exposure to the patient's healthy tissue.

Typically, a patient prescribed with radiotherapy has his internal anatomy imaged using diagnostic imaging systems. These diagnostic imaging techniques typically provide information regarding the relative location and shape of any tumor(s) requiring

treatment within the patient, which can then be used to plan treatment delivery by defining a variety of control parameters for delivering the therapeutic radiation to the patient's tumors. *See* Technology Stipulation at 3-4.

2. Patents at Issue

The "Shapiro Patents": U.S. Patent Nos. 7,945,021; 8,116,430; and 8,867,703

United States Patent No. 7,945,021 ("the '021 patent), entitled "Multi-mode cone beam CT radiotherapy simulator and treatment machine with a flat panel imager," issued on May 17, 2011, to named inventors Edward G. Shapiro, Edward J. Seppi, John M. Pavkovich, Peter Munro, Stanley W. Johnsen, and Richard E. Colbeth. JX-0001 ('021 Patent). The '021 patent issued from Application No. 10/324,227, filed on December 18, 2002. *Id.* The '021 patent generally relates to "therapeutic radiology," and in particular, "involves imaging devices." JX-0001 at col. 1, lns. 8-10. The '021 patent has a total of 77 claims.

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.

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.

The "Otto Patents": U.S. Patent Nos. 7,880,154; 7,906,770; and 8,696,538

United States Patent No. 7,906,770 ("the '770 patent), entitled "Methods and apparatus for the planning and delivery of radiation treatments," issued on March 15, 2011, to named inventor Karl Otto. JX-0005 ('770 Patent). The '770 patent issued from Application No. 11/996,932, filed on July 25, 2006. *Id.* The '770 patent relates to "radiation treatment," and "particularly to methods and apparatus for planning and delivering radiation to a subject to provide a desired three-dimensional distribution of radiation dose." JX-0005 ('770 Patent) at col. 1, lns. 19-22. The '770 patent has a total of 70 claims.

United States Patent No. 7,880,154 ("the '154 patent), entitled "Methods and apparatus for the planning and delivery of radiation treatments," issued on February 1, 2011, to named inventor Karl Otto. JX-0004 ('154 Patent). The '154 patent issued from Application No. 12/132,597, filed on June 3, 2008, which is a continuation in part of Application No. 11/996,932 (now the '770 patent). *Id.* The '154 patent relates to "radiation treatment," and "particularly to methods and apparatus for planning and

delivering radiation to a subject to provide a desired three-dimensional distribution of radiation dose." JX-0004 at col. 1, lns. 24-27. The '154 patent has a total of 38 claims.

United States Patent No. 8,696,538 ("the '538 patent"), entitled "Methods and apparatus for the planning and delivery of radiation treatments," issued on April 15, 2014, to named inventor Karl Otto. JX-0006 ('538 Patent). The '538 patent issued from Application No. 12/986,420, filed on January 7, 2011, which a continuation of Application No. 12/132,597 (now the '154 patent), which is a continuation-in-part of Application No. 11/996,932 (now the '770 patent). *Id.* The '538 patent relates to "radiation treatment," and "particularly to methods and apparatus for planning and delivering radiation to a subject to provide a desired three-dimensional distribution of radiation dose." JX-0006 ('538 Patent) at col. 1, lns. 22-25. The '538 patent has a total of 50 claims.

II. Jurisdiction and Importation

Section 337(a)(1)(B) declares unlawful, *inter alia*, "[t]he 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 . . . infringe a valid and enforceable United States patent." 19 U.S.C. § 1337(a)(1)(B). Complainants have filed a complaint alleging a violation of this subsection, and the Commission therefore has subject matter jurisdiction. *See Amgen, Inc. v. United States Int'l Trade Comm'n*, 902 F.2d 1532, 1535-37 (Fed. Cir. 1990); Resps. Br. at 13 (not contesting subject matter jurisdiction).

No respondent contested the Commission's personal jurisdiction. *See* Resps. Br. at 13. Indeed, all respondents have appeared and participated in the investigation. The

Commission therefore has personal jurisdiction over those respondents. *See e.g., Certain Liquid Crystal Display Modules, Products Containing Same, and Methods for Using the Same*, Inv. No. 337-TA-634, Final Initial and Recommended Determinations at 3 (June 12, 2009) (unreviewed).

Respondents argue:

> Elekta does not contest that certain products among those accused of infringement have been imported into the United States. These products include, for instance, Elekta's Infinity and Synergy linear accelerator products, the Gamma Knife Icon, and several linac components such as the Agility multi-leaf collimator and the XVI imaging system. A number of Elekta products have also been discontinued and are no longer imported, including, for example, Elekta's Axesse and Synergy S linear accelerator products. However, Elekta's Monaco treatment planning software, accused of infringing the Otto patents, was developed in the United States, and is supplied from Elekta's location in the United States, which employs U.S. employees. Monaco has not been imported. Similarly, Elekta's MosaiQ software is supplied from the United States, and is not imported.

Resps. Br. at 13 (citations omitted).

Thus, there is no dispute that certain accused products have been imported into the United States, and the Commission has *in rem* jurisdiction as to those products. *See* Resps. Br. at 13 (not contesting importation for "Elekta's Infinity and Synergy linear accelerator products, the Gamma Knife Icon, and several linac components such as the Agility multi-leaf collimator and the XVI imaging system").[3]

[3] Contested products are discussed in the relevant sections for the individual patents below.

III. General Principles of Applicable Law

A. Claim Construction

Claim construction begins with the plain language of the claim.[4] 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.[5] *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

---

[4] 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).

[5] 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.*

B. Infringement

1. Direct Infringement

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.[6] *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."[7] *Id.* at 40.

"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.*

---

[6] 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).

[7] "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. 2011).

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.[8]

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. Indirect Infringement

a. Induced Infringement

Section 271(b) of the Patent Act provides: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b).

"To prevail on a claim of induced infringement, in addition to inducement by the defendant, the patentee must also show that the asserted patent was directly infringed." *Epcon Gas Sys. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1033 (Fed. Cir. 2002). Further, "[s]ection 271(b) covers active inducement of infringement, which typically includes acts that intentionally cause, urge, encourage, or aid another to directly infringe

[8] "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.

a patent." *Arris Group v. British Telecomm. PLC*, 639 F.3d 1368, 1379 n.13 (Fed. Cir. 2011). The Supreme Court held that "induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement." *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011). The Court further held: "[g]iven the long history of willful blindness[9] and its wide acceptance in the Federal Judiciary, we can see no reason why the doctrine should not apply in civil lawsuits for induced patent infringement under 35 U.S.C. § 271(b)." *Global-Tech*, 563 U.S. at 768 (footnote omitted).

b. Contributory Infringement

Section 271(c) of the Patent Act provides: "Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer. 35 U.S.C. § 271(c).

Section 271(c) "covers both contributory infringement of system claims and method claims."[10] *Arris*, 639 F.3d at 1376 (footnotes omitted). To hold a component

---

[9] "While the Courts of Appeals articulate the doctrine of willful blindness in slightly different ways, all appear to agree on two basic requirements: (1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact. We think these requirements give willful blindness an appropriately limited scope that surpasses recklessness and negligence." *Global-Tech*, 563 U.S. at 769.

[10] "Claims which recite a 'system,' 'apparatus,' 'combination,' or the like are all

supplier liable for contributory infringement, a patent holder must show, *inter alia*, that (a) the supplier's product was used to commit acts of direct infringement; (b) the product's use constituted a material part of the invention; (c) the supplier knew its product was especially made or especially adapted for use in an infringement" of the patent; and (d) the product is not a staple article or commodity of commerce suitable for substantial noninfringing use. *Id.*

C. Validity

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). 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).

1. 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

---

analytically similar in the sense that their claim limitations include elements rather than method steps. All such claims can be contributorily infringed by a component supplier." *Arris*, 639 F.3d at 1376 n.8.

(*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).

2. 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."[11] 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.*, 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

[11] 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).

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).[12]

[12] 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)).

3. 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*)).

4. 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).[13]

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

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

> 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 (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.").

5. Inequitable Conduct

Every individual associated with the filing and prosecution of a patent application has a duty to disclose to the patent examiner all information known to be

material to patentability. 37 C.F.R. § 1.56(a). "If inequitable conduct occur[s] with respect to one or more claims of an application, the entire patent is unenforceable." *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1375 (Fed. Cir. 2006).

A patent is unenforceable on the grounds of inequitable conduct if an applicant provides materially false information or withholds material information from the USPTO with an intent to mislead or deceive. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (*en banc*). The Federal Circuit has stressed that "materiality and intent are separate requirements, and intent to deceive cannot be found based on materiality alone." *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 733 (Fed. Cir. 2010). Both materiality and intent to deceive must be proven by clear and convincing evidence. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

To establish an intent to deceive, an accused infringer must show that the patentee acted with the specific intent to deceive the PTO:

> A finding that the misrepresentation or omission amounts to gross negligence or negligence under a "should have known" standard does not satisfy this intent requirement. . . . "In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference." . . . In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.

Therasense, 649 F.3d at 1290 (citations omitted). The intent element "rarely can be, and need not be, proven by direct evidence. . . . Instead, an intent to deceive is usually inferred from the facts and circumstances surrounding the conduct at issue." *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1364 (Fed. Cir. 2007). To meet the clear and

convincing evidence standard, however, "the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" *Therasense*, 649 F.3d at 1290 (citations omitted). The evidence "'must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances.'" *Id.* at 1290 (emphasis in original). "Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Id.* at 1290-91.

6. Patent Eligible Subject Matter - 35 U.S.C. § 101

Whether patent claims are directed to subject matter that is patentable under 35 U.S.C. § 101 is an issue of law. *CLS Bank Int'l v. Alice Corp Pty.*, 717 F.3d 1269, 1276 (2013) (*en banc*) (citing *Bancorp Servs., LLC v. Sun Life Assurance Co. of Can.*, 687 F.3d 1266, 1273 (Fed. Cir. 2012)). "While there may be cases in which the legal question as to patentable subject matter may turn on subsidiary factual issues," a patentee must clearly identify the fact issues that must be resolved in order to address patentability. *See In re Comiskey*, 554 F.3d 967, 975 (Fed. Cir. 2009).

"[T]he law remains unsettled as to whether the presumption of patent validity under 35 U.S.C. § 282 applies to subject matter eligibility challenges under 35 U.S.C. § 101." Notice of Commission Determination (1) to Review an Initial Determination Granting Respondents' Motion for Summary Determination that Certain Asserted Claims are Directed to Ineligible Subject Matter Under 35 U.S.C. § 101; and (2) on Review to Affirm the Initial Determination with Modification, Inv. No. 337-TA-963 (Apr. 4, 2016) ("Notice") at 2. In its Notice, the Commission held in that instance that: "Regardless of whether or not such a presumption applies, the record here warrants a finding that the asserted patent claims are directed to ineligible subject matter." *Id.*

Section 101 of the Patent Act sets forth four categories of patentable inventions: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." 35 U.S.C. §101; *see also Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d 1363, 1366 (Fed. Cir. 2015). The Supreme Court has recognized three exceptions to 35 U.S.C. § 101, holding ineligible for patenting "'[l]aws of nature, natural phenomena, and abstract ideas.'" *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 714 (Fed. Cir. 2014), *cert denied. sub nom. Ultramercial, LLC v. WildTangent, Inc.*, 135 S. Ct. 2907 (June 29, 2015) (quoting *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014)) ("*Alice*"). "Patents that merely claim well-established, fundamental concepts fall within the category of abstract ideas." *Cyberfone Sys., LLC v. CNN Interactive Grp., Inc.*, 558 Fed. Appx. 988, 991 (Fed. Cir. 2014) (citing *Bilski v. Kappos*, 561 U.S. 593, 611-12 (2010)).

An invention, however, "is not rendered ineligible for patent simply because it involves an abstract concept." *Alice*, 134 S. Ct. at 2354 (citing *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)). The courts have recognized that "'[a]t some level,' all inventions . . . embody, use reflect, rest upon, or apply laws of nature, natural phenomena or abstract ideas.'" *Ultramercial*, 772 F.3d at 715 (quoting *Alice*, 134 S. Ct. at 2354).

To identify claims that are ineligible, the Supreme Court has articulated a two-step test. *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1374 (Fed. Cir. 2016). In the first step, the court must decide whether a claim is drawn to an abstract idea. *Id.* (citing *Alice*, 134 S. Ct. at 2355). If the patent claims an abstract idea, the court in the

second step seeks to identify an "'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." *Alice*, 134 S. Ct. at 2357 (quoting *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1294, 1298 (2012) ("*Mayo*")). The claim limitations must disclose additional features indicating more than "well-understood, routine, conventional activity." *Mayo*, 132 S. Ct. at 1292. The limitations must "'narrow, confine, or otherwise tie down the claim so that, in practical terms, it does not cover the full abstract idea itself.'" *Cyberfone*, 558 Fed. Appx. at 992 (quoting *Accenture Global Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336, 1341 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 2871 (Jun. 30, 2014)).

Configuring a standard, computerized system to implement an abstract idea does not make the claimed configuration patent-eligible. Manipulation of abstractions on a computer "'cannot meet the test because they are not physical objects or substances, and they are not representative of physical objects or substances.'" *Ultramercial,* 772 F.3d at 717 (quoting *In re Bilski*, 545 F.3d 943, 963 (Fed. Cir. 2008)); *see also Bancorp Servs.*, 687 F.3d at 1278, *cert. denied*, 134 S. Ct. 2870 (2014) ("[A]dding a 'computer aided' limitation to a claim covering an abstract concept, without more, is insufficient to render the claim patent eligible.'") (quoting *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1333 (Fed. Cir. 2012)). The use of sensors does not render such a system patent-eligible. "[M]onitoring, recording, and inputting information represent insignificant 'data-gathering steps,' and "thus add nothing of practical significance to the underlying abstract idea." *Wireless Media Innovations, LLC v. Maher Terminals, LLC,* 100 F. Supp.3d 405, 416 (D.N.J. 2015), *aff'd*, 636 Fed.Appx. 1014, (Fed. Cir. 2016) (quoting *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1370 (Fed. Cir. 2011)); *see also OIP*

Technologies, Inc. v. Amazon.com, Inc., 788 F.3d 1359, 1364 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 701 (Dec. 14, 2015) (invalidating patent implementing the abstract idea of price optimization on a generic computer); *accord Certain Activity Tracking Devices, Sys., & Components Thereof*, Inv. No. 337-TA-963, Order No. 54 at 13-14 (Apr. 27, 2016) (unreviewed).

Claims that are not merely drawn to abstract ideas implemented by the use of computers, however, may be eligible. Specifically, claims directed to improving computer functioning by the use of unconventional methods may appropriately be patented. *See Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016) ("[W]e find it relevant to ask whether the claims are directed to an improvement to computer functionality versus being directed to an abstract idea, even at the first step of the *Alice* analysis.").

Indeed, the use of generic computer technology, however "specific" to the particular environment, will not provide eligibility, if the functionality described constitutes an abstract idea. *See TLI Comm'n's LLC v. AV Auto., LLC*, 823 F.3d 607, 611 (Fed. Cir. 2016) ("*TLI*") (holding that 35 U.S.C. § 101 applies where "the specification makes clear that the recited physical components merely provide a generic environment in which to carry out the abstract idea of classifying and storing digital images in an organized manner").

In *TLI*, the Federal Circuit considered and held invalid a method for uploading digital photos from a mobile device. *TLI*, 823 F.3d at 609. The Federal Circuit clarified that a relevant inquiry under step one is "'whether the claims are directed to an improvement to computer functionality versus being directed to an abstract idea.'" *Id.* at

612 (quoting *Enfish*, 822 F.3d at 1335). The Circuit contrasted claims "'directed to an improvement in the functioning of a computer with claims 'simply adding conventional computer components to well-known business practices . . . or 'generalized steps to be performed on a computer using conventional computer activity.'" *Id.* (quoting *Enfish*, 822 F.3d at 1338).

D. Domestic Industry

A violation of section 337(a)(1)(B), (C), (D), or (E) can be found "only if an industry in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Section 337(a) further provides:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned—
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or
>
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

These statutory requirements consist of an economic prong (which requires certain activities)[14] and a technical prong (which requires that these activities relate to the

[14] The Commission practice is usually to assess the facts relating to the economic prong at the time that the complaint was filed. *See Certain Coaxial Cable Connectors and Components Thereof and Products Containing Same*, Inv. No. 337-TA-560, Comm'n Op. at 39 n.17 (Apr. 14, 2010) ("We note that only activities that occurred before the filing of a complaint with the Commission are relevant to whether a domestic industry exists or is in the process of being established under sections 337(a)(2)-(3).") (citing *Bally/Midway*

intellectual property being protected). *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 13 (May 16, 2008) ("*Stringed Musical Instruments*"). The burden is on the complainant to show by a preponderance of the evidence that the domestic industry requirement is satisfied. *Certain Multimedia Display and Navigation Devices and Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-694, Comm'n Op. at 5 (July 22, 2011) ("*Navigation Devices*").

With respect to the economic prong, and whether or not section 337(a)(3)(A) or (B) is satisfied, the Commission has held that "whether a complainant has established that its investment and/or employment activities are significant with respect to the articles protected by the intellectual property right concerned is not evaluated according to any rigid mathematical formula." *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 27 (Feb. 17, 2011) ("*Printing and Imaging Devices*") (citing *Certain Male Prophylactic Devices*, Inv. No. 337 TA-546, Comm'n Op. at 39 (Aug. 1, 2007)). Rather, the Commission examines "the facts in each investigation, the article of commerce, and the realities of the marketplace." *Id.* "The determination takes into account the nature of the investment and/or employment activities, 'the industry in question, and the complainant's relative size.'" *Id.* (citing *Stringed Musical Instruments* at 26).

Mfg. Co. v. U.S. Int'l Trade Comm'n, 714 F.2d 1117, 1121 (Fed. Cir. 1983)). In some cases, however, the Commission will consider later developments in the alleged industry, such as "when a significant and unusual development occurred after the complaint has been filed." *See Certain Video Game Systems and Controllers*, Inv. No. 337-TA-743, Comm'n Op., at 5-6 (Jan. 20, 2012) ("[I]n appropriate situations based on the specific facts and circumstances of an investigation, the Commission may consider activities and investments beyond the filing of the complaint.").

With respect to section 337(a)(3)(C), whether an investment in domestic industry is "substantial" is a fact-dependent inquiry for which the complainant bears the burden of proof. *Stringed Musical Instruments* at 14. There is no minimum monetary expenditure that a complainant must demonstrate to qualify as a domestic industry under the "substantial investment" requirement of this section. *Id.* at 25. There is no need to define or quantify an industry in absolute mathematical terms. *Id.* at 26. Rather, "the requirement for showing the existence of a domestic industry will depend on the industry in question, and the complainant's relative size." *Id.* at 25-26.

E. Public Interest

The Commission has delegated the taking of evidence or other information with respect to the public interest in this investigation to the administrative law judge. *See* 80 Fed. Reg. 66934 (October 30, 2015); 19 C.F.R. §210.10(b). Before issuing any remedial order for a violation of section 337, the Commission must weigh the effects of the remedy on the public interest by considering four factors. *Certain Inclined-Field Acceleration Tubes*, Inv. No. 337-TA-67, Comm'n. Op. (Dec. 29, 1980). These public interest factors are: (1) the public health and welfare; (2) the competitive conditions in the United States economy; (3) the production of like or directly competitive articles in the United States; and (4) the United States consumers. 19 U.S.C. § 1337(d)(1). The Commission must then balance any potentially adverse impact on the public interest against the public's interest in protecting and enforcing intellectual property rights. *See id.* If the negative impact of the remedial order outweighs its benefit, the Commission must deny the requested relief. *Id.*

In the few instances where the Commission has found a public interest impact significant enough to deny relief, "the exclusion order was denied because inadequate supply within the United States—by both the patentee and domestic licensees—meant that an exclusion order would deprive the public of products necessary for some important health or welfare need...." *Spansion, Inc. v. ITC*, 629 F.3d 1331, 1360 (Fed. Cir. 2010) (citing *Certain Fluidized Supporting Apparatus*, Inv. No. 337-TA-182/188, Comm'n. Op. (Oct. 1984), *Inclined-Field Acceleration Tubes*, (Dec. 1980); and *Certain Automatic Crankpin Grinders*, Inv. No. 337-TA-60, Comm'n. Op. (Dec. 1979)).

IV. U.S. Patent No. 7,945,021

United States Patent No. 7,945,021 ("the '021 patent"), entitled "Multi-mode cone beam CT radiotherapy simulator and treatment machine with a flat panel imager," issued on May 17, 2011, to named inventors Edward G. Shapiro, Edward J. Seppi, John M. Pavkovich, Peter Munro, Stanley W. Johnsen, and Richard E. Colbeth. JX-0001 ('021 Patent). The '021 patent issued from Application No. 10/324,227, filed on December 18, 2002. *Id.* The '021 patent generally relates to "therapeutic radiology," and in particular, "involves imaging devices." JX-0001 at col. 1, lns. 8-10. The '021 patent has a total of 77 claims.

Complainants allege infringement of independent apparatus claim 1 and dependent apparatus claims 4, 9 and 15 (which depends from unasserted independent apparatus claim 14) of the '021 patent. *See* Compls. Br. at 53-78. Complainants argue that they have a domestic industry based on claims 1 and 4. *See* Compls. Br. at 78-85.

As discussed below, the evidence shows that the asserted claims are infringed by some of the accused products, that complaints have satisfied the technical prong of the domestic industry requirement, but that the asserted claims are not valid.

As noted, complainants assert independent apparatus claim 1 and dependent apparatus claims 4, 9 and 15 (which depends from unasserted independent apparatus claim 14). Those claims read as follows:

> **1**. An apparatus, comprising:
>
> a radiation treatment system capable of implementing a treatment plan, the system comprising:
>
> a frame;
>
> a rotatable gantry coupled to the frame;
>
> a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;
>
> a cone-beam radiation source coupled to the rotatable gantry to radiate the patient;
>
> 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
>
> a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager.
>
> **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.
>
> **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.

14. An apparatus, comprising:

a radiation treatment system capable of implementing a treatment plan, the system comprising:

a frame;

a rotatable gantry coupled to the frame;

a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation;

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

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

a translatable treatment couch coupled to the rotatable gantry via a communications network.

15. The apparatus of claim **14**, wherein the translatable treatment couch is capable of movement in three planes plus angulation.

JX-0001 ('021 Patent) at col. 8, ln. 56 – col. 9, ln. 6; col. 9, lns. 12-14, lns. 28-3; col. 10, lns. 16-36.

A. Claim Construction

1. Applicable Law

Claim construction begins with the plain language of the claim.[15] Claims should be given their ordinary and customary meaning as understood by a person of ordinary

[15] 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).

skill in the art, viewing the claim terms in the context of the entire patent.[16] *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 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).

---

[16] 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).

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 Staff is of the view that there is no material difference between Varian's first definition and Elekta's definition. However, the Staff is of the view that Varian's alternative definition, which encompasses any

> "computer programming related to medical applications" is too broad. Likewise, Elekta's definition is too broad because it encompasses "three years of work in radiation oncology beyond the completion date of their degree" regardless of the nature of the work.
>
> The Staff therefor believes that Varian's first definition is most appropriate: 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. Regardless, the evidence has not shown that any issue in this investigation will be affected by the application of one of these definitions over the other.

Staff Br. at 24 (citations omitted).

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. "treatment plan"

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

"treatment plan"		
Complainants' Construction	**Respondents' Construction**	**Staff's Construction**
"the set of instructions used by the radiation treatment system to deliver radiation to a target volume"	"the set of instructions used by the radiation treatment system to deliver radiation to a target volume"	"the set of instructions used by the radiation treatment system to deliver radiation to a target volume"

See Compls. Br. at 45; Resps. Br. at 16; Staff Br. at 25.

The term "treatment plan" appears in all of the asserted claims (1, 4, 9 and 15) of the '021 patent. *See* JX-0001 ('021 Patent). The parties agree that the construction of "treatment plan" is "the set of instructions used by the radiation treatment system to deliver radiation to a target volume." *See* Compls. Br. at 45; Resps. Br. at 16; Staff Br. at 25.

The '021 patent discloses that "[t]he image data may further be used to generate a treatment plan to tailor a dose of therapeutic radiation to the target volume," (*id.* at col. 2, lns. 46-49); "[t]he treatment plan may then be transferred, at block 340, to a clinical treatment machine to provide instructions to the clinical treatment machine," (*id.* at col. 2, lns. 62-64); and "[t]he identified target volume may be applied to a radiotherapy planning computer system 220, which creates a treatment plan to be implemented by a clinical treatment machine," (*id.* at col. 5, lns. 8-10; *see also id.* at Figs. 2 and 4).

Accordingly, as argued by the parties, the administrative law judge adopts the joint proposed claim construction and has determined that the claim term "treatment plan" should be construed to mean "the set of instructions used by the radiation treatment system to deliver radiation to a target volume."

4. "radiation treatment system"

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

"radiation treatment system"		
Complainants' Construction	**Respondents' Construction**	**Staff's Construction**
"a system for treating a patient with a therapeutic dose of radiation"	"a system for treating a patient with a therapeutic dose of radiation"	"a system for treating a patient with a therapeutic dose of radiation"

See Compls. Br. at 45; Resps. Br. at 16; Staff Br. at 29.

The term "radiation treatment system" appears in unasserted claim 14, from which asserted claim 15 depends. *See* JX-0001 ('021 Patent). The parties agree that the construction of "treatment plan" is "the set of instructions used by the radiation treatment system to deliver radiation to a target volume "a system for treating a patient with a therapeutic dose of radiation." *See* Compls. Br. at 45; Resps. Br. at 16; Staff Br. at 29.

Accordingly, as argued by the parties, the administrative law judge adopts the joint proposed claim construction and has determined that the claim term "radiation treatment system" should be construed to mean "a system for treating a patient with a therapeutic dose of radiation."

5. "communications network" (Claims 1, 4, 9, and 15)

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 25, 29.

All parties agree that the claim term "communications network" should be given its plain and ordinary meaning. Compls. Br. at 45; Resps. Br. at 17; Staff Br. at 25, 29. As an initial matter, any argument that alters the construction of this term from the plain and ordinary meaning has been waived because it was not raised during the parties' claim construction exchange. *See id.*

Complainants argue:

> Dr. Mutic explained that one of ordinary skill in the art reading the specification and figures of the Shapiro patents would understand that communications network means more than the simple dedicated data link or coupling of the prior art. In Dr. Mutic's words:
>
> > [T]his figure shows multiple components of a linear accelerator, and it shows them interconnected via different connections. There is a command processor, there is an interface control box. So my belief of communications network is a product called -- the communications networks require a protocol for selectively routing messages. So if you look at here, there are multiple situations where a signal comes into a box and clearly needs to be routed. And this supports that.

Compls. Br. at 48-49 (citing Mutic Tr. 1044).

Complainants argue:

> Respondents, as well as the Staff, also make much of an alleged dispute regarding "one-way" versus "two-way" communications links, but the issue has no bearing on the construction of the term "communications network." Varian's construction does not depend on the directionality (either unidirectional or bidirectional) of data flow on a given link. In fact, Dr. Papanikolaou is the only expert that has raised this issue, opining that the prior art disclosed only "one way" links. Dr. Mutic never contended that directionality is dispositive of whether a communications network is present in a system.

Compls. Reply Br. at 8 (citations omitted).

Respondents argue:

> The AMERICAN HERITAGE DICTIONARY (3d ed. 2000) defines a "network" in the electrical context to mean "[a] group or system of electric components and connecting circuity," and in the computer science context to mean "[a] system of computers interconnected by telephone wires or other means in order to share information." RX-339 at 916 (definitions 4a and 4b). These dictionary definitions represent the ordinary, everyday meaning of "network" circa 2002, and they should therefore be accepted as an appropriate construction of this term—to the extent any construction is needed. Notably, these definitions do *not* require any sort of "network communications protocol," or two-way communications, or any of the other technical nuances Varian is now attempting to read into this claim limitation to distinguish the prior art.

Resps. Br. at 17.

The Staff argues:

> The evidence thus supports the plain and ordinary meaning of "communications network" as the correct construction. To the extent that a particularized definition is needed, the Staff submits that "a system of electrical components interconnected in order to share information" would be appropriate. *See* RPHB at 17 (citing RX-339 at 916 (AMERICAN HERITAGE DICTIONARY (3d ed. 2000)) (definitions 4a and 4b)).

Staff Br. at 29 (citing RX-339 at 916 (AMERICAN HERITAGE DICTIONARY (3d ed. 2000)) (definitions 4a and 4b)).

For the reasons discussed below, the administrative law judge has 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."

Claim 1 of the '021 patent recites: "a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat panel imager." Claim 15 of the '021 patent and claim 6 of the '430 patent recite: "a translatable treatment couch coupled to the rotatable gantry via a communications network."

As an initial matter, inasmuch as the parties did not identify this term as requiring construction, they have conceded it should be given its ordinary, lay meaning. *See Phillips v. AWH Corp.*, 415 F.3d 1305, 1314 (Fed. Cir. 2005) (*en banc*) ("In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful.") (citing *Brown v. 3M,* 265 F.3d 1349, 1352 (Fed. Cir. 2001)). Thus, "communications network" should be given its ordinary, "widely accepted meaning," *e.g.*, the meaning typically found in a general purpose dictionary. *Id.*

The AMERICAN HERITAGE DICTIONARY (3d ed. 2000) defines a "network" in the electrical context to mean "[a] group or system of electric components and connecting circuity," and in the computer science context to mean "[a] system of computers interconnected by telephone wires or other means in order to share information." RX-339 at 916 (definitions 4a and 4b). These dictionary definitions represent the ordinary, everyday meaning of "network" in about 2002.

Dr. Papanikolaou, Elekta's expert, testified that his understanding of "communications network" is consistent with the dictionary definition:

> A network requires more than one computer or device. It requires two things that talk to each other, and it can be done many different ways. It is a direct pathway for device A to talk to device B. Those devices could be two computers or they could be two control boxes. They could be something that one generates data, and the other has a way to request to receive the data. There could be something else in between as well.

RX-0494C (Papanikolaou RWS) at Q43.

In contrast, Varian's expert Dr. Mutic provided a narrow definition of "communications network." Dr. Mutic testified that "a communications network is a communications system that facilitates communication between many devices, and uses a networking protocol to selectively route messages to their intended devices." CX-0848C (Mutic WS) at Q75.

Claim construction always begins with the claim language itself. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1476, 1582 (Fed. Cir. 1995). "The words of a claim are generally given their ordinary and customary meaning," which is the "meaning [they] would have to a person of ordinary skill in the art at the time of the invention." *Phillips*, 415 F.3d at 1312-13.

Here, claim 1 of the '021 patent recites: "a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager." JX-0001 ('021 Patent) at col. 9, lns. 4-6. The stated purpose of the "communications network" in claim 1 is to couple a computing unit to the rotatable gantry (to which the flat-panel imager is mounted) such that the computing unit can "store the image projection data captured by the flat-panel imager." *Id.*

Nothing in this claim requires or implies a "communications protocol that selectively routes messages to their intended devices." Indeed, there are only two devices in this claim that must be connected by a communications link: (1) the flat-panel imager attached to the gantry, and (2) the computing unit that stores the image projection data acquired by the flat-panel imager.

Similarly, claim 15 of the '021 patent (and claim 6 of the '430 patent (JX -0002) at col. 9, lns. 27-29), discussed *infra*) recite "a translatable treatment couch coupled to the

rotatable gantry via a communications network." JX-0001 ('021 Patent) at col. 10, lns. 31-32; col. 14, ln. 66 – col. 15, ln. 1. Nothing in this claim language requires a "communications protocol." Instead, only two components in these claims are required to be connected by a communications link: (1) the treatment couch, and (2) the gantry. Nothing in these claims requires a "communications protocol that selectively routes messages to their intended devices."

"[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Phillips,* 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). Outside of the claims, the phrase "communications network" appears three times in the '021 patent specification. First, the specification states: "The couch 218 may be connected to the therapy simulator rotatable gantry via a communications network and is capable of translating in multiple planes plus angulation 219 for positioning and re-positioning the patient 205 and therefore the target volume." JX-0001 ('021 Patent) at col. 2, lns.36-40. Second, the specification states: "As shown in FIG. 1, the computer 220 connects to the simulator 100 and the command processor 225 via communications network 240." *Id.* at col. 4,lns. 16-19. Third, the specification states: "As shown in FIG. 3, box 451, a processor 425, and computer 450 connect to simulator 400 via communications network 440."[17] *Id.* at col. 6, lns. 16-18.

Aside from these three references to a "communications network," there is no discussion of "networking" anywhere in the '021 patent specification. For instance, the

[17] This sentence was not included in the original application. *See* RX-0270 (*Jaffray WIPO*) at 29 (paragraph [0033]). It was added two years later by amendment. *Id.* at 538, 545 (2/15/05 amendment).

specification does not discuss the use of any particular networking protocol to route messages selectively to their intended devices. No examples are given of any such networking protocols.

Dr. Mutic agreed that the claim term "communications network" could have a very broad meaning or a narrow meaning, depending on the context of how it is used. *See* Mutic Tr. 983. The '021 patent is not directed to computer networking, and there is no discussion of computer networking or network communications protocols. The drawings are simple schematics, not detailed circuit diagrams.

As discussed above, a court "should also consider the patent's prosecution history, if it is in evidence." *Phillips*, 415 F.3d at 1317 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995 (*en banc*)). "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Id.*

During prosecution of the '021 patent, application claim 7 included the limitation "a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager." *See* RX-0270 (*Jaffray WIPO*)[18] at 7. Application claim 7 was later combined with application claim 1 when the '021 patent issued, resulting in issued claim 1 reciting this same "communications network" limitation. *Id.* at 2101. In the first Office Action, the PTO rejected application claim 7 as obvious over the Jaffray Application in combination with Suzuki et al. *Id.* at 577. Thus, the PTO found this limitation satisfied by the disclosure at column 24, lines 39-40 of the Jaffray Application. That portion of the Jaffray Application recites:

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

"Thirdly, a plurality of 2-D images are read from the flat panel imager 404 by a control/acquisition computer." RX-0136 (U.S. Patent No. 6,842,502) at col. 24, lns. 39-40. The PTO concluded that this single sentence in the Jaffray Application was sufficient to disclose "a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager." This is consistent with the ordinary, everyday meaning of a "communications network."

The PTO likewise rejected other application claims that included the "communications network" limitation as anticipated by the Jaffray Application, citing the same sentence at column 24, lines 39-40. RX-0270 (*Jaffray WIPO*) at 1231. The PTO similarly rejected application claims requiring a "communications network" between the treatment couch and the gantry as anticipated by the Jaffray Application. RX-0270 (*Jaffray WIPO*) at 1231. The '021 patent applicants never challenged the PTO's finding that the Jaffray Application expressly discloses the "communications network" limitations that are now recited in claims 1 and 15 of the '021 patent. Rather, they filed Rule 131 Declarations to swear behind the Jaffray Application, and the PTO eventually withdrew the rejection on that basis alone. *See* RX-0270 (*Jaffray WIPO*) at 904, 915-991, 1050, 1064, 1305, 1348, 1387, 1395-1502, 1541. These unchallenged rejections provide an additional basis for rejecting Varian's narrow construction of "communications network." *See Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1358-59 (Fed. Cir. 2012) (rejecting patentee's proposed narrow construction of "mower deck" in part because it contradicted unchallenged rejections made during prosecution based on a broader construction).

Although extrinsic evidence may be considered during claim construction, it is generally considered "less reliable than the patent and its prosecution history in determining how to read claim terms." *Phillips,* 415 F.3d at 1318. As the Federal Circuit has warned, "undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents." *Id.* at 1318-19 (quoting *Southwall Techs., Inc. v. Cardinal IG, Co.,* 54 F.3d 1570, 1578 (Fed. Cir. 1995)). Thus, as a general rule, courts may rely on extrinsic evidence only if "the patent documents, taken as a whole, are insufficient to enable the court to construe disputed claim terms." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308-09 (Fed. Cir. 1999).

In this instance, the AMERICAN HERITAGE DICTIONARY (3d ed. 2000) has been consulted because, as discussed above, the parties agreed that one should construe "communications network" to have its plain and ordinary meaning. The dictionary defines a "network" in the electrical context to mean "[a] group or system of electric components and connecting circuity," and in the computer science context to mean "[a] system of computers interconnected by telephone wires or other means in order to share information." RX-339 at 916 (definitions 4a and 4b).

Accordingly, the administrative law judge has determined that the claim term "communications network" should be given its plain and ordinary meaning, which may be defined as "a system of computers interconnected by telephone wires or other means in order to share information."

B. Infringement Analysis of the '021 Patent

As discussed above, complainants allege infringement of independent apparatus claim 1 and dependent apparatus claims 4, 9 and 15 (which depends from unasserted independent apparatus claim 14) of the '021 patent. *See* Compls. Br. at 53-78.

Respondents argue that they do not infringe the asserted claims. *See* Resps. Br. at 55-78.

The Staff argues that the Accused Linacs products infringe the asserted claims but the Gamma Knife Icon products do not infringe the asserted claims. *See* Staff Br. at 30-42.

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.[19] *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).

[19] 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

2. Accused Products

Complainants argue: "Elekta's Accused Linacs infringe claims 1, 4, 9, and 15 of the '021 patent as shown by the documentary and testimonial evidence." Compls. Br. at 53, 53-67. Complainants argue that "Elekta's Icon Product infringes claims 1, 4, 9, and 15 of the '021 patent as shown by the evidence produced in this case, deposition testimony of Elekta's witnesses, and Dr. Mutic." Compls. Br. at 67.

3. Infringement of Accused Linacs

Complainants argue: "Elekta's Accused Linacs infringe claims 1, 4, 9, and 15 of the '021 patent as shown by the documentary and testimonial evidence." Compls. Br. at 53, 53-67.

Respondents disagree. *See* Resps. Br. at 55-63.

The Staff argues that the Accused Linacs infringe the asserted claims. *See* Staff Br. at 30-33.

a. Claim 1

Complainants argue: "Claim 1 is an independent apparatus claim. All limitations of claim 1 are met by Elekta's Accused Linacs." Compls. Br. at 53, 53-64.

Respondents disagree. *See* Resps. Br. at 55-58. Respondents argue:

> As explained above, claim 1 of the '021 patent is clearly anticipated by, *inter alia*, *Jaffray WIPO*. Varian's expert, Dr. Mutic, has identified just *one* limitation of claim 1—the "communications network" limitation—that he believes is missing from *Jaffray WIPO*. But as explained above, his opinion is based on an unduly narrow construction of "communications network" that contradicts the term's ordinary meaning and finds no support in the intrinsic record or the relevant extrinsic

---

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).

> evidence. For the reasons explained above, Varian's narrow construction of "communications network" is incorrect and should be rejected. However, if that construction were to be adopted, then the accused Elekta linacs would not infringe claim 1 because Varian has failed to prove that, under its construction, the accused Elekta linacs have "a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat panel imager."

Resps. Br. at 53 (citations omitted) (emphasis in original).

The Staff argues that claim 1 is literally infringed. Staff Br. at 30-31.

The only reason respondents argue the Accused Linacs do not infringe claim 1 (and consequently dependent claims 4 and 9) is that they allegedly do not meet the "communications network" limitation in claim 1 under Varian's narrow claim construction. *See* Resps. Br. at 55-58. As discussed above, the administrative law judge agreed with respondents and the Staff concerning the claim construction of "communications network," and 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." When the correct construction of "communications network" is used, the evidence shows that all limitations of claim 1 are met by the Accused Linacs. Nonetheless, the full analysis follows below.

i. "An apparatus, comprising"

The preamble "[a]n apparatus, comprising" is not a limitation of the claim. Regardless, if it were limiting, Elekta's linac systems are each an apparatus as shown in Elekta documents. For example, the representative [

]. *See, e.g.*, CX-0920.3C; CX-0888.3C; *see*

also CX-0233.37C ([

]).

ii. "a radiation treatment system capable of implementing a treatment plan, the system comprising:"

Elekta does not dispute that the Accused Linacs are each "a radiation treatment system capable of implementing a treatment plan." Elekta's documents and witnesses, as well as Dr. Mutic, all demonstrate that the [

] *See* CX-0958.26; CX-0277.48C; CX-0891.1C; JX-0025C (Brown Dep. Tr.) at 17; CX-0848C (Mutic WS) at Q38-42, 48-52, 59-60.

iii. "a frame"

Elekta does not dispute that the Accused Linacs have "a frame." Dr. Mutic has explained that [

]. *See* CX-0848C (Mutic WS) at Q61-64. In Elekta's [

]. *See id.*; RX-0494.66C. Elekta's documents also confirm that [ ]." *See* RX-0407.96-103C.

iv. "a rotatable gantry coupled to the frame"

Elekta does not dispute that its Accused Linacs have "a rotatable gantry" and, as set forth in the preceding section, "a frame." The Accused Linacs have a rotatable gantry, as demonstrated by Elekta's documents and witnesses, as well as by Dr. Mutic.

There is a [ ] and Elekta documents demonstrate the [ ]. *See* CX-0848C (Mutic WS) at Q39-52, 65.

v. "a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation."

Elekta does not dispute the Accused Linacs have "a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation." The Accused Linacs use [ ], as Elekta's documents show. *See, e.g.*, CX-0891.1C. The linear accelerator is used to [ ]. *See, e.g.*, CX-0233.51C. Dr. Mutic also explained that this claim limitation has been met. *See* CX-0848C (Mutic WS) at Q38-52, 70.

vi. "a cone-beam radiation source coupled to the rotatable gantry to radiate the patient"

Elekta does not dispute that its Accused Linacs have "a cone-beam radiation source coupled to the rotatable gantry to radiate the patient." The [ ] as well as other Elekta documentation and witness testimony confirm that [ ]. *See, e.g.*, CX-0233.51C; CX-0233.58C; CX-0233.54-55C. Dr. Mutic explained that this claim limitation is met. *See* CX-0848C (Mutic WS) at Q38-52, 71-72.

vii. "a flat-panel imager coupled to the rotatable gantry"

Elekta does not dispute that its Accused Linacs have "a flat-panel imager coupled

to the rotatable gantry." The [ ] as well as other Elekta documentation confirms that Elekta's Accused Linacs include a [ ]. *See, e.g.*, CX-0233.51C; CX-0233.58C; CX-0233.54-55C. Dr. Mutic explained that this claim limitation is met. *See* CX-0848C (Mutic WS) at Q38-52, 71-72.

viii. "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"

Elekta does not dispute that the [ ] satisfies the element of "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." Elekta's internal documents explain, for example, that [ ]." *See* CX-0235.58C. " [ ]." *Id.* Elekta's witnesses have also confirmed this element. *See, e.g.*, JX 0025C (Brown Dep. Tr.) 114; JX-0048C (Sankey Dep. Tr.) at 62. Dr. Mutic also explained how this limitation has been met. *See* CX-0848C (Mutic WS) at Q38-52, 73.

ix. "a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager"

Claim 1 of the '021 patent recites "a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager." As discussed below, Dr. Mutic's testimony, Elekta documents, and the testimony of Dr. Papanikolaou, show the Accused Linacs satisfy this limitation when it is properly construed. *See* CX-0848C (Mutic WS) at Q38-52, 74-84.

"computing unit . . . to store the image projection data captured by the flat panel imager"

Elekta does not dispute that the Accused Linacs have a "computing unit . . . to store the image projection data captured by the flat panel imager." Elekta's documents and witnesses, as well as Dr. Mutic, confirm that the [

]. *See* CX-0235.58C; *see also, e.g.*, JX-0048C (Sankey Dep. Tr.) at 64-65, 72-75; CX-0848C (Mutic WS) at Q73-74. [

]. *See* CX-0233.235C; CX-0848C (Mutic WS) at Q74.

"a computing unit, coupled to the rotatable gantry via a communications network"

The XVI imaging subsystem is fully integrated via a communications network within the control and overall operations of the Accused Linacs. Elekta's documentation and witnesses confirm [

[. *See* CX-0278.6C; CX-0251.6C; CX-3831.11C; JX-0048C (Sankey Dep. Tr.) at 72-74; JX-0025C (Brown Dep. Tr.) at 162-163. Elekta's Global Vice President of Scientific Research, Mr. Kevin Brown, testified about the [

]. *See* RX-0435C (Brown WS) at Q4. He confirmed that [

]. *See* Brown Tr. 652-653. Elekta's FDA submission for XVI further expressly states that " [

]." *See* CX-0250.550C.

Dr. Mutic testified that [

]. *See* CX-0848C (Mutic WS) at Q75-84. First, Dr. Mutic explained that the [

]." *See* CX-0848C (Mutic WS) at Q79; CX-0278.6C; CX-0250.555C. Dr. Mutic's identification of this [

] is confirmed by Elekta's FDA submission, which demonstrates the [ ] (CX-0250.548C) [

] (CX-0250.550C, CX-3829.50). The interconnectivity between the [ ], is further demonstrated by additional Elekta documents that demonstrate [ ]. *See*

e.g., CX-0278.5C; *see also* CX-0235.63C ("[

] . . . .").

Accordingly, the evidence shows that the Accused Linacs infringe asserted claim 1 of the '021 patent.

b. Claims 4 and 9

Complainants argue that the Accused Linacs infringe dependent claims 4 and 9. *See* Compls. Br. at 64-65.

Respondents argue:

> Because dependent claims 4 and 9 depend from claim 1 and include all of claim 1's limitations, they cannot be infringed if claim 1 is not infringed. Therefore, for the reasons explained above, under Varian's unduly narrow and incorrect construction of "communications network," the accused Elekta linacs would not infringe claims 4 and 9.

Resps. Br. at 58.

The Staff argues: "Because the evidence has shown that the Accused Linacs infringe claim 1, they also have been shown to infringe claims 4 and 9." Staff Br. at 31.

As noted, respondents argue that the Accused Linacs do not infringe claims 4 or 9 solely because they do not meet the "communications network" limitation in claim 1, from which claims 4 and 9 depend. *See* Resps. Br. at 58. As with claim 1, when the correct construction of "communications network" is used, the evidence shows that all limitations of claim 4 and 9 are met by the Accused Linacs. Nonetheless, infringement of claims 4 and 9 are discussed below.

Claim 4

Claim 4 is dependent on claim 1 and recites: "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." As discussed above, every element of claim 1 is met by Elekta's Accused Linacs. Elekta does not dispute that the [

]. This feature of XVI is also shown by Elekta documents and witness testimony. *See, e.g.*, JX-0025C (Brown Dep. Tr.) at 114, 162-163; JX-0048C (Sankey Dep. Tr.) at 64-65, 74. As Dr. Mutic testifed, the limitation of dependent claim 4 is met by Elekta's Accused Linacs. *See* CX-0848C (Mutic WS) at Q89-91. The Accused Linacs infringe claim 4.

Claim 9

Claim 9 is dependent on claim 1 and recites: "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." As discussed above, every element of claim 1 is met by Elekta's Accused Linacs. Elekta does not dispute that its [

]. Varian presented detailed evidence showing infringement of dependent claim 9. *See* CX-0848C (Mutic WS) at Q38-52, 101-03.

Accordingly, the Accused Linacs infringe claim 9.

c. Claim 15

Complainants argue that the Accused Linacs infringe asserted dependent claim

15. *See* Compls. Br. at 65-67.

Respondents argue: "Claim 15 depends from claim 14, which requires, *inter alia,* "a translatable treatment couch coupled to the rotatable gantry via a communications network." The accused linacs do not have a treatment couch that is coupled to the rotatable gantry via a communications network under either party's interpretation of that term. Accordingly, the accused linacs do not infringe claim 14, or claim 15 which depends from it." *See* Resps. Br. at 58, 58-63.

The Staff argues that claim 15 is literally infringed by the Accused Linacs. Staff Br. at 33.

The shared limitations between claim 15 and claim 1

Claim 15 of the '021 patent depends on independent apparatus claim 14. Many of the limitations of claim 14 are identical to elements recited in claim 1. The shared limitations include "An apparatus, comprising," "a radiation treatment system capable of implementing a treatment plan, the system comprising," "a frame," "a rotatable gantry coupled to the frame," "a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation," "a cone-beam radiation source coupled to the rotatable gantry to radiate the patient," "a flat-panel imager coupled to the rotatable gantry, wherein," and "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." As discussed above with respect to claim 1, these elements are satisfied by the Accused Linacs. *See* CX-0848C (Mutic WS) at Q38-118.

"a translatable treatment couch coupled to the rotatable gantry via a communications network." (claim 14)

Elekta's Accused Linacs are integrated systems that include a "translatable treatment couch coupled to the rotatable gantry via a communications network." *See* CX-0848C (Mutic WS) at Q114-15. Elekta does not dispute that the Accused Linacs have a "translatable treatment couch." As explained by Dr. Mutic, and Elekta's documents, and witnesses, the [

]. *See e.g.*, CX-0233.184C. Elekta's documents explain that the [

]. *See, e.g.*, CX-0233.296C; CX-0235.63C; CX-0232.27C; CX-0232.41-55C; CX-0232.135 ([

]); CX-0232.136 ("[

]…."). Communications occur between the [

]. *See* Mutic Tr. 495-498, 459-462.

Elekta's non-infringement position limits the manner in which networked components of the Accused Linacs can be coupled to only direct communications that occur entirely over a "communications network." As discussed above, 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." This construction does not exclude indirect communications over a network. Thus, under the plain and ordinary meaning of the term "communications network," the evidence shows that the accused treatment couch is coupled to the rotatable gantry via a communications network as required by claim 15. In particular, the [

]" as can be seen in the following diagram from an Elekta User Manual:

[

]

See RX-0406.27C. As Elekta admits, "[ ]." *See* Resps. Br. at 59; RX-0406.027C; *see also* RX-0494C (Papanikolaou RWS) at Q78. The

[ ]. *See* RX-406.0032C; RX-0494C (Papanikolaou RWS) at Q78; Resps. Br. at 59. Elekta argues that "[ ]," because data does not "[ ]." Yet, the evidence shows that data flows [ ], and in this way the translatable treatment couch is coupled to the rotatable gantry via a communications network.

"The apparatus of claim 14, wherein the translatable treatment couch is capable of movement in three planes plus angulation" (claim 15)

Claim 15 recites: "The apparatus of claim 14, wherein the translatable treatment couch is capable of movement in three planes plus angulation." Elekta does not dispute that the Accused Linacs meet the limitation recited in dependent claim 15. Elekta's documents and witnesses confirm that [ ]. Elekta's [ ]. CX-0233.184C. Dr. Mutic has further shown that the limitation of dependent claim 15 is met by Elekta's Accused Linacs. *See* CX-0848C (Mutic WS) at Q116-18.

* * *

Accordingly, the evidence shows that the Accused Linacs infringe asserted claim 15.

4. Infringement of Gamma Knife Icon[20]

Complainants argue that "Elekta's Icon Product infringes claims 1, 4, 9, and 15 of the '021 patent as shown by the evidence produced in this case, deposition testimony of Elekta's witnesses, and Dr. Mutic." Compls. Br. at 67.

a. Claim 1

Complainants argue that "[a]ll limitations of claim 1 are met by Elekta's Icon Product." Compls. Br. at 68.

Respondents argue that the Elekta's Icon products do not have "a rotatable gantry coupled to the frame" or a "high-energy radiation source coupled to the rotatable gantry to radiate the patient with therapeutic radiation." *See* Resps. Br. at 63-78. In particular, Elekta argues that the Icon products do not have the claimed "frame," or the claimed "gantry," and that the high-energy radiation source is not "coupled to the rotatable gantry." *Id.* at "63-73."

The Staff argues that "the evidence has shown that the Gamma Knife Icon does not infringe claim 1 of the '021 patent because it does not have a 'a high-energy radiation source *coupled* to the rotatable gantry.'" Staff Br. at 38 (emphasis in original).

Those claim elements that are disputed by respondents and the Staff are discussed below. For the reasons discussed below, complainants have not shown that respondents' Gamma Knife Icon products infringe claim 1 because those products do not meet the limitation of "a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation."

[20] "Gamma Knife Icon" is also referred to as "Icon Product" or "Icon."

"frame"

Respondents argue that Elekta's Icon products do not have "a rotatable gantry coupled to the frame." *See* Resps. Br. at 63-66.

No party offered the claim term "frame" for construction, although respondents now argue that complainants have defined the limitation in a way that is inconsistent with its plain and ordinary meaning. *See id.* Respondents argue that the claimed "frame" is "the basic supporting structure of a device or system. It carries the weight of the other components of the device or system." *Id.* at 63.

The '021 patent does not restrict or otherwise define the claimed "frame" and thus the term should be given its plain and ordinary meaning.[21] Nothing in the record suggests that the frame must be weight-bearing, touch the floor, or be particularly stable. *See* Compls. Br. at 68-69 (citing CX-0848C (Mutic WS) at Q196-198). Moreover, respondents' expert Dr. Papanikolaou agrees that there is structure [

]." *See* RX-0494C (Papanikolaou RWS) at Q154. The Gamma Knife Icon has a [ ]. *See* CX-0238.C (Gamma Knife Icon Instructions for Use) at .26, .27 and .30.

Accordingly, the evidence shows that the Gamma Knife Icon has a "frame" within the meaning of claim 1.

"rotatable gantry"

The Icon Product has a rotatable gantry coupled to the frame as shown in Elekta's

[21] The many references to a "frame" in the '021 patent refer to image frames, which are analogous to snapshots taken by a camera, not the structural frame of the apparatus.

documents and by the deposition testimony of Elekta's corporate witness. Elekta's corporate witness testified that the [ ]." *See* JX-0026C (Carlsson Dep. Tr.) at 34. Mr. Carlsson further confirmed at the hearing that the [ ]. Carlsson Tr. 827-828. As Dr. Mutic testified, this [ ] is the rotatable gantry claimed in the '021 patent. *See* CX-0848C (Mutic WS) at Q199. Dr. Papanikolaou narrows the term "rotatable gantry" by requiring that it must support the therapeutic radiation source. There is nothing in the specification of the '021 patent that requires this, and Elekta's own documents refer to a [ ]." *See, e.g.*, CX-0238.30C.

Further, the rotatable gantry and the frame are coupled together. The rotatable gantry and the frame are coupled together both in a spatial sense and a mechanical sense, which allows the system to precisely define exactly where the CBCT is in relation to the radiation source. As Dr. Mutic explained, this enables the Icon Product's submillimeter precision. Mutic Tr. 498-500. The evidence shows that this limitation is met by the Icon Product. CX-0848C (Mutic WS) at Q199-201.

"coupled"

Respondents argue:

> Claims 1 and 15 of the '021 patent require "a high-energy radiation source coupled to the rotatable gantry to radiate a patient with a therapeutic radiation." Varian contends [ ]."

Resps. Br. at 68-69 (citations omitted) (emphasis in original).

Claim 1 requires both "a rotatable gantry coupled to the frame" and "a high-energy radiation source coupled to the rotatable gantry to radiate a patient with therapeutic radiation." *See* JX-0001 ('021 Patent) at col. 8, lns. 60-62. Thus, although not all gantries on radiotherapy devices necessarily must be coupled to a high-energy radiation source, for the '021 patent, it is an explicit requirement of claim 1.

As Elekta argues, the '021 patent does not give any special meaning to "coupled." *See* Resps. Br. at 68-69. Instead, it uses "coupled" to describe to the attachment of the high energy radiation source to a rotatable gantry such that the radiation source rotates with the gantry. *See* JX-0001 ('021 Patent) at Fig. 3; col. 5, lns. 20-24 ("A cone-beam CT radiation source 404 and a flat panel imager 406 oppose each other and are coupled to the rotatable gantry 402. In one embodiment, the cone-beam CT radiation source 404 is a megavoltage (MV) radiation source"); col. 7, lns. 14-18 ("For example, the kV cone-beam CT radiation source and opposing flat panel imager may be coupled to the treatment machine gantry 404 at an off axis of e.g. forty-five or ninety degrees from the MV cone-beam radiation source 404 and opposing imager 406."); col. 7, lns. 26-29 ("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"); *see also* RX-0045 (dictionary definition of "couple") at 4; RX-0494C (Papanikolaou RWS) at Q173. Thus, in the context of the '021 patent, "coupled" means that the high-energy radiation source is mounted on or otherwise directly affixed to the gantry such that the high-energy radiation source and the gantry rotate together. *See* Mutic Tr. 498-500 (testifying that Gamma Knife Icon radiation source and the gantry rotate together).

The evidence shows that the accused Gamma Knife Icon has a [

]. *See* RX-0494C (Papanikolaou RWS) at Q/A166 (citing RX-409C.027 and .0030 (Gamma Knife Instructions for Use)). In the Gamma Knife Icon, the [

], as shown in the following image:

[

]

See RX-0409C.0028; Mutic Tr. 466-467 (testifying that [ ]); *cf.* *id.* 498-500 (testifying that [ ]). Thus, the evidence does not show that the Gamma Knife Icon meets this limitation.

"a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager"

Respondents argue:

> Varian has propounded an overly narrow construction of "communications network" in an effort to distinguish the prior art. That construction is incorrect and should be rejected for the reasons explained above. However, if that construction were to be adopted, then the accused Gamma Knife Icon would not infringe claim 1 because Varian has failed to prove that the Icon has "a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat panel imager."

See Resps. Br. at 71, 71-73.

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."

The evidence shows that the Gamma Knife Icon has "a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager" under the correct plain and ordinary meaning of the

term "communications network." *See* Compls. Br. at 73-74 (citing CX-0848C (Mutic WS) at Q209; CX-0927C (Gamma Knife Icon design specification) at .27 and .30; CX-0926.9C (Gamma Knife Icon electronics specification); CX-0922.9C (Gamma Knife Icon subsystem specification)).

* * *

Accordingly, the evidence shows that the Gamma Knife Icon does not infringe claim 1 of the '021 patent because it does not have a "a high-energy radiation source coupled to the rotatable gantry."

b. Claims 4 and 9

Complainants argue that Gamma Knife Icon products infringe dependent claims 4 and 9. *See* Compls. Br. at 74-75.

Respondents argue: "Because the Icon does not infringe claim 1, it also does not infringe claims 4 and 9, which depend from claim 1." Resps. Br. at 73. Respondents do not dispute that the Gamma Knife Icon otherwise meets the additional limitations of these claims. *See id.*

As discussed above, the evidence shows that the Gamma Knife Icon does not infringe claim 1 of the '021 patent because it does not have a "a high-energy radiation source coupled to the rotatable gantry." Thus, the Gamma Knife Icon does not infringe dependent claims 4 and 9.

b. Claim 15

Complainants argue that Gamma Knife Icon products infringe dependent claim

15. *See* Compls. Br. at 75-78.

Respondents disagree. *See* Resps. Br. at 73-78.

The Staff argues that the Gamma Knife Icon does not infringe claim 15 because "[t]he evidence has shown that the Gamma Knife Icon does not meet the 'high-energy radiation source coupled to the rotatable gantry' limitation in claim 14, for the same reasons explained above with regard to claim 1." Staff Br. at 39.

Claim 14 contains many of the same limitations as claim 1, *i.e.*, "a rotatable gantry coupled to the frame"; "a high-energy radiation source coupled to the rotatable gantry to radiate a patient with a therapeutic radiation"; "a cone-beam radiation source coupled to the rotatable gantry to radiate the patient"; and "a flat-panel imager coupled to the rotatable gantry." As an initial matter, the evidence shows that the Gamma Knife Icon does not meet the "high-energy radiation source coupled to the rotatable gantry" limitation in claim 14, for the same reasons explained above with respect to claim 1. Nonetheless, additional arguments raised by respondents are discussed below.

Respondents also argue that the Gamma Knife Icon does not meet the "a translatable treatment couch coupled to the rotatable gantry via a communications network" limitation of claim 14. *See* Resps. Br. at 74-75. Respondents argue that the [

]. *See* Resps. Br. at 74.

However, the evidence shows that the Gamma Knife Icon meets this limitation. The limitation does not require that the gantry and the couch communicate directly with each other, but rather that they be coupled via a communications network. Elekta's schematic document shows that the [

], as depicted in the following diagram:

[

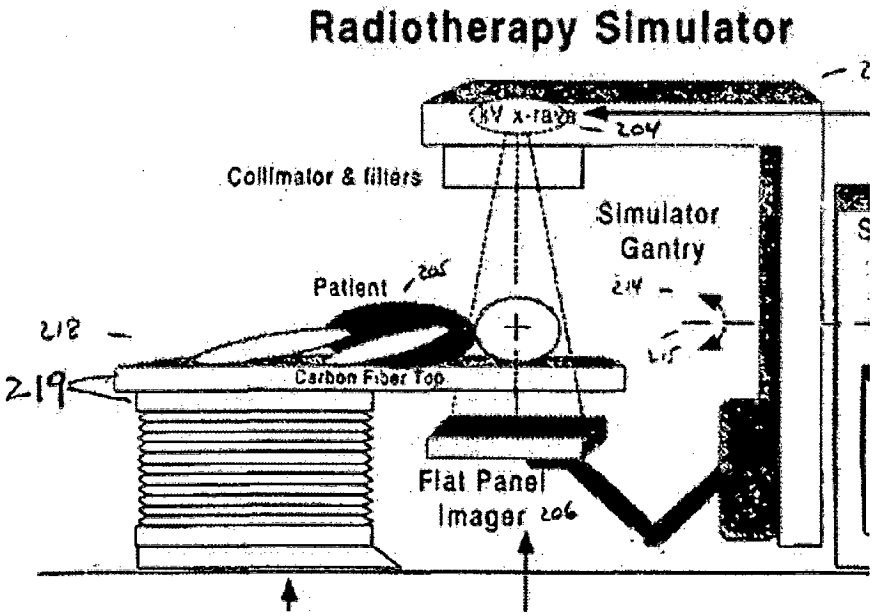
]

See CX-0926.09C (electrical subsystems design specifications for LGK Perfexion); *see also* CX-0848C (Mutic WS) at Q238-39.

Respondents also argue that the Gamma Knife Icon does not meet limitation "the translatable treatment couch is capable of movement in three planes plus angulation" in claim 15. *See* Resps. Br. at 76-78. Respondents argue that the Gamma Knife Icon's couch [ ]." *See id.*

No party offered the term "angulation" for construction. The description of "angulation" in the '021 patent is sparse. *See* JX-0001 ('021 Patent) at col. 2, lns. 36-40 ("The couch 218 may be connected to the therapy simulator rotatable gantry via a communications network and is capable of translating in multiple planes plus angulation

219 for positioning and re-positioning the patient 205 and therefore the target volume"). "Angulation 219" is depicted in Figure 1 of the '021 patent:



See JX-0001 ('021 Patent) at Fig. 1 (excerpt); *see also id.* at col. 5, lns. 29-32 (same description regarding angulation 419 in Figure 3). The "angulation" in this context refers to rotational movement of the couch as opposed to orthogonal movement of the couch in the X, Y, and Z planes. *See* Resps. Br. at 76-78; *see also* RX-0494C (Papanikolaou RWS) at Q191-200, 203; RX-0499C (Carlsson WS) at Q41.

Complainants argue that the Icon infringes because the [

]. *See* Compls. Br. at 77-78. The [

], and thus satisfies this claim limitation. *See* Mutic Tr. 480-482. The evidence shows that [

]. *See* RX-0494C (Papanikolaou RWS at Q194); RX-0409C.726 (Gamma Knife Icon Instructions for Use); CX-0848C (Mutic WS) at Q241; CX-0238.84C (Gamma Knife Icon Instructions for Use).

C. Domestic Industry (Technical Prong)

Complainants argue that their "Clinac iX, Trilogy, TrueBeam, and Edge systems practice the '021 patent." Compls. Br. at 78. It is argued that "[r]espondents do not dispute that Varian's Clinac iX and Trilogy radiotherapy systems with the On-Board Imager ("OBI") practice claims 1 Clinac iX and Trilogy systems." *Id.* at 78. Complainants argue that "[r]espondents do not dispute that Varian has shown that the Clinac practices each limitation of claim 4 of the '021 patent. *Id.* at 81.

The Staff argues: "Varian's arguments regarding its technical domestic industry on the '021 patent are not disputed by Elekta, and the evidence has shown that Varian has satisfied the technical prong of the domestic industry requirement with respect to claim 1 and 4 of the '021 patent." Staff Br. at 43.

Indeed, respondents did not brief the technical prong with respect to claims 1 and 4 of the '021 patent. *See* Joint Outline at 1 (showing "n/a" for pages corresponding to the technical prong issue for the '021 patent); Resps. Reply Br. at 4-24 (showing no arguments concerning the technical prong issue for the '021 patent).

Complainants' arguments regarding the technical prong of the domestic industry requirement for the '021 patent are not disputed, and supported by substantial evidence. *See* Compls. Br. at 29-31, 78-84. The administrative law judge finds that complainants

have satisfied the technical prong of the domestic industry requirement with respect to claims 1 and 4 of the '021 patent.

D. Validity of the '021 Patent

Respondents argue that asserted claims 1, 4, 9 and 15 of the '021 patent are anticipated by three different prior art references: *Jaffray WIPO*,[22] *Jaffray 2001*,[23] and *Jaffray 2000*.[24] *See* Resps. Br. at 28-51. Respondents argue that the asserted claims are rendered obvious by two prior art combinations. *See* Resps. Br. at 51-55.

Complainants disagree. *See* Compls. Br. at 85-102. The Staff argues that the asserted claims are anticipated, but are not rendered obvious. *See* Staff Br. at 43-57.

For the reasons set forth below, respondents have shown by clear and convincing evidence that the asserted claims of the '021 patent are anticipated, but they have not shown by clear and convincing evidence that the asserted claims are rendered obvious.

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). 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).

---

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

[23] *See* RX-0262 (David A. Jaffray, *et al.*, *A Volumetric Cone-Beam CT System Based on a 41x41 cm^2 Flat-Panel Imager*, Medical Imaging 2001: Physics of Medical Imaging, Proceedings of SPIE Vol 4320 (2001) (hereinafter, "*Jaffray 2001*").

[24] *See* RX-0275 (David A. Jaffray, *et al.*, *Cone-Beam Computed Tomography on a Medical Linear Accelerator Using a Flat-Panel Imager*, Session: EPID & Patient Positioning, IXXX ICCR 558-560 (2000) (hereinafter, "*Jaffray 2000*").

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."[25] 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.*, 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

[25] 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).

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).[26]

2. Anticipation

Respondents argue that asserted claims 1, 4, 9 and 15 of the '021 patent are anticipated by *Jaffray WIPO*, *Jaffray 2001*, and *Jaffray 2000*. *See* Resps. Br. at 28-51.

Complainants disagree. *See* Compls. Br. at 85-95. The Staff argues that the asserted claims are anticipated. *See* Staff Br. at 43-53.

For the reasons set forth below, it is found by clear and convincing evidence that the asserted claims of the '021 patent are anticipated.

a. *Jeffray WIPO*

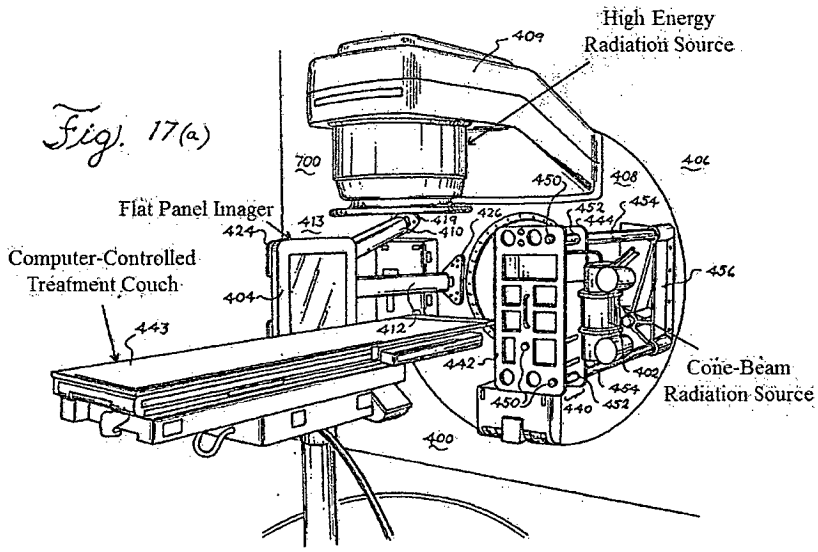
Overview of *Jeffray WIPO*

WIPO Publication No. WO 01/60236 ("*Jaffray WIPO*") (RX-0270) was filed on February 16, 2001. Like the U.S. Jaffray Application applied during prosecution, it is titled "Cone-Beam Computerized Tomography with a Flat-Panel Imager." Unlike the U.S. Jaffray Application, it was published more than one year before the '021 patent was

[26] 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)).

filed on August 23, 2001, and thus it is prior art against the Shapiro patents under 35 U.S.C. § 102(b).

Jaffray WIPO discloses a linear accelerator equipped with a traditional high energy treatment radiation source, a cone beam radiation source, a flat panel imager to capture image projection data used to create volumetric cone beam computed tomography (CBCT) images, and a computer-controlled treatment couch:



RX-0270 (*Jaffray WIPO*) at Figs. 17(a)-(c).

Varian's expert, Dr. Mutic, opined that a single limitation of claims 1, 4, and 9 is missing from *Jaffray WIPO* ("a computing unit, coupled to the rotatable gantry via a communications network, to store the image projection data captured by the flat-panel imager"), and that only a single limitation of claim 15 is missing from *Jaffray WIPO* ("a translatable treatment couch coupled to the rotatable gantry via a communications network"). *See* Resps. Br. at 29 (citing Mutic Tr. 985, 988, 991). These opinions, however, are based on Varian's proposed construction of "communications network," rejected above.

Element-by-Element Analysis

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

This uncontested limitation is shown in Figs. 17(a)-(e), which show a radiotherapy system that is an apparatus. RX-0270 (*Jaffray WIPO*) at FIGS 17(a)-(e); *see also* RX-0433C (Papanikolaou WS) at Q131-32, 190.

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

Jaffray WIPO discloses this uncontested limitation via the teaching of a radiotherapy system that is capable of executing a treatment plan that is determined from a cone beam computerized tomography image. RX-0270 (*Jaffray WIPO*) at col. 46, lns. 24-27; Mutic Tr. 969. *Jaffray WIPO* states that "several embodiments of a flat panel imager-based kilovoltage cone beam computerized tomography scanner for guiding radiation therapy on a medical linear accelerator are envisioned." RX-0270 (*Jaffray WIPO*) at col. 33, lns. 17-20. *Jaffray WIPO* also states, "[f]ollowing transferal of the prescription to the delivery system, the treatment plan is executed according to the patient setup and treatment plan determined from the cone beam computerized tomography image." *Id.* at col. 46, lns. 24-27; *see also* RX-0433C (Papanikolaou WS) at Q133-43.

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

Jaffray WIPO discloses this uncontested limitation by discussing that the system is a wall-mounted gantry: "For example, FIGS. 17(a)-(e) and 18 are diagrammatic and schematic views of an embodiment of a wall-mounted cone beam computerized tomography system 400." RX-0270 (*Jaffray WIPO*) at col. 33, lns. 20-22. Further, the linear accelerator shown in *Jaffray WIPO* was an Elekta SL-20, which included a support

structure that could be considered a frame. RX-0433C (Papanikolaou WS) at Q135; RX-0435C (Brown WS) at Q18, 19.

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

Jaffray WIPO discloses this uncontested limitation: "As shown in FIGS. 17(a)-(e) and 18-19, the flat-panel imager 404 can 10 be mounted to the face of a flat, circular, rotatable drum 408 of the gantry 406 of a medical linear accelerator 409, where the x-ray beam 407 produced by the x-ray tube 402 is approximately orthogonal to the treatment beam 411 produced by the radiation therapy source 409." RX-0270 (*Jaffray WIPO*) at col. 34, lns. 9-13. Further, the linear accelerator shown in *Jaffray WIPO* was an Elekta SL-20, which included a support structure for the rotating drum that could be considered a frame. RX-0433C (Papanikolaou WS) at Q135.

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

Jaffray WIPO discloses this uncontested limitation: "The system 400 may be retrofitted onto an existing or new radiation therapy system 700 that includes a separate radiation therapy x-ray source, such as a linear source 409, that operates at a power level higher than that of x-ray tube 402 so as to allow for treatment of a target volume in a patient. The linear source 409 generates a beam of x-rays or particles 411, such as photons or electrons, that have an energy ranging from 4 MeV to 25 MeV." RX-0270 (*Jaffray WIPO*) at FIGS. 17(a)-(e), col. 33, ln. 29 – col. 34, ln. 2; *see also* RX-0433C (Papanikolaou WS) at Q156-57.

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

Jaffray WIPO discloses this uncontested limitation: "The cone beam computerized tomography system 400 includes an x-ray source, such as x-ray tube 402, and a flat-panel imager 404 mounted on a gantry 406." RX-0270 (*Jaffray WIPO*) at col. 33, lns. 22-24. "The x-ray tube 402 generates a beam of x-rays 407 in the form of a cone or pyramid ..." *Id.* at col. 33, lns. 24-25; *see also* RX-0433C (Papanikolaou WS) at Q158-59.

- **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 WIPO discloses this uncontested limitation: "The cone beam computerized tomography system 400 includes an x-ray source, such as x-ray tube 402, and a flat-panel imager 404 mounted on a gantry 406." RX-0270 (*Jaffray WIPO*) at col. 33, lns. 22-24. "The preferred embodiment includes a mechanism (reconstruction engine) for high-speed cone beam computerized tomography image reconstruction. The plurality of 2-D projections is first processed by dark and flood field correction, and the measurements of orbit non-ideality (below), tube output variations, and gantry rotation are used together with the processed 2-D projections to form 3-D cone beam computerized tomography image reconstructions of the patient 441. A variety of cone-beam reconstruction techniques are known within the art, including cone-beam filtered back-projection. The cone beam computerized tomography image is then made available

to a system for on-line treatment planning." *Id.* at col. 41, lns. 21-30; *see also* RX-0433C (Papanikolaou WS) at Q160-61.

- **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 WIPO discloses this limitation because it teaches that a centralized "control/acquisition computer" both receives "a plurality of 2-D images [that] are read from the flat panel imager 404" and controls the "orbit traversed by the [gantry-mounted] x-ray tube 402 and the flat panel imager 404" by controlling rotation of the gantry 406. RX-0270 (*Jaffray WIPO*) at col. 41, lns. 4-5; col. 40, lns. 18-21. *Jaffray WIPO* explains that "the preferred embodiment includes *computer-control* of: 1.) x-ray pulses generated by the x-ray source 402; 2.) *gantry rotation* (e.g., in increments of -1° through -360°); and *flat panel imager readout* (e.g., at a readout rate consistent with the limitations in x-ray tube output and gantry rotation)." *Id.* at col. 41, lns. 12-16 (emphasis added). The integration of these control functionalities is shown in Fig. 24:

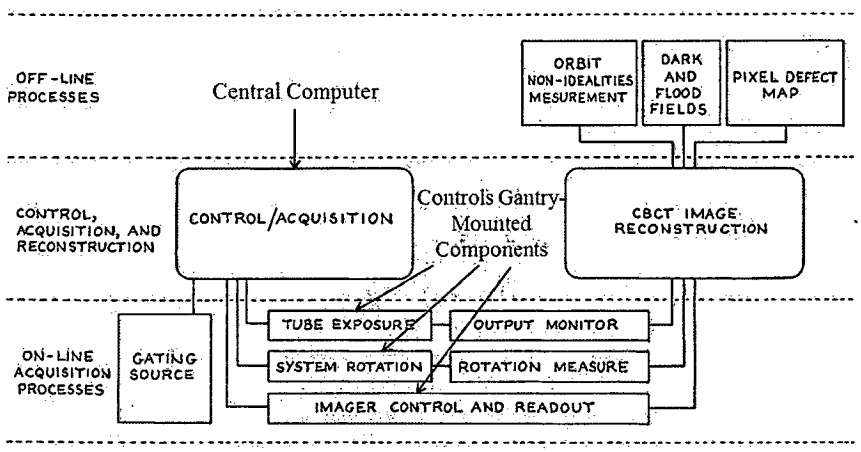


Fig. 24

Under the correct claim construction of "communications network,"[27] this limitation is met because *Jaffray WIPO* discloses communications between several components on the gantry, including the "imager control and readout," and the control/acquisition computer. Indeed, the PTO found that the nearly identical Jaffray Application discloses this limitation. *See* JX-0011 (File History for '021 Patent) at 1231 ("With regard to claim 49, Jaffray *et al.* disclosed the apparatus of claim 45, the method further comprises a computing unit, coupled to the rotatable gantry via a ***communications network*** to store the image projection data captured by the flat panel imager column 24, lines 39-40), wherein the computing unit generates a treatment plan based on the image projection data (column 26, line 39 - column 28, line 10).") (emphasis added).

Thus, the PTO found this limitation satisfied by the disclosure at column 24, lines 39-40 of the Jaffray Application, which recites: "Thirdly, a plurality of 2-D images are read from the flat panel imager 404 by a control/acquisition computer." RX-0136 (US Patent No. 6,842,502) at col. 24, lns. 39-40. That same sentence is recited in *Jaffray WIPO*. RX-0270 (*Jaffray WIPO*) at col. 41, lns. 4-5. As explained above, *Jaffray WIPO* discloses additional details about the communications between the gantry and the control/acquisition computer.

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

[27] 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 WIPO discloses this limitation because it teaches "a ***computer-controlled treatment table*** 443 for correction of lesion localization errors" as shown above in Fig. 17(a). RX-0270 (*Jaffray WIPO*) at col. 42, lns. 5-6 (emphasis added). Translations of the "target volume/lesion 444" with respect to the planning image position "may be corrected by translation of the computer-controlled treatment table 443." RX-0270 (*Jaffray WIPO*) at col. 46, lns. 9-10. The centralized computer control disclosed in *Jaffray WIPO* includes control of the treatment couch 443:

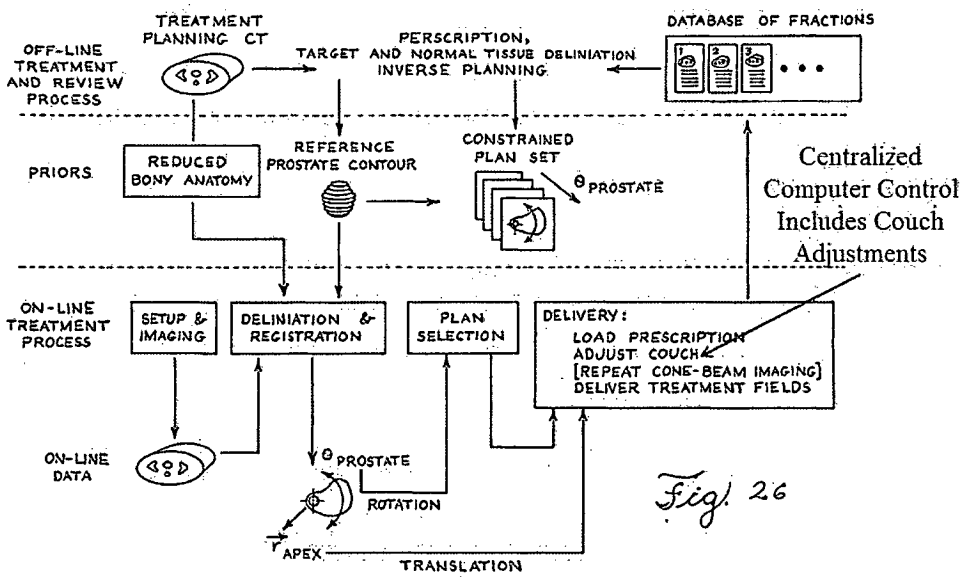


Fig. 26

Thus, the computer-controlled treatment couch 443 of *Jaffray WIPO* is part of the "communications network" discussed above for the "computing unit" limitation. Therefore, *Jaffray WIPO* also meets the contested "translatable treatment couch" limitation of claim 15.

Indeed, during prosecution, the PTO found that this limitation is satisfied by the nearly identical Jaffray Application. *See, e.g.*, RX-0270 (*Jaffray WIPO*) at 1231 ("With regard to claim 51, Jaffray *et al.* disclosed the apparatus of claim 45, the apparatus further

comprises: a translatable treatment couch coupled to the rotatable gantry via a communications network...").

The Shapiro applicants never challenged the PTO's finding. Instead, they were only able to overcome the rejection by swearing behind the Jaffray Application, which they cannot do for the *Jaffray WIPO* publication. *Jaffray WIPO* contains the same disclosure that the PTO repeatedly found satisfies this limitation. RX-0270 (*Jaffray WIPO*) at col. 42, lns. 5-16 (corresponding to col. 25, lines 15-29 of the Jaffray Application).

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

Jaffray WIPO discloses this uncontested limitation: "The table 443 preferably allows translation of the patient 441 in the x, y, and z directions as well as rotation about the x axis. Rotation about the y axis (tilt) and z axis (roll) is possible for an embodiment in which lesion localization errors are corrected by such motions (as opposed to correction of such errors through selection of an appropriate RTTP from a constrained plan set), provided that such motions do not cause uncertainty in the location/orientation of the lesion 444 and/or surrounding structures, e.g., due to the effects of gravity." RX-0270 (*Jaffray WIPO*) at col. 42, lns. 6-13; Mutic Tr. 987; *see also* RX-0433C (Papanikolaou) at Q194-96; RX-0435C (Brown WS) at Q20-24 (discussing SL-20 treatment couch).

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

Jaffray WIPO meets this limitation because the "cone beam computerized tomography system reconstructs three-dimensional (3-D) images from a plurality of two

dimensional (2-D) projection images acquired at various angles about the subject." RX-0270 (*Jaffray WIPO*) at col. 5, lns. 15-18. *Jaffray WIPO* further describes that "[t]he volumetric data set is illustrated further in FIG. 14, in which volume renderings demonstrate the fully 3-D nature of the data set and show the level of detail contained within the cone beam computerized tomography data." *Id.* at Fig. 14, col. 28, lns. 20-22; *see also* RX-0433C (Papanikolaou WS) at Q174-76.

Varian's expert opines in his witness statement that *Jaffray WIPO* does not meet this limitation because the Shapiro inventors allegedly "taught a separate cone-beam reconstruction computer." CX-3879C (Mutic RWS) at Q63. However, claim 4 does not require a separate computer for reconstruction and another for system control. Instead, claim 4 refers to the same "computing unit" as recited in claim 1, which is the only computing unit recited by the claim. *See* Mutic Tr. 991. Indeed, other dependent claims recite functions in addition to volumetric reconstruction that are performed by the same "computing unit." For example, claim 3 recites that "the computing unit generates a treatment plan based on the image data." JX-0001 ('021 Patent) at col. 9, lns. 10-11. Varian's expert admitted that *Jaffray WIPO* discloses the functionality of claim 4 performed by a single computer. *See* Mutic Tr. 994.

- **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 WIPO discloses this undisputed limitation: "The system 400 may be retrofitted onto an existing or new radiation therapy system 700 that includes a separate

radiation therapy x-ray source, such as a linear source 409, that operates at a power level higher than that of x-ray tube 402 so as to allow for treatment of a target volume in a patient. The linear source 409 generates a beam of x-rays or particles 411, such as photons or electrons, that have an energy ranging from 4 MeV to 25 MeV." RX-0270 (*Jaffray WIPO*) at col. 33, ln. 29 – col. 34, ln. 2. *Jaffray WIPO* "[n]ote[s] that the x-ray sources 402 and 409 may be separate and contained with the same structure or be combined into a single source that can generate x-rays of different energies." *Id.* at col. 34, lns. 6-8; *see also id.* at col. 7, lns. 27-31; RX-0433C (Papanikolaou WS) at Q186-88; Mutic Tr. 985, 988.

* * *

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

b. *Jeffray 2001*

Overview

Dr. Jaffray's work is also memorialized in a printed publication in Medical Imaging titled, "A Volumetric Cone-Beam CT System Based on a 41x41 Cm2 Flat-Panel Imager", published more than one year before the '021 patent was filed. *See* RX-0262 ("*Jaffray 2001*"). *Jaffray 2001* publicizes Dr. Jaffray's work modifying a known type of medical linear accelerator, an Elekta SL-20, to include online image guidance capabilities. RX-0433C (Papanikolaou WS) at Q219; RX-0262 (*Jaffray 2001*) at Abstract; RX-0435C (Brown WS) at Q26. The system that Dr. Jaffray built and tested