Filed on behalf of: Best Medical International, Inc.
By: Barry J. Coyne, Lead Counsel
Kent E. Baldauf, Jr., Backup Counsel
Bryan P. Clark, Backup Counsel
THE WEBB LAW FIRM
One Gateway Center
420 Ft. Duquesne Blvd., Suite 1200
Pittsburgh, PA 15222
412.471.8815
412.471.4094(fax)
bcoyne@webblaw.com
kbaldaufjr@webblaw.com
bclark@webblaw.com
litigation@webblaw.com

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.

IPR2020-00071[1]
U.S. Patent No. 6,393,096

PATENT OWNER'S NOTICE OF APPEAL

[1] IPR2020-00971 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 70) 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. IPR2020-0071.

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 claim 1 of the '096 patent is unpatentable over the combination of Oldham and Viggars 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;
- The Board's decision to address the patentability of claim 1 despite the cancellation of claim 1 in a reexamination; 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

/*Barry J. Coyne*/

Barry J. Coyne (Reg. No. 43,566)
Kent E. Baldauf, Jr. (Reg. No. 36,082)
Bryan P. Clark (Reg. No. 60,465)
One Gateway Center
420 Ft. Duquesne Blvd., Suite 1200
Pittsburgh, PA 15222

412.471.8815
412.471.4094 (fax)
bcoyne@webblaw.com
kbaldaufjr@webblaw.com
bclark@webblaw.com
litigation@webblaw.com
Attorneys for Patent Owner

Copy to:

Director Drew Hirshfeld
United States Patent and Trademark Office
Madison Building
600 Dulany Street
Alexandria, VA 22314

Copy e-filed with:
United States Court of Appeals for the Federal Circuit
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:

Heidi L. Keefe
Xiaozhen Yu
hkeefe@cooley.com
syu@cooley.com
(*Attorneys for Petitioner Varian*)

Tamara D. Fraizer
Christopher W. Adams
Vid R. Bhakar
tamara.fraizer@squirepb.com
christopher.adams@squirepb.com
vid.bhakar@squirepb.com
(*Attorneys for Petitioner Elekta*)

THE WEBB LAW FIRM

/*Barry J. Coyne*/
Barry J. Coyne

Trials@uspto.gov
571-272-7822

Paper 70
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.

IPR2020-00071[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 Some 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

Varian Medical Systems, Inc. ("Varian") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1 and 18 of U.S. Patent No. 6,393,096 B1 (Ex. 1001, "the '096 patent"). Patent Owner, Best

[1] Petitioner from IPR2020-00971 has joined this proceeding.

Medical International, Inc. ("Patent Owner"), filed a Preliminary Response (Paper 6, "Prelim. Resp."). Varian also filed a Preliminary Reply (Paper 8), and Patent Owner filed a Preliminary Sur-reply (Paper 9). 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 14 ("Dec. on Inst.").

Elekta Inc. ("Elekta") subsequently filed a similar petition and motion for joinder in IPR2020-00971. *See* IPR2020-00971, Papers 2, 3. We instituted an *inter partes* review and joined Elekta as a party to this proceeding in a limited capacity. *See* IPR2020-00971, Paper 7. Henceforth, we refer collectively to Varian and Elekta as "Petitioner."

During the course of trial, Patent Owner filed a Patent Owner Response (Papers 33,[2] 34,[3] "PO Resp."), and Petitioner filed a Reply to the Patent Owner Response (Paper 47, "Pet. Reply"). Patent Owner also filed a Sur-reply. Paper 52 ("PO Sur-reply"). An oral hearing was held on January 28, 2021, and a transcript of the hearing is included in the record. Paper 68 ("Tr.").

[2] This paper was sealed in accordance with the Protective Order entered in this case. *See* Paper 32, Attach. A (copy of protective order); Paper 43 (entering protective order).

[3] This paper is the public version.

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. 2043), Merle E. Romesberg III (Ex. 2044[4]), and Thomas Rowden (Ex. 2045) with its Response. The parties also filed transcripts of the depositions of Dr. Gall (Ex. 2041), Mr. Chase (Exs. 1044, 1045), Dr. Carol (Ex. 1046), Mr. Rowden (Ex. 1047), and Mr. Romesberg (Exs. 1048,[5] 1049, 1050[6]).

Petitioner filed a motion to exclude certain testimony from Mr. Chase and Mr. Romesberg. Paper 56 ("Exclude Mot."). Patent Owner filed an opposition (Paper 58, "Exclude Opp."), and Petitioner filed a reply (Paper 62, "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 1 and 18 of the '096 patent. For the reasons discussed below, Petitioner has demonstrated by a preponderance of the evidence that claim 1 of the '096 patent is unpatentable. Petitioner has not demonstrated by a preponderance of the evidence that claim 18 of the '096 patent is unpatentable.

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

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

[6] 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. IPR2020-00971, Paper 2, 4. Patent Owner identifies Best Medical International, Inc. as the real party-in-interest. Paper 3, 1.

B. Related Proceedings

The parties identify the following proceedings related to the '096 patent (Pet. 4; Paper 3, 1–2; IPR2020-00971, Paper 2, 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., IPR2020-00072, which challenges claims 43, 44, and 46 of the '096 patent. We issue a final written decision in IPR2020-00072 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.

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. PO Sur-reply 1; Paper 65, 2–3; Paper 67, 1; Ex. 1051 (reexamination request); Ex. 1052 (order and decision granting request). As part of the reexamination, Patent Owner has canceled claim 1 in an amendment. PO Sur-reply 1; Ex. 1053 (excerpts from Nov. 23, 2020, amendment), 1, 4.[7] Although Patent Owner contends that, as a result, claim 18 "is the only claim now at issue" (PO Sur-reply 1), we note that the reexamination is still pending, and that Patent Owner has not filed a statutory disclaimer of claim 1. Accordingly, because claim 1 has not yet been canceled by any final action, we address the patentability of claim 1 below.

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

[7] We refer to Petitioner's added page numbers in Exhibit 1053.

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 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

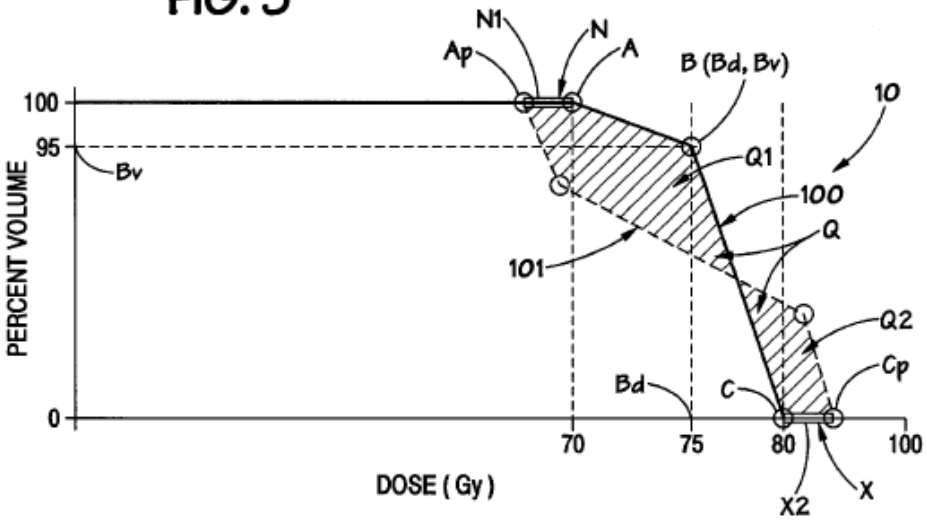
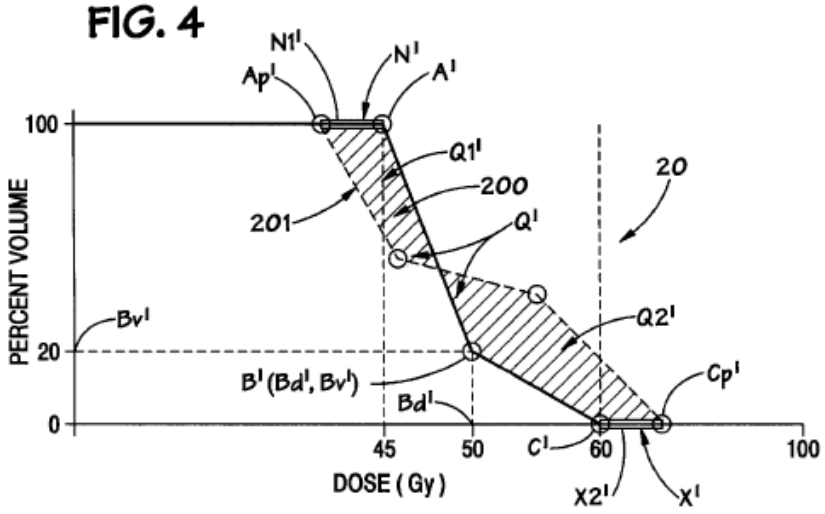


FIG. 4



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[8] and proposed CDVH structure curve 201, the latter of which again reflects the

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

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 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. 28.

D. Illustrative Claim

Of the challenged claims, claim 1 is independent. Claim 18 is a multiple dependent claim that depends from, *inter alia*, claim 1. Claim 1 is illustrative of the challenged claims:

> 1. A method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume

while minimizing radiation of a structure volume in a patient, comprising the steps of:

using a computer to computationally obtain a proposed radiation beam arrangement;

using a computer to computationally change the proposed radiation beam arrangement iteratively,

incorporating a cost function at each iteration to approach correspondence of a CDVH associated with the proposed radiation beam arrangement to a CDVH associated with a predetermined desired dose prescription;

comparing the dose distribution to a prescribed dose for the tumor volume and surrounding tissue structures, and

increasing or decreasing radiation beam intensity if the change of the proposed beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

Ex. 1001, 16:39–57.

E. Prior Art

Petitioner relies on the following prior art:

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");

Oldham, M. et al., "A comparison of conventional 'forward planning' with inverse planning for 3D conformal radiotherapy of the prostrate," *Radiotherapy and Oncology*, 35:248–62 (1995) (Ex. 1019, "Oldham");

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"); and

Morrill, S.M. et al., "Treatment planning optimization using constrained simulated annealing," *Phys. Med. Biol.*, 36(10):1341–61 (1991) (Ex. 1022, "Morrill-1991").

F. The Instituted Grounds

We instituted *inter partes* review of claims 1 and 18 of the '096 patent on the following grounds (Dec. on Inst. 35), which are all the grounds presented in the Petition (Pet. 7):

Claim(s) Challenged	35 U.S.C. §	References
1	103(a)[9]	Oldham, Viggars
18	103(a)	Oldham, Viggars, Morrill-1991
1, 18	103(a)	Carol-2, Carol-17
18	103(a)	Carol-2, Carol-17, Morrill-1991

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).

[9] 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.

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.[10] *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)).

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 the 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.").

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

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. 20–21 (citing Ex. 1002 ¶ 16). 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. 15–16 (citing Ex. 2037 ¶¶ 60, 67–72); *see also* Prelim. Resp. 18–19 (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. 15–16.

Nevertheless, the parties have put forth great effort disputing the type of experience that an ordinarily skilled artisan would have possessed.[11]

[11] We note that the parties' definitions do not differ meaningfully as to the number of years' experience that would have been possessed by an

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 ¶¶ 5–11). 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 2–3 (citing Ex. 1043 ¶ 8; Ex. 1045, 10:7–17).

Citing testimony from Mr. Chase, Patent Owner draws a distinction regarding Petitioner's requirement for computer programming 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 ¶ 69). 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, 18:23–26).

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

ordinarily skilled artisan, i.e., "two or more" for Petitioner versus "three" for Patent Owner. As mentioned below, we apply two years of experience.

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.

Id. at 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. 20–21. 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. 15–16)—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 2 (citing Ex. 2002 ¶ 69); *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 ¶ 69), 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" Limitations

Petitioner contends that the limitations "a computer to computationally obtain a proposed radiation beam arrangement" and "a computer to computationally change the proposed radiation beam arrangement iteratively" in claim 1 should be construed as means-plus-function limitations under pre-AIA 35 U.S.C. § 112 ¶ 6. Pet. 21–27. Petitioner contends an ordinarily skilled artisan would not have understood these terms to have a sufficiently definite meaning as a name for structure. *Id.* at 23 (citing Ex. 1002 ¶ 60), 26 (citing Ex. 1002 ¶ 65); *see also* Pet. Reply 4–5 (same argument).

Patent Owner disputes that treatment under § 112 ¶ 6 should apply. PO Resp. 16–17; *see also* Prelim. Resp. 19–22. In its Preliminary Response, Patent Owner argued that the lack of the words "means for" in these limitations creates a rebuttable presumption that § 112 ¶ 6 does not apply. Prelim. Resp. 19–20 (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 21–22 (citing Ex. 2002 ¶ 78); *see also* Pet. 27–28 (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. 17 (citing Ex. 2042, 2, 6–8).

In our Decision on Institution, we agreed with Patent Owner's reasoning that § 112 ¶ 6 does not apply to these limitations. Dec. on Inst. 10. 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. The Effect of the Transitional Word "Comprising" on Claims 1 and 18

The parties also put forth arguments about how the limitation "incorporating a cost function at each iteration" of claim 1 should be construed in light of the transitional word "comprising." These arguments arise in the context of claim 18, which depends from and includes the

limitations of claim 1.[12] PO Resp. 38–42; Pet. Reply 16–23; PO Sur-reply 6–7. Petitioner argues that the transitional word "comprising" in claim 1 is open-ended and allows for additional steps. Pet. Reply 16 (citing *In re Affinity Labs of Tex., LLC*, 856 F.3d 902, 907 (Fed. Cir. 2017). As a result, Petitioner argues that we should reject any interpretation of "incorporating a cost function *at each iteration*" that requires a cost function to be calculated after each and every iteratively proposed beam arrangement of an optimization. *Id*. According to Petitioner, any such interpretation "is improperly narrow and would be trivial to design around." *Id.* at 17 (citing Ex. 1043 ¶ 38). Patent Owner disputes Petitioner's argument and contends that Petitioner's argument based on the word "comprising" would allow it to entirely omit the added limitation in claim 18. PO Sur-reply 7.

Although we do not agree with Patent Owner's exact reasoning, we do agree with Patent Owner that Petitioner's proposed construction based on the word "comprising" goes too far. The issue is whether—even despite the transitional word "comprising"—the method of claim 1 must always incorporate a cost function for each cycle of the recited method (i.e., "at each iteration"). We determine that it must. Our reviewing court considered a similar situation in a case styled *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337 (Fed. Cir. 2007). The plaintiff brought an infringement action based on a method claim for making a form of cryogenically prepared novelty ice cream product in the form of "beads." *Id.* at 1339–40. The steps of the method recited various actions with respect to the "beads," and the trial court construed "beads" to require droplets with spherical appearance at the

[12] The parties do not raise any disputes regarding these limitations with respect to Petitioner's analysis of claim 1.

exclusion of irregular or odd-shaped particles. *Id.* at 1342–43. The plaintiff argued that the transition word "comprising" in the claim extended the scope of the claimed method beyond a beads-only process. *Id.* at 1343. The *Dippin' Dots* court disagreed, noting that "'[c]omprising' is not a weasel word with which to abrogate claim limitations." *Id.* (internal quotation omitted). The court reasoned that, although the word "comprising" indicated "that an infringing process could practice other steps in addition to the ones mentioned," the steps of the method claim "must, however, all be practiced as recited in the claim for a process to infringe." *Id.* Importantly, the court also reasoned that "[t]he presumption raised by the term 'comprising' does not reach into each of the [method] steps to render every word and phrase therein open-ended." *Id.*

Petitioner advances the same argument here based on the transition word "comprising." Following the reasoning of *Dippin' Dots*, we reject Petitioner's proposed construction because it would abrogate the limitation "incorporating a cost function *at each iteration*." *See id.* In other words, Petitioner is wrong to suggest that the presence of the word "comprising" allows it to interpret the "incorporating" limitation as only requiring incorporation of a cost function at *some iterations* of the method. *See id.* Thus, we determine that the limitation "incorporating a cost function at each iteration" requires incorporating a cost function for each and every cycle of the recited method.

3. 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 104–110, 113–115, 128, and 129 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 104–110, 113–115, 128, and 129 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 write computer code or design a computer system that performed the steps of claim 1. *See* Ex. 1045, 10:7–17; Ex. 2035 ¶ 67; *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"); Ex. 1019, 249–50 (Oldham 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 Oldham and Viggars

Petitioner contends the subject matter of claim 1 would have been obvious over the combination of Oldham and Viggars. Pet. 28–47; Pet. Reply 5–15. Patent Owner disputes Petitioner's contentions. PO Resp. 21–35; PO Sur-reply 8–12.

1. Oldham

Oldham is a paper directed to a radiotherapy treatment plan optimization algorithm that uses a cost function to achieve a homogenous

dose for a planning target volume and to minimize the integral dose to organs at risk. Ex. 1019, 248. The algorithm is based on fast simulated annealing. *Id.* Beam weights are independently perturbed by adding a "grain" of beam weight until the algorithm finds beam weight sets that successively converge to the minimum of the cost function. *Id.* at 249.

Oldham's cost function is segmented into component terms for different regions: the target (PTV), organs-at-risk (OAR), and all other tissue (BODY). *Id.* at 250. Equations (2)–(4) of Oldham are reproduced below.

$$C_{PTV} = \Sigma_{i \text{ in PTV}} (D_i - 100)^2 \quad (2)$$

$$C_{OAR} = \Sigma_{i \text{ in OAR}} (D_i) \quad (3)$$

$$C_{BODY} = \Sigma_{i \text{ in BODY}} (D_i) \quad (4)$$

Equations (2)–(4) reflect the desired clinical dose to each region (C_{PTV}, C_{OAR}, and C_{BODY}) where D_i is the dose to the ith cubic voxel of each segmented region. *Id.* These component terms are merged linearly into a total cost function (Equation (5)), which is reproduced below.

$$C_{TOTAL}(n) = \text{WEIGHT}_{PTV} \times C_{PTV}(n)/C_{PTVST}(1) + \sum_{j=1}^{m} (\text{WEIGHT}_{OAR_j} \times C_{OAR_j}(n)/C_{OARST_j}(1)) + \text{WEIGHT}_{BODY} \times C_{BODY}(n)/C_{BODYST}(1) \quad (5)$$

For this total cost function C_{TOTAL} in Equation (5), each term is weighted by an "importance factor" (i.e., "WEIGHT") to define its relative importance at the start of the optimization. *Id.* The importance factors were implemented by making "informed importance factor set 'guesses,'" which were then evaluated. *Id.* at 253. "Minimising the cost function C_{TOTAL} thus corresponds to minimising the integral dose in the OAR and BODY regions,

while attempting to achieve a uniform dose of 100% in the PTV." *Id.* at 250.

Petitioner contends Oldham qualifies as prior art under 35 U.S.C. § 102(b). Pet. 28–29 (citing, *inter alia*, Ex. 1003 ¶¶ 65–70). In support of Oldham'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 Oldham "was publicly accessible as early as September 1, 1995, and in any event, more than one year before the May 27, 1998 priority date," based on a record of Oldham in the National Library of Medicine. *Id.* ¶¶ 65–70. The journal in which Oldham appears (*Radiotherapy and Oncology: Journal of the European Society for Therapeutic Radiology and Oncology*) is dated June 1995, and it includes a 1995 copyright date. Ex. 1019, 1–3. The journal also includes stickers from the National Library of Medicine including the date "09/01/95." *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 ¶ 73.

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 Oldham appears. Dec. on Inst. 13. Thus, at that stage, we determined that Oldham qualified as prior art under 35 U.S.C. § 102(b). *Id.* Since the time of institution, neither party has put forth further arguments about the prior art status of Oldham, so we perceive no reason to change our determination from that stage. Accordingly, we determine that Oldham qualifies as prior art under 35 U.S.C. § 102(b) because Oldham'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. 1003 ¶¶ 65–70; Ex. 1019, 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. 28–29 (citing, *inter alia*, Ex. 1003 ¶¶ 54–59). In support of Viggars's status as prior art, Dr. Hall-Ellis 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 ¶ 73.

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. 15. Thus, at that stage, we determined that Viggars qualified as prior art under 35 U.S.C. § 102(b). *Id.* 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 1

a. Preamble and Claim Limitations

The preamble of claim 1 recites "[a] method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising the steps of[.]" Ex. 1001, 16:39–42. Petitioner cites Oldham's simulated annealing optimization method and its teaching of a cost function used to find beam weights that achieve a homogenous dose in the target volume while minimizing the dose to organs at risk. Pet. 38 (citing Ex. 1019, 248–49). Petitioner also cites Viggars's CDVH-based cost function for evaluating DVHs, which includes "overdose and underdose limits for the radiation applied to the target, as well as dose-volume limits on the radiation received by the organs-at-risk and non-target tissue." *Id.* at 39 (citing Ex. 1015, 420–21).

Patent Owner does not dispute Petitioner's analysis of the preamble of claim 1. Neither party addresses whether the preamble is limiting. Because Petitioner has shown that the combination of Oldham and Viggars teaches the preamble, we need not determine whether the preamble is limiting. *See Nidec*, 868 F.3d at 1017.

Claim 1 further recites "using a computer to computationally obtain a proposed radiation beam arrangement" ("first 'using' limitation"). Ex. 1001, 16:43–44. Petitioner cites Oldham's disclosure of the COVIRAOPT

computer program, which uses a fast simulated annealing algorithm that converges on a beam-weight set that corresponds to a minimum of the cost function. Pet. 39–40 (citing Ex. 1019, 249, 261). Patent Owner does not dispute Petitioner's analysis of the first "using" limitation. We are persuaded that Oldham's use of a computer-implemented fast simulated annealing algorithm in COVIRAOPT teaches the first "using" limitation. *See, e.g.*, Ex. 1019, 249, 261.

Claim 1 further recites "using a computer to computationally change the proposed radiation beam arrangement iteratively" ("second 'using' limitation"). Ex. 1001, 16:45–46. Petitioner again cites Oldham's fast simulated annealing algorithm and Oldham's teaching that the algorithm is iterative, wherein "at each iteration all beam-weights are independently perturbed by adding a 'grain' of beam-weight." Pet. 40 (quoting Ex. 1019, 249). Patent Owner does not dispute Petitioner's analysis of the second "using" limitation. We are persuaded that Oldham's perturbation of beam-weights teaches the second "using" limitation. *See, e.g.*, Ex. 1019, 249.

Claim 1 further recites "incorporating a cost function at each iteration to approach correspondence of a CDVH associated with the proposed radiation beam arrangement to a CDVH associated with a predetermined desired dose prescription." Ex. 1001, 16:47–50. Petitioner cites Oldham's algorithm, which iteratively perturbs beam weights and then evaluates a cost function. *Id.* at 41–42 (citing Ex. 1019, 249). According to Petitioner, the algorithm successively converges to a minimum value of the cost function. *Id.* at 42 (citing Ex. 1019, 249). Petitioner also cites Oldham's "total cost function that is segmented into component terms for each of the target (PTV), organs-at-risk (OAR), and surrounding tissue (BODY)." *Id.* (citing

Ex. 1019, 250). Petitioner notes the component terms are weighted by "importance factor" and merged linearly to form the total cost function. *Id.*

Petitioner contends "[i]t would have been obvious to a[n ordinarily skilled artisan] to incorporate the segmented score functions of Viggars for the target, organs-at-risk, and non-target tissue into an overall cost function that replicates the merged and weighted total cost function of Oldham."[13] Pet. 42–43 (citing Ex. 1002 ¶ 107). In particular, Petitioner contends Viggars's "segmented score functions merged into the overall weighted cost function compare the actual deviations of a plan from the ideal CDVH with the maximum deviations allowed by the dose prescription." *Id.* at 43 (citing Ex. 1002 ¶ 108; Ex. 1015, 422–23) (internal quotation omitted).

Petitioner explains its proposed combination as follows. Petitioner starts with equation (5) of Oldham, which is reproduced below.

$$C_{TOTAL}(n) = \mathrm{WEIGHT}_{PTV} \times C_{PTV}(n)/C_{PTVST}(1) + \sum_{j=1}^{m} (\mathrm{WEIGHT}_{OAR_j} \times C_{OAR_j}(n)/C_{OARST_j}(1)) + \mathrm{WEIGHT}_{BODY} \times C_{BODY}(n)/C_{BODYST}(1) \quad (5)$$

Equation (5) of Oldham is a "total cost function" C_{TOTAL}, which linearly merges segmented cost functions for the target (C_{PTV}), organs-at-risk (C_{OAR}), and surrounding tissue (C_{BODY}). Ex. 1019, 250. Each of the segmented cost functions is "weighted by an 'importance factor' to define its relative importance at the start of the optimisation." *Id.* The subscript "ST" denotes the starting value of a term. *Id.*

[13] We further discuss the parties' arguments regarding Petitioner's rationale for combining Viggars with Oldham below. *See infra* II.E.3.b.

Petitioner proposes replacing Oldham's segmented cost functions with Viggars's score function S_i, which "compare[s] the actual deviations of a plan from the ideal CDVH with the maximum deviations allowed by the dose prescription." Pet. 42–43 (citing, *inter alia*, Ex. 1015, 422). In particular, Petitioner cites Viggars's score function S_i, which is reproduced below.

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

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." Ex. 1015, 423. Petitioner notes the value r_i "is the measure of the plan's deviation from the ideal dose prescription CDVH." Pet. 43 (citing Ex. 1002 ¶ 109); *see also* Ex. 1015, 422 (defining r_i).

Petitioner proposes combining these two teachings into the following combined cost function C_{TOTAL}.

$$C_{TOTAL}(n) = \mathrm{WEIGHT}_{PTV} \times -S_{target} + \sum_{j=1}^{m} (\mathrm{WEIGHT}_{OAR_j} \times -S_{OAR,j}) + \mathrm{WEIGHT}_{BODY} \times -S_{BODY}$$

In Petitioner's proposed equation reproduced above, the combined cost function C_{TOTAL} represents "the overall cost function of Viggars to determine an optimal treatment plan using Oldham's segmented-cost method." Pet. 44 (citing Ex. 1002 ¶ 113). Petitioner notes the sign has been changed in the S_{target}, S_{OAR}, and S_{BODY} terms to achieve minimization by Oldham's fast simulated annealing algorithm. *Id.* at 43–44 (citing Ex. 1002 ¶ 111). Petitioner contends such a change would have been trivial and readily

apparent to a person of ordinary skill in the art. *Id.* Petitioner further contends that

> [d]etermining the three suitable weighting factors to achieve a clinical objective could easily be arrived at using the straightforward trial-and-error approach taught by Oldham and guided by the clinician's judgment concerning the relative importance of applying the appropriate dose to the target versus the dose tolerated by the organ-at-risk or body tissue.

Id. at 44–45 (citing Ex. 1002 ¶ 114).

Patent Owner criticizes Petitioner's analysis of the "incorporating" step as being "premised on the fallacy that Viggars discloses an 'overall CDVH-based cost function.'" PO Resp. 27. Rather, Patent Owner calls Viggars's OSCAR scoring system "a standalone scoring program" that "does not teach any use of, or how to use, these scores in a cost function." PO Sur-reply 8. Patent Owner also characterizes Viggars as stating that "(1) the authors did not attempt to derive an overall cost function, (2) it was unclear how to do that, and (3) it was preferable not to do that." PO Resp. 27 (citing Ex. 1015, 425–26; Ex. 2037 ¶¶ 100–101); *see also* PO Sur-reply 8 (same argument). In particular, Patent Owner highlights Viggars's statement on assigning weights for a single figure of merit that "[i]t is not clear how such weighting should be carried out, and it seems preferable at present to retain the separate scores." PO Resp. 27 (quoting Ex. 1015, 425–26) (emphasis omitted). Patent Owner argues that "Viggars' suggestion that one could, in principle, assign weights to each score to derive an overall objective function was negated by the remaining discussion in Viggars." *Id.* at 28.

We do not agree with Patent Owner's arguments. Viggars expressly states that its CDVH-based score functions could, in principle, be weighted

"to derive an *overall* objective function." Ex. 1015, 425 (emphasis added). In light of this, Petitioner's characterization of Viggars teaching "an overall CDVH-based cost function" is apt. Indeed, Viggars teaches judging "how far [a proposed plan's] CDVH departs from the ideal histograms." *Id.* at 420. We also do not agree with Patent Owner's argument (PO Resp. 28) that Viggars's teachings "negate" the idea that an ordinarily skilled artisan would have assigned weights as part of a cost function. Although the authors of Viggars did not themselves create a single figure of merit (Ex. 1015, 426), they certainly suggested it could be done. *Id.* at 425 ("[A]n optimal plan could, in principle, be selected by assigning weights to each score to derive an overall objective function.").

Importantly, we must consider Viggars "for everything it teaches by way of technology," which is "not limited to the particular invention it is describing." *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985). This includes Viggars's express teaching that one could "assign[] weights to each score to derive an overall objective function." Ex. 1015, 425. We also note record evidence that, in general, weighting is patient-dependent, and no universal set of weights applies across all treatment plans. *See* Ex. 1015, 426; Ex. 1043 ¶¶ 24–25, 27; Ex. 1045, 87:23–89:19. We further note that Petitioner additionally relies on Oldham's express teachings of assigning weights via a trial-and-error approach. *See* Pet. 36–37 (citing Ex. 1002 ¶ 92; Ex. 1019, 253); Pet. Reply 8–9 (citing Ex. 1043 ¶ 24). All of these teachings support Dr. Gall's testimony "that it would have been a routine and straightforward exercise to determine the relative values for the weights of the overall CDVH-based cost function" (Ex. 1043 ¶ 24), which we credit.

Therefore, we are persuaded by Petitioner's analysis of the "incorporating" step. Petitioner relies on a modified version of Oldham's combined cost function C_{TOTAL} that incorporates Viggars's teaching of a score function that compares actual deviations of a plan from the ideal CDVH. *See* Pet. 42–44. As such, Petitioner establishes that its proposed version of Oldham's combined cost function C_{TOTAL}—as modified to incorporate Viggars's CDVH score functions—teaches the "incorporating" limitation. *See* Pet. 44.

Claim 1 further recites "comparing the dose distribution to a prescribed dose for the tumor volume and surrounding tissue structures." Ex. 1001, 16:51–52. Petitioner cites Viggars's teaching of objective cost functions, "which quantify the deviation of the dose distribution from the dose prescription," and notes this functionality is included in Petitioner's proposed combined cost function (discussed above). Pet. 45 (citing Ex. 1002 ¶ 116; Ex. 1015, 420). Petitioner also contends its combined cost function "'provide[s] a quantitative measure of how well a proposed treatment plan conforms to the dose prescription,' and thus compares the dose distribution to a prescribed dose for the tumor volume and surrounding tissue structures." *Id.* (quoting Ex. 1015, 422). Petitioner additionally cites Viggars's teachings of visual displays for CDVHs, dose limits, histograms of regret, isodose charts, and images of regret. *Id.* at 45–46 (citing Ex. 1015, 419–20, 422). Patent Owner does not dispute Petitioner's analysis of the "comparing" limitation. We are persuaded that Viggars's CDVH-based score functions to quantify conformity—as implemented in Petitioner's proposed overall cost function based on Oldham and Viggars—teach the "comparing" limitation. *See, e.g.*, Ex. 1015, 422–23.

Claim 1 further recites "increasing or decreasing radiation beam intensity if the change of the proposed beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement." Ex. 1001, 16:54–57. Petitioner cites Oldham's teachings of iteratively adding (or subtracting) "a 'grain' of beam-weight" to determine the effect on a cost function. Pet. 46–47 (citing Ex. 1002 ¶ 117; Ex. 1019, 249). According to Petitioner, this process successively converges on a minimum of the cost function, which is associated with correspondence to a desired dose prescription. *Id.* Patent Owner does not dispute Petitioner's analysis of the "increasing or decreasing" limitation. We are persuaded that Oldham's iterative method of adding or subtracting "grain[s] of beam-weight" in an effort to minimize a cost function teaches the "increasing or decreasing" limitation. *See, e.g.*, Ex. 1019, 249.

Based on the entire trial record, Petitioner has established that the combination of Oldham and Viggars teaches all limitations of claim 1.

b. Reasons for the Combination

As part of its rationale for the combination, Petitioner notes Viggars's teaching of "an overall CDVH-based cost function to determine an optimal treatment plan." Pet. 33 (citing Ex. 1015, 425). Petitioner also notes Oldham's teaching of "how to determine suitable weights for the individual costs associated with an overall cost function." *Id.* (citing Ex. 1019, 253). In light of these teachings, Petitioner contends an ordinarily skilled artisan "would have been motivated by Oldham to construct and incorporate the overall cost function disclosed in Viggars within Oldham's optimization

algorithm." *Id.* (citing Ex. 1002 ¶ 85); *see also id.* at 35 (citing Viggars (Ex. 1015, 426) for teaching the ease of interpreting "a single figure of merit for a treatment plan"). This would have resulted in using "the cost function expressly disclosed in Viggars in order to perform computer-implemented optimization of a treatment plan of Oldham to implement the same CDVH-based evaluations of proposed treatment plans that were already being performed by the physician." *Id.* at 33–34 (citing Ex. 1002 ¶ 87). Petitioner cites the advantage of "being able to effectively and efficiently screen a vast set of different beam configurations with the SARP algorithm of Oldham to arrive at a more optimal treatment configuration." *Id.* at 34 (citing Ex. 1002 ¶ 88). As another advantage, Petitioner cites the ability to "account[] for dose-volume limits associated with partial volumes identified in the physician's dose prescription," which Oldham's cost function alone cannot do. *Id.* at 34–35 (citing Ex. 1002 ¶ 88).

Petitioner contends it would have been "obvious to try the overall CDVH-based cost function suggested by Viggars with Oldham's SARP algorithm in order to determine an 'optimal plan'" based on "Oldham's teaching of how to assign suitable weights to the individual components." Pet. 36 (citing Ex. 1002 ¶ 92). In particular, Petitioner notes that SARP optimization methods were known to "permit[] the straightforward utilization of any objective function," which leads to expected success. *Id.* (quoting Ex. 1014, 135) (citing Ex. 1002 ¶ 90). Petitioner also cites Oldham's teaching of weighting the target, organ, and tissue based on an "importance factor," wherein Oldham teaches making "informed importance factor set 'guesses'" and then evaluating them. *Id.* at 36–37 (citing Ex. 1002 ¶ 92; Ex. 1019, 253). Thus, in light of Oldham's teachings, Petitioner

contends that an ordinarily skilled artisan would have reasonably expected success in identifying the weights to be applied to the target, organs, and tissue. *Id.* at 36–37 (citing Ex. 1002 ¶¶ 91–92, 94).

Patent Owner argues that Viggars expressly states a preference against incorporating its score functions into an overall cost function, and instead suggests the scores should "be kept separate and used by clinicians." PO Resp. 28 (citing Ex. 1037 ¶ 106). As discussed above with respect to the "incorporating" step of claim 1, however, Viggars states expressly that "an optimal plan could, in principle, be selected by assigning weights to each score to derive an overall objective function." Ex. 1015, 425. Viggars also states that a clinician could make a final decision on the relative importance of the scores "in accordance with the needs of individual patients." *Id.* at 426. This is consistent with the idea that the assignment of weights to targets and structures is unique to each patient. Ex. 1043 ¶¶ 24–25, 27; Ex. 1045, 87:23–89:19. We are persuaded that an ordinarily skilled artisan considering these passages from Viggars would have known how to assign weights during the trial-and-error inverse planning process based on Oldham's teachings. *See, e.g.*, Ex. 1002 ¶¶ 85, 91–94; Ex. 1043 ¶¶ 18–20. Therefore, we do not agree that Viggars's other statements about its authors not implementing such an overall cost function—or even preferring "*at present* to retain the separate scores" (*id.* at 426 (emphasis added))—would have discouraged an ordinarily skilled artisan from making Petitioner's proposed combination.

Patent Owner argues that an ordinarily skilled artisan "would not have been motivated to complicate Oldham's relatively simple cost function with the more complex score functions of Viggars." PO Resp. 29 (citing

Ex. 2037 ¶ 103). Patent Owner also argues that "[i]t would not have been obvious that the more complicated score functions of Viggars would yield more optimal results than Oldham's Equations." *Id.*

Contrary to Patent Owner's arguments, Petitioner does provide a reason why an ordinarily skilled artisan would have added Viggars's more complex CDVH scoring to Oldham's cost function C_{TOTAL}: to create a single figure of merit for a treatment plan that incorporates Viggars's accounting for dose-volume limits associated with partial volumes identified in the physician's dose prescription. *See* Pet. 34–35 (citing Ex. 1002 ¶¶ 88–89). Petitioner's rationale is persuasive given that Oldham acknowledged a shortcoming of its cost function as failing "to model complicated volume effects." Ex. 1019, 250. In addition, Oldham already taught "plan evaluation tool[s]" such as DVHs (*see* PO Resp. 31 (citing Ex. 1019, 254–56)), albeit in a way that was not quantified in a single cost function. Correspondingly, Viggars touts the ability of the OSCAR system to "select[] and improv[e] a treatment plan . . . without the ongoing intervention of a radiation oncologist." Ex. 1015, 425. We agree with Petitioner that this would have provided motivation to automate Viggars's CDVH-based evaluation of beam configurations. Pet. 34 (citing Ex. 1002 ¶ 88). As such, Petitioner's combination remedies Oldham's acknowledged shortcoming and systematizes the use of DVHs as an evaluation tool.

Patent Owner questions whether the "score functions of Viggars would yield more optimal results than Oldham's Equations." PO Resp. 29 (citing Ex. 2037 ¶ 103). Mr. Chase offers supporting testimony (Ex. 2037 ¶ 103) in which he purports to compare the effectiveness of Petitioner's combination with that of Oldham alone. But these arguments miss the point

of the combination, which is to automate the optimization process by creating a single figure of merit that accounts for dose-volume limits. *See* Pet. 34–35. Petitioner establishes that its proposed combination would have been a desirable improvement regardless of whether a clinician might still use Oldham's scoring functions alone while effectively optimizing a given treatment plan. *Id.*; Ex. 1002 ¶¶ 88–89.

Patent Owner argues that this modification would have come at a significant cost, namely, increased computation time. PO Resp. 30–31 (citing, *inter alia*, Ex. 2037 ¶¶ 104–105). Patent Owner contends the combination would eliminate the time savings of Oldham, which is allegedly based on a "computational short cut" whereby "voxel summation need only be done once, for each beam, at the start of the optimisation." *Id.* (quoting Ex. 1019, 250) (citing Ex. 2037 ¶ 104). In reply, Petitioner argues any additional computational time associated with Petitioner's combination "would not have outweighed or discouraged a POSA from pursuing the recognized benefits of the combination." Pet. Reply 12 (citing Ex. 1043 ¶ 30). We agree with Petitioner that additional computational time would not have discouraged the combination. *See Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) ("[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine." (internal quotation omitted)). As noted by Petitioner, Petitioner's proposed combination of Oldham and Viggars obtains benefits that are not possible using Oldham's cost function alone, namely, modeling dose volume effects and systematizing the use of CDVHs as a plan evaluation tool. PO Resp. 12 (citing Ex. 1043 ¶ 30). In this way, Patent Owner's attempt to compare the

processing speed of Oldham alone with that of Petitioner's combination is not apt. Thus, regardless of increased processing time, we are persuaded that an ordinarily skilled artisan would have been motivated to obtain the benefits of Petitioner's combination. *See* Ex. 1002 ¶¶ 88–89; Ex. 1043 ¶ 30. Furthermore, the record contains evidence that the computational time of Petitioner's proposed combination would have been commensurate with typical inverse treatment planning optimization programs from the time of the invention. Ex. 1006, 60; Ex. 1019, 248, 250; Ex. 1043 ¶ 29; Ex. 1045, 91:21–93:1; Ex. 2037 ¶ 90.

The fact that Oldham already mentions dose value histograms as a plan evaluation tool (*see* PO Resp. 31 (citing Ex. 1019, 254–56; Ex. 2037 ¶ 111)) likewise does not undermine the combination. Oldham's teachings do not purport to test fidelity to a dose value histogram in an automated way, as is proposed by Petitioner. *See* Ex. 1019, 254–56.

Patent Owner additionally argues that it would not have been obvious how to incorporate the score functions of Viggars into the objective function of Oldham and that an ordinarily skilled artisan would not have had a reasonable expectation of doing it successfully. PO Resp. 32–35. Patent Owner notes that Viggars does not teach how to assign weights to its score functions and that the authors stated that they preferred not to do so. *Id.* at 32 (citing Ex. 1015, 425–26; Ex. 2037 ¶ 106). Patent Owner further criticizes Petitioner's reliance on Oldham for teaching "guesses" and a trial-and-error approach to assigning weights because these teachings pertain to the simpler objective function of Oldham. *Id.* at 32–33 (citing Ex. 2037 ¶ 109). In particular, Patent Owner argues that such an approach does not establish a reasonable expectation of success in making the combination. *Id.*

at 33 (citing Ex. 2037 ¶¶ 108–109). Patent Owner also cites a portion of an article (Ex. 1008, "Webb-1993") by a co-author of Oldham for the proposition that "[i]t may not however be entirely clear how to clinically set the dose limits or how to interpret the regret if dose limits cannot be met." *Id.* (quoting Ex. 1008, 20–21). Patent Owner argues that "[t]his suggests that a POSA would not have had a reasonable expectation of success in using Viggars' regret scores to drive a planning method." *Id.* (citing Ex. 2037 ¶ 110).

We do not agree with Patent Owner that Petitioner has failed to establish a reasonable expectation of success in making Petitioner's proposed combination. Record evidence, including cross-examination testimony from Mr. Chase, reflects that Petitioner's proposed trial-and-error process for determining weights was routine in the art. Ex. 1002 ¶¶ 85, 91–94; Ex. 1019, 253; Ex. 1043 ¶¶ 18, 31–32, Ex. 1045, 19:15–22:11. Petitioner also establishes that there is an intuitive correspondence between the weights assigned to components in a cost function, i.e., target, organ, and tissue, and the resulting dose distribution. Pet. 36 (citing Ex. 1029, 887). In addition, Dr. Gall testifies that Viggars's score functions had a "convenient numerical form and linear nature" that makes them simple to weight. Ex. 1002 ¶ 91; Ex. 1043 ¶ 32. Dr. Gall explains that "it would have been a trivial matter to have given greater relative weight to a structure when the target CDVH is clinically acceptable but a structure CDVH is not, and vice versa, as part of a trial-and-error process towards a clinically acceptable plan." Ex. 1043 ¶ 32. We credit Dr. Gall's testimony over Mr. Chase's testimony for the reasons discussed above. *See supra* § II.D. All of these factors support Petitioner's argument that

> [a] POSA reading Viggars would have understood, based on the express teachings of Oldham and the understanding by clinicians regarding how to assign weights during the trial-and-error inverse planning process, that it would have been a routine and straightforward exercise to determine the relative values for the weights of the overall CDVH-based cost function.

Pet. Reply 8–9 (citing Ex. 1043 ¶ 24); *see also* Pet. 44–45 (citing Ex. 1002 ¶ 114).

We also have considered Patent Owner's arguments (PO Resp. 33) based on the quote from Webb-1993 that "[i]t may not however be entirely clear how to clinically set the dose limits or how to interpret the regret if dose limits cannot be met." Ex. 1008, 21. We agree with Petitioner that this statement, which concerns Viggars's score functions, only applies if dose limits cannot be met by a given plan. Pet. Reply 14 (citing Ex. 1043 ¶ 43). As noted by Petitioner, its proposed combination "screens thousands of beam configurations to find an optimal plan that would, in fact, satisfy all of the dose-volume limits of the prescription." *Id.* Petitioner additionally notes that a sentence in the same paragraph of Webb-1993 extols a situation where Viggars's score function leads to a positive outcome. *Id.* (quoting Ex. 1008, 21) ("Provided the treatment planner derives a scheme with positive score function, the plan can be considered acceptable . . . the prescription having been met."). Given this context, we do not agree with Patent Owner (PO Resp. 33) that Webb-1993's commentary "contradicts Petitioner's obviousness argument."

Patent Owner also argues that an ordinarily skilled artisan "would not have reasonably expected success in combining the *forward planning* tool of Viggars with the *inverse planning* tool of Oldham." PO Resp. 34. According to Patent Owner, "[f]orward planning and inverse planning were

fundamentally different techniques with their own processes and terminologies, that did not have common terms of evaluation." *Id.* (citing Ex. 2037 ¶¶ 113–114). Nevertheless, Patent Owner's counsel acknowledged at the oral hearing that Viggars's CDVH-based cost function is an evaluation tool that can be applied to inverse planning treatment plans. *See* Tr. 84:18–86:7. And simulated annealing optimization methods (such as Oldham's) "permit[] the straightforward utilization of *any* objective function." Pet. 36 (quoting Ex. 1013, 135) (citing Ex. 1002 ¶ 90) (emphasis added). Thus, we do not agree with Patent Owner's arguments.

Having considered the entire trial record, we are persuaded by Petitioner's showing that an ordinarily skilled artisan would have had reasons to combine Oldham and Viggars.

c. Conclusion Regarding Claim 1

Petitioner has persuasively shown that the combination of Oldham and Viggars teaches all the limitations of claim 1. 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 1 would have been obvious over the combination of Oldham and Viggars.

F. Obviousness Ground Based on Oldham, Viggars, and Morrill-1991

Petitioner contends the subject matter of claim 18 would have been obvious over the combination of Oldham, Viggars, and Morrill-1991.

Pet. 47–55; Pet. Reply 15–23. Patent Owner disputes Petitioner's contentions. PO Resp. 35–42; PO Sur-reply 6–7, 12–14.

1. Morrill-1991

Morrill-1991 is a paper directed to "[a] variation of simulated annealing optimization called 'constrained simulated annealing' [that] is used with a simple annealing schedule to optimize beam weights and angles in radiation therapy treatment planning." Ex. 1022, 1341. According to Morrill-1991, "[t]he use of dose-volume information effectively removes the dependence of the optimized solution upon the position of any single dose constraint point." *Id.* at 1344. Morrill-1991 describes an objective function called "maximize dose with dose-volume limits" (MDVL) that "maximizes the dose to isocentre, subject to target volume dose heterogeneity limits as well as maximum dose and dose-volume limits on the normal organs." *Id.* at 1345.

Table 2 of Morrill-1991 is reproduced below.

Table 2. Dose-volume constraints for the normal organs used by the MDVL objective function in the optimization of a treatment plan for a pancreatic tumour. The constraints are given as a maximum dose to the organ and a maximum volume to receive less than a given volume dose. Notice that the left kidney (distal to the tumour) has been given more restrictive dose constraints.

Organ	Maximum dose (Gy) (100% volume)	Maximum volume (%)	Volume dose (Gy)
External	63	75	45
Vertebral body	60	50	45
Spinal cord	45	50	40
Bowel	60	75	45
Liver	60	80	30
Left kidney	18	100	18
Right kidney	30	75	18

Table 2 depicts "[d]ose-volume constraints for the normal organs used by the MDVL objective function in the optimization of a treatment plan for a pancreatic tumour." *Id.* at 1347.

2. Claim 18

Claim 18 depends from claim 1, 2, or 14 and further recites "the step of allowing a radiation limit on the tissue structure to be exceeded by a set amount if such excess allows better conformation to the desired target CDVH curve." Ex. 1001, 18:23–26. The analysis that follows addresses only the direct dependency of claim 18 from claim 1, which reflects the broadest scope of claim 18. Building on its obviousness contentions for claim 1 in the Oldham–Viggars ground, Petitioner proposes applying Morrill-1991's constrained simulated annealing approach within Oldham's fast simulated annealing algorithm and Viggars's CDVH-based cost function. Pet. 51 (citing Ex. 1002 ¶ 127; Ex. 1022, 1343). Addressing the "radiation limit" language of claim 18 in particular, Petitioner cites "[t]he maximum dose constraints placed on the treatment plan within the constrained variation of simulated annealing taught by Morrill-1991." *Id.* at 52 (citing Ex. 1002 ¶ 130). Petitioner provides an example keyed to the "Spinal cord" entry in Table 2 of Morrill-1991 (reproduced above). *See* Ex. 1022, 1347. According to Petitioner, this table "indicates that the spinal cord has a maximum dose of 45 Gy, a maximum volume of 50%, and a volume dose of 40 Gy," which "means that the dose to the spinal cord is subject to a radiation limit of 40 Gy, but up to 50% of the spinal cord volume can exceed this radiation limit by a set amount of 5 Gy to the maximum dose of 45 Gy." Pet. 53 (citing Ex. 1002 ¶ 133). Petitioner

explains that allowing the radiation limit on a normal organ to be exceeded can result in better conformation to the target CDVH, albeit at the expense of excess radiation to the normal organ up to the maximum dose constraint. *Id.* at 54 (citing Ex. 1002 ¶ 133).

Petitioner contends an ordinarily skilled artisan would have been motivated to combine the dose-volume constraints of Morrill-1991's constrained simulated annealing method with the optimization algorithm of Oldham and the cost function of Viggars. Pet. 50 (citing Ex. 1002 ¶ 125). Petitioner notes that Oldham and Morrill-1991 both use simulated annealing algorithm and cost functions for the optimization of beam arrangement for conformal radiotherapy. *Id.* Petitioner cites several advantages to Morrill-1991's constrained simulated annealing method, including "the flexibility to specify individual organ dose-volume limits (especially to the spinal cord and kidneys) which implement the clinician's personal treatment methodology." *Id.* (quoting Ex. 1022, 1354). Petitioner notes that using constraints rather than weighted penalties in a cost function "is computationally more efficient." *Id.* (quoting Ex. 1022, 1343) (citing Ex. 1002 ¶ 126). Petitioner also cites the ability "to place strict limits on maximum doses not to be violated by a treatment plan in accordance with a dose prescription." *Id.* at 49–50 (citing Ex. 1002 ¶ 126). Petitioner additionally contends an ordinarily skilled artisan would have expected success in making the combination because introducing Morrill-1991's constraints "would merely require a step within [Oldham's] SARP algorithm that checks whether the constraints are satisfied with every sample beam arrangement configuration at each iteration of the simulated annealing algorithm." *Id.* at 51 (citing Ex. 1002 ¶ 128; Ex. 1013, 139; Ex. 1022,

1343). Petitioner also cites Morrill-1991's own teaching that "[d]ifferent objective functions, constraints and annealing schedules are straightforward to implement." *Id.* (quoting Ex. 1022, 1358).

Patent Owner argues that Morrill-1991's constrained simulated annealing method rejects sample configurations outright if they fail to satisfy the dose-volume constraints. *See* PO Resp. 39–41 (citing, *inter alia*, Ex. 1022, 1343; Ex. 2037 ¶¶ 132, 134); *see also* PO Sur-reply 6–7 (same argument). According to Patent Owner, "the steps of evaluating the cost function and accepting or rejecting the proposed beam weights are entirely skipped" in such a scenario. PO Resp. 41 (citing Ex. 2037 ¶ 135). In our Decision on Institution, we found that this teaching conflicted with the method of claim 18, which—via its dependency from claim 1—seeks conformance to a desired CDVH curve by evaluating a cost function *at each iteration*. Dec. on Inst. 28.

In reply, Petitioner argues that its obviousness arguments are based on "iterations where the constraints are *not* violated and the Viggars's overall CDVH-based cost function *is* evaluated." Pet. Reply 16. According to Petitioner, "[t]here would be numerous iterations, including many sequential iterations, in which the constraints would be met, a cost function incorporated, and an optimal plan determine[d]." *Id.* at 17–18 (citing Ex. 1043 ¶¶ 39–40). Petitioner argues that these iterations are sufficient to establish obviousness in light of the open-ended transition "comprising" in claim 1. *Id.* at 16, 18. Petitioner also criticizes Patent Owner's arguments to the extent that Patent Owner conflates a "radiation limit" with a "dose-volume limit." *Id.* at 22–23 (citing PO Resp. 41). According to Petitioner, the cost function *is* evaluated in its proposed combination when the radiation

limit for a structure is exceeded so long as the dose-volume constraints are satisfied. *Id.* (citing Ex. 1043 ¶ 18).

In its Sur-reply, Patent Owner argues that Petitioner is attempting to omit limitations in claims 1 and 18 based on the transitional word "comprising." *See* PO Sur-reply 6–7.

Our disposition of claim 18 turns on the interplay of the transitional word "comprising" with the "incorporating" limitation in claim 1, from which claim 18 ultimately depends. As discussed above, we reject Petitioner's arguments based on the transitional word "comprising" and determine that the "incorporating a cost function at each iteration" in claim 1 requires incorporating a cost function for each and every cycle of the recited method. *See supra* § II.C.2.

In its analysis for claim 18, Petitioner proposes combining the dose-volume constraints of Morrill-1991's constrained simulated annealing method with the optimization algorithm of Oldham and the cost function of Viggars. *See* Pet. 50. As a reason for combining Morrill-1991 with Oldham and Viggars, Petitioner touts Morrill-1991's use of constraints as being "computationally more efficient" than merely using weighted penalties. *Id.* (quoting Ex. 1022, 1343) (citing Ex. 1002 ¶ 126). Yet Morrill-1991 provides a specific explanation why the use of constraints results in computational efficiency: "If the sample configuration fails to satisfy these additional constraints, it is rejected outright (i.e. the [cost function] algorithm is not called)." Ex. 1022, 1343. Thus, in contrast to the Oldham–Viggars ground where the cost function is always evaluated, Petitioner's proposed optimization process of the instant ground (with Morrill-1991's added constraints) rejects some proposed beam configurations outright

because they fail to meet constraints, in which case the cost function is not called. Petitioner tacitly acknowledges as much when it asks us to focus on "the undisputed iterations where the constraints are not violated and the Viggars's overall CDVH-based cost function *is* evaluated." Pet. Reply 16; *see also id.* at 16–18. But Petitioner's argument belies our construction of the "at each iteration" limitation of claim 1. *See supra* § II.C.2. Therefore, because Petitioner's proposed obviousness combination in this ground does not incorporate a cost function for each and every cycle of the recited method, it does not teach the "incorporating a cost function at each iteration" limitation of claim 1.

Thus, we determine Petitioner has not shown, by a preponderance of the evidence, that the subject matter of claim 18 would have been obvious over the combination of Oldham, Viggars, and Morrill-1991.

G. Obviousness Ground Based on Carol-2 and Carol-17

Petitioner contends the subject matter of claims 1 and 18 would have been obvious over the combination of Carol-2 and Carol-17. Pet. 55–66; Pet. Reply 23–34. Patent Owner disputes Petitioner's contentions. PO Resp. 42–66; PO Sur-reply 14–33. We already have found claim 1 to be unpatentable over the combination of Oldham and Viggars (*see supra* § II.E.3), so we confine our analysis to claim 18 for this ground. *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 decide additional instituted grounds once the petitioner has prevailed on all its challenged claims").

1. Carol-2

Carol-2 is a book chapter from 1997 that sets forth "an overview of the current status of the clinical implementation of IMRT."[14] Ex. 1020, 17. Carol-2 describes computer-based inverse treatment planning operations, including simulated annealing. *Id.* at 20. Simulated annealing is an iterative process that "proceeds by randomly changing beam weights, then evaluating the effect of each change on the dose distribution. The acceptability of a change is determined by a cost function which is a mathematical quantification of how conflicting goals will be resolved." *Id.*

Carol-2 also describes the PEACOCK Plan treatment planning system, in which "the target cost function is the mean-squared difference between realized dose and prescribed dose" and the structure cost function "is the mean-squared difference between realized dose and zero dose." *Id.* at 21. The overall calculated cost is based on the weight assigned to each structure and target. *Id.* Accordingly, PEACOCK Plan "uses an interface which involves assigning graded weights and priorities to the structures and targets in order to achieve the desired result." *Id.*

[14] Although Patent Owner disputes the prior art status of Carol-2 (PO Resp. 42–60; PO Sur-reply 14–32), we do not reach those arguments because we resolve the remaining grounds on the merits.

2. Carol-17

Carol-17 is a book chapter that attempts to anticipate areas of IMRT that would be investigated in the years after its publication in 1997.[15] Ex. 1021, 243. Carol-17 describes a system for an inverse planning called CORVUS that "uses partial volume information for each structure out of which CDVH curves are generated and used as the goal by the optimizer." *Id.* at 247. Carol-17 describes the process:

> For each target, the user enters: goal, minimum dose, maximum dose and percent volume which is allowed to be underdosed. For each structure, the user enters: desired limit, minimum dose, maximum dose and percent volume which can be greater than limit. The system creates CDVH curves for the targets and structures from these entries which are used by the optimizer as a representation of the desired dose distribution.

Id. "After a CDVH is constructed from user-entered partial volume values, the system divides the CDVH into regions and automatically assigns a relative weight to each," which are "used to resolve conflicts between the various CDVH regions defined by the target goals and structure limits." *Id.*

3. Claim 18

Claim 18 recites "the step of allowing a radiation limit on the tissue structure to be exceeded by a set amount if such excess allows better conformation to the desired target CDVH curve." Ex. 1001, 18:23–26. Petitioner's entire analysis for claim 18 from the Petition is reproduced below.

---

[15] Although Patent Owner disputes the prior art status of Carol-17 (PO Resp. 42–60; PO Sur-reply 14–32), we do not reach those arguments because we resolve the remaining grounds on the merits.

> Carol-17 teaches that "weights are used to resolve conflicts between the various CDVH regions defined by the target goals and structure limits;" "[t]he default weights favor structures over targets when such conflicts exist; all structure limits, no matter how severe, will be met before target goals are met;" and "[t]he user has the option of selecting, on a target-by-target basis, whether target goals or structure limits will prevail." (Carol-17 at 247.) When the user sets the weights to favor targets over structures, the "target goals" prevail over the "structure limits" and the step of claim 18 is satisfied. (Ex. 1002 ¶159.)

Pet. 66.

Patent Owner argues that Petitioner fails to explain how "the step of claim 18 is satisfied" when "weights assigned to CDVH regions are set to permit target goals to 'prevail' over structure limits." PO Resp. 61 (citing Pet. 66; Ex. 1002 ¶ 159; Ex. 2037 ¶ 151). Patent Owner also argues that Carol-17 does not disclose whether or how its disclosed system, CORVUS, "identifies any 'set amount' of excess radiation that the tissue structure can be allowed to receive." *Id.* at 62 (citing Ex. 2037 ¶ 153). Patent Owner further argues that Petitioner does not explain "how Carol-17 discloses or suggests whether or how CORVUS permits excess radiation only if doing so 'allows better conformation to the desired target CDVH curve.'" *Id.* (citing Ex. 2037 ¶ 154).

In reply, Petitioner argues that an ordinarily skilled artisan would have known that one of the "fundamental and inherent features of a SARP optimization" is "exceeding a radiation limit on a tissue structure by a set amount." Pet. Reply 31 (citing Ex. 1043 ¶ 53). Petitioner provides the following explanation:

> A POSA would have understood that when a user sets the weights to favor greater correspondence to the target limits at

> the sacrifice of allowing structure limits to be exceeded, the simulated annealing algorithm would guide the beam arrangements toward configurations in which the structure radiation limit is exceeded by a set amount as a trade-off for better conformation to the prioritized target CDVH. The set amount by which the radiation limit on the structure can be exceeded is based on the magnitude of the relative weights applied to the target and structures.

Pet Reply 32 (citing Ex. 1043 ¶ 55).

In its Sur-Reply, Patent Owner argues that we should ignore Petitioner's theory regarding inherent features of simulated annealing as being an improper new argument under 37 C.F.R. § 42.23(b). PO Sur-reply 32–33.

We agree with Patent Owner that Petitioner's analysis from the Petition fails to show how Carol-17 teaches the limitation of claim 18. Importantly, the Petition does not show how Carol-17 teaches that any particular "radiation limit" is "exceeded by a set amount." Nor does the Petition show how Carol-17 teaches exceeding a "radiation limit" if such excess "allows better conformation to the desired target CDVH curve." We also have considered Petitioner's statement that "[w]hen the user sets the weights to favor targets over structures, the 'target goals' prevail over the 'structure limits' and the step of claim 18 is satisfied." Pet. 66 (citing Ex. 1002 ¶ 159). Dr. Gall's initial declaration includes the same conclusory statement. Ex. 1002 ¶ 159. We do not credit these statements because they are devoid of supporting evidence or reasoning and they do not address the specific limitation in claim 18. Thus, Petitioner's arguments from the Petition are insufficient to establish obviousness based on the combination of Carol-2 and Carol-17.

We additionally agree with Patent Owner that Petitioner's reply arguments about "fundamental and inherent features" of simulated annealing are improper reply arguments under 37 C.F.R. § 42.23(b). A reply may only respond to arguments raised in the preceding brief, and, importantly, "'[r]espond,' in the context of 37 C.F.R. § 42.23(b), does not mean proceed in a new direction with a new approach as compared to the positions taken in a prior filing." Consolidated Trial Practice Guide 74. In its Reply, Petitioner contends that Patent Owner ignores "relevant evidence and fails to acknowledge the fundamental and inherent features of a SARP optimization" (Pet. Reply 31), but Petitioner provides wholly new arguments and testimony about the alleged "fundamental and inherent features." *See id.* at 31–33. In particular, Petitioner bases its analysis almost entirely on extensive new testimony from Dr. Gall. *See id.*; Ex. 1043 ¶¶ 53–58. And, for the first time, Petitioner maps certain recitations of claim 18 to the teachings of Carol-17. *See, e.g.*, Pet. Reply 32 (citing Ex. 1043 ¶ 55) (addressing the "exceeded by a set amount" recitation in the first instance). Thus, contrary to Petitioner's argument, Patent Owner could not have "ignore[d] relevant evidence" (Pet. Reply 31) where Petitioner did not explain its position in the Petition. Because we find Petitioner's reply arguments about "fundamental and inherent features of a SARP optimization" and its mapping of the "exceeded by a set amount" recitation to be a new direction with a new approach as compared to the positions taken in the Petition, we do not consider Petitioner's new reply arguments. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369–70 (Fed. Cir. 2016) (holding that the Board did not err in refusing the reply brief as improper under 37 C.F.R. § 42.23(b) because petitioner relied

on an entirely new rationale to explain why one of skill in the art would have combined the references at issue).

Thus, we determine Petitioner has not shown, by a preponderance of the evidence, that the subject matter of claim 18 would have been obvious over the combination of Carol-2 and Carol-17.

H. Obviousness Ground Based on Carol-2, Carol-17, and Morrill-1991

Petitioner contends the subject matter of claim 18 would have been obvious over the combination of Carol-2, Carol-17, and Morrill-1991. Pet. 66–69; Pet. Reply 23–31, 34–35. Patent Owner disputes Petitioner's contentions. PO Resp. 42–60, 66–67; PO Sur-reply 14–33.

As with the Oldham–Viggars–Morrill-1991 ground above, Petitioner cites Morrill-1991 in this ground for teaching the added limitation of claim 18. *See* Pet. 66–69. Also similar to above, Petitioner proposes applying the constrained simulated annealing approach of Morrill-1991 in the simulated annealing methodology Carol-2 with the CDVH-based cost functions of Carol-17. *Id.* at 67 (citing Ex. 1002 ¶ 161). Petitioner relies on the same rationale for combining Morrill-1991 with the other references as in the Oldham–Viggars–Morrill-1991 ground. *Compare* Pet. 67–68, *with id.* at 50–52. Petitioner additionally relies on the same arguments that it puts forth in reply for the Oldham–Viggars–Morrill-1991 ground. Pet. Reply 34–35.

Patent Owner argues that Petitioner's obviousness challenges for this ground should fail based on the same arguments Patent Owner makes with respect to the Oldham–Viggars–Morrill-1991 ground. PO Resp. 66–67; PO Sur-reply 33. We agree with Patent Owner. Petitioner's proposed

combination for this ground incorporates the use of Morrill-1991's constraints. Pet. 67. Radiation beam configurations that fail the constraints would be rejected outright (*see* Ex. 1022, 1343), so a cost function would not be incorporated in such a scenario. That means that Petitioner's combination does not teach "incorporating a cost function *at each iteration*" for the same reasons discussed above. *See supra* § II.F.2. Thus, we determine Petitioner has not shown, by a preponderance of the evidence, that the subject matter of claim 18 would have been obvious over the combination of Carol-2, Carol-17, and Morrill-1991.

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

Petitioner moves to exclude paragraphs 13–18 from Mr. Romesberg's declaration (Exhibit 2044) under Federal Rules of Evidence 602 and 702. Exclude Mot. 1–2, 9–15. Because we do not rely upon Exhibit 2044 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 claim 1 would have been obvious over the combination of Oldham and Viggars. Petitioner has not shown, by a preponderance of the evidence, that (1) the subject matter of claim 18 would have been obvious over the combination of Oldham, Viggars, and Morrill-1991; (2) that the subject matter of claim 18 would have been obvious over the combination of

Carol-2 and Carol-17; and (3) the subject matter of claim 18 would have been obvious over the combination of Carol-2, Carol-17, and Morrill-1991.[16]

IV. ORDER

Accordingly, it is

ORDERED that claim 1 of the '096 patent is unpatentable;

FURTHER ORDERED that claim 18 of the '096 patent is not unpatentable;

FURTHER ORDERED that Petitioner's motion to exclude paragraphs 104–110, 113–115, 128, and 129 of Exhibit 2037 is *denied*;

FURTHER ORDERED that Petitioner's motion to exclude paragraphs 13–18 of Exhibit 2044 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.

[16] 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).

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1	103(a)	Oldham, Viggars	1	
18	103(a)	Oldham, Viggars, Morrill-1991		18
1, 18	103(a)[17]	Carol-2, Carol-17		18
18	103(a)	Carol-2, Carol-17, Morrill-1991		18
Overall Outcome			1	18

[17] As explained above, we do not reach claim 1 for this ground. *See supra* § II.G.

For PETITIONER:

Heidi Keefe
Xiaozhen YU
COOLEY LLP
hkeefe@cooley.com
syu@cooley.com

For PATENT OWNER:

Barry J. Coyne
Kent E. Baldauf, Jr.
Bryan P. Clark
THE WEBB LAW FIRM
bcoyne@webblaw.com
kbaldaufjr@webblaw.com
bclark@webblaw.com