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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VARIAN MEDICAL SYSTEMS, INC. and ELEKTA, INC.,
Petitioners,

v.

BEST MEDICAL INTERNATIONAL, INC.,
Patent Owner.

IPR2020-00072[1]
U.S. Patent No. 6,393,096

PATENT OWNER'S NOTICE OF APPEAL

[1] IPR2020-00970 has been joined with this proceeding.

Pursuant to 35 U.S.C. §§ 141(c), 142, and 319 and 37 C.F.R. §§ 90.2(a) and 90.3, Patent Owner, Best Medical International, Inc. ("Patent Owner") hereby provides notice that it appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision entered April 23, 2021 (Paper 71) and from all underlying orders, decisions, rulings, and opinions regarding U.S. Patent No. 6,393,096 ("the '096 patent") decided adversely or potentially adversely to Patent Owner set forth in Inter Partes Review No. IPR2020-00072.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), the issues on appeal are anticipated to include, but are not limited to:

- The Board's finding that challenged claims 43, 44, and 46 of the '096 patent are unpatentable under 35 U.S.C. § 103;
- The Board's determination of an ordinary skilled artisan;
- The Board's finding that it would discount Mr. Chase's testimony related to system development in its obviousness analysis; and
- Any Board finding decided adversely to Patent Owner unsupported by substantial evidence.

Patent Owner further reserves the right to challenge any finding or determination supporting or relating to the issues above, and to challenge other issues decided adversely to Patent Owner in any order, decision, ruling, or opinion underlying or supporting the Final Written Decision.

A copy of the decision being appealed is attached to this Notice.

This Notice of Appeal is timely filed pursuant to 37 C.F.R. § 90.3, as it is filed within sixty-three (63) days after the final decision of the Board, the same of which was issued on April 23, 2021.

Pursuant to 35 U.S.C. § 142 and 37 C.F.R. § 90.2(a), this Notice is being filed with the Director of the United States Patent and Trademark Office, and a copy of this Notice is being concurrently filed with the Patent Trial and Appeal Board. In addition, a copy of this Notice and the required docketing fees are being filed with the Clerk's Office for the United States Court of Appeals for the Federal Circuit via CM/ECF.

Respectfully submitted,

THE WEBB LAW FIRM

Dated: June 25, 2021

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Patent Trial and Appeal Board

CERTIFICATE OF SERVICE

I hereby certify that on the 25th day of June, 2021, I electronically filed the foregoing **PATENT OWNER'S NOTICE OF APPEAL** with the PTAB E2E which sent notification to all counsel of record. A true and correct copy of same was also served on opposing counsel, via email, to the following:

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Paper 71
Entered: April 23, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VARIAN MEDICAL SYSTEMS, INC. and ELEKTA INC.,
Petitioner,

v.

BEST MEDICAL INTERNATIONAL, INC.,
Patent Owner.

IPR2020-00072[1]
Patent 6,393,096 B1

Before KARL D. EASTHOM, JOHN A. HUDALLA, and AVELYN M. ROSS, *Administrative Patent Judges*.

HUDALLA, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying-in-Part and Dismissing-in-Part Petitioner's Motion to Exclude
35 U.S.C. § 318(a); 37 C.F.R. § 42.64

[1] Petitioner from IPR2020-00970 has joined this proceeding.

Varian Medical Systems, Inc. ("Varian") filed a Petition (Paper 3,[2] "Pet.") requesting an *inter partes* review of claims 43, 44, and 46 of U.S. Patent No. 6,393,096 B1 (Ex. 1001, "the '096 patent"). Patent Owner, Best Medical International, Inc. ("Patent Owner"), filed a Preliminary Response (Paper 7, "Prelim. Resp."). Varian also filed a Preliminary Reply (Paper 9), and Patent Owner filed a Preliminary Sur-reply (Paper 10). Taking into account the arguments presented in these papers, we determined that the information presented in the Petition established that there was a reasonable likelihood that Varian would prevail with respect to its unpatentability challenges. Pursuant to 35 U.S.C. § 314, we instituted this proceeding on May 1, 2020, as to all challenged claims and all grounds of unpatentability. Paper 15 ("Dec. on Inst.").

Elekta Inc. ("Elekta") subsequently filed a similar petition and motion for joinder in IPR2020-00970. *See* IPR2020-00970, Papers 2, 3. We instituted an *inter partes* review and joined Elekta as a party to this proceeding in a limited capacity. *See* IPR2020-00970, Paper 8. Henceforth, we refer collectively to Varian and Elekta as "Petitioner."

During the course of trial, Patent Owner filed a Patent Owner Response (Papers 34,[3] 35,[4] "PO Resp."), and Petitioner filed a Reply to the Patent Owner Response (Paper 46, "Pet. Reply"). Patent Owner also filed a Sur-reply. Paper 53 ("PO Sur-reply"). An oral hearing was held on

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[2] Petitioner appears to have filed the same petition twice as Papers 2 and 3. We refer to the version at Paper 3.

[3] This paper was sealed in accordance with the Protective Order entered in this case. *See* Paper 33, Attach. A (copy of protective order); Paper 44 (entering protective order).

[4] This paper is the public version.

January 28, 2021, and a transcript of the hearing is included in the record. Paper 69 ("Tr.").

Petitioner filed declarations of Kenneth P. Gall, Ph.D. with its Petition (Ex. 1002) and its Reply (Ex. 1043). Petitioner also filed declarations of Sylvia Hall-Ellis, Ph.D. (Ex. 1003) and Christopher Butler (Ex. 1004) with its Petition. Patent Owner filed declarations of Daniel J. Chase with its Preliminary Response (Ex. 2002) and with its Response (Ex. 2037). Patent Owner also filed declarations of Dr. Mark P. Carol (Ex. 2044), Merle E. Romesberg III (Ex. 2048[5]), and Thomas Rowden (Ex. 2049) with its Response. The parties also filed transcripts of the depositions of Dr. Gall (Ex. 2038), Mr. Chase (Exs. 1044, 1045), Dr. Carol (Ex. 1046), Mr. Rowden (Ex. 1047), and Mr. Romesberg (Exs. 1048,[6] 1049, 1050[7]).

Petitioner filed a motion to exclude certain testimony from Mr. Chase and Mr. Romesberg. Paper 57 ("Exclude Mot."). Patent Owner filed an opposition (Paper 59, "Exclude Opp."), and Petitioner filed a reply (Paper 63, "Exclude Reply").

We have jurisdiction under 35 U.S.C. § 6. This decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of claims 43, 44, and 46 of the '096 patent. For the reasons discussed below, Petitioner has demonstrated by a preponderance of the evidence that claims 43, 44, and 46 of the '096 patent are unpatentable.

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[5] The record includes sealed and public versions of this exhibit in accordance with the protective order in this case.

[6] This exhibit is the public version of the transcript at Exhibit 1050.

[7] This exhibit was sealed in accordance with the Protective Order entered in this case.

I. BACKGROUND

A. Real Parties-in-Interest

Varian identifies Varian Medical Systems, Inc., VMS International AG, VMS International Holdings, Inc., VMS Netherlands Holdings, Inc., and VMS Nederland BV as real parties-in-interest. Pet. 3. Elekta identifies Elekta Limited (UK), Elekta Holdings U.S., Inc., and Elekta AB as real parties-in-interest. IPR2020-00970, Paper 2, 3. Patent Owner identifies Best Medical International, Inc. as the real party-in-interest. Paper 4, 1.

B. Related Proceedings

The parties identify the following proceedings related to the '096 patent (Pet. 3–4; Paper 3, 1–2; IPR2020-00970, Paper 2, 3–4):

Best Med. Int'l, Inc. v. Elekta Inc., No. 1:19-cv-03409-MLB (N.D. Ga.);

Best Med. Int'l, Inc. v. Elekta AB, No. 1:18-cv-01600-MN (D. Del.);

Best Med. Int'l, Inc. v. Varian Med. Sys., Inc., No. 1:18-cv-01599 (D. Del.); and

Varian Med. Sys., Inc. v. Best Med. Int'l, Inc., IPR2020-00071, which challenges claims 1 and 18 of the '096 patent. We issue a final written decision in IPR2020-00071 concurrently herewith.

We also note that another petitioner filed a petition requesting an *inter partes* review of the '096 patent in IPR2020-00074. We denied institution in that case.

Furthermore, the parties belatedly notified us of a pending *ex parte* reexamination of claims 1, 3–8, 18, 21–24, and 37–42 of the '096 patent in

Reexamination Control No. 90/014,424. Paper 66, 2; Paper 68, 1; Ex. 1051[8] (reexamination request); Ex. 1052 (order and decision granting request).

We additionally note that Petitioner challenged other patents owned by Patent Owner in IPR2020-00053, IPR2020-00075, IPR2020-00076, and IPR2020-00077. We denied institution in all of these cases except for IPR2020-00076, for which we recently issued a final written decision.

C. The '096 patent

The '096 patent is directed to "determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of [another] structure volume in a patient." Ex. 1001, Abstr. Optimized treatment plans are created using a computational method (such as simulated annealing radiotherapy planning (SARP)) based on an objective cost function that attributes costs of radiation of various portions of both the tumor and surrounding tissues/structures. *Id.* at 3:17–22, 5:3–10. Nevertheless, the '096 patent alleges that the cost functions in then-existing methods relied merely on costs related to discrete points within the structure, and did not account for the structure volumes as a whole or for the relative importance of varying surrounding structure types. *Id.* at 3:25–29. Further, the '096 patent alleges that then-existing methods did not allow physicians to utilize Cumulative Dose Volume Histogram (CDVH) curves in establishing desired dose distributions. *Id.* at 3:48–51.

The '096 patent describes a treatment planning system that accounts for multiple treatment parameters for both a target and multiple surrounding

[8] The record contains two different exhibits numbered Exhibit 1051. The cited exhibit is the second such exhibit that was filed on January 29, 2021.

structure types. Ex. 1001, 5:54–56. The system arrives at an optimal beam arrangement "by computationally increasing the proposed beam weight iteratively [and] incorporating cost functions to ensure that an iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose." *Id.* at 5:39–44. The system includes a modified cost function that allows a physician to use conventional CDVHs to establish a desired dose for both the target volume and each involved structure; the CDVHs are used as input for the treatment planning system. *Id.* at 5:57–64.

Figures 3 and 4 of the '096 patent are reproduced below.

FIG. 3

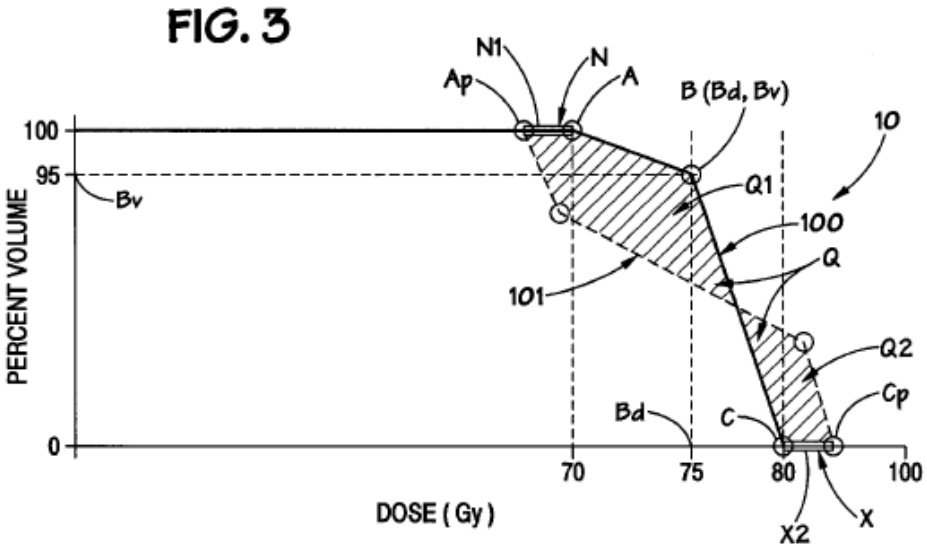
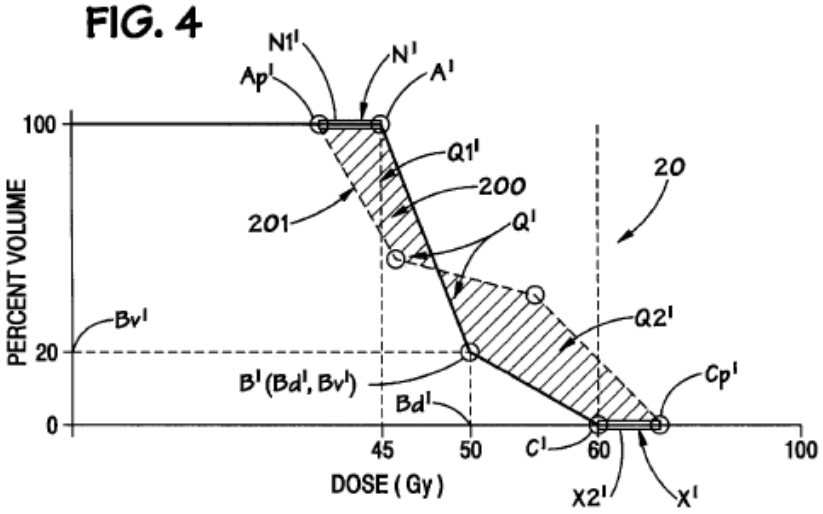


FIG. 4



Figures 3 and 4 show composite CDVH curves 10, 20, respectively. *Id.* at 8:64–65. In Figure 3, composite CDVH curve 10 includes desired target CDVH curve 100 and proposed CDVH target curve 101, the latter of which reflects the effect of a prescription proposed by the system during a given iteration of plan optimization. *Id.* at 6:40–44, 8:60–64. In Figure 4, composite CDVH curve 20 includes desired structure CDVH curve 200[9] and proposed CDVH structure curve 201, the latter of which again reflects the effect of a prescription proposed by the system during a given iteration of plan optimization. *Id.* Certain control points or regions N, N′, Q, Q′, X, and X′ of composite CDVH curves 10, 20 may be identified as being more important for a particular type of target or structure. *Id.* at 8:67–9:3. Each control point or control region value is used as an input variable to a parameterized influence function for each target or structure. *Id.* at 10:40–44. The resultant values from the influence function calculation for each control point or control region value are summed to produce a final cost of

[9] In Figure 4, the callout arrow for reference numeral 200 appears displaced slightly from the CDVH curve it references (which is a solid line).

the proposed beam weights reflected by proposed CDVH curve 101, 201 during a given iteration. *Id.* at 10:44–50.

The '096 patent issued from an application that was filed May 27, 1999, which claims priority to a provisional application filed on May 27, 1998. Ex. 1001, codes (22), (60). As discussed below, Petitioner attempts to establish that, at a minimum, its asserted references qualify as prior art relative to the May 27, 1998, filing date of the provisional application. *See* Pet. 26.

D. Illustrative Claim

Of the challenged claims, claim 43 is independent. Claims 44 and 46 depend from claim 43. Claim 43 is illustrative of the challenged claims and recites:

> 43. A method of determining an optimized radiation beam arrangement for applying radiation to at least one tumor target volume while minimizing radiation to at least one structure volume in a patient, comprising the steps of:
>
> distinguishing each of the at least one tumor target volume and each of the at least one structure volume by target or structure type;
>
> determining desired partial volume data for each of the at least one target volume and structure volume associated with a desired dose prescription;
>
> entering the desired partial volume data into a computer;
>
> providing a user with a range of values to indicate the importance of objects to be irradiated;
>
> providing the user with a range of conformality control factors; and

using the computer to computationally calculate an optimized radiation beam arrangement.

Ex. 1001, 21:19–22:13.

E. Prior Art

Petitioner relies on the following prior art:

Peacock™: A System for Planning and Rotational Delivery of Intensity-Modulated Fields," *International Journal of Imaging Systems and Technology* 56–61 (Spring 1995) (Ex. 1006, "Carol-1995");

Curran, B.H., *Chapter 5 – Conformal Radiation Therapy Using a Multileaf Intensity Modulating Collimator*, The Theory & Practice of Intensity Modulated Radiation Therapy 75–90 (1997) (Ex. 1007, "Curran-5");

Viggars D.A., et al., "The Objective Evaluation of Alternative Treatment Plans III: The Quantitative Analysis of Dose Volume Histograms," *International Journal of Radiation Oncology • Biology • Physics*, 23:419–27 (1992) (Ex. 1015, "Viggars");

Carol, M.P., *Chapter 2 – IMRT: Where We Are Today*, The Theory & Practice of Intensity Modulated Radiation Therapy 17–36 (1997) (Ex. 1020, "Carol-2");

Carol, M.P., *Chapter 17 – Where We Go From Here: One Person's Vision*, The Theory & Practice of Intensity Modulated Radiation Therapy 243–52 (1997) (Ex. 1021, "Carol-17").

F. The Instituted Grounds

We instituted *inter partes* review of claims 43, 44, and 46 of the '096 patent on the following grounds (Dec. on Inst. 33), which are all the grounds presented in the Petition (Pet. 6–7):

Claims Challenged	35 U.S.C. §	References
43, 44, 46	103(a)[10]	Carol-1995, Viggars
43, 44, 46	103(a)	Curran-5, Carol-2
43, 44, 46	103(a)	Curran-5, Carol-17

II. ANALYSIS

A. Legal Standards

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations.[11] *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We also recognize that prior art references must be "considered together with the knowledge of one of ordinary skill in the pertinent art." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (quoting *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)).

[10] The Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103. Because the '096 patent was filed before March 16, 2013 (the effective date of the relevant amendment), the pre-AIA version of § 103 applies.

[11] The record does not contain any evidence of secondary considerations of nonobviousness.

B. Level of Ordinary Skill in the Art

The level of ordinary skill in the art is "a prism or lens through which . . . the Board views the prior art and claimed invention" to prevent hindsight bias. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). In determining the level of ordinary skill, various factors may be considered, including the "types of problems encountered in the art; prior art solutions to those problems; rapidity with which innovation are made; sophistication of the technology; and educational level of active workers in the field." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (internal quotation and citation omitted). Generally, it is easier to establish obviousness under a higher level of ordinary skill in the art. *Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011) ("A less sophisticated level of skill generally favors a determination of nonobviousness . . . while a higher level of skill favors the reverse.").

Citing testimony from Dr. Gall, Petitioner contends a person having ordinary skill in the art (POSA) would have been "a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field," and would have had "two or more years of experience in radiation oncology physics, treatment planning, treatment plan optimization related to radiation oncology applications, and computer programming associated with treatment plan optimization." Pet. 20 (citing Ex. 1002 ¶¶ 15–17). Patent Owner cites testimony from Mr. Chase and contends an ordinarily skilled artisan would have "earned at least a master's or doctoral degree in radiation dosimetry, physics, medical physics, or medicine, or equivalent disciplines" and would have had "three years of clinical experience in radiation treatment planning." PO Resp. 12 (citing Ex. 2037 ¶¶ 81–82); *see also* Prelim.

Resp. 21 (same definition). For purposes of our Decision on Institution, we adopted Patent Owner's definition. Dec. on Inst. 9.

The parties' proposed definitions do not differ greatly as to the level and type of formal education, and the parties have not raised any dispute related to formal education. Thus, as to that aspect, we continue to apply Patent Owner's articulation that a person of ordinary skill in the art would have "earned at least a master's or doctoral degree in radiation dosimetry, physics, medical physics, or medicine, or equivalent disciplines." *See* PO Resp. 12.

Nevertheless, the parties have put forth great effort disputing the type of experience that an ordinarily skilled artisan would have possessed.[12] Specifically, Petitioner criticizes Patent Owner's definition insofar as "Patent Owner's purported POSA is unable to design and write the computer programming necessary to understand and implement the teachings of the '096 patent and asserted prior art." Pet. Reply 2 (citing Ex. 1043 ¶¶ 5–10). Petitioner also argues that Patent Owner's definition would result in "a POSA [who] did not [have] the knowledge or skill to be able to *make* the inventions disclosed and claimed in the '096 patent." *Id.* at 3–4 (citing Ex. 1044, 40:18–22, 46:13–18, 59:19–60:3; Ex. 1045, 9:1–10:5, 10:7–17, 10:21–11:3).

Citing testimony from Mr. Chase, Patent Owner draws a distinction regarding Petitioner's requirement for computer programming experience

[12] We note that the parties' definitions do not differ meaningfully as to the number of years' experience that would have been possessed by an ordinarily skilled artisan, i.e., "two or more" for Petitioner versus "three" for Patent Owner. As mentioned below, we apply two years of experience.

between "the use and manipulation of programs by users" and "the writing of the underlying software code by the system designer and author of such programs." PO Sur-reply 1–2 (citing Ex. 2002 ¶¶ 67–68). Patent Owner also notes that the challenged claims are method claims directed to optimization planning, and, as such, do not require software programming. *Id.* at 2–3 (citing Ex. 1001, 21:19–21).

At the outset, we note that in determining the level of ordinary skill in the art, we consider the inventions of the '096 patent as a whole, and not just inventions related to individual claims. *See Hologic, Inc. v. Minerva Surgical, Inc.*, 764 F. App'x 873, 879 (Fed. Cir. 2019) (considering broader teachings in a challenged patent's specification, and not just the more narrowly drawn claims, when evaluating the Board's determination of a level of ordinary skill). At the oral hearing, Patent Owner's counsel acknowledged that this was the proper approach. Tr. 61:8–63:11. Thus, we do not agree with Patent Owner's attempt (PO Sur-reply 2–3) to limit the level of ordinary skill based on the fact that the challenged claims here are method claims. We instead consider the totality of the '096 patent disclosure when determining the level of ordinary skill.

The '096 patent "relates to a method and apparatus for conformal radiation therapy of tumors with a radiation beam having a pre-determined, constant beam intensity." Ex. 1001, 1:10–12. The disclosed methods and apparatus are based on known SARP methods, where "[t]he optimal beam arrangement is arrived at by computationally increasing the proposed beam weight iteratively, incorporating cost functions to ensure that an iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed

dose." *Id.* at 5:39–44; *see also id.* at 8:37–39 ("A SARP technique is utilized to do this optimization"). According to the specification of the '096 patent,

> [t]he system of the present invention includes . . . a modified cost function, which allows a physician to use conventional cumulative dose volume histographs ("CDVH"s) to establish a desired prescription of dosage to both the target volume, or target, and each involved structure volume, or structure, which will then be used as input for the system for determining the proposed dose distribution for delivery to a patient. The optimization method may be carried out using conventional equipment, including a conventional linear accelerator ("LINAC") 300, as shown in FIG. 1, having a rotatable gantry, a conventional computer or set of computers, and plan optimization software, which utilizes the optimization method of the present invention.

Id. at 5:54–6:2. Therefore, the '096 patent describes a different way of optimizing a treatment plan for use with "conventional" radiation therapy equipment. The main difference from the prior art is the modified cost function that is used.

The specification goes on to describe the cost function with respect to "Plan Optimization step 803" of Figure 2. The mathematical formulas for two exemplary cost/influence functions (INF_1 and INF_2) are provided at column 10, line 51 through column 11, line 39. According to the specification,

> [a] value is calculated for each control point value . . . of each CDVH curve of each target and structure according to the influence function INF_1 or INF_2. The total cost for the proposed dose represented by the proposed CDVH curve may then be obtained by summing each value of INF_1 or INF_2 for each control point value of each CDVH curve of each target and structure.

Ex. 1001, 11:40–47. As such, the modified cost functions are based on CDVH curve conformity, which is different from the prior art, but they are applied iteratively just as in prior art SARP methods. *See id.* at 5:39–53.

The specification also describes exemplary computer hardware for implementing the disclosed invention:

> A suitable computer is utilized in performing the Plan Optimization step 802 [sic, 803] (FIG. 2), as well as the other steps of the radiation planning system. For illustration purposes only, a programmable 150 Mhz pentium computer with four symmetric multiprocessors, running the Sun Solaris operating system, and having 256 megabytes RAM could be utilized in performing the Plan Optimization step 802 [sic, 803] (FIG. 2).

Ex. 1001, 8:52–59.

As indicated by the specification of the '096 patent, the disclosed invention is implemented with computers and involves iterative calculations of cost functions, just like prior art SARP methods. *See* Ex. 1001, 3:17–22 ("Existing methods and apparatus utilize a computational method of establishing optimized treatment plans based on an objective cost function that attributes costs of radiation of various portions of both the tumor and surrounding tissues, or structures. One such computational method is known in the art as simulated annealing."). This supports Petitioner's contention that a person of ordinary skill in the art would have had experience in programming computers in the context of treatment plan optimization. *See* Pet. 20. This type of experience is consistent with implementing different cost functions using SARP techniques.

In contrast, Patent Owner's proposed type of experience—"clinical experience in radiation treatment planning" (PO Resp. 12)—does not reflect the type of skills necessary to implement different types of cost functions in

an iterative SARP-based plan optimization system. We are not aware of any record evidence that a clinician in 1998 would have been able to program different types of cost functions in a treatment planning system. And, even if certain clinicians might have possessed these skills at the time, we find Petitioner's proposed level of experience to better reflect the relevant skills necessary to implement various cost functions in a treatment planning system, thereby changing the way a system iteratively computes costs as part of an optimization method. For this reason, we reject Patent Owner's proposed type of experience and adopt Petitioner's formulation: two years of experience in radiation oncology physics, treatment planning, treatment plan optimization related to radiation oncology applications, and computer programming associated with treatment plan optimization.

We additionally reject Patent Owner's and Mr. Chase's suggestion that "computer programming" as used in Petitioner's proposed level of ordinary skill "could refer to . . . the use and manipulation of programs by users, including medical physicists such as [Mr. Chase]." PO Sur-reply 1 (citing Ex. 2002 ¶¶ 67–68); *see also* Exclude Opp. 3–4 (same argument). Mere use and manipulation of existing treatment planning system programs is not the same as programming such systems in the first instance. In making this determination, we have considered certain instances in the '096 patent specification where the word "program" describes the entry of data into existing treatment planning systems by a clinician. *See* Ex. 1001, 1:35–43, 13:30–35 (both using the word "program" in the sense of a clinician using existing systems). Although the specification sometimes uses the word "program" in the sense that a clinician enters a desired radiation prescription or selects influence parameters in an existing system

(*see id.*), our articulation of ordinary skill is meant to reflect "*formal* computer programming, *i.e.*, designing and writing underlying computer code" (*see* Ex. 2002 ¶ 67), as would have been necessary to implement different cost functions in an iterative optimization method.

For these reasons, and based on the entire trial record, we determine that an ordinarily skilled artisan (1) would have earned at least a master's or doctoral degree in radiation dosimetry, physics, medical physics, or medicine, or equivalent disciplines, and (2) would have had two years of experience in radiation oncology physics, treatment planning, treatment plan optimization related to radiation oncology applications, and computer programming associated with treatment plan optimization.

C. Claim Interpretation

In an *inter partes* review, we construe each claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b) (2019). Accordingly, our claim construction standard is the same as that of a district court. *See id.* Under the standard applied by district courts, claim terms are generally given their plain and ordinary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the

specification or during prosecution." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

1. "Computer to Computationally Calculate" Limitation

Petitioner contends that the limitation "the computer to computationally calculate an optimized radiation beam arrangement" in claim 43 should be construed as a means-plus-function limitation under pre-AIA 35 U.S.C. § 112 ¶ 6. Pet. 21–26. Petitioner contends an ordinarily skilled artisan would not have understood this term to have a sufficiently definite meaning as a name for structure. *Id.* at 22–23 (citing Ex. 1002 ¶¶ 60–64); *see also* Pet. Reply 8 (same argument).

Patent Owner disputes that treatment under § 112 ¶ 6 should apply. PO Resp. 14; *see also* Prelim. Resp. 22–23, 25. In its Preliminary Response, Patent Owner argued that the lack of the words "means for" in this limitation creates a rebuttable presumption that § 112 ¶ 6 does not apply. Prelim. Resp. 23 (citing *Phillips*, 415 F.3d at 1310). Patent Owner also contended that an ordinarily skilled artisan would have readily understood what a computer is. *Id.* at 25 (citing Ex. 2002 ¶ 73); *see also* Pet. 26 (Petitioner's alternate position that its grounds sufficiently identify the recited computer). In its Response, Patent Owner notes that the district court in the underlying litigation did not treat these limitations under § 112 ¶ 6. PO Resp. 14 (citing Ex. 2045, 1–2).

In our Decision on Institution, we agreed with Patent Owner's reasoning that § 112 ¶ 6 does not apply to this limitation. Dec. on Inst. 10–11. The parties' positions have not changed since the time of institution, and we discern no reason to change our initial construction. Therefore, we apply

the plain and ordinary meaning to these limitations, and we do not apply § 112 ¶ 6.

2. Other Terms

We determine that no other terms require explicit construction. *See, e.g.*, *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy' . . . ." (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

D. Mr. Chase's Testimony and Petitioner's Motion to Exclude Portions of Mr. Chase's Declaration

Patent Owner puts forth a declaration of Mr. Chase as an expert witness in the field of the '096 patent. *See* Ex. 2037. Petitioner moves to exclude paragraphs 178, 181, 184, 191, 192, 194, and 196 of Mr. Chase's declaration (*id.*) under Federal Rule of Evidence 702 "because Mr. Chase is unqualified to render opinions directed to subject matter beyond his limited expertise in the use of commercially available treatment planning systems." Exclude Mot. 1. Petitioner further contends that Mr. Chase lacks "specialized knowledge or experience on the design and development of treatment planning systems and/or software as required by Fed. R. Evid. 702." *Id.* at 2 (internal quotation omitted).

Petitioner argues that, "[i]n a patent case, a witness is only permitted to testify as an expert on issues of noninfringement or invalidity if 'qualified as an expert in the ***pertinent art***.'" Exclude Mot. 3 (quoting *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008)).

According to Petitioner, a witness who does not qualify as an ordinarily skilled artisan may not testify on obviousness, including whether there is a motivation to combine references. *Id.* at 3–4 (citing *Sundance*, 550 F.3d at 1364). Petitioner purports to define the "relevant art" under *Sundance* as not being "limited to a clinical application," but as "extend[ing] more broadly to treatment planning system design in the field of conformal radiation therapy." *Id.* at 4 (citing Ex. 1001, 1:10–12, 9:6, 11:54, 13:11–25). By this standard, Petitioner contends that "Mr. Chase is unversed in this specific subject matter of the '096 patent." *Id.* at 5. Petitioner also contends that we should exclude Mr. Chase's opinions "with respect to the design and development of treatment planning systems and/or software" because he "cannot implement the teachings of the '096 patent or asserted prior art, and he asserted that *extraordinary skill* is required to implement the teachings of the '096 patent." *Id.* at 5–6 & n.5 (citing Ex. 1044, 33:12–20). Petitioner further notes that Mr. Chase is not a person of ordinary skill under Petitioner's proposed level of ordinary skill in the art, though Petitioner contends we need not resolve this issue in order to grant Petitioner's motion. *Id.* at 3 n.4.

Patent Owner contends that there is an "adequate relationship" between Mr. Chase's experience and the claimed inventions disclosed in the '096 patent. Exclude Opp. 8 (quoting *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010); *see also id.* at 7–8 (discussing Mr. Chase's experience as a medical physicist with "extensive clinical experience including extensive work with linear accelerators ('LINACs'), treatment planning systems and their associated software," among other

things). Patent Owner also argues that an expert witness's expertise need not be coextensive with the scope of the patent. *Id.* at 6 (citing Board cases).

As stated above, the '096 patent relates to a method and apparatus for conformal radiation therapy of tumors. Ex. 1001, 1:10–12. We agree with Patent Owner (Exclude Opp. 7–8) that Mr. Chase's background in nuclear engineering and experience with treatment planning systems is adequately related to the disclosed methods and apparatus for conformal radiation therapy of tumors in the '096 patent. *See SEB*, 594 F.3d at 1373; Ex. 2037 ¶¶ 7–12. In addition, Mr. Chase is not required to have the exact experience in our adopted definition of the level of ordinary skill, namely "computer programming associated with treatment plan optimization." *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide 34 (Nov. 2019) ("Consolidated Trial Practice Guide"), *available at* https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf ("There is . . . no requirement of a perfect match between the expert's experience and the relevant field."); *see also Mytee Prods., Inc. v. Harris Research, Inc.*, 439 F. App'x 882, 886–87 (Fed. Cir. 2011) (nonprecedential) (upholding admission of the testimony of an expert who "had experience relevant to the field of the invention," despite admission that he was not a person of ordinary skill in the art). Thus, Mr. Chase is qualified to provide expert testimony in this proceeding under Federal Rule of Evidence 702.

We also note that the Board acts as both the gatekeeper and the weigher of evidence. Similar to a district court in a bench trial, the Board, sitting as a non-jury tribunal with administrative expertise, is well positioned to determine and assign appropriate weight to evidence presented, including giving it no weight. *See, e.g.*, *Donnelly Garment Co. v. NLRB*, 123 F.2d

215, 224 (8th Cir. 1941) ("One who is capable of ruling accurately upon the admissibility of evidence is equally capable of sifting it accurately after it has been received . . . ."). For these reasons, we *deny* Petitioner's motion to exclude paragraphs 178, 181, 184, 191, 192, 194, and 196 of Mr. Chase's declaration. Rather than excluding evidence that is allegedly confusing, misleading, unsupported, and/or irrelevant, we will simply not rely on it or give it little or no probative weight, as appropriate, in our analysis.

Despite our denial of Petitioner's motion to exclude with respect to Mr. Chase, we consider the facts underlying Petitioner's motion to be significant in our weighing of Mr. Chase's testimony vis-à-vis the testimony of Petitioner's declarant Dr. Gall. According to Mr. Chase, a person of ordinary skill in the art would have been a mere clinician who would not have been able to design and write computer code to calculate an optimized radiation beam arrangement as recited in claim 43. Ex. 1044, 46:13–18; Ex. 2037 ¶ 81; *see also* Ex. 1044, 59:24–60:3 (Mr. Chase testifying that a person of ordinary skill in the art would not have been able to make the radiation planning system that is described in the flowchart at Figure 2 of the '096 patent). Moreover, Mr. Chase testified that a person of ordinary skill in the art would not have known how to write code that calculated a CDVH from a dose distribution. Ex. 1044, 46:21–49:10. In fact, Mr. Chase testified that the people making and developing the systems claimed and disclosed in the '096 patent would have had *extraordinary* skill in the art. *Id.* at 33:12–20. Mr. Chase likewise testified that the authors of Viggars exhibited extraordinary skill in integrating a treatment planning system with a CDVH-based evaluation program. *Id.* at 66:16–67:2. Yet it strains credulity to say that an ordinarily artisan working in the art of the

'096 patent could not have developed methods and systems like those disclosed in the '096 patent itself.

Importantly, Mr. Chase acknowledged that he is not an expert in the field of designing and developing treatment planning systems. Ex. 1044, 59:10–13, 67:18–68:5. Mr. Chase's analysis also is distorted insofar as he bases his opinions on the perspective of an artisan who had familiarity only with commercial systems and not with "homemade systems," i.e., those being researched and developed in the art. *See* Ex. 1045, 21:25–24:4. This perspective does not square with the notion that the '096 patent allegedly advanced the existing art. Ex. 1001, 3:53–4:9 (noting that "the art ha[d] sought a method and apparatus for conformal radiation therapy . . . which utilizes CDVH curves in establishing the desired dose distributions for each target tumor volume and tissue and structure types" and that no such method or apparatus had existed before the '096 patent). In addition, the asserted prior art is not necessarily limited to commercial methods and systems. *See, e.g.*, Ex. 1015, 420, 422–23 (Viggars describing scoring functions for evaluating dose-volume histograms that were developed for the OSCAR computer program, which was integrated with "conventional software"); *see also* Ex. 1019, 249–50 (Oldham, a reference asserted against the '096 patent in companion case IPR2020-00071, describing the development of cost functions for use in a radiotherapy treatment plan optimization algorithm). This indicates that an ordinarily skilled artisan would not have been confined to commercialized systems as suggested by Mr. Chase. For these reasons, we discount Mr. Chase's testimony related to system development in our obviousness analysis below.

E. Obviousness Ground Based on Carol-1995 and Viggars

Petitioner contends the subject matter of claims 43, 44, and 46 would have been obvious over the combination of Carol-1995 and Viggars. Pet. 27–41; Pet. Reply 8–20. Patent Owner disputes Petitioner's contentions. PO Resp. 18–46; PO Sur-reply 5–13.

1. Carol-1995

Carol-1995 is a paper pertaining to "[t]he Peacock three-Dimensional Conformal System[, which] plans for and implements, through the use of a multileaf intensity modulating collimator . . . , conformal treatment plans in a slice-by-slice fashion." Ex. 1006, 56. "The parameters driving beam modulation and field shaping are generated by a three-dimensional planning computer using a simulated annealing algorithm guided by cost functions which quantify prescribed treatment constraints." *Id.*

The Peacock system determines a set of beam weights that will deliver only the prescribed dose to the identified target volume while keeping the dose to avoidance volumes and sensitive volumes below user-defined limits. Ex. 1006, 57. The value of the cost function is calculated at each iteration and is minimized by adjusting the beam transmittance. *Id.* at 58. The relative values of "WeightI" (target weight) and "WeightJ" (structure weights) emphasize or deemphasize the contribution of each target and structure to the total cost. *Id.*

The user has direct control over a treatment "aggressiveness" constraint, which "influences the relative importance of delivering the prescribed dose to the complete target versus sparing avoidance and sensitive structures (relative values of 'WeightI' and 'WeightJ')." Ex. 1006,

58. The user also has direct control over a "treatment time" constraint, which influences the amount of time the patient spends on the treatment table per treatment. *Id.*

Petitioner contends Carol-1995 qualifies as prior art under 35 U.S.C. § 102(b). Pet. 27. Patent Owner does not contest the prior art status of Carol-1995.

In our Decision on Institution, we noted that the journal in which Carol-1995 appears (*International Journal of Imaging Systems and Technology*) is dated Spring 1995, and it includes a 1995 copyright date. Dec. on Inst. 12 (citing Ex. 1006, 1–3). We further noted that the journal includes a stamp from the University of Michigan Engineering Library that is dated August 4, 1995. *Id.* (citing Ex. 1006, 3). We also cited Dr. Gall's testimony that this journal is a "well-known and long-standing scientific journal[] in the field of radiotherapy." *Id.* (citing Ex. 1002 ¶ 69). In light of these indicators of publication in 1995, we determined at that stage that Carol-1995 qualified as prior art under 35 U.S.C. § 102(b). *Id.* at 12–13. Since the time of institution, neither party has put forth further arguments about the prior art status of Carol-1995, so we perceive no reason to change our determination from that stage. Accordingly, we determine that Carol-1995 qualifies as prior art under 35 U.S.C. § 102(b) because Carol-1995's publication date in 1995, is more than one year before the earliest possible effective filing date of the challenged claims, which is May 27, 1998. Ex. 1001, code (60); Ex. 1006, 1–3.

2. Viggars

Viggars is a paper directed to the OSCAR computer program, which "evaluates dose-volume histograms in a consistent way for use in 3-dimensional treatment planning." Ex. 1015, 419. Viggars states that "[d]ose volume histograms (DVH) are a convenient way of summarizing the information in a 3-dimensional dose distribution." *Id.* The aim of Viggars is to use DVHs to compare and evaluate alternative plans objectively and consistently such that DVHs may be used in defining and ensuring adherence to a treatment protocol. *Id.*

According to Viggars, the quality of a proposed treatment plan may be judged by how far its cumulative dose volume histogram (CDVH) departs from the ideal histograms, and a dose prescription can be defined by specifying the maximum acceptable deviations from the ideal shape. Ex. 1015, 420. Such deviations are referred to as "regret." *Id.* A set of score functions may be used to compare the actual deviations of a plan from the ideal CDVH with the maximum deviations allowed by the dose prescription. *Id.* at 422.

"For each dose volume limit [D_i,R_i(max)] in the prescription, the score function is derived from a ratio r_i," which is defined in the equation reproduced below. Ex. 1015, 422.

$$r_i = R_i(D_i)/R_i(\max)$$

This ratio r_i is then used in a score function S_i, which is reproduced below. *Id.* at 423.

$$S_i = 10[1 - r_i]$$

This score function S_i results in "10 for an ideal distribution, zero at the limit of acceptability, and [a] negative [value] when the dose-volume limit is

violated." *Id.* An optimal plan could, in principle, be selected by assigning weights to each score to derive an overall objective function. *Id.* at 425.

Petitioner contends Viggars qualifies as prior art under 35 U.S.C. § 102(b). Pet. 27. Patent Owner does not contest the prior art status of Viggars.

In support of Viggars's status as prior art, Petitioner includes testimony from Sylvia Hall-Ellis, Ph.D., a professor with experience in the field of library science. Ex. 1003 ¶¶ 6–8. She testifies that Viggars "was publicly accessible as early as June 10, 1992, and in any event, more than one year before the May 27, 1998 priority date," based on a record of Viggars in the University of California San Diego. Ex. 1003 ¶¶ 54–59. The journal in which Viggars appears (*International Journal of Radiation Oncology · Biology · Physics*) is dated 1992, and it includes a 1992 copyright date. Ex. 1015, 1–3. The journal also includes a sticker from the University of California San Diego that states "Received on: 06-10-92." *Id.* at 1. Dr. Gall additionally testifies that this journal is a "well-known and long-standing scientific journal[] in the field of radiotherapy." Ex. 1002 ¶ 69.

In our Decision on Institution, we credited Dr. Hall-Ellis's testimony regarding public accessibility and various indicators of publication appearing on the front matter of the journal in which Viggars appears. Dec. on Inst. 14. Thus, at that stage, we determined that Viggars qualified as prior art under 35 U.S.C. § 102(b). *Id.* at 14–15. Since the time of institution, neither party has put forth further arguments about the prior art status of Viggars, so we perceive no reason to change our determination from that stage. Accordingly, we determine that Viggars qualifies as prior art under 35 U.S.C. § 102(b) because Viggars's publication date in 1992 is

more than one year before the earliest possible effective filing date of the challenged claims, which is May 27, 1998. Ex. 1001, code (60); Ex. 1003 ¶¶ 54–59; Ex. 1015, 1–3.

3. Claim 43

a. Preamble and Claim Limitations

The preamble of claim 43 recites "[a] method of determining an optimized radiation beam arrangement for applying radiation to at least one tumor target volume while minimizing radiation to at least one structure volume in a patient, comprising the steps of[.]" Ex. 1001, 21:19–22. Petitioner cites Carol-1995's teaching of "conformal therapy—delivering a high dose of radiation in a spatial distribution conforming to the shape of the target volume while concomitantly decreasing the volume of the surrounding normal tissue receiving that same dose." Pet. 34 (quoting Ex. 1006, 56). Petitioner also contends Carol-1995's "Peacock" system plans and implements conformal treatment plans generated by a simulated annealing algorithm. *Id.* at 34–35 (citing Ex. 1006, 56).

Patent Owner does not dispute Petitioner's analysis of the preamble of claim 43. Neither party addresses whether the preamble is limiting. Because Petitioner has shown that Carol-1995 teaches the preamble, we need not determine whether the preamble is limiting. *See Nidec*, 868 F.3d at 1017.

Claim 43 further recites "distinguishing each of the at least one tumor target volume and each of the at least one structure volume by target or structure type." Ex. 1001, 21:23–25. Petitioner cites Carol-1995's identified target volume and avoidance/sensitive volumes. Pet. 35 (citing

Ex. 1006, 57). Petitioner also cites Carol-1995's cost function, which weights costs for each structure and target. *Id.* Petitioner additionally cites Viggars's Table 1, which shows a dose prescription for target, sensitive organs, and non-target tissue. *Id.* (citing Ex. 1015, 421). Patent Owner does not dispute Petitioner's analysis for the "distinguishing" limitation. We are persuaded that Carol-1995's identified target volume and avoidance/ sensitive volumes teach distinguishing between "target structure" and "structure volume." *See, e.g.*, Ex. 1006, 57. Viggars's Table 1 also teaches dose prescriptions based on whether something is a target or structure. *See, e.g.*, Ex. 1015, 421. Therefore, the combination of Carol-1995 and Viggars teaches the "distinguishing" limitation.

Claim 43 further recites "determining desired partial volume data for each of the at least one target volume and structure volume associated with a desired dose prescription." Ex. 1001, 22:1–3. Petitioner cites Viggars's "dose prescription that uses 'maximum partial target volume' and dose-volume limits for organs." Pet. 36 (citing Ex. 1015, 420). Petitioner also notes that Viggars's dose prescriptions in Table 1 are expressed as a percentage of target or structure volume. *Id.* (citing Ex. 1015, 421). Patent Owner does not dispute Petitioner's analysis for the "determining" limitation. We are persuaded that Viggars teaches the "determining" step via Table 1, which lists dose prescriptions (in the form of desired partial volume data) based on whether something is a target or structure. *See, e.g.*, Ex. 1015, 421.

Claim 43 further recites "entering the desired partial volume data into a computer." Ex. 1001, 22:4. Petitioner contends Viggars's dose prescription "is a form of partial volume data and can also be used as part of

the definition of a treatment protocol." Pet. 36 (citing Ex. 1015, 420) (internal quotation omitted). In light of this teaching, Petitioner contends

> [i]t would have been . . . obvious to one of ordinary skill in the art that the partial volume data in Viggars' dose prescription would have to be entered into the computer running the OSCAR program since the program relies on the entered dose prescription to perform the functions of quantitatively scoring a treatment plan and generating images and histograms of regret.

Id. at 36–37 (citing Ex. 1002 ¶ 89[13]). Patent Owner does not dispute Petitioner's analysis for the "entering" limitation. We are persuaded that, based on Viggars's teachings, an ordinarily skilled artisan would have known to enter partial volume data from a dose prescription into the OSCAR evaluation program. *See* Ex. 1002 ¶ 89; Ex. 1015, 420. Thus, Petitioner establishes that Viggars teaches the "entering" limitation.

Claim 43 further recites "providing a user with a range of values to indicate the importance of objects to be irradiated" ("first 'providing' limitation"). Ex. 1001, 22:6–7. Petitioner cites Carol-1995's teaching of a cost function that "defines cost as the sum of weighted costs for each structure and target," wherein "[t]he relative values of WeightI (target weight) and WeightJ (structure weights) emphasize or deemphasize the contribution of each target and structure to the total cost." Pet. 37 (citing Ex. 1006, 57–58) (internal quotations and emphasis omitted). Petitioner further cites the user's control over an "aggressiveness" constraint described in Carol-1995, which "influences the relative importance of delivering the prescribed dose to the complete target versus sparing avoidance and

[13] Petitioner mistakenly cites to paragraph 9, but the context makes clear Petitioner intended to cite to paragraph 89.

sensitive structures (relative values of WeightI and WeightJ)." *Id.* at 37 (citing Ex. 1006, 58) (internal quotations and emphases omitted). Petitioner notes that Carol-1995 also discloses a user interface for inputting data. *Id.* at 38 (citing Ex. 1006, 60). In light of these teachings, Petitioner contends an ordinarily skilled artisan "would have recognized . . . that control over 'aggressiveness' is based on . . . relative values of WeightI/WeightJ" and it would have been obvious for the artisan to "provide the user with a range of 'aggressiveness' values to select from." *Id.* (citing Ex. 1002 ¶ 91). Petitioner further argues that the relative values of WeightI and WeightJ favor the target over sensitive structures or vice versa, so an ordinarily skilled artisan would have "found it obvious that a range of relative values for WeightI and WeightJ could be provided to the user to indicate the importance of objects to be irradiated." *Id.* (citing Ex. 1002 ¶ 92).

Patent Owner argues that "Carol-1995 does not provide a specific and precise explanation or disclosure of how a user provides . . . 'direct control' over 'aggressiveness' in relation to relative values of ['']WeightI' and 'WeightJ' to arrive at" the first "providing" limitation. PO Resp. 29 (citing Ex. 2037 ¶ 162). In support of its argument, Patent Owner cites testimony from Dr. Gall in which he acknowledges "Carol-1995 does not describe[] precisely how the user is provided with 'direct control' over the 'aggressiveness' based on the relative values of WeightI and WeightJ." *Id.* (quoting Ex. 1002 ¶ 91).

We do not agree with Patent Owner's arguments. On cross-examination, Mr. Chase agreed with the premises of Petitioner's contentions for the first "providing" limitation: (1) that aggressiveness is the relative weight in a cost function given to a target term versus a structure term

(Ex. 1045, 25:16–26:1); and (2) that the user controlled relative weights in the Peacock system (*id.* at 26:17–22). This testimony supports Petitioner's assertion that an ordinarily skilled artisan would have known to use Carol-1995's user interface (*see* Ex. 1006, 60) to input a range of a range of relative values for WeightI and WeightJ (*see id.* at 57–58) to control aggressiveness. Pet. 37–38 (citing Ex. 1002 ¶¶ 91–92). Based on Petitioner's analysis, we are persuaded that the combination of Carol-1995 and Viggars teaches the first "providing" limitation.

Claim 43 further recites "providing the user with a range of conformality control factors" ("second 'providing' limitation"). Ex. 1001, 22:8–9. Petitioner cites Carol-1995's teaching that "[t]reatment time . . . is directly proportional to the number of arcs used in the treatment (in turn related to the number of table angles and the thickness of the treatment slice) and roughly proportional to the degree of conformation which will result from implementing the plan." Pet. 39 (quoting Ex. 1006, 58) (emphases omitted). Petitioner also cites Carol-1995 for teaching different numbers of table angles (1 and 5) and slice thicknesses (5 mm and 1 cm) for various exemplary treatments. *Id.* (citing Ex. 1006, 60). In light of these teachings, Petitioner contends "the number of table angles and the thickness of the treatment slice are a range of conformality control factors taught by Carol-1995." *Id.* (citing Ex. 1002 ¶ 93). Petitioner further contends it would have been obvious to an ordinarily skilled artisan "to provide the user with a range of treatment angles (e.g., 1 to 5) and slice thicknesses (e.g., 1 cm to 5 cm [sic]) in the user interface to facilitate and simplify the user's entry of constraints when using the Peacock system." *Id.* at 39–40 (citing Ex. 1002 ¶ 94).

Patent Owner seeks to distinguish Carol-1995's teachings on controlling the number of table angles and the thickness of the treatment slice from various disclosures about "conformality control" in the '096 patent specification. *See* PO Resp. 26–28. Specifically, Patent Owner contends that "'conformality control' in the context of . . . an embodiment refers to a specific mathematically defined parameter that the user may opt to include in the cost function, which is used to optimize the plan produced by Peacock." *Id.* at 28 (citing 2037 ¶ 156); *see also id.* at 27–28 (quoting Ex. 1001, 14:42–64); PO Sur-reply 7 (same argument).

In reply, Petitioner argues that Patent Owner's quotations from the specification merely show examples and do not constitute "an exhaustive list or definition of conformity control factors." Pet. Reply 12 (citing Ex. 1043 ¶ 23). Petitioner also argues that Patent Owner does not dispute that the number of table angles and thickness of the treatment slice are factors that control conformality of the plans output by Peacock. *Id.* at 11 (citing Ex. 1043 ¶ 22).

We are persuaded by Petitioner's showing from Carol-1995 that the number of table angles and thickness of the treatment slice are factors that control conformality. *See* Ex. 1002 ¶ 93; Ex. 1006, 58, 60; Ex. 1043 ¶ 22. We do not agree with Patent Owner's arguments. Patent Owner's examples from the specification of the '096 patent are tied to specific embodiments of the disclosed Peacock system. But "we do not read limitations from the embodiments in the specification into the claims." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) (citing *Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 (Fed. Cir. 2004)). As such, Petitioner need not show "a specific mathematically defined

parameter" similar to that disclosed in the '096 patent specification (*see* PO Resp. 28) in order to teach the recited "conformality control factors." Based on Petitioner's analysis, we are persuaded that Carol-1995 teaches the second "providing" limitation.

Claim 43 further recites "using the computer to computationally calculate an optimized radiation beam arrangement." Ex. 1001, 22:11–12. Petitioner cites Carol-1995's teaching of the Peacock system's "so-called fast simulated annealing process to determine a set of beam weights," which is a "very computer-intensive process." Pet. 40 (quoting Ex. 1006, 57–58).

Patent Owner argues that the "determining" and "entering" steps "must be part of the method of, and for the purpose of, 'using the computer to computationally calculate an optimized radiation beam arrangement' to 'apply[] radiation to at least one tumor target volume while minimizing radiation to at least one structure volume in a patient.'" PO Resp. 25 (alteration by Patent Owner). According to Patent Owner, an ordinarily skilled artisan "would have understood the plain meaning of these limitations to convey that the computer's calculation of an optimized plan is based at least in part on analysis of the inputted partial volume data." *Id.* (citing Ex. 2037 ¶ 149). In a similar way, Patent Owner criticizes Petitioner's showing insofar as partial volume data entered in Viggars's OSCAR system is not being used in Carol-1995's Peacock system, even though Peacock does the optimization. PO Resp. 25–26 (citing Ex. 2037 ¶¶ 150–151).

Petitioner argues that Patent Owner's argument improperly seeks to import certain requirements into the "using" step based on other steps of claim 43. Pet. Reply 9. Petitioner also argues that Patent Owner has not

presented any justification to depart from standard claim construction principles with respect to the interplay of the recited steps. *Id.* at 9–10 (citing Ex. 1043 ¶¶ 16–18). Petitioner also criticizes as conclusory Patent Owner's arguments about what an ordinarily skilled artisan would have understood about the sequence of limitations in claim 43. *Id.* at 10.

We are persuaded by Petitioner's showing that the computer of Carol-1995's Peacock system calculates a set of beam weights in determining an optimized treatment plan, which teaches the "using" step of claim 43. Pet. 40 (citing Ex. 1002 ¶ 95; Ex. 1006, 57–58). We also agree with Petitioner (Pet. Reply 9–10) that Patent Owner's arguments improperly seek to read in requirements to the language of the "using" step based on the preamble and other method steps. Specifically, Patent Owner urges us to find an inconsistency with Petitioner's mapping because Petitioner cites Viggars for teaching the earlier-recited "determining" and "entering" steps (*see* Pet. 36–37) and Carol-1995 for teaching the later-recited "using" step (*see id.* at 40) even though Carol-1995's optimization occurs before Viggars's evaluation in Petitioner's proposed combination (*see id.* at 33). Yet the plain language of the "using" limitation requires no particular inputs from earlier-recited steps to perform the later-recited "computationally calculat[ing]." In this way, Patent Owner's arguments are not commensurate with the scope of the "using" limitation. We further note that the steps in claim 43 do not recite a particular order; nor do Patent Owner's arguments seek to establish as much. *See Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001) ("Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one."); Tr. 97:5–13 (Patent Owner's counsel agreeing that Patent

Owner did not put forth arguments about a specific order of steps in claim 43). For these reasons, we do not agree with Patent Owner's arguments.

Patent Owner also makes new arguments in its Sur-reply about how the recited "computer" in the "entering" step is the same "computer" in the "using" step. PO Sur-reply 5–6. According to Patent Owner, this means that "the same computer both receives the partial volume data and calculates the optimized beam arrangement." *Id.* at 6. Yet we understand Petitioner to be relying on the combined computer-implemented *functions* of Carol-1995's optimization program and Viggars's evaluation program for teaching claim 43, which is a method claim. *See* Pet. 31 (citing Ex. 1002 ¶ 78), 33 (citing Ex. 1002 ¶ 82). Furthermore, the specification of the '096 patent, contemplates that the disclosed optimization method may be performed with "a conventional computer or *set of computers*." Ex. 1001, 5:64–6:2 (emphasis added). Thus, we do not agree with Patent Owner's argument based on "computer" recitations. Patent Owner makes additional new arguments based on how partial volume data are entered and used for calculating an optimized plan in embodiments disclosed in the '096 patent specification. PO Sur-reply 6–7 (citing Ex. 1001, 6:35–39, 6:44–57, 6:61–63). We do not agree with Patent Owner's arguments, however, because "we do not read limitations from the embodiments in the specification into the claims." *Hill-Rom*, 755 F.3d at 1371.

Based on the entire trial record, Petitioner has established that the combination of Carol-1995 and Viggars teaches all limitations of claim 43.

b. Reasons for the Combination

Petitioner contends an ordinarily skilled artisan "would have been motivated to use the OSCAR program of Viggars to evaluate the clinical acceptability of the 'optimized' treatment plans calculated by Carol-1995's Peacock program to ensure that the plans comply with the radiation oncologist's dose prescription requirements." Pet. 31 (citing Ex. 1002 ¶ 78). In particular, Petitioner posits generating an "optimized" treatment plan using Carol-1995's Peacock program and then inputting the "optimized" plan for evaluation by Viggars's OSCAR program. *Id.* at 33 (citing Ex. 1002 ¶ 82). According to Petitioner, "the objective scoring and visual displays of Viggars' OSCAR program [would have] be[en] a desirable and facile way of evaluating the clinical acceptability of plans generated by the Peacock system of Carol-1995." *Id.* at 32 (citing Ex. 1002 ¶ 79). In support of this notion, Petitioner cites Viggars's statement that "[t]he power of the method is derived from the OSCAR prescription which allows the clinician to express the needs of his or her patient in a simple quantitative way taking into account clinical experience." *Id.* at 31–32 (citing Ex. 1015, 426). Petitioner further cites Viggars for teaching that the OSCAR program can be used to decide, in an objective and systematic way, whether a particular treatment plan is acceptable. *Id.* at 32 (citing Ex. 1015, 425). Petitioner also cites the recognition of another contemporaneous prior art reference that Viggars's treatment plan scoring "addressed the problem of basing a decision on the degree of acceptability of a treatment plan in terms of simple parameters." *Id.* (quoting Ex. 1008 ("Webb-1993"), 20).

Petitioner contends an ordinarily skilled artisan would have expected success in making the combination "because the combination simply uses

the established functions of each disclosed system." Pet. 33 (citing Ex. 1002 ¶ 82). Petitioner contends that Carol-1995's Peacock system outputs a dose distribution and dose volume histograms. Pet. Reply 13 (citing Ex. 1043 ¶ 26; Ex. 1044, 49:17–24, 57:23–59:5), 15 (citing Ex. 1043 ¶¶ 31–32), 17. According to Petitioner, an ordinarily skilled artisan "would have known how to conform the file formatting" of the Peacock output dose distribution "in order to provide the requisite input data for [Viggars's] OSCAR to calculate the S-scores and generate the histograms of regret." *Id.* at 17–18 (citing Ex. 1043 ¶ 37); *see also* Pet. 33 (citing Ex. 1002 ¶ 82) (same argument). Petitioner also notes Viggars's express statement that the OSCAR program had been "fully integrated with the conventional software so that it can be used easily on a routine basis." Pet. 33 (quoting Ex. 1015, 420). Petitioner contends this statement would have given an ordinarily skilled artisan an expectation of success in combining Viggars's OSCAR program with Carol-1995's Peacock system. *Id.* at 33–34 (citing Ex. 1002 ¶ 83).

Patent Owner notes that Carol-1995's Peacock system is an inverse intensity modulated radiation therapy (IMRT) system, which Patent Owner calls "a different and distinct transformative paradigm-shifting system" that is "based on different parameters, mathematics and decision-making than those used in forward-planning systems." PO Resp. 30–31 (citing Ex. 2037 ¶¶ 48, 169; Ex. 2040, 8; Ex. 2041, 2089). As such, Patent Owner attempts to distinguish Viggars's OSCAR program as "merely part of an outmoded and inferior forward-planning system, with its own mathematics, parameters and decision-making process." *Id.* at 31–32. Thus, according to Patent Owner, an ordinarily skilled artisan would not have been motivated "to combine the

state of the art solution, with an inferior older partial solution." *Id.* at 32 (citing Ex. 2037 ¶¶ 170–171). Patent Owner also argues that Carol-1995's Peacock system "already perform[s] the function of identifying and evaluating hundreds or thousands of proposed plans" and does so "exponentially faster and better than a user could attempt to replicate on a trial-and-error basis with [Viggars's] subjectively-evaluated S-scores and beam parameters." *Id.* at 32–33 (citing Ex. 2037 ¶ 171).

In reply, Petitioner argues that Viggars's OSCAR program is not a forward treatment planning program and, rather, is used to analyze any proposed dose distribution. Pet. Reply 13 (citing Ex. 1015, 419; Ex. 1043 ¶ 27). Petitioner also notes Mr. Chase's agreement that "the S-scores [and] histograms disclosed in the Viggars reference would help in evaluating the clinical acceptability of a Peacock treatment plan." *Id.* at 16 (citing Ex. 1044, 65:9–14).

We are persuaded by Petitioner's showing that an ordinarily skilled artisan would have had reasons to evaluate treatment plans from Carol-1995's Peacock program using Viggars's OSCAR program. Specifically, Viggars states that the OSCAR program can be "used to decide, in an objective and systematic way, whether a particular plan is acceptable." Ex. 1015, 425. OSCAR also "allows a clinician to express the needs of his or her patient in a simple quantitative way taking into account clinical experience as well as any dose response data which may be available." *Id.* at 426. Petitioner shows that these benefits had already been recognized in the art. *See* Pet. 32–33 (citing Ex. 1008, 20–21).

We also do not agree with Patent Owner's argument (PO Resp. 30–33) that Viggars's OSCAR scoring program was associated exclusively with

forward-planning systems. As Patent Owner's counsel acknowledged at the oral hearing, Viggars's evaluation tools can be applied to inverse planning treatment plans, such as those coming from Carol-1995's Peacock system. *See* Tr. 84:18–86:7. And, as Mr. Chase acknowledged, even optimized plans from Carol-1995's Peacock system would need to be evaluated for their clinical acceptability before they would be used on a patient. Ex. 1044, 65:4–8. Mr. Chase further agreed that the S-scores and histograms disclosed in Viggars would help in evaluating the clinical acceptability of a Peacock treatment plan. *Id.* at 65:9–14. This testimony supports Petitioner's assertion that an ordinarily skilled artisan would have had a reason to evaluate plans from Carol-1995's Peacock system using the tools provided by Viggars's OSCAR program.

Patent Owner also disputes Petitioner's rationale for the combination to the extent that an ordinarily skilled artisan "would not have been motivated to look to the particular S-scoring of the Viggars reference, over all other available scoring programs." PO Resp. 33 (citing Ex. 2037 ¶¶ 172–173). Patent Owner notes that other scoring programs were available at the time of the '096 patent and that all of them could have performed the function of Viggars's evaluation program in Petitioner's proposed combination. *Id.* (citing Ex. 2038, 97:21–98:2); *see also id.* at 34–35 (discussing other available scoring systems). As such, Patent Owner argues that "[t]he motivation to use the OSCAR S-score posited by [Petitioner] . . . would apply to the use of any of the multiple other scoring systems available in the art at the time." *Id.* at 34 (citing Ex. 2037 ¶ 175). Patent Owner also argues that Petitioner fails to show why an ordinarily skilled artisan would

have selected Viggars's scoring system over any other available scoring programs. *Id.* at 35; *see also* PO Sur-reply 8–9 (same arguments).

We do not agree with Patent Owner's arguments because Petitioner is not required to show that Viggars's scoring system would have been superior to other available scoring systems in order to prove obviousness. *See In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) ("[O]ur case law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention."). Rather, Petitioner need only show persuasive reasons why an ordinarily skilled artisan would have combined Viggars's scoring system to evaluate Carol-1995's optimized treatment plans from the OSCAR system. *See id.* And, regardless of other available systems, Petitioner establishes that an ordinarily skilled artisan would have had reasons to use Viggars's S-scores to evaluate optimized plans from OSCAR. Ex. 1002 ¶¶ 78–79; Ex. 1015, 425–26; Ex. 1043 ¶ 36.

Patent Owner disputes that an ordinarily skilled artisan would have reasonably expected success in combining Viggars with Carol-1995. PO Resp. 35–44. Patent Owner contends that the output of Carol-1995's Peacock system would have been in a proprietary format that was not necessarily compatible with Viggars's OSCAR program. *See id.* at 35–37 (citing, *inter alia*, Ex. 2037 ¶¶ 178–180). Patent Owner also addresses Viggars's teaching of using OSCAR to evaluate treatment plans from a commercial program known as Theraplan, but notes that Viggars does not discuss how integration between Theraplan and OSCAR was achieved. *Id.* at 37–38 (citing Ex. 1015, 420; Ex. 2037 ¶ 184). Patent Owner goes on to cite another reference for the proposition that Theraplan required

modification to achieve this integration. *Id.* at 39 (citing Ex. 2034 ("Shalev-1988"), 763). As a result, Patent Owner contends an ordinarily skilled artisan would have expected "***a modification or re-programming*** of the Peacock System" in order to integrate it with Viggars's OSCAR program." *Id.* (citing Ex. 2037 ¶ 181).

We do not agree with Patent Owner's arguments. Record evidence establishes that Carol-1995's Peacock system generates a dose distribution and dose volume histogram data just like conventional forward treatment planning systems. Ex. 1006, 57 ("Peacock Plan starts with the desired dose distribution and works in reverse to generate the beam weights needed to produce this distribution"); Ex. 2032, 594 (noting that the Peacock system generates "dose distribution in three dimensions" and "dose-volume histograms"); Ex. 1043 ¶¶ 26, 28 (Dr. Gall's testimony regarding the same); Ex. 1044, 49:17–24, 52:11–18, 57:23–59:5 (Mr. Chase's cross-examination testimony regarding the same). This evidence undermines Patent Owner's suggestion that Peacock's output was in a proprietary format. *See* PO Resp. 35–37. Moreover, Viggars teaches that, "[b]ased on a dose prescription specified by a radiation oncologist," the OSCAR system "provides a quantitative and easily understood visual analysis of *a proposed dose distribution*." Ex. 1015, 419 (emphasis added). In other words, one of the inputs to Viggars's OSCAR program is a proposed dose distribution, which is exactly what is produced as output by Carol-1995's Peacock system. This supports Petitioner's assertion that "an 'optimized' treatment plan could be generated as expressly taught by Carol-1995 using the Peacock system and this 'optimized' plan would be used as input for

evaluation by the OSCAR program of Viggars." Pet. 33 (citing Ex. 1002 ¶ 82).

We also have considered Patent Owner's argument that the Peacock system would have needed modification or reprogramming to work with OSCAR. *See* PO Resp. 39–40, 42–43. Petitioner does not propose any reprogramming, however: "the combination simply uses the established functions of each disclosed system." Pet. 33. Given the match between Peacock's output and OSCAR's input discussed above, we do not agree that any reprogramming would have been required. The only remaining issue relates to whether an ordinarily skilled artisan would have reasonably expected success in conforming the file formats of the two systems to ensure compatibility. Patent Owner calls Petitioner's showing of expected success in this regard deficient and conclusory. PO Resp. 40–42; PO Sur-reply 11–12. Yet Petitioner need not establish an absolute certainty for success. *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1198 (Fed. Cir. 2014). For the reasons mentioned above (*see supra* § II.D), we discount Mr. Chase's testimony regarding the alleged need for modification and reprogramming, and we instead credit Dr. Gall's testimony (Ex. 1002 ¶ 82; Ex. 1043 ¶¶ 30–31) that an ordinarily skilled artisan would have known how to conform files from Peacock for processing by OSCAR. Ensuring the compatibility of file formats between the two systems strikes us as the sort of implementation detail that would have been an exercise of ordinary skill, particularly given our finding that an ordinarily skilled artisan would have had experience in computer programming. *See supra* § II.B. The fact that Viggars discusses the successful integration of another commercial system, Theraplan, with OSCAR also supports this conclusion. *See* Ex. 1015, 420.

Finally, we have considered Patent Owner's argument that an ordinarily skilled artisan would not have been motivated to increase the "already-lengthy" processing time required by Carol-1995's Peacock optimization method by reprogramming the Peacock system to "perform the additional function of generating the partial dose data needed by OSCAR." PO Resp. 42–44 (citing Ex. 2037 ¶¶ 191–194). Yet Patent Owner's argument misapprehends the combination proposed by Petitioner. As discussed above, Petitioner does not propose modifying the existing functions of Peacock and OSCAR. *See* Pet. 33. Rather, Petitioner merely proposes linking the two functions so that OSCAR's scoring program is used to evaluate "optimized" plans from Peacock. *See id.* at 31. Because "reprogramming" of Peacock is not required, we do not agree that the combination would result in increased planning time.

Patent Owner argues that Petitioner fails to show why an ordinarily skilled artisan "would have selected Varian's chosen description of OSCAR in Viggars – above the rest of the OSCAR articles in the 'Objective Evaluation of Alternative Treatment Plans' series by Viggars and his co-authors." PO Resp. 44 (citing Exs. 1015, 2034, 2039). Patent Owner speculates that Dr. Gall's opinions about the proposed combination would have been different if he had first considered another of the articles, Shalev-1988, which allegedly requires "'modifying' the Theraplan system." *Id.* at 45 (citing Ex. 2034, 763; Ex. 2037 ¶ 197). Patent Owner also argues that the data in Viggars's Table 1 and certain CDVH illustrations in Viggars are unique in this series of articles. *See id.* at 45–46. Patent Owner calls this an exercise in "litigation-inspired hindsight." *Id.* at 46. Nevertheless, we have already considered (and do not agree with) Patent Owner's argument

about "modifying" Theraplan above. And, as discussed above, Petitioner need not account for the relative strengths and weaknesses of other non-asserted prior art references. *See Fulton*, 391 F.3d at 1200. Moreover, Petitioner is entitled to rely on Viggars for everything it teaches by way of technology. *See EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985). Thus, we do not agree with Patent Owner's arguments.

Having considered the entire trial record, we are persuaded that an ordinarily skilled artisan would have had reasons to combine Carol-1995 and Viggars.

c. Conclusion Regarding Claim 43

Petitioner has persuasively shown that the combination of Carol-1995 and Viggars teaches all the limitations of claim 43. Petitioner also has put forth persuasive reasons for combining these references and has established that an ordinarily skilled artisan would have had a reasonable expectation of success in making the combination. On the entire trial record, we determine Petitioner has shown, by a preponderance of the evidence, that the subject matter of claim 43 would have been obvious over the combination of Carol-1995 and Viggars.

4. Claim 44

Claim 44 depends from claim 43 and further recites "the step of applying the optimized radiation beam arrangement to the patient with a conformal radiation therapy apparatus." Ex. 1001, 22:13–15. Petitioner cites Carol-1995 for teaching that "the obvious goal of using a clinically

acceptable optimized treatment plan [is] for patient treatment." Pet. 40 (citing, *inter alia*, Ex. 1002 ¶ 96; Ex. 1006, 56, 61).

Patent Owner relies on the same arguments discussed above with respect to claim 43. We are persuaded that Carol-1995 teaches using optimized treatment plans for treating patients with a radiation therapy apparatus. *See* Ex. 1006, 56 ("The Peacock three-Dimensional Conformal System plans and implements . . . conformal treatment plans"), 61 ("Patients[']treatments with Peacock began in March 1994"). Thus, we determine Petitioner has shown by a preponderance of the evidence that the subject matter of claim 44 would have been obvious over the combination of Carol-1995 and Viggars.

5. Claim 46

Claim 46 depends from claim 44 and recites that "the optimized radiation beam arrangement is calculated using different cost function parameters depending on the target or structure type." Ex. 1001, 22:20–23. Petitioner cites the differences in how Carol-1995 defines cost for targets and structures: "For targets, cost is the mean-squared difference between realized dose and prescribed dose. For structures, cost is the mean-squared difference between realized dose and zero dose." Pet. 41 (quoting Ex. 1006, 57) (citing Ex. 1002 ¶ 97). Petitioner further cites Carol-1995's cost function parameters WeightI and WeightJ for targets and structures, respectively, which are used to calculate the optimized beam arrangement. *Id.* (citing Ex. 1006, 58).

Patent Owner relies on the same arguments discussed above with respect to claim 43. We are persuaded that Carol-1995's cost function

accounts for targets and structures with different parameters. In particular, Carol-1995 teaches calculating cost differently for targets and structures. *See* Ex. 1006, 57. As explained by Dr. Gall, "the cost to the target is evaluated based on the minimum dose parameter, whereas structures are not." Ex. 1002 ¶ 97 (citing Ex. 1006, 57). Carol-1995 also teaches that "[t]he relative values of 'WeightI' (target weight) and 'WeightJ' (structure weights) emphasize or deemphasize the contribution of each target and structure to the total cost." Ex. 1006, 58. Thus, we determine Petitioner has shown by a preponderance of the evidence that the subject matter of claim 46 would have been obvious over the combination of Carol-1995 and Viggars.

F. Obviousness Grounds Based on (1) Curran-5 and Carol-2 and (2) Curran-5 and Carol-17

Petitioner contends the subject matter of claims 43, 44, and 46 would have been obvious over the combination of Curran-5 and Carol-2. Pet. 41–52. Petitioner also contends the subject matter of claims 43, 44, and 46 would have been obvious over the combination of Curran-5 and Carol-17. *Id.* at 41–52. As discussed above, Petitioner has demonstrated that the subject matter of claims 43, 44, and 46 would have been obvious over the combination of Carol-1995 and Viggars, so we do not reach the grounds based on (1) Curran-5 and Carol-2 and (2) Curran-5 and Carol-17. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) (non-precedential) (recognizing that the "Board need not address issues that are not necessary to the resolution of the proceeding"

and, thus, agreeing that the Board has "discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims").

G. Petitioner's Motion to Exclude Portions of Mr. Romesberg's Declaration

Petitioner moves to exclude paragraphs 13–18 from Mr. Romesberg's declaration (Exhibit 2048) under Federal Rules of Evidence 602 and 702. Exclude Mot. 1–2, 9–14. Because we do not rely upon Exhibit 2048 in rendering this Decision, we *dismiss as moot* Petitioner's motion to exclude paragraphs 13–18 of Mr. Romesberg's declaration.

III. CONCLUSION

Petitioner has shown, by a preponderance of the evidence, that the subject matter of claims 43, 44, and 46 would have been obvious over the combination of Carol-1995 and Viggars.[14]

[14] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

IV. ORDER

Accordingly, it is

ORDERED that claims 43, 44, and 46 of the '096 patent are unpatentable;

FURTHER ORDERED that Petitioner's motion to exclude paragraphs 178, 181, 184, 191, 192, 194, and 196 of Exhibit 2037 is *denied*;

FURTHER ORDERED that Petitioner's motion to exclude paragraphs 13–18 of Exhibit 2048 is *dismissed as moot*; and

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

In summary:

Claims	**35 U.S.C. §**	**Reference(s)/Basis**	**Claims Shown Unpatentable**	**Claims Not shown Unpatentable**
43, 44, 46	103(a)	Carol-1995, Viggars	43, 44, 46	
43, 44, 46	103(a)[15]	Curran-5, Carol-2		
43, 44, 46	103(a)[16]	Curran-5, Carol-17		
Overall Outcome			43, 44, 46	

[15] As explained above, we do not reach this ground. *See supra* § II.F.

[16] As explained above, we do not reach this ground. *See supra* § II.F.

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