

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELEKTA, INC.,
Petitioner,

v.

VARIAN MEDICAL SYSTEMS, INC.,
Patent Owner.

Case IPR2016-00315
Case IPR2016-00380
Patent 8,867,703 B2

Before BRIAN J. McNAMARA, PATRICK M. BOUCHER, and
GARTH D. BAER, *Administrative Patent Judges*.

BOUCHER, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

Elekta Inc. (“Petitioner”) filed four Petitions pursuant to 35 U.S.C. §§ 311–319 to institute *inter partes* reviews challenging claims of U.S. Patent No. 8,867,703 B2 (“the ’703 patent”). IPR2016-00315, Paper 2 (“Pet. 315”); IPR2016-00341, Paper 2; IPR2016-00380, Paper 2 (“Pet. 380”); IPR2016-00551, Paper 2. After consideration of respective

IPR2016-00315
IPR2016-00380
Patent 8,867,703 B2

Preliminary Responses filed by Varian Medical Systems, Inc. (“Patent Owner”), we instituted review in each of the proceedings. IPR2016-00315, Paper 12 (“Dec. 315”); IPR2016-00341, Paper 12; IPR2016-00380, Paper 12 (“Dec. 380”); IPR2016-00551, Paper 12. Two of the proceedings were subsequently terminated after Patent Owner filed respective Motions to Amend, requesting cancellation of all claims instituted in those proceedings. IPR2016-00341, Paper 20; IPR2016-00551, Paper 16. Across the two proceedings in which trial proceeded, review was instituted for claims 1, 2, 4–9, 13, and 18. Dec. 315, 20; Dec. 380, 22. Subsequently, Patent Owner filed a Motion to Amend, requesting cancellation of claims 13 and 18. IPR2016-00380, Paper 18.

During the trials, Patent Owner timely filed a Response in each proceeding. IPR2016-00315, Paper 17 (“PO Resp. 315”); IPR2016-00380, Paper 19 (“PO Resp. 380”). Petitioner timely filed respective Replies to the Patent Owner Responses. IPR2016-00315, Paper 26 (“Pet. Reply 315”); IPR2016-00380, Paper 26 (“Pet. Reply 380”). A consolidated oral hearing was held on April 12, 2017, and a copy of the transcript was entered into the record for each proceeding. IPR2016-00315, Paper 40; IPR2016-00380, Paper 40 (collectively, “Tr.”).

We have jurisdiction under 35 U.S.C. § 6. This Decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of the claims for which trial proceeded. Based on the record before us, Petitioner

has not shown, by a preponderance of the evidence, that claims 1, 2, or 4–9 are unpatentable.¹

I. BACKGROUND

A. The '703 Patent

The '703 patent “pertains in general to therapeutic radiology.” Ex. 1001, col. 1, ll. 17–18. The Specification describes a need for “identifying the precise location of the target volume immediately prior to a dose of therapeutic radiation,” and, to that end, discloses a “multi-mode cone beam computed tomography radiotherapy simulator and treatment machine.” *Id.* at col. 1, ll. 26–28, 54–55.

A portion of Figure 3 of the '703 patent is reproduced below.

¹ There is considerable duplication in the content of documents filed in the two proceedings. In the interest of efficiency and clarity, we cite below to the record of one proceeding, usually IPR2016-00315, where the same argument or evidence has been filed in both proceedings. Unless otherwise indicated explicitly, citation below to a paper or exhibit should be understood to be a citation to the record of IPR2016-00315. The evidence relied upon in this Decision is of record in both proceedings.

B. Illustrative Claim

Challenged claim 1 is illustrative of the claims at issue:

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

Ex. 1001, col. 8, l. 64–col. 9, l. 14.

C. References

Petitioner relies on the following references:

David A. Jaffray, Jeffrey H. Siewerdsen, Burkhard Groh, Douglas G. Drake, John W. Wong, and Alvaro A. Martinez, *Cone-beam computed tomography on a medical linear accelerator using a flat-panel imager*, XIII. ICCR 2000, 558–60 (2000) (Ex. 1005, “Jaffray 2000”);

David A. Jaffray, Douglas G. Drake, Michel Moreau, Alvaro A. Martinez, and John W. Wong, *A Radiographic and Tomographic Imaging System Integrated into a Medical Linear Accelerator for Localization of Bone and Soft-Tissue Targets*, 45 INT. J. RADIATION ONCOLOGY BIOL. PHYS. 773–89 (1999) (Ex. 1007, “Jaffray JRO 1999”);

D.A. Jaffray, J.H. Siewerdsen, and D.G. Drake, *Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager*, 3659 SPIE 204–14 (1999) (Ex. 1008, “Jaffray SPIE 1999”); and

D.A. Jaffray and J.H. Siewerdsen, *Cone-beam computed tomography with a flat-panel imager: Initial performance characterization*, 27 MED. PHYS. 1311–23 (2000) (Ex. 1009, “Jaffray June 2000”).

D. Instituted Grounds of Unpatentability

We instituted trial based on 35 U.S.C. § 103(a) over the following combinations of references. Dec. 315, 20; Dec. 380, 22.

References	Challenged Claims
Jaffray 2000, Jaffray JRO 1999, and Jaffray SPIE 1999	1, 2, 4–9, 13 and 18
Jaffray June 2000 and Jaffray JRO 1999	1, 2, 4–9, 13 and 18

E. Real Parties-in-Interest

Petitioner identifies Elekta Ltd., Elekta AB, and Elekta Holdings U.S., Inc. as real parties-in-interest with Petitioner. Pet. 315, 1.

Patent Owner identifies VMS International AG, VMS Nederland Holdings BV, and VMS Nederland BV as real parties-in-interest with Patent Owner. Paper 5, 2.

F. Related Proceedings

The parties assert that the ’703 patent is involved in proceedings before the International Trade Commission, No. 377-TA-968. Pet. 315, 1; Paper 5, 2.

II. MOTION TO AMEND

In IPR2016-00380, Patent Owner filed a Motion to Amend, requesting cancellation of claims 13 and 18, without proposing any substitute claims. IPR2016-00380, Paper 18. Petitioner did not file an opposition to the Motion. We grant the unopposed Motion, and, accordingly, do not address claims 13 or 18 further herein.

III. ANALYSIS

A. *Claim Construction*

The Board interprets claims of an unexpired patent using the broadest reasonable construction in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). In the Institution Decisions, we made certain preliminary constructions. *See, e.g.*, Dec. 315, 5–10. We consider the claim-construction issues anew in light of the full record developed during the trials. Our reconsidered constructions are consistent with the preliminary constructions.

1. “*treatment source*” and “*cone-beam radiation source*”

Independent claim 1 recites “a treatment source” and “a cone-beam radiation source coupled to the rotatable gantry.” Petitioner argues that, under the broadest reasonable interpretation standard, these terms should be construed “such that the claimed radiation treatment system encompasses

those in which the treatment source and the cone-beam radiation source are the same radiation source and those in which they are separate radiation sources.” Pet. 315, 7–8. Petitioner contends that the Specification of the ’703 patent “discloses an embodiment in which both an MV treatment source and a diagnostic kV cone-beam radiation source are coupled to the rotatable gantry.” *Id.* at 7 (citing Ex. 1001, col. 7, ll. 19–45). Petitioner also contends that, during prosecution, the applicant “argued that claims requiring a ‘high-energy radiation source’ (such as an MV treatment source) and a ‘cone-beam radiation source’ do not ‘require that the cone beam source is necessarily different from the high energy source claimed.’” *Id.* at 7 (citing Ex. 1017 at Elekta_000001041, 1047, 1055). Patent Owner does not dispute the contention.

We are mindful that “[w]here a claim lists elements separately, ‘the clear implication of the claim language’ is that those elements are ‘distinct component[s]’ of the patented invention.” *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010). Nevertheless, the Federal Circuit has recognized that such a presumption can be overcome when the specification suggests that a single component can function as both elements. *See Powell v. The Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231–32 (Fed. Cir. 2011) (claim terms “cutting box” and “dust collection structure” do not require separate structures); *Retractable Techs, Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1303 (Fed. Cir. 2011) (claim terms “needle holder” and “retainer member” do not require separately molded pieces). Petitioner supports its position with sufficient evidence and reasoning.

Accordingly, we construe the “high energy radiation source” and “cone-beam radiation source” recited in claim 1 as encompassing embodiments that have two separate sources, as well as embodiments that have the same source performing two separate functions.

2. “logic”

Petitioner contends that the “first logic” and “second logic” recitations of challenged independent claim 1 should be construed as means-plus-function limitations under 35 U.S.C. § 112 ¶ 6² because “the term ‘logic’ does not connote a sufficiently definite structure for performing the claimed functions.” Pet. 351, 8 (citing Ex. 1021 ¶ 122). Patent Owner agrees that means-plus-function constructions are appropriate for these limitations. See PO Resp. 315, 5 (“second logic” limitation “is a means-plus-function term that is supported by corresponding structure and algorithm in the specification of the ’703 patent”), 7 (“Patent Owner does not dispute Petitioner’s proposed claim construction” for the “first logic” limitation).

Although a claim term that does not include the word “means” is presumed not to invoke a means-plus-function analysis, that presumption may be overcome if the limitation does not “recite sufficiently definite structure” or recites a “function without reciting sufficient structure for performing that function.” *Williamson v. Citrix Online, LLC*, 792 F.3d

² Section 4(c) of the Leahy-Smith America Invents Act (“AIA”) redesignated 35 U.S.C. § 112, ¶ 6, as 35 U.S.C. § 112(f). Pub. L. No. 112-29, 125 Stat. 284, 296 (2011). Because the ’703 patent has a filing date before September 16, 2012 (effective date of § 4(c)), we refer to the pre-AIA version of § 112.

1339, 1349 (Fed. Cir. 2015). Petitioner’s expert, Russell J. Hamilton, Ph.D., testifies that “the term ‘logic’ would not be recognized by one of ordinary skill in the art as providing sufficiently definite structure for performing the claimed functions,” and that “[l]ogic can be implemented in software, in hardware, and in combinations of hardware and software.” Ex. 1021 ¶ 122.

The parties provide sufficient reasoning to overcome the presumption against a means-plus-function construction, and we accordingly construe “first logic” and “second logic” in accordance with 35 U.S.C. § 112 ¶ 6.

a. “first logic”

The function recited for the “first logic” in claim 1 is “reconstruct[ing] a cone-beam computer tomography (CT) volumetric image data based on the image projection data.” Petitioner asserts that “[t]he specification of the ’703 Patent identifies computer software employing a Feldkamp algorithm as the corresponding structure” and that “[t]he specification also states that this function can be carried out by computer hardware components hardwired to carry out this function.” Pet. 315, 9 (citing Ex. 1021 ¶¶ 123–124); *see* Ex. 1001, col. 4, ll. 37–43, col. 4, l. 62–col. 5, l. 10, col. 8, ll. 12–16. As noted above, Patent Owner does not dispute Petitioner’s proposed construction for purposes of these proceedings.

We construe the “first logic” limitation as Petitioner proposes, namely as “computer software and/or computer hardware that uses a Feldkamp-based algorithm to reconstruct cone-beam CT volumetric image data based on the projection data.” *See* Pet. 315, 3.

b. “second logic”

The “second logic” in claim 1 is recited as “configured to control the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data.”³ Petitioner contends that the “second logic” limitation “appears to be indefinite” because “[t]he specification of the ’703 Patent identifies computer software and hardwired computer hardware components to carry out this function but does not disclose an algorithm to perform this function.” Pet. 315, 9–10. To the extent the limitation is not indefinite, Petitioner proposes that “it should be construed to mean computer software and/or computer hardware to control the patient support and to place the patient in an operative position to begin treatment based on the cone-beam CT volumetric image data or the image projection data.” *Id.* at 10.

Patent Owner disagrees that the Specification of the ’703 patent fails to disclose sufficient algorithmic structure, and points to Figure 4 of the patent, reproduced below. PO Resp. 315, 5.

³ The “second logic” limitation appears to have been decisively relevant to the Examiner’s decision to allow the application that matured into the ’703 patent during prosecution. In his statement of reasons for allowance, the Examiner noted that certain elements of independent claim 1 were disclosed in a considered prior-art reference, but asserted that “the prior art fails to disclose or fairly suggest that the radiation treatment system further comprises: a treatment source; and a second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data.” Ex. 1002, 189–190 (paragraphing omitted).

Figure 4

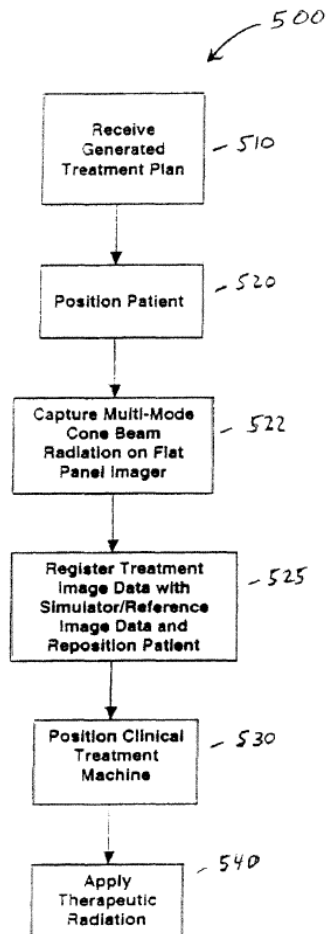


Figure 4 is a flow diagram illustrating “a process flow . . . of a method for implementing a treatment plan.” Ex. 1001, col. 2, ll. 7–8. The Specification includes the following as part of its description of the drawing:

At block 520, a patient 405 is placed on the treatment couch 418 and the couch 418 is positioned relative to the clinical treatment machine 400. At block 522, multi-mode cone beam radiation from the radiation source 404 is captured by the imager 406 to generate images of the target volume. At block 525, the captured image data can be compared/registered with the simulator or other reference images to determine the patient repositioning required, if any, before treatment.

Id. at col. 5, ll. 51–59. In addition, the Specification explains that “[t]he clinical treatment machine 400 may use the kV cone-beam CT image data to

make any necessary adjustments to the treatment plan based on identified movement of the target volume or to determine the amount of patient repositioning required by the treatment couch 418 or collimator movements.” *Id.* at col. 7, ll. 32–37 (emphases added). According to the Specification, such determinations may be performed in the implementation of the method of Figure 4 with “machine-executable instructions (e.g. software)” or “by specific hardware components that contain hardwired logic for performing the operations, or by any combination of programmed computer components and custom hardware components.” *Id.* at col. 8, ll. 7–16. In light of these disclosures, Patent Owner advocates adoption of the preliminary construction of “second logic” applied in the Institution Decision, namely, in accordance with the following function and structure:

Function: to control the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data.

[]Structure: a hardwired logic or a programmable computer component with software for controlling the patient support and plac[ing] the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data as described at 5:33-39, 5:51-59, 7:32-41 (“The clinical treatment machine 400 may use the kV cone-beam CT image data [deleted portion] to determine the amount of patient repositioning required by the treatment couch 418 [deleted portion]. In this way, the kV cone-beam CT radiation source and flat panel imager share a common axis of rotation with the MV cone-beam CT radiation source 404 and provide additional information for aligning the patient to the generated simulation treatment plan.”), 8:7-34, Fig. 4 (520, 525, 530), and structural equivalents thereof.[]

PO Resp. 315, 5 (alterations by Patent Owner).

Petitioner's proposed construction of the "second logic" element is untenable because its broad identification only of "computer software and/or computer hardware" as structure for performing the recited function is too generic. The law regarding construction of means-plus-function limitations as applied to computer-implemented elements is well-established:

For computer-implemented means-plus-function claims where the disclosed structure is a computer programmed to implement an algorithm, "the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." . . . This court permits a patentee to express that algorithm in any understandable terms including as a mathematical formula, in prose, . . . , or as a flow chart, or in any other manner that provides sufficient structure.

Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1340 (Fed. Cir. 2008) (citations omitted). Patent Owner's proposed construction is superior because it identifies the algorithm through explicit reference to the flow chart of Figure 4 and related disclosure in the Specification. Patent Owner's position is supported by testimony of its expert, Sasa Mutic, Ph.D., who refers to those disclosures in opining that "the ['703] patent describes a process of steps for obtaining the result of properly positioning a patient to begin a treatment" and that "Fig. 4 of the ['703] patent provides a flowchart of a process for use of an embodiment of the invention." Ex. 2012 ¶ 69.

Petitioner takes the position that the ultimate scope of the corresponding algorithm "does not matter" because Petitioner contends that the challenged claims are unpatentable even under Patent Owner's proposed construction. Pet. Reply 315, 3. Nevertheless, Petitioner attacks Patent Owner's proposed construction as "implicitly adopt[ing]" two "additional

but unreasonable limitations.” *Id.* First, Petitioner contends that “the claims do not require the performance of the function of the second logic to be fully automated and instead permit human interaction with the second logic.” *Id.* Second, Petitioner contends that blocks 520 (“Position Patient”), 525 (“Register Treatment Image Data with Simulator/Reference Image Data and Reposition Patient”), and 530 (“Position Clinical Treatment Machine”) of Figure 4 “need not be performed in their entirety by logic so long as the second logic is used for some step in each block.” *Id.* at 4. We find no inconsistency in these positions with Patent Owner’s proposed construction.

In light of the foregoing considerations, we adopt Patent Owner’s proposed construction.

B. Estoppel

In IPR2016-00341, Patent Owner filed a motion to amend that requested cancellation of claims 10, 12, 14, 15, 17, 20, and 21 of the ’703 patent, i.e., requested cancellation of all claims challenged in that proceeding. *Elekta Inc. v. Varian Medical Systems, Inc.*, Case IPR2016-00341, Paper 18. In its motion to amend, Patent Owner asserted that it made “its request to simplify the issues in related concurrent proceedings [such as the instant proceedings]” and that “[n]othing in this motion to amend shall be construed to amend or otherwise affect the validity or enforceability of claims which are not the subject of this motion.” *Id.* at 1, 2. Because the motion requested cancellation of all claims in the trial, it was construed as a request for adverse judgment. *Elekta*, IPR2016-00341, Paper 20, 2; *see* 37 C.F.R. § 42.73(b)(2). The motion was granted and judgment entered against

Patent Owner with respect to claims 10, 12, 14, 15, 17, 20, and 21. *Id.*

Petitioner contends that the claims canceled in IPR2016-00341 “were directed to methods that recited the function performed by the second logic,” and that “Patent Owner is now estopped from arguing the subject matter of the same scope is patentable.” Pet. Reply 315, 1. Petitioner cites no authority to support this position, which improperly focuses on only one limitation of the claims, divorced from the claims’ other limitations. We reject Petitioner’s contention because the method claims canceled in IPR2016-00341 do not constitute “subject matter of the same scope” as the apparatus claims challenged in these proceedings.

C. Asserted Grounds of Unpatentability

1. Legal Principles

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter 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.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).⁴

⁴ The parties do not address secondary considerations of nonobviousness, and we therefore do not consider them in our analysis.

Additionally, the obviousness inquiry typically requires an analysis of “whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”)); see *In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016) (citing *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006)).

2. Level of Skill in the Art

Petitioner’s expert, Dr. Hamilton, opines that a person of ordinary skill in the art relevant to the ’703 patent “would be a person with a graduate degree (MS or PhD) in medical physics or a related field (e.g. Physics, Engineering) and three years of experience in radiation oncology beyond the completion date of their degree.” Ex. 1021 ¶ 17. Patent Owner’s expert, Dr. Mutic, expresses a level of ordinary skill that is generally similar to Petitioner’s expert, but accounts for the possibility of a medical education instead of a medical-physics education:

[A] person of ordinary skill in the art . . . 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 in the same relevant fields and two or more years of practical experience with image processing and the use of computer systems that is related to medical applications.

Ex. 2012 ¶ 36.

The similarity in the experts' opinions is reinforced by Dr. Mutic's assertion that he has "considered Dr. Hamilton's definition of the level of ordinary skill in the art and determined that it does not differ from [his] own expressions of this concept in any way that is relevant to the opinions" he expresses in his Declaration. *Id.* ¶ 38. Based on the expert testimony in the record, we agree with and adopt the level of skill expressed by Dr. Hamilton.

3. Scope and Content of the Prior Art

a. Jaffray 2000

Jaffray 2000 describes a cone-beam flat-panel imager on a linear accelerator. Ex. 1005, 558. Figure 3 of Jaffray 2000 is reproduced below.

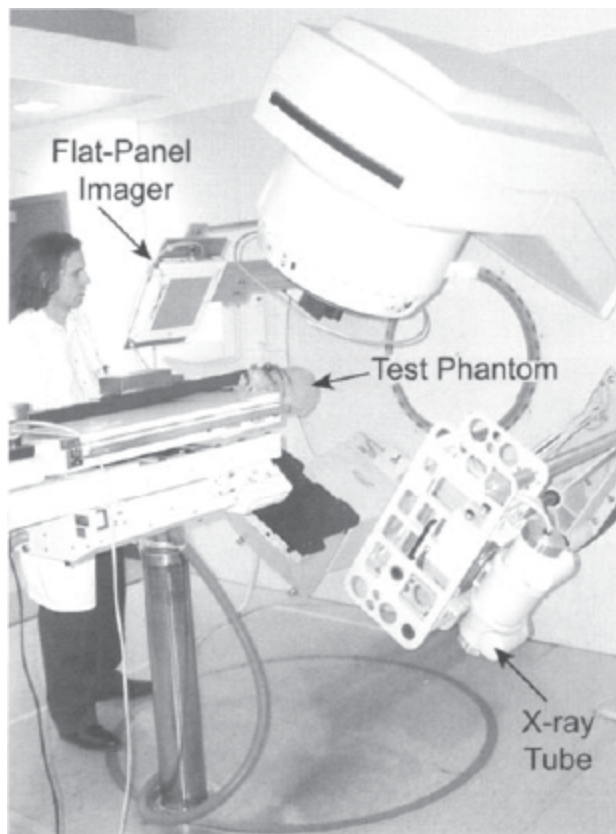


Figure 3 depicts a prototype flat-panel-imager-based cone-beam computed-tomography system on an Elekta SL-20 medical linear accelerator. Ex. 1005, 559. Jaffray 2000 explains that “[a] major roadblock to the full exploitation of radiation’s therapeutic effect is the lack of geometric precision that can be obtained over the fractionated course of therapy.” *Id.* at 558. Accordingly, Jaffray 2000 describes an approach based on cone-beam computed tomography “to acquire on-line volumetric CT images in the reference frame of the machine.” *Id.* As Patent Owner observes, “[t]he disclosures in the paper are focused entirely on the use and performance of the system purely for imaging – not for the delivery of radiation treatment to a patient.” PO Resp. 315, 21.

b. Jaffray JRO 1999

Jaffray JRO 1999 discloses a medical linear accelerator with an integrated kV imaging system. Ex. 1007, 773. Figure 1(b) of Jaffray JRO 1999 is reproduced below.

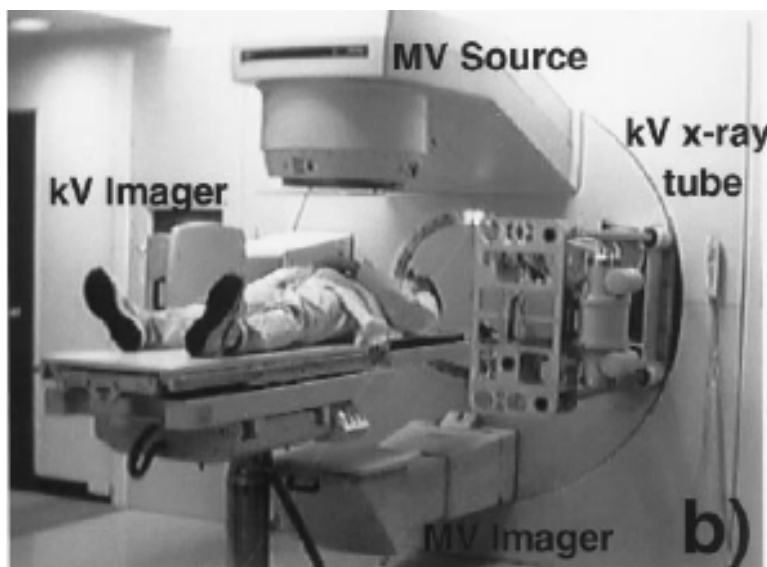


Figure 1(b) depicts a kV x-ray tube and imager integrated into an Elekta SL-20 medical linear accelerator. *Id.* at 775. “A personal computer (Pentium-based) controls the x-ray generator and the acquisition of images and also monitors the gantry angle reported by the accelerator.” *Id.*

c. Jaffray SPIE 1999

Jaffray SPIE 1999 describes details of a cone-beam computed-tomography flat-panel imaging system. *See* Ex. 1008, 205, 205–208. Petitioner characterizes Jaffray SPIE 1999 as “describ[ing] the details of the flat panel imager used in . . . Jaffray 2000.” Pet. 315, 11.

d. Jaffray June 2000

Jaffray June 2000 describes a flat-panel-imager-based cone-beam computed-tomography system for bone and soft-tissue localization. Ex. 1009, 1311. Jaffray June 2000 “propose[s] the construction of a [cone-beam computed tomography system for radiotherapy guidance on a treatment-by-treatment basis using CT data obtained with a kV x-ray source and a large-area, indirect detection flat-panel imager (FPI).” *Id.* at 1312. The paper describes system components, imaging geometry, and methods of image acquisition and reconstruction, so that “[u]ltimately, an imaging system based on this technology will be installed on a conventional radiotherapy linear accelerator.” *Id.*

*e. Image-Guided Radiation Therapy (“IGRT”) with
Verify and Record Systems*

The “second logic” limitation of independent claim 1 is the only limitation disputed by the parties. At oral hearing, Petitioner characterized “what this limitation in dispute is talking about” as “really what we have here is the use of logic or a computer to perform standard Image-Guided Radiation Therapy, or IGRT.” Tr. 6:13–17. Petitioner’s expert, Dr. Hamilton, testifies that IGRT “employs a comparison of target images to accurately position the target at the isocenter prior to and during treatment” and that

[b]y comparing the in-room image of a target tumor just prior to (or even during) treatment with a reference image of the target tumor (*e.g.*, an image of the target tumor acquired in the treatment simulator), the therapeutic radiation dose can be accurately guided to the correct location of the target tumor by adjusting the patient position (or position of the radiation source) until the on-line image and reference images align.

Ex. 1021 ¶¶ 102–103. According to Dr. Hamilton, “[t]his is the defining feature of IGRT.” *Id.* ¶ 103.

In contending that the combinations of references that form the bases for its challenges disclose the “second logic” limitation, Petitioner contends that the Elekta SL-20 system—which is explicitly identified by at least one reference in each combination—“had a computer-implemented ‘verify and record’ system in which in-room images are compared to simulation images and the patient couch is adjusted accordingly to correctly position the target at the isocenter prior to exposure to therapeutic radiation.” See Pet. 315, 27 (citing Ex. 1005, 559; Ex. 1015, 220–221; Ex. 1010, 1, 39–48; Ex. 1021

¶¶ 217–221). According to Petitioner, “[i]t was also standard for computer systems (verify and record systems) to exchange data via a communications network with linear accelerators to monitor and record the patient support and gantry positions to ensure that their positions matched the treatment plan by interlocking (preventing) radiation beam delivery if they did not match.” *Id.* at 28 (citing Ex. 1010, 39–48; Ex. 1021 ¶¶ 88, 244–259).

This characterization of verify and record systems is refuted by Patent Owner’s expert, Dr. Mutic, who explains that such a system “was an accessory feature used in connection with SL-series linear accelerators sold by Philips (and later by Elekta).” Ex. 2012 ¶ 118. According to Dr. Mutic, the verify and record system “performed the function of using a computer to take certain machine parameters (things like gantry angle, table location, beam intensity, collimator position, etc.) that had been pre-set as part of the treatment plan, and compare those with the settings that were present when the technician was prepared to begin a treatment.” *Id.* The system would detect whether the technician had made an error in setting one of those machine parameters and lock the system from use or otherwise alert the technician of the fault. *Id.* Dr. Mutic emphasizes that “the ‘verify and record’ system was fundamentally a system for reducing safety accidents caused by technician errors. It was not an imaging system for use in the treatment room.” *Id.*

We have reviewed Petitioner’s evidence regarding the functionality of verify and record systems, and agree with Dr. Mutic’s characterizations. First, Petitioner relies on Exhibit 1010, C.J. Karzmark and Robert J. Morton, *A Primer on Theory and Operation of Linear Accelerators in Radiation*

Therapy (U.S. Dept. of Health and Human Services 1981) (“Karzmark”).
See Pet. 315, 14–15, 27–28, 47–48. This exhibit provides a general overview of radiotherapy around 1981, including a description of the SL-20 accelerator and the verify and record system associated with that accelerator. Karzmark generically describes the verify and record systems as follows:

Before the treatment begins, however, an internal check system is automatically activated which sequentially verifies linac operating parameters for correct values. Included in many units is a method for testing the dosimetry system used to ensure that the prescribed dose will be delivered. The treatment unit may also include a computer-based RECORD AND VERIFY PROGRAM, which compares the treatment that has been set up with a record of the intended treatment (Fig. 4). *This treatment prescription may include field size and collimator angulation, gantry angle, couch position, the daily dose for that field, and the preset monitor readings to provide the dose.* Such record and verify programs identify setup errors prior to treatment so that they can be corrected when they exceed a preset magnitude; for example, more than one degree or arc. Such programs verify and record each treated field on a continuing, daily basis throughout the course of treatment.

Ex. 1010, 37 (emphasis added). This description is consistent with Karzmark’s description of record and verify systems for Philips accelerators. *Id.* at 43 (“All parameters are verified before a treatment can commence (individual tolerance levels can be prescribed) and all treatment data are printed out automatically on a patient card.”). We also find this description consistent with Dr. Mutic’s characterization of such systems as not necessarily involving any in-room images of the patient. See Ex. 2012 ¶ 119.

Second, Petitioner relies on Exhibit 1015, R. Anderson, *Software system for automatic parameter logging on Philips SL20 linear accelerator*, 33 Med. & Biol. Eng. & Comput. 220 (March 1995). See Pet. 315, 14–15, 27–28, 47–48. Although Petitioner cites this exhibit with its assertions regarding verify and record systems, we discern insufficient unambiguous discussion in the reference to support those assertions, and agree with Dr. Mutic’s observation that Petitioner’s expert, Dr. Hamilton, “did not cite Ex. 1015 for any possible disclosure of the second logic limitation, instead he cited only to Ex. 1010 and Ex. 1015 only in the context of discussing the fact that an SL-20 had a patient couch, the position of which could be moved by a technician using a computer.” Ex. 2012 ¶ 130.

We recognize that, under cross-examination, Dr. Hamilton testified that “[r]ecord and verify systems in 2002 provided mechanisms to include in-room imaging” and that “[p]eople using the record and verify system used them to confirm field placement and patient positioning.” Ex. 2014, 70:8–71:19. We accord this testimony little weight in our analysis. First, Dr. Hamilton acknowledged that his original Declaration did not cite to any document or exhibit “specifically to the point that . . . as of 2002 record and verify systems were available that could compare an in-room image to a pretreatment image.” *Id.* at 77:17–21. Second, and more significant, Dr. Hamilton’s testimony on this point is equivocal and insufficient to support a conclusion that the SL-20 accelerator inherently included a mechanism for image comparison. See, e.g., *id.* at 71:16–72:5 (repeated explanations of what the SL-20 accelerator “could” have included); *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (inherency established by making clear that

missing descriptive matter is “necessarily present” in the thing described in the reference).

*4. Obviousness over Jaffray 2000,
Jaffray JRO 1999, and Jaffray SPIE 1999*

Petitioner’s challenges of claims 1, 2, and 4–9 as unpatentable under 35 U.S.C. § 103(a) over Jaffray 2000, Jaffray JRO 1999, and Jaffray SPIE 1999 rely on arguments presented as part of Petitioner’s challenge of those claims as anticipated by Jaffray 2000, a ground upon which we did not institute review. *See* Pet. 315, 42–43; Pet. 380, 43–44. In particular, rather than rely on incorporation by reference of Jaffray JRO 1999 and Jaffray SPIE 1999 into Jaffray 2000 as in its original anticipation challenge, Petitioner’s arguments addressing the instituted ground contend that “it would have been obvious to one of ordinary skill in the art to combine Jaffray 2000 with Jaffray JRO 1999 and Jaffray SPIE 1999.” Pet. 315, 42–43; Pet. 380, 43.

Petitioner contends that “Jaffray 2000 directly provides a motivation to combine teachings of his articles by stating that details of the flat-panel imaging system are described in reference 2, which is Jaffray SPIE 1999, and by teaching that he is transferring that imager to the Elekta SL20 linear accelerator system used in prior work with a CCD imager described in reference 1, which is Jaffray JRO 1999.” Pet. 315, 43 (citing Ex. 1005, 558; Ex. 1021 ¶ 260); *see* Pet. 380, 43 (similar contention). Patent Owner does not contest, in its Responses, that one of skill in the art would combine the

teachings of the references, and we find that Petitioner articulates sufficient reason to do so.

Nevertheless, we agree with Patent Owner that Petitioner has not demonstrated, by a preponderance of the evidence, that the combination of the references discloses or suggests the “second logic” limitation recited in independent claim 1. In addressing the “second logic” limitation, the Petition provides the following argument:

Regarding a second logic, Jaffray 2000 discloses performing IGRT using an SL20 linear accelerator, which had a computer-implemented “verify and record” system in which in-room images are compared to simulation images and the patient couch is adjusted accordingly to correctly position the target at the isocenter prior to exposure to therapeutic radiation.

Pet. 315, 27 (citing Ex. 1005, 559; Ex. 1015, 220–221; Ex. 1011, 1, 39–48, Ex. 1021 ¶¶ 217–221). In addition, a claim chart provided in the Petition reproduces: (1) a portion of Jaffray 2000 that describes integration of a kV imaging system onto a medical linear accelerator; (2) portions of Jaffray JRO 1999 that describe controlling image acquisition, as well as controlling the x-ray generator and monitoring the gantry angle, by a personal computer; and (3) portions of Jaffray SPIE 1999 that describe an aspiration to use an imager for acquisition of soft-tissue localization of tissue structures in a clinical setting. *Id.* at 34–36 (citing Ex. 1005, 558, 559; Ex. 1007, 775–776; Ex. 1008, 213–214).

These identifications and argument are insufficient to carry Petitioner’s burden because they do not disclose the use of hardwired logic or a programmable computer component with software for controlling the patient support and placing the patient in an operative position to begin a

treatment based on cone-beam CT image data, consistent with the construction we adopt herein. Moreover, Petitioner does not identify in the references an algorithmic part of the structure that performs image registration (corresponding to block 525 of Figure 4 of the '703 patent Specification). Petitioner's reliance on a "verify and record" system as an inherent component of the SL-20 accelerator disclosed in the references is insufficient for the reasons expressed above, namely that Petitioner provides insufficient evidence that such a system was indeed inherent.

In reply, Petitioner contends that "[b]lock 525 [of Figure 4 of the '703 patent] requires nothing more than a computer for image registration in communication with a computer-controlled treatment table, as both parties' experts agree," and that "the Petition shows that the computerized verify and record system of the SL-20 was used for communicating the image registration information from the [cone-beam computed-tomography flat-panel imager] system to the computer-controlled treatment couch." Pet. Reply 315, 20 (citing Ex. 1028, 104:21–111:5; Ex. 1038 ¶ 88; Pet. 315, 27–28). This contention is not persuasive, at least because Petitioner insufficiently identifies disclosure of the verify and record system in the references that form the basis for its challenge. In particular, Petitioner insufficiently demonstrates that the verify and record system was inherent. As a result, Petitioner's challenge fails to identify explicit or implicit disclosure of the "second logic" limitation among the references on which it relies.

More generally, Petitioner provides considerably more extensive argument regarding the "second logic" limitation in its Replies, at a level

that goes beyond merely responding to Patent Owner's arguments and at a level that sets forth an initial case of reasoning for finding the "second logic" limitation in the combination of references. In doing so, Petitioner relies on exhibits, such as Exhibits 1016 and 1018, to support its contention that image-guided radiation therapy and software tools for quantitative evaluation of patient set-up were well-known at the time of the '703 patent. Pet. Reply 315, 13–15. Although these exhibits were submitted with the Petition in each proceeding, they were not discussed at all in the respective Petitions. *See generally* Pet. 315, Pet. 380. Petitioner also relies on a new Declaration by Dr. Hamilton that similarly presents opinions that go beyond merely addressing Patent Owner's arguments regarding deficiencies in the original Petitions. *See generally* Ex. 1038.

Petitioner uses these materials fundamentally to reformulate its arguments regarding the "second logic" limitation. *See* Tr. 52:22–53:8 ("[W]e are prepared to meet the arguments that Petitioner made in reply, and I will do that, but it is important to note that we started off with a very specific rationale for institution about verify and record and about the supposedly inherent characteristics of the system. And in reply basically the papers got thrown up in the air and were shuffled and brought back down to us, and now we hear about generic meaning of IGRT and new computer systems." (statement by counsel for Patent Owner)). Although we have considered the portions of the Replies that are responsive to Patent Owner's rebuttal of the Petition's original argument, we have otherwise limited our consideration of the Replies. "It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition

identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim.’ *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (quoting 35 U.S.C. § 312(a)(3)).

We conclude that Petitioner has not demonstrated, by a preponderance of the evidence, that claims 1, 2, or 4–9 are unpatentable under 35 U.S.C. § 103(a) over Jaffray 2000, Jaffray JRO 1999, and Jaffray SPIE 1999.

5. Obviousness over Jaffray June 2000 and Jaffray JRO 1999

Petitioner’s challenges of claims 1, 2, and 4–9 as unpatentable under 35 U.S.C. § 103(a) over Jaffray June 2000 and Jaffray JRO 1999 present an argument regarding the “second logic” limitation that parallels the argument made in the challenges discussed above. Specifically, the Petition provides the following argument:

Regarding a second logic, Jaffray June 2000 discloses performing IGRT using an SL20 linear accelerator, which had a computer-implemented “verify and record” system in which in-room images are compared to simulation images and the patient couch is adjusted accordingly to correctly position the target at the isocenter prior to exposure to therapeutic radiation.

Pet. 315, 47 (citing Ex. 1007, 773, 779; Ex. 1015, 220–221; Ex. 1010, 1, 39–48; Ex. 1021 ¶¶ 303–305). A claim chart provided in the Petition reproduces the cited passages. *Id.* at 55–56.

These identifications and argument are also insufficient to carry Petitioner’s burden because they do not disclose the use of hardwired logic or a programmable computer component with software for controlling the patient support and placing the patient in an operative position to begin a

treatment based on cone-beam CT image data, consistent with the construction we adopt herein. Moreover, Petitioner does not identify in the references an algorithmic part of the structure that performs image registration (corresponding to block 525 of Figure 4 of the '703 patent Specification). Petitioner's reliance on a "verify and record" system as an inherent component of the SL-20 accelerator disclosed in the references is insufficient for the reasons expressed above, namely that Petitioner provides insufficient evidence that such a system was indeed inherent.

Petitioner reiterates its Reply arguments for the ground discussed above in replying to this ground also. *See* Pet. Reply 315, 24–25 ("Those arguments are therefore equally applicable to this ground."). For the same reasons discussed above, those arguments are not persuasive.

Accordingly, we conclude that Petitioner has not demonstrated, by a preponderance of the evidence, that claims 1, 2, or 4–9 are unpatentable under 35 U.S.C. § 103(a) Jaffray June 2000 and Jaffray JRO 1999.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, based on a preponderance of the evidence, claims 1, 2, and 4–9 of U.S. Patent No. 8,867,703 B2 have not been shown to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Amend in IPR2016-00380 is *granted* and that claims 13 and 18 of U.S. Patent No. 8,867,703 B2 shall be *canceled*; and

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FURTHER ORDERED that, because this is a final written decision, parties to this proceeding seeking judicial review of our decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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