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Paper 27
May 1, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELEKTA INC.,
Petitioner,

v.

BEST MEDICAL INTERNATIONAL, INC.,
Patent Owner.

IPR2020-00070
Patent 6,038,283

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

EASTHOM, *Administrative Patent Judge.*

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

I. INTRODUCTION

Elekta Inc. ("Petitioner") filed a petition requesting *inter partes* review of claims 1, 6, 10, 22, 23, 24, 25, 26, 27, 28, 33, 34, 40, 42, 44 and 46 of U.S. Patent No. 6,038,283 (Ex. 1001, the "'283 patent"). Paper 10 ("Pet."). Best Medical International, Inc. ("Patent Owner") filed a Preliminary Response. Paper 12 ("Prelim. Resp.").

The Board's authority under 35 U.S.C. § 314 to determine whether to institute an *inter partes* review requires a demonstration of "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the parties' contentions and the evidence of record, we determine that Petitioner does not establish a reasonable likelihood of prevailing in demonstrating the unpatentability of any of the challenged claims. Accordingly, we deny Petitioner's request and do not institute an *inter partes* review of the challenged claims.

A. Related Matters

Patent Owner identifies the following as related matters involving the '283 patent: *Best Medical International, Inc. v. Accuray, Inc. et al.*, Case No. 2:10-cv-01043 (W.D. Pa.) (dismissed June 26, 2014); *Best Medical International, Inc. v. Elekta Inc. et al.*, No. 1:18-cv-01600-MN (D. Del.) (complaint filed October 16, 2018) (transferred to N.D. Ga.); *Best Medical International, Inc. v. Elekta Inc. et al.* No. 1:19-cv-03409-MLB (N.D. Ga.); *Best Medical International, Inc. v. Varian Medical Systems, Inc. et al.*, No. 1:18-cv-01599 (D. Del.) (complaint filed October 16, 2018). Paper 4, 1–2.

Another petitioner challenged the '283 patent in *Varian Medical*

Systems, Inc. v. Best Medical International, Inc., IPR2020-00075, Paper 13 (PTAB April 20, 2020) (denying institution).

B. Real Parties-In-Interest

Petitioner identifies Elekta Limited (UK), Elekta Holdings U.S., Inc., and Elekta AB as real parties-in-interest. Pet. 2. Patent Owner identifies Best Medical International, Inc. as the real party-in-interest. Paper 3, 1.

C. The ’283 Patent

The ’283 patent describes “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, Abstract. According to the ’283 patent, prior art optimization methods calculate how much radiation a given treatment plan delivers to discrete points in the body without “account[ing] for the relative importance of varying surrounding structure types.” *Id.* at 3:17–29. Instead of optimizing based on radiation delivered to discrete points, the ’283 patent proposes optimizing delivery based on cumulative dose volume histogram (CDVH) curves. *Id.* at 4:13–6:22.

1. Optimization

Iterative optimization techniques mathematically attempt to find the best solution to a problem under certain constraints. Key components of iterative optimization techniques include parameters, constraints, and a cost function. Ex. 1003 ¶¶ 106–111. Parameters, typically beam weights or intensity map values, vary at each iteration. *Id.* ¶¶ 110–111. A given set of parameter values serves to define one possible real-world scenario. *Id.*

The constraints serve to limit parameters within certain boundaries (e.g., pertaining to real-world limitations). Ex. 1004, 9 ("the optimization goal is to find a solution . . . which maximizes the objective function . . . in the space of feasible . . . solutions which satisfy all constraints"), 8 ("If the constraints are too tight (which is not known a priori) there is no solution. If the constraints are too loose, there is an infinite space of solutions . . . ."); Ex. 2002 ¶ 88 ("constraints define the solution parameter space in which optimization occurs").

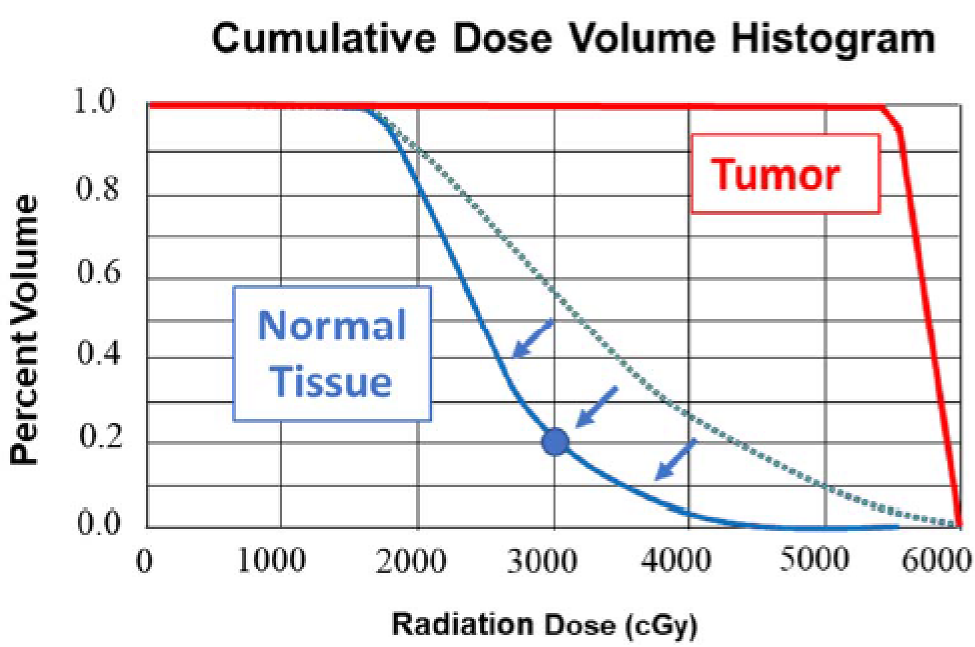
The cost function, also called the objective function, measures how well a given set of parameters provides a desired real-world result. Ex. 1011 ¶ 71. In other words, it provides a numerical score upon which to measure different permutations of parameter values against each other. *Id.* During the iterative optimization process, the algorithm "searches" for the best solution, as measured by the cost function, by varying the parameters in some prescribed fashion many times until the algorithm meets an identified terminating condition. *Id.* ¶¶ 77–78.

Known algorithm "search" techniques include a gradient method (also known as the "down-hill" method) and a simulated annealing method. *Id.* ¶¶ 79–80. The gradient method searches around the current point (defined by the parameter values) to find a new set of parameter values that move the cost function to a lower value. *Id.* ¶ 79; *see also* Ex. 1003 ¶¶ 113–115 (providing more detailed examples). Simulated annealing, another known technique, involves a model built upon an analogy with the way liquids crystallize. Ex. 1004 ¶ 90. Unlike the gradient method, which simply looks for the next adjacent lower value, simulated annealing allows the algorithm to "escape" local minima. *See* Ex. 1003 ¶ 115 (visual example).

2. Cumulative Dose Volume Histogram (CDVH)

CDVH graphs allow physicians to determine at a glance how much radiation a tumor or surrounding organ absorbs. Physicians know how much radiation to deliver to a certain percent of a tumor mass to treat it with a lethal dose. *See* Ex. 1011 ¶¶ 10, 11, 48. Likewise, they know how much radiation to deliver to a healthy tissue to prevent a lethal dose. *See id.* Therefore, a CDVH graph shows at a glance whether the amount of radiation a volume of tissue receives represents a lethal or non-lethal dose. *See id.*

The following Figure illustrates a CDVH graph:



Ex. 2002 ¶ 48. The above graph shows hypothetical CDVH curves for normal tissue (blue) and a tumor (red). For the tumor, the graph shows that 100% of the volume of the tumor will receive at least 5500 units of radiation. For the normal tissue, the graph shows that 100% of the volume of the tissue will receive at least 1500 units of radiation, but only 20% of the volume of the tissue will receive more than 3000 units (i.e., 80% of the tissue receives no more than 3000 units). *See also* Ex. 1006, 8–10 (describing CDVH curves in depth).

D. Challenged Claims

The challenged claims consist of independent claims 1, 22, 25, 33, and 40, and dependent claims 6, 10, 23, 24, 25, 26, 27, 28, 34, 42, 44 and 46. Independent claims 1 and 33 follow:

> 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 pre-determined desired dose prescription; and
>
> rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired prescription and accepting the change of the proposed beam arrangement 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.
>
> 33. A method of determining an optimized radiation beam arrangement for applying radiation to at least one tumor target volume while minimizing radiation to at least one structure volume in a patient, comprising the steps of:
>
> distinguishing each of the at least one tumor target volume and each of the at least one structure volume by target or structure type, wherein the target or structure types are distinguished as either Biologically Uniform or Biologically Polymorphic;

> determining desired partial volume data for each of the at least one target volume and structure volume associated with a desired dose prescription;
>
> entering the desired partial volume data into a computer; in response to the desired partial volume data and in response to the target or structure type of each of the at least one tumor target volume and each of the at least one structure volume, using the computer to computationally calculate an optimized radiation beam arrangement.

E. Prior Art and Asserted Grounds

Petitioner asserts the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1, 10, 22, 25	103[1]	Niemierko[2]
23, 24, 26, 33, 40, 44	103	Niemierko, Goitein[3]
6	103	Niemierko, Mohan[4]
27, 28, 34, 42, 46	103	Niemierko, Goitein, Mohan

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[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103 (effective March 16, 2013) after the '283 patent's effective filing date, so the pre-AIA version of § 103 applies.

[2] Andrzej Niemierko, Ph.D., *Random Search Algorithm (RONSC) for Optimization of Radiation Therapy with both Physical and Biological End Points and Constraints*, Int'l J. of Radiation Oncology, Biology, Physics, V. 23, No. 1, 89–98 (1992) (Ex. 1004).

[3] Michael Goitein, *The Comparison of Treatment Plans*, Seminars in Radiation Oncology, V. 2, No. 4, 246–56 (1992) (Ex. 1006).

[4] Radhe Mohan, et al., *The Potential and Limitations of the Inverse Radiotherapy Technique*, Radiotherapy and Oncology, V. 32, No. 3, 232–45 (1994) (Ex. 1008).

II. PATENTABILITY ANALYSIS

A. Claim Construction

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

B. Level of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have had an "undergraduate degree in science, computer science, engineering or math, and have additional training in radiation dosimetry, medical physics, medicine, or an equivalent field of study, with at least 2–3 years of computer programming experience and some clinical experience in radiation therapy or radiation therapy treatment planning." Pet. 24 (citing Ex. 1003 ¶ 62).

Patent Owner asserts that a person with ordinary skill in the art would have had "a master's or doctoral degree in radiation dosimetry, physics, medical physics, or medicine, or equivalent disciplines, and three years of clinical experience in radiation treatment planning." Prelim. Resp. 19 (citing Ex. 2002 ¶ 67). Patent Owner asserts that 2–3 years of formal computer programming experience would not be a typical requirement. *Id.* (citing Ex. 2002 ¶ 68). Patent Owner also urges a flexible approach that involves trading some formal education for experience and vice versa. *See id.* at 19–20.

The prior art references and the '283 patent imply a highly skilled and technically proficient audience. *See, e.g., W.L. Gore & Assoc., Inc. v.*

Garlock, Inc., 721 F.2d 1540, 1556 (Fed. Cir. 1983) ("Patents . . . are written to enable those skilled in the art to practice the invention."). For purposes of this Decision, Petitioner's and Patent Owner's proposals do not differ materially. The prior art of record and the '283 patent support both proposals, and we adopt Patent Owner's.

C. The Niemierko Obviousness Ground (Claims 1, 10, 22, and 25)

Petitioner asserts that claims 1, 10, 22, and 25 would have been obvious in view of Niemierko. Pet. 26–40.

1. Niemierko

Niemierko describes a Random Optimization with Non-linear Score Functions and Constraints (RONSC) algorithm to develop an optimized radiotherapy treatment plan. *See* Ex. 1004, 7. Niemierko explains that even simplified optimization methods take hours to compute. *Id.* at 8 ("even for the 2D cases investigated, and with a simplified dose model, the optimization required 12 or more hours"), 10 ("optimization . . . is computationally very demanding").

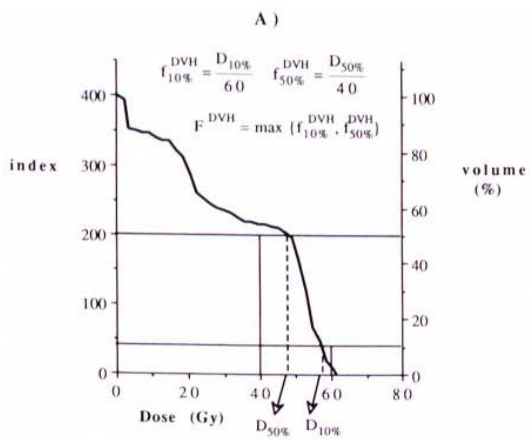
Niemierko also explains that computation time improves dramatically by limiting the number of optimization parameters and forcing them to be non-negative. *Id.* at 10. Niemierko's method binds the optimization search space to a region, defined by the constraints, called the space of feasible solutions. *Id.*; *see also id.* at Fig. 1 (showing a simplified example a feasible solution space).

Niemierko's algorithm identifies the most demanding constraint that prevents a given feasible solution, and then scales the values of the parameters to satisfy the constraint. *See generally id.* at 11 (steps 1–8).

Thereafter, Niemierko's optimization algorithm quickly finds the best solution within that space. *See id.* (steps 9–14); *see also id.* Figs. 3, 4. For example, Niemierko's algorithm finds a solution "within minutes." *Id.* at 15.

Niemierko states its "algorithm is very flexible and can be applied to any type of objective function and constraint." *Id.* at 15. Niemierko's Table 1 lists three specific objective functions for optimization and a number of different constraints. *Id.* at 14. One constraint listed for several objective functions includes DVH (dose-volume histogram). *Id.*

Figures 5A and 5B of Niemierko follows:



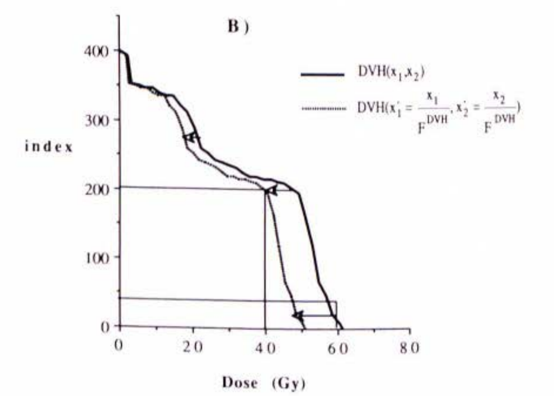


Fig. 5. (a) DVH constraints are evaluated in the same manner as the linear dose constraints. For the given example, the dose to 50% of the volume of interest exceeds the prescribed limit (i.e., the constraint is not satisfied) and the parameters have to be renormalized by a factor F^{DVH}. (b) The renormalized DVH (dotted line) satisfies the prescribed constraints.

Figures 5A and 5B of Niemierko above represents how the algorithm scales or normalizes parameters to meet the DVH constraints. *Id.* at 13. For example, as shown in Figures 5A and 5B, the initially proposed solution for a particular beam arrangement does not meet the desired dose constraint of 4.0 Gy at $D_{50\%}$ (representing 50% of the tumor volume), but scaling the parameters forces the curve to shift left and likewise forces the possible set of optimal solutions (not depicted) to meet that particular dose constraint. *Id.* The possible set of solutions for the particular beam arrangement meets the desired dose constraint at $D_{10\%}$ (representing 10% of the volume) before and after the shift. However, the curve at Figure 5B represents movement further away from the desired constraint at $D_{10\%}$ in order to satisfy the most stringent constraint at $D_{50\%}$. *Compare id.* at Fig. 5A, *with id.* at Fig. 5B.

2. Discussion

Claim 1 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." Petitioner asserts that Niemierko discloses the cost function, reading it onto Niemierko's objective function, which considers DVH constraints.[5] Pet. 28–33. Patent Owner argues that Niemierko's objective function uses the DVH as a constraint, not as the objective function. Prelim. Resp. 32–34. For the reasons explained below, we agree with Patent Owner that Niemierko does not disclose the cost function as claimed.

As explained above, a cost function mathematically scores how well a particular set of inputs achieves a particular desired result. *See supra* Section I.C.1. Constraints, on the other hand, mathematically set the boundaries for each set of inputs in order for the algorithm to arrive at an optimal desired result (as scored by a cost function). *See supra* Sections I.C.1, II.C.1.

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[5] For purposes of this Decision and in accordance with Petitioner's unpatentability contentions, we assume that no material difference exists between (1) an "objective function," as described in Niemierko, and a "cost function," as claimed; and (2) a DVH, as described in Niemierko, and a CDVH, as claimed.

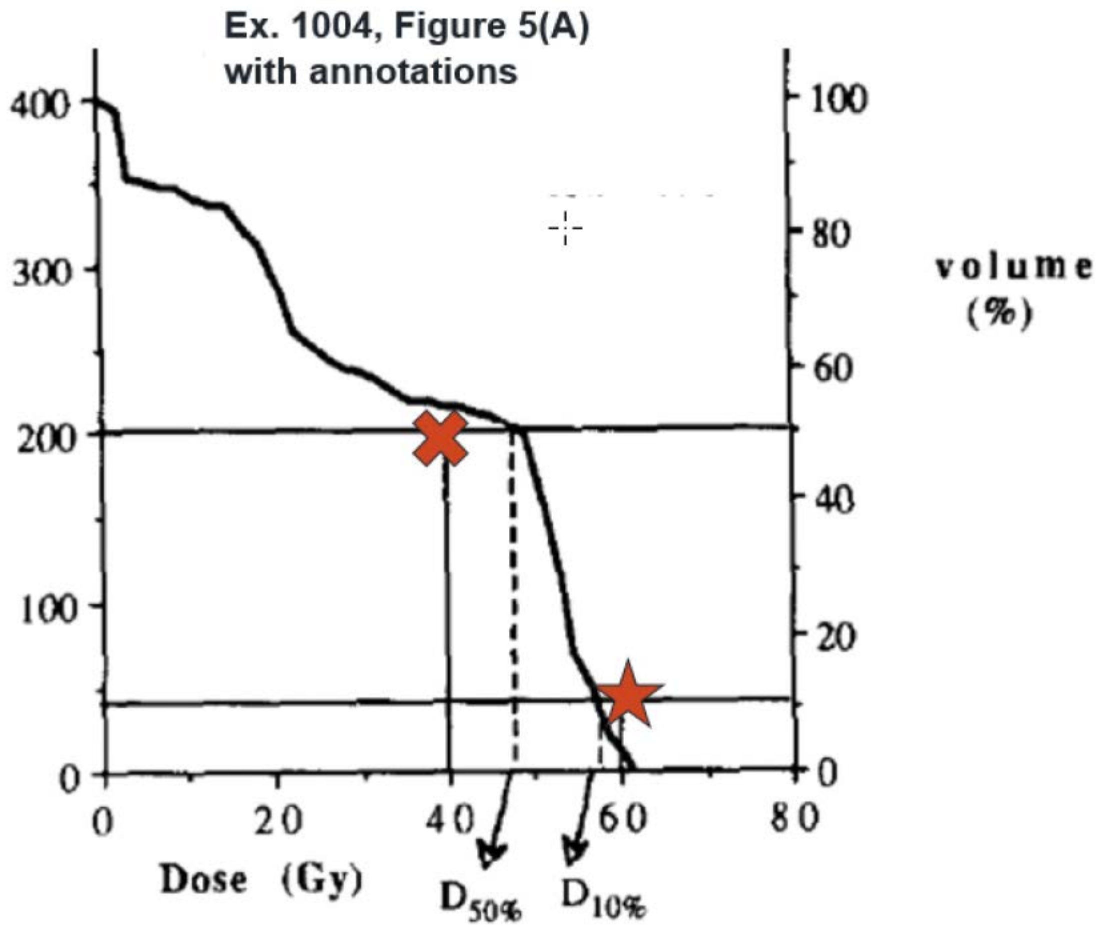
Claim 1 "incorporates a cost function . . . to approach correspondence" between two CDVHs—a proposed and a desired dose CDVH. In other words, claim 1 requires determining the numerical value, or "score," reported by the cost function, by comparing the two CDVHs. On this limited record, Petitioner fails to show sufficiently that Niemierko discloses this type of cost function.

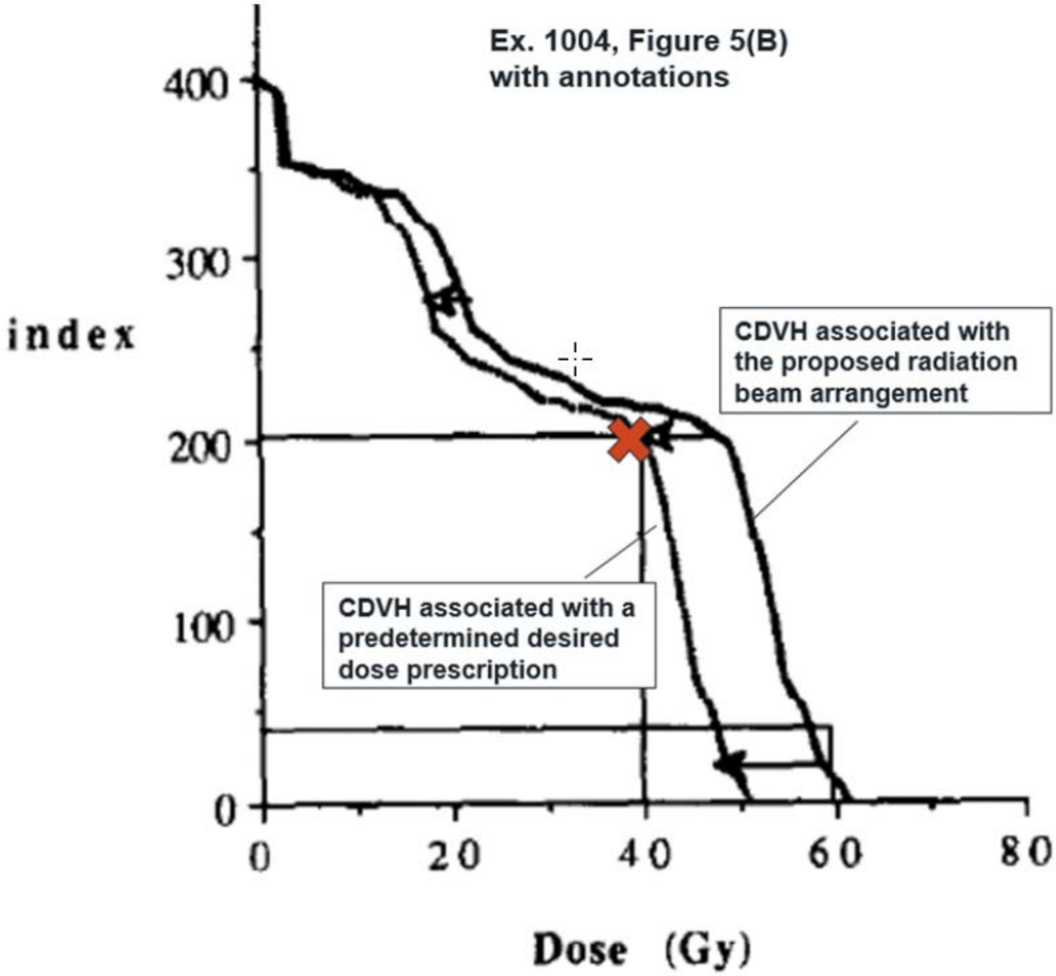
Instead, Niemierko's cost functions seek to (1) maximize tumor control probability (TCP), (2) minimize the difference between the highest and lowest doses to a target tissue, or (3) minimize the non-tumor complication probability (NTCP). Ex. 1004, 14 (Table 3). None of these assign a score by comparing two CDVHs.

Rather, Niemierko discloses employing DVH constraints such that the algorithm forces a proposed set of solutions not to exceed a certain dose at a particular DVH, where typically that dose represents the most stringent constraint. *See, e.g.*, Ex. 1004, Figs. 5A, 5B. In other words, Niemierko's algorithm simply forces the set of possible solutions to satisfy the most stringent constraint of a DVH value. *See id.* After forcing the set of solutions to fall within a set region to satisfy the most stringent constraint, the algorithm does not calculate a cost or score based on comparing two CDVHs. Ex. 1004, 11–12. Claim 1 requires this comparison by "incorporating a cost function at each iteration to approach correspondence" of a proposed CDVH to a desired CDVH.

Although Petitioner generally asserts obviousness, Petitioner specifically relies on what Niemierko *discloses* in conjunction with Figures 5A and 5B without articulating any modification to Niemierko's disclosure. *See* Pet. 28–30 (annotating Ex. 1004, Figs. 5A and 5B). Petitioner fails to show sufficiently that Niemierko's cost function optimization algorithm necessarily results in the CDVH associated with a proposed beam arrangement (as represented in Figures 5A and 5B of Niemierko) to approach a CDVH associated with a predetermined desired dose prescription at each iteration.

Petitioner relies on annotated versions of Niemierko's Figures 5A and 5B, which follow:





Petitioner's annotations of Niemierko's Figures 5A and 5B portray a leftward shift of the CDVH curve representing a beam arrangement toward a dose volume constraint of 40 Gys associated with 50% of the volume of the tumor, $D_{50\%}$. Pet. 31–32. Although Figure 5B portrays a leftward shift toward the desired dose constraint for $D_{50\%}$ (red X), the curve also shifts away from the desired dose constraint for $D_{10\%}$ (red star). *Compare id.* at 31 (annotated Fig. 5A), *with id.* at 32 (annotated Fig. 5B). Then, after the shift, Niemierko's cost function algorithm searches for a solution that best meets one of the three objectives listed in Niemierko's Table 3 as outlined above—*instead of* a solution that approaches correspondence of two CDVHs *at each* *iteration*. *See* Ex. 1004, 12–14 (Table 3, Objective Functions). As such, Petitioner has not shown sufficiently that Niemierko discloses the claimed cost function.

Petitioner relies on the same unpersuasive assertion in its analysis of independent claims 22 and 25. Pet. 35–39. Similar to claim 1, these claims require incorporating "a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription." So unlike claim 1, claims 22 and 25 require the cost function to approach correspondence of partial volume data instead of CDVHs. As noted, Petitioner relies on its showing with respect to claim 1. *See* Pet. 22, 38.

As discussed above, Petitioner relies upon Niemierko's Figures 5A and 5B. Assuming the two points $D_{50\%}$ and $D_{10\%}$ in Niemierko's Figure 5A as annotated by Petitioner represent a pre-determined dose prescription (*see* Pet. 31), these points also represent constraints utilized by Niemierko's algorithm. *See* Ex. 1004, 13, Fig. 5 ("For the given example, the dose to 50% of the volume of interest exceeds the prescribed limit (i.e., the constraint is not satisfied) and the parameters have to be normalized by a factor F^{DVH}.").

We agree with Petitioner that Figures 5A and 5B of Niemierko show the CDVH curve shifting to satisfy the most stringent constraint. *See, e.g.*, *supra* Section II.C.1. For example, Petitioner asserts that prior to the shift, "the 'star' dose prescription [$D_{10\%}$] is satisfied by the CDVH for the proposed beam arrangement, but the dose prescription [$D_{50\%}$] 'is not satisfied.'" Pet. 31 (quoting Ex. 1004, Figure 5A caption). In addition, Petitioner's annotations reveal that Figure 5B represents a shift of the partial volume data associated with the radiation beam toward the desired "most demanding" dose prescription for $D_{50\%}$, but away from the "star" representing the desired dose prescription for $D_{10\%}$. *See id.* at 31–32; Ex. 1004, 11 (normalizing via the constraints "shift[s] the solution to the hyper-surface in parameter space defined by the most demanding linear constraint") (discussing Equation (7)).

In other words, Niemierko's constraint-based normalization and resultant shift (which confines the possible set of optimal solutions) may result in movement away from lesser-demanding constraint points, such as it does with respect to the constraint point $D_{10\%.}$ On this limited record, Petitioner fails to show sufficiently how shifting the initial beam representative curve at a single instance to satisfy a single desired most demanding partial volume point constraint at $D_{50\%}$ (while moving away from other data points such as $D_{10\%}$), represents "a cost function *at each iteration to approach* correspondence of partial volume data." In addition, similar to the discussion above with respect to claim 1, after the shift, Niemierko's cost function optimizes for solutions *other than* what claims 22 and 25 require, i.e., the partial dose volume. So the solutions do not necessarily approach the claimed correspondence of partial dose volumes at each iteration. *See* Ex. 1003, 8–9; Prelim. Resp. 29–30 (citing Ex. 2002 ¶¶ 91–92).

Petitioner's analysis regarding dependent claim 10 does not remedy the deficiency in the analysis of independent claim 1. *See id.* at 34–35. In view of the above, we determine that Petitioner has not established a reasonable likelihood of success in showing that claims 1, 10, 22, or 25 would have been obvious in view of Niemierko.

D. The Niemierko-Goitein Ground (Claims 23, 24, 26, 33, 40, and 44); the Niemierko-Mohan Ground (Claim 6); and the Niemierko-Goitein-Mohan Ground (Claims 27, 28, 34, 42, and 46)

Independent claim 33 recites "distinguishing . . . at least one tumor target volume and . . . at least one structure volume . . . as either Biologically Uniform or Biologically Polymorphic," and "in response to . . . the target or structure type of each of the at least one tumor target volume and each of the at least one structure volume, using the computer to computationally calculate an optimized radiation beam arrangement." Relying on Goitein, Petitioner asserts that a person of ordinary skill would have known the concepts associated with the claim terms "Biologically Uniform" and "Biologically Polymorphic." Pet. 43.

However, as Patent Owner argues, Petitioner does not show sufficiently that the combined references teach or suggest "*in response to . . . the target or structure type of each of the at least one tumor target volume and each of the at least one structure volume*, using the computer to computationally calculate an optimized radiation beam arrangement" as recited in claim 33 (emphasis added). *See* Prelim. Resp. 45. Rather, Petitioner refers to its analysis "in Section IX.B.a" to address this limitation. Pet. 45. But Section IX.B provides a challenge to claim 10, and that challenge does not include a discussion of the limitation at issue here. *See* Pet. 34–35; Prelim. Resp. 44–45.

Claim 40, recites "in response to the desired partial volume data, using the computer to computationally approximate desired CDVHs for each of the at least one target and structure associated with the desired dose prescription." Petitioner again relies on its showing with respect to claim 1. Pet. 46 (relying "on the reasons discussed in Section IX.A[c]"). However, as Patent Owner argues, Petitioner's citations with respect to claim 1 do not show "desired CDVHs for each of the at least one target and structure associated with the desired dose prescription." *See* Prelim. Resp. 45.

Rather, the shifted curve in annotated Figure 5B that Petitioner relies upon shows a shift to the left of a CDVH associated with the proposed beam arrangement so that it satisfies the most demanding constraint as discussed above. *See* Pet. 32. Petitioner fails to explain sufficiently how shifting the curve associated with a proposed beam arrangement toward a single partial volume data point discloses CDVHs for a target and a structure associated with the desired dose prescription in the manner recited by claim 40. *See id.*

Petitioner's analysis of the dependent claims does not remedy the deficiency of the independent claims. Accordingly, we determine that Petitioner has not established a reasonable likelihood of success in showing that claims 6, 23, 24, 26–28, 33, 34, 40, 42, 44, and 46 would have been obvious.

III. ORDER

We determine that Petitioner has not demonstrated a reasonable likelihood that it would succeed in demonstrating that one or more claims of the '283 patent would have been unpatentable under any of the grounds asserted in its Petition.

In view of the foregoing, it is hereby ORDERED that the Petition seeking institution of an *inter partes* review of the challenged claims of the '283 patent is *denied*.

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