UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELEKTA INC.

Petitioner

v.

VARIAN MEDICAL SYSTEMS, INC. AND VARIAN MEDICAL SYSTEMS INTERNATIONAL AG

Patent Owner

U.S. Patent No. 7,906,770

Filing date April 4, 2016

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,906,770

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

REGULATIONS

LIST OF EXHIBITS

Petition Exhibit No.	Description
1001	U.S. Patent No. 7,906,770 to Otto
1002	Declaration of Ryan Flynn, Ph.D.
1003	U.S. Patent Application Publication No. 2004/0071261 to Earl et al. ("*Earl '261*")
1004	U.S. Patent Application Publication No. 2003/0086530 to Otto ("*Otto '530*")
1005	Duthoy et al., "Whole Abdominopelvic Radiotherapy (WAPRT) Using Intensity-Modulated Arc Therapy (IMAT): First Clinical Experience" ("*Duthoy*")
1006	U.S. Patent No. 6,546,073 to Lee ("*Lee*")
1007	Wang et al., "Development of Methods for Beam Angle Optimization for IMRT Using an Accelerated Exhaustive Search Strategy" ("*Wang*")
1008	U.S. Patent No. 5,818,902 to Yu ("*Yu '902*")
1009	Earl et al., "Inverse planning for intensity-modulated arc therapy using direct aperture optimization," Phys. Med. Biol. 48 (2003) 1075–89 ("the *Earl Article*")
1010	Reserved
1011	Meedt et al., "Non-coplanar beam direction optimization for intensity-modulated radiotherapy," Phys. Med. Biol. 48 (2003) 2999–3019 ("*Meedt*")
1012	Reserved
1013	Löf, "Development of a general framework for optimization of radiation therapy," Department of Medical Radiation Physics, Stockholm 2000 ("*Löf*")
1014	Reserved
1015	Reserved
1016	File Wrapper for U.S. Patent Application No. 11/996,932 (U.S. Patent No. 7,906,770)
1017	Notice of Allowance dated September 21, 2010, in U.S. Patent Application No. 12/132,597
1018	Images from the International Journal of Radiation Oncology website (http://redjournal.org/issue/S0360-3016(00)X0403-8 and http://www.redjournal.org/article/S0360-3016(03)00663-1/abstract) indicating the publication date of *Duthoy*

Petition Exhibit No.	**Description**
1019	Joint Submission Regarding Constructions of Disputed and Undisputed Claim Terms dated March 1, 2016, in *Certain Radiotherapy Systems and Treatment Planning Software, and Components Thereof*, Investigation No. 337-TA-968
1020	Images from the International Journal of Radiation Oncology website (http://www.redjournal.org/issue/S0360-3016(00)X0430-0 and http://www.redjournal.org/article/S0360-3016(04)00972-1/abstract) indicating the publication date of *Wang*
1021	Images from the IOPscience website (http://iopscience.iop.org/0031-9155/48/8 and http://iopscience.iop.org/article/10.1088/0031-9155/48/8/309) indicating the publication date of *Earl Article*
1022	Reserved
1023	Images from the IOPscience website (http://iopscience.iop.org/0031-9155/48/8 and http://iopscience.iop.org/article/10.1088/0031-9155/48/8/309) indicating the publication date of *Meedt*
1024-1038	Reserved
1039	U.S. Patent No. 6,445,766 to Whitham ("*Whitham*")
1040-1042	Reserved
1043	U.S. Patent No. 7,162,008 to Earl et al. ("*Earl '008*")
1044-1045	Reserved
1046	Selected pages of Appendix 2 to Complainants' Eighth Supplemental Responses and Objections to Respondents' First Set of Interrogatories, dated March 28, 2016, in *Certain Radiotherapy Systems and Treatment Planning Software, and Components Thereof*, Investigation No. 337-TA-968
1047	Declaration of Justin E. Loffredo
1048	Digital Imaging and Communications in Medicine (DICOM), Supplement 11, Radiotherapy Objects, final text dated June 4, 1997, as a supplement to the DICOM Standard, and an extension to Parts 3, 4, and 6 of the published DICOM Standard
1049-1054	Reserved
1055	Verfaillie et al., "Russian Doll Search for Solving Constraint Optimization Problems," AAAI-96 Proceedings, 1996

Elekta Inc. ("Elekta" or "Petitioner") requests that the Board institute *inter partes* review of claim 68 of U.S. Patent No. 7,906,770 ("the '770 patent") (Ex. 1001) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.

I. PRELIMINARY STATEMENT

The '770 patent is directed to "methods and apparatus for planning and delivering radiation to a subject." Ex. 1001 at 1:19-22. In general, the '770 patent describes delivering a radiation beam via a radiation source that rotates, continuously or intermittently, along a "trajectory" having a number of "control points." *Id.* at Abstract. As known in the art, each control point defines one or more radiation delivery parameters associated with the source as it rotates along the trajectory. *See, e.g.,* Ex. 1002 ¶¶ 80-81. For example, a parameter may define the beam's shape or the beam's intensity. *Id.*

The '770 patent then describes a "very simple" optimization process used to determine the radiation delivery parameters associated with each control point. Ex. 1001 at 14:23-24, 22:21-22. In some instances, the optimization process starts with a small number of control points and then repeats the optimization process after adding more control points. *See id.* at 19:1-33.

Radiation treatment plans, along with methods to optimize these plans, have long been known in the radiation therapy industry. Ex. 1002 ¶ 23. For example, *Earl '261* (Ex. 1003) describes a computerized optimization method for planning

and delivering radiation therapy via a source that rotates along a trajectory or arc. *See* Ex. 1003 ¶ 5. As another example, *Duthoy* (Ex. 1005) discusses optimized intensity-modulated arc therapy where the radiation delivery parameters are defined by "control points" along an arc of the rotatable radiation source. *See* Ex. 1005 at 1019. As yet another example, *Otto '530* (Ex. 1004)—a prior art U.S. patent application publication to the same inventor as the '770 patent—is likewise directed to optimized radiation therapy. *See* Ex. 1004 at Abstract, ¶ 2. Similar to the '770 patent's disclosure of starting with an initial number of control points and then adding more during optimization, *Otto '530* employs the same smaller-then-larger optimization technique. *Id.*

As discussed in more detail below, claim 68 of the '770 patent is anticipated by and/or obvious over the prior art. Claim 68 is thus unpatentable and the Board should cancel it.

II. BACKGROUND OF RADIATION THERAPY TECHNOLOGY

The '770 patent is not the first reference to disclose treatment plans for rotatable radiation therapy machines, or the general use of iterative optimization for optimizing such treatment plans. *See* Ex. 1001 at 1:26-2:30; Ex. 1002 ¶ 23. These features were known in the art. Ex. 1002 ¶ 23. By July 2004, it was well known in the radiation therapy industry to develop and deliver treatment plans by a machine that rotates a radiation source around a patient. *Id.*

In radiation therapy, a device such as a linear accelerator ("linac") generates a source of radiation for the treatment of patients. *Id.* ¶ 24. The radiation source outputs a beam having a controlled amount of radiation. *Id.* A typical linac includes a gantry to rotate the radiation source, and thus the beam, around a horizontal axis. *Id.* Because the gantry's horizontal axis is fixed and the source is fixed to the gantry, the source rotates in a plane around the patient. *Id.* A patient table (or couch) supports the patient laying down along the horizontal axis. *Id.* Fig. 1 of *Whitham* (Ex. 1039) (annotated version reproduced here) shows a typical radiation therapy machine.

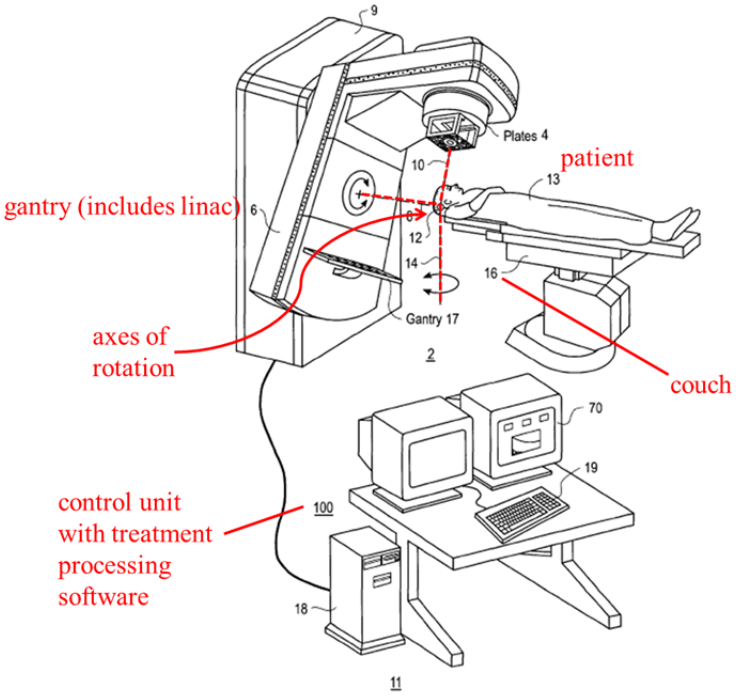


FIG. 1

During therapy, a patient is positioned on the couch so that a specified target (*e.g.*, a tumor) to be irradiated coincides with the beam's isocenter, which is the location where the beam's central axis intersects the gantry's rotational axis. Ex. 1002 ¶ 25. As the gantry rotates, the beam output at each angle of rotation irradiates the tumor. *Id.* An objective of radiation therapy is to irradiate target

tissue while minimizing radiation delivered to healthy tissue. *Id.*; *see also* Ex. 1008 at Abstract; 3:15-17.

To protect healthy tissue, a typical treatment plan will shape the beam to conform it to a cross-sectional shape of the target tumor as viewed from the beam direction. Ex. 1002 ¶ 28. The treatment machine uses a multi-leaf collimator ("MLC"), with two opposing banks of movable "leaves" (also referred to as "veins"), to form an aperture that shapes the cross-section of the beam passing through this aperture. *Id.* The shape of the beam can then roughly match the target shape. *Id.* Fig. 1a of *Yu* (Ex. 1008) (reproduced below left) shows leaves 21 of an MLC to shape a beam to match a target shape, and Fig. 4 of *Earl Article* (Ex. 1009) (reproduced below right) shows a sample sequence of MLC shapes defined by an optimizer. In the figure on the right, the darkened area represents the MLC aperture, while the remaining area represents the MLC leaves that block or absorb any impinging portion of the field. Ex. 1002 ¶ 29. The portion of the beam passing through the MLC aperture will thus have a cross-sectional shape defined by the aperture (*e.g.*, the darkened area in the figure at below right). *Id.*

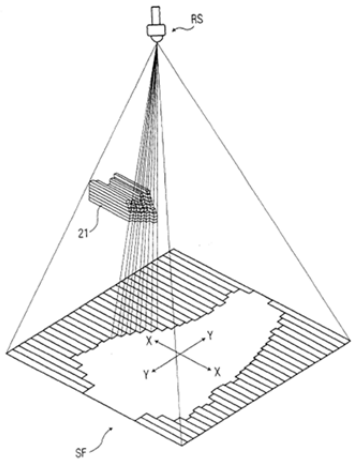


FIG. 1a

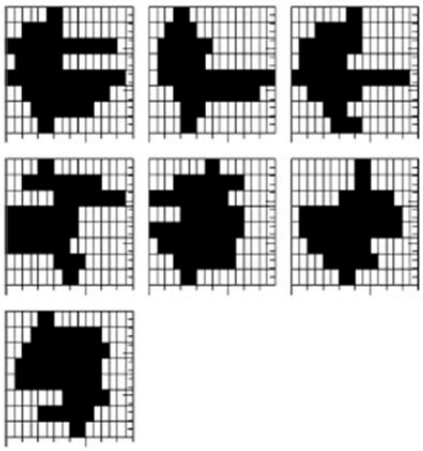
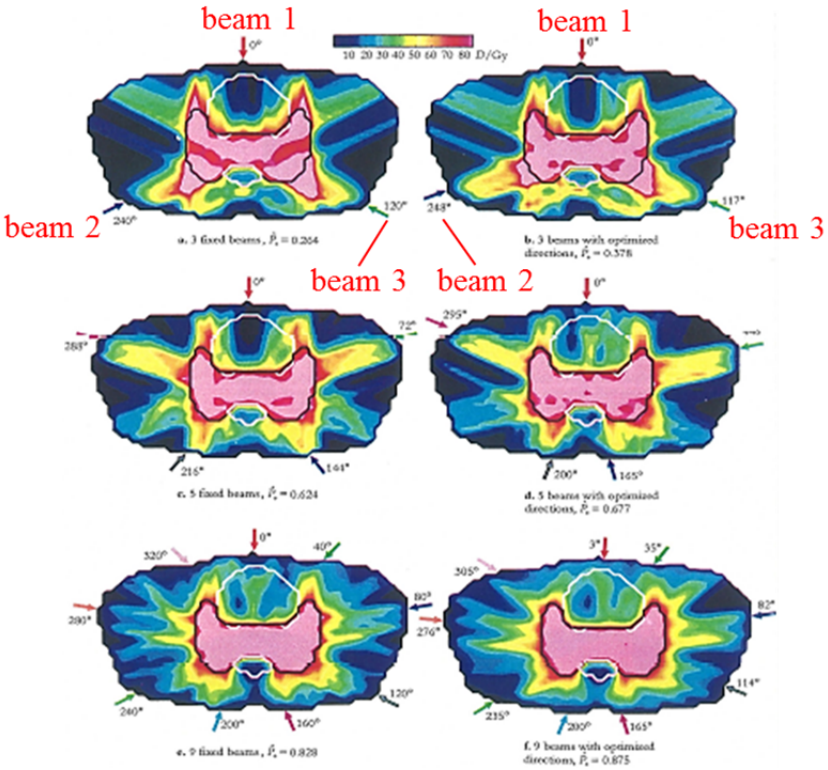


Figure 4. Sample sequence of aperture shapes for an arc of the pseudo-prostate case. Steps are denoted by the vertical lines and are separated by 0.5 cm. The maximum leaf travel between consecutive angles is always 3 cm or less.

In developing a treatment plan, the arrangement of beams is chosen so the dose distribution meets a clinician's prescription. Ex. 1002 ¶ 32. Thus, the main objective of treatment planning is designing a collection of beams (*e.g.*, beams of particular shapes, orientations, and associated doses) to optimize the dose distribution in the patient. *Id.* A treatment planning system typically uses computers to optimize the dose distribution based on a set of parameters that control the delivery machine. *Id.* After optimization, the parameters defined by the treatment plan, such as gantry beam angles, couch angles, and corresponding MLC aperture shapes and doses (or intensity), are transferred to the linac's control system to deliver radiation to the patient. *Id.*

In one common type of radiation therapy, intensity-modulated radiation therapy ("IMRT"), radiation beams shaped by an MLC are delivered at different angles around the patient. *Id.* ¶ 34. The beam shapes either remain constant during radiation delivery or can dynamically change during delivery. *Id.* Fig. 17 of *Löf*

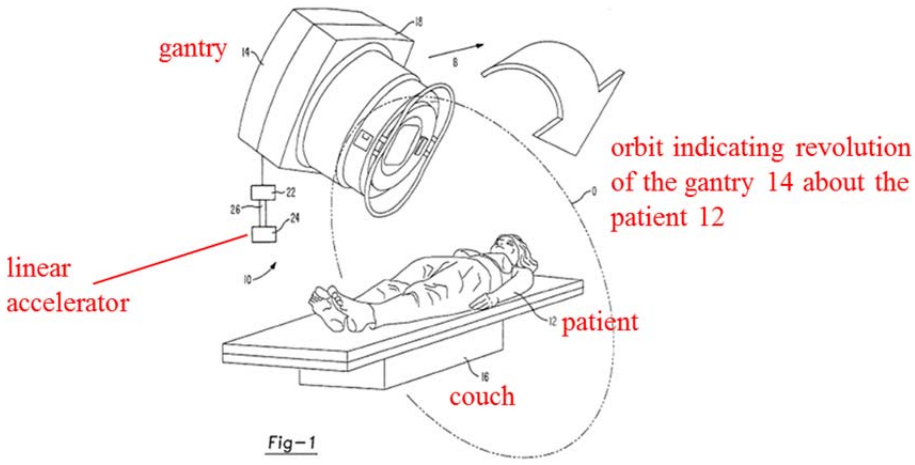
(Ex. 1013) (reproduced and annotated below) shows examples of beams delivered at different gantry angles as is typical in IMRT. Ex. 1013 at Fig. 17.



The above annotated version of Fig. 17 identifies the different beam angles for scenarios with 3 fixed beams (the top two images). Although not annotated, Fig. 17 also shows the different beam angles for scenarios with 5 fixed beams (the middle two images) and for scenarios with 9 fixed beams (the bottom two images). The greater the number of subfields for each beam direction, the more likely it is that the IMRT treatment plan will achieve the clinical goals. Ex. 1002 ¶ 35. For this reason, it is common for more complicated IMRT plans to include multiple subfields at each angular beam direction. *Id.*

In another type of known radiation therapy, intensity modulated arc therapy ("IMAT"), radiation is delivered continuously by a source that travels continuously along one or more arcs around the patient. *Id.* ¶ 41. During delivery, the MLC changes the shape of the radiation beam in accordance with the treatment planning optimization process. *Id.* The beam's intensity can also change along the arcs. *Id.*

Fig. 1 of *Yu* (Ex. 1008) (reproduced and annotated below) shows a subject undergoing IMAT. The apparatus 10 includes a rotatable gantry 14, a moveable couch 16, an MLC controller 22, and a linear accelerator 24, where the gantry 14 has a radiation source 18 and an MLC 20 (not labeled). *See* Ex. 1008 at 6:8-62.



When performing radiation treatment planning for techniques like IMRT and IMAT, the complexity is such that generating a treatment plan via manual trial and error is undesirable in a clinical environment. Ex. 1002 ¶ 47. Instead, automated software systems optimize these plans through "inverse-planning" optimization techniques. *Id.* These optimization techniques determine the parameters that

produce an optimal radiation treatment plan. *Id.* In solving the complex optimization problem, the optimization process determines values for the various parameters, such as the beam intensity and MLC positions associated with each radiation field or beam. *Id.* People skilled in the art have recognized the complexity of optimization techniques and have sought to reduce the complexity while generating optimal radiation treatment plans. *Id.* ¶ 48.

III. THE '770 PATENT

A. Overview

In describing the background of the technology, the '770 patent notes it is "desirable" to irradiate a target tumor volume "while minimizing the dose of radiation delivered to surrounding tissues." Ex. 1001 at 1:32-35. To accomplish this, the '770 patent explains that IMRT "deliver[s] shaped radiation beams from a few different directions[,] . . . each [of which] contribute to the desired dose in the target volume." *Id.* at 1:38-41. In line with what was known at the time, the '770 patent admits that "[a] typical radiation delivery apparatus has a source of radiation, such as a linear accelerator, and a rotatable gantry," *id.* at 1:42-43, and a rotatable MLC to shape the beam, *id.* at 1:45-53. The '770 patent also admits that standard treatment planning identifies an "optimal . . . set of parameters for delivering radiation to a particular treatment volume." *Id.* at 1:63-65.

The ’770 patent purports to address the desire of treating the patient in a short amount of time. *Id.* at 2:34-42. But broad claim 68 of the ’770 patent challenged in this Petition recites nothing more than what was already well known in the art: a program that executes a method for planning delivery of radiation dose to a target area of a subject. *Id.* at 37:17-39.

B. Prosecution History

During prosecution, the Examiner rejected the claims under obviousness-type double patenting based on claims 1-34 of a copending application. Ex. 1016 at 243-44. The Applicant overcame the rejection by filing a Terminal Disclaimer in the copending application, *id.* at 36, after which the claims were allowed. *Id.* at 13-15.

In allowing the claims, the Examiner asserted the following is a “key element of the applicant’s invention, not disclosed in prior art but present in all of the independent claims”:

> defining a set of one or more optimization goals, the set of one or more optimization goals comprising a desired dose distribution in the subject;
>
> defining an initial trajectory for relative movement between a radiation source and the subject and an initial plurality of control points along the initial trajectory;
>
> iteratively optimizing a simulated dose distribution relative to the set of one or more optimization goals and subject to one or more initial

> optimization constraints to determine one or more radiation delivery parameters associated with each of the control points; and
>
> wherein iteratively optimizing the simulated dose distribution comprises defining an optimized trajectory for relative movement between the radiation source and the subject on the basis of the radiation delivery parameters.

Id. at 14-15.

Contrary to the Examiner's assertion, these features are not included in "all" the independent claims. Indeed, claim 68, which Elekta challenges here, lacks these features, including the emphasized features of "defining an initial trajectory" and "defining an optimized trajectory." *Id.*(emphases added).

Notably, the application that issued as the '770 patent was reviewed by the same Examiner who previously examined the related copending application. *Id.* at 9, 241; Ex. 1017 at 1. Although the Examiner did not reject the claims based on prior art during prosecution, the Examiner allowed the claims only about one month after allowing the copending application. Ex. 1016 at 9-16; Ex. 1017 at 1.

IV. A PERSON OF ORDINARY SKILL IN THE ART

The '770 patent claims priority to a U.S. provisional application filed on July 25, 2005. A person of ordinary skill in the art would be a person with a graduate degree (MS or PhD) in medical physics or a related field (e.g., physics or engineering), and three years of work in radiation oncology beyond the completion

of his or her degree, including at least three years of experience with programming of treatment planning software systems and programming of optimization processes. Ex. 1002 ¶ 22.

V. CLAIM CONSTRUCTION

Claim terms are given their ordinary and accustomed meaning as understood by one of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). A claim in an unexpired patent subject to *inter partes* review receives the "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). Thus, the constructions in this proceeding may differ from the constructions in any district court or International Trade Commission ("ITC") proceedings, including Civil Action No. 3:14-CV-00757. Although the broadest reasonable interpretation ("BRI") should be applied to any claim terms construed in this proceeding, the following term(s), in particular, require construction.

Elekta's constructions below for "control point," "initial termination conditions," and "iteratively optimizing" are the same as those agreed to by both Elekta and the ITC Investigative Staff in the related ITC investigation. Ex. 1019 (Ex. 1 at 5-6).

A. "control point"

"Control point" should be construed as "a set of one or more radiation delivery parameters associated with a point along the trajectory of the radiation source." *See id.*; Ex. 1002 ¶ 72. The specification supports this construction. *See, e.g.*, Ex. 1001 at 6:4-7 ("For each of a number of control points along a trajectory, a radiation delivery plan may comprise: a set of motion axes parameters, a set of beam shape parameters and a beam intensity." (emphases added)); *see also id.* at 7:50-58, 8:15-29. The specification thus uses the term "set" to clarify that a "control point" refers to a collection of one or more parameters—*e.g.*, not multiple parameters that are disassociated with one another and, thus, not part of a "set." Ex. 1002 ¶ 72.

The specification also expressly describes "control points" as locations along a trajectory. For instance, the '770 patent states that, "[f]or the purpose of implementing the present invention, it is useful to discretize a desired trajectory into a number of 'control points' at various locations along the trajectory." Ex. 1001 at 7:50-52 (emphasis added). Fig. 2 is consistent with this explanation by using arrows to identify a "point" or location on trajectory 30 as corresponding to each control point 32. *Id.* at Fig. 2. In fact, construing "control point" to be

associated with a "portion" of a trajectory (as suggested by Patent Owner in the ITC, Ex. 1019 at 9-10 (Ex. 1 at 5-6)) would flatly contradict Fig. 2.[1] Ex. 1002 ¶ 72.

At the ITC, it is apparent from Patent Owner's infringement contentions, Ex. 1046, that Patent Owner seeks to unreasonably broaden the meaning of "control point" beyond its proper construction explained above and confirmed by Dr. Flynn. Ex. 1002 ¶ 72, n.4; *see also* Ex. 1046. Because an infringement analysis begins by construing the claim terms, *see, e.g.*, *Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1372 (Fed. Cir. 2006), Patent Owner, through its infringement contentions, proposes a construction of "control point" that encompasses, *e.g.*, fluence maps and/or beam directions. *See* Ex. 1046 at 12 ("Fluence maps generated during stage-one are computed at the increment gantry angles."), 24; Ex. 1002 ¶ 120. But Patent Owner's apparent construction of "control point" does not comport with its proper meaning as understood by one of ordinary skill in the art or the teachings of the '770 patent specification. The Board should thus adopt Elekta's construction of "control point" as "a set of one or more radiation delivery parameters associated with a point along the trajectory of the radiation source."

[1] The term "portion," unlike the term "point," is used to describe the part of a trajectory existing between control points. *See, e.g.*, Ex. 1001 at 8:10-14.

B. "initial termination conditions"

"Initial termination conditions" should be construed as "criteria indicating termination of initial optimization." *See* Ex. 1019 (Ex. 1 at 5); Ex. 1002 ¶ 73. The specification supports this construction. *See, e.g.,* Ex. 1001 at 19:64-20:13; 20:21-26; *see also id.* at 14:3-22. In the ITC, Patent Owner agrees with this construction. *See* Ex. 1019 (Ex. 1 at 5).

C. "iteratively optimizing"

"Iteratively optimizing" should be construed as "repeatedly modifying parameters to achieve an optimization goal." *See* Ex. 1019 (Ex. 1 at 5); Ex. 1002 ¶ 74. The specification supports this construction. *See, e.g.,* Ex. 1001 at 14:4-11, Fig. 4A, 20:33-35, Fig. 8. In the ITC, Patent Owner agrees with this construction. *See* Ex. 1019 (Ex. 1 at 5).

VI. CLAIM 68 IS UNPATENTABLE BASED ON THE DISCLOSURE OF *OTTO '530*

A. *Otto '530* anticipates claim 68

Otto '530, which published on May 8, 2003, and is therefore prior art under pre-AIA 35 U.S.C. § 102(b), is directed to "radiotherapy devices and to systems and methods for controlling radiotherapy devices to deliver radiation treatments." Ex. 1004 ¶ 2. As provided below, *Otto '530* discloses each element of claim 68.

68.a. "A program product comprising computer readable instructions which, when executed by a processor, cause the processor to execute a method for planning delivery of

radiation dose to a target area within a subject"

Otto '530 discloses a "method for controlling a radiotherapy device to deliver a desired radiation field in a treatment area" [the claimed "target area"] of a patient. *Id.* ¶ 24. The term "field" here refers to the two-dimensional field of radiation delivered by a beam having a particular shape. Ex. 1002 ¶¶ 29, 77. When multiple beams of different shapes deliver radiation along the same direction, then each beam has a corresponding "sub-field" and, together, the multiple beams create an "overall radiation field." *Id*.

Otto '530 explains that the method "may be performed on a treatment planning computer system or on another suitable programmed data processing device." Ex. 1004 ¶ 44. The desired "overall radiation field may be specified in output from treatment planning software." *Id.* ¶ 44; *see also id.* ¶ 79 (explaining that "the invention may be embodied in a computer-based treatment planning system" and "may comprise any medium which carries a set of computer-readable signals").

68.b. "defining a set of one or more optimization goals, the set of one or more optimization goals comprising a desired dose distribution in the subject"

Otto '530 describes optimization techniques for developing MLC configurations. *See, e.g., id.* at Abstract; ¶¶ 51, 57, Figs. 5, 6. At block 130 of the optimization process in Fig. 6, it is determined whether "termination criteria" (the

claimed "optimization goals") are met. *See id.* ¶¶ 71-74. Termination criteria may, for example,

> require that the calculated radiation field must not exceed the desired radiation field at any point by more than a first threshold amount . . . ; require that the calculated radiation field must not be less than the desired radiation field at any point by more than a second threshold amount . . . ; and, require that the amount of radiation delivered to tissues outside the treatment area be kept below a third threshold amount.

Id. (emphases added). *Otto '530* also explains that the delivered radiation field has a "desired spatial distribution of radiation." *Id.* ¶ 14. These requirements for the termination criteria, along with the "desired" distribution of radiation, are examples of defined "optimization goals," as recited in claim 68. Ex. 1002 ¶ 79.

68.c. "specifying an initial plurality of control points along an initial trajectory which involves relative movement between a radiation source and the subject"

Different MLC leaf configurations in *Otto '530* define different beam shapes and corresponding sub-fields. *See, e.g.,* Ex. 1004 ¶¶ 24, 29. As shown in Fig. 3 (reproduced below), the MLC can also be rotated between sub-fields. *Id*. ¶¶ 24, 29, 36-37. *Otto '530* thus describes "collimator angles" to refer to the different rotational angles of the MLC itself. *Id.*; Ex. 1002 ¶ 80. For example, Fig. 3 shows the MLC at one rotational angle for shape 34A and at a different rotational angle for shapes 34B, 34C, 34D, and 34E. Ex. 1004 at Fig. 3; Ex. 1002 ¶ 80. These

different sub-fields can then be combined "to build up an arbitrary spatial distribution of radiation." Ex. 1004 ¶ 29; Ex. 1002 ¶ 80.

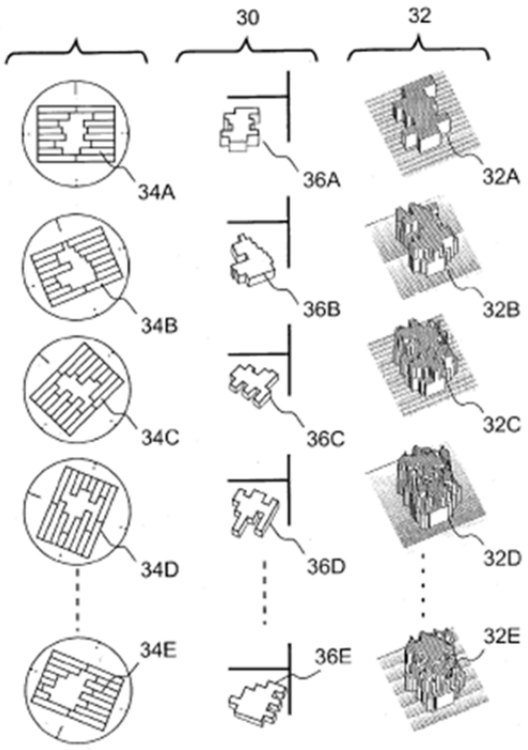


FIGURE 3

The MLC configuration for each sub-field has a set of radiation delivery parameters: "leaf positions," "collimator angles," and "radiation contribution" for each sub-field. *See* Ex. 1002 ¶ 80; Ex. 1004 ¶¶ 26, 52-53, 60-63. The sets of radiation delivery parameters associated with the sub-fields of *Otto '530* correspond to the claimed "initial . . . control points." Ex. 1002 ¶ 80.

The control points in *Otto '530* are specified "along an initial trajectory which involves relative movement between a radiation source and the subject," as recited in claim 68. *Id.* ¶ 81. In *Otto '530*, "[r]adiation is emitted from a source (not

shown) in a portion 11 of the radiotherapy device [10]." Ex. 1004 ¶ 25. A person of ordinary skill in the art reading *Otto '530* would understand that the portion 11 of radiotherapy device 10 is part of a rotating gantry (not fully shown in Fig. 1) that rotates the radiation source about an arc or trajectory, thereby defining the claimed "initial trajectory which involves relative movement between [the] radiation source [(not shown but part of portion 11)] and the subject [P]." *See, e.g.,* Ex. 1002 ¶ 81 (alterations in original); Ex. 1004 ¶¶ 3-5, 25.

Indeed, *Otto '530* explains that "[a] typical radiotherapy device is mounted on a rotating gantry that allows radiation beams focused on a target to intersect the patient at various orientations." Ex. 1004 ¶ 3. A typical device also includes a multi-leaf collimator ("MLC") in the radiation beam's path to selectively shape the beam and block areas where lower amounts of radiation are desired. *Id.* ¶ 4. By having an MLC on a rotating gantry, the therapy device of *Otto '530* can deliver "an [sic] different intensity modulated radiation field from each of a plurality of gantry angles." *Id.* ¶ 5.

Otto '530 thus contemplates delivering different radiation fields from different gantry angles. *See* Ex. 1002 ¶ 82. The collection of different gantry angles is used to rotate the radiation source along an arc or "trajectory." *Id.* And because, as explained above, each combination of sub-fields corresponds to a set of radiation delivery parameters (e.g., leaf positions, collimator angle, etc.) at the

corresponding gantry angle, Ex. 1004 ¶ 37, *Otto '530* discloses a plurality of the claimed "control points" along the "trajectory." Ex. 1002 ¶ 82; *see also* Ex. 1004 ¶ 37 ("Further sub-fields are added until the desired intensity-modulated field 32C [shown in Fig. 3] is achieved.").

68.d. "iteratively optimizing a simulated dose distribution relative to the set of one or more optimization goals to determine one or more radiation delivery parameters associated with each of the initial plurality of control points"

To derive the MLC configurations, *Otto '530* describes selecting a set of optimization routines and termination criteria. Ex. 1004 ¶ 51. In block 104 of Fig. 5 (reproduced below), the method optimizes the MLC configuration parameters for each sub-field. *Id.* ¶ 53. The MLC configuration parameters include leaf positions, collimator angles, and sub-field contributions. *Id*. Further, *Otto '530* explains that these parameters are iteratively optimized:

> If the termination criteria has not been attained as determined in block 108, then method 100 returns to block 104 for further optimization. Method 100 continues in this fashion until the termination criteria have been attained or the discrepancies between the desired and optimized treatments no longer improve. If the termination criteria are obtained then the treatment parameters may be transferred to a radiation device in block 109.

Id. ¶ 56 (emphases added).

Fig. 6 depicts an iterative optimization process 120, which "is an example of one way to implement block 104." *Id.* ¶ 57. As shown in Fig. 6 (annotated version reproduced below), the method determines whether the above termination criteria (the claimed "optimization goals") are met, where these termination criteria define how the calculated radiation field (the claimed "simulated dose distribution") compares to the desired radiation field. *See id.* ¶¶ 71-72; Ex. 1002 ¶ 84.

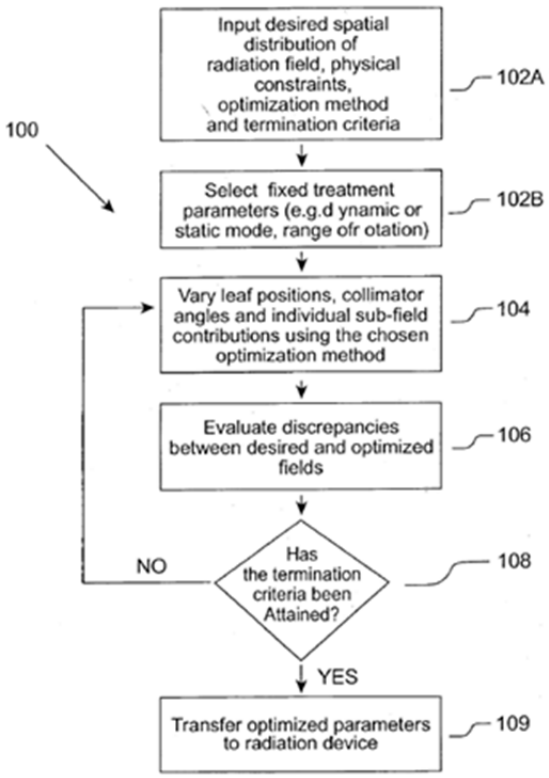
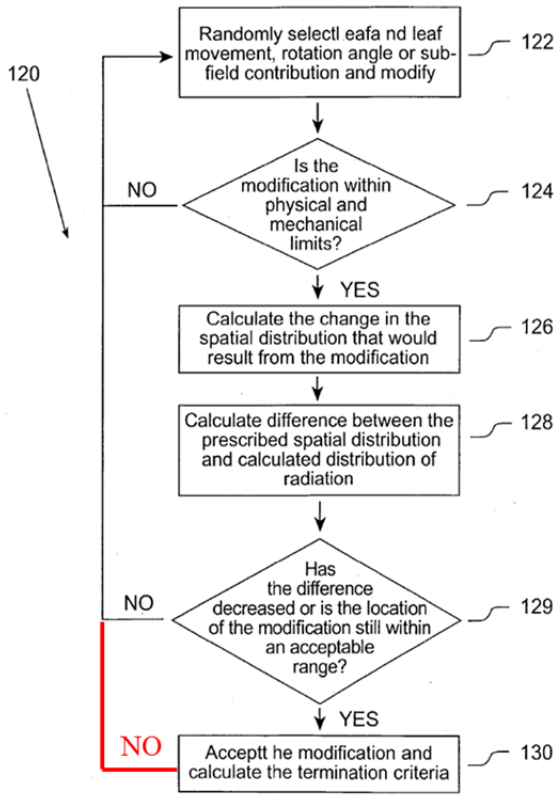


FIGURE 5



See ¶[0071]

FIGURE 6

Otto '530 explains that, during the optimization process, selected parameters associated with each sub-field (the claimed "radiation delivery parameters associated with each of the initial plurality of control points") are modified. *See, e.g.,* Ex. 1004 ¶¶ 60-63; Ex. 1002 ¶ 85. As noted above, these parameters include

"the position of each leaf for each sub-field; the collimator angle for each sub field; [and] the radiation contribution for each sub-field." Ex. 1004 ¶¶ 60-63. The method determines if any modification to these parameters "is physically possible." *Id.* ¶ 65. If not, the method attempts another modification. *Id.* If the modification is possible, the method "proceeds to block 126 which determines the spatial distribution of radiation that would result if the modification were made." *Id.* ¶ 66. If termination criteria are met, the process terminates; but if not, the process continues with further optimization. *See id.* ¶ 71. The method thus iteratively optimizes the calculated radiation field (the claimed "simulated dose distribution") relative to the termination criteria (the claimed "optimization goals") to determine the parameters associated with each sub-field (the claimed "control points").

68.e. "upon reaching one or more initial termination conditions: adding one or more additional control points to obtain an increased plurality of control points"

Otto '530 discloses that "[i]n developing a set of configurations for dynamic delivery of radiation it can be desirable to commence with a few sub-fields and to increase the number of sub-fields as the method proceeds." *Id.* ¶ 75 (emphases added). For example, if after a number of iterations the process determines that further iterations do not produce significant improvement (this determination corresponding to the claimed "one or more initial termination conditions"), then "additional sub-fields may be added." *Id.* ¶ 76; *see also* Ex. 1002 ¶ 86. This is the

same smaller-then-larger optimization technique described in the '770 patent. Ex. 1004 ¶ 76; *see also* Ex. 1002 ¶ 86.

Like the '770 patent, *Otto '530* describes that the "added" sub-fields are also along the "trajectory" that the source follows during rotation. Ex. 1002 ¶ 86. As noted above, each sub-field is associated with an MLC collimator angle at a point along the trajectory that the radiation source follows when rotated by the gantry. *Id. Otto '530* also explains that the added sub-fields can be associated with "a collimator angle intermediate (preferably half way) between each existing pair of sub-fields," where initial leaf positions of the additional sub-fields "are linearly interpolated between the leaf positions of the angularly adjacent sub-fields." Ex. 1004 ¶ 77; Ex. 1002 ¶ 86. In other words, each newly added sub-field may be associated with a different collimator angle of the MLC. Ex. 1002 ¶ 86.

Because the MLC itself rotates, the added sub-fields are also associated with a point along the trajectory. *Id.* And even though the newly "added" sub-fields may be associated with the same point on the trajectory as the "initial" sub-fields (although at a different collimator angle), this falls squarely within the scope of claim 68. *Id.* Indeed, as the '770 patent explains:

> [T]he motion axes of a radiation delivery apparatus <u>are permitted to stop at one or more locations along trajectory</u> 30. <u>Multiple control points 32 may be provided at such locations</u> to allow the beam shape

> and/or beam intensity to be varied while the position and orientation of the beam is maintained constant.

Ex. 1001 at 8:61-67 (emphases added). In other words, as the '770 patent explains, multiple control points may be located at the same gantry angle to define different MLC shapes at that gantry angle. Ex. 1002 ¶ 86. This corresponds precisely to the disclosure of *Otto '530* describing multiple sub-fields (the claimed "control points") associated with different collimator angles (to define different shapes) located at the same gantry angle along the claimed "trajectory." *Id.*

68.f. "iteratively optimizing the simulated dose distribution relative to the set of optimization goals to determine one or more radiation delivery parameters associated with each of the increased plurality of control points"

See elements 68.d. and 68.e. above. The only differences between these and elements 68.f. and 68.d. are: (1) 68.d. recites "one or more optimization goals" while 68.f. recites "optimization goals," and (2) 68.d. recites "initial plurality of control points" while 68.f. recites "increased plurality of control points."

As explained in Section 68.d., *Otto '530* discloses an iterative optimization process that "iteratively optimiz[es] a simulated dose distribution relative to [a] set of one or more optimization goals to determine one or more radiation delivery parameters associated with each of [an] initial plurality of control points." Ex. 1002 ¶ 87 (alterations in original). And as explained in Section 68.e., *Otto '530* further discloses "upon reaching one or more initial termination conditions: adding

one or more additional control points to obtain an increased plurality of control points." *Id.* After adding the sub-fields, "[t]he optimization then continues," Ex. 1004 ¶ 77, such that the method optimizes over the increased number of sub-fields (the parameters of which are the claimed "control points"), *see also id.* ¶¶ 75-78; Ex. 1002 ¶ 87. *Otto '530* thus discloses element 68.f. Ex. 1002 ¶ 87.

VII. CLAIM 68 IS UNPATENTABLE BASED ON THE DISCLOSURE OF *EARL '261* AND OTHER PRIOR ART

A. The combination of *Earl '261* and *Otto '530* renders obvious claim 68

Earl '261, which published on April 15, 2004, and is therefore prior art under pre-AIA 35 U.S.C. § 102(b), is directed to "a computerized method that determines the optimal treatment plan for a patient using specified clinical objectives." Ex. 1003 ¶ 5. As provided below, the combination of *Earl '261* and *Otto '530* renders obvious claim 68.

68.a. "A program product comprising computer readable instructions which, when executed by a processor, cause the processor to execute a method for planning delivery of radiation dose to a target area within a subject"

Earl '261 teaches "an inverse-planning method that . . . allows for the planning for either IMRT, IMAT, or a new type of intensity-modulated radiotherapy which comprises a combination of IMRT and IMAT." *Id.* ¶ 16. *Earl '261* discloses that the treatment planning method may be implemented as "[a] computer listing of a program . . . in a CD-ROM." *Id.* ¶ 2. The treatment plan may

also be loaded on a linac control system "via a diskette, a computer network link, or any other means known in the art field capable of transferring data between two distinct computers." *Id.* ¶ 50. A person of ordinary skill in the art would thus understand that *Earl '261* discloses a "program product," as claimed. Ex. 1002 ¶ 90.

68.b. "defining a set of one or more optimization goals, the set of one or more optimization goals comprising a desired dose distribution in the subject"

The method in *Earl '261* defines an "initial score for the dose distribution quality," as well as other "objective[s]" (the claimed "optimization goals"), and uses these to define an objective function that calculates a desired "dose distribution." *See* Ex. 1003 ¶¶ 41-43; Ex. 1002 ¶ 91.

More specifically, Fig. 1 of *Earl '261* illustrates an iterative optimization process. In step 65 of Fig. 1, "the user defines the clinical objectives of the treatment plan . . . used to score the quality of the treatment plan throughout the optimization process." Ex. 1003 ¶ 39. The treatment plan is "scored by an objective function." *Id*. Then, the system "calculates the radiation dose, the radiation dose distribution, and the dose distribution quality (objective function)." *Id.* ¶ 40 (emphasis added).

68.c. "specifying an initial plurality of control points along an initial trajectory which involves relative movement between a radiation source and the subject"

Earl '261 discloses a linac for "controlled delivery of radiation to a patient in need of radiation therapy." *Id.* ¶ 25. Radiation exits through an end of a treatment head of the linac mounted on a gantry. *Id.* The treatment head can include an MLC to shape the radiation field. *Id.* The linac includes "a control unit," *id.*, and "a gantry which can rotate about a horizontal axis H of rotation around the patient who is lying on the bed," *id.* This rotation "allow[s] for a change in the angle of treatment." *Id.* ¶ 26. The linac is a "radiation source" because it emits a beam of radiation that is aimed at the patient. Ex. 1002 ¶ 93. And the path along which the linac and gantry rotate is the claimed "trajectory." *Id.* Along this trajectory, the *Earl '261* system specifies evenly spaced discrete angles or the number and range of each arc at which parameters are calculated. Ex. 1003 ¶¶ 25, 36-37. The trajectory of *Earl '261* thus involves "relative movement," as claimed, between a radiation source and the patient or subject. Ex. 1002 ¶ 93.

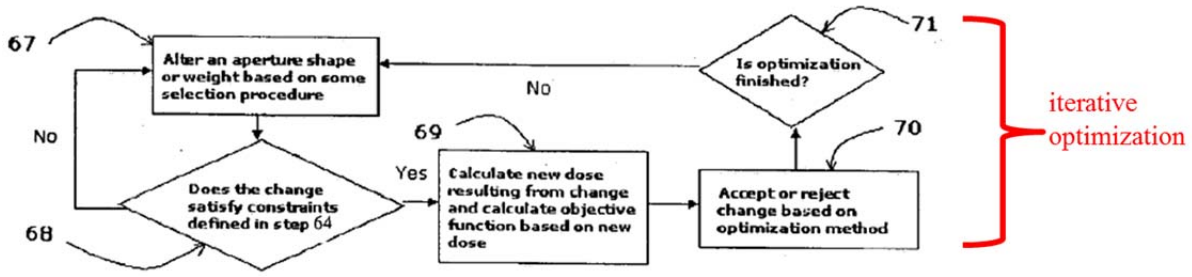
Earl '261 further discloses that "[f]or fixed-field delivery, the user specifies the number of beams and their angles, the beam energies, and the number of apertures per beam angle." Ex. 1003 ¶ 18. "For rotational delivery, the user specifies the number and range of the arcs." *Id.* Based on these inputs, the treatment planning system then "automatically calculates evenly spaced radiation

beams to approximate the range of rotation of the gantry." *Id.* ¶ 37. The different beam angles, beam energies, and number of apertures per beam angle in IMRT, and the number and range of arcs in IMAT, each constitute a set of one or more radiation delivery parameters associated with various points along the trajectory of the radiation source. Ex. 1002 ¶ 94. Other radiation delivery parameters include "the positions of the MLC leaves used to shape each aperture for each beam angle, and the relative weight (intensity) of each aperture shape assigned to each aperture." Ex. 1003 ¶ 41. Each of these sets of parameters is associated with a point along the trajectory, and thus these parameters make up the claimed "control points." Ex. 1002 ¶ 94.

68.d. "iteratively optimizing a simulated dose distribution relative to the set of one or more optimization goals to determine one or more radiation delivery parameters associated with each of the initial plurality of control points"

Earl '261 discloses that "[t]he optimization process begins in a step 66, where the treatment planning system assigns an initial aperture shape for each beam angle." Ex. 1003 ¶ 40. As shown in Fig. 1 (annotated version below), the optimization process continues through the following steps: step 67 ("Alter an aperture shape or weight based on some selection procedure"); step 68 ("Does the change satisfy constraints defined in step 64?"); if step 68 is "No" go back to step 67; if step 68 is "Yes," go to step 69 ("Calculate new dose resulting from change

and calculate objective function based on new dose"); step 70 ("Accept or reject change based on optimization method"); step 71 ("Is optimization finished?"); if step 71 is "Yes" go to step 72; if step 71 is "No" go back to step 67. *Id.* at Fig. 1; *see also id.* ¶¶ 40-50. As discussed above, the claimed "radiation delivery parameters" include the "aperture shape" and other parameters determined in step 67 as part of the optimization process. *Id.* ¶ 41.



The processing loop of these steps, which accounts for the "optimization goals" of claim element 68.b., corresponds to "iteratively optimizing a simulated dose distribution relative to the set of one or more optimization goals to determine one or more radiation delivery parameters associated with each of the initial plurality of control points," as claimed. Ex. 1002 ¶ 96; Ex. 1003 at Fig. 1.

68.e. "upon reaching one or more initial termination conditions: adding one or more additional control points to obtain an increased plurality of control points"

Earl '261 discloses that "[b]ased on pre-defined termination criteria which are dictated by the optimization algorithm, the treatment planning system will cease the optimization process in step 71." Ex. 1003 ¶ 47; *see also id.* at FIG. 1,

step 71 ("Is optimization finished?"). Step 71 thus corresponds to "one or more initial termination conditions." Ex. 1002 ¶ 97.

Earl '261 explains that "[t]he goal of this invention is to achieve the optimal aperture shape for each beam angle as quickly as possible." Ex. 1003 ¶ 45. But to the extent Patent Owner argues that *Earl '261* does not disclose "upon reaching one or more initial termination conditions: adding one or more additional control points to obtain an increased plurality of control points," as recited in claim 68, *Otto '530* does. For example, *Otto '530* describes optimization techniques to improve treatments. Ex. 1004 at Abstract, ¶¶ 56, 76-78. The optimization techniques can be used to derive treatment parameters including, for example, different shape configurations of a multi-leaf collimator. *Id.* at Abstract, ¶¶ 6, 31, 39. Referring to the optimization process of Fig. 6 (annotated version in Section VI.A. above), *Otto '530* explains that the process first determines if a termination criterion is satisfied. *Id.* ¶ 71. If so, the process terminates; but if not, it proceeds with further optimization. *Id.*

As explained in Section VI.A., *Otto '530* discloses that good results may be achieved by providing a "large number of sub-fields" separated from one another by small angular increments. *Id.* ¶ 75. The set of one or more radiation delivery parameters (*e.g.*, leaf positions, collimator angles, and radiation contribution for each sub-field) associated with the sub-fields of *Otto '530* correspond to the

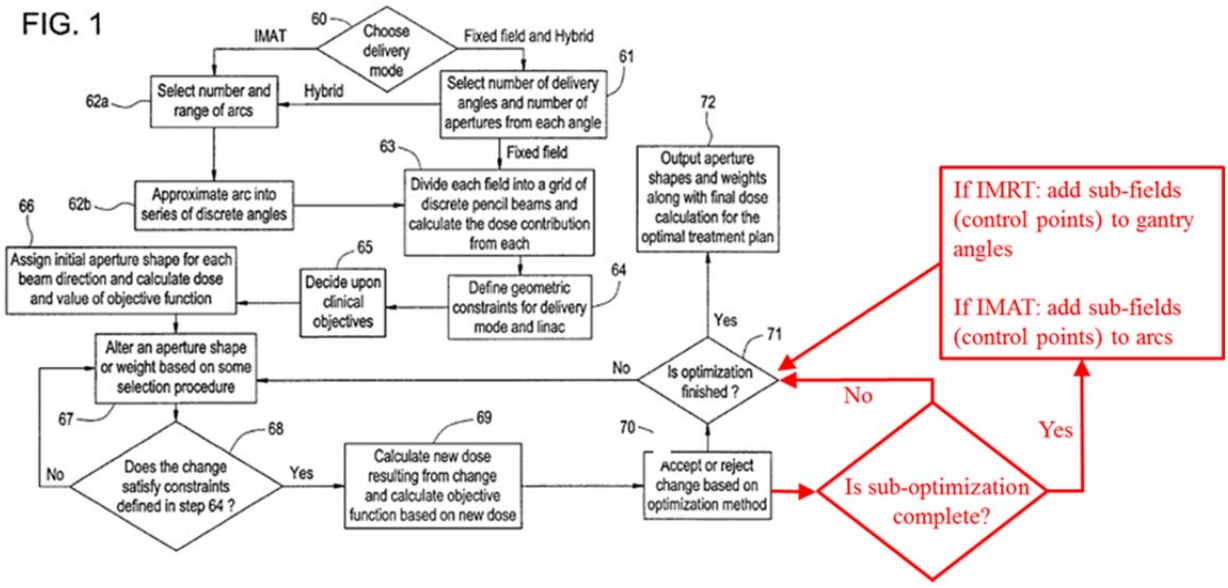
claimed "control points." *See* Ex. 1002 ¶ 100; Ex. 1004 ¶¶ 26, 52, 60-63. *Otto '530* teaches that "[i]n developing a set of configurations for dynamic delivery of radiation, it can be desirable to commence with a few sub-fields and to increase the number of sub-fields as the method proceeds." Ex. 1004 ¶ 75 (emphasis added). "For example, the method may begin by initializing 10 sub-fields." *Id.* ¶ 76. "After a number of iterations it may be found that additional iterations do not yield significant improvement." *Id.* "At this point, additional sub-fields may be added." *Id.* (emphasis added). For example, the number of sub-fields can be increased if more than a predetermined number of iterations occur with improvement below a threshold amount. *See, e.g., id.* The optimization process of *Otto '530* is then repeated after the additional sub-fields are added. *Id.* ¶ 77.

It would have been obvious to a person of ordinary skill in the art to modify the optimization process of *Earl '261* so that, upon reaching the one or more initial termination conditions, the process adds more control points to obtain an increased plurality of control points, based on the teachings of *Otto '530*. Ex. 1002 ¶ 101. Doing so would refine the optimization process of *Earl '261* and prevent redundant unproductive iterations. *Id.*; *see also* Ex. 1004 ¶ 76 ("After a number of iterations it may be found that additional iterations do not yield significant improvement. At this point, additional sub-fields may be added."); *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007). Preventing unproductive iterations could in turn reduce

the amount of time needed for optimization. Ex. 1002 ¶ 101. Adding control points can also improve the results of the optimization process by allowing optimization to continue and provide a result that would have been impossible with a lower number of control points due to the increased intensity modulation available due to the additional control points, rather than simply stopping at a suboptimal solution when further iterations have not yielded significant improvement. *Id.* Moreover, *Earl '261* does not preclude adding more control points. *Id.*

The following annotated version of Fig. 1 of the *Earl '008* patent (Ex. 1043) illustrates how the optimization process could be easily modified based on *Otto '530* to include a sub-optimization routine that may be repeated after increasing the number of control points to be optimized.[2]

[2] The *Earl '008* patent issued from the application that published as *Earl '261*. Ex. 1043 at cover page. Elekta reproduced Fig. 1 of the *Earl '008* patent rather than Fig. 1 of *Earl '261* because, while the figures are substantively identical, Fig. 1 of the *Earl '008* patent is clearer.



Ex. 1002 ¶ 102.

The knowledge of one of ordinary skill in the art, as evidenced by disclosures of additional prior art, also support this conclusion of obviousness. For example, as discussed in detail in Dr. Flynn's declaration, at the time of the alleged invention, people in the radiotherapy field understood the computational complexity associated with optimizing IMRT or IMAT plans. *See id.* ¶ 103. The understanding of this complexity repeatedly led others to address this complexity by using progressive optimization techniques. *Id.* ¶¶ 47-60 (referring to prior art including the *Earl Article*, *Lee*, *Meedt*, and *Wang*), ¶ 103.[3] Progressively adding

[3] *Meedt* published on September 3, 2003, and is also § 102(b) prior art to the '770 patent. Ex. 1011; Ex. 1023 (the IOPscience website lists *Meedt* in the table of contents for Volume 48, Number 18, dated September 21, 2003, and confirms it

more control points during the optimization process is a form of progressive optimization. *Id.*

68.f. "iteratively optimizing the simulated dose distribution relative to the set of optimization goals to determine one or more radiation delivery parameters associated with each of the increased plurality of control points"

See elements 68.d. and 68.e. above. The only differences between elements 68.f. and 68.d. are (1) 68.d. recites "one or more optimization goals" while 68.f. recites "optimization goals"; and (2) 68.d. recites "initial plurality of control points" while 68.f. recites "increased plurality of control points." As explained in Section 68.d., *Earl '261* discloses an iterative optimization process that "iteratively optimiz[es] a simulated dose distribution relative to [a] set of one or more optimization goals to determine one or more radiation delivery parameters

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was published September 3, 2003); Ex. 1047. *Wang* published on November 15, 2004, and is thus prior art. Ex. 1007; Ex. 1020 (the International Journal of Radiation Oncology, Biology, Physics website lists *Wang* as a journal article published on November 15, 2004, in Volume 60, Issue 4.); Ex. 1047. *Earl Article* published on April 1, 2003, and is thus § 102(b) prior art. Ex. 1009; Ex. 1021 (the IOPscience website lists the *Earl Article* in the table of contents for Volume 48, Number 8, dated Apr. 21, 2003, and confirms it was published April 1, 2003); Ex. 1047.

associated with each of [an] initial plurality of control points." Ex. 1002 ¶ 104 (alterations in original). And as explained in Section 68.e., *Otto '530* discloses "upon reaching one or more initial termination conditions: adding one or more additional control points to obtain an increased plurality of control points." *Id.* After adding sub-fields, "[t]he optimization then continues," Ex. 1004 ¶ 77, such that the method optimizes over the increased number of sub-fields (the parameters of which are the claimed "control points"), *see also id.* ¶¶ 75-78; Ex. 1002 ¶ 104. The combination of *Earl '261* and *Otto '530* thus teaches element 68.f. Ex. 1002 ¶ 104.

VIII. CLAIM 68 IS UNPATENTABLE BASED ON THE DISCLOSURE OF *DUTHOY* AND OTHER PRIOR ART

A. The combination of *Duthoy* and *Otto '530* renders obvious claim 68

Duthoy is prior art under pre-AIA 35 U.S.C. § 102(b) based on its November 15, 2003 publication date. Ex. 1005; Ex. 1018 (the International Journal of Radiation Oncology, Biology, Physics website lists *Duthoy* as a journal article published on November 15, 2003, in Volume 57, Issue 4); Ex. 1047. It discusses clinical results of whole abdominopelvic radiotherapy (WAPRT) using arc therapy, specifically IMAT. *See, e.g.,* Ex. 1005 at 1019.

Like the '770 patent, *Duthoy* expressly uses the industry term "control points," noting that "[t]he machine instruction file to deliver arc therapy with

dynamic MLC consists of a sequence of control points." *Id.* at 1021. As discussed in more detail below, Fig. 1 of *Duthoy* even shows "control points" that are created and associated with points located along an arc or trajectory. *Id.* at Fig. 1. And like the '770 patent, *Duthoy* teaches a technique for optimizing the created control points. *Id.* at 1021-22.

While *Otto '530* and *Earl '261* do not explicitly use the term "control points," the term "control points" became commonly adopted in this industry by July 2004, Ex. 1002 ¶ 106. Regardless, as discussed above, *Otto '530* and *Earl '261* disclose techniques for optimizing a set of radiation delivery parameters ("control points") associated with a point along the trajectory of the radiation source. *Id.* As provided below, *Duthoy* includes explicit disclosure of control points and, in combination with *Otto '530*, renders obvious claim 68.

68.a. "A program product comprising computer readable instructions which, when executed by a processor, cause the processor to execute a method for planning delivery of radiation dose to a target area within a subject"

Duthoy discloses an IMAT planning strategy, where IMAT is then used to deliver radiation to a target volume of a patient. *See* Ex. 1005 at 1019. For each arc in IMAT treatment delivery, "a prescription file containing [a] sequence of control points and related monitor units is generated and networked to an SLiPlus 18-MV linear accelerator (Elekta)." *Id.* at 1023. "The final control points (machine states plus associated cumulative monitor unit counts) were calculated using a collapsed

cone convolution/superposition algorithm." *Id.* at 1019. A person of ordinary skill in the art would understand that at least this disclosure of *Duthoy* necessarily includes the claimed "program product comprising computer readable instructions which, when executed by a processor, cause the processor to execute a method for planning delivery of radiation dose to a target area within a subject." Ex. 1002 ¶ 107.

However, to the extent an argument may be made that *Duthoy* does not explicitly disclose the mechanism for generating the prescription file, *Otto '530* fills the gap. Specifically, *Otto '530* discloses that the desired "overall radiation field may be specified in output from treatment planning software." Ex. 1004 ¶ 44 (describing a "treatment planning computer system" or "programmed data processing device"); *see also id.* ¶ 79 (explaining "the invention may be embodied in a computer-based treatment planning system" and "may comprise any medium which carries a set of computer-readable signals").

It would have at least been obvious to a person of ordinary skill in the art at the time of the alleged invention to modify the method taught by *Duthoy* to utilize a computer-based treatment planning system with treatment planning software and a medium to carry a set of computer-readable signals as disclosed by *Otto '530*. Ex. 1002 ¶ 109. Doing so would provide *Duthoy* with the ability to automatically generate its prescription file and carry out a method for planning delivery of a

radiation dose to a target area within a patient. *Id.* Indeed, it would have been obvious to provide an IMAT treatment planning strategy, like that in *Duthoy*, with the ability to be executed by a processor via computer-readable instructions. *Id.*; *see also KSR*, 127 S. Ct. at 1739. Multiple treatment planning systems were available at the time that had the claimed capability. Ex. 1002 ¶ 109.

68.b. "defining a set of one or more optimization goals, the set of one or more optimization goals comprising a desired dose distribution in the subject"

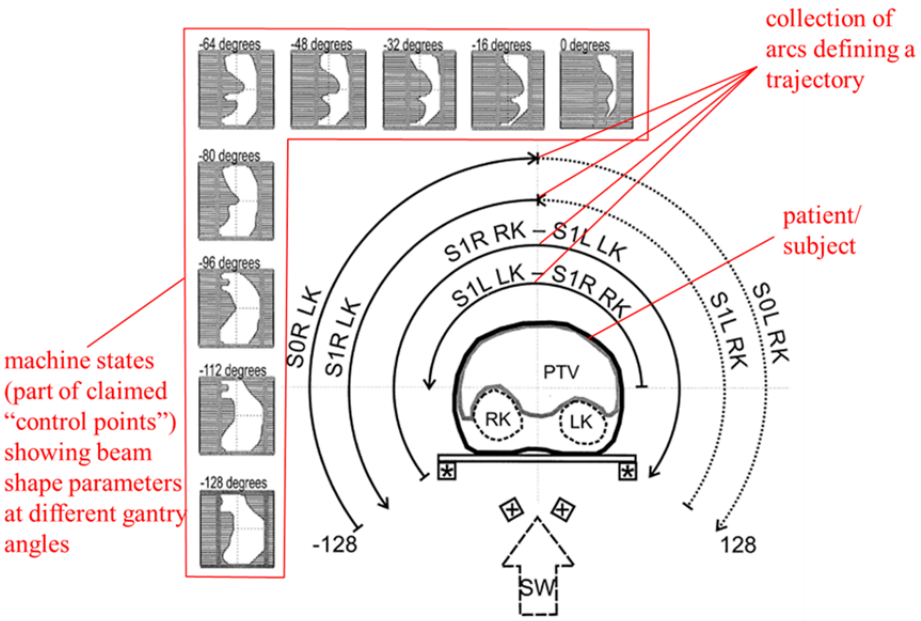
Duthoy explains that "[t]he optimization of IMAT was done in several steps, using a biophysical objective function." Ex. 1005 at 1019. "These steps included weight optimization of machine states, leaf position optimization adapted to meet the maximal leaf speed constraint, and planner-interactive optimization of the start and stop angles." *Id.*

Fig. 2 of *Duthoy* shows a "'virtual' arc (dashed line) as well as three deliverable arcs (solid lines)." *Id.* at 1022 (Fig. 2 caption). *Duthoy* explains that the virtual arc is not deliverable so "[t]he deliverable arcs approximate the optimized virtual arc"—i.e., the goal of the optimization. *Id.* This virtual arc is thus an example of "one or more optimization goals," as claimed. Ex. 1002 ¶ 111. *Duthoy* also explains that the goal of "IMAT . . . [is] to produce dose distributions that are more homogeneous than those obtained with a [conventional] plan." *Id.* (quoting Ex. 1005 at 1019 (alterations in original)).

Duthoy thus discloses the claimed "set of one or more optimization goals comprising a desired dose distribution in the subject." *Id.*

68.c. "specifying an initial plurality of control points along an initial trajectory which involves relative movement between a radiation source and the subject"

Duthoy explains, as known in this art, that IMAT delivers arc therapy according to a specified "sequence of control points." Ex. 1005 at 1021; Ex. 1002 at ¶18 n.2. As shown in Fig. 1 (annotated version reproduced below), each machine state, and thus each "control point," can be associated with a corresponding angle of the radiation beam as it rotates along an arc around the patient. *See* Ex. 1002 ¶ 112. Each "control point is defined as a machine state plus a monitor unit count (MUC) value," Ex. 1005 at 1021, where each "machine state is described by a set of machine parameters that uniquely define the beam incidence, aperture, and photon beam quality," *id.* at 1020. Thus, "[f]or each gantry angle, [the *Duthoy* system] generates multiple machine states that differ only by apertures of the multileaf collimator (MLC)." *Id.* Fig. 1 illustrates for the S0R LK arc, the "[m]achine states [that are created] every 16°, from -128° to 0°." *Id.* at 1021 (Fig. 1 caption).



The collection of arcs prior to optimization define the claimed "initial trajectory." Ex. 1002 ¶ 113. Because *Duthoy* discloses a linac to deliver the arcs from a rotating gantry, Ex. 1005 at 1019, 1021-22, the linac is the claimed "radiation source" and the initial trajectory "involves relative movement between [the] radiation source and the subject," as claimed. Ex. 1002 ¶ 113 (alteration in original).

68.d. "iteratively optimizing a simulated dose distribution relative to the set of one or more optimization goals to determine one or more radiation delivery parameters associated with each of the initial plurality of control points"

Duthoy explains that "[c]ontrol point optimization involves the machine states—and more precisely, the leaf positions—as well as the MUC values and is done by a segment outline and weight adapting tool (SOWAT) (14), modified for

IMAT purposes (SOWAT-IMAT)." Ex. 1005 at 1022. The MUCs (the counted amounts of radiation) are thus "optimized for each step, a step being defined as the transition from one control point to the next." *Id.* An IMAT optimization cycle then finalizes the plan by optimizing leaf positions and the angular delivery rate. *Id.* at 1019-22. This optimization uses an objective function that accounts for the "weight optimization of machine states, leaf position optimization adapted to meet the maximal leaf speed constraint, and planner-interactive optimization of the start and stop angles." *Id.* at 1019. During optimization, the "transition from a control point to the next is slaved by the monitor unit (MU) counter; each parameter (leaf positions, jaw positions, and gantry angle) that changes between two control points is linearly interpolated as function of the MUC value." *Id.* at 1022.

Because *Duthoy* discloses iteratively optimizing the control point parameters to achieve the desired dose distribution, *Duthoy* discloses claim element 68.d. Ex. 1002 ¶ 114.

68.e. "upon reaching one or more initial termination conditions: adding one or more additional control points to obtain an increased plurality of control points"

Fig. 9 of *Duthoy* identifies potential benefits of using more beam angles ("increase of incidences (45º and 135º))". *Id.* at 1031 (Fig. 9 caption); *see also* Ex. 1002 ¶ 115. This suggests adding beam angles (a parameter of "control points" as claimed) was desirable. Ex. 1002 ¶ 115. To the extent an argument is made that

Duthoy may not disclose "upon reaching one or more initial termination conditions: adding one or more additional control points to obtain an increased plurality of control points," as explained in Section VII.A., *Otto '530* does. *Id.*

It would have been obvious to a person of ordinary skill in the art to modify the optimization process of *Duthoy* so that, upon reaching the one or more initial termination conditions, the process adds more control points to obtain an increased plurality of control points, based on the teachings of *Otto '530*. Ex. 1002 ¶ 116. Doing so would refine the optimization process of *Duthoy* and prevent redundant unproductive iterations. *Id.*; *see also* Ex. 1004 ¶ 76 ("After a number of iterations it may be found that additional iterations do not yield significant improvement. At this point, additional sub-fields may be added."); *KSR*, 127 S. Ct. at 1739.

Preventing unproductive iterations could in turn reduce the amount of time needed for *Duthoy*'s optimization. Ex. 1002 ¶ 116. Adding control points could also improve the results of *Duthoy*'s optimization process by allowing the optimization to continue and provide a result that would have been impossible with a lower number of control points due to the increased intensity modulation available from the additional control points, rather than simply stopping at a suboptimal solution, when additional iterations do not yield significant improvement. *Id.* Moreover, *Duthoy* does not preclude adding more control points. *Id.* And as mentioned above, it even suggests that it was desirable to add beam

angles, which are parameters of the claimed "control points." Ex. 1005 at 1031 (Fig. 9 caption); Ex. 1002 ¶ 116.

Moreover, as discussed in Section VII.A., above, the knowledge of one of ordinary skill in the art, as evidenced by disclosures of additional prior art, also support this conclusion of obviousness. As discussed in detail in Dr. Flynn's declaration, at the time of the alleged invention, people in the radiotherapy field understood the computational complexity associated with optimizing IMRT or IMAT plans. *See* Ex. 1002 ¶¶ 103, 117. The understanding of this complexity repeatedly led others to address this complexity by using progressive optimization techniques. *Id.* ¶¶ 47-60 (referring to prior art including the *Earl Article*, *Lee*, *Meedt*, and *Wang*), ¶¶ 103, 117. Progressively adding more control points during the optimization process is a form of progressive optimization. *Id.*

68.f. "iteratively optimizing the simulated dose distribution relative to the set of optimization goals to determine one or more radiation delivery parameters associated with each of the increased plurality of control points"

See elements 68.d. and 68.e. above. The only differences between these and elements 68.f. and 68.d. are (1) 68.d. recites "one or more optimization goals" while 68.f. recites "optimization goals"; and (2) 68.d. recites "initial plurality of control points" while 68.f. recites "increased plurality of control points." And as explained in Section 68.d., *Duthoy* discloses an iterative optimization process that "iteratively optimiz[es] a simulated dose distribution relative to [a] set of one or

more optimization goals to determine one or more radiation delivery parameters associated with each of [an] initial plurality of control points." *Id.* ¶ 118 (alterations in original). And as explained in Section 68.e., *Otto '530* discloses "upon reaching one or more initial termination conditions: adding one or more additional control points to obtain an increased plurality of control points." *Id.* After adding sub-fields, "[t]he optimization then continues," Ex. 1004 ¶ 77, such that the method optimizes over the increased number of sub-fields (the parameters of which are the claimed "control points"), *see also id.* ¶¶ 75-78; Ex. 1002 ¶ 118.

The combination of *Duthoy* and *Otto '530* thus teaches element 68.f. Ex. 1002 ¶ 118.

IX. CLAIM 68 IS UNPATENTABLE BASED ON THE DISCLOSURE OF *MEEDT* AND OTHER PRIOR ART

A. Under Patent Owner's broad construction of "control point," the combination of *Meedt* and *Otto '530* renders obvious claim 68

In the related investigation before the ITC, Patent Owner has construed "control point" broader than "a set of one or more radiation delivery parameters associated with a point along the trajectory of the radiation source," as discussed above in Section V. Ex. 1002 ¶ 120. As shown by Patent Owner's infringement contentions for claim 68 of the '770 patent, *see, e.g.,* Ex. 1046 at 12, 24, Patent Owner has also construed "control point," and particularly the radiation delivery parameters associated with a "control point," broadly enough to encompass

"fluence maps". Ex. 1002 ¶ 120 (see annotated red boxes identifying where Patent Owner appears to broadly construe "control point" as covering a "fluence map"). Elekta does not agree with this construction. *See supra* Section V.A. But to the extent the Board determines this broad construction of "control point" is warranted for purposes of the requested *inter partes* review, then, as shown below, *Meedt* discloses features that meet this broader construction. Ex. 1002 ¶ 120.

68.a. "A program product comprising computer readable instructions which, when executed by a processor, cause the processor to execute a method for planning delivery of radiation dose to a target area within a subject"

Meedt relates to IMRT and discloses an algorithm to optimize beam directions in intensity-modulated radiotherapy. Ex. 1011 at 2999; Ex. 1002 ¶ 121. *Meedt* explains that "there has been continuous development of inverse [treatment] planning algorithms for intensity-modulated radiotherapy (IMRT)." Ex. 1011 at 2999; Ex. 1002 ¶ 121. A person of ordinary skill in the art would understand that the disclosure of *Meedt* necessarily incorporates the claimed "program product comprising computer readable instructions which, when executed by a processor, cause the processor to execute a method for planning delivery of radiation dose to a target area within a subject." Ex. 1002 ¶ 121.

However, to the extent an argument may be made that *Meedt* does not explicitly disclose this element, *Otto '530* fills the gap. Specifically, *Otto '530* discloses that the desired "overall radiation field may be specified in output from

treatment planning software." Ex. 1004 ¶ 44 (describing a "treatment planning computer system" or "programmed data processing device"); *see also id.* ¶ 79 (explaining that "the invention may be embodied in a computer-based treatment planning system" and "may comprise any medium which carries a set of computer-readable signals").

It would have been obvious to a person of ordinary skill in the art at the time of the alleged invention to modify the algorithm and method of execution taught by *Meedt* to utilize a computer-based treatment planning system with treatment planning software and a medium to carry a set of computer-readable signals as disclosed by *Otto '530*. Ex. 1002 ¶ 123. Doing so would provide *Meedt* with the ability to automatically generate its prescription file and carry out a method for planning delivery of a radiation dose to a target area within a patient. *Id.* Indeed, it would have been obvious to provide an IMRT treatment planning strategy, like that in *Meedt*, with the ability to be executed by a processor via computer-readable instructions. *Id.*; *see also KSR*, 127 S. Ct. at 1739. Multiple treatment planning systems were available at the time that had the claimed capability. Ex. 1002 ¶ 123.

68.b. "defining a set of one or more optimization goals, the set of one or more optimization goals comprising a desired dose distribution in the subject"

Meedt describes a beam direction optimization technique whereby a "'path of least resistance' is formalized with respect to [an] objective function." Ex. 1011

at 3001. In developing an "evolving beam configuration," *id.*, *Meedt* teaches that "[i]f beams impinging from other directions find a path of little resistance to resolve an existing conflict, the target becomes more accessible," *id.* "[A]ny optimum dose distribution employs the maximum number of paths of little resistance available to resolve the conflict posed by the interplay of patient geometry and the physics of dose deposition." *Id.* at 3001-02. "As the dose optimization problem for IMRT is very highly degenerate, it can be required that a beam configuration be found whose optimum dose distribution is equivalent to the global optimum with respect to the objective function." *Id.* at 3002; *see also id.* at 3007 ("When considering an elongated symmetry of the patient or [target volume] geometry, coplanar configurations can be expected to be sufficient to reach optimum dose distributions.").

Meedt further teaches that IMRT algorithms are "designed to determine fluence profiles for a given configuration of beams such that the goal of shaping high dose regions to the target volume (TV) is achieved while organs at risk (OARs) are avoided." *Id.* at 2999-3000. Because ideal dose distributions are not typically realizable, optimization methods "have been devised which utilize an objective function (*F*) that translates the clinical trade-off strategies with respect to the TV and the OARs into mathematical terms." *Id.* at 3000. And in further describing beam direction optimization, *Meedt* explains that "[a] precise and

comprehensive definition of the optimization goals that avoids underspecification is essential . . . [to] limit the degree of degeneracy and prevent the algorithm from creating unwanted dose features." *Id.* at 3017.

The method in *Meedt* thus "defin[es] a set of one or more optimization goals, the set of one or more optimization goals comprising a desired dose distribution in the subject," as recited in claim 68. Ex. 1002 ¶ 126 (alteration in original).

68.c. "specifying an initial plurality of control points along an initial trajectory which involves relative movement between a radiation source and the subject"

Meedt discusses "development of inverse planning algorithms for intensity-modulated radiotherapy (IMRT)." Ex. 1011 at 2999. The described method addresses the dose optimization problem for IMRT, noting it "is very highly degenerate, [and] it can be required that a beam configuration be found whose optimum dose distribution is equivalent to the global optimum with respect to the objective function." *Id.* at 3002. Indeed, *Meedt* notes that "[t]he search space for this task is enormous: a discretization of the search space as in figure 1 allows approximately 5×10^{15} different configurations of five beam directions." *Id.* Fig. 1 of *Meedt* (reproduced below) shows the search space for a non-coplanar beam search, where "[e]very dot on the unit sphere denotes a candidate beam direction." *Id.* (Fig. 1 caption).

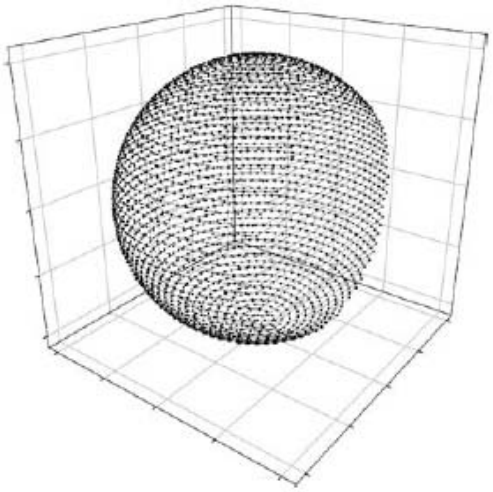
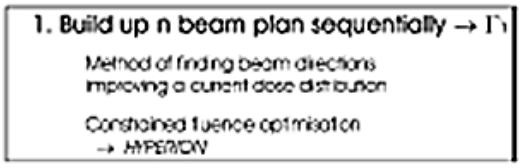


Figure 1. Search space S_Ω of the non-coplanar beam search. Every dot on the unit sphere denotes a candidate beam direction.

Meedt explains that there are three elements of the disclosed beam direction optimization concept: (1) "construction of a configuration of beam directions," (2) "evaluation of this configuration," and (3) "verification that it is not a local optimum (see figure 2)." *Id.* at 3002. "The initial beam configuration $\Gamma_1 = \{\Omega_1, \ldots, \Omega_n\}$ is achieved by building up *n* beams sequentially, *n* being the desired number of beams." *Id.* "This first stage starts with one beam direction and iteratively adds a single new beam direction to the configuration." *Id.*

The first stage of the beam direction optimization process of *Meedt* is shown in Fig. 2 (partially reproduced below). Indeed, the first stage involves sequentially building up the "initial beam configuration Γ_1" to consist of *n* beam directions. *Id.*



In discussing the addition of beams, *Meedt* notes that "[t]he search space S_Ω of possible beam directions Ω is defined by the discretization of either gantry angle alone or the discretization of solid angle (table, gantry) in the non-coplanar case." *Id.* at 3004.

As explained above, under Patent Owner's broad construction of "control point," each beam direction in *Meedt* corresponds to a "control point" as claimed. Ex. 1002 ¶ 130. Because the first stage of *Meedt* involves the building up of a plurality of beam directions, the first stage includes "an initial plurality of control points" as claimed. *Id.* And because the gantry must necessarily move in order to deliver radiation from each different beam direction, the beam directions (claimed "control points") are "along an initial trajectory," as claimed. *Id.* Thus, within the first stage, the beam direction optimization process of *Meedt* "specif[ies] an initial plurality of control points along an initial trajectory which involves relative movement between a radiation source and the subject," as recited in claim 68. *Id.* (alteration in original).

68.d. "iteratively optimizing a simulated dose distribution relative to the set of one or more optimization goals to determine one or more radiation delivery parameters associated with each of the initial plurality of control points"

Meedt explains that fluence shape (profile), corresponding dose distribution, and weight are parts of "the derivative of the objective function with respect to the

weight *w*." Ex. 1011 at 3001. And as discussed above, *Meedt* discloses that the "first stage starts with one beam direction and iteratively adds a single new beam direction to the configuration." *Id.* at 3002. "At each iteration, the phase space is searched for a beam that finds the path of least resistance . . . ." *Id.* "Once a new beam direction has been found and integrated into Γ_1 the fluence profiles of all beams are optimized." *Id.*

By the Patent Owner's broad construction of "control point," the fluence profile optimization of *Meedt* constitutes optimization of the delivery parameters associated with each of the initial plurality of control points, as claimed. Ex. 1002 ¶ 131. *Meedt* further teaches that, "[b]ased on the result of the fluence profile optimization, the new beam search can be executed again." Ex. 1011 at 3003. Indeed, *Meedt* teaches that its disclosed process "creates a configuration in an iterative manner and uses approximations to accelerate the beam search and deletion of redundant beams." *Id.* at 3017.

68.e. "upon reaching one or more initial termination conditions: adding one or more additional control points to obtain an increased plurality of control points"

As discussed above, "[t]he initial beam configuration $\Gamma_1 = \{\Omega_1, \ldots, \Omega_n\}$ is achieved by building up *n* beams sequentially, *n* being the desired number of beams." *Id.* at 3002. In each iteration, the algorithm identifies the beam with the path of least resistance, integrates it into Γ_1, and optimizes the fluence profiles of

all beams. *Id.*; Ex. 1002 ¶ 132. The process in *Meedt* thus optimizes the fluence profiles of each beam direction after each new beam direction is added to Γ_1. Ex. 1011 at 3002; Ex. 1002 ¶ 132. The end of each optimization process after the addition of each new beam direction to Γ_1 is criteria indicating termination of an initial optimization, and thus corresponds to the claimed "initial termination conditions." Ex. 1002 ¶ 132. And the additional beam directions (*e.g.*, the third, fourth, fifth, etc.), which are added after the first two beam directions are added to Γ_1 and optimized, correspond to the claimed "one or more additional control points to obtain an increased plurality of control points." *Id.*

68.f. "iteratively optimizing the simulated dose distribution relative to the set of optimization goals to determine one or more radiation delivery parameters associated with each of the increased plurality of control points"

See elements 68.d. and 68.e. above. *Meedt* iteratively adds beam directions to the configuration Γ_1. Ex. 1011 at 3002. For each iteration, "[o]nce a new beam direction has been found and integrated into Γ_1 the fluence profiles of all beams are optimized." *Id.* "Based on the result of the fluence profile optimization, the new beam search can be executed again." *Id.* at 3003. And as discussed in element 68.e. above, the additional beam directions added after the first two beam directions are added to Γ_1 and optimized make up to the claimed "increased plurality of control points." Ex. 1002 ¶ 133.

X. MANDATORY NOTICES

A. Real Party-in-Interest

Petitioner Elekta Inc., along with Elekta Ltd., Elekta AB, and Elekta Holdings U.S., Inc., are real parties-in-interest.

B. Related Matters

Patent Owner asserted the '770 patent in *In re Certain Radiotherapy Systems and Treatment Planning Software, and Components Thereof*, Investigation No. 337-TA-968, filed on September 25, 2015. Patent Owner also asserted the '770 patent in *Varian Medical Systems, Inc. et al v. Elekta AB et al*., No. 3:15-cv-04428, filed on September 25, 2015 (N.D. Cal.).

C. Lead and Backup Counsel, and Service Information

Lead Counsel: Timothy J. May (Reg. No. 41,538; e-mail: timothy.may@finnegan.com). Backup Counsel: James R. Barney (Reg. No. 46,539; e-mail: james.barney@finnegan.com); Joshua L. Goldberg (Reg. No. 59,369; e-mail: joshua.goldberg@finnegan.com); Justin E. Loffredo (Reg. No. 67,287; e-mail: justin.loffredo@finnegan.com); Christopher C. Johns (Reg. No. 68,664); e-mail: christopher.johns@finnegan.com). All consent to electronic service via e-mail and can be reached at Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, 901 New York Avenue, NW, Washington, DC 20001; phone: 202.408.4000; fax: 202.408.4400.

XI. GROUNDS FOR STANDING

Elekta certifies that the '770 patent is available for *inter partes* review and that Elekta is not barred or estopped from requesting *inter partes* review of the '770 patent challenging the patent claim on the grounds identified in this Petition.

XII. PAYMENT OF FEES

The required fees are submitted herewith in accordance with 37 C.F.R. §§ 42.103(a) and 42.15(a). If any additional fees are due during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 06-0916.

XIII. STATEMENT OF PRECISE RELIEF REQUESTED FOR EACH CLAIM CHALLENGED

Elekta requests review and cancellation of claim 68 based on each of the above grounds. Claim 68 is unpatentable under 35 U.S.C. §§ 102 and/or 103. The claim construction, reasons for unpatentability, and specific evidence supporting this request are detailed above.

XIV. CONCLUSION

For the reasons set forth above, the challenged claim 68 is unpatentable, and Petitioner requests that trial be instituted and the claims cancelled.

Respectfully submitted,

Dated: April 4, 2016

By: /Timothy J. May/
Timothy J. May
Reg. No. 41,538

CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) on the Patent Owner by Express Mail of a copy of this Petition for *Inter Partes* Review of U.S. Patent No. 7,906,770 and supporting materials at the correspondence address of record:

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