UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELEKTA INC.,
Petitioner,

v.

BEST MEDICAL INTERNATIONAL, INC.,
Patent Owner.

IPR2020-00074
Patent 6,393,096 B1

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

SAINDON, *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, 18, 21–24, 31–34, 36–38, 40, and 43–46 of U.S. Patent No. 6,393,096 B1 (Ex. 1001, "the '096 patent"). Paper 5 ("Pet."). Best Medical International, Inc. ("Patent Owner") filed a Preliminary Response. Paper 8 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented 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." 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.4(a) ("The Board institutes the trial on behalf of the Director."). Taking into account the arguments presented in the Petition and Preliminary Response, we conclude that the information presented in the Petition does not establish a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim. Accordingly, we do not institute an *inter partes* review.

A. Related Matters

The '096 patent is the subject of IPR2020-00071 and IPR2020-00072, brought by a different petitioner, which are decided at the same time as this proceeding.

Petitioner also challenges related patents: U.S. Patent No. 7,266,175 ("the '175 patent") in IPR2020-00073, U.S. Patent No. 7,015,490 ("the '490 patent") in IPR2020-00067, and U.S. Patent No. 6,038,283 ("the '283 patent") in IPR2020-00070. The '175 patent is also the subject of

IPR2020-00053 and IPR2020-00077. The ’490 patent is also the subject of IPR2020-00076, and the ’283 patent is the subject of IPR2020-00075.

According to the parties, the ’096 patent is involved in *Best Medical International, Inc.* v. *Elekta Inc.*, 1:19-cv-03409-MLB (N.D. Ga.) and *Best Medical International, Inc. v. Varian Medical Systems, Inc.*, 1:18-cv-01599 (D. Del.). Pet. 2; Paper 3, 1–2 (Patent Owner’s Mandatory Notice).

B. Real Parties In Interest

The parties do not present any dispute over real parties in interest. Petitioner asserts that Elekta Limited (UK), Elekta Holdings U.S., Inc., and Elekta AB are the real parties in interest. Pet. 2. Patent Owner asserts that Best Medical International, Inc. is the real party in interest. Paper 3, 1.

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, Abstract. According to the ’096 patent, optimization methods use mathematical functions to determine how much radiation a given treatment plan would deliver to discrete points in the body. *Id.* at 3:17–29. Instead of optimizing based on radiation delivered to discrete points, the ’096 patent proposes to optimize based on Cumulative Dose Volume Histogram (CDVH) curves. *Id.* at 5:57–64, 10:37–50. The concepts of optimization and CDVH curves are explained in more detail below.

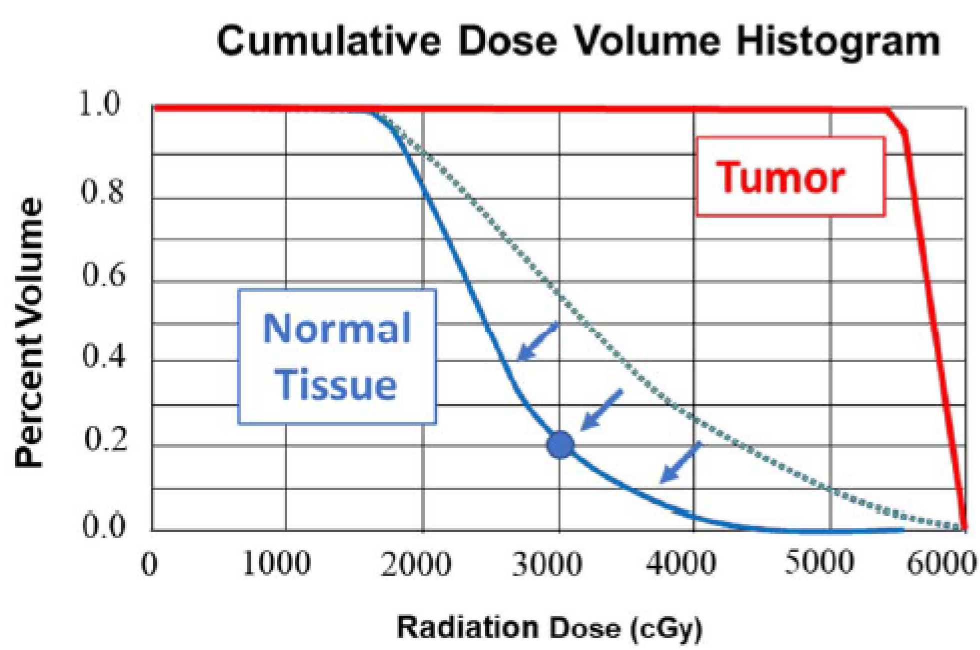
1. *Optimization*

Iterative optimization is a mathematical technique used to find the best solution to a problem, given certain constraints. The key components of iterative optimization are the parameters, the constraints, and the cost function. The parameters are the values that can vary at each iteration. Ex. 1003 ¶ 110. A given set of parameter values serve 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, 91 ("the optimization goal is to find a solution . . . which maximizes the objective function . . . in the space of feasible . . . solutions which satisfy all constraints"); Ex. 2002 ¶ 89 ("constraints define the solution parameter space in which optimization occurs"). The cost function, also sometimes known as the objective function, is the component that serves to measure 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 different permutations of parameter values can be measured against each other. *Id.* In the process of optimization, the algorithm "searches" for the best solution, as measured by the cost function, by varying the parameters in some prescribed fashion many times, until some stopping criteria are met. *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 is another known technique, modeled on an analogy with the way liquids crystallize when cooled. Ex. 1004 ¶ 90. Unlike the gradient method, which simply looks for the next adjacent lower value, simulated annealing has increased tolerance for accepting a temporarily "worse" solution, which then allows it to "escape" local minima. *See* Ex. 1003 ¶ 115 (providing a visual example).

2. *Cumulative Dose Volume Histogram (CDVH)*

Cumulative dose volume histograms (CDVH) are graphs used by physicians to determine how much radiation is being absorbed by a given volume in the body, generally a tumor or surrounding organs. Ex. 1011 ¶ 46. It is typically known how much radiation needs to be delivered to what percent of the tumor mass in order to deliver a lethal dose. *Id.* ¶ 48. Likewise, it is typically known how much radiation can be delivered to a given healthy tissue before it receives a lethal dose. *Id.* The physician uses the CDVH graph to ascertain at a glance how much of a tissue receives how much radiation, to know whether or not a given tissue is likely to die in response to the radiation therapy. *Id.* ¶ 46. 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, it 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 (or, to put it another way, 80% of the tissue receives no more than 3000 units). *See also* Ex. 1006, 251–53 (explaining in depth how CDVH curves are made and how they are used by physicians).

D. Challenged Claims

Claims 1, 18, 21–24, 31–34, 36–38, 40, and 43–46 in the ’096 patent are challenged. Claims 1, 21, 31, 34, 37, and 43 are independent. Independent claim 1 is reproduced below:

> 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.

Independent claim 21 is also reproduced below:

21. 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:

(a) determining a desired CDVH associated with each target and structure;

(b) using a computer to iteratively compare a cost of a radiation beam arrangement proposed during a given iteration to a radiation beam arrangement proposed during the previous iteration based on the relative costs associated with the proposed radiation beam arrangement, the costs being calculated by:

(1) determining a CDVH associated with each target and structure based on the proposed radiation beam arrangement of a given iteration;

(2) assigning cost zones to the desired CDVH and the proposed CDVH of a given iteration associated with each target and structure;

(3) assigning a weight value to each cost zone of each CDVH associated with each target and structure;

(4) for each target and structure, multiplying the weight value of each zone by the quotient of a value representing the area of the zone of the CDVH associated with the proposed radiation beam arrangement and a value representing the area of the zone of the CDVH associated with the desired radiation beam arrangement;

(5) summing the results of step (4) for each zone of each CDVH of each target and structure to obtain a total dosage cost;

(c) increasing or decreasing radiation beam intensity if the change of the proposed beam arrangement leads to a greater correspondence to the desired dose prescription;

(d) 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; and

(e) repeating steps b through d until the proposed radiation beam arrangement has obtained an optimized radiation beam arrangement.

E. Prior Art and Asserted Grounds

Petitioner asserts the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)
1, 18, 31, 32, 34	103	Niemierko[1]
21, 22, 33, 37, 38, 40, 43, 45, 46	103	Niemierko, Goitein[2]
36, 44	103	Niemierko, Mohan[3]
23, 24	103	Niemierko, Goitein, Mohan

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

[1] Andrzej Niemierko, Ph.D., *Random search algorithm (RONSC) for optimization of radiation therapy with both physical and biological end points and constraints*, International Journal of Radiation Oncology, Biology, Physics, Vol. 23, No. 1, 89–98 (1992) (Ex. 1004).

[2] Michael Goitein, *The comparison of treatment plans*, Seminars in Radiation Oncology, Vol. 2, No. 4, 246–56 (1992) (Ex. 1006).

[3] Radhe Mohan, et al., *The potential and limitations of the inverse radiotherapy technique*, Radiotherapy and Oncology, Vol. 32, No. 3, 23–245 (1994) (Ex. 1008).

math, and additional training in radiation dosimetry, medical physics, medicine, or an equivalent field of study. Pet. 25 (citing Ex. 1003 ¶ 62). Petitioner further asserts the person would have had "at least 2–3 years of computer programming experience and some clinical experience in radiation therapy or radiation therapy treatment planning." *Id.*

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. 16 (citing Ex. 2002 ¶ 67). Contrary to Petitioner, Patent Owner asserts that 2–3 years of formal computer programming experience would not be a typical requirement. *Id.* (citing Ex. 2002 ¶ 68).

The prior art references and the '096 patent are written with a highly skilled and technically proficient audience in mind. *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, we see little practical difference between selecting Petitioner's or Patent Owner's proposed definitions. Given the relatively high level of skill reflected in the '096 patent and the prior art, we choose Patent Owner's proposed level of skill.

C. The Niemierko Obviousness Ground (Claims 1, 18, 31, 32, and 34)

Petitioner asserts that claims 1, 18, 31, 32, and 34 are obvious in view of Niemierko. Pet. 26–40. Like the '096 patent, Niemierko is directed to an algorithm for optimizing a radiotherapy plan. A dispositive issue for the Niemierko ground is whether Niemierko describes the same type of cost function that is required by the claims. To resolve this issue, we first turn to the relevant teachings of Niemierko, and then to the parties' contentions.

1. *Niemierko (Ex. 1004)*

Niemierko is a non-patent literature reference published in a radiation oncology journal in 1992 that suggests a particular algorithm to develop an optimized radiotherapy treatment plan. *See generally* Ex. 1004. Niemierko discusses how even simplified optimization methods take a very long time to compute. *Id.* at 90 ("even for the 2D cases investigated, and with a simplified dose model, the optimization required 12 or more hours"), 92 ("optimization . . . is computationally very demanding"). Niemierko recognized that computation time can be improved dramatically by limiting the number of optimization parameters and forcing them to be non-negative. *Id.* at 92. By doing this, the optimization search space is bound to a region, defined by the constraints, called the space of feasible solutions. *Id.* at 92; *see also id.* at Fig. 1 (showing a simplified example of what a feasible solution space may look like). Niemierko's algorithm iteratively identifies the constraint that is keeping a given solution from being feasible, and then scales back the values of the parameters until the constraint is met. *See generally id.* at 93 (e.g., steps 1–8). By this process, the parameter values are scaled such that they increasingly only exist in the feasible solution space, and the optimization algorithm more quickly zeroes in on the best solution within that space. *See id.* (steps 9–14); *see also id.* at Figs. 3, 4. Niemierko reports that its algorithm allows for a solution "within minutes." *Id.* at 97.

Niemierko states that its algorithm is "flexible and can be applied to any type of objective function and constraint." *Id.* at 97. Table 1 in

Niemierko lists three specific objective functions and a number of different constraints. *Id.* at 96. One constraint, listed for several objective functions, is "DVH," which stands for a dose-volume histogram. *Id.* Figure 5 of Niemierko is reproduced below:

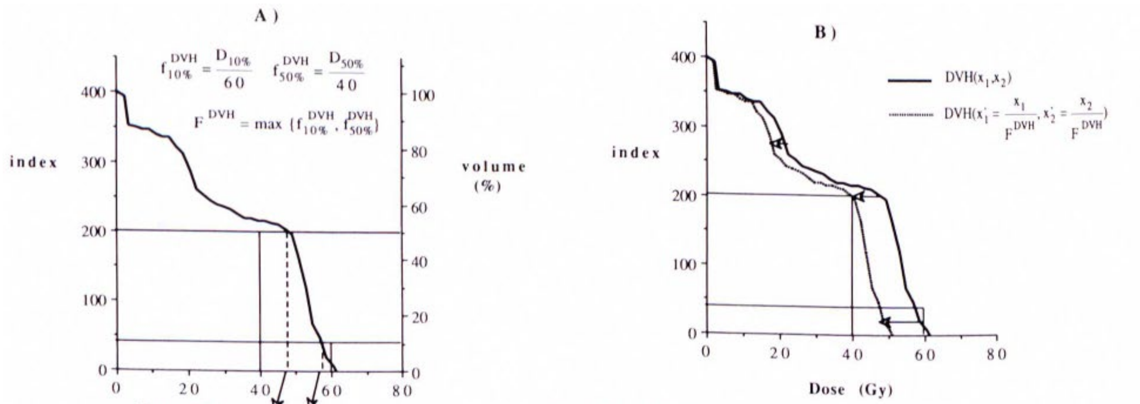


Fig. 5. (a) DVH constraints are evaluated in the same manner as the linear dose constraints. For the given example, the dose to 50% of the volume of interest exceeds the prescribed limit (i.e., the constraint is not satisfied) and the parameters have to be renormalized by a factor F^{DVH}. (b) The renormalized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

Figure 5 of Niemierko explains that DVH constraints are among the constraints evaluated by its algorithm. For example, as shown in Figure 5 A and B, a dose constraint was not met by a proposed solution, such that parameters have to be scaled in a manner that allows them to satisfy the specified dose constraint. *Id.* at 95.

2. *Discussion*

Claim 1 requires a cost function that is used to "approach correspondence of a CDVH [of the] proposed radiation beam arrangement to a CDVH [of the] desired dose." Petitioner asserts that Niemierko's objective function, which considers DVH constraints, satisfies this limitation.[4] Pet. 29–34. Patent Owner argues that Niemierko's objective function uses the DVH as a constraint, not as the objective function. Prelim. Resp. 26–31. For the reasons explained below, we agree with Patent Owner that Niemierko does not disclose the cost function claimed.

As explained above, a cost function is used to assign a numerical score to how well a particular set of inputs achieves a particular desired result. It provides the lens through which options are evaluated. Constraints, on the other hand, provide boundaries that each set of inputs must meet in order to be evaluated by the cost function.

Claim 1 requires not just any cost function, but a particular cost function. Claim 1 states that the cost function is used "to approach correspondence" between two CDVHs—a proposed and a desired dose CDVH. In other words, claim 1 requires that the numerical value, or "score," reported by the cost function is determined by comparing the two CDVHs. Reviewing Niemierko, we find that it does not disclose 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, 96. None of these are assigning a score by comparing two CDVHs. We recognize that Niemierko discloses DVH constraints, which, practically speaking, means that the algorithm does consider whether a proposed solution does not exceed certain

[4] For purposes of this Decision, we consider there to be no practical difference between a "cost function" and an "objective function" or between a DVH and a CDVH.

values on a DVH. *See, e.g., id.* at Fig. 5. But the algorithm simply looks to whether the constraint is met. The algorithm does not calculate a cost or score based on comparing two CDVHs, which claim 1 requires. 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 31 and 34. Pet. 37, 39. Petitioner's analysis regarding dependent claims 18 and 32 does not remedy the deficiency in their corresponding independent claims. In view of the above, we determine that Petitioner has not established a reasonable likelihood of success in showing that claims 1, 18, 31, 32, or 34 are obvious in view of Niemierko.

D. The Niemierko-Goitein Ground (Claims 21, 22, 33, 37, 38, 40, 43, 45, and 46); the Niemierko-Mohan Ground (Claims 36 and 44); and the Niemierko-Goitein-Mohan Ground (Claims 23, 24)

Petitioner's analysis of independent claims 21 and 37 refers back to its analysis of independent claim 1 discussed above and found deficient. Pet. 43–45, 53. In addition, Petitioner's analysis of the claims that depend therefrom does not remedy the deficiency.

As to independent claim 43, Petitioner's analysis does not establish a reasonable likelihood of success. *See* Pet. 56–59. For example, claim 43 recites a step of distinguishing a tumor and structure volume "by target or structure type," but Petitioner's analysis as to that element is directed to providing definitions for elements recited in dependent claim 45 rather than showing how the prior art discloses the "distinguishing" step recited. *Id.* at 56. As another example, claim 43 recites a step of providing users with values that indicate the importance of the object to be irradiated. Petitioner directs our attention to color coding in Goitein that shows isodose levels, but fails to explain (nor do we see) how color coding meets the claim limitation of indicating the importance of the object. *Id.* at 58. Petitioner's analysis of claims 44–46, which depend therefrom, are likewise deficient.

Accordingly, we determine that Petitioner has not established a reasonable likelihood of success in showing that claims 21–24, 33, 36–38, 40, and 43–46 are 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 '096 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 is *denied* and that we do not institute an *inter partes* review of the '096 patent.

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