Trials@uspto.gov
571-272-7822

Paper 14
Entered: May 1, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VARIAN MEDICAL SYSTEMS, INC.,
Petitioner,

v.

BEST MEDICAL INTERNATIONAL, INC.,
Patent Owner.

IPR2020-00071
Patent 6,393,096 B1

Before KARL D. EASTHOM, WILLIAM V. SAINDON, and JOHN A. HUDALLA, *Administrative Patent Judges*.

HUDALLA, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

Varian Medical Systems, Inc. ("Petitioner") 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"). Petitioner filed a Declaration of Kenneth P. Gall, Ph.D. (Ex. 1002) with its Petition. Patent Owner, Best Medical International, Inc. ("Patent Owner"), filed a

Preliminary Response (Paper 6, "Prelim. Resp."). Patent Owner filed a Declaration of Daniel J. Chase (Ex. 2002) with its Preliminary Response.

With our authorization (Paper 7), Petitioner also filed a Reply (Paper 8, "Pet. Reply") and Patent Owner filed a Sur-Reply (Paper 9, "PO Sur-reply") addressing certain issues related to service of the Petition raised by Patent Owner in the Preliminary Response.

We have authority to determine whether to institute an *inter partes* review. *See* 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). Under 35 U.S.C. § 314(a), we may not authorize an *inter partes* review unless the information in the petition and the preliminary response "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." For the reasons that follow, we institute an *inter partes* review as to claims 1 and 18 of the '096 patent on all grounds of unpatentability presented.

I. BACKGROUND

A. Real Parties-in-Interest

Petitioner 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. 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):

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. We grant institution of an *inter partes* review in IPR2020-00072 in a decision issued concurrently herewith.

We also note that Petitioner has challenged other patents owned by Patent Owner in IPR2020-00053, IPR2020-00075, IPR2020-00076, and IPR2020-00077.

We further note that another petitioner filed a petition requesting an *inter partes* review of the '096 patent in IPR2020-00074. In that case, we deny institution in a decision issued concurrently herewith.

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 the cost functions in then-existing methods relied merely on costs related to discrete points within the structure, and did not account for the structure volumes as a whole or for the relative

importance of varying surrounding structure types. *Id.* at 3:25–29. Further, the '096 patent alleges then-existing methods did not allow the physician 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. *Id.* at 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

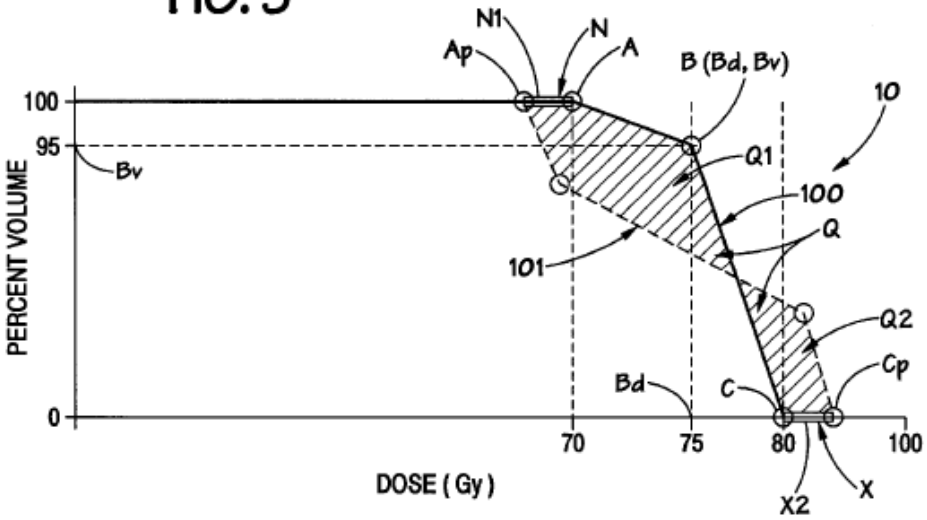
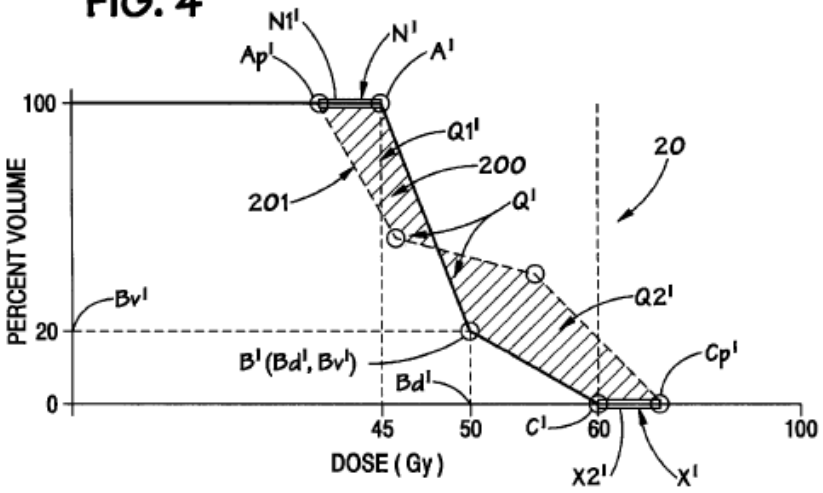


FIG. 4



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

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

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

The '096 patent issued from an application that was filed May 27, 1999, which claims priority to a provisional application filed on May 27, 1998. *Id.*, 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.

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 and recites:

> 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.

Id. at 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 (1997) 17–36 (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 (1997) 243–52 (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 Asserted Grounds

Petitioner challenges claims 1 and 18 of the '096 patent on the following grounds (Pet. 7):

Claim(s) Challenged	35 U.S.C. §	References
1	103(a)[2]	Oldham, Viggars
18	103(a)	Oldham, Viggars, Morrill-1999

[2] 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.

Claim(s) Challenged	35 U.S.C. §	References
1, 18	103(a)	Carol-2, Carol-17
18	103(a)	Carol-2, Carol-17, Morrill-1999

II. ANALYSIS

We now consider Petitioner's asserted grounds and Patent Owner's arguments in the Preliminary Response to determine whether Petitioner has met the "reasonable likelihood" standard for institution under 35 U.S.C. § 314(a).

A. Legal Standards

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *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) (citing *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)).

B. Level of Ordinary Skill in the Art

Citing testimony from Dr. Gall, Petitioner contends a person having ordinary skill in the art would have been

> a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field, and two or more years of experience in radiation oncology physics, 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." Prelim. Resp. 18 (citing Ex. 2002 ¶¶ 60, 67–70).

For purposes of this Decision, we adopt Patent Owner's definition of the level of ordinary skill in the art. On the present record, we are satisfied that this definition comports with the relatively high level of skill necessary to understand and implement the teachings of the '096 patent and the asserted prior art.

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).

Petitioner contends 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. Patent Owner disputes that treatment under § 112 ¶ 6 should apply. Prelim. Resp. 19–22. Patent Owner argues that the lack of the words "means for" in these limitations creates a rebuttable presumption that § 112 ¶ 6 does not apply. *Id.* at 19–20 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1310 (Fed. Cir. 2005)). Patent Owner also contends 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). We agree with Patent Owner for at least these reasons. Thus, we do not apply § 112 ¶ 6 to this limitation.

Based on the current record, we determine that no 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. 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. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 24–40.

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). Patent Owner does not contest the prior art status of Oldham.

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. On this preliminary record, we consider these to be indicators of publication in 1995. We also credit Dr. Hall-Ellis's testimony regarding public accessibility, which is consistent with other evidence of record. Thus, for purposes of this Decision, 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. *Id.* at 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. *Id.*

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

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). Patent Owner does not contest the prior art status of Viggars.

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. On this preliminary record, we consider these to be indicators of publication in 1992. We also credit Dr. Hall-Ellis's testimony regarding public accessibility, which is consistent with other evidence of record. Thus, for purposes of this Decision, 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. Based on Petitioner's analysis, we are persuaded that the combination of Oldham and Viggars teaches the first "using" limitation.

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. Based on Petitioner's analysis, we are persuaded that the combination of Oldham and Viggars teaches the second "using" limitation.

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." 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.

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

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.*

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}.

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

This 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.*

Patent Owner criticizes Petitioner's statement regarding "Viggars' overall CDVH-based cost function." Prelim. Resp. 39–40 (citing Pet. 41). Patent Owner argues "Viggars did not disclose an overall CDVH-based cost function." *Id.* at 39 (citing Ex. 2002 ¶ 104).

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. And, regardless of how Petitioner characterizes Viggars's teachings, 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. On this record, we are persuaded by Petitioner's showing 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 also 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. Based on Petitioner's analysis, we are persuaded that the combination of Oldham and Viggars teaches the "comparing" limitation.

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. Based on Petitioner's analysis, we are persuaded that the combination of Oldham and Viggars teaches the "increasing or decreasing" limitation.

On the present record, Petitioner has established that the combination of Oldham and Viggars teaches all limitations of claim 1.

b. Reasons for the Combination

In 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 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 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). Citing testimony from Dr. Gall, Petitioner contends an ordinarily skilled artisan would have reasonably expected success in identifying the weights. *Id.* at 36 (citing Ex. 1002 ¶ 91).

Patent Owner argues it would not have been "intuitively obvious . . . to switch from, or add to, [Oldham's] simple cost terms to the more computationally complex score functions of Viggars." Prelim. Resp. 34 (citing Ex. 2002 ¶ 96). Patent Owner also argues that this modification would have come at a significant cost, namely, increased computation time. *Id.* at 34–36 (citing, *inter alia*, Ex. 2002 ¶¶ 97–98). 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. *Id.* at 36–37 (citing Ex. 2002 ¶ 99). As part of this argument, Patent Owner explains that it would not have been obvious how to assign weights within the score function, particularly because Viggars made no attempt to assign weights to its score functions and because Viggars says "[i]t is not clear how such weighting should be carried out." *Id.* at 32, 37 (citing Ex. 1015, 425–27). Patent Owner also criticizes Petitioner's reliance on Oldham's importance factor set guesses because this teaching pertains to the simpler

objective function of Oldham. *Id.* at 37–38 (citing Ex. 1019, 253). Finally, Patent Owner contends Oldham already disclosed plan evaluation tools, including dose value histograms. *Id.* at 38 (citing Ex. 1019, 254–56).

Contrary to Patent Owner's arguments, however, 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* 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 tools" such as DVHs (*see* Prelim. Resp. 38 (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.

We also do not agree with Patent Owner that the assignment of importance factors (or weights) in the combined cost function would have impeded the combination. Viggars expressly states that "an optimal plan could, in principle, be selected by assigning weights to each score to derive an overall objective function." Ex. 1015, 425. In addition, Oldham teaches

that one could make "guesses" and evaluate whether a given set of importance factors "would yield good results over as wide a range of patient geometry as possible," a task Oldham characterized as "surprisingly easy." Ex. 1019, 253. Although Patent Owner is correct that experimentation would have been required to obtain a set of weights for its proposed cost function incorporating Viggars's score functions (*see* Prelim. Resp. 36–37), we are persuaded that an ordinarily skilled artisan would have been "readily familiar with and accustomed to the trial-and-error approach taught by Oldham for identifying appropriate parameters for treatment plan optimization," which was "done routinely by clinicians." Ex. 1002 ¶ 85. This is consistent with Oldham's teaching that there naturally is a subjective aspect to how a clinician assigns weights. *See* Ex. 1019, 253–54 (discussing weights being based on "the perceived clinical importance of structures"). As such, we are persuaded preliminarily that an ordinarily skilled artisan would have predicted success in assigning weights. *See* Ex. 1002 ¶ 91. In addition, Viggars's statement that it was not clear how to weight its scoring functions for a single figure of merit (Ex. 1015, 426) does not undermine the combination, because Petitioner relies on Oldham for teaching the weighting. *See* Pet. 36–37, 42–43.

Furthermore, even if the combined system proposed by Petitioner resulted in longer computational times, as is suggested by Patent Owner (*see* Prelim. Resp. 34–36), we do not agree that this would undermine the combination. In particular, claim 1 does not recite any limitations related to processing speed. Nor does the present record suggest that increases in computational time, if any, would have been so significant as to have discouraged a person of ordinary skill from pursuing the apparent benefits.

And, regardless of increased processing time, we are persuaded that an ordinarily skilled artisan would have been motivated to screen beam configurations from Oldham's SARP algorithm, using Oldham's cost function as modified with Viggars's CDVH scoring, to arrive at a more optimal treatment configuration. *See* Ex. 1002 ¶ 88.

The fact that Oldham already mentions dose value histograms (*see* Prelim. Resp. 38–39) 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.

Thus, based on the present record, we are persuaded 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 has also put forth persuasive reasons for combining these references. Based on the present record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing that the subject matter of claim 1 would have been obvious over the combination of Oldham and Viggars.

E. Obviousness Ground Based on Oldham, Viggars, and Morrill-1999

Petitioner contends the subject matter of claim 1 would have been obvious over the combination of Oldham, Viggars, and Morrill-1999. Pet. 47–55. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 41–52. Because we have already determined that Petitioner has established a reasonable likelihood of success with respect to the Oldham–

Viggars ground, we will be instituting on all challenged claims and all grounds in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018). Nevertheless, we provide the following comments regarding the Oldham–Viggars–Morrill-1999 ground.

1. Morrill-1999

Morrill-1999 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-1999, "[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-1999 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 "dose-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 ultimately depends from claim 1 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. Petitioner proposes applying Morrill-1991's partial dose volume constraints within Oldham's fast simulated annealing algorithm. *See* Pet. 51 (citing, *inter alia*, Ex. 1002 ¶¶ 127–128; Ex. 1022, 1343). According to Petitioner, this would result in "combin[ing] the dose-volume constraints of Morrill-1991's constrained simulated annealing method with the optimization algorithm of Oldham and the cost function of Viggars." *Id.* at 50.

Patent Owner argues that Morrill-1991's constrained simulated annealing rejects sample configurations outright if they fail to satisfy the constraints. *See* Prelim. Resp. 46–48 (citing, *inter alia*, Ex. 1022, 1343, 1347; Ex. 2002 ¶¶ 118, 120). Patent Owner further argues that, in Morrill-1991, rejecting a configuration precludes evaluating the objective function. *Id.* at 50 (citing Ex. 1022, 1343; Ex. 2002 ¶ 122). According to Patent Owner, this would undermine Petitioner's suggestion that adding Morrill-1991's constraints would have improved conformation to a desired CDVH as a further feature of the combined Oldham–Viggars cost function. *See id.*

On this preliminary record, we agree with Patent Owner. It is unclear how Morrill-1991's partial dose volume constraints would have been applied to the combined cost function of Oldham and Viggars in a way that improves conformance to a desired CDVH curve. Specifically, Petitioner proposes "a step within the SARP algorithm that checks whether the constraints are satisfied with every sample beam arrangement configuration at each iteration of the simulated annealing algorithm." Pet. 51. But rejecting a particular iteration based on a failed constraint moots the need to evaluate a cost function for CDVH correspondence. *See* Ex. 1022, 1343 ("If the sample configuration fails to satisfy the[] . . . constraints, it is rejected outright (i.e. the [objective function] algorithm is not called)"); Ex. 2002 ¶ 124 (Mr. Chase testifying that "constraints are evaluated before, and in a step separate from, evaluation of any cost function" (emphasis omitted)). As such, Petitioner's proposal conflicts with the method of claim 18, which, via its ultimate dependency from claim 1, seeks conformance to a desired CDVH curve by evaluating a cost function *at each iteration*.

F. Obviousness Grounds Based on (1) Carol-2 and Carol-17 and (2) Carol-2, Carol-17, and Morrill-1999

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. Petitioner also contends the subject matter of claim 18 would have been obvious over the combination of Carol-2 and Carol-17. *Id.* at 66–69. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 52–59. We again provide the following preliminary comments given that we will be instituting on all challenged claims and all grounds in the Petition under *SAS*.

Carol-2 and Carol-17 are chapters that appear in the same book ("IMRT Book"). Pet. 55; *see also supra* § I.E. Petitioner contends Carol-2 and Carol-17 qualify as prior art under 35 U.S.C. § 102(b) because they were publicly available more than one year before the filing date of the provisional application that led to the '096 patent, May 27, 1998. *Id.* at 55–56. In support of its argument, Petitioner provides printouts from the Internet Archive along with a declaration from Christopher Butler, an Internet Archive employee. *See* Ex. 1004. One printout allegedly shows IMRT Book being "available now" on the website of Patent Owner's alleged predecessor-in-interest as of February 12, 1997. *See id.* at 10. Another printout allegedly shows that IMRT Book was for sale on a publisher's website as of April 12, 1997. *See id.* at 19.

Petitioner alternatively contends Carol-2 and Carol-17 qualify as prior art under 35 U.S.C. § 102(a) based on testimony of Dr. Hall-Ellis. Pet. 56 (citing Ex. 1003 ¶¶ 60–64). She testifies that IMRT Book "was publicly accessible as early as May 19, 1998, and in any event, before the May 27, 1998 priority date" based on a record of IMRT Book in the British Library. *Id.* ¶¶ 60–64.

Patent Owner disputes the prior art status of Carol-2 and Carol-17. Prelim. Resp. 52–59. Patent Owner notes that the book cover depicted in the evidence from the Internet Archive differs from the IMRT Book cover depicted in Carol-2 and Carol-17 and the IMRT Book cover in Dr. Hall-Ellis's declaration. *Id.* at 54–57 (citing Ex. 1003, 166; Ex. 1004, 8, 10; Ex. 1020, 1; Ex. 1021, 1). Patent Owner also notes that the publisher's website lists the date of IMRT Book as December 1997, which contradicts Petitioner's Internet Archive evidence. *Id.* at 57 (citing Ex. 2035). Based on

these inconsistencies, Patent Owner argues that Petitioner has not established that Carol-2 and Carol-17 are printed publications that were available more than one year before the earliest effective filing date of the '096 patent, which is May 27, 1998. *See id.* at 57–58.

"[A]t the institution stage, the petition must identify, with particularity, evidence sufficient to establish a reasonable likelihood that the reference was publicly accessible before the critical date of the challenged patent and therefore that there is a reasonable likelihood that it qualifies as a printed publication." *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 13 (PTAB Dec. 20, 2019) (precedential). The determination of whether a document is a "printed publication" under 35 U.S.C. § 102 "involves a case-by-case inquiry into the facts and circumstances surrounding the reference's disclosure to members of the public." *Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1380 (Fed. Cir. 2018) (citing *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004)). "A given reference is 'publicly accessible' upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." *SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008) (quoting *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006)).

Patent Owner raises valid concerns about Petitioner's attempt to qualify Carol-2 and Carol-17 as printed publications under § 102(b). In particular, Petitioner's evidence from the Internet Archive depicts a book cover that is different than the cover of IMRT Book in Exhibits 1020 and 1021. *Compare* Ex. 1004, 8, 10, *with* Ex. 1020, 1, *and* Ex. 1021, 1. This

difference calls into question whether the Internet Archive materials refer to the same book Petitioner relies upon in its unpatentability challenges. And, importantly, even if we were to credit the Internet Archive materials as referring to the same version of IMRT Book asserted here, these materials do not show that the book had been disseminated or otherwise was made available so that a reasonably diligent artisan could locate it. *See SRI*, 511 F.3d at 1194. Thus, on the present record, we do not credit the Internet Archive materials as sufficient evidence of publication more than one year before the May 27, 1998, filing date of the provisional application that led to the '096 patent.

We also note that the copyright page of IMRT Book lists an International Standard Book Number (ISBN) and a copyright date of 1997. *See* Ex. 1020, 3; Ex. 1021, 3. But even if we were to credit this as evidence of publication, it does not substantiate publication more than one year before the May 27, 1998, filing date of the provisional application that led to the '096 patent. By way of explanation, if IMRT Book was published in the latter half of 1997, then it would not qualify for the one-year bar of § 102(b). And, in fact, Patent Owner puts forth some evidence that IMRT Book may have been published in December 1997. *See* Ex. 2035, 1–2. As such, the copyright page information from IMRT Book itself does not substantiate publication more than one year before the May 27, 1998.

Next, we consider Petitioner's bid to qualify Carol-2 and Carol-17 as prior art under 35 U.S.C. § 102(a) based on testimony and evidence from Dr. Hall-Ellis. We credit Dr. Hall-Ellis's testimony that IMRT Book was available in the British Library as of May 19, 1998, because it is supported by certain library records that she attaches to her declaration. *See* Ex. 1003

¶¶ 60–64. Although Patent Owner does not dispute this evidence, Patent Owner argues that Carol-2 and Carol-17 cannot be applied as prior art under § 102(a) because the author of Carol-2 and Carol-17 is an inventor of the '096 patent. Prelim. Resp. 58–59 (citing, *inter alia*, *In re DeBaun*, 687 F.2d 459, 462 (CCPA 1982)).

35 U.S.C. § 102(a) states "[a] person shall be entitled to a patent unless . . . (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." Nevertheless, "one's own work is not prior art under § 102(a) even though it has been disclosed to the public in a manner or form which otherwise would fall under § 102(a)." *In re Katz*, 687 F.2d 450, 454 (Fed. Cir. 1982).

The author of Carol-2 and Carol-17 is *one* of the four named inventors of the '096 patent. *Compare* Ex. 1020, 17, *and* Ex. 1021, 243, *with* Ex. 1001, code (75). Thus, on the present record, the inventive entity of the '096 patent appears to be different from the author of Carol-2 and Carol-17. *See EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 859 F.3d 1341, 1345 (Fed. Cir. 2017) (quoting *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1356 (Fed. Cir. 2003)) (holding that a reference is not "by another" if "the portions of the reference relied on as prior art, and the subject matter of the claims in question, represent the work of a common inventive entity"). In the absence of evidence showing a common inventive entity for the challenged claims and the cited portions of Carol-2 and Carol-17, we determine preliminarily that Carol-2 and Carol-17 qualify as prior art under § 102(a). *See Katz*, 687 F.2d at 454–56.

G. Patent Owner's Arguments Regarding Service of the Petition

Patent Owner contends we should dismiss the Petition because Petitioner "did not timely and properly serve [Patent Owner], as required by paragraph (5) of 35 U.S.C. § 312(a) with the documents required by paragraphs (2)-(4) of that section until after October 18, 2019, the one-year bar date." PO Sur-reply 1; *see also* Prelim. Resp. 59. Specifically, Patent Owner contends that Petitioner dropped off the Petition with FedEx on Friday, October 18, 2019, after the deadline for FedEx overnight delivery, so the Petition materials were not delivered timely. Prelim. Resp. 61. Patent Owner contends it received the Petition on Monday, October 21, 2019, which is two days after delivery "by means at least as fast and reliable as Priority Mail Express" would have been completed in accordance with 37 C.F.R. § 42.6(e)(1). *Id.* at 59. Patent Owner contends this is "not harmless error, and prejudicial to [Patent Owner's] right to repose." PO Sur-reply 1.

Petitioner argues "Patent Owner does not contend that the mere use of 'FedEx Priority Overnight' delivery is a *per se* failure to comply with § 42.105(b)." Pet. Reply 1. Rather, Petitioner characterizes Patent Owner's argument as seeking a conclusion that next-day service was required for compliance with this rule. *Id.* Petitioner also requests that we "waive any procedural defects in the interests of justice since Petitioner acted in good faith." *Id.* at 3.

Patent Owner's arguments would have us read a next-day service requirement into 37 C.F.R. § 42.105(b). We decline to do that. Based on the particular facts of this case, we are satisfied that Petitioner's use of FedEx on a Friday evening followed by delivery on a Monday—the next

business day—is sufficiently akin to Priority Mail Express to satisfy the service requirement § 42.105(b). Further, to the extent necessary, we waive regulatory requirements related to the timing of Petitioner's service based on the particular facts of this case. *See* 37 C.F.R. § 42.5(b). In particular, Patent Owner has not established any actual prejudice or harm arising from Petitioner's next-business-day service. Finally, we do not agree with Patent Owner's implication (PO Sur-reply 1) that the timing of service is a statutory requirement under 35 U.S.C. § 312(a); the plain language of that statute does not address service deadlines.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition and the Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, we institute an *inter partes* review on all of the challenged claims and all of the grounds presented in the Petition. At this stage of the proceeding, we have not made a final determination as to the patentability of these challenged claims.

IV. ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 314, *inter partes* review is instituted as to claims 1 and 18 of the '096 patent with respect to all grounds of unpatentability presented in the Petition; and

FURTHER ORDERED that *inter partes* review is commenced on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

For PETITIONER:

Heidi L. Keefe
Xiaozhen Yu
COOLEY LLP
hkeefe@cooley.com
syu@cooley.com

For PATENT OWNER:

Anthony H. Son
Matthew C. Ruedy
Jeremy J. Edwards
Kaveh V. Saba
MADDOX EDWARDS PLLC
ason@meiplaw.com
mruedy@meiplaw.com
jedwards@meiplaw.com
ksaba@meiplaw.com