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Paper 69
Entered May 4, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VARIAN MEDICAL SYSTEMS, INC.,
Petitioner,

v.

WILLIAM BEAUMONT HOSPITAL,
Patent Owner.

Case IPR2016-00170
Patent 7,471,765 B2

Before MICHAEL W. KIM, KALYAN K. DESHPANDE, and
MATTHEW R. CLEMENTS, *Administrative Patent Judges*.

DESH PANDE, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Inter Partes Review
35 U.S.C. § 318(a); 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Varian Medical Systems, Inc. (“Petitioner”) filed a Petition to institute an *inter partes* review of claims 1–13 and 20–31 of U.S. Patent No. 7,471,765 B2 (Ex. 1101, “the ’765 patent”). Paper 1 (“Pet.”). William Beaumont Hospital (“Patent Owner”) filed a Preliminary Response. Paper 11 (“Prelim. Resp.”).

Pursuant to 35 U.S.C. § 314, we instituted *inter partes* review of the ’765 patent, on May 5, 2016, under 35 U.S.C. § 103(a), as to claims 1–13 and 20–31 on the basis that these claims would have been obvious over Cho,¹ Antonuk,² Jaffray 1997,³ Adler,⁴ and Depp.⁵ Paper 14 (“Dec.”).

Patent Owner filed a Response (Paper 26, “PO Resp.”), and Petitioner filed a Reply (Paper 42, “Pet. Reply”). A consolidated oral hearing was held on January 31, 2017, and the hearing transcript has been entered in the record. Paper 66 (“Tr.”). Patent Owner also filed a Motion to Exclude

¹ P.S. Cho et al., *Cone-beam CT for radiotherapy applications*, Phys. Med. Biol., 40:1863-83 (1995) (Ex. 1105, “Cho”).

² L.E. Antonuk et al., *Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging*, IEEE Transactions on Medical Imaging, 13:482-90 (1994) (Ex. 1106, “Antonuk”).

³ D.A. Jaffray et al., *Exploring “Target Of The Day” Strategies for A Medical Linear Accelerator With Conebeam-CT Scanning Capability*, Proceedings of the 12th International Conference on the Use of Computers in Radiation Therapy, Medical Physics Publishing, pp. 172-75 (1997) (Ex. 1107, “Jaffray 1997”).

⁴ U.S. Patent No. 5,207,223, issued May 4, 1993 (Ex. 1103).

⁵ U.S. Patent No. 5,427,097, issued June 27, 1995 (Ex. 1104).

(Paper 49, “PO Mot.”), to which Petitioner filed an Opposition (Paper 55, “Pet. Opp.”) and Patent Owner filed a Reply (Paper 59, “PO Reply”).

After the oral hearing, we authorized additional briefing on the proper claim construction of the phrase “wherein said computer receives said image of said object and based on said image sends a signal to said radiation source that controls said path of said radiation source,” as recited by independent claim 1 of U.S. Patent 6,842,502 B2, and as similarly recited by independent claims 1, 7, 20, and 26. Paper 65. Patent Owner filed a Response (Paper 67) and Petitioner filed a Response (Paper 68).

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Pursuant to our jurisdiction under 35 U.S.C. § 6, we conclude, for the reasons discussed below, Petitioner has not shown by a preponderance of the evidence that claims 1–13 and 20–31 of the ’765 patent are unpatentable under 35 U.S.C. § 103(a).

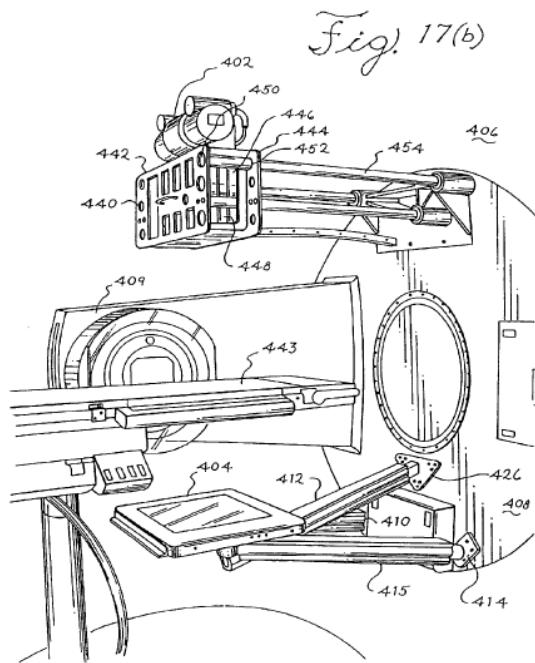
B. Related Proceedings

The parties indicate that the ’765 patent is involved in the following district court case: *Elekta Ltd. and William Beaumont Hosp. v. Varian Med. Sys., Inc.*, Case No. 2:15-cv-12169-AC-MKM (E.D. Mich.). Pet. 1; Paper 4, 2. Petitioner and Patent Owner identify further the following *inter partes* reviews that also involve the ’765 patent: IPR2016-00169 and IPR2016-00171. Pet. 1; Paper 4, 1. Patent Owner identifies further the following *inter partes* reviews directed to U.S. Patent 6,842,502 B2 (“the ’502 patent”), which the ’765 patent claims priority to: IPR2016-00160, IPR2016-00162, IPR2016-00163, and IPR2016-00166. Paper 4, 2. Patent Owner identifies further the following *inter partes* reviews directed to U.S.

Patent 7,826,592 B2, which claims priority to the '765 patent: IPR2016-00187. *Id.*

C. The '765 Patent

The '765 patent discloses that it is directed to a cone-beam computed tomography system that employs an amorphous silicon flat-panel imager for use in radiotherapy applications where images of a patient are acquired with the patient in a treatment position on a treatment table. Ex. 1101, 1:16–21. Figure 17(b) (below) depicts a diagrammatic view of one orientation of an exemplary wall-mounted cone beam computerized tomography system employing a flat-panel imager. *Id.* at 6:48–52.



Specifically, Figure 17(b) above shows wall-mounted cone beam computerized tomography system 400 including an x-ray source, such as x-ray tube 402, and flat-panel imager 404 mounted on gantry 406. *Id.* at 19:41–43. X-ray tube 402 generates beam of x-rays 407 in a form of a cone

or pyramid. *Id.* at 19:43–46. Flat-panel imager 404 employs amorphous silicon detectors. *Id.* at 19:46–47.

D. Illustrative Claim

Petitioner challenges claims 1–13 and 20–31 of the '765 patent. Pet. 14–59. Claim 1 is illustrative of the claims at issue and is reproduced below:

1. A radiation therapy system comprising:
 - a radiation source that moves about an object and directs a beam of radiation towards said object;
 - a cone-beam computed tomography system comprising:
 - an x-ray source that moves about said object and emits toward said object from multiple positions around said object x-ray beams in a cone-beam form;
 - a flat-panel imager positioned to receive x-rays after at least a portion of said x-ray beams pass through said object, said imager providing an image that contains three-dimensional information concerning said object based on a plurality of two-dimensional projection images; and
 - a computer coupled to said cone-beam computed tomography system, wherein said computer receives said three-dimensional information and based on said three dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object, wherein said receiving said x-rays by said flat panel imager is performed substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.

Ex. 1001, 28:2–24.

E. Instituted Ground of Unpatentability

We instituted *inter partes* review of claims 1–13 and 20–31 of the '765 patent under 35 U.S.C. § 103(a) as obvious over a combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp. Dec. 23.

II. ANALYSIS

A. *Claim Construction*

We interpret claims of an unexpired patent using the broadest reasonable interpretation in light of the specification of the patent in which they appear. *See 37 C.F.R. § 42.100(b); see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard as the claim construction standard to be applied in an *inter partes* review proceeding). Under the broadest reasonable interpretation standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art, in the context of the entire disclosure. *In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”).

In our Decision on Institution, we were not persuaded that the terms “computer” (claim 1), “controller” (claim 7), “structure” (claim 20), and “support table” (claim 26) fail to recite sufficiently definite structure, and, therefore, we declined to construe these terms as means-plus-function limitations in accordance with 35 U.S.C. § 112 ¶ 6. Dec. 10–12. Neither Patent Owner nor Petitioner provide any more argument or evidence to disturb our interpretation of these terms. *See* PO Resp. 12. Accordingly, we do not construe these terms as means-plus-function limitations under 35 U.S.C. § 112 ¶ 6. *See SAS Institute, Inc. v. ComplementSoft, LLC.*, 825 F.3d 1341, 1351 (Fed. Cir. 2016) (The Board may not change a claim

interpretation from the institution decision where neither party anticipated that “already-interpreted terms were actually moving targets.”).

Patent Owner offers constructions for the terms “radiation therapy system,” “cone-beam tomography system,” and “an image that contains three-dimensional information concerning said object based on a plurality of two-dimensional projection images.” PO Resp. 12–17. In addition, after oral argument, we authorized briefing on the construction of “wherein said computer receives said image of said object and based on said image sends a signal to said radiation source that controls said path of said radiation source,” as recited by independent claim 1 of the ’502 patent, and as similarly recited by independent claims 1, 7, 20, and 26. Paper 65. Both parties submitted briefing. Papers 67, 68.

For purposes of this Decision, we determine that it is necessary to construe only (1) “substantially at a time;” (2) the claim phrase containing “three-dimensional information;” and (3) “wherein said computer receives said three-dimensional information and based on said three dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object.”

1. “substantially at a time”

In our Decision on Institution, we construed “substantially at a time” to mean “substantially at the same time,” where the “receiving” of the x-rays is substantially at the same time of the “controlling” of the radiation path. Dec. 7–9. Neither Patent Owner nor Petitioner provides any more argument or evidence to disturb our construction of this term. *See* PO Resp. 12. Accordingly, after considering our initial construction anew in light of

Patent Owner’s assertions, we construe “substantially at a time” to mean “substantially at the same time,” where the “receiving” of the x-rays is substantially at the same time of the “controlling” of the radiation path.

2. *“an image that contains three-dimensional information concerning said object based on a plurality of two-dimensional projection images”*

Independent claim 1 recites “an image that contains three-dimensional information concerning said object based on a plurality of two-dimensional projection images.” Independent claims 7, 20, and 26 recite substantially similar limitations. Petitioner asserts that “three-dimensional information” should be construed as “information concerning three dimensions of an object (such as length, width, and depth).” Pet. 17 (citing Ex. 1101, 3:41–44; Ex. 1102 ¶ 39); Pet. Reply 1–4 (citing Exs. 1500 ¶¶ 9–23;⁶ 1502, 78:22–80:16, 83:14–87:11, 135:10–136:11).⁷ Patent Owner asserts that the aforementioned claim limitation, in its entirety, should be construed as “a volumetric image of an object generated by reconstructing 2-D projection images.” PO Resp. 14–17 (citing Ex. 1101, 1:40–50, 2:44–56, 3:41–56, 5:5–9, 16:24–28, 16:39–42; Ex. 2080 ¶¶ 84–89). We agree with Petitioner.

We begin first with the claim language, and note that “three-dimensional information” appears facially to be co-extensive with any information relevant to three-dimensions. We discern that “length, width,

⁶ In evaluating the assertions set forth in the Declaration of James Balter Ph.D. in Support of Petitioner’ Reply (Ex. 1500), we considered Patent Owner’s Motion for Observations on the Cross-Examination of Dr. James Balter (Paper 48) and Petitioner’s Response to Patent Owner’s Motion for Observations on Cross-Examination (Paper 56).

⁷ In the Decision on Institution, we preliminarily agreed with Petitioner’s proposed construction of “three-dimensional information.” Dec. 9–10.

and depth” are just such information. We have considered Patent Owner’s above-cited portions of the ’765 patent, but are unpersuaded that those portions narrow “three-dimensional information” with sufficient “reasonable clarity, deliberateness, and precision” such that one of ordinary skill would have understood “three-dimensional information” as co-extensive with Patent Owner’s proffered construction. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). For example, column 2, lines 44–56 certainly disclose that “volume” is desirable, but does not provide any equivalence between “three-dimensional information” and “volume.” Indeed, column 2, lines 55–56 disclose “provide information regarding the location of soft-tissue target volumes,” indicating that “information” is a subset of “volume.” In another example, column 3, lines 41–56, mentions “three-dimensional (3-D) images,” which we agree would appear to require “volumetric data;” however, the claim limitation at issue is the broader term “three-dimensional information.” In a further example, column 9, line 54–64, clearly refers to “volumetric data,” but does not indicate its relation to “three-dimensional information.” In yet another example, column 16, lines 23–25 and 38–42, do not recite “three-dimensional information,” instead disclosing “3-D structure” and “3-D nature” in relation generally to “volumetric data,” but, again, not in a manner sufficient to indicate a particular relationship.

Finally, in regards to assertions set forth in the Declaration of Dr. Hashemi, we discern some merit in his assertion that when reading the claim limitation “three-dimensional information” in conjunction with another claim limitation “cone-beam computed tomography,” “a CBCT image is a volumetric image that provides the location, shape, and spatial orientation of the target volume in all directions, not just its length, width,

and depth.” Ex. 2080 ¶ 85. Furthermore, the claim limitation does not preclude an image having *more* information than “three-dimensional information concerning said object” (such as length, width, and depth), “based on a plurality of two-dimensional projection images.” Under Patent Owner’s construction, however, the image would be *required* to have such information. We are unpersuaded that such information is required under a proper construction of “three-dimensional information” for the reasons set forth *supra*.

We construe “three-dimensional information” as “information concerning three dimensions of an object (such as length, width, and depth).”

3. *“wherein said computer receives said three-dimensional information and based on said three dimensional information received controls a path of said beam of radiation through said object”*

Independent claim 1 recites “wherein said computer receives said three-dimensional information and based on said three-dimensional information received controls a path of said beam of radiation through said object.” Independent claims 7, 20 and 26 recite substantially similar limitations.⁸

⁸ Patent Owner asserts that the limitation “wherein said computer receives said three-dimensional information and based on said three dimensional information received controls a path of said beam of radiation through said object” (hereinafter “controls a path”) is unique to independent claim 1, and “is not found in any other claims in this proceeding.” Paper 67, 1 n.1. We do not agree with Patent Owner. As an initial matter, dependent claims 2–6 incorporate this limitation by dependence on independent claim 1. Furthermore, independent claim 7 recites “a controller to control a path of said radiation through said object,” independent claim 20 recites “said radiation therapy system has a structure for controlling a path of said beam

Petitioner asserts that “[a person of ordinary skill in the art] would understand this claim language to encompass both a computer system operated by a user and a system that autonomously carries out the recited control function.” Paper 68, 1. Patent Owner agrees that “based on the intrinsic evidence and basic principles of claim construction, the relevant limitation of claim 1 of the ’765 patent should be construed to encompass a computer configured to permit human operation to perform the recited control function.” Paper 67, 5.

Both parties agree that this construction is supported by both the intrinsic evidence and the extrinsic evidence. Paper 68, 1–5 (citing Ex. 1101, Abstract, 4:56–61, claims 1, 7, 13, 20, 26, 31);⁹ Paper 67, 1–5 (citing Ex. 1001, 26:12–27, claim 1; Ex. 1112, 125–126; Paper 66, 44:22–45:13; Ex. 2084, WBH_Elekta_02082, WBH_Elekta_02116, WBH_Elekta_02169).

We agree. We, therefore, construe “wherein said computer receives said image of said object and based on said image sends a signal to said

of radiation through said object,” and independent claim 26 recites “said support table controls a path of said beam of radiation through said object.” As neither party has explained, and we are unable to discern independently, any substantive differences between the aforementioned limitations, we determine that all of these limitations are substantially similar to the “controls a path” limitation of independent claim 1. Dependent claims 8–13, 21–25, and 27–31 incorporate these limitations from independent claims 7, 20, and 26 respectively. Accordingly, we determine that all of the remaining challenged claims, claims 2–13 and 20–31, recite substantially similar limitations to the “controls a path” limitation of independent claim 1.

⁹ Petitioner further cites to papers and exhibits filed in IPR2016-00169. Paper 68 (citing IPR2016-00169: Ex. 1500 ¶¶ 36–38; Ex. 1502, 120:14–121:11; Ex. 2080 ¶¶ 61–65, 108, 109, 126–130).

radiation source that controls said path of said radiation source” to encompass a person or user operating the computer to perform the recited control functions. As discussed above, independent claims 7, 20, and 26 recite similar limitations, and, therefore, we interpret these limitations to similarly encompass a person or user operating the computer to perform the recited control functions.

B. Level of Ordinary Skill in the Art

“Section 103(a) forbids issuance of a patent when ‘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.’” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

Dr. Balter, Petitioner’s expert, proffers that a hypothetical person of ordinary skill in the art, with respect to and at the time of the ’765 Patent, would have the following qualifications: “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.” Ex. 1102 ¶ 13. Dr. Hashemi, Patent Owner’s expert, essentially agrees, with the only major differences to the above being that an M.S. is acceptable in lieu of a Ph.D., and that three years of experience is preferred. Ex. 2080 ¶ 17. Nominally, we accept Petitioner’s proffered level of ordinary skill in the art based on Dr. Balter more complete explanation. We note, however, that neither party has explained substantively any significance that the difference in the proffered levels of ordinary skill in the

art would have in the obviousness analysis. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (“[T]he level of skill in the art is a prism or lens through which a judge, jury, or the Board views the prior art and the claimed invention.”); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991) (“The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry.”). To that end, we note that the prior art itself often reflects an appropriate skill level. *See Okajima*, 261 F.3d at 1355.

C. *The Parties’ Post-Institution Arguments*

In our Decision on Institution, we concluded that the arguments and evidence advanced by Petitioner demonstrated a reasonable likelihood that claims 1–13 and 20–31 were unpatentable as obvious based on Cho, Antonuk, Jaffray 1997, Adler, and Depp. Dec. 23. We must now determine whether Petitioner has established by a preponderance of the evidence that the specified claims are unpatentable over the cited prior art. 35 U.S.C. § 316(e). We previously instructed Patent Owner that “any arguments for patentability not raised in the [Patent Owner Response] will be deemed waived.” Paper 15, 3; *see also* 37 C.F.R. § 42.23(a) (“Any material fact not specifically denied may be considered admitted.”). Additionally, the Board’s Trial Practice Guide states that the Patent Owner Response “should identify all the involved claims that are believed to be patentable and state the basis for that belief.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012).

In connection with the arguments and evidence advanced by Petitioner to support its positions that Patent Owner chose not to address in

its Patent Owner Response, the record now contains persuasive, unrebutted arguments and evidence presented by Petitioner regarding the manner in which the asserted prior art teaches corresponding elements of the claims against which that prior art is asserted. Based on the preponderance of the evidence before us, we conclude that the prior art identified by Petitioner describes all other limitations of the reviewed claims, except for those that Patent Owner contested in the Patent Owner Response, which we address below.

D. Claims 1–13 and 20–31 as Unpatentable over Cho, Antonuk, Jaffray 1997, Adler, and Depp

Petitioner asserts that a combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp renders obvious claims 1–13 and 20–31. Pet. 31–59. Patent Owner disagrees. PO Resp. 17–62. Petitioner replies. Pet. Reply 5–24. Claims 1, 7, 20, and 26 are the independent claims for this ground.

1. Cho (Ex. 1105)

Cho describes a cone-beam CT system for radiotherapy applications, and algorithm used therein to permit an increased reconstruction volume to be imaged using a detector of a given size. Ex. 1105, Abstract. The system described in Cho is a digital spot imager (*id.* at 6), but Cho also describes the use of a flat panel detector for real-time diagnostic X-ray imaging. Ex. 1105, 24 (citing Antonuk). Cho describes generating a 3-D image “by rotating the gantry over 360° at approximately 1° increments.” Ex. 1105, 9, 15–17.

2. Antonuk (Ex. 1106)

Antonuk describes “Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging.” Ex. 1106, Title. Specifically, Antonuk describes how “[t]he recent development of large-area, flat-panel a-

Si:H imaging arrays is generally expected to lead to real-time diagnostic and megavoltage x-ray projection imagers with film-cassette-like profiles.” Ex. 1106, Abstract. According to Antonuk, “[t]he construction, operation, and properties of the arrays have been extensively reported.” Ex. 1106, 3. “It is widely perceived that part of the solution is to obtain imaging information with the portal beam immediately prior to and/or during the treatment.” Ex. 1106, 5. “Toward this aim of patient verification, a variety of real-time megavoltage imaging devices, including our a-Si:H imager, have been developed over the last decade.” Ex. 1106, 5. “This composite imager would be positioned behind the patient in the middle of the megavoltage radiation field during imaging.” Ex. 1106, 6, Fig. 5. In an alternative configuration, “[s]everal a-Si:H x-ray detectors rotate with an x-ray tube collecting conebeam projection data inside the bore of a PET machine.” Ex. 1106, 8.

3. Jaffray 1997 (Ex. 1107)

Jaffray 1997 describes “a conebeam-computed tomography (CB-CT) scanner for installation on our medical linear accelerator.” Ex. 1107, 4.¹⁰ A schematic of the dual-beam imaging system is shown in Figure 1 of Jaffray 1997, which is reproduced below.

¹⁰ Many Exhibits, such as Exhibit 1107, include two page numbers: the original page number from the source material itself, and the page numbers added by the parties. For consistency, we use the page numbers added by the parties.

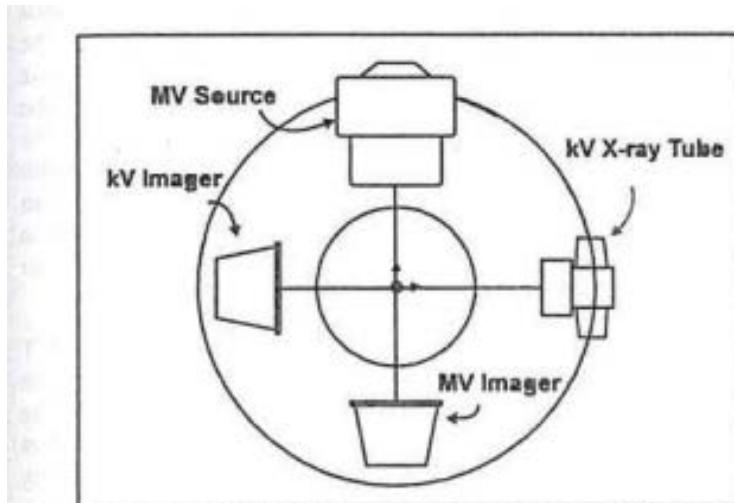


Figure 1: Schematic of dual-beam system to be used for conebeam computed tomography (CBCT). The kV x-ray beam is orthogonal to the treatment beam.

Ex. 1107, 5. As shown in Figure 1, “[t]wo fluoroscopic imaging systems are attached to a Philips SL-20 medical linear accelerator; one detects the megavoltage image, the other a kV image produced with a kV beam projected at 90° to the treatment beam axis.” Ex. 1107, 4. Jaffray 1997 states that the “gantry is rotated continuously” in order to generate a “conebeam imaging sequence consist[ing] of ~100 exposures over 194° of rotation.” Ex. 1107, 5.

4. Adler (Ex. 1103)

Adler teaches an apparatus and method for extending a surgical instrumentality to a target region in a patient, for example, for performing stereotaxic surgery using an x-ray linear accelerator. Ex. 1103, 1:6–10. Specifically, Adler teaches that a 3-dimensional mapping of a mapping region of at least a portion of a living organism is prepared. Ex. 1103, 3:64–68. First and second diagnostic beams are then passed through the mapping region, and are used to produce respective first and second images of respective first and second projections within the mapping region. Ex. 1103,

4:5–10. Adler then teaches that the 3-dimensional mapping and the first and second images are compared to derive therefrom data representative of a real-time location of a target portion of the mapping region. Ex. 1103, 4:41–46. Adler teaches further “adjusting the relative position of the beaming apparatus 20 and the patient 14 as needed in response to data which is representative of the real time location of the target region 18.” Ex. 1103, 7:37–40.

5. Depp (Ex. 1104)

Depp teaches an apparatus for and method of carrying out stereotaxic radiosurgery and/or radiotherapy on a particular target region within a patient utilizing previously obtained reference data indicating the position of the target region with respect to its surrounding area, which also contains certain nearby reference points. Ex. 1104, 1:6–12. Depp further teaches the following:

The apparatus also utilizes a pair of diagnostic beams of radiation or target locating beams, as they will be referred to in this discussion. These beams are passed through the surrounding area containing the target region and reference points and, after passing through the surrounding area, contain data indicating the positions of the reference points within the surrounding area. This position data is collected by cooperating detectors, as described previously, and delivered to the multiprocessor computer where the latter compares it with previously obtained reference data for determining the position of the target region with respect to each of the reference points during each such comparison. The radiosurgical beam is accurately directed into the target region in substantially real time based on this information.

Ex. 1104, 11:46–61.

6. Petitioner's Initial Positions

Petitioner asserts that a combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp renders obvious claims 1–13 and 20–31. Pet. 31–59. For example, claim 1 recites “[a] radiation therapy system.” Petitioner argues that Adler and Depp disclose a system for radiotherapy that is configured for selectively irradiating a target within a patient. *Id.* at 31–32 (citing Ex. 1103, Abstract, 3:62–68; Ex. 1104, Abstract, 1:6–12, 1:18–26; Ex. 1102 ¶¶ 64–65). Petitioner further argues that Antonuk and Jaffray 1997 also disclose radiotherapy systems using a medical linear accelerator device. *Id.* at 32.

Claim 1 further recites “a radiation source that moves about an object and directs a beam of radiation towards said object.” Petitioner argues that Adler/Depp discloses that the beaming apparatus can be adjusted such that the collimated beam is continuously focused on the target region. *Id.* at 32–33 (citing Ex. 1103, 7:52–58; Ex. 1104, 5:25–31). Petitioner further argues that Jaffray 1997 and Antonuk disclose the use of a radiation source. *Id.* at 33 (citing Ex. 1107, 4; Ex. 1106, 3, 5).

Claim 1 also recites “a cone-beam computed tomography system comprising: an x-ray source that moves about said object and emits toward said object from multiple positions around said object x-ray beams in a cone-beam form.” Petitioner argues that Cho discloses a cone-beam computed tomography (“CBCT”) system that generates a 3-D image by rotating an x-ray source around an object. *Id.* at 33–34 (citing Ex. 1105, 15). Petitioner further argues that Jaffray 1997 discloses a cone beam CT apparatus that uses a linear accelerator that obtains 3-D information from a plurality of 2-D projection images by rotating the gantry around a patient.

Id. at 34 (citing Ex. 1107, 4–5). Petitioner further argues, applying the testimony of Dr. Balter, that Antonuk discloses an x-ray source that emits beams in a con-beam geometry. Pet. 34–35 (citing Ex. 1106, Fig. 5; Ex. 1102 ¶ 72).

Claim 1 additionally recites “a flat-panel imager positioned to receive x-rays after at least a portion of said x-ray beams pass through said object, said imager providing an image that contains three-dimensional information concerning said object based on a plurality of two-dimensional projection images.” Petitioner argues that Cho discloses an amorphous silicon flat panel imager (“FPI”) that detects cone-beam x-ray projection images, and Cho specifically references to Antonuk for its FPI. *Id.* at 35 (citing Ex. 1105, 24). Petitioner then argues that Antonuk discloses flat panel imagers as diagnostic x-ray detectors mounted on a linear accelerator for imaging during radiotherapy. *Id.* (citing Ex. 1106, 3). Petitioner argues, as explained by Dr. Balter, the FPI devices detect multiple x-ray beams that pass through an object being imaged, and each FPI receives a plurality of 2-D x-rays. *Id.* at 35–36 (citing Ex. 1106, Fig. 5; Ex. 1102 ¶¶ 58, 73–74). Petitioner argues that Adler/Depp disclose obtaining two x-ray images at a known angle relative to one another, and, therefore, providing three-dimensional information about the imaged object. *Id.* at 36–37 (citing 1103, 7:6–12, 7:17–23; Ex. 1102 ¶ 75).

Claim 1 further recites:

a computer coupled to said cone-beam computed tomography system, wherein said computer receives said three-dimensional information and based on said three dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object, wherein said receiving said x-rays by said

flat panel imager is performed substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.

Petitioner argues that Adler discloses a computer, coupled to the x-ray system, that receives three-dimensional information, as discussed above, and adjusts the position of the radiation beam in response to the real-time three-dimensional location information of the target. Pet. 37–38 (citing Ex. 1103, 7:37–40). Petitioner argues that the radiation source is adjusted in the gantry or by moving the patient table. *Id.* at 38 (citing Ex. 1103, 7:42–58).

Petitioner further argues that Depp discloses the use of diagnostic beams that pass through target region and surrounding area, and then contain data indicating the position of the target. *Id.* at 39 (citing Ex. 1104, 11:46–61). The substantially real time position data is used to direct the radio surgical beam to the target region. *Id.* (citing Ex. 1104, 11:46–61).

For a rationale to modify Cho, Antonuk, Jaffray 1997, Adler, and Depp in view of each other, Petitioner sets forth such a rationale on pages 46–50 of the Petition. Petitioner performs a similar analysis for dependent claims 2–6, 8–13, 21–25, and 27–31. *Id.* at 50–59.

7. Patent Owner’s Assertions Concerning the References

i. Missing Limitation

Patent Owner asserts that the Petition does not account sufficiently for “the element of controlling the relative position of the radiation source and tumor based on the three-dimensional information contained in the claimed image,” because Petitioner solely relies on Adler/Depp for the aforementioned claim element, and Adler/Depp does not disclose an image containing three-dimensional information. PO Resp. 23–25, 29–30. As an initial matter, we note that Patent Owner’s assertions are unpersuasive

because they appear to presume a construction of “three-dimensional information” as requiring volumetric information. As set forth above, we construe “three-dimensional information” as “information concerning three dimensions of an object (such as length, width, and depth).” Adler discloses conducting radiosurgery using a 3-dimensional mapping (Ex. 1103, 4:41–46) and Depp discloses conducting radiosurgery and radiotherapy on a target region and reference points in 3-dimensional space (Ex. 1104, 11:46–61), each of which we find corresponds properly to the aforementioned claim limitation.

Moreover, Patent Owner’s assertions are misplaced, because Petitioner does not rely solely on Adler/Depp for “the element of controlling the relative position of the radiation source and tumor based on the three-dimensional information contained in the claimed image.” PO Response 29–30; *see* Pet. 31–41; Pet. Reply 5. More specifically, the aforementioned claim “element” is not recited in a single limitation of independent claim 1, but instead appears to be an amalgamation of several express limitations, namely, “said imager providing an image that contains three-dimensional information concerning said object based on a plurality of two-dimensional projection images” and “a computer coupled to said cone-beam computed tomography system, wherein said computer receives said three-dimensional information and based on said three dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object.” While for the latter limitation, Petitioner may rely solely on Adler/Depp, for the former limitation, Petitioner also relies on Cho/Antonuk/Jaffray 1997, the

combination of which we are persuaded meet the entire limitation at issue.
Pet. 35–39; Pet. Reply 5.

Patent Owner asserts also that “[n]one of these references . . . either alone or in combination, shows the actual use of an FPI in the context of CBCT in the treatment room. (Ex. 2080 ¶ 119).” PO Resp. 27. Patent Owner’s assertions are misplaced, as Petitioner relies on a combination of references for the above, e.g., Cho/Antonuk for the FPI, Cho/Jaffray ’97 for CBCT, and Adler/Depp for the treatment room. *See* Pet. 31–36. Patent Owner’s arguments are unpersuasive because they are directed to each individual reference’s failure to disclose the claim limitations, rather than to the combination of prior art disclosures. *See In re Merck & Co. Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Insofar as Patent Owner requires more by using the word “actual,” we note that obviousness is a hypothetical exercise, given certain factual underpinnings, and so an example of “actual use” is unnecessary and beside the point.

ii. Teaching Away

Petitioner sets forth their rationale, for their proffered modification of the radiation therapy systems of Adler/Depp to include the CBCT/FPI system of Cho/Antonuk/Jaffray 1997, on pages 46–50 of the Petition which, for the reasons set forth below, we agree with and adopt. Patent Owner asserts that one of ordinary skill would not have modified the radiation therapy systems of Adler/Depp to include the CBCT/FPI system of Cho/Antonuk/Jaffray 1997, because both timing and dosage considerations teach away from the proposed combination. PO Resp. 31–39. We disagree.

We begin with timing considerations. PO Resp. 31–36. Fundamentally, Patent Owner asserts that replacing the orthogonal 2-D

images projections of Adler/Depp with the CBCT-acquired images of Cho/Antonuk/Jaffray 1997 would represent “very poor methodology” because the CBCT system takes a significantly longer period of time to acquire and process images from a patient than the 2-D image system, e.g., 60 seconds to acquire the image, and 30–50 minutes to reconstruct the entire CT conebeam data set. *Id.* at 33–35. According to Patent Owner, such a delay is detrimental in the context of sending targeted radiation to a specific volume within the patient, because during that time, the patient from whom the images was acquired would most likely have shifted positions. *Id.*

We are unpersuaded for several reasons. Primarily, we are unpersuaded because a fundamental assumption made by Patent Owner is that the patient must remain unrestrained. Patent Owner makes this assumption based on the assertion that “the primary goal of the Adler/Depp systems is to permit a patient to be relatively unrestrained during the radiotherapy procedure.” PO Resp. 33. We have reviewed Patent Owner’s supporting evidence, and are unpersuaded that the evidence supports Patent Owner’s assertion that “the primary goal of the Adler/Depp systems is to permit a patient to be relatively unrestrained during the radiotherapy procedure.” For example, Patent Owner cites to certain paragraphs of Dr. Hashemi’s Declaration, which in turn cite to certain portions of Depp. Ex. 2080 ¶¶ 117, 133, 136 (citing Ex. 1104, 11:66–12:23, Fig. 9). We have reviewed those portions of Depp, and find that while they do disclose that target location and treatment periods are on the order of seconds, they do not mention anything about “the primary goal of the Adler/Depp systems is to permit a patient to be relatively unrestrained during the radiotherapy

procedure.”¹¹ Accordingly, absent such an evidentiary foundation, we do not find credible Dr. Hashemi’s assertions concerning this matter.

Even without explicit analysis by Patent Owner, we logically understand the connection between longer image acquisition and processing times, and the higher likelihood of interim patient movement. Absent the aforementioned “primary goal,” however, we are unclear as to why the converse of that goal would not be correct, i.e., that one of ordinary skill would have resolved the timing consideration by restraining the patient. Indeed, in opposition, Petitioner asserts, and we agree, that “POSA would understand that in the majority of radiotherapy treatment settings, patients are in fact restrained to some degree.” Pet. Reply 7–8 (citing Ex. 1500 ¶¶ 33–35; Ex. 2080 ¶¶ 54–55; Ex. 1502, 142:23–143:19). In particular, we are persuaded by the consistency of Dr. Balter’s and Dr. Hashemi’s testimony that molds were used in 2000 to minimize unwanted patient motion during treatment. Ex. 1500 ¶ 35; Ex. 2080 ¶ 55.

Patent Owner also cites to the cross-examination testimony of Dr. Balter in support of its assertions concerning timing consideration. PO Resp. 33–34 (citing Ex. 2011, 95:14–96:8, 98:9–98:19). We have reviewed that testimony, however, and have determined it is inapposite because there, Dr. Balter was opining on the appropriateness of certain methodologies concerning how to detect “gross patient body motion,” and not acquiring images for rendering treatment. Furthermore, Dr. Balter

¹¹ We also note that the use of the word “primary” indicates a general preference, which “does not criticize, discredit, or otherwise discourage the solution claimed . . . ,” as generally required for a showing of a teaching away. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

testified CBCT may be an acceptable methodology for other forms of motion, such as “prostate motion,” depending on the timing. *See* Pet. Reply 8 (“Dr. Balter made this point clear when he explained that there are many facets of ‘intratreatment’ imaging, of which ‘gross patient body motion’ is but one”) So, here, we have another way in which any longer timing from CBCT image acquisition and processing can be dealt with, namely, by restricting the volume from which an image is acquired.

Patent Owner admits that “Jaffray 1997 suggests that this reconstruction time can be reduced by various methods.” PO Resp. 35. Petitioner asserts the same. Pet. Reply 8–9 (citing Ex. 1107, 5–6). Patent Owner goes on to fault Petitioner for not providing sufficient analysis as to how such reconstruction could be accomplished to meet the primary goals of Adler/Depp. PO Resp. 35–36 (citing Ex. 2080 ¶¶ 133–138). As noted above, however, we are unpersuaded that Patent Owner’s assertions concerning the primary goals of Adler/Depp are credible, and, thus, a finding that the reconstruction times could be reduced actually weighs against Patent Owner’s assertions.

Finally, Petitioner asserts that “[Patent Owner] has failed to account for the trade-offs associated with the combination of a 3D CBCT system with the apparatus and methods disclosed in Adler/Depp.” Pet. Reply 8–9 (citing Pet. 49; Dec. 19–21). As an initial matter, we note that it is Petitioner’s, and not Patent Owner’s burden, to account for the tradeoffs. Moreover, we note that the cited portions of the Petition and Decision on Institution referenced possible benefits to the proffered combination, and made no mention of tradeoffs. Finally, Petitioner does not cite to any

evidence to support this assertion. Accordingly, it is accorded little weight in our above analysis.

We move on to dosage considerations. PO Resp. 31–32, 36–38 (citing Ex. 2011, 99:19–101:22; Ex. 2080 ¶¶ 133, 139–142). Specifically, Patent Owner asserts that replacing the orthogonal 2-D images projections of Adler/Depp with the CBCT acquired images of Cho/Antonuk/Jaffray 1997 would significantly increase the amount of radiation to which a patient is exposed, increasing significantly and commensurately the risk of cancer from that radiation. *Id.* According to Patent Owner, one CBCT image already requires 300 exposures while one 2-D x-ray snapshot only requires two, and that an unrestrained patient would require multiple image acquisitions due to movement. *Id.* at 37 (citing Ex. 2080 ¶ 140). We are unpersuaded by these assertions as well, primarily because Patent Owner again assumes the patient is unrestrained. As set forth above, however, we are unpersuaded that such an assumption is credible, in which case, for a restrained patient, there is less of a need for multiple exposures from the CBCT system. Petitioner asserts the same. Pet. Reply 9. Furthermore, we find that multiple 2-D x-ray snapshots would be necessary to convey the same amount of information as one 3-D CBCT image, indicating that the exposure disparity between the two systems would be significantly less than the 150:1 ratio proffered by Patent Owner.

Along those lines, Petitioner provides analysis and evidence that the radiation dosage from one full rotation CBCT scan is well within acceptable parameters, as measured in centigray (“cGy”). Pet. Reply 10 (citing Ex. 1105, 22; Ex. 1107, 5; Ex. 1500 ¶¶ 38–48; Ex. 1507, 7). Specifically, Jaffray 1997 discloses that “[d]aily imaging dose of up to 10 cGy will

exceed the doses currently accepted for portal filming practice,” and further discloses that “[t]he total dose required to locate the prostate – fat boundary is estimated to be ~4 cGy for a 5mm slice thickness.” Ex. 1107, 5. Pouliot discloses that “[i]n this study, the radiation dose delivered to the patient by MV CBCT was 15 cGy. As will be discussed below, we hope to decrease the dose per scan to 2 cGy.” Ex. 1507, 7. Dr. Balter calculates that the total exposure of 1590 mR from one CBCT scan in Cho is equivalent to about 1.4 cGy (Pet. Reply 10 (citing Ex. 1105, 22; Ex. 1500 ¶ 40)), and Cho discloses that such a dosage “compares favourably with exposures from diagnostic CT” (Ex. 1105, 22). Accordingly, while we acknowledge that other considerations, such as volume of scan image desired, may affect dosage, we find, in general, that dosages at issue for one full rotation CBCT scan are on the order of 1.4 to 4 cGy, are below the accepted limits of around 10 to 15 cGy, and “compare[] favourably with exposures from diagnostic CT.” Ex. 1105, 22. We determine that this finding weighs heavily against Patent Owner’s assertions concerning dosage.

In summary, Patent Owner asserts that Petitioner’s proffered rationale for replacing the orthogonal 2-D image projections of Adler/Depp with the CBCT-acquired images of Cho/Antonuk/Jaffray 1997, namely, “improved image accuracy,” is insufficient because it is outweighed by the aforementioned timing and dosage considerations. PO Resp. 38–39 (citing Ex. 2011, 87:13–88:16; Ex. 2080 ¶¶ 137, 143–146). As set forth above, however, we are unpersuaded that Patent Owner’s assertions concerning timing and dosage considerations are credible. Instead, absent that factual basis, we are persuaded that Petitioner’s proffered rationale is sufficient.

iii. Reasonable Expectation of Success

Patent Owner asserts further that one of ordinary skill would not have modified the radiation therapy systems of Adler/Depp to include the CBCT/FPI system of Cho/Antonuk/Jaffray 1997, because one of ordinary skill would not have had a reasonable expectation of success with respect to the modification. PO Resp. 39–53. We disagree.

Patent Owner asserts that one of ordinary skill would not have had a reasonable expectation of success with respect to the modification because “[a]t the time of the ’765 patent—and even today—the quality of CBCT images suffered greatly for two reasons.” PO Resp. 41 (citing Ex. 2080 ¶¶ 150–160). First, Patent Owner asserts that the presence of various “artifacts” resulting from the modification would have led one of ordinary skill to conclude that the resulting image quality to be so poor as to be “‘inadequate for medical diagnosis.’” Ex. 2080 ¶ 151 (quoting Ex. 2020, 2:28–34) (emphasis omitted); PO Resp. 41–43 (citing Exs. 2020, 2021, 2022, 2080 ¶¶ 150–160). Petitioner responds that (1) the challenged claims do not require any specific level of image quality, and (2) that while certain levels of image quality may be insufficient for some medical diagnoses, it does not follow that the image of that quality is unsuitable for all medical diagnoses. Pet. Reply 11–13 (citing Exs. 1500 ¶¶ 51–59, 1502). We agree with Petitioner.

We begin with Patent Owner’s citation to Exhibit 2020, the full excerpt of which reads as follows:

Depending on the scanning configuration employed to obtain the cone beam projection data, the data set in Radon space may be incomplete. While image reconstruction through inverse Radon transformation certainly can proceed, artifacts

may be introduced, resulting in images which can be inadequate for medical diagnosis or part quality determination purposes.

Ex. 2020, 2:28–34 (emphasis added). We do not read Exhibit 2020 as disclosing that *all* CBCT/FIP images are so poor as to be ““inadequate for medical diagnosis’;” only that some such images may be inadequate, “[d]epending on the scanning configuration employed,” indicating that under some scanning configurations, the image quality would be adequate. *Id.*

We next proceed to Patent Owner’s citation to Exhibit 2022, the full excerpt of which reads as follows:

Various scanning geometries have been developed to ensure that the sufficiency criterion of Smith is complied with. In one such geometry, the scan path comprises a circular orbit in combination with a linear path, which is orthogonal to the plane of the circular orbit. Such combination scan path is of great practical interest, since it can be readily implemented by means of a conventional CT gantry configuration. *Various algorithms are currently available for use in processing cone beam data acquired by scanning along a combined circle and line path, and constructing an image therefrom.* However, one of such algorithms is of the shift-variant filtering back projection form, which is comparatively difficult to implement in practice. *Other of such algorithms* have been found to contain artifacts, and are not sufficiently exact or accurate. Still other algorithms require excessive data processing steps, resulting in inefficient image reconstruction.

Ex. 2022, 1:42–51 (emphases added). Similar to our analysis above, we do not read Exhibit 2022 as disclosing that *all* algorithms have inadequate image quality; only that various algorithms have various strengths and weakness, one weakness of *certain* algorithms being “artifacts.”

Patent Owner further cites to paragraphs 150–160 of Dr. Hashemi’s Declaration which, in addition to providing analysis, cite to additional Exhibits 2021, 2023, 2025, 2026 for support. We have reviewed

Dr. Hashemi’s testimony, as well as the cited portions of those Exhibits, and determine that our analysis is the same as set forth above; that while the presence of artifacts is certainly undesirable, their presence alone is insufficient to support Patent Owner’s assertion that the resulting image quality for the proffered modification would have been ““inadequate for medical diagnosis.””

Finally, there is no doubt that the claims do not specify any minimum level of image quality to be considered a success. When viewed in conjunction with the fact that the aforementioned evidence, as a whole, indicates that at least some of the resulting images would have sufficient quality for certain medical diagnoses, even with artifacts, we are persuaded that Petitioner has met its burden of showing adequately a reasonable expectation of success with respect to image quality.

Second, Patent Owner makes similar assertions with respect to “increased noise” and “image quality.” PO Resp. 43–45 (citing Exs. 2023–2026, 2080 ¶¶ 155, 157–160). Petitioner’s response and our analysis is similar to that set forth above for “artifacts.”

For Exhibit 2023, Patent Owner’s assertion that “[t]his is one of the ‘major limiting factors for the current image quality in flat-panel based CBCT’” (PO Resp. 43 (quoting Ex. 2023, 187)) is somewhat misplaced, because that paragraph is discussing “scatter,” as opposed to “noise,” although we acknowledge that Exhibit 2026 discloses that “noise” and “scatter” are related (Ex. 2026, 708). In any case, later in that same paragraph, Exhibit 2023 notes “[s]everal scatter correction algorithms have been proposed in the literature to control these artifacts,” indicating that the presence of “scatter” is not fatal to image quality. Ex. 2023, 187–188.

Patent Owner’s later citation to the subsequent paragraph of Exhibit 2023 is more relevant, in that it explicitly is directed to “noise,” has a “loss of diagnostic information,” and concludes with “a practical solution to suppress noise has not yet been developed.” Ex. 2023, 188. While seemingly phrased in the absolute, i.e., that there is *no* practical solution to suppress noise, the previous sentence provides context that some algorithms do exist to reduce noise “by a factor of 3.6” and “from 10.6% to 1.7%.” Ex. 2023, 188. Accordingly, this paragraph also supports the conclusion that some noise suppression techniques are known, and, in any case, does not indicate that the “noise” results in a completely unusable image, especially given that the claim does not require any particular image quality.

Regarding the rest of the cited portions of Exhibits 2023, 2024, 2025, and 2026, we agree with Patent Owner that the cited portions support the proposition that noise is certainly a disadvantage of CBCT. It does not follow, however, that noise in itself would definitively counsel against a reasonable expectation of success.

Patent Owner asserts additionally that “Antonuk discloses using a CBCT-FPI system for the purpose of calculating attenuation coefficient factors in the context of PET and SPECT scanning,” which uses radioactive contrast agents and not x-rays, and, thus, “would not have suggested using CBCT for patient setup in the context of radiotherapy, which does not use a radioactive contrast agent.” PO Resp. 45–46 (citing ¶¶ 163–165). As an initial matter, we note that this appears to be directed more to a teaching away, as opposed to a reasonable expectation of success. In any case, the assertion is misplaced because Petitioner relies on Adler, not Antonuk, for

radiotherapy. Pet. 31–33. Moreover, we disagree because Antonuk explicitly discloses radiotherapy. Ex. 1106, 5.

Patent Owner asserts further that one of ordinary skill would not have had a reasonable expectation of success with respect to the modification based on Antonuk, because Antonuk discloses a helical scan, which would eliminate artifacts, but would significantly increase reconstruction time, making it impractical for radiation therapy. PO Resp. 46 (citing Ex. 2080 ¶ 165). These assertions are unpersuasive for the same reasons as set forth above with respect to Patent Owner’s assertions concerning timing considerations. *See also* Pet. Reply 13–14 (citing Exs. 1106, 1500 ¶¶ 60–63, 1502) (Fig. 5 of Antonuk discloses a patient being subjected to both diagnostic and therapeutic x-rays).

Patent Owner makes similar assertions concerning Cho, i.e., that Cho does not provide any evidence that the images would be of sufficient quality, and that Cho discloses a more time-intensive reconstruction. PO Resp. 46–47 (citing Ex. 2080 ¶¶ 166–170; Ex. 1112). These assertions are unpersuasive for the same reasons as set forth *supra*. *See also* Pet. Reply 14 (citing Exs. 1105, 1500 ¶¶ 64–65, 1502).

Patent Owner repeats the above assertions for both Jaffray ’97 and FPIs generally. PO Resp. 47–50 (citing Exs. 1129, 2028, 2073–2075, 2080 ¶¶ 171–183). Our analysis is similar to that set forth above, and need not be repeated here. *See also* Pet. Reply 14–15 (citing Exs. 1101, 1500 ¶¶ 66–68, 1502, 1508) (“[E]ffects of image lag in flat-panel CBCT under conditions typical of medical imaging are small, given the image lag performance of state-of-the-art FPIs.” (Ex. 1508, 12)).

In summary, Patent Owner asserts that one of ordinary skill would have had no reasonable expectation of success for Petitioner's proffered replacement of the orthogonal 2-D image projections of Adler/Depp with the CBCT-acquired images of Cho/Antonuk/Jaffray 1997, due to poor image quality and timing considerations. As set forth above, however, we are unpersuaded that image quality is relevant to the extent advocated by Patent Owner, and that the timing considerations are not dire enough to counsel definitively against a reasonable expectation of success. Instead, we are persuaded that Petitioner has shown sufficiently that one of ordinary skill would have had a reasonable expectation of success concerning Petitioner's proffered modification.¹²

8. Evidence of Secondary Considerations

Patent Owner asserts that even if all of the other factors weigh in favor of the obviousness of certain claims, those factors are outweighed by Patent Owner's proffered evidence concerning objective indicia of non-obviousness, i.e., secondary considerations. PO Resp. 54–62 (citing Exs. 2011–2015, 2034, 2035, 2048, 2052, 2054, 2080, 2083). Petitioner disagrees. Pet. Reply 15–24 (citing Exs. 1500, 1502, 1509–1515, 2011, 2015, 2033, 2035, 2048, 2056, 2071, 2072, 2080).

i. Law – Objective Indicia of Nonobviousness

Factual inquiries for an obviousness determination include secondary considerations based on objective evidence of non-obviousness. *Graham v.*

¹² Patent Owner addresses other references cited by Dr. Balter only in his Declaration. PO Resp. 50–53 (citing Exs. 1102, 1131, 1132, 2029–2031, 2080). As noted by Patent Owner, however, it is inappropriate for Petitioner to rely on these references to “‘fill-in’ any ‘gap’ in the Petition,” and so we have not considered those references in rendering our Decision.

John Deere Co., 383 U.S. 1, 17–18 (1966). Notwithstanding what the teachings of the prior art would have suggested to one of ordinary skill in the art at the time of the invention, the totality of the evidence submitted, including objective evidence of non-obviousness, may lead to a conclusion that the challenged claims would not have been obvious to one of ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984).

We note that it is not sufficient that a product or its use merely be within the scope of a claim in order for objective evidence of nonobviousness tied to that product to be given substantial weight. There must also be a causal relationship, termed a “nexus,” between the evidence and the claimed invention. *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). A nexus is required in order to establish that the evidence relied upon traces its basis to a novel element in the claim, not to something in the prior art. *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013). Objective evidence that results from something that is not “both claimed and *novel* in the claim” lacks a nexus to the merits of the invention. *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011).

All types of objective evidence of nonobviousness must be shown to have nexus. *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) (nexus generally); *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) (commercial success); *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012) (copying); *Rambus Inc. v. Rea*, 731 F.3d 1248, 1256 (Fed. Cir. 2013) (long-felt need); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328 (Fed. Cir. 2008) (praise). The stronger the showing of nexus, the greater the weight accorded the objective evidence of

nonobviousness. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986).

“Where the allegedly obvious patent claim is a combination of prior art elements, . . . the patent owner can show that it is the claimed combination as a whole that serves as a nexus for the objective evidence” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330 (Fed. Cir. 2016) (citing *Rambus*, 731 F.3d at 1258). “[T]here is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘is the invention disclosed and claimed in the patent.’” *WBIP*, 829 F.3d at 1329 (citations omitted). Secondary consideration evidence is accorded less weight for claims that are considerably broader than the particular features in the merits of the claimed invention. *See ClassCo, Inc. v. Apple, Inc.*, 838 F.3d 1214, 1221 (Fed. Circ. 2016).

ii. *Industry Praise*

Patent Owner asserts that their proffered evidence of industry-wide praise suggests that the aforementioned claims are non-obvious. PO Resp. 54–57 (citing Exs. 2012–2015, 2052, 2054, 2080). Petitioner disagrees. Pet. Reply 17–18 (citing Exs. 1500, 1515, 2011, 2015).

a. *Linear Accelerator of Jaffray 2002*

Beginning with nexus, Patent Owner cites the analysis of Dr. Hashemi for the proposition that “the linear accelerator described in Jaffray 2002 meets each and every limitation of at least the independent Challenged Claims.” PO Resp. 54–55 (citing Ex. 2080 ¶¶ 195–200). Petitioner does not directly address nexus for the linear accelerator of Jaffray 2002, in that Petitioner’s purported assertions concerning nexus actually go to the weight

to be accorded the evidence of secondary considerations, and not nexus. *See generally* Pet. Reply 16–17. Specifically, nexus is more of a preliminary determination as to whether the claims literally cover the content set forth in the evidence of secondary considerations. *See WBIP*, 829 F.3d at 1329 (“[T]here is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘is the invention disclosed and claimed in the patent.’”) (citations omitted). There is no factual dispute that the linear accelerator described in Jaffray 2002 meets each and every limitation of at least the challenged independent claims. Tr. 55:19–24 (“JUDGE KIM: That’s what I’m trying to get at. I understand that point, but yeah, literally infringe. Is there any exhibit where they don’t literally infringe the claim? MR. SMITH: Your Honor, I’m not aware of -- in the little time I have left, we’ll go through it, but I’m not aware of one as I stand up here today.”).^{13,14}

Any disagreement that exists, between Patent Owner and Petitioner, goes to the weight to be accorded that evidence of secondary considerations having a nexus. For example, Petitioner asserts “both Elekta and Varian linear accelerator systems including CBCT-FPI can be (and often are) used in IGRT methods that do not employ any localization based on images with 3-D information and thus have no nexus with the claims.” Pet. Reply 17 (emphasis omitted). Our reviewing court has instructed us, however, that

¹³ This exchange is applicable to all evidence of secondary considerations.

¹⁴ This discussion involves whether Jaffray 2002 meets each and every limitation of the challenged independent claims of both the ’502 patent and the ’765 patent with regard to the nexus requirement. *See* Tr. 54:6–14, 55:1–3 (“... he praised the ’502 and the ’765 technology as one of the most significant developments in the scientific literature.”).

such an assertion should be addressed by according less weight to the evidence of secondary considerations, and not by determining a lack of nexus. *See ClassCo*, 838 F.3d at 1221 (secondary consideration evidence is accorded less weight for claims that are considerably broader than the particular features in the merits of the claimed invention). To that end, all of Petitioner’s assertions concerning “nexus” have been considered when determining the weight to be accorded the relevant evidence of secondary considerations.

Given the above rubric, we have reviewed the relevant portions of Dr. Hashemi’s Declaration, and find that the system described in, and praised by, Jaffray 2002 has a nexus with independent claims 1, 7, 20, and 26. In particular, Jaffray 2002 discloses the following:

Conclusions: A kV cone-beam CT imaging system based on a large-area, flat-panel detector has been successfully adapted to a medical linear accelerator. The system is capable of producing images of soft tissue with excellent spatial resolution at acceptable imaging doses. Integration of this technology with the medical accelerator will result in an ideal platform for high-precision, image-guided radiation therapy.

Ex. 2012, WBH_Elekta_00412, Abstract. We are persuaded that this conclusion is indisputably the focus of Jaffray 2002, and that it is coextensive with the scope of independent claims 1, 7, 20, and 26.

Patent Owner then cites to the following sentence in a textbook published in 2015 as both referring to, and praising, the system set forth in Jaffray 2002: “[t]he advent of cone-beam computed tomography (CBCT) on board another Elekta SL-20 linear accelerator was another major breakthrough reported by Jaffray and others at William Beaumont Hospital (Jaffray et al. 2002).” Ex. 2013, WBH_Elekta_0057; *see* PO Resp. 55

(quoting Ex. 2013, WBH_Elekta_0057). Petitioner does not challenge the weight of this citation. *See generally* Pet. Reply 17–18. We find that Exhibit 2013 supports heavily Patent Owner’s assertion that there was industry praise for the system set forth in Jaffray 2002.

Patent Owner further cites to the following sentences in an article co-authored by Petitioner’s expert: “[p]erhaps the most significant developments that have brought IGRT to the forefront are enhancements recently made in application of imaging and other remote sensing devices within treatment rooms”; “most modern treatment machines can now be outfitted with CT devices mounted directly to the treatment gantry” (footnote citing Jaffray 2002). PO Resp. 55–56 (citing Ex. 2015, WBH_Elekta_00575–76). Petitioner asserts that the weight accorded these sentences should be heavily discounted because “[t]he quotes referenced are not tied solely to CBCT-FPI systems for IGRT, as Patent Owner argues, but instead refer broadly to all classes of imaging modalities for IGRT,” which includes digital radiography, cone-beam CT, and ultrasound, and “nothing in Dr. Balter’s paper amounts to any specific praise for what is actually recited in the claims.” Pet. Reply 17–18. We agree that the aforementioned citations should be discounted somewhat for the reasons asserted by Petitioner. While we acknowledge that it is listed as only one of a plurality of options, the article nevertheless specifically identifies cone-beam CT and Jaffray 2002 as an advance in the field, and, thus, is still compelling evidence of industry praise of the system of Jaffray 2002. *See also* Ex. 2011, 111:3–8 (Dr. Balter crediting the early work of Jaffray 2002 as follows: “there was certainly several efforts associated with doing this in the community at the time. However, ***he certainly had a very early publication,***

and we knew his work, and it was quite appropriate to credit his work”) (emphasis added)). Accordingly, we find that Exhibit 2015 supports heavily Patent Owner’s assertion that there was industry praise for the system set forth in Jaffray 2002.

Finally, Patent Owner cites Dr. Hashemi’s testimony that “Jaffray 2002 has been cited by more than 1,000 other scientific articles.” PO Resp. 54–55 (citing Ex. 2080 ¶¶ 75, 200–201).¹⁵ More specifically, Dr. Hashemi testifies that this conclusion is based “on a Google Scholar search conducted by me on September 24, 2016.” Ex. 2080 ¶ 75. Petitioner does not challenge this assertion. *See generally* Pet. Reply 17–18. We find that this assertion supports heavily Patent Owner’s assertion that there was industry praise for the system set forth in Jaffray 2002.

b. Petitioner’s Patented Radiation Therapy System

Patent Owner asserts that industry praise of Petitioner’s “patented radiation therapy system,” embodied in U.S. Patent No. 7,945,021 (“the ’021 patent”), supports their assertion concerning industry praise of the invention set forth in the challenged claims. PO Resp. 56 (citing Ex. 2014, 31:10–32:22; Ex. 2080 ¶ 77). We have reviewed Patent Owner’s assertions and supporting evidence, and we determine that Patent Owner has not established the required analysis concerning the nexus between the system set forth in Petitioner’s ’021 patent and independent claims 1, 7, 20, and 26. At best, Exhibit 2014 accounts generally, concerning the ’021 patent, for

¹⁵ Patent Owner also cites paragraphs 76, 79, 202–203, 289, 293 of Dr. Hashemi’s Declaration as identifying further industry praise of the system set forth in Jaffray 2002. PO Resp. 56. The content of those paragraphs are subsumed within the analysis of the “1,000 other scientific articles.”

“[t]he addition of onboard cone-beam CT and flat-panel imaging, and integration with a treatment machine.” Ex. 2014, 32:10–12. That citation, however, does not account adequately for “wherein said computer receives said three-dimensional information and based on said three dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object,” as recited by independent claim 1 and similarly recited by independent claim 7, 20, and 26.

c. Petitioner’s On-Board Imager and Clinac/Trilogy Linear Accelerators

Patent Owner asserts that industry praise of the combination of Petitioner’s On-Board Imager and each of Petitioner’s Clinac and Trilogy linear accelerators support their assertion concerning industry praise of the invention set forth in independent claims 1, 7, 20, and 26. PO Resp. 56 (citing Ex. 2052, WBH_Elekta_01164; Ex. 2054, WBH_Elekta_01198; Ex. 2080 ¶¶ 260, 262). For nexus, Patent Owner asserts that the aforementioned combination of Petitioner’s products meets every limitation of independent claims 1, 7, 20, and 26. PO Resp. 59–61 (citing Ex. 2080 ¶¶ 250–258).¹⁶ Petitioner disagrees, asserting (1) Petitioner’s aforementioned products include “many functionalities beyond the challenged claims,” and (2) at least some of Petitioner’s aforementioned products were successful without CBCT or three-dimensional (“3D”)

¹⁶ Although this portion of the Patent Owner Response also addresses the nexus between Petitioner’s TrueBeam system and independent claim 1 (PO Resp. 59–61 (citing Ex. 2080 ¶¶ 266–272)), the portion of the Patent Owner Response directed to industry praise does not provide evidence concerning industry praise for the TrueBeam system.

imaging, as required by independent claim 1. Pet. Reply 18, 22–23 (citing Ex. 1500 ¶¶ 76, 80, 81; Ex. 1502, 166:25–167:3; Exs. 1509–1511; Ex. 1515, 6; Ex. 2056, WBH_Elekta_01359). As an initial matter, we discern that Petitioner’s assertion (1) goes more to the weight to be accorded the evidence, as opposed to nexus.¹⁷

For assertion (2), after reviewing the evidence, we discern that the key is whether or not the praise directed to the aforementioned product was before or after approximately November 3, 2004. More specifically, Petitioner asserts, and we agree, that prior to November 3, 2004, the aforementioned product did not have either CBCT or 3-D imaging capabilities, as required by independent claims 1, 7, 20, and 26, and, thus, did not have a nexus with the challenged independent claims. Pet. Reply 22. In particular, we find that the evidence shows that the aforementioned product launched at or around March 3, 2004 (Ex. 1509) without either CBCT or 3-D imaging capabilities, and that such capability was added at or around November 3, 2004 (Ex. 1510). Consequently, we find that subsequent to November 3, 2004, the aforementioned products did meet, and, thus, had a nexus with, independent claims 1, 7, 20, and 26.

With that in mind, we evaluate Exhibit 2054, entitled “Varian Medical Systems 2006 Annual Report.” As an initial matter, we find that Exhibit

¹⁷ When broad claims capture a single (or multiple) commercial embodiment(s), nexus is presumed. *See ClassCo*, 838 F.3d at 1222 (nexus presumed when the commercial “products embodied the claimed features” and the “Board’s blanket dismissal of it was in error”). In this situation, the Board must evaluate the evidence “taking into account the degree of the connection between the features presented in the evidence and the elements recited in the claims.” *See ClassCo*, 838 F.3d at 1221 (explaining that “[t]here is no hard-and-fast rule for this calculus”).

2054 is directed to products sold during fiscal year 2006 which, under any definition of fiscal year, is well after November 3, 2004. Ex. 2054, WBH_Elekta_01198; *accord* Ex. 2052, WBH_Elekta_01187 (fiscal year 2005 ran from October 1, 2004 to September 30, 2005). Thus, the relevant products referenced in Exhibit 2054 have a nexus with independent claims 1, 7, 20, and 26.

Moving on, Patent Owner identifies (PO Resp. 56 (citing Ex. 2080 ¶ 262)) the following two portions of Exhibit 2054 as support for its assertions concerning industry praise of Petitioner's aforementioned product:

Varian's On-Board Imager® device for image-guided radiotherapy (IGRT) and image-guided radiosurgery (IGRS) is a hit with customers around the world, and it was among the top 100 new product designs recognized by *R&D* magazine in 2006.
Ex. 2054, WBH_Elekta_01198.

Leadership in image-guided radiation therapy. The On-Board Imager® device earned an “*R&D* 100” award from *R&D* magazine as one of the most technologically significant products of the last year.

Ex. 2054, WBH_Elekta_01201. Petitioner asserts that the evidence is at least somewhat undercut because the referenced products include “many functionalities beyond the challenged claims.” Pet. Reply 18. We agree with both parties to an extent. Specifically, we find that Exhibit 2054 does support Patent Owner’s assertion of industry praise for the referenced product, in that the key feature praised was image-guided radiation therapy using an On-Board Imager, which we find had CBCT or 3-D imaging capabilities in 2006. We also find, however, that such support is somewhat undercut by the fact that the referenced products had implementations, i.e., imaging capabilities other than CBCT or 3-D equivalent, that did not meet

every limitation of independent claims 1, 7, 20, and 26. Accordingly, we find that Exhibit 2054 supports moderately Patent Owner's assertion that there was industry praise for Petitioner's aforementioned product.

d. Conclusion

In summary, we weigh Patent Owner's proffered evidence of industry praise as follows: (a) heavy weight to industry praise of Jaffray 2002; (b) no weight to industry praise of Petitioner's patented radiation therapy system; and (c) moderate weight to industry praise of the combination of Petitioner's On-Board Imager and each of Petitioner's Clinac and Trilogy linear accelerators. When weighed in the aggregate, we find that Patent Owner has proffered very strong evidence of industry praise for, and, hence, non-obviousness of, the invention set forth in independent claims 1, 7, 20, and 26.

iii. Long-Felt Need

Establishing long-felt need first requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. *See In re Gershon*, 372 F.2d 535, 539, (CCPA 1967); *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376 (Fed. Cir. 1983). Second, the long-felt need must not have been satisfied by another before the invention by applicant. *Newell Companies v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Third, the invention must in fact satisfy the long-felt need. *In re Cavanagh*, 436 F.2d 491. *See also Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332-33 (Fed. Cir. 2009) (articulating all three factors).

a. Recognized Need for Long Period of Time

Patent Owner asserts that there was a long-felt need for the following: “how to accurately deliver the requisite dose to a soft-tissue tumor that undergoes movement or displacement between treatment fractions.”

Ex. 2080 ¶ 72; *see generally* PO Resp. 57–58. As supporting evidence concerning the need to be solved, Patent Owner cites McBain (Ex. 2071) through Dr. Hashemi’s Declaration. Ex. 2080 ¶¶ 285–290. Most pertinently, McBain discloses the following:

Current standard methods of treatment verification rely on the acquisition of two-dimensional (2D) electronic megavoltage portal images (EPIs), which demonstrate bony anatomy but do not provide soft-tissue definition. This means that although EPIs can be compared with a reference image to correct for setup errors, they do not assess internal organ motion.

The measurement of position and shape of soft-tissue target structures, at the point of treatment delivery, has been the subject of study by a number of investigators. Since the early 1990s, there has been much interest in the use of the portal imaging system to provide megavoltage (MV) projection images that can be reconstructed using cone beam reconstruction algorithms (5). This technology has progressed considerably but is fundamentally limited by detector sensitivity, which means imaging doses are as high as 5% of the fraction dose (6) and the inherent inability of megavoltage X-rays to discriminate the contrast due to density differences between soft-tissue structures such as muscle and fat.

Ex. 2071, WBH_Elekta_01463.

Petitioner asserts that under cross-examination, Dr. Hashemi narrowed the need to be solved to “acquiring a volumetric image with soft-tissue contrast at the time of treatment.” Ex. 1500 ¶ 78; *see* Pet. Reply 19–20 (citing Ex. 1500 ¶ 78 (citing Ex. 1502, 155:25–156:12)). We disagree.

The full exchange between Petitioner’s counsel and Dr. Hashemi is set forth below:

Q. So what I’m trying to figure out is, what problem exactly was solved by the ’502 patent, in your opinion?

A. The ability to acquire a volumetric image, see the soft tissues within that volumetric image at the time of treatment, be able to see what organs are being treated under the beam, whether the target that is intended to be treated is in the right position and have the surrounding organs at risk, have they gone through any changes or movement that now they are in danger of becoming subject to radiation. These are all the solutions that IGRT provides.

Ex. 1502, 155:25–156:12.¹⁸ We discern that Dr. Hashemi’s testimony here more accurately supports Patent Owner’s formulation of long-felt need, and not Petitioner’s prematurely truncated version.

Petitioner also asserts that McBain should be discounted because it was “supported by an educational grant from Elekta (Crawley, United Kingdom).” Pet. Reply 19 (quoting Ex. 2071, WBH_Elekta_01462). The implication, of course, is that McBain was biased toward overstating the need articulated and solution provided. While Petitioner’s assertion has some merit, especially with regards to the adequacy of the solution provided, we are unpersuaded that it casts doubt on the articulation of the need to be solved, as set forth in McBain. Furthermore, as noted by Dr. Hashemi, “Exhibit 2071 is a peer-reviewed article entitled *X-ray Volumetric Imaging in Image-Guided Radiotherapy: The New Standard in On-Treatment Imaging*, authored by Catherine A. McBain and co-workers at Christie

¹⁸ Although the question posed to Dr. Hashemi was with respect to the ’502 patent, the same question and response from Dr. Hashemi is equally relevant to the ’765 patent.

Hospital and published in the International Journal of Radiation Oncology Biology & Physics in 2006.” Ex. 2080 ¶ 287. We discern that such independent indicia of reliability mitigate at least somewhat against any biased impugned to McBain by Patent Owner’s funding.

Accordingly, when all of the above is considered in the aggregate, we find that the aforementioned portion of McBain supports adequately Patent Owner’s assertion as to the articulation of the need to be solved, and that it was long-felt at least since “the early 1990s.” Ex. 2071, WBH_Elekta_01463.

b. Not Satisfied Earlier by Another

By asserting that Patent Owner was the first to satisfy the aforementioned long-felt need, Patent Owner is implicitly asserting that the need was not satisfied earlier by another. *See generally* PO Resp. 57–58. Petitioner asserts that at least the work of three others, Jaffray 1997 (Ex. 1107), Simpson, and fan-beam techniques, had earlier satisfied the aforementioned long-felt need. Pet. Reply 19–20.

Beginning with Jaffray 1997, Petitioner asserts that “Patent Owner also focuses on the article titled ‘X-Ray Volumetric Imaging in Image-Guided Radiotherapy’ (*see* Ex. 2080, ¶ 287), ignoring the fact that this title actually describes the prior art disclosures of, for example, Jaffray 1997.” Pet. Reply 19–20. Petitioner does not provide any further analysis in support of this assertion, however, and without such analysis, we are unpersuaded by Petitioner.

Regarding Simpson, Petitioner appears to be referring to the following sentence in Dabaja: “Cone-beam CT was originally explored by Simpson et al. [6] as a way of generating single-slice tomograms with one gantry

rotation of the linear particle accelerator (LINAC).” Ex. 2072, WBH_Elekta_01474. We are unpersuaded as the aforementioned citation refers to “single-slice tomograms,” while independent claim 1 recites “an image that contains three-dimensional information,” and independent claims 7, 20, and 26 each recite substantially similar limitations. Petitioner has not shown adequately whether the “single-slice tomogram” of Simpson includes such “three dimensional information.”¹⁹

Concerning fan-beam techniques, Petitioner cites the following portion of Exhibit 2033: “kV CBCT offers high-resolution images with lower soft tissue contrast compared to fan-beam CTs due to scattered X-rays reaching the flat panel detector, however CBCTs generally deliver less dose due to differences in filtration techniques and lower photon fluences.” Ex. 2033, WBH_Elekta_00816. While we acknowledge that, in view of the above-articulated need, higher soft tissue contrast would appear to be preferable, Petitioner has not explained sufficiently why the soft tissue contrast in the CBCT image would have been inadequate to meet Patent Owner’s articulated need.

Based on the above, we find that the evidence provided does not indicate that the aforementioned need was satisfied earlier by another.

c. Nexus of Proposed Solution

Patent Owner asserts that their Synergy System was both the proposed solution to the aforementioned problem, and coextensive with independent

¹⁹ Dabaja discloses later in that paragraph “[a] volumetric CT image is reconstructed from data collected during a single gantry rotation.” Ex. 2072, WBH_Elekta_01475. That disclosure, however, is not concerning Simpson.

claim 1²⁰ of the '765 patent. PO Resp. 57–58 (citing Ex. 2080 ¶¶ 222–229, 285–294). Other than asserting that Patent Owner's Synergy System includes features not articulated in independent claims 1, 7, 20, and 26, an assertion we discern goes to weight, and not nexus, Petitioner does not dispute either of the above assertions. *See generally* Pet. Reply 19–20. After reviewing Patent Owner's assertions, as well as the relevant analysis of Dr. Hashemi, we find that Patent Owner's Synergy System meets all the limitations of, and, thus, has a nexus with, independent claim 1.

d. Whether Proposed Solution Satisfies Need

Patent Owner asserts that the above-proposed solution satisfies the aforementioned need. PO Resp. 58 (citing Ex. 2080 ¶¶ 287–293). In particular, Patent Owner asserts that “[t]he '765 patent solved this problem by creating 3-D tomographic images of the target volume at the time of treatment that were of sufficient quality to permit significant reduction in the treatment margins.” PO Resp. 58. In support, Patent Owner cites a prediction from McBain for such success (Ex. 2071, WBH_Elekta_01463), as well as an example of a successful treatment using the proposed solution. PO Resp. 58 (citing Ex. 2080 ¶¶ 291–293 (discussing Ex. 2072, WBH_Elekta_01473–75)).

Petitioner asserts that Patent Owner's proposed solution is inadequate, because “even today kV CBCT methodologies have not ‘solved’ the tumor targeting problem.” Pet. Reply 19. For support, Petitioner cites the following portion of Exhibit 2033: “Unfortunately, IGRT strategies cannot completely correct for patient setup errors and considerable CTV-to-PTV

²⁰ Independent claims 7, 20, and 26 recite substantially similar limitations, and, therefore, we apply our analysis to all of the independent claims.

margins are still required due to large internal organ motion in prostate patients.” Ex. 2033, WBH_Elekta_00814. We determine that Petitioner overstates their assertion, in that we do not read the aforementioned disclosure of Exhibit 2033 as asserting that CBCT is an inadequate solution to the aforementioned need. Instead, we discern it merely states the unremarkable proposition that further improvement is desirable.

Petitioner asserts further that McBain should be discounted because it was “supported by an educational grant from Elekta (Crawley, United Kingdom),” and it only opines as to a prediction concerning potential usefulness of Patent Owner’s Synergy System. Pet. Reply 19–20 (citing Ex. 2071, WBH_Elekta_01462). Generally, we agree with Petitioner, although we note that any bias imputed to McBain from Patent Owner’s funding is at least somewhat mitigated by independent indicia of reliability referenced above concerning our discussion of “*Recognized Need for Long Period of Time.*”

Petitioner asserts also that “Patent Owner’s reference to the use of 3-D CBCT in a specific individual patient case report (*see id.*, ¶¶ 288–289) does not prove a general solution to a long-felt need.” Pet. Reply 20. As an initial matter, we note that Petitioner does not dispute that Exhibit 2072 sets forth a solution to the aforementioned need, and there appears to be nexus, in that Exhibit 2072 discloses using Petitioner’s “cone-beam CT device equipped with on-board imaging,” which has a nexus with independent claims 1, 7, 20, and 26 for the reasons set forth above. Moreover, we are unclear as to why one “specific individual patient case report” cannot be a sufficient basis to “prove a general solution to a long-felt need,” especially where the solution articulated in the “specific individual patient case report”

both acknowledges expressly and appears to adequately resolve the long-felt need. *See e.g.*, Ex. 2072, WBH_Elekta_01474–75 (“Before the era of 3DCRT, the abdominal mass in this patient would have been missed in the course of daily treatments. Our use of cone-beam CT with on-board imaging capability was extremely useful in this case and allowed us to successfully treat this patient We conclude from this experience that image-guided radiation therapy is both valid and useful for tracking the motion of highly mobile abdominal masses.”)

Accordingly, in summary, even when we discount heavily McBain for the reasons set forth above, we discern that Patent Owner has shown sufficiently that their proffered solution satisfies the aforementioned long-felt need.

e. Conclusion

In summary, we find that Patent Owner has provided sufficient supporting evidence and analysis to show adequately that (1) there was a recognized long-felt need, (2) the need was not earlier satisfied by another, and (3) Patent Owner’s proffered solution satisfied that need. When weighed in the aggregate, we find that Patent Owner has proffered very strong evidence of long-felt need for, and, hence, non-obviousness of, the invention set forth in independent claims 1, 7, 20, and 26.

iv. Commercial Success

a. Patent Owner’s Synergy, Infinity, and Versa HD Systems

Patent Owner asserts the following concerning the commercial success of their Synergy, Infinity, and Versa HD Systems:

William Beaumont Hospital has exclusively licensed the ’765 patent to Elekta, who has paid approximately \$40 million in

licensing fees since 2003. (Ex. 2083 ¶ 3; Ex. 2080 ¶ 249). Under that license, Elekta has sold its Synergy XVI, Infinity, and Versa HD systems, which are medical linear accelerators with an integrated CBCT-FPI system embodying the Challenged Claims and are coextensive with them. (*Id.* ¶¶ 222–248). Elekta’s Synergy XVI, Infinity, and Versa HD systems have been commercially successful, and they now represent more than 85 percent of the linear accelerators Elekta sells. (Ex. 2048 ¶ 4; Ex. 2080 ¶ 249).

PO Resp. 59.

Starting with nexus between Patent Owner’s Synergy, Infinity, and Versa HD systems and independent claim 1,²¹ Patent Owner relies on the testimony and analysis of Dr. Hashemi. Ex. 2080 ¶¶ 222–248. Petitioner asserts that Patent Owner’s nexus is flawed, because the aforementioned systems include many unclaimed features, and can be used in ways that do not have relevance to the limitations of independent claim 1. Pet. Reply 20–21. As noted above, we discern that this assertion goes to weight, and not nexus. Accordingly, after reviewing Patent Owner’s assertions, as well as the relevant analysis of Dr. Hashemi, we find that Patent Owner’s Synergy, Infinity, and Versa HD systems each meet all the limitations of, and, thus, have a nexus with, independent claim 1.

With nexus addressed, we next turn to the relevant evidence, beginning with Exhibit 2048. Petitioner’s above assertion concerning additional features is relevant to the amount of weight to be accorded Exhibit 2048 concerning the commercial success of Patent Owner’s Synergy, Infinity, and Versa HD systems. To that end, we agree with

²¹ Independent claims 7, 20, and 26 recite substantially similar limitations, and, therefore, we apply our analysis to all of the independent claims.

Petitioner that the weight to be accorded Exhibit 2048 should be discounted somewhat in that regard. More specifically, we agree that in a machine as complex as Patent Owner's systems, commercial success would have been driven by many features and considerations, of which the features coextensive with independent claim 1 would certainly have been a factor, however, absent further elaboration by Patent Owner, we also discern that it could not have been the only factor driving commercial success.

Relatedly, we discern that Patent Owner's evidence should be further discounted because Patent Owner admits that only 85% of their linear accelerators installed in the United States include CBCT capability, indicating that 15% do not have a nexus with independent claim 1.

Ex. 2048, WBH_Elekta_01153–54. Indeed, we note that Patent Owner's Declarant, Mr. Jaime Gonzalez, admits further that “[t]he linear accelerators that *can be* equipped with these XVI systems include the Synergy, Infinity, Axesse and Versa HD linear accelerators.” Ex. 2048, WBH_Elekta_01145 (emphasis added). Without further analysis that the aforementioned systems *were* equipped with CBCT capability, we discount further Patent Owner's evidence in that regard, although the amount discounted is somewhat mitigated by Patent Owner's assertion, with which we are in agreement, that in order to show commercial success, “you don't have to have a product that completely supplants the market by a hundred percent. You just have to show that the product was commercially successful. And it certainly was here because the majority worldwide and almost all of them in North America were sold with this functionality.” Tr. 43:8–14.

Finally, we additionally discount Exhibit 2048 because Patent Owner includes in the 85% their Axesse system. Ex. 2048, WBH_Elekta_01153.

As set forth above, Mr. Gonzalez purports that Patent Owner’s Axesse linear accelerator can also be equipped with CBCT capability. This is the first mention of the relevance of Patent Owner’s Axesse system, and neither Patent Owner nor Dr. Hashemi indicates that they compared the Axesse system to independent claim 1. *See generally* PO Resp. 59; Ex. 2080 ¶¶ 244–248. Nevertheless, Patent Owner appears to have included the Axesse system in the 85%. Accordingly, Patent Owner’s aforementioned evidence is further discounted for this reason.

Petitioner asserts further that “the sales data is insufficient because Patent Owner has provided no evidence establishing the importance of these sales in the relevant market.” Pet. Reply 21. We agree with Petitioner that Exhibit 2048 should be discounted heavily for those reasons.

Along similar lines, turning next to Exhibit 2083, Petitioner asserts that Patent Owner’s licensing evidence should be discounted heavily for the following reasons:

The license in question admittedly relates to three separate patents, only one of which is at issue in this case, and no contextual evidence is provided to explain why the license was taken or to tie any aspect of it to the claims. Concerns about this lack of context, and the knowledge that licenses may be taken for many reasons unrelated to patentability is why “the mere existence” of licenses, “without more specific information about the circumstances surrounding the licensing, is often not a good indicator of nonobviousness.” *See Cisco [Sys., Inc. v. Crossroads Sys., Inc., IPR2014-01463, Paper 49 at 36 (PTAB Mar. 16, 2016)]*.

Pet. Reply 21–22. Again, we are in agreement with Petitioner for these reasons.

In summary, for the reasons set forth above, we discount almost entirely the weight to be accorded Exhibit 2048, and discount heavily the

weight to be accorded Exhibit 2083. Accordingly, after considering all of Patent Owner’s assertions and evidence in the aggregate, in view of Petitioner’s assertions, we find that Patent Owner has provided very weak evidence of commercial success of their Synergy, Infinity, and Versa HD systems.

b. Petitioner’s On-Board Imager and Clinac/Trilogy Linear Accelerators

Patent Owner asserts the following concerning the commercial success of Petitioner’s On-Board Imager and Clinac/Trilogy linear accelerators:

Petitioner Varian’s Clinac and Trilogy lines of linear accelerators equipped with a CBCT-FPI system (the “On-Board Imager”) have likewise been commercially successful. As Dr. Bani-Hashemi notes, these linear accelerators meet the limitations of the independent Challenged Claims. (Ex. 2080 ¶¶ 250–258). Petitioner publicized that after the first installation in 2005, demand for its On-Board Imager was “overwhelming” and “exceeded . . . expectations.” (*Id.* ¶ 259). In fact, order volume for Varian’s On-Board Imager grew by more than 70 percent from 2005 to 2006, a rate of adoption three times greater than Varian experienced with its prior product lines. (*Id.* ¶¶ 261–263). By 2007, over 70% of [Petitioner’s] linear accelerators sold were equipped with a CBCT-FPI system. (*Id.* ¶ 264). . . . The commercial successes of Varian’s On-Board Imager and TrueBeam systems are attributable to the claimed features of the ’765 patent. (*Id.* ¶¶ 265, 272, 283–284).

PO Resp. 59–60. For nexus, for the same reasons set forth above in addressing industry praise, we find that subsequent to November 3, 2004,

the aforementioned products did meet, and, thus, had a nexus with, independent claim 1.²²

With that in mind, Patent Owner first identifies, through Dr. Hashemi's Declaration, Exhibit 2051, which is a press release dated August 1, 2005, and entitled "Varian Medical Systems Reports Rapid Adoption of On-Board Imager™ Device for Image-Guided Radiotherapy." PO Resp. 59–60 (citing Ex. 2080 ¶ 259 (discussing Ex. 2051)). In Exhibit 2051, Patent Owner identifies two disclosures as supporting their assertion concerning the commercial success of Petitioner's aforementioned products:

Varian Medical Systems today announced that it is experiencing robust demand for its Image Guided Radiation Therapy (IGRT) products. The company reports that it has now installed or commenced installation of more than 80 of its new On-Board Imager™ devices, a technology that enhances treatment precision.

Ex. 2051, WBH_Elekta_01157

"It's clear that radiation oncology is rapidly embracing IGRT as a crucial aid to enhancing the accuracy, effectiveness and reach of radiotherapy We have seen this new imaging technology take off very quickly. . . . The first On-Board Imager was installed at Sweden's Karolinska Institute in Stockholm a year ago, and since then there has been an overwhelming demand that has exceeded our expectations."

Ex. 2051, WBH_Elekta_01157 (quotation from Petitioner's Chief Operating Officer). Petitioner asserts that Patent Owner has failed to show nexus between the commercial success of the aforementioned products and independent claim 1. Pet. Reply 22. We largely agree with Petitioner.

²² Independent claims 7, 20, and 26 recite substantially similar limitations, and, therefore, we apply our analysis to all of the independent claims.

Exhibit 2051 is dated August 1, 2005, and as set forth above, we find that the aforementioned products sold after November 3, 2004 had a nexus with independent claim 1. Accordingly, at an initial glance, the products referenced in Exhibit 2051 would appear to have a nexus with independent claim 1. On closer inspection, however, Exhibit 2051 refers to **installed** On-Board Imager Devices, and that “[t]he first On-Board Imager was installed at Sweden’s Karolinska Institute in Stockholm *a year ago.*” Ex. 2051, WBH_Elekta_01157 (emphasis added). Both quotations refer to past systems, and given that the August 1, 2005 date of Exhibit 2051 is not so far removed from November 3, 2004, we discern that it was necessary for Patent Owner to provide some explanation as to how many of the aforementioned products were installed on or after November 3, 2004. Absent such an explanation by Patent Owner, we agree with Petitioner that it is unclear how many of the aforementioned products were installed prior to November 3, 2004, and, thus, would not have a nexus with independent claim 1. For these reasons, we discount heavily the weight to be accorded Exhibit 2051 in support of Patent Owner’s assertions, and, accordingly, find that Exhibit 2051 is weak evidence of the commercial success of Petitioner’s aforementioned products.

Patent Owner next identifies Exhibit 2052 in support of its assertion. PO Resp. 56, 59–60 (citing Ex. 2080 ¶ 260 (discussing Ex. 2052)). Exhibit 2052 is entitled “VARIAN 05: Varian Medical Systems 2005 Annual Report,” and accounts for data during Fiscal Year 2005, which Exhibit 2052 discloses as running from October 1, 2004 to September 30, 2005. Ex. 2052, WBH_Elekta_01167, WBH_Elekta_01195. In Exhibit 2052,

Patent Owner identifies the following disclosure as supporting their assertion concerning the commercial success of Petitioner's aforementioned products:

A new process, known as image-guided radiation therapy (IGRT), has been hailed as a technological breakthrough. We have led the field in practical implementation of this technology with more than 275 orders and 110 shipments of automated, robotically controlled On-Board Imager devices for IGRT since their introduction in fiscal 2004. . . . By the end of fiscal 2005, Varian had received more than 275 orders for On-Board Imager™ devices for either Clinac® or Trilogy™ accelerators.

Ex. 2052, WBH_Elekta_01164, WBH_Elekta_01168. Petitioner asserts that Patent Owner has failed to show a nexus between the commercial success of the aforementioned products and independent claim 1. Pet. Reply 22. For similar reasons set forth above with respect to Exhibit 2051, we largely agree with Petitioner. In short, the relevant order and shipment numbers from Exhibit 2052 include products ordered/shipped in fiscal year 2004, of which none would have had a nexus with independent claim 1, and at least a part of fiscal year 2005 is prior to November 3, 2004, and, thus, at least some of the products ordered/shipped in fiscal year 2005 do not have a nexus with independent claim 1. For these reasons, we discount heavily the weight to be accorded Exhibit 2052 in support of Patent Owner's assertions, and, accordingly, find that Exhibit 2052 is also weak evidence of the commercial success of Petitioner's aforementioned products.

Patent Owner also identifies Exhibit 2053, which is a press release dated July 27, 2006, and entitled "Varian Medical Systems Reports Rapid Adoption of the Company's Technology for Image-Guided Radiotherapy." PO Resp. 59–60 (citing Ex. 2080 ¶ 261 (discussing Ex. 2053)). In Exhibit 2053, Patent Owner identifies the following disclosure as supporting their

assertion concerning the commercial success of Petitioner's aforementioned products:

“We are seeing tremendous demand for our image-guided radiotherapy machines with the On-Board Imager—both at freestanding clinics as well as at hospitals and large academic centers IGRT is clearly moving into the medical mainstream. Because the On-Board Imager yields two-dimensional images, 3-D cone-beam CT images, and fluoroscopic moving images, it’s the most versatile IGRT tool available and doctors have been capitalizing on all of those capabilities to enhance the quality of patient care.”

Ex. 2053, WBH_Elekta_01191 (quoting Petitioner's President and CEO).

Petitioner asserts that Patent Owner has failed to show a nexus between the commercial success of the aforementioned products and independent claim

1. Pet. Reply 22. We disagree. Unlike Exhibits 2051 and 2052, Exhibit 2053 is dated well after November 3, 2004, and, indeed, even mentions expressly “3-D cone-beam CT images.” Thus, we find that Exhibit 2053 has a nexus with independent claim 1.

Petitioner asserts that the weight accorded to Exhibit 2053 should be discounted because “Patent Owner’s expert . . . incorrectly assumed that the Clinac+OBI product had full rotation CBCT capability when it was launched” (Ex. 1502, 166:25–167:3). Pet. Reply 22. We agree that the weight should be discounted somewhat for these reasons. Accordingly, we find that Exhibit 2053 is some evidence of the commercial success of Petitioner's aforementioned products.

Patent Owner further identifies Exhibit 2054 in support of its assertion. PO Resp. 59–60 (citing Ex. 2080 ¶¶ 262–263 (discussing Ex. 2054)). Exhibit 2054 is entitled “Varian Medical Systems 2006 Annual Report,” and accounts for data during Fiscal Year 2006, which we found

above encompasses a time period well after November 3, 2004. Ex. 2054, WBH_Elekta_01194. Patent Owner identifies the following disclosures as supporting their assertion concerning the commercial success of Petitioner's aforementioned products:

This X-ray imaging accessory for improving the precision and effectiveness of treatments was included in more than 60 percent of the orders we received during the year for our high-energy Clinac® and Trilogy® linear accelerators.

Ex. 2054, WBH_Elekta_01198.

IGRT adoption is occurring three times faster than what we experienced with the introduction of our highly successful products for intensity-modulated radiation therapy (IMRT) earlier this decade.

Ex. 2054, WBH_Elekta_01198.

Order volume for the powerful and ultraprecise Trilogy linear accelerator for both radiotherapy and radiosurgery grew by more than 70 percent to more than 85 units.

Ex. 2054, WBH_Elekta_01201. Petitioner asserts that Patent Owner has failed to show a nexus between the commercial success of the aforementioned products and independent claim 1. Pet. Reply 22. We disagree. Unlike Exhibits 2051 and 2052, Exhibit 2054 is dated well after November 3, 2004. Thus, we find that Exhibit 2054 has a nexus with independent claim 1.

Petitioner asserts tangentially that the weight accorded to Exhibit 2054 should be discounted because "because of a lack of nexus." Pet. Reply 20–21. We agree that the weight should be discounted slightly for these reasons. Accordingly, we find that Exhibit 2054 is moderately strong evidence of the commercial success of Petitioner's aforementioned products.

Patent Owner additionally identifies Exhibit 2055 in support of its assertion. PO Resp. 60 (citing Ex. 2080 ¶ 264 (discussing Ex. 2055)). Exhibit 2055 is a Form 10K Annual Report for Varian Medical Systems, Inc. submitted on November 26, 2007. Ex. 2055, WBH_Elekta_01214, WBH_Elekta_01348. Patent Owner identifies the following disclosures as supporting their assertion concerning the commercial success of Petitioner's aforementioned products:

We are seeing customers accept IGRT as the next significant enhancement in curative radiation therapy, and demand for our products for IGRT has been one of the main contributors to net orders and revenue growth in our Oncology Systems business segment.

Ex. 2055, WBH_Elekta_01231.

Nearly all of our high energy accelerators ordered in North America and over 70% of high energy accelerators ordered worldwide during fiscal year 2007 were ordered with our On-Board Imager product, or OBI, which enables IGRT.

Ex. 2055, WBH_Elekta_01257. Petitioner asserts that Patent Owner has failed to show a nexus between the commercial success of the aforementioned products and independent claim 1. Pet. Reply 22. We disagree. Unlike Exhibits 2051 and 2052, Exhibit 2055 is dated well after November 3, 2004. Thus, we find that Exhibit 2055 has a nexus with independent claim 1.

Petitioner asserts tangentially that the weight accorded to Exhibit 2055 should be discounted because “because of a lack of nexus.” Pet. Reply 20. We agree that the weight should be discounted slightly for these reasons. Accordingly, we find that Exhibit 2055 is moderately strong evidence of the commercial success of Petitioner’s aforementioned products.

In summary, for the reasons set forth above, we discount heavily the weight to be accorded Exhibits 2051 and 2052, discount moderately the weight to be accorded Exhibit 2053, and discount slightly the weight to be accorded Exhibits 2054 and 2055. Accordingly, after considering all of Patent Owner's assertions and evidence in the aggregate, in view of Petitioner's assertions, we find that Patent Owner has provided moderately strong evidence of commercial success of Petitioner's aforementioned products.

c. Petitioner's TrueBeam Linear Accelerator

Patent Owner asserts the following concerning the commercial success of Petitioner's TrueBeam linear accelerators:

Varian experienced similar "overwhelmingly positive" customer response to its TrueBeam linear accelerator, the introduction of which Varian described as, among other superlatives, "the most successful launch of a medical linear accelerator" in its history. (*Id.* ¶¶ 273–283). As Dr. Bani-Hashemi explains, Varian's TrueBeam linear accelerator also meets the limitations of the independent Challenged Claims. (*Id.* ¶¶ 266–272). The commercial successes of Varian's On-Board Imager and TrueBeam systems are attributable to the claimed features of the '765 patent. (*Id.* ¶¶ 262, 272, 283–284).

PO Resp. 60.

For nexus, Patent Owner asserts that the aforementioned combination of Petitioner's products meets every limitation of independent claim 1.

PO Resp. 60 (citing Ex. 2080 ¶¶ 266–283). Petitioner disagrees, asserting the following:

Patent Owner's attempt to encircle Varian's TrueBeam product within its nonobviousness arguments also fails. First, TrueBeam is a highly complex product with many unique features (none of which are germane to the limitations of the challenged claims) that are not present on Clinac+OBI. (See Ex.

1500, ¶ 82.) Second, Patent Owner is mistaken when it again assumes that all uses of the TrueBeam imaging system are pertinent to the limitations of the claims. To the contrary, as with Clinac+OBI, Patent Owner’s evidence shows that TrueBeam imaging includes “kV planar” and “fluoroscopic imaging” modes that have no nexus to any limitation of the claims. (*See* Ex. 2056 at WBH_Elekta_01359.)

Pet. Reply 22–23. We discern that Petitioner’s assertions are relevant to the weight to be accorded the evidence of commercial success, and not nexus. Based on the above, we find that Patent Owner has shown the Petitioner’s TrueBeam linear accelerator includes every limitation of, and, thus, has a nexus with, independent claim 1.

Having said that, we acknowledge that Patent Owner references Exhibits 2061–2070 at paragraphs 273–282 of Dr. Hashemi’s Declaration. We further acknowledge that page 60 of the Patent Owner Response references paragraphs 273–282 of Dr. Hashemi’s Declaration, as follows: “Varian experienced similar ‘overwhelmingly positive’ customer response to its TrueBeam linear accelerator, the introduction of which Varian described as, among other superlatives, ‘the most successful launch of a medical linear accelerator’ in its history. (*Id.* ¶¶ 273–283).” Thus, it would appear that based on this one line of argument in the Patent Owner Response, Patent Owner would like the Board to consider and evaluate in detail, with no further guidance in the Patent Owner Response, the disclosures of Exhibits 2061–2070 as it relates to their above assertion. We decline to do so, as we determine that this represents an impermissible attempt by Patent Owner to circumvent the page limits for this proceeding by incorporating, by reference, substantive arguments concerning Exhibits 2061–2070, and paragraphs 273–283 of Dr. Hashemi’s Declaration, that should have been set

forth in the Patent Owner Response. *See* 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”) Thus, we determine that for these reasons, Patent Owner has, effectively, not advanced any evidence to support their assertions concerning the commercial success of Petitioner’s TrueBeam linear accelerator.

For these reasons, we find that Patent Owner has provided no evidence of commercial success of Petitioner’s aforementioned product.

d. Industry-Wide Commercial Success

Patent Owner asserts the following:

Given the widespread clinical adoption of using a CBCT-FPI system for image-guided radiation therapy, it is no surprise that Elekta’s Versa HD and Varian’s TrueBeam linear accelerators all come equipped with these imaging systems, which were once add-ons. Even Dr. Balter acknowledged that, since the introduction of the ’765 patent, an integrated CBCT-FPI system has become a standard feature on most linear accelerators. (Ex. 2011 at 148:10–17, 149:15–150:9; Ex. 2080 ¶ 221). Accordingly, the industry-wide commercial success of linear accelerators equipped with CBCT-FPI systems weighs heavily in favor of nonobviousness. *See Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) (“Our case law provides that the success of an infringing product is considered to be evidence of the commercial success of the claimed invention.”).

PO Resp. 60–61.²³ In particular, we find particularly relevant Dr. Balter’s cross-examination testimony as follows:

²³ As set forth above, we find that Patent Owner’s Versa HD and Petitioner’s TrueBeam linear accelerators account for each limitation of, and thus, have a nexus with, independent claim 1. *See* PO Resp. 59–60 (citing Ex. 2080 ¶¶ 222–248, 273–283).

Q. And has the introduction of those products --

A. Uh-huh.

Q. -- had a substantial impact on the field of radiation therapy?

MR. KNAUSS: Objection. Form. Foundation.

THE WITNESS: So I would say that – that in-room volumetric, in-room three-dimensional, in-room monitoring, all the advances in imaging have had a dramatic impact on the field.

Q. (BY MR. ROSENTHAL) Okay. And one of those advances was the introduction of on-board CBCT with flat-panel imaging by Varian and Elekta in the mid-2000s; correct?

MR. KNAUSS: Object to the form.

THE WITNESS: One of those advances was the commercial introduction of cone-beam CT on a linear accelerator.

Ex. 2011, 149:15–150:9. Petitioner asserts tangentially that the weight accorded to evidence of industry-wide commercial success should be discounted because “it contains several other unclaimed features,” such as the “in-room monitoring” mentioned here by Dr. Balter. Pet. Reply 20–21. We agree that the weight should be discounted slightly for these reasons. Accordingly, we find that Exhibit 2011 is moderately strong evidence of the industry-wide commercial success of the claimed invention.

e. Conclusion

In summary, we find that Patent Owner has provided (1) very weak evidence of commercial success of their Synergy, Infinity, and Versa HD systems, (2) moderately strong evidence of commercial success of Petitioner’s OBI and Clinac/Trilogy linear accelerator, (3) no evidence of

commercial success of Petitioner’s TrueBeam linear accelerator, and (4) moderately strong evidence of the industry-wide commercial success of the claimed invention, with particularly strong weight given to the aforementioned portions of Exhibits 2011, 2054, and 2055. When weighed in the aggregate, we find that Patent Owner has proffered moderately strong evidence of commercial success of, and, hence, non-obviousness of, the invention set forth in independent claim 1. As discussed above, independent claims 7, 20, and 26 recite substantially the similar limitation and, therefore, our analysis applies to these claims as well.

v. *Copying*

a. *Thilmann*

Patent Owner asserts that Thilmann copied Jaffray 2002 as follows:

Thilmann and co-workers (Exs. 2034, 2035) modified a Siemens linear accelerator to incorporate a CBCT-FPI system for verification of tumor position while the patient is on the treatment table. (Ex. 2080 ¶¶ 205–207). Thilmann’s linear accelerator meets each and every limitation of at least the independent Challenged Claims. (*Id.* ¶¶ 208–212). Thilmann praised “the acquisition of cone beam computed tomograph[y] at the linac with the patient in treatment position” as “[o]ne of the most prominent imaging techniques in image guided radiotherapy.” (Ex. 2035 at 62, Abstract; Ex. 2080 ¶¶ 213–214).

PO Resp. 61.²⁴ For nexus, Patent Owner asserts that the aforementioned combination of Petitioner’s products meets every limitation of independent claim 1. PO Resp. 61 (citing Ex. 2080 ¶¶ 208–212). Petitioner disagrees, asserting that Thilmann did not attribute their work to the copying of the

²⁴ As set forth above, we find that Jaffray 2002 accounts for each limitation of, and thus, has a nexus with, independent claim 1. See PO Resp. 54–55 (citing Ex. 2080 ¶¶ 195–200).

'765 invention. Pet. Reply 23. We discern that Petitioner's assertions are relevant to the weight to be accorded the evidence of copying, and not to nexus. Based on the above, we find that Patent Owner has shown that the system created by Thilmann includes every limitation of, and, thus, has a nexus with, independent claim 1.

Petitioner asserts that the weight accorded to Exhibits 2034 and 2035 in support of Patent Owner's assertions of copying should be discounted because Thilmann did not expressly attribute their work to the copying of the '765 invention. Pet. Reply 23–24. We disagree. We find that Exhibit 2035 expressly cites Jaffray 2002 in support of the following disclosure: “[f]or the radiation source, . . . as all common linac vendors presently propose[,] one can integrate an additional kilovoltage (kV)-x-ray source with the linac’s gantry.” Ex. 2035, WBH_Elekta_00829. We discern that citation of a concept is very strong circumstantial evidence of copying of that concept.²⁵

b. Petitioner's Patent Applications

Patent Owner asserts that Petitioner's pursuit of their own “patent protection on a radiation therapy system that mimics the '765 patent,” presumably Jaffray 2002, is evidence of copying. PO Resp. 61–62 (citing Ex. 2014, 31:10–32:22; Ex. 2080 ¶¶ 77, 215–220). As an initial matter, we are unclear as to the relevance of Petitioner's statements concerning non-obviousness and praise of their own invention in the context of copying.

²⁵ Petitioner does cite the cross-examination testimony of Dr. Hashemi as purportedly casting doubt on this assertion. Pet. Reply 23 (citing Ex. 1502, 159:10-19, 160:8-161:22). We note, however, that none of the testimony refers to the citation.

Moreover, Petitioner replies that Patent Owner has not provided any evidence as to how exactly Petitioner copied Jaffray 2002, other than arguing that the content of Petitioner’s patent application meets the limitations of independent claim 1, which itself is not sufficient to showing copying. *See Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (“[C]opying requires evidence of efforts to replicate a specific product.”) Additionally, Petitioner provides further evidence that the work on the content of Petitioner’s patent applications predicated, and, thus, could not have copied, Jaffray 2002. Pet. Reply 23–24 (citing Ex. 1500 ¶ 84; Ex. 1512, 103–118; Ex. 1513; Ex. 1514). We agree with Petitioner on all accounts.

c. Conclusion

In summary, we find that Patent Owner has provided (1) very strong circumstantial evidence of copying by Thilmann, and (2) no evidence of copying by Petitioner. When weighed in the aggregate, we find that Patent Owner has proffered moderately strong evidence of copying of, and, hence, non-obviousness of, the invention set forth in independent claim 1. As discussed above, independent claims 7, 20, and 26 recite substantially the similar limitation, and, therefore, our analysis applies to these claims as well.

vi. Overall Weighing of Relevant Factors Concerning Obviousness, Including Secondary Considerations

We now weigh Patent Owner’s evidence of secondary consideration in conjunction with the other factors relevant to obviousness for independent claim 1. In summary, we find, for the reasons set forth above, that Adler/Depp accounts for all of the limitations of independent claim 1, with the exception of 3D cone-beam computed tomography. For that, we find that it would have been within the abilities and knowledge of one of ordinary

skill in the art, at the time of the claimed invention, to modify the radiotherapy systems of Adler/Depp to include the 3D cone-beam computed tomography system of Cho, Antonuk, and Jaffray 1997 in order to, among several reasons, improve the quality and accuracy of Adler/Depp's imaging during radiotherapy. *See* Pet. 46–50; *accord* PO Resp. 21–22 ("[T]he ground raised in the Petition should be limited to the combination of the radiotherapy systems of Adler/Depp as the primary reference modified to include a CBCT-FPI system allegedly disclosed in the combination of Cho, Antonuk, and Jaffray 1997.") We find further that Petitioner has identified sufficient evidence, in the cited prior art, that the modification itself, as well as the rationale for the modification, were well known to one of ordinary skill in the art, at the time of the invention.

Against the above findings, we weigh the Patent Owner's evidence of secondary considerations, each of which we have analyzed above, and summarize as follows: (1) very strong evidence of industry praise; (2) very strong evidence of long-felt need; (3) moderately strong evidence of commercial success; and (4) moderately strong evidence of copying.

Overall, upon weighing the factors, we determine that the very strong evidence of each of industry praise and long-felt need, as well as the moderately strong evidence of each of commercial success and copying, outweigh our finding that the radiotherapy systems of Adler/Depp, as modified to include the 3D cone-beam computed tomography system of Cho, Antonuk, and Jaffray 1997, account for every limitation of independent claim 1. In particular, we find that the evidence of secondary considerations is in agreement with the key advance in technology being the exact modification of Adler/Depp, in view of Cho, Antonuk, and Jaffray 1997, as

advanced by Petitioner. The Exhibits we find especially compelling are as follows: 2012, 2015, 2071, and 2072. The Exhibits we find moderately favorable to Patent Owner are as follows: 2034, 2035, 2054, and 2055. As discussed above, independent claims 7, 20, and 26 recite substantially the similar limitation and, therefore, our analysis applies to these claims as well. Furthermore, as claims 2–6, 8–13, 21–25, and 27–31 each depend ultimately from independent claims 1, 6, 20, and 26, we determine that a similar weighing for each of claims 2–6, 8–13, 21–25, and 27–31 results in the same conclusion.

Accordingly, for these reasons, we determine that Petitioner has not met its burden of showing that claims 1–13 and 20–31 are obvious in view of the combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp, for the reasons discussed above.

9. Conclusion

For the foregoing reasons, we are unpersuaded that Petitioner has shown, by a preponderance of the evidence, that claims 1–13 and 20–31 are obvious in view of the combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp.

E. Patent Owner’s Motion to Exclude

Patent Owner requests that “Exhibits 1114–1128, 1130, 1133, and 1135 (‘Exhibits’) and Paragraphs 115–143 of Exhibit 1102 (‘Balter Testimony’) be excluded and expunged from the record” because they are “irrelevant to the ground on which this proceeding was instituted” and “the exhibits have not been cited by either Party.” PO Mot. 1. Petitioner responds that Exhibits 1112–1138 were cited, albeit in a cursory manner, at

pages 3–4 of the Petition (Pet. Opp. 1), and that the Board has, effectively, already excluded the referenced Exhibits and testimony as follows:

This interpretation is also consistent with the Board’s determination in its Institution Decision that the exhibits in question should not be relied upon to “‘fill in’ any ‘gap’ in the Petition.” (See Paper 14 at 23.) Thus, in this case Patent Owner already obtained adequate relief for its concerns regarding the supposedly “extraneous” Exhibits and Balter Testimony by virtue of the Institution Decision. As Patent Owner acknowledged in its motion, Petitioner complied with the Board’s directive did not rely on this evidence in its Reply papers. (See Paper 48 at 2.)

Pet. Opp. 2. Patent Owner replies that retaining the Exhibits and testimony leaves open the possibility that Petitioner may attempt to rely on them during appeal. PO Reply 2–3.

Patent Owner’s Motion is *denied*. Petitioner does refer to the referenced Exhibits, however, briefly, in the Petition, and so retaining the papers would assist the public, however minimally, in better understanding the record. Furthermore, this Decision does not rely on portions of those Exhibits or testimony, and we determine expressly that it is improper for Petitioner to rely on those Exhibits and testimony, because, other than the cursory mention, their relevance was not explained adequately with respect to any ground of unpatentability in the Petition. Additionally, that Petitioner may use such Exhibits and testimony on appeal is speculative. Finally, as this Decision determined that the evidence of secondary considerations outweighed the other factors of obviousness, and these Exhibits and testimony would, at best, be of use only to potentially bolster Petitioner’s positions on those other factors on which Petitioner already prevailed, we do

not discern sufficient prejudice to Patent Owner to justify exclusion and expungement.

F. Petitioner's Allegedly Improper New Arguments and Evidence in Reply

We have considered Patent Owner's listing (Paper 50) and Petitioner's responsive listing (Paper 58) on this issue. Patent Owner's assertions are moot, because our Decision does not rely on those portions of the Reply and Dr. Balter's Supplemental Declaration.

G. Papers Under Seal

This Final Written Decision discusses or cites information in papers that are subject to a Protective Order. For those papers, the Parties should follow the guidance related to 37 C.F.R. § 42.56. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,761 (Aug. 14, 2012).

III. CONCLUSION

Petitioner has not demonstrated, by a preponderance of the evidence, that claims 1–13 and 20–31 of the '765 patent are unpatentable. Patent Owner's Motion to Exclude is *denied*.

IV. ORDER

In consideration of the foregoing, it is hereby:
ORDERED that claims 1–13 and 20–31 of the '765 patent are not held unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude is *denied*; and

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

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