on the cone-beam CT volumetric image data or the image projection data." This limitation specifies a function and a corresponding structure, the function being "to control the patient support to place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data" and the structure being a hardwired logic or a programmable computer component with software for controlling the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data. The specification describes an algorithm that performs the function. *See, e.g.*, CX-0848C (Mutic WS) at Q318.

The Clinac is configured to control the patient support to place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data. The OBI application [

]. CX-0848C (Mutic WS) at Q319-20; *see also* CX-0964.73C.

Respondents argue this claim limitation is not met because the patient is not positioned by software before the cone-beam volumetric image data is collected. *See* RX-0494C (Papanikolaou RWS) at Q245-46, 266-67. Yet, during cross examination, Dr. Papanikolaou conceded that the patient couch can be automatically positioned before CBCT. Specifically, Dr. Papanikolaou admitted that the On-Board Imager ("OBI") Guide for the Clinac explains that the patient couch can be automatically positioned before cone-beam volumetric image data is collected. CX-0424C, CX Page 241;

Papanikolaou Tr. 896-897. Indeed, Dr. Papanikolaou admitted that, according to the OBI Guide, the patient couch can be automatically positioned before CBCT acquisition. *Id.*

Dr. Papanikolaou was shown the OBI Guide section *Couch Centering Motions before CBCT Acquisition*, which describes this pre-CBCT positioning function:

[

]

CX-0424.241C. This pre-CBCT automatic couch motion is further described in the section *Couch Centering During CBCT Acquisition.*[54] CX-0424.162–63C. Dr. Papanikolaou conceded that this couch centering motion occurs automatically. Papanikolaou Tr. 897-898. The TrueBeam systems are capable of these same pre-CBCT automatic couch motions, as described in the analogous section of the TrueBeam guide. CX-1021.79–82C ("*Couch Centering During CBCT Acquisition*"). Thus, the only disputed limitation is satisfied.

Thus, the Clinac meets each limitation of claim 1 of the '703 patent and therefore practices that claim.

TrueBeam System

Varian's TrueBeam and Edge systems practice each limitation of claim 1 of the

[54] Although entitled *Couch Centering During CBCT Acquisition*, it describes couch movement that occurs *before* the CBCT scan, *i.e.*, before the cone-beam volumetric image data is collected. *See* CX-0424.163C ("Once the couch has been centered the CBCT acquisition process can continue as normal."). The same is true of pre-CBCT couch movement for TrueBeam. *See* CX-1021C.81C ("Once the couch is in position, the CBCT image can be acquired.").

'703 patent, and therefore practice claim 1 of the '703 patent. CX-0848C (Mutic WS) at Q371. The TrueBeam and Edge function similarly, and practice the '703 patent in the same way, as evidenced by their shared technical manuals. *See, e.g.*, CX-0420C; CX-1020C; CX-1021C. Hereinafter, the TrueBeam and Edge systems are collectively referred to as "TrueBeam."

TrueBeam: Undisputed Elements

Claim 1 of the '703 patent recites: "A radiation treatment system, comprising …." This is a preamble and as such is not limiting. To the extent it is limiting, the TrueBeam is a radiation treatment system. *See, e.g.*, CX-0848C (Mutic WS) at Q374.

Claim 1 recites: [the system comprising] "a rotatable gantry; a treatment source …." TrueBeam has a rotatable gantry and a treatment source. *See* CX-0848C (Mutic WS) at Q375-376.

Claim 1 recites: [the system comprising] "a cone-beam radiation source coupled to the rotatable gantry …." The TrueBeam's X-Ray Imaging System radiation source is a cone-beam radiation source and it is coupled to the gantry. *See, e.g.*, CX-0848C (Mutic WS) at Q377.

Claim 1 recites: [the system comprising] "a flat-panel imager coupled to the rotatable gantry, wherein the flat-panel imager is operable to capture image projection data of a patient …." TBX has a flat-panel imager coupled to the rotatable gantry. This imager is operable to capture image projection data of a patient. *See, e.g.*, CX-0848C (Mutic WS) at Q378-379.

Claim 1 recites: [the system comprising] "a first logic that reconstructs a cone-beam computer tomography (CT) volumetric image data based on the image projection

data ...." This claim element specifies a function and a corresponding structure, the function being "to reconstruct a cone-beam computed tomography (CT) volumetric image data based on the image projection data," and the corresponding structure being a hardwired logic or programmable computer component with software for reconstructing a cone-beam CT volumetric image data based on the image projection data. The specification describes an algorithm that performs the function. *See, e.g.*, CX-0848C (Mutic WS) at Q380.

The TrueBeam captures image projection data, which is used to generate CBCT volumetric image data of the patient. The TBX Node and CBCT Reconstructor software applications generate the CBCT volumetric image data using a Feldkamp algorithm. *See, e.g.*, CX-1021.180C. The TBX Node and CBCT Reconstructor applications run on programmable computers. *See, e.g.*, CX-0848C (Mutic WS) at Q381-82.

Claim 1 recites: [the system comprising] "a patient support to support the patient ...." TrueBeam has a patient support that supports the patient. *See*, CX-0848C (Mutic WS) at Q383.

TrueBeam: Disputed "second logic"

Claim 1 recites: [the system comprising] "a second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data." This limitation specifies a function and a corresponding structure, the function being "to control the patient support to place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data" and the structure being a hardwired logic or a programmable computer component

with software for controlling the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data. The specification describes an algorithm that performs the function. *See, e.g.*, CX-0848C (Mutic WS) at Q384.

The TrueBeam is configured to control the patient support to place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data. The TrueBeam performs this function using the TrueBeam Workstation, which is made up of a hardwired logic or a programmable computer component with software. *See, e.g.*, CX-0848C (Mutic WS) at Q385-86.

As explained above in reference to the Clinac, Elekta's expert, Dr. Papanikolaou, argues this claim limitation is not met because the patient is not positioned by software before the cone-beam volumetric image data is collected. RX-0494C (Papanikolaou RWS) at Q266-67. However, the TrueBeam can perform patient positioning before performing a CBCT scan, *see, e.g.*, CX-1021.79-82C, contradicting Dr. Papanikolaou's opinion.

Accordingly, the TrueBeam meets each limitation of claim 1 of the '703 patent and therefore practices that claim.

D. Validity of the '703 Patent

Elekta argues that *Jaffray WIPO*, *Jaffray 2001*, and *Jaffray 2000* each anticipates claims 1 of the '703 patent. *See* Resps. Br. at 143-60. Elekta argues that claim 1 of the '703 patent is rendered invalid as obvious by *Jaffray 2001* by itself. *See id.* at 160-61. Elekta also argues that claim 1 is rendered invalid as obvious by *Jaffray 2000* in light of *Jaffray JRO 1999* and *Jaffray SPIE 1999*. *See id.* at 161-63.

Complainants and the Staff disagree. *See* Compls. Br. at 162-66; Staff Br. at 86-88.

For the reasons discussed below, respondents have not shown by clear and convincing evidence that asserted claim 1 of the '703 patent is invalid as anticipated or rendered obvious.

1. Applicable Law

One cannot be held liable for practicing an invalid patent claim. *See Pandrol USA, LP v. AirBoss Railway Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003). Nevertheless, each claim of a patent is presumed to be valid, even if it depends from a claim found to be invalid. 35 U.S.C. § 282; *DMI Inc. v. Deere & Co.*, 802 F.2d 421 (Fed. Cir. 1986).

A respondent that has raised patent invalidity as an affirmative defense must overcome the presumption by "clear and convincing" evidence of invalidity. *Checkpoint Systems, Inc. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995).

a. Anticipation

Anticipation under 35 U.S.C. § 102 is a question of fact. *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1347 (Fed. Cir. 2007). Section 102 provides that, depending on the circumstances, a claimed invention may be anticipated by variety of prior art, including publications, earlier-sold products, and patents. *See* 35 U.S.C. § 102 (*e.g.*, section 102(b) provides that one is not entitled to a patent if the claimed invention "was patented or described in a printed publication in this or a foreign country or in

public use or on sale in this country, more than one year prior to the date of the application for patent in the United States").

The general law of anticipation may be summarized, as follows:

> A reference is anticipatory under § 102(b) when it satisfies particular requirements. First, the reference must disclose each and every element of the claimed invention, whether it does so explicitly or inherently. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed.Cir.2006). While those elements must be "arranged or combined in the same way as in the claim," *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1370 (Fed.Cir.2008), the reference need not satisfy an *ipsissimis verbis* test, *In re Bond*, 910 F.2d 831, 832-33 (Fed.Cir.1990). Second, the reference must "enable one of ordinary skill in the art to make the invention without undue experimentation." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed.Cir.2008); *see In re LeGrice*, 49 C.C.P.A. 1124, 301 F.2d 929, 940-44 (1962). As long as the reference discloses all of the claim limitations and enables the "subject matter that falls within the scope of the claims at issue," the reference anticipates -- no "actual creation or reduction to practice" is required. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1380-81 (Fed.Cir.2003); *see In re Donohue*, 766 F.2d 531, 533 (Fed.Cir.1985). This is so despite the fact that the description provided in the anticipating reference might not otherwise entitle its author to a patent. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed.Cir.1991) (discussing the "distinction between a written description adequate to support a claim under § 112 and a written description sufficient to anticipate its subject matter under § 102(b)").

In re Gleave, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

b. Obviousness

Under section 103 of the Patent Act, a patent claim is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a

person having ordinary skill in the art to which said subject matter pertains."[55] 35 U.S.C. § 103. While the ultimate determination of whether an invention would have been obvious is a legal conclusion, it is based on "underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness." *Eli Lilly and Co. v. Teva Pharmaceuticals USA, Inc.*, 619 F.3d 1329 (Fed. Cir. 2010).

The objective evidence, also known as "secondary considerations," includes commercial success, long felt need, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 13-17 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006). "[E]vidence arising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). Secondary considerations, such as commercial success, will not always dislodge a determination of obviousness based on analysis of the prior art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007) (commercial success did not alter conclusion of obviousness).

"One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *KSR*, 550 U.S. at 419-20. "[A]ny

[55] The standard for determining whether a patent or publication is prior art under section 103 is the same as under 35 U.S.C. § 102, which is a legal question. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987).

need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.*

Specific teachings, suggestions, or motivations to combine prior art may provide helpful insights into the state of the art at the time of the alleged invention. *Id.* at 420. Nevertheless, "an obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way." *Id.* "Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* A "person of ordinary skill is also a person of ordinary creativity." *Id.* at 421.

Nevertheless, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); *see KSR*, 550 U.S. at 416 (a combination of elements must do more than yield a predictable result; combining elements that work together in an "unexpected and fruitful manner" would not have been obvious).[56]

[56] Further, "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 550 U.S. at 416 (citing *United States v. Adams*, 383 U.S. 39, 52 (1966)).

2. Anticipation

Elekta argues that Jaffray WIPO, Jaffray 2001, and Jaffray 2000 each anticipates claims 1 of the '703 patent. *See* Resps. Br. at 143-60.

Complainants and the Staff disagree. *See* Compls. Br. at 162-64; Staff Br. at 86-87.

As discussed below, respondents have not shown by clear and convincing evidence that each of Jaffray WIPO, Jaffray 2001, and Jaffray 2000, anticipates asserted claim 1 of the '703 patent.

As noted, respondents identify three grounds of anticipation against claim 1 of the '703 patent, based on Jaffray WIPO, Jaffray 2001, and Jaffray 2000. Each of these arguments fails because none of the prior art references (alone or in combination) teaches the limitation of "a second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data." JX-0003. This "second logic" limitation cannot be satisfied by operations that are performed only manually, and the prior art teaches only manual movement of the treatment table, not movement by any logic whatsoever.

The disclosure relied on by Dr. Papanikolaou from Jaffray WIPO discusses a treatment couch, that the accelerator can be under computer control for gantry "assisted set-up (ASU)," and two generic statements about "image-guided" "radiation therapy." As explained by Dr. Mutic, none of these teachings discloses a "logic" that is configured to control the patient support and place it in an operative position to begin treatment, all

based on image data, because, for example, nothing in the steps discussed in the Jaffray WIPO reference necessarily must be performed by a logic:

> So, sir, there's 520, there's 525, there's 530, there's corresponding text. What this shows on the right side with the Jaffray WIPO, it just tells me that they're going to do image registration and that they're going to translate patient on the couch based on that. It does not tell me that they are going to use a logic, which is a hardware logic or computer programmable software, to drive the couch.

Mutic Tr. 1023-1024.

It is possible that the step of adjusting the patient support to position the patient in an operative position could be performed by hand or by using a set of analog motor controls in a treatment couch rather than by a logic. *Id.* Furthermore, the computer controlled treatment table disclosed in *Jaffray WIPO* relays the manual table positions entered by the user to the table motor controls to allow remote control of the table. This disclosure teaches nothing about the use of a logic to position the treatment table and place the patient in an operative position based on imaging data, as claim 1 expressly requires. *Jaffray WIPO* thus does not disclose the claim limitation expressly, nor can inherency be shown because at most the reference offers the possibility of what might have been done, falling far short of the necessary aspects of the prior art required to prove inherency. *See In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Thus, Dr. Mutic confirmed again under cross examination that *Jaffray WIPO* at most teaches the manual movement of the treatment table by the researchers to accomplish translation of the patient.

Jaffray 2001, like *Jaffray WIPO*, does not contain an express disclosure of a logic for performing the function of controlling the patient support and placing the patient in an

operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data. At most, *Jaffray 2001* discloses bolting certain imaging components onto the gantry of a linear accelerator and some vague, aspirational statements regarding advancing the goal of image-guided radiation therapy. As explained by Dr. Mutic, these disclosures fail to provide any express or inherent disclosure of the "second logic." *See* CX-3879C (Mutic RWS) at Q212-214. Likewise, *Jaffray 2000* and the *Jaffray 1999* references fail for the same reasons as *Jaffray 2001*. None discloses logic for controlling the patient support and placing the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data. *See* CX-3879C (Mutic RWS) at Q216-18.

Moreover, respondents were required to identify structure in the prior art corresponding to the structure they proposed in their construction of the "second logic" means-plus-function term. They did not do so. *See* Resps. Br. at 143-60. Hence, respondents cannot meet their burden of proof for anticipation by clear and convincing evidence.

3. Obviousness

Elekta argues that claim 1 of the '703 patent is rendered invalid as obvious by Jaffray 2001 by itself. *See* Resps. Br. at 160-61. Elekta also argues that claim 1 is rendered invalid as obvious by Jaffray 2000 in light of Jaffray JRO 1999 and Jaffray SPIE 1999. *See* Resps. Br. at 161-63.

Complainants and the Staff disagree. *See* Compls. Br. at 164-66; Staff Br. at 87-88.

Respondents advance three obviousness arguments for claim 1 of the '703 patent, based on the same *Jaffray 2001*, *Jaffray 2000*, *Jaffray JRO 1999*, and *Jaffray SPIE 1999* references discussed above. These combinations all fail because, as discussed above, none of these references, alone or in combination, disclose "a second logic configured to control the patient support and place the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data." Claim 1 cannot be shown to be obvious, given that respondents failed to show that all claim elements were disclosed in the art and failed to present any evidence at the hearing that would establish that the requirements of claim 1 could be found in the prior art.

Dr. Papanikolaou points to an old system in the prior art known as the "verify and record" system and alleges, with no factual support, that this system performed the function of the "second logic" of controlling the patient support and placing the patient in an operative position to begin a treatment based on the cone-beam CT volumetric image data or the image projection data. As explained by Dr. Mutic, these opinions are not supported by examination of the prior art. Indeed, the verify and record system cited by Dr. Papanikolaou actually has nothing to do with patient positioning based on imaging. *See* CX-3879C (Mutic RWS) at Q221.

For example, the 1981 *Karzmark* reference relied on by Dr. Papanikolaou explains in reference to the SL-20 that the system was only concerned with verification of proper machine settings. No mention of imaging is made in the reference, which is expected because the linear accelerator disclosed in the section of *Karzmark* relied on by Dr. Papanikolaou had no imaging capability. *See id.* Indeed, as Dr. Mutic explains, a full

examination of the prior art makes clear that no implementation of the "verify and record" systems identified by Dr. Papanikolaou had any imaging aspects. *See id.*, Q221-33. The prior art disclosures identified by Dr. Papanikolaou cannot teach the function of controlling patient position based on imaging as recited in claim 1 if they don't implicate imaging at all. *See id.*, Q223.

In light of the absence of any teaching of this claim element in the prior art, respondents have the burden to identify some reason why one of ordinary skill in the art would have known to create the "second logic" as recited in claim 1. Inasmuch as respondents did not identify any such motivation or provide any analysis as to why this would allegedly have been obvious, respondents cannot meet their burden of proof to show obviousness by clear and convincing evidence.

E. Inequitable Conduct Related to the Shapiro Patents

Respondents argue:

> During prosecution of the Shapiro patents, the named inventors submitted several admittedly false declarations to the PTO in an effort to "swear behind" (i.e., antedate) certain prior art references, including the Jaffray Application. Varian admits these declarations were *false* when filed.
>
> The Federal Circuit has long held that false declarations submitted during prosecution are *per se* material. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc) ("When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material."); *accord Intellect Wireless, Inc. v. HTC Corp.*, 732 F.3d 1339, 1342 (Fed. Cir. 2013). Thus, there is no question that the materiality prong is satisfied here.
>
> As for the intent prong, the Federal Circuit has held that intent can be inferred from the submission of false declarations, especially when there is a pattern of doing so, as is certainly the case here. *Intellect Wireless*, 732 F.3d at 1345-46 ("Submission of an affidavit containing

fabricated examples of actual reduction to practice in order to overcome a prior art reference raises a strong inference of intent to deceive.") Accordingly, for the reasons explained below, the Commission should find the Shapiro patents unenforceable due to inequitable conduct.

See Resps. Br. at 179, 179-200.

Complainants argue:

> Elekta asks the Commission to render unenforceable the entire Shapiro patent family based on a mistake that is demonstrably immaterial. Elekta relies exclusively on the fact that Dr. Munro signed declarations stating that he participated in or directed activities evidencing conception and reduction to practice that predated his time at Varian. There is no dispute that Dr. Munro did *not* participate in any of those activities. Dr. Munro's mistaken declaration is immaterial because the mistake: 1) is self-evident on the face of the allegedly false declarations; 2) has already been corrected by the Patent Office's removal of Dr. Munro as a named inventor; and 3) provided no demonstrable benefit to Varian at any time. Even if the mistake were somehow material, there is no evidence to support an inference of intent, much less prove by clear and convincing evidence, that the single most reasonable inference is a specific intent to deceive the PTO.

See Compls. Br. at 166, 166-75 (emphasis in original).

The Staff argues:

> The salient facts regarding the timing and content of the declarations submitted to the PTO by the Shapiro patents' inventors are detailed in Elekta's brief. The Staff does not dispute these facts. The Staff also does not dispute that false declarations are per se material for purposes of inequitable conduct.
>
> However, the evidence does not show the requisite intent to deceive the PTO. The Federal Circuit has stated that in order to find inequitable conduct, a specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence," and that when "multiple reasonable inferences" may be drawn, intent to deceive cannot be found. The evidence showed that Dr. Munro signed multiple false declarations upon penalty of perjury, which were submitted to the PTO, and which Dr. Munro admits he did not read prior to signing. The record does not contain any testimony from Varian's in-house patent counsel, Angelo Gaz who facilitated Dr. Munro's signing of the false declarations, nor does the record contain testimony from the outside counsel at Blakely

> Sokoloff who prosecuted the patent applications and submitted the false declarations. In the Staff's view, at best the record shows gross negligence by Dr. Munro. However, gross negligence is insufficient to meet the intent element of inequitable conduct.

See Staff Br. at 88-89 (citations omitted).

1. Applicable Law

Every individual associated with the filing and prosecution of a patent application has a duty to disclose to the patent examiner all information known to be material to patentability. 37 C.F.R. § 1.56(a). "If inequitable conduct occur[s] with respect to one or more claims of an application, the entire patent is unenforceable." *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1375 (Fed. Cir. 2006).

A patent is unenforceable on the grounds of inequitable conduct if an applicant provides materially false information or withholds material information from the USPTO with an intent to mislead or deceive. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (*en banc*). The Federal Circuit has stressed that "materiality and intent are separate requirements, and intent to deceive cannot be found based on materiality alone." *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 733 (Fed. Cir. 2010). Both materiality and intent to deceive must be proven by clear and convincing evidence. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

To establish an intent to deceive, an accused infringer must show that the patentee acted with the specific intent to deceive the PTO:

> A finding that the misrepresentation or omission amounts to gross negligence or negligence under a "should have known" standard does not satisfy this intent requirement. . . . "In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant

> made a deliberate decision to withhold a known material reference." . . . In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.

Therasense, 649 F.3d at 1290 (citations omitted). The intent element "rarely can be, and need not be, proven by direct evidence. . . . Instead, an intent to deceive is usually inferred from the facts and circumstances surrounding the conduct at issue." *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1364 (Fed. Cir. 2007). To meet the clear and convincing evidence standard, however, "the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" *Therasense*, 649 F.3d at 1290 (citations omitted). The evidence "'must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances.'" *Id.* at 1290 (emphasis in original). "Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Id.* at 1290-91.

* * *

For the reasons discussed below, the evidence does not show that the Shapiro patents are unenforceable for inequitable conduct.

Materiality

Elekta has not proven the element of materiality with respect to the Munro Declarations. "[A]s a general matter, the materiality required to establish inequitable conduct is but-for materiality." *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011) (*en banc*). There is no evidence that would establish that but for Dr. Munro's mistaken declarations, the Shapiro patents would not have issued.

Indeed, five other properly named inventors submitted accurate declarations that were identical in all material respects to those submitted by Dr. Munro and were sufficient to justify the Examiner's allowance. There is no dispute that five of the six inventors originally named on the Shapiro patents participated in the activities illustrated in exhibits G-I of their prosecution declarations and that those declarations evidence internal Varian activities dating back to the early 1990s. There is also no dispute that those declarations were used to confirm a conception and reduction to practice date of at least February 12, 2000 for the Shapiro inventions.

The evidence shows that the Munro Declarations erroneously state that Dr. Munro participated in these activities. This error is apparent from the face of Dr. Munro's declarations. The declarations reflect that he first started working at Varian on May 7, 2001, which is after the February 12, 2000 date of conception and reduction to practice set forth in the exhibits attached to those same declarations and credited by the Examiner.

"egregious misconduct"

Elekta argues that the Munro Declarations are *per se* material because they are "unmistakably false." Resps. Br. at 179. Elekta's argument is both factually and legally incorrect. Legally, the term "unmistakably false" applies only to statements that are unmistakable falsehoods, *i.e.*, statements made with the intention to deceive, and not mere errors or mistakes of fact. As discussed above, the Munro Declarations are not "unmistakably false" as the error in including Dr. Munro as an inventor is apparent on the face of the declarations, indicating no intent to deceive. Elekta concedes that Dr. Munro "did not participate in the preparation of Attachments G-I to his declaration because those internal Varian documents were created more than a year before he came to Varian." *Id.*

at 183. Elekta does not claim that the Examiner ever specifically considered Dr. Munro's declarations apart from those of the properly named inventors. It appears that no one, including the Examiner, noticed that the contradictory dates meant that Dr. Munro should not have been named as an inventor. Elekta did not elicit any testimony showing that Dr. Munro contributed to the Shapiro patents at any point in time from any witness.[57] The evidence shows that Dr. Munro's inclusion as a named inventor was a mistake, not fraud, and one which has been corrected at the PTO.

Correcting inventorship upon discovering the facial error in Dr. Munro's declarations is not the type of "affirmative egregious misconduct" that would allow the materiality prong for inequitable conduct to be satisfied as an equitable matter in the absence of but-for materiality. *See Therasense*, 649 F.3d at 1292 ("Because inequitable conduct renders an entire patent (or even a patent family) unenforceable, as a general rule, this doctrine should only be applied in instances where the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted claim."). Rather, such cases are reserved for those rare instances that deal with "particularly egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence" and that succeed in employing "'deliberately planned and carefully executed scheme[s] to defraud' not only the PTO but also the courts." *Id.* at 1287 (citations omitted). In these instances, "materiality is premised on the notion that 'a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that falsehood will affect issuance of the patent.'" *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1345

[57] Indeed, Dr. Munro testified repeatedly, when asked at his deposition, that he did not contribute to any claim of the Shapiro patents. JX-0041C (Munro Dep. Tr.) at 125-126, 140, 143, 162.

(Fed. Cir. 2013) (quoting *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1294 (Fed. Cir. 2012)).

The cases cited by the *Therasense* court to support the "egregious misconduct" exception involved facts clearly distinguishable from those in this case. Issuance of the patent in those cases depended on the PTO's reliance on the intentional misconduct. For example, in *Hazel-Atlas Co. v. Hartford Co.*, the patentee's lawyers wrote an article that was later published under the name of the National President of the Flint Glass Workers' Union, who was paid for his services, praising the then patent-pending invention. *Hazel-Atlas Co. v. Hartford Co.*, 322 U.S. 238, 240-41 (1944). The article was later submitted at the PTO to support issuance, and at trial and on appeal to support the validity and alleged infringement of the asserted patent. *Id.* At no point was the identity of the authors or the relationship between the article's named author and the patentee disclosed. *Id.* at 242-43.

Similarly, *Rohm & Hass Co. v. Crystal Chemical Co.*, involved submission of false data to expressly overcome a rejection based on prior art, and the PTO would not have withdrawn the rejection absent that false data. *Rohm & Hass Co. v. Crystal Chemical Co.*,722 F.2d 1556, 1570-71 (Fed. Cir. 1983); *see also Refac Int'l., Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1580-83 (Fed. Cir. 1996) (inequitable conduct found due to declarant's failure to disclose declarant's past relationship with patentee and familiarity with patented system where subject of declaration was whether disclosure was enabling); *Precision Co. v. Automotive Co.*, 324 U.S. 806, 809-20 (1945) (declarations submitted by sole inventor found to have false dates intended to pre-date prior art); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 243-44 (1933) (patentee paid

declarant to suppress evidence of prior use and declare that prior use was experimental). In all those cases, the patentee's egregious misconduct, conduct amounting to a fraud, led to the issuance of the patent.

Elekta argues that the conduct of the patentee in *Intellect Wireless, Inc. v. HTC Corp.*, which was found to be sufficient to find inequitable conduct, was less egregious than Varian's conduct in the prosecution of the Shapiro patents. Resps. Br. at 198 ("Indeed, the extent of Dr. Munro's deceptive behavior during prosecution of the Shapiro patents far *exceeds* what was shown in *Intellect Wireless*.") (emphasis in original). The patentee in *Intellect Wireless* asserted that he had actually reduced a device to practice and demonstrated it at a meeting when he had, in fact, not done so. *See Intellect Wireless, Inc. v. HTC Corp.*, 732 F.3d 1339, 1342 (Fed. Cir. 2013). Moreover, the patentee told the PTO that the Smithsonian had acquired "two prototypes" when in fact the Smithsonian had been given non-functioning "imitation smartphones made of wood and plastic." *Id.* at 1344. The fraud thus related to the substantive aspects of an actual reduction to practice in *Intellect Wireless*, and was clearly material to patentability, because the patent would not have issued without it. No such misconduct is found here.

The other cases Elekta cites involved conduct indicating an intent to deceive with respect to a material fact, unlike Varian's conduct in the prosecution of the Shapiro patents. For example, *Rohm and Haas Co.* involved actual falsified data to overcome a prior art rejection. 722 F.2d at 1570-71. In *Intellect Wireless*, *Rohm and Haas Co.*, and the other cases cited by Elekta, if the information was not submitted, the patents would not have issued. That is not the case here because the PTO accepted the substantive

swear behind information in the declarations from the properly named inventors, and has now also accepted the petition to remove Dr. Munro as an inventor.

* * *

Accordingly, respondents have not shown the element of materiality with respect to the Munro Declarations.

Specific Intent to Deceive

Even if there were materiality or the narrow *Therasense* exception applied, Elekta's inequitable conduct defense is insufficient because Elekta cannot prove the requisite intent to deceive. *Therasense* requires that "a court must weigh the evidence of intent to deceive independent of its analysis of materiality." 649 F.3d at 1290. In order to find the specific intent necessary to support inequitable conduct, "the evidence must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances." *Id.* at 1290 (emphasis in original; quotations omitted). There is no evidence of intent.

Elekta relies on *Intellect Wireless* to support its argument that intent should be inferred based on the facts in this investigation. However, as discussed above, the fraudulent acts committed in *Intellect Wireless* were different in nature than any alleged misconduct during prosecution of the Shapiro patents. Indeed, in another case relied on by Elekta, the Federal Circuit was presented with more analogous facts and reversed a finding of inequitable conduct. *See Outside Box Innovations*, 695 F.3d at 1294-95. In *Outside Box*, the patentee had submitted declarations claiming small entity status when it turned out that it was not entitled to claim small entity status. *Id.* at 1293-94. The Federal Circuit expressly declined to decide whether those declarations were *per se*

material under *Therasense*, holding instead that "there was no clear and convincing evidence of intent to deceive the PTO." *Id.* at 1294. The Federal Circuit explained: "Importantly, the regulations do not contemplate that an incorrect claim of entity status, with no evidence of bad faith, is punishable by loss of the patent." *Id.* Inasmuch as the PTO's regulations allowed for retroactive correction of entity status by payment of fees, the Federal Circuit interpreted this to mean that there are other reasonable inferences that can be drawn from mistakenly claiming small entity status. *Id.* at 1294-95. Similarly, PTO regulations contemplate that mistakes can be made in the naming of inventors and provide a mechanism for removing them.

Absent evidence, whether direct or circumstantial, that a specific intent to deceive the PTO is the single most reasonable inference, Elekta has failed to satisfy *Therasense*. *Therasense*, 649 F.3d at 1290. ("[T]o meet the clear and convincing evidence standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence.") (quotations omitted). As Dr. Munro explained during his deposition, he trusted and relied upon Varian's prosecution counsel to prepare documents with the appropriate information for him to sign. *See, e.g.*, JX-0041C (Munro Dep. Tr.) at 137-138. While Dr. Munro should have carefully reviewed documents Varian's attorneys asked him to sign, it has not been shown that he had specific intent to deceive the PTO.

* * *

Accordingly, the evidence does not show that the Shapiro patents are unenforceable for inequitable conduct.

VII. U.S. Patent No. 7,880,154[58]

United States Patent No. 7,880,154 ("the '154 patent), entitled "Methods and apparatus for the planning and delivery of radiation treatments," issued on February 1, 2011, to named inventor Karl Otto. JX-0004 ('154 Patent). The '154 patent issued from Application No. 12/132,597, filed on June 3, 2008, which is a continuation in part of Application No. 11/996,932 (now the '770 patent). *Id.* The '154 patent relates to "radiation treatment," and "particularly to methods and apparatus for planning and delivering radiation to a subject to provide a desired three-dimensional distribution of radiation dose." JX-0004 at col. 1, lns. 24-27. The '154 patent has a total of 38 claims.

Complainants allege infringement of dependent method claims 23 (which depends from independent claim 19) and 26 (which depends from dependent claim 24, which in turn depends from dependent claim 23) of the '154 patent. *See* Compls. Br. at 176-214. Complaints argue that they have a domestic industry based on claim 23. *See* Compls. Br. at 214-17. Those claims read as follows:

> **19.** A method for delivering radiation dose to a target area within a subject, the method comprising:
>
> defining a trajectory for relative movement between a treatment radiation source and the subject in a source trajectory direction;
>
> determining a radiation delivery plan;

[58] It is noted that on September 29, 2016, respondents filed a letter requesting the administrative law judge to take judicial notice of "USPTO Institution Decisions, indicating that all asserted claims from the Otto Patents in this Investigation are now currently under review by the Patent Trial and Appeal Board (PTAB) at the U.S. Patent and Trademark Office in four separate *inter partes* review (IPR) proceedings." *See* Letter to Administrative Law Judge re Otto IPRs (emphasis in original) (EDIS Doc. ID No. 591647). On October 4, 2016, complainants filed a "Letter to Judge Shaw regarding Elekta's Request for Judicial Notice" in response to respondents letter. *See* Letter to Judge Shaw regarding Elekta's Request for Judicial Notice (EDIS Doc. ID No. 591922).

while effecting relative movement between the treatment radiation source and the subject along the trajectory in the source trajectory direction, delivering a treatment radiation beam from the treatment radiation source to the subject according to the radiation delivery plan to impart a dose distribution on the subject;

wherein delivering the treatment radiation beam from the treatment radiation source to the subject comprises varying an intensity of the treatment radiation beam over at least a portion of the trajectory.

23. A radiation delivery method according to claim **19** wherein varying the intensity of the treatment radiation beam over at least the portion of the trajectory comprises varying a rate of radiation output of the radiation source while effecting continuous relative movement between the treatment radiation source and the subject along the trajectory.

24. A radiation delivery method according to claim **23** wherein the trajectory comprises a plurality of arcs, each arc involving relative movement between the radiation source and the subject within a corresponding plane.

26. A radiation delivery method according to claim **24** wherein, between successive ones of the plurality of arcs, the trajectory comprises inter-arc relative movement between the radiation source and the subject, the inter-arc relative movement comprising movement such that the corresponding planes associated with each arc intersect one another.

JX-0004 ('154 Patent) at col. 34, lns. 21-37, lns. 54-63; col. 35, lns. 3-8.

A. Claim Construction

1. Applicable Law

Claim construction begins with the plain language of the claim.[59] Claims should

[59] Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vanderlande Indus. Nederland BV v. Int'l Trade Comm.*, 366 F.3d 1311, 1323 (Fed. Cir. 2004); *Vivid Tech., Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

be given their ordinary and customary meaning as understood by a person of ordinary skill in the art, viewing the claim terms in the context of the entire patent.[60] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006).

In some instances, claim terms do not have particular meaning in a field of art, and claim construction involves little more than the application of the widely accepted meaning of commonly understood words. *Phillips*, 415 F.3d at 1314. "In such circumstances, general purpose dictionaries may be helpful." *Id.*

In many cases, claim terms have a specialized meaning, and it is necessary to determine what a person of skill in the art would have understood the disputed claim language to mean. "Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.'" *Phillips*, 415 F.3d at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). The public sources identified in *Phillips* include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant

[60] Factors that may be considered when determining the level of ordinary skill in the art include: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

scientific principles, the meaning of technical terms, and the state of the art." *Id.* (quoting *Innova*, 381 F.3d at 1116).

In cases in which the meaning of a claim term is uncertain, the specification usually is the best guide to the meaning of the term. *Phillips*, 415 F.3d at 1315. As a general rule, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). The specification is, however, always highly relevant to the claim construction analysis, and is usually dispositive. *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Moreover, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316.

Claims are not necessarily, and are not usually, limited in scope to the preferred embodiment. *RF Delaware, Inc. v. Pacific Keystone Techs., Inc.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003); *Decisioning.com, Inc. v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1314 (Fed. Cir. 2008) ("[The] description of a preferred embodiment, in the absence of a clear intention to limit claim scope, is an insufficient basis on which to narrow the claims."). Nevertheless, claim constructions that exclude the preferred embodiment are "rarely, if ever, correct and require highly persuasive evidentiary support." *Vitronics*, 90 F.3d at 1583. Such a conclusion can be mandated in rare instances by clear intrinsic evidence, such as unambiguous claim language or a clear disclaimer by the patentees during patent prosecution. *Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc.*, 214 F.3d 1302, 1308 (Fed. Cir. 2000); *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319 (Fed. Cir. 2002).

If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence consists of all evidence external to the patent and the prosecution history, and includes inventor testimony, expert testimony, and learned treatises. *Phillips*, 415 F.3d at 1317. Inventor testimony can be useful to shed light on the relevant art. In evaluating expert testimony, a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent. *Id.* at 1318. Extrinsic evidence may be considered if a court deems it helpful in determining the true meaning of language used in the patent claims. *Id.*

2. A Person of Ordinary Skill in the Art

Complainants argue:

> In the context of the Otto patents, a person of ordinary skill in the art as of July 2005 would have: (a) at least a post-graduate degree in medicine or at least two years of experience in the field of radiation therapy; and (b) at least a Bachelors of Science in computer science, applied physics, or electrical engineering; or the equivalent to all of the above.
>
> Elekta disagrees, contending that a person of ordinary skill with respect to the Otto patents would require a graduate degree, specifically an M.S. or Ph.D., in medical physics or a related field, for example, Physics or Engineering, and three years of work in radiation oncology beyond the completion of their degree, including at least three years of experience with programming of treatment planning software systems and programming of optimization processes. Elekta's definition requires a person of ordinary skill in the art to have extraordinary and highly specialized skill, and it is inflexible in how that skill is acquired. Both are unnecessary. Physicians or engineers with a Bachelors of Science in computer science, applied physics or electrical engineering and a post-graduate degree in medicine or two years of experience in radiation therapy, or equivalent experience, would have a deep understanding of all the underlying technologies necessary to understand the Otto patents from

their education and practical experience in medicine, including knowledge of applied physics, electrical engineering, computer science, radiation medicine, and radiotherapy concepts.

Elekta's argument for an inflexible, extraordinarily high level of skill is inspired by this litigation rather than by a reasonable interpretation of the Otto patents. Elekta's purpose simply is to attempt to disqualify Varian's infringement expert, Dr. Bergeron. Elekta has failed, however, to identify ***any aspects*** of Dr. Bergeron's opinions or testimony that are unreliable because of his lack of qualifications. Indeed, Dr. Bergeron's witness statement was admitted without objection, and Elekta's own expert (Dr. McNutt) even admitted that he had no technical disagreement with Dr. Bergeron's detailed source code analysis of the accused Elekta systems. Elekta cannot square its inflexible standards for a person of ordinary skill with its failure to identify any substantive deficiencies in Dr. Bergeron's expert analysis.

Compls. Br. at 31-33 (citations omitted) (emphasis in original).

Respondents argue:

A person of ordinary skill in the art for the Otto patents would be a person with a Master's degree or PhD in medical physics or a related field, such as, physics or engineering. In addition, a skilled person would need to have three years of work in radiation oncology beyond the completion of their degree, including at least three years of experience with programming of treatment planning software systems and programming of optimization processes. A person of skill would need this additional work experience in order to analyze and apply the terms of art that appear in the patents, technical documents, and prior art.

Resps. Br. at 205 (citations omitted).

The Staff argues:

The Staff agrees with Elekta's definition of a person of ordinary skill in the art. In particular, the Staff is of the view that Varian's proposed level of skill is too low, given the complex algorithms, mathematics, functionality of radiotherapy devices and clinical radiation oncology that one would need understand in order to understand the Otto patents. For example, combinations of Varian's criteria result in level of skill that is simply too low, such as (1) a person with a undergraduate degree in physics and two years or work in "the field of radiation therapy" (which could include many supporting roles that do not involve developing radiation treatment technologies) or (2) a person with a

> computer science degree and an MD, but no experience in radiation oncology.
>
> Nevertheless, the Staff is of the view that the differences in the proposed levels of ordinary skill in the art do not significantly impact the substantive issues of the investigation; for example, the parties have not argued that persons of the respective proposed levels of skill in the art would interpret the claims or prior art, or apply the claims to the accused products or domestic industry products differently.

Staff Br. at 90-91 (citations omitted).

As argued by complainants, respondents' proposed definition requires a person of ordinary skill in the art to have extraordinary and highly specialized skill which is not necessary. Physicians or engineers with a bachelor's of science degree in computer science, applied physics or electrical engineering and a post-graduate degree in medicine or two years of experience in radiation therapy, or equivalent experience, would understand the Otto patents.

Thus, as proposed by complainants, the administrative law judge finds that with respect to the Otto patents, a person of ordinary skill in the art as of July 2005 would have: (a) at least a post-graduate degree in medicine or at least two years of experience in the field of radiation therapy; and (b) at least a bachelor's of science degree in computer science, applied physics, or electrical engineering; or the equivalent to all of the above.

3. "source trajectory direction"

Below is a chart showing the parties' proposed claim constructions.

"source trajectory direction"		
Complainants' Construction	**Respondents' Construction**	**Staff's Construction**
"direction in which the radiation source moves"		

See Compls. Br. at 176; Resps. Br. at 207; Staff Br. at 91.

The parties jointly propose that the proper construction of the claim term "source trajectory direction" is "direction in which the radiation source moves." *See* Compls. Br. at 176; Resps. Br. at 207; Staff Br. at 91.

The '154 patent uses the term "source trajectory direction" in multiple locations, in addition to the claims, without disclosing a precise definition. *See. e.g.,* JX-0004 ('154 Patent) at Fig 16B (element 43), col. 3, lns. 1, 12-13, 19, 38; col. 28, ln. 17; col. 29, ln. 45. These portions of the specification show that the "source" is the radiation source, *e.g.*, linear accelerator, that is located on the gantry of the device, and its "trajectory direction" is the direction in which the source moves around the patient.

Accordingly, as proposed by the parties, the administrative law judge has determined that the claim term "source trajectory direction" should be construed to mean "direction in which the radiation source moves."

B. Infringement Analysis of the '154 Patent

Complainants allege infringement of dependent method claims 23 (which depends from independent claim 19) and 26 (which depends from dependent claim 24, which in turn depends from dependent claim 23) of the '154 patent. *See* Compls. Br. at 176-214.

Respondents argue that the accused products do not infringe the asserted claims of the '154 patent. *See* Resps. Br. at 217-37.

The Staff argues that "the evidence has shown that claim 23 is infringed, subject to Varian's proof of indirect infringement," and "the evidence has shown that claim 26 is infringed, subject to Varian's proof of indirect infringement." *See* Staff Br. at 97, 98, 92-101. The Staff argues that "the Staff agrees with Elekta that the 'subject' in claim 19 who is receiving the 'radiation dose' must be a living person," and "[t]he Staff agrees that Varian's proof that Elekta tested claim 19 (and thus dependent claims 23 and 26) on dummies or phantoms is not be sufficient to prove direct infringement of the claim by Elekta." *Id.* at 99, 100. With respect to indirect infringement, the Staff argues: "The evidence has shown that Elekta provided testing and training materials to its customers, and otherwise has the requisite intent to induce or contribute to infringement, at least since the filing of Varian's original complaint." Staff Br. at 101, 101-03.

1. Applicable Law

Under 35 U.S.C. §271(a), direct infringement consists of making, using, offering to sell, or selling a patented invention without consent of the patent owner. The complainant in a section 337 investigation bears the burden of proving infringement of the asserted patent claims by a "preponderance of the evidence." *Certain Flooring Products*, Inv. No. 337-TA-443, Comm'n Notice of Final Determination of No Violation of Section 337, 2002 WL 448690, at *59, (Mar. 22, 2002); *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376 (Fed. Cir. 1998).

Literal infringement of a claim occurs when every limitation recited in the claim appears in the accused device, *i.e.*, when the properly construed claim reads on the

accused device exactly.[61] *Amhil Enters., Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1562 (Fed. Cir. 1996); *Southwall Tech. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed Cir. 1995).

If the accused product does not literally infringe the patent claim, infringement might be found under the doctrine of equivalents. "Under this doctrine, a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 21 (1997) (citing *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 609 (1950)). "The determination of equivalence should be applied as an objective inquiry on an element-by-element basis."[62] *Id.* at 40.

"An element in the accused product is equivalent to a claim limitation if the differences between the two are insubstantial. The analysis focuses on whether the element in the accused device 'performs substantially the same function in substantially the same way to obtain the same result' as the claim limitation." *AquaTex Indus. v. Techniche Solutions*, 419 F.3d 1374, 1382 (Fed. Cir. 2005) (quoting *Graver Tank*, 339 U.S. at 608); *accord Absolute Software*, 659 F.3d at 1139-40.[63]

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[61] Each patent claim element or limitation is considered material and essential. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). If an accused device lacks a limitation of an independent claim, the device cannot infringe a dependent claim. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).

[62] "Infringement, whether literal or under the doctrine of equivalents, is a question of fact." *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1130 (Fed. Cir. 2011).

[63] "The known interchangeability of substitutes for an element of a patent is one of the express objective factors noted by *Graver Tank* as bearing upon whether the accused

Prosecution history estoppel can prevent a patentee from relying on the doctrine of equivalents when the patentee relinquished subject matter during the prosecution of the patent, either by amendment or argument. *AquaTex*, 419 F.3d at 1382. In particular, "[t]he doctrine of prosecution history estoppel limits the doctrine of equivalents when an applicant makes a narrowing amendment for purposes of patentability, or clearly and unmistakably surrenders subject matter by arguments made to an examiner." *Id.* (quoting *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1344 (Fed. Cir. 2005)).

2. Accused Products

Complainants argue: "The Accused '154 Products are the Accused Linacs when used in combination with a treatment planning system such as Elekta's Monaco treatment planning software. As discussed above, the Accused Linacs include Versa HD, Infinity, Axesse, and Synergy/Synergy S linac systems." Compls. Br. at 175 (citations omitted); Resps. Br. at 212 (the accused products are the accused Elekta linacs with Monaco software).

The Staff argues: "Respondents' products accused of infringing the '154 patent are the Accused Linacs (*i.e.*, Versa HD, Infinity, Axesse, and Synergy/Synergy S) when used with a treatment planning system such as the Monaco treatment planning software." Staff Br. at 92.

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device is substantially the same as the patented invention. Independent experimentation by the alleged infringer would not always reflect upon the objective question whether a person skilled in the art would have known of the interchangeability between two elements, but in many cases it would likely be probative of such knowledge." *Warner-Jenkinson*, 520 U.S. at 36.

3. Direct Infringement of Accused Products

Complainants argue: "The evidence shows that the combination of the Accused Linacs and treatment planning software such as Monaco practices every limitation of claim 23, which include all of the limitations of parent claim 19 as well the limitation particular to claim 23." *See* Compls. Br. at 176, 176-96.

Complainants argue:

> The evidence shows that Elekta directly infringes claims 23 and 26 of the '154 patent in the United States. Elekta directly infringes claims 23 and 26 when it tests the ability of the Accused Linacs it has sold to customers in combination with treatment planning software such as Monaco to create and deliver VMAT treatment plans at customer sites in the United States. Elekta also directly infringes claims 23 and 26 when it trains customers how to use treatment planning software in combination with the Accused Linacs to create and deliver VMAT treatment plans at customer sites or at its own facilities in the United States.

See Compls. Br. at 196, 196-205.

Respondents argue that the accused products do not directly infringe the asserted claims. *See* Resps. Br. at 212-31. Respondents argue: "Specifically, the accused Elekta linacs and Monaco software do not practice at least limitations 19B and 19C of the '154 patent. Infringement of a method claim requires infringement of the 'exact method prescribed by the patent.'" *Id.* at 212. Respondents further argue:

> "In the field of radiation therapy and the medical field generally, the term "subject," used in claim 19 of the '154 patent, JX-0004, refers to a patient, that is, a living being, that is undergoing treatment. Under a consistent interpretation of the term "subject" in claim 19, it is either satisfied by *both* the prior art and Elekta's use on phantoms, or neither. It cannot—as Varian contends—be met by a phantom for purposes of proving infringement but not for purposes of proving invalidity."

Id. at 228 (citations omitted) (emphasis in original).

The Staff argues that "the evidence has shown that claim 23 is infringed, subject to Varian's proof of indirect infringement," and "the evidence has shown that claim 26 is infringed, subject to Varian's proof of indirect infringement." *See* Staff Br. at 97, 98, 92-101. It is argued that "the Staff agrees with Elekta that the 'subject' in claim 19 who is receiving the 'radiation dose' must be a living person," and "[t]he Staff agrees that Varian's proof that Elekta tested claim 19 (and thus dependent claims 23 and 26) on dummies or phantoms is not be sufficient to prove direct infringement of the claim by Elekta." *Id.* at 99, 100.

a. Claims 19 and 23

As noted, complainants assert dependent method claim 23 (which depends from independent claim 19) and claim 26 (which depends from dependent claim 24, which in turn depends from claim 23) of the '154 patent. Independent method claim 19 is discussed below.

Complainants argue: "The evidence shows that the combination of the Accused Linacs and treatment planning software such as Monaco practices every limitation of claim 23, which include all of the limitations of parent claim 19 as well the limitation particular to claim 23." Compls. Br. at 176.

Respondents argue that the accused products do not directly infringe the asserted claims. *See* Resps. Br. at 212-31. Respondents argue: "Specifically, the accused Elekta linacs and Monaco software do not practice at least limitations 19B and 19C of the '154 patent. Infringement of a method claim requires infringement of the 'exact method prescribed by the patent.'" *Id.* at 212.

The Staff argues: "Because the Staff is of the view that the evidence has shown that claim 19 is infringed, the evidence has shown that claim 23 is infringed, subject to Varian's proof of indirect infringement." Staff Br. at 97.

Independent claim 19 reads as follows:

> **19**. A method for delivering radiation dose to a target area within a subject, the method comprising:
>
> defining a trajectory for relative movement between a treatment radiation source and the subject in a source trajectory direction;
>
> determining a radiation delivery plan;
>
> while effecting relative movement between the treatment radiation source and the subject along the trajectory in the source trajectory direction, delivering a treatment radiation beam from the treatment radiation source to the subject according to the radiation delivery plan to impart a dose distribution on the subject;
>
> wherein delivering the treatment radiation beam from the treatment radiation source to the subject comprises varying an intensity of the treatment radiation beam over at least a portion of the trajectory.

JX-0004 ('154 Patent) at col. 34, lns. 21-37.

As discussed below, the evidence shows that the combination of the Accused Linacs and treatment planning software such as Monaco practices every limitation of claim 23 of the '154 patent, which includes all of the limitations of parent claim 19 as well as the limitation particular to claim 23.

Limitation A (Claim 19): A method for delivering radiation dose to a target area within a subject, the method comprising

The evidence shows that the combination of the Accused Linacs and treatment planning software such as Monaco performs a method for delivering radiation dose to a targeted area within a subject, such as a phantom or a patient. Dr. Bergeron explained

how a VMAT treatment plan that is compatible with the Accused Linacs can be generated on treatment planning software such as Monaco, and then transferred to the Accused Linacs, which deliver a radiation dose that targets an area of a subject, such as a tumor within a patient's body, according to the treatment plan. *See* CX-3835C (Bergeron WS) at Q361. Dr. Bergeron's testimony is supported by documentation, press releases and video demonstrations of the Accused Linacs and Monaco, the deposition testimony of Elekta's witnesses, and Elekta's source code for Monaco. *See e.g.*, CX-3588.001; CPX-0037 at 1:04 to 1:18; CPX-0032 at 0:06; CX-3688.002, 005-006; CX-3686; CX-0279C.003-004; CPX-0036 at 0:59, 1:09; CPX-0025C (printed as CX-3683C) at [ ]; JX-0025C (Brown Dep. Tr.) at 17, 20, 27-28; JX-0055C (Smith Dep. Tr.) at 52-53, 73-74. Accordingly, the evidence shows that the combination of treatment planning software such as Monaco and the Accused Linacs practice *Limitation A* of claim 19. Elekta has not disputed that the Accused '154 Products practice *Limitation A*.

Limitation B (Claim 19): defining a trajectory for relative movement between a treatment radiation source and the subject in a source trajectory direction.

The evidence shows that treatment planning software such as Monaco defines a trajectory for relative movement between the radiation source and a subject in a source trajectory direction.

As Dr. Bergeron explained, a trajectory is first defined in Monaco in preparation for [ ]. Monaco has the capability to define one or more arcs along which the gantry upon which the radiation source is mounted rotates while radiation is being delivered. *See* CX-3835C (Bergeron WS) at Q364. The Monaco brochure,

training guides, and user guides show how a user defines one or more arcs during stage one optimization, associating the arc with the rotation of the gantry. *See e.g.*, CX-3688.005; CX-1135C.071, 075, CX-0308C.052-053, 057; CX-1148C.071, 075; CX-3690C.334-335; CX-3620.218-219.

Dr. Bergeron analyzed the Monaco source code which shows the instructions that (a) specify the one or more arcs based on the trajectory defined by the user, (b) divide each arc into [ ] "composed of [ ], with continuous gantry rotation, and one fixed collimator position," and (c) assign increment gantry angles [ ], storing them in an [ ] in the order corresponding to their placement along the arc. *See* CX-3835C (Bergeron WS) at Q364; *see also, e.g.,* CPX-0025C (printed as CX-3683C) at [ ]. The order in which the [ ] are placed in the [ ] defines the direction in which the radiation source is moving along the user-defined trajectory. *Id.* Additionally, the Monaco source code instructions ensure that the [ ] represent rotational movement of the gantry along the arc by performing a [ ], verifying whether the arc defining the trajectory covers a full circle by [ ]. *See* CX-3835C (Bergeron WS) at Q364; CPX-0025 at [ ]. Accordingly, the evidence shows that Monaco practices *Limitation B.*

Dr. Bergeron explained that Monaco is just an example of a treatment planning software that can define a trajectory for relative movement between the radiation source on an Accused Linac and a subject, in the direction the radiation source is moving. *See* CX-3835C (Bergeron WS) at Q365. Deposition testimony from Elekta witnesses,

marketing materials, and documentation for the Accused Linacs show that the Accused Linacs are part of an open system that can accept a VMAT radiation treatment plan that has an arc-based trajectory from any compatible treatment planning software, and then deliver the radiation according to that treatment plan. *See* CX-3684.8 (Elekta VMAT Brochure); CX-0279C.2-3 (Elekta Integrity White Paper); CX-3680C.48, 51-52 (Elekta Instructions For Use); CX-0254 (Unkelbach Article) at 1372; JX-0055C (Smith Dep. Tr.) at 82. Additionally, during the evidentiary hearing, Dr. McNutt, Elekta's technical expert, admitted to a working knowledge of the Pinnacle VMAT software from Philips, and agreed that the VMAT software from Pinnacle uses the same three [ ] as Monaco: (1) fluence map optimization, (2) arc sequencing and (3) direct aperture optimization, to generate a VMAT plan. *See* McNutt Tr. 693-695. Thus, Pinnacle is an example of treatment planning software that has a trajectory. In addition, as discussed below, Elekta's customers [

], testified that they [

].

Accordingly the evidence shows that treatment planning software other than Monaco that can create a VMAT treatment plan and is compatible with the Accused Linacs also practices *Limitation B.*

Whether Limitations 19B and 19C Must Be Performed in Order

Claim limitation "19B" is "defining a trajectory for relative movement between a treatment radiation source and the subject in a source trajectory direction." *See* JX-0004 ('154 Patent) at col. 34, lns. 23-25. Although no party offered this limitation for

construction, respondents now argue that "the correct interpretation of claim 19 requires defining a trajectory for relative movement before determining a radiation delivery plan using that defined trajectory." *See* Resps. Br. at 219-20 (citing RX-0495C (McNutt RWS) at Q295-316).

In essence, respondents argue that steps in claim 19 must be performed in the order they are recited, and because this limitation is first, "the defined trajectory becomes a constraint on the radiation delivery plan, such that other parameters must be optimized around that defined trajectory." *See* Resps. Br. at 215 (citing RX-0495C (McNutt RWS) at Q297). The Staff agrees. *See* Staff Br. at 93-94 ("The Staff agrees that the steps of claim 19 must be performed in the order in which they are listed, and that information about the 'desired trajectory' is input before the optimization process starts.").

The administrative law judge agrees with respondents and the Staff. As discussed below, the evidence shows that the steps of claim 19 must be performed in the order in which they are listed.

The Federal Circuit has determined that method steps may be construed as occurring in a particular order "if, [(1)] as a matter of logic or grammar, they must be performed in the order written." *See Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369 (Fed. Cir. 2003) (citing *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1343 (Fed. Cir. 2001)). "If not, [(2)] we next look to the rest of the specification to determine whether *it* 'directly or implicitly requires such a narrow construction.'" *See Altiris*, 318 F.3d at 1370 (emphasis in original).

Dr. Verhey agrees with Dr. McNutt – the trajectory must be defined before determining a radiation delivery plan. *See* Verhey Tr. 1087-1088; *see also* RX-0495C

(McNutt RWS) at Q338-43. Claim 19 of the '154 patent requires "defining a trajectory for relative movement between a treatment radiation source and the subject in a source trajectory direction," (Limitation 19B) and then "determining a radiation delivery plan" based on that defined trajectory (Limitation 19C). *See* RX-0495C (McNutt RWS) at Q295-316, 339-43. The specification of the '154 patent requires this order of the steps by performing the step of "determining a radiation delivery plan" (Limitation 19C) using the defined "trajectory for relative movement" (Limitation 19B). *See* RX-0495C (McNutt RWS) at Q312, 339-43. In other words, the defined trajectory becomes a constraint on the radiation delivery plan, such that other parameters must be optimized around that defined trajectory.[64] *See* RX-0495C (McNutt RWS) at Q297. This is illustrated in Figure 4A from the '154 patent, showing method 50 where a trajectory is defined (in step 52) before a radiation delivery plan can be determined (in block 54) using that defined trajectory. *See* RX-0495C (McNutt RWS) at Q301, 311.

The '154 patent explains that "defining a trajectory," as recited in claim 19, requires receiving a trajectory from a user. *See* RX-0495C (McNutt RWS) at Q301. The

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[64] Limitation 19D is "delivering a treatment radiation beam from the treatment radiation source to the subject according to the radiation delivery plan." The step of actually exposing a patient to high-dose radiation (19D) would necessarily have to come after steps 19B "defining a trajectory..." and 19C "determining a radiation delivery plan," which suggests that the method of claim 19 is limited to the order in which the steps are listed. *See e.g.*, *Combined Systems, Inc. v. Defense Technology Corp.*, 350 F.3d 1207 (Fed. Cir. 2003), (as a matter of grammar, a claim that called for "forming folds" and "inserting said formed folds" required a particular order of steps) 350 F.3d at 1211-12. Other Federal Circuit opinions have reached similar results. *See Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1321-22 (Fed. Cir. 1999) (the literal language of the claim requires one step to have been performed before the other), *cert. denied*, 528 U.S. 1075 (2000); *Mantech Environmental Corp. v. Hudson Environmental Servs., Inc.*, 152 F.3d 1368, 1375-76 (Fed. Cir. 1998) ("the sequential nature of the claim steps is apparent from the plain meaning of the claim language").

first step of method 50 is a "Get Data" step in block 52. *See id.* In block 52, a set of optimization goals 61 and a desired trajectory 62 are obtained from a user. *See id.* The '154 patent confirms that a trajectory is input by a user, such as a radiation oncologist, in advance of running method 50. *See id.* "Optimization goals 61 and/or trajectory data 62 may have been developed by health professionals, such as a radiation oncologist in consultation with a radiation physicist [and] may be specified by an operator as a part of block 52." *See* JX-0004 ('154 Patent) at col. 10, lns. 36-41; RX-0495C (McNutt RWS) at Q301.[65]

After a user inputs the predefined trajectory in step 52, the optimization process 54 begins. JX-0004 ('154 Patent) at col. 11, lns. 32-35; RX-0495C (McNutt RWS) at Q311. Optimization process 54 is the process by which a radiation delivery plan is determined. It optimizes the beam shapes and intensities "as a function of the position of source 12 and/or beam 14 *along [the] trajectory 30*" that was received in step 52. JX-0004 ('154 Patent) at col. 11, lns. 32-35 (emphasis added); RX-0495C (McNutt RWS) at Q311. Optimization occurs with the predefined trajectory input by the user, while other variables related to that trajectory are permitted to change to achieve the desired optimization. RX-0495C (McNutt RWS) at Q303, 312. For example, the "intensity" and the "beam shaping parameters" may change. *Id.*

After "determining a radiation delivery plan" as shown in Figures 4A and 8, the linac may perform the step of "delivering a treatment radiation beam." JX-0004 ('154

[65] For the purposes of understanding elements 19B and 19C, Figures 4A and 8 are identical. The '154 patent explains that "method 150 of FIG. 8 is similar to method 50 of FIG. 4A," and that the "principal difference between...FIG. 4A and...FIG. 8 is that [Fig. 8] involves a repetition of the optimization process over a number of levels." *See* JX-0004 ('154 Patent) at col. 19, lns. 11-33; RX-0495C (McNutt RWS) at Q299.

Patent) at col. 34, lns. 27-32. Varian's experts agreed during the hearing that the steps of "defining a trajectory" (limitation 19B) and "determining a radiation delivery plan" (limitation 19C) must occur before "delivering a treatment radiation beam" (limitation 19D). *See* Bergeron Tr. 309; Verhey Tr. 1087.

Other portions of the '154 patent confirm that the trajectory defined by the user is the trajectory at the end of optimization, and that is eventually used for delivery of the radiation. Figure 4B of the '154 patent, like Figures 4A and 8, depicts elements 19B and 19C as separate steps. *See* RX-0495C (McNutt RWS) at Q314-16. The first step of "defining a trajectory for relative movement" (limitation 19B) is depicted as block 310. The '154 patent explains that block 310 "involves obtaining a desired trajectory 30." JX-0004 ('154 Patent) at col. 14, lns. 37-39; RX-0495C (McNutt RWS) at Q314-16. The second step of "determining a radiation delivery plan" (limitation 19C) is depicted as block 320. The '154 patent explains that block 320 is the step whose "result…is a radiation delivery plan" (limitation 19C). *See* JX-0004 ('154 Patent) at col. 14, lns. 45-46; RX-0495C (McNutt RWS) at Q314-16. One of skill in the art reading Figure 4B would understand that "obtaining a desired trajectory 30" (limitation 19B) occurs before "determining a radiation delivery plan" (limitation 19C). *See* RX-0495C (McNutt RWS) at Q314-16.

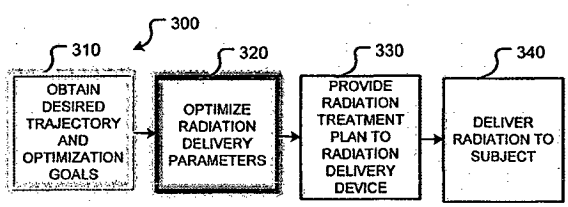


FIGURE 4B

See JX-0004 ('154 Patent) at Fig. 4B.

Whether Trajectory Can Be Subsequently Modified

Respondents argue that "[o]nce the trajectory is defined by the user it does not change throughout the optimization process." *See* Resps. Br. at 217. Complainants and the Staff do not agree that this is the case. *See* Compls. Br. at 182; Staff Br. at 94-95. The administrative law judge agrees with complainants and the Staff. As discussed below, the evidence shows that the defined trajectory can be subsequently modified.

The '154 patent discloses that health professionals may select from "one or more pre-defined trajectories" or "a template that partially defines a trajectory 30 and can be completed to fully define the trajectory 30." *See id.* at col. 10, lns. 51-59. If a trajectory template that "partially defines a trajectory" is used, the claimed method must allow for the trajectory to be completed with additional trajectory information, even if the (partial) trajectory acts as an initial constraint, as respondents argue. *See* Verhey Tr. 1153-1155; *accord*, Bergeron Tr. 349-351. Once some trajectory information is input by the user, the optimization process 54 begins. *See* JX-0004 ('154 Patent) at Figure 4B; col. 11, lns. 32-35; col. 14, lns. 37-39; col. 14, lns. 45-46.

The '154 patent discloses that the trajectory is allowed to change during the planning process. The '154 patent discloses that the "optimization processes" can "optimize the trajectory . . . of the radiation delivery apparatus," thus changing that trajectory during optimization. *See* JX-0004 ('154 Patent) at col. 31, lns. 28-34 ("In other embodiments, the beam position and beam orientation parameters (i.e. the set of motion axis positions at each control point **32**) are additionally or alternatively varied and optimized as a part of optimization processes **54**, **154**, such that optimization processes **54**, **154** optimize the trajectory **30** of the radiation delivery apparatus."); CX-3835C

(Bergeron WS) at Q364. Dr. McNutt opined that this disclosure is a single sentence in the specification that he characterized as "conflicting" with the other disclosed embodiments. *See* RX-0495C (McNutt RWS) at Q309-10.

Trajectory

Elekta argues that "Monaco does not infringe claim 19 of the '154 patent, JX-0004, because Monaco does not 'define a trajectory for relative movement' (limitation 19B) in advance of "determining a radiation plan" using that defined trajectory (limitation 19C). *See* Resps. Br. at 223, 221-23. Complainants and the Staff disagree. *See* Compls. Br. at 182-86; Staff Br. at 95-96. The administrative law judge agrees with complainants and the Staff. As discussed below, the evidence shows that complainants and the Staff are correct on this issue.

The evidence shows that in Monaco, a trajectory is defined before the determination of a radiation delivery plan. As Dr. Bergeron explained, Monaco defines a trajectory during a [ ] based on user input. *See* CX-3835C (Bergeron WS) at Q364; CPX-0025, [ ]. Dr. McNutt cannot substantively dispute Dr. Bergeron's source code analysis because he already agreed with it at his deposition. *See* Bergeron Tr. 673-675. Instead, Dr. McNutt's witness statement provides his conclusion that the Monaco source code does not support Dr. Bergeron's contention that *Limitation B* is met, without substantive explanation. *See* RX-0495C (McNutt RWS) Rebuttal WS at Q331.

Dr. McNutt opines that "Dr. Bergeron fails to show that the [ ] includes beam positions or beam orientations." Here, Dr. McNutt is importing limitations into the claims that do not exist, specifically that a trajectory must

contain "beam positions" and "beam orientations." The basis for Dr. McNutt's construction of "trajectory" is incorrect. Elekta relies on a single sentence from the specification as a definition, ignoring that the immediately previous sentence states that this passage in the specification is referring to a trajectory for "particular embodiments of the invention . . . ." *See* RX-0495C (McNutt RWS) at Q364; JX-0004 ('154 Patent) at col. 6, lns. 16-18. Indeed, this portion of the specification is discussing the trajectory for "an ***example*** radiation delivery apparatus," not a trajectory in the context of treatment planning software. *See* JX-0004 ('154 Patent) at col. 5, lns. 16-25 (emphasis added). The asserted claims use the claim term "trajectory" in both contexts. Thus, Elekta is not only ignoring the plain and ordinary meaning of "trajectory," but impermissibly limiting the claim term "trajectory" to a single exemplary embodiment in the specification. *Liebel-Flarsheim*, 358 F.3d at 913 (Fed. Cir. 2004) ("[I]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.") In addition, as discussed above, contrary to the particular embodiment Dr. McNutt relies on, other embodiments in the specification disclose that the trajectory can change as part of the optimization process, and thus a trajectory is not tied to the beam positions and orientations that are ultimately used at delivery. *See* CX-3835C (Bergeron WS) at Q364; JX-0004 ('154 Patent) at col. 31, lns. 28-34.

Even if Dr. McNutt' is correct that a trajectory did require "beam positions" and "beam orientations," the evidence shows that the trajectory used during Monaco's [

] has both beam positions and beam orientations. Dr. Bergeron's

analysis of the Monaco source code shows that beam positions (increment gantry angles) and orientations (collimator angles) are stored in the [ ], associated with the [ ], and further stored in an [ ] in the order corresponding to their placement along the arc. *See* CX-3835C (Bergeron WS) at Q364; *see also, e.g.,* CPX-0025C (printed as CX-3683C) at [ ]. Dr. McNutt did not directly address that source code. Moreover, Dr. McNutt's position that there is no trajectory during Monaco's [ ] is at odds with his testimony at the hearing. He acknowledged that a user sets up an arc through the Monaco user interface, which can be a full 360-degree rotation and specifies the starting gantry angle, the direction of rotation of the gantry, and the amount of rotation for the arc, and then Monaco divides the arc into a [ ], all of which occurs prior to [ ], and thus prior to the determination of a radiation delivery plan. *See* McNutt Tr. 754-757.

Even if Elekta is correct that a trajectory is not defined until "mid-way through the optimization process" (RX-0495C (McNutt RWS) at Q335), *i.e.*, during [ ], that is still before the final radiation delivery plan is determined. As Dr. McNutt acknowledges, the treatment plan is not "final" until the DICOM file is generated, that is after the "user accepts a treatment plan as final." *See* RX-0495C (McNutt RWS) at Q120.

Limitation C (Claim 19): determining a radiation delivery plan.

The evidence shows that a treatment planning software such as Monaco can be used to determine a VMAT radiation delivery plan for an Accused Linac. Monaco can be used to determine a VMAT treatment plan for an Accused Linac. *See* CX-3835C

(Bergeron WS) at Q369. In particular, the Monaco documentation, source code and deposition testimony of Elekta witnesses show that Monaco employs a [ ] to optimize a desired dose distribution, including a desired dose rate, in order to determine a VMAT treatment plan for delivery on an Accused Linac. *See e.g.*, CX-3688.005; CX-1135C.013; CX-0308C.007; CX-1148C.011; CX-3690C.325, 527; CX-3620.035, 313; JX-0025C (Brown Dep. Tr.) at 20, 35; JX-0055C (Smith Dep. Tr.) at 52-53, 73-74; CPX-0025C (printed as CX-3683C) at [ ] at lines 14-30, 476-491, [ ] at lines 517-552, 543-558, 686, 705-789, [ ] at lines 163-457, [ ] at lines 30-323, 564-578; [ ] lines at 1529-1539; [ ] at lines 595-608, [ ] at lines 19, 42, 48, [ ] at lines 34-54, [ ], [ ] at lines 458-47. Accordingly, the evidence shows that Monaco practices *Limitation C*.

In addition, Dr. Bergeron explained that Monaco is an exemplary treatment planning system that can determine a VMAT radiation delivery plan because the Accused Linacs can deliver a VMAT treatment plan that has been generated by any compatible treatment planning software. *See* CX-3835C (Bergeron WS) at Q369; *see also, e.g.*, CX-3684 (Elekta VMAT Brochure, VMSITC00021843 at p. 8; CX-0279C (Integrity White Paper) at ELEKTA-ITC-00207734 to 35; CX-3680C (Linac Instructions For Use) at pp. 48, 51-52; JX-0055C (Smith Dep. Tr.) at 82; JX-0025C (Brown Dep. Tr.) at 51-52. Additionally, during the hearing, Dr. McNutt, who has a working knowledge of the Pinnacle VMAT software from Philips, agreed that the VMAT software from Pinnacle uses the same three [ ] as Monaco to generate a VMAT plan. *See* McNutt Tr. 693-

695. Thus, Pinnacle is an example of treatment planning software that can determine a radiation delivery plan. In addition, as discussed below, Elekta's customers [

], testified that they [

]. Thus, the evidence shows that treatment planning software other than Monaco that can create a VMAT treatment plan and is compatible with the Accused Linacs also practices *Limitation C.*

Limitation D (Claim 19): while effecting relative movement between the treatment radiation source and the subject along the trajectory in the source trajectory direction, delivering a treatment radiation beam from the treatment radiation source to the subject according to the radiation delivery plan to impart a dose distribution on the subject.

The evidence shows that the Accused Linacs deliver a radiation beam from the treatment radiation source, while the gantry upon which the radiation source is mounted is moving, along the trajectory in the direction in which the radiation source is moving, in order to impart a dose distribution on a subject, according to the VMAT treatment plan generated by treatment planning software such as Monaco.

As Dr. Bergeron explains, and as the Monaco documentation shows, Monaco can package a radiation treatment plan into a DICOM file and then transfer that plan to an Accused Linac using a record and verify system such as MOSAIQ. *See* CX-3835C (Bergeron WS) at Q373; *see also, e.g.*, CX-3688.005; CX-3620.791; CX-3690C.1176. Further, as discussed above, and as the source code and documentation show, the Accused Linacs can deliver radiation according to a VMAT treatment plan generated by any compatible treatment planning software, including the Integrity software, ensuring that the Accused Linacs deliver the radiation dose distribution, including a variable dose

rate, to the patient according to the radiation delivery treatment plan while the gantry is rotating around the patient. *See* CX-3835C (Bergeron WS) at Q373; *see also, e.g.*, CX-3684.008, Elekta VMAT Brochure; CX-0279C.002-004, Integrity White Paper; CX-3680C.048, 051-052 (Elekta Linac Instructions for Use); CX-0251C.10, Elekta Linac Overall Navigation; CPX-0009, VMAT Linac Video at 0:32; JX-0025C (Brown Dep. Tr.) at 17, 27-28, 51-53; JX-0055C (Smith Dep. Tr.) at 82; CPX-0027 (printed as CX-3683C) ([ ] lines 797-813, [ ] lines 585-921, [ ].

Accordingly, the evidence shows that the combination of treatment planning software such as Monaco and the Accused Linacs practices *Limitation D* of claim 19. Neither Elekta nor Dr. McNutt dispute that the Accused '154 Products practice *Limitation D.*

Limitation E (Claim 19): wherein delivering the treatment radiation beam from the treatment radiation source to the subject comprises varying an intensity of the treatment radiation beam over at least a portion of the trajectory.

The evidence shows that while an Accused Linac is delivering a radiation beam to a subject according to a VMAT treatment plan, the Accused Linac will vary the dose rate of the treatment radiation beam over at least a portion of the trajectory, that is the one or more arcs along which radiation is being delivered.

As Dr. Bergeron explains, the Monaco documentation shows that the VMAT treatment plans generated by Monaco will vary the dose rate of the radiation, and thus the intensity of the radiation, while the gantry is continuously moving. *See* CX-3835C

(Bergeron WS) at Q376; *see also, e.g.,* CX-3688.005; CX-1135C.071, 075 CX-0308C.052-053, 057; CX-1148C.071, 075; CX-3690C.334-335; CX-3620.218-019. Elekta's witness, Markus Alber, who testified that he wrote the portions of the source code that [ ], agrees that dose rate is optimized [ ]. *See* RX-0500C (Alber WS) (emphasis added) at Q18 ("Finally, constraints associated with the delivery of radiation, ***such as dose rates,*** minimum and maximum monitor units per control point, ***and changes of dose rate between control points are taken into account.***"); Q19 ("For example, and as I explained, [ ] ***are associated with a number of machine constraint parameters, such as*** the geometry of the collimator, the speed of the collimator jaws, the speed of the collimator leaves, the rotational speed of the gantry, ***the available dose rates,*** the minimum and maximum monitor units per control point, ***and the maximum change of dose rate between control points.***").

The varying of dose rate can also be seen in the Monaco source code, which [ ] when determining a radiation delivery plan. *See* CX-3835C (Bergeron WS) at Q369, Q376; CPX-0025C (printed as CX-3683C) at [ ] at lines 14-30, 476-491, [ ] at lines 517-552, 543-558, 686, 705-789; [ ] at lines 163-457, [ ] at lines 30-323, 564-578; [ ] at lines 1529-1539; [ ] at lines 595-608, [ ] at lines 19, 42, 48, [ ] at lines 34-54, [ ] at lines 548-563, [ ] at lines 458-473.

The documentation and source code for the Accused Linacs, and deposition testimony from Elekta witnesses, show that once a VMAT treatment plan is transferred

from Monaco or any other compatible treatment planning software, the Accused Linacs will vary the dose rate while the gantry is moving. *See* CX-3835C (Bergeron WS) at Q376; *see also, e.g.*, CX-3684.008; CX-0279C.002-004; CX-3680C.048, 051-052; CX-0251C.10; CX-0904C.004; CPX-0037 at 0:29; CPX-0008 at 3:13; CPX-0009 at 0:34; JX-0025C (Brown Dep. Tr.) at 17, 51-53; JX-0055C (Smith Dep. Tr.) at 52-53, 138-139; CPX-027 (printed as CX-3683C) at [ ] at lines 797-813, [ ], [ ] at lines 585-921, [ ], [ ].

Accordingly, the evidence shows that the combination of treatment planning software such as Monaco and the Accused Linacs practices *Limitation E* of claim 19. Neither Elekta nor Dr. McNutt disputes that the Accused '154 Products practice *Limitation E.*

Claim 23: A radiation delivery method according to claim 19 wherein varying the intensity of the treatment radiation beam over at least the portion of the trajectory comprises varying a rate of radiation output of the radiation source while effecting continuous relative movement between the treatment radiation source and the subject along the trajectory.

Asserted dependent method claims 23, which depends from independent claim 19, reads as follows:

> **23**. A radiation delivery method according to claim **19** wherein varying the intensity of the treatment radiation beam over at least the portion of the trajectory comprises varying a rate of radiation output of the radiation source while effecting continuous relative movement between the treatment radiation source and the subject along the trajectory.

JX-0004 ('154 Patent) at col. 34, lns. 54-59.

As discussed with respect to *Limitation E* of claim 19, the evidence shows that while an Accused Linac is delivering a radiation beam to a subject according to a VMAT treatment plan, the Accused Linac will vary the dose rate of the treatment radiation beam, and thus the rate of radiation output of the radiation source, over at least a portion of the trajectory, that is the one or more arcs along which radiation is being delivered, according to the VMAT treatment plan which also optimizes the dose rate. *See e.g.* CX-3835C (Bergeron WS) at Q369, Q376, Q383. Further, the radiation is varied while the gantry upon which the radiation source is mounted is continuously rotating around the subject. *See e.g.* CX-3835C (Bergeron WS) at Q383; CX-0279C.003-004; CX-3680C.48; CX-0904C.004; CX-0251C.10; CPX-0037 at 0:29; CPX-0008 at 3:13; CPX-0009 at 0:34; JX-0025C (Brown Dep. Tr.) at 17; JX-0055C (Smith Dep. Tr.) at 52-53, 138-139; CPX-0027 (printed as CX-3683C) at [ ] at lines 797-813, [ ], [ ] at lines 585-921, [ ]. Thus, the evidence shows that the combination of treatment planning software such as Monaco and the Accused Linacs practice the limitation of claim 23.

Accordingly, the evidence shows that the combination of the Accused Linacs and treatment planning software such as Monaco meets each limitation of claim 23 of the '154 patent.

b. Claims 24 and 26

Dependent method claim 24 (which depends from claim 23) and claim 26 (which depends from claim 24), read as follows:

> **24**. A radiation delivery method according to claim **23** wherein the trajectory comprises a plurality of arcs, each

> arc involving relative movement between the radiation source and the subject within a corresponding plane.
>
> **26**. A radiation delivery method according to claim **24** wherein, between successive ones of the plurality of arcs, the trajectory comprises inter-arc relative movement between the radiation source and the subject, the inter-arc relative movement comprising movement such that the corresponding planes associated with each arc intersect one another.

JX-0004 ('154 Patent) at col. 34, lns. 60-63; col. 35, lns. 3-8.

Claim 26 is dependent on claim 24, which is dependent on claim 23, which is dependent on claim 19. As discussed above in connection with claims 19 and 23, the evidence already establishes that the accused products practice each limitation of claims 19 and 23.

Regarding the additional limitations of claim 24 and 26: claim 24 adds the limitation "wherein the trajectory comprises a plurality of arcs, each arc involving relative movement between the radiation source and the subject within a corresponding plane," and claim 26 adds the limitation "wherein, between successive ones of the plurality of arcs, the trajectory comprises inter-arc relative movement between the radiation source and the subject, the inter-arc relative movement comprising movement such that the corresponding planes associated with each arc intersect one another." The evidence shows that the combination of treatment planning software such as Monaco and the Accused Linacs satisfies both of these limitations because (i) Monaco and the Accused Linacs support the creation and delivery of treatment plans along a trajectory involving multiple arcs; and (ii) the gantry upon which the radiation source is mounted rotates along those multiple arcs, which can intersect.

Dr. Bergeron analyzed the Monaco documentation and source code showing that Monaco can be used to define a trajectory that consists of multiple arcs, each arc involving relative movement of the gantry along different planes when defining a trajectory for a VMAT radiation plan. *See* CX-3835C (Bergeron WS) at Q389; *see also, e.g.*, CX-3688.005; CX-1135C.071-072; CX-0308C.057-058; CX-1148C.075-076; CX-3690C.334-335; CX-3620.218-219; JX-0055C (Smith Dep. Tr.) at 73, 80, 82-84; CPX-0025 (printed as CX-3683C) at [ ] at lines 140-260, [ ] at lines 44-512. Dr. Bergeron also testified how the Monaco documentation, testimony from Elekta witnesses and testimony from Elekta customers shows that Monaco can specify multiple arcs that correspond to planes which will intersect when the treatment plan is delivered. In particular, Monaco can specify a different isocenter for each arc or have a different couch position, *i.e.,* the position of the table upon which the patient is situated, for each arc. *See* CX-3835C (Bergeron WS) at Q392; *see also, e.g.*, CX-1135C.065-066, 138; CX-0308C.047-048, 106-107; CX-1148C.050-051; JX-0047C (Rodriguez Dep. Tr.) at 156-157. As Dr. Bergeron testified, by adjusting the couch position for each arc while keeping the isocenter constant, or alternatively by adjusting the isocenter of the arc while keeping the couch position constant, Monaco is capable of generating a multiarc VMAT radiation treatment plan where the arcs correspond to planes that intersect while the radiation source is moving around the patient. *See* CX-3835C (Bergeron WS) at Q392.

In turn, as Dr. Bergeron explained, and the documentation for the Accused Linacs and deposition testimony of Elekta witnesses and Elekta customers show, the Accused Linacs are capable of delivering VMAT treatment plans generated by treatment planning software such as Monaco, such that the radiation is delivered along multiple arcs that

intersect while the radiation is being delivered and the gantry is moving around the subject. *See* CX-3835C (Bergeron WS) at Q392; *see also, e.g.,* CX-0279C.002; CX-3684.004; CPX-0008 at 4:28; CX-3680C.36, 131; JX-0055C (Smith Dep. Tr.) at 80, 82-83; JX-0023C ([ ] Dep. Tr.) at 116- 118; JX-0034C ([ ] Dep. Tr.) at 61-62.

Accordingly, the evidence shows that the combination of treatment planning software such as Monaco and the Accused Linacs practices the limitations of claims 24 and 26 of the '154 patent.

Neither Elekta nor Dr. McNutt disputes that Monaco has the capability to generate a VMAT treatment plan for the delivery of radiation along a trajectory consisting of multiple arcs on corresponding planes that intersect. Nor does Elekta or Dr. McNutt dispute that the Accused Linacs are capable of delivering radiation along a trajectory consisting of multiple arcs or corresponding planes that intersect in accordance with a VMAT treatment plan generated by Monaco or any other compatible treatment planning software. Instead, Dr. McNutt interprets claims 24 and 26 to require that the radiation dose delivered along both arcs must be delivered in the same direction. *See* RX-0495C (McNutt RWS) at Q414-17. Dr. McNutt's sole basis for reading this limitation into the claims is that claim 19 recites that the "trajectory" comprises "relative movement" in "a source trajectory direction," and according to Dr. McNutt, that means that the trajectory direction can never change—that is, all of the arcs must be delivered in a "single source trajectory direction." *See* RX-0495C (McNutt RWS) at Q417. Based on that reading of the claims, Dr. McNutt opines that the couch or isocenter cannot be changed because that would change the direction, and that the direction changes when

delivering multiple arcs because the linacs wind in one direction and then unwind in the other direction. *See* RX-0495C (McNutt RWS) at Q415-17.

As an initial matter, nothing in the language of claim 19 states that the "source trajectory direction" can never change. The claim term is "a source trajectory direction," not "a single source trajectory direction." Thus, Dr. McNutt is adding a word to the claim language. Additionally, Dr. McNutt's position that moving the couch or switching direction violates the claim language, contradicts the specification of the '154 patent disclosing the subject matter of claim 26. The portion of the specification that describes embodiments involving a trajectory comprising a "plurality of arcs, wherein each arc is confined to a corresponding plane" teaches that "the motion axes of radiation delivery apparatus **10** may be moved between individual arcs such that the corresponding planes to which the arcs are confined intersect with one another (e.g. by suitable rotation of couch **15** about axis **22**)." *See* JX-0004 ('154 Patent) at col. 8, lns. 18-31. Thus, the '154 patent discloses a couch movement as an exemplary way to specify intersecting arcs.

Dr. McNutt opines that the beam can never pause in order for Claim 26 to be satisfied, and thus contends the Accused Linacs do not practice this limitation because in order for the couch to be moved or rotated, or deliver in multiple arcs, the beam would have to be turned off. *See* RX-0495C (McNutt RWS) at Q418. However, as Dr. Bergeron explained, that same passage in the '154 specification which disproves Dr. McNutt's first noninfringement argument, also disproves his second, explaining that "In some cases, radiation may not be delivered to subject S when the motion axes of radiation delivery apparatus 10 are moved between individual arcs." *See* CX-3835C (Bergeron WS) at Q394; JX-0004 ('154 Patent) at col. 8, lns. 34-37. Thus, the '154 patent explicitly

teaches that the beam can be turned off in-between the delivery of radiation along each arc.

Accordingly, the evidence shows that the combination of the Accused Linacs and treatment planning software such as Monaco meets each limitation of claim 26 of the '154 patent.

c. Direct Infringement of Accused Products by Respondents Under *Electronic Devices*; and Claim Term "subject"

Respondents argue: "In the field of radiation therapy and the medical field generally, the term "subject," used in claim 19 of the '154 patent, JX-0004, refers to a patient, that is, a living being, that is undergoing treatment. Under a consistent interpretation of the term "subject" in claim 19, it is either satisfied by *both* the prior art and Elekta's use on phantoms, or neither. It cannot—as Varian contends—be met by a phantom for purposes of proving infringement but not for purposes of proving invalidity." *Id.* at 228 (citations omitted) (emphasis in original).

Complainants argue:

> [ ] Dr. McNutt and Elekta's argument that there was no direct infringement during Elekta's training and testing in the United States because the claim term "subject" should be construed to mean a live patient, is incorrect. As Dr. Bergeron explained in his witness statement, there is nothing in the claim language or specification that requires the claimed steps to be performed only on a live human being or animal. Dr. McNutt and Elekta submit medical dictionaries as evidence that a "subject" is a patient, but those medical dictionaries are divorced from the context of the Otto patents and the claims at issue, which use the term "subject" in steps used during the planning and delivery process. For example, *Limitation B* requires "defining a trajectory for relative movement between a treatment radiation source ***and the subject*** in a source trajectory direction." When the plain and ordinary meaning of "subject" is considered in the context of the claims and specification of the '154 patent, the plain and ordinary meaning of "subject" could mean a

> patient or a thing, such as a phantom. During the hearing, Dr. Verhey explained that phantoms can be humanoid in appearance and simulate human tissue—and expressed his own opinion that in using the term "subject", the Otto patents were intentionally encompassing both patients and phantoms:

Compls. Br. at 200-01 (citations omitted) (emphasis in original).

The Staff argues:

> As the threshold matter, the Staff notes that the Commission has previously determined that performance of a claimed method directly by a respondent is not proof of a violation under Section 337. *See Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, 337-TA-724, Comm'n Op. at 14, 17-19 (Nov. 21, 2011). Thus, it appears that performance of claim 19 by Elekta, whether on a patient or a dummy, is not proof of a violation.

Staff Br. at 99.

The Staff also argues that "the Staff agrees with Elekta that the 'subject' in claim 19 who is receiving the 'radiation dose' must be a living person," and "[t]he Staff agrees that Varian's proof that Elekta tested claim 19 (and thus dependent claims 23 and 26) on dummies or phantoms is not be sufficient to prove direct infringement of the claim by Elekta." *Id.* at 99, 100.

Respondents argue that claim 19 (and thus asserted claims 23 and 26) of the '154 patent are for a method of delivering a radiation dose to a "subject," and a "phantom" is not a subject. *See* Resps. Br. at 228. In other words, respondents argue that although "subject" was not offered for claim construction, complainants have failed to prove direct infringement by way of respondents' testing on things that are not living. *See* Resps. Br. at 227-29.

Infringement of Method Claims Under *Electronic Devices*

As the Staff noted, the Commission has previously determined that performance

of a claimed method directly by a respondent is not proof of a violation under section 337. *See Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, 337-TA-724, Comm'n Op. at 14, 17-19 (Nov. 21, 2011) ("*Electronic Devices*").

The Commission's opinion in *Electronic Devices* holds that the practice of an asserted method claim within the United States after importation cannot serve as the basis for an exclusion order. *Electronic Devices*, Comm'n Op. at 17. As discussed in *Electronic Devices*, section 337 prohibits:

> (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that –
>
> > (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17; or
> >
> > (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337(a)(1)(B).

The statute is violated only by the importation, sale for importation, or sale after importation of articles that either infringe a valid U.S. patent claim or are made by a method covered by a valid U.S. patent claim. An article, standing alone, cannot directly infringe a method claim. *Electronic Devices*, Comm'n Op. at 17; *see also Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 576 F.3d 1348, 1364 (Fed. Cir. 2009). A method claim is infringed only where someone performs all of the claimed method steps. *See NTP v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) ("[T]he use of a [claimed] process necessarily involves doing or performing each of the steps

recited."); *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) ("A method claim is directly infringed only by one practicing the patented method.").

In *Electronic Devices*, the Commission ruled that complainant did not have a legally cognizable claim that respondent violated the statute by using articles within the United States when infringement allegedly occurred by virtue of that use. *Electronic Devices*, Comm'n Op. at 19 ("domestic use of such a method, without more, is not a sufficient basis for a violation of Section 337(a)(1)(B)(i)"). Relying expressly on the statutory language of section 337 and applicable Federal Circuit law, the Commission ruled that the act of importation "is not an act that practices the steps of the asserted method claim," and "[m]erely importing a device that may be used to perform a patented method does not constitute direct infringement of a claim to that method." *Id.* at 17-18 (citing *Cardiac Pacemakers*, 576 F.3d at 1364; *NTP*, 418 F.3d at 1319; *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1335 (Fed. Cir. 2008) ("[A] party that sells or offers to sell software containing instructions to perform a patented method does not infringe the patent under § 271(a)."); *Joy Techs.*, 6 F.3d at 773 ("The law is unequivocal that the sale of equipment to perform a process is not a sale of the process within the meaning of section 271(a).")).

The Commission stated:

> [S]ection 337(a)(1)(B)(i) covers imported articles that directly or indirectly infringe when it refers to "articles that – infringe." We also interpret the phrase "articles that – infringe" to reference the status of the articles at the time of importation. Thus, infringement, direct or indirect, must be based on the articles as imported to satisfy the requirements of section 337.

Electronic Devices, Comm'n Op. at 13-14. The Commission determined that the importation requirement was not met in that case by the respondent's post-importation performance of a claimed method. *Id.* at 18. Nevertheless, the Commission stated that the complainant "might have proved a violation of section 337 if it had proved indirect infringement" of the method claim. *Id.* The Commission cited, as an example, *Certain Chemiluminescent Compositions, and Components Thereof and Methods of Using, and Products Incorporating the Same*, Inv. No. 337-TA-285, USITC Pub. No. 2370, Order No. 25 (Initial Determination) at 38 n.12 (March 1991), in which "the ALJ found that the 'importation and sale' of the accused articles constituted contributory and induced infringement of the method claim at issue in that investigation." *Electronic Devices*, Comm'n Op. at 18 n.11.

Complainants argue that "the Federal Circuit effectively overruled 337-TA-724 in *Suprema*, holding that 'Section 337 contemplates that infringement may occur *after* importation.'" *See* Compls. Reply Br. at 204 (citing *Suprema, Inc. v. International Trade Comm'n*, 796 F.3d 1338, 1359 (Fed. Cir. 2015) (emphasis original).

Suprema held that "the Commission's interpretation that the phrase 'articles that infringe' covers goods that were used by an importer to directly infringe post-importation as a result of the seller's inducement is reasonable." *See Suprema*, 796 F.3d 1338 at 1352-53. Thus, *Suprema* addressed the situation where a respondent induced the direct infringement of a method claim post-importation by another. The majority in *Suprema* did not directly address the situation here, in which the respondent itself is accused of directly infringing a method claim post-importation. *But see Suprema*, 796 F.3d 1338 at 1356 and n. 1 (dissent) (citing *Electronic Devices* generally with approval). *Suprema*

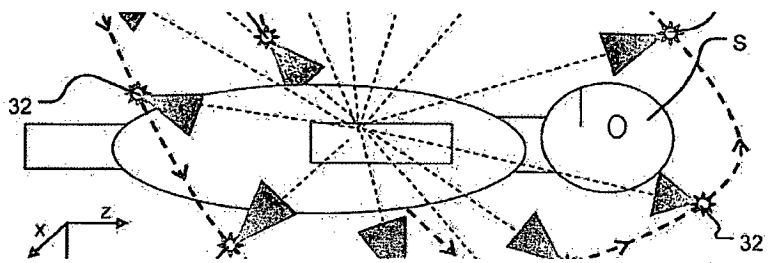
thus did not overrule *Electronic Devices*. As such, the determination of *Electronic Devices*, that a respondent's own direct post-importation practice of a patented method in the United States using imported products cannot be the basis for a violation of section 337, still remains Commission precedent, notwithstanding the Federal Circuit's holding in *Suprema*. *See Electronic Devices*, at 14, 17-19.

Accordingly, performance of claim 19 by respondents, whether on a patient or a "phantom," is not sufficient to prove a violation under section 337.

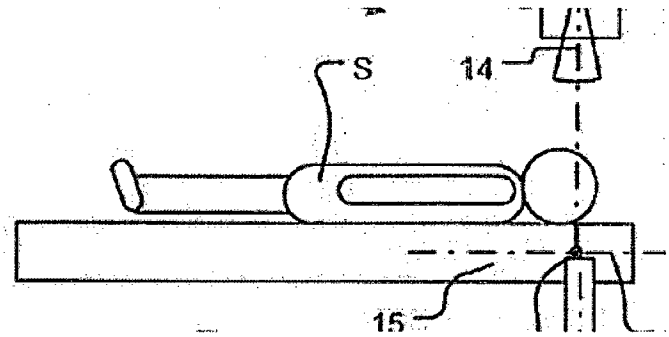
Claim Term "subject"

For the reasons discussed below, the administrative law judge agrees with respondents and the Staff that the "subject" in claim 19 who is receiving the "radiation dose" must be a living person.

The word "subject" is used frequently in the '154 patent. Yet, the '154 patent does not define "subject." However, the meaning of "subject" can be derived from the '154 patent. For example, the '154 patent refers to the "patient" (col. 11, ln. 6; col. 27, ln. 61), who could be a "child" (col. 11, lns. 7-11), and a "subject S" (*e.g.*, col. 5, ln. 19; col. 5, ln. 23, col. 5, ln. 37; col. 6, lns. 3,11), who looks like this:



or this:



See JX-0004 ('154 Patent) at Figs. 1 and 2 (excerpts).

"Subject S" has "target tissue 200 and healthy tissue 202 located within the body of a subject S" (*id.* at col. 25, lns. 1-2) and the '154 patent discloses that the claimed trajectory may be selected "to avoid important healthy organs or the like." *See id.* at col. 6, lns. 57-58. The "Background" section of the '154 patent describes the need for the claimed radiation treatment methods and apparatus in the context of prior art techniques to "deliver radiation to target volumes in living subjects" to "treat various medical conditions" while avoiding harm to "living tissue." *See id.* at col. 1, lns. 31-42.

Complainants' proof that respondents tested claim 19 (and thus dependent claims 23 and 26) on dummies or phantoms is not sufficient to prove direct infringement of the claim. With respect to this issue, while Dr. Bergeron was qualified as an expert in this investigation, his interpretation of this term (*i.e.*, CX-3835C (Bergeron WS) at Q421), is given less weight than that of Dr. McNutt, given Dr. McNutt's superior expertise in the field of "fields of radiation oncology physics, radiation therapy planning, optimization algorithms, imaging and related computer science technologies." *See* McNutt Tr. 661. While complainants' validity expert, Dr. Verhey, is as qualified as Dr. McNutt, his explanation to the administrative law judge of the term "phantom" discussed the different categories of "humanoid phantoms," "tissue-equivalent material," "plastic, a big cube of

plastic," or "water phantom," that are encompassed by the general category of "phantoms." *See* Verhey Tr. 1115-1117. Dr. Verhey did not equate use on phantoms with use on actual human subjects. *See Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("[e]ven 'a nonsensical result does not require the court to redraft the claims.') (citations omitted).

4. Indirect Infringement

Complainants argue:

> The evidence shows that Elekta's customers directly infringe claims 23 and 26 of the '154 patent in the United States when: (a) testing how to create and deliver VMAT treatment plans using a combination of an Accused Linac and treatment planning software such as Monaco; (b) receiving training from Elekta on how to create and deliver VMAT treatment plans using treatment planning software such as Monaco and an Accused Linac; and (c) treating patients by creating and delivering VMAT treatment plans using treatment planning software such as Monaco in combination with an Accused Linac.

See Compls. Br. at 205, 205-14.

Respondents argue that "Varian has failed to show that Elekta had a specific intent to induce direct infringement by another," and that respondents do not contributorily infringe. *See* Resps. Br. at 231, 231-37.

The Staff argues: "The evidence has shown that Elekta provided testing and training materials to its customers, and otherwise has the requisite intent to induce or contribute to infringement, at least since the filing of Varian's original complaint." Staff Br. at 101. The Staff argues: "The record also contains circumstantial evidence that Elekta customers directly infringe." *Id.* at 102.

As discussed below, the evidence shows that Elekta's customers directly infringe claims 23 and 26 of the '154 patent in the United States when: (a) testing how to create

and deliver VMAT treatment plans using a combination of an Accused Linac and treatment planning software such as Monaco; (b) receiving training from Elekta on how to create and deliver VMAT treatment plans using treatment planning software such as Monaco and an Accused Linac; and (c) treating patients by creating and delivering VMAT treatment plans using treatment planning software such as Monaco in combination with an Accused Linac.

Testing

As discussed above and as Dr. Bergeron explained, Elekta performs testing of Monaco and the Accused Linacs that a customer has purchased at the customer site, including the creation and delivery of a VMAT treatment plan—but Elekta performs this testing in concert with the customer. *See* CX-3835C (Bergeron WS) at Q431. For example, [ ] testified that an Elekta installation engineer performed the testing together with [ ] physicist. *See* JX-0034C ([ ] Dep. Tr.) at 100. Accordingly, the evidence shows that Elekta's customers directly infringe claims 23 and 26 in the United States when they perform testing of the creation and delivery of a treatment plan using treatment planning software such as Monaco and one or more Accused Linacs that the customer has purchased.

Training

As discussed above, and as Dr. Bergeron testified, Elekta provides training to its customers in the United States on Monaco, MOSAIQ, VMAT planning and VMAT delivery on a linear accelerator, either at the customer site or at Elekta's training facilities in Atlanta, Georgia. *See* CX-3835C (Bergeron WS) at Q435; *see also, e.g.*, CX-

3768C.013, 018, 024-025; JX-0056C (Symons Dep. Tr.) at 208, 244-248, 250-251.

[

]. *See* CX-1109C ([ ]); CX-1110C ([ ]); CX-1113C ([ ]); CX-1125C ([ ]); CX-1127C ([ ]); CX-3706C ([ ]). Further, [ ] testified that its employees did receive training in the United States on how to create a VMAT treatment plan with Monaco and deliver it on the Accused Linacs. *See, e.g.*, JX-0034C ([ ]) Dep. Tr.) at 82-84, 86-87, 89.

Accordingly, the evidence shows that Elekta's customers directly infringed claims 23 and 26 of the '154 patent in the United States when receiving training on how to use the combination of treatment planning software such as Monaco and the Accused Linacs in the United States to create and deliver VMAT treatment plans.

Treating Patients

As discussed above, [

]. *See e.g.*, CX-1109C through CX-1111C, CX-1113C through CX1129C; CX-3706C; CX-3857C through CX-3860. As Dr. Bergeron testified, it is highly unlikely customers would have [ ], and not have used that functionality. *See* CX-3835C (Bergeron WS) at Q439. Moreover, [ ], all of whom are Elekta customers located in the United States, purchased a number of Accused Linacs, in [ ] case with Monaco. These customers all admitted

to repeatedly creating VMAT treatment plans and delivering them on an Accused Linac, including VMAT treatment plans that included multiple arcs and arcs on intersecting planes. *See* CX-3835C (Bergeron WS) at Q439; *see also, e.g.,* JX-0034C ([ ]) Dep. Tr.) at 25-26, 33, 40-43, 61-62, 63-64; JX-0023C ([ ] Dep. Tr.) at 67-70, 74, 80-86, 112-113, 117, 118; JX-0035C ([ ] Dep. Tr.) at 16-17, 19, 21-22, 25-26, 58, 59, 61, 65-67. Accordingly, the evidence shows that Elekta's customers directly infringed claims 23 and 26 in the United States when creating a VMAT treatment plan using treatment planning software such as Monaco and delivering that treatment plan to a patient using an Accused Linac.

Accordingly, the evidence shows that Elekta's customers directly infringe claims 23 and 26 of the '154 patent when they perform testing, training, and/or actually treat patients by creating and delivering VMAT plans using the Accused '154 Products in the United States.

Inducement

Dr. Bergeron cited substantial evidence showing that Elekta encourages its customers to create and deliver VMAT treatment plans using a combination of treatment planning software such as Monaco and an Accused Linac, *i.e.*, encouraging its customers to practice each limitation of claims 23 and 26, including through advertisements on its website, marketing materials and presentations; white papers, user guides, training guides, Instructions for Use and other technical manuals; live and video demonstrations, animations, FDA and regulatory documentation, technical support for customers, training for customers, and warning customers that it will disclaim liability for damages from the customers' failure to follow Elekta's guidance. *See* CX-3835C (Bergeron WS) at Q447;

see also, e.g., CX-3684C; CX-1135C; CX-3589; CX-3872; CX-3870; CX-3584; CX-3622C; CX-1135C; CX-1148C; CX-3680C; CX-0251C; CX-0279C; CX-0233C; CPX-0008; CPX-0009; CPX-0030 to CPX-0031; CPX-0033; CX-0036 to CPX-0039; CPX-0042 to CPX-0043; CPX-0046; CX-0299C; CX-3620.469-85, 487-89, 536; CX-3690C.612-632, 730; CX-3697C; CX-0299C; CX-1133C; CX-3689; CX-3685; CX-3768C; CX-0308C.3; CX-0233C; CX-0357C; CX-1113C; JX-0025C (Brown Dep. Tr.) at 167-168; JX-0056C (Symons Dep. Tr.) at 215-217, 223, 229-231, 256. Neither Elekta nor Dr. McNutt disputes that these materials encourage customers to perform the functionality discussed above that practices claims 23 and 26 of the '154 patent.

Further, Elekta knew that it was encouraging its customers to infringe, and thus had the requisite specific intent. In particular, Dr. Bergeron testified that Elekta had knowledge of its infringement of the '154 patent (1) patent as early as April 11, 2011 when the '154 patent was cited in connection with the Notice of Allowance in one of its own patent applications, (2) in March 3, 2015 when Varian informed Elekta of its infringement of the '154 patent, and (3) yet again when it received the Complaint in this Investigation. Yet, Elekta continued to encourage customers to use the accused functionality, and continues to do so today. *See* CX-3835C (Bergeron WS) at Q448.

Thus, the evidence shows that Elekta indirectly infringes claims 23 and 26 of the '154 patent by actively inducing customers in the United States to create VMAT treatment plans and deliver them using a combination of the treatment planning software such as Monaco and an Accused Linac.

Contributory Infringement

The evidence shows that Elekta contributes to customers' infringement of claims

23 and 26 in the United States by importing the Accused Linacs into the United States, which as discussed above, are used by Elekta's customers in the United States, in combination with treatment planning software such as Monaco, to practice claims 23 and 26 of the '154 patent.

As explained by Dr. Bergeron, customers use the Accused Linacs that are imported into the United States in combination with treatment planning software such as Monaco to create and deliver VMAT treatment plans in the United States. Dr. Bergeron further concluded that the Accused Linacs do not have a substantial noninfringing use after they are imported into the United States because they are specifically designed and adapted to deliver VMAT treatment plans, which is one of the major reasons Elekta's customers purchase the Accused Linacs. *See* CX-3835C (Bergeron WS) at Q445-46; *see also, e.g.*, JX-0025C (Brown Dep. Tr.) at 17 ("We have got a number of different brands of device, but the Versa HD is our flagship product that delivers the VMAT plans, but also the Synergy also does that."); JX-0055C (Smith Dep. Tr.) at 52-53, 138-139.

Dr. McNutt opines that the Accused '154 Products are staple articles of commerce suitable for substantial noninfringing use for three reasons: (a) Monaco is not imported, only the Accused Linacs are imported; (b) the Accused Linacs can be used to deliver non-VMAT treatment plans; and (c) the Accused Linacs can be used with Varian's treatment planning software and Monaco's treatment planning software can be used with the Elekta linacs. *See* RX-0495C (McNutt RWS) at Q398-411. The evidence and law do not support Dr. McNutt's conclusion.

The contributory infringement inquiry focuses on whether there are substantial noninfringing uses for the particular functionality that practices the claims at issue, not

the functionality of the device as a whole. *See, Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1312 (Fed. Cir. 2005) ("In order to succeed on a claim of contributory infringement, in addition to proving an act of direct infringement, plaintiff must show that defendant knew that the combination for which its components were especially made was both patented and infringing and that defendant's components have 'no substantial non-infringing uses.'") (quotations omitted); *see also Lucent Techs., Inc. v. Gateway, Inc.*, 580 F. 3d 1301, 1321 (Fed. Cir. 2009) (holding that inclusion of an accused feature within a larger device does not change the accused functionality's ability to infringe). Accordingly, the contributory infringement inquiry cannot focus on the combination of Accused Linacs and multi-mode treatment planning software such as Monaco as a whole, but must focus on whether there are substantial noninfringing uses for the specific mode of functionality that practices claims 23 and 26 of the '154 patent: the creation and delivery of VMAT treatment plans using software such as Monaco and the Accused Linacs.

As Dr. Bergeron explained and the Monaco source code and documentation show, Monaco is tailored to work with and has specific documentation and source code tied to the Accused Linacs, using the parameters specific to the Accused Linacs as inputs into its [ ] for VMAT plans. The Accused Linacs are adapted to work with compatible treatment software such as Monaco because their parameters have been built into the source code itself. *See* CX-3835C (Bergeron WS) at Q101, Q118, Q125; *see also, e.g.*, CX-3862C.007; 3861C.0051; CPX-0025C (printed as CX-3683C) at [ ] at lines 114-120, 147-148, 163-195, 270, [ ] at lines 221-312, 410-659, [

] at lines 64-182, [ ] at lines 162-460,

[ ].

Thus, the evidence shows that Elekta indirectly infringes claims 23 and 26 of the '154 patent by contributing to its customers' infringement of claims 23 and 26 when selling Accused Linacs which are especially adapted to be combined with Monaco or with other treatment planning software to create VMAT treatment plans and deliver them.

C. Domestic Industry (Technical Prong)

Complainants argue: "The evidence shows that Varian's Domestic Industry Products practice claim 23 of the '154 patent. This is not disputed by Elekta." *See* Compls. Br. at 214 (citations omitted), 214-17.

Respondents argue: "Varian cannot satisfy the technical prong of the domestic industry requirement for claim 23. As explained below and demonstrated during the hearing, claim 23 is invalid. A domestic industry cannot be based on an invalid claim." Resps. Br. at 237-38 (citations omitted).

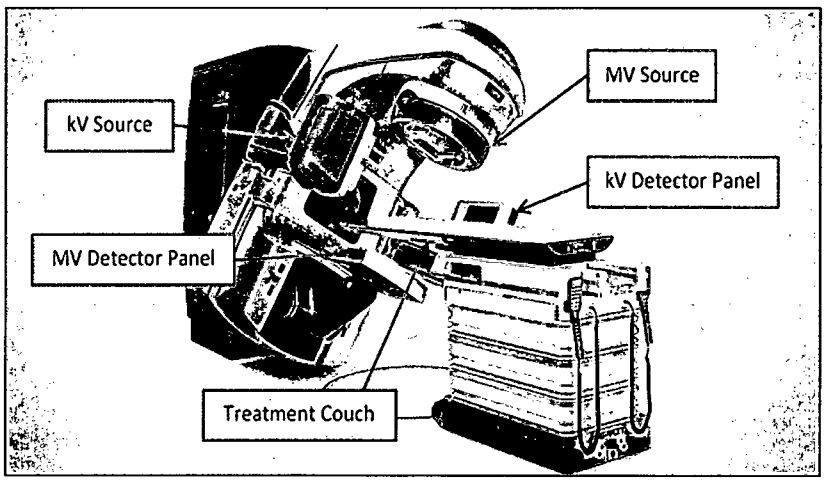
The Staff argues:

> Respondents do not dispute that complainants' domestic industry products practice claim 23 of the '154 patent. However, respondents argue that complainants cannot satisfy the technical prong of the domestic industry requirement because the claims are invalid. This relates to the question of whether the domestic industry can be based on an invalid claim, not as to whether the technical prong is satisfied. Complainants cannot have a domestic industry in an invalid claim. However, the evidence has shown that claim 23 is valid (as discussed below). Thus, respondents have not rebutted complainants' showing that they have satisfied the technical prong of the domestic industry requirement.

Staff Br. at 103-04 (citations omitted).

Varian's Clinac iX and TrueBeam Linacs

Varian's domestic industry products include the Clinac iX and Trilogy linac systems when used with the On-Board Imager system, and the TrueBeam and Edge linac systems. *See, e.g.*, CX-0848C (Mutic WS) at Q289. Varian's linacs are integrated and networked computer-controlled systems used to perform imaging and implement radiotherapy treatments, such as treatment plans generated by Varian's RapidArc VMAT planning software. *See, e.g.*, CX-0848C (Mutic WS) at 289; CX-3835C (Bergeron WS) at Q11. They all function similarly and their basic configuration is the same: a rotatable gantry with a high-energy MV source and opposing MV flat-panel imager and an orthogonal kV source and opposing kV flat-panel imager coupled to the gantry, as shown with respect to the Clinac iX. *See, e.g.*, CX-3835C (Bergeron WS).



The Clinac iX and Trilogy systems optionally include the "On-Board Imager," a kV imaging system used with the linacs. *See, e.g.*, CX-0848C (Mutic WS) at 298-300, 312-14. The integrated kV imaging system of the TrueBeam and Edge systems is called the "X-Ray Imaging System." *See, e.g.*, CX-0848C (Mutic WS) at 331-33, 366-67, 377-

79.

RapidArc

RapidArc is a VMAT treatment technology sold by Varian. It includes both treatment planning and treatment delivery components. For treatment planning, it consists of optimization algorithms used within Eclipse for developing VMAT treatment plans. For treatment delivery, it consists of hardware modifications to TrueBeam (including Edge) and Clinac (including Clinac iX and Trilogy) treatment delivery platforms to enable delivery of VMAT treatment plans. During these VMAT treatments, the delivering linac varies both the dose rate and beam shape while moving in a trajectory around the patient and delivering radiation. *See* CX-3835C (Bergeron WS) at Q224.

As discussed below, the evidence shows that Varian's Domestic Industry Products practice claim 23 of the '154 patent. CX-3835C (Bergeron WS) at Q460-467. This is not disputed by respondents. *See* Resps. Br. at 237-38. The Domestic Industry Products for the '154 patent include Varian's TrueBeam and Clinac linear accelerators in combination with Varian's Eclipse treatment planning software. These systems work together to allow clinicians to create and deliver Varian's proprietary VMAT treatment plans, known as RapidArc. CX-0855C (Zankowski WS) at Q29-30, 44-58. RapidArc plans are optimized using the Progressive Resolution Optimization (PRO) algorithm, based directly on Dr. Otto's work. CX-0853C (Pyyry WS) at Q17; CX-3835C (Bergeron WS) at Q241-242; CX-0378C.204; CX-0379.2; CDX-0495C; CX-0496.

As noted, complainants assert dependent method claim 23 (which depends from independent claim 19) and claim 26 (which depends from dependent claim 24, which in turn depends from claim 23) of the '154 patent.

Claim 19

Independent claim 19 reads as follows:

> **19**. A method for delivering radiation dose to a target area within a subject, the method comprising:
>
> defining a trajectory for relative movement between a treatment radiation source and the subject in a source trajectory direction;
>
> determining a radiation delivery plan;
>
> while effecting relative movement between the treatment radiation source and the subject along the trajectory in the source trajectory direction, delivering a treatment radiation beam from the treatment radiation source to the subject according to the radiation delivery plan to impart a dose distribution on the subject;
>
> wherein delivering the treatment radiation beam from the treatment radiation source to the subject comprises varying an intensity of the treatment radiation beam over at least a portion of the trajectory.

JX-0004 ('154 Patent) at col. 34.

The Domestic Industry Products perform the preamble, "A method for planning delivery of radiation dose to a target region within a subject." The Eclipse treatment planning software allows an operator to create and optimize radiation treatment plans to irradiate specific patient target volumes. RapidArc treatment plans use the PRO algorithm to optimize the dose distribution delivered to the patient target volume. After a RapidArc treatment plan is optimized and approved for delivery, it is exported to a DICOM file. The DICOM files are provided to the TrueBeam and Clinac linear accelerators, which read the DICOM files and generate instructions to implement the treatment plans. CX-3835C (Bergeron WS) at Q462; CX-1661C.130-144; CX-0378C.204-205.

The Domestic Industry Products perform the step of "defining a trajectory for relative movement between a treatment radiation source and the subject in a source trajectory direction." For RapidArc treatment plans, the Eclipse software receives as an input an arc geometry representing a trajectory that the radiation source will follow relative to the patient during treatment. CX-853C, Pyyry at Q14; CX-3835C (Bergeron WS) at Q463; CX-1661C.130-144; CX-0378C.204-205; CDX-0488C.

The Domestic Industry Products perform the step of "determining a radiation delivery plan." After the Eclipse software has received a treatment trajectory through the Arc Geometry Tool, it causes the processor to optimize the treatment plan using the PRO algorithm. The PRO algorithm optimizes a simulated dose distribution along the treatment trajectory relative to the clinical objectives, including the desired dose distribution to the patient target volume and surrounding tissue. The PRO algorithm includes multiple levels of optimization, called MR levels, and each MR level includes a series of iterations where radiation delivery parameters including dose amount and MLC leaf position are adjusted. At the end of the final MR level, the treatment plan is deliverable by a TrueBeam or Clinac linear accelerator. CX-853C, Pyyry at Q14; CX-3835C (Bergeron WS) at Q464; CX-1661C.140-145; CX-0378C.204-205; CDX-0488C-0493C.

The Domestic Industry Products perform the step of "while effecting relative movement between the treatment radiation source and the subject along the trajectory in the source trajectory direction, delivering a treatment radiation beam from the treatment radiation source to the subject according to the radiation delivery plan to impart a dose distribution on the subject." After a RapidArc treatment plan is optimized and approved

for delivery, it is exported to a DICOM file. The DICOM files are provided to linacs including the TrueBeam and Clinac linacs, which read the DICOM files and generate instructions to implement the treatment plans. In TrueBeam, the Supervisor node of the control system unpacks the data from the DICOM file and prepares instructions that direct the other machine nodes, including the gantry, MLC, and beam generation components, to deliver the radiation dose to the patient target volume. In Clinac, the Clinac Controller and MLC Controller extract the DICOM control point data and implement the treatment plan to deliver the radiation dose to the patient target volume. CX-853C, Pyyry at Q36-38; CX-3835C (Bergeron WS) at Q465; CX-0378C.204-205; CX-1661C.24.

The Domestic Industry Products perform the step of "wherein delivering the treatment radiation beam from the treatment radiation source to the subject comprises varying an intensity of the treatment radiation beam over at least a portion of the trajectory." The delivery of a RapidArc treatment plan on a TrueBeam or Clinac linac is characterized by continuous movement of the gantry along the treatment trajectory, while varying radiation beam intensity. As Dr. Bergeron testified based on his review of Varian documents and source code, the varying intensity of a RapidArc treatment plan results from the PRO algorithm optimization process, which adjusts the dose amount, or intensity of the radiation source for each Dose Calculation Sector along a treatment trajectory. The varying dose amounts are encoded into a DICOM file and delivered by the TrueBeam and Clinac machines. CX-853C, Pyyry at Q36-38; CX-3835C (Bergeron WS) at Q466; CX-0378C.204-205; CX-1661C.24; CX-1683C.14; CPX-0013.

Claim 23

Asserted dependent method claims 23, which depends from independent claim 19, reads as follows:

> **23**. A radiation delivery method according to claim **19** wherein varying the intensity of the treatment radiation beam over at least the portion of the trajectory comprises varying a rate of radiation output of the radiation source while effecting continuous relative movement between the treatment radiation source and the subject along the trajectory.

JX-0004 ('154 Patent) at col. 34, lns. 54-59.

The Domestic Industry Products perform "A radiation delivery method according to claim 19 wherein varying the intensity of the treatment radiation beam over at least the portion of the trajectory comprises varying a rate of radiation output of the radiation source while effecting continuous relative movement between the treatment radiation source and the subject along the trajectory." For a RapidArc treatment plan, when optimization is complete, the plan is exported to a DICOM file. This information is transferred to the TrueBeam or Clinac linacs and the machine control systems determine how intensity of the radiation beam and gantry speed should be modulated to deliver the plan. In delivering the plan, the linacs vary the dose rate of the radiation source while effecting continuous relative movement between the treatment radiation source and the subject along the trajectory. The electron gun component of each machine generates the necessary variable dose rate to deliver the varying-intensity RapidArc plan. CX-853C, Pyyry at Q36-38; CX-3835C (Bergeron WS) at Q467; CX-0378C.204-205; CX-1661C.24; CX-1671.20; CX-1683C.14.

D. Validity of the '154 Patent

Respondents argue that the Earl Article[66] anticipates claim 23. Resps. Br. at 239-52. Respondents argue that five combinations of between two and three references render both asserted claims 23 and 26 as obvious. Resps. Br. at 252-57.

Complainants and the Staff disagree. *See* Compls. Br. at 217-35; Staff Br. at 104-11.

For the reasons set forth below, respondents have not shown by clear and convincing evidence that asserted claims 23 and 26 of the '154 patent are anticipated or rendered obvious.

1. Applicable Law

One cannot be held liable for practicing an invalid patent claim. *See Pandrol USA, LP v. AirBoss Railway Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003). Nevertheless, each claim of a patent is presumed to be valid, even if it depends from a claim found to be invalid. 35 U.S.C. § 282; *DMI Inc. v. Deere & Co.*, 802 F.2d 421 (Fed. Cir. 1986).

A respondent that has raised patent invalidity as an affirmative defense must overcome the presumption by "clear and convincing" evidence of invalidity. *Checkpoint Systems, Inc. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995).

a. Anticipation

Anticipation under 35 U.S.C. § 102 is a question of fact. *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1347 (Fed. Cir. 2007). Section 102 provides that,

[66] *See* RX-233 (M. A. Earl *et al.*, *Inverse Planning for Intensity-Modulated Arc Therapy Using Direct Aperture Optimization*, Phys. Med. Biol. 48, 1075-1089 (2003)) ("Earl Article").

depending on the circumstances, a claimed invention may be anticipated by variety of prior art, including publications, earlier-sold products, and patents. *See* 35 U.S.C. § 102 (*e.g.*, section 102(b) provides that one is not entitled to a patent if the claimed invention "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States").

The general law of anticipation may be summarized, as follows:

> A reference is anticipatory under § 102(b) when it satisfies particular requirements. First, the reference must disclose each and every element of the claimed invention, whether it does so explicitly or inherently. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed.Cir.2006). While those elements must be "arranged or combined in the same way as in the claim," *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1370 (Fed.Cir.2008), the reference need not satisfy an *ipsissimis verbis* test, *In re Bond*, 910 F.2d 831, 832-33 (Fed.Cir.1990). Second, the reference must "enable one of ordinary skill in the art to make the invention without undue experimentation." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed.Cir.2008); *see In re LeGrice*, 49 C.C.P.A. 1124, 301 F.2d 929, 940-44 (1962). As long as the reference discloses all of the claim limitations and enables the "subject matter that falls within the scope of the claims at issue," the reference anticipates -- no "actual creation or reduction to practice" is required. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1380-81 (Fed.Cir.2003); *see In re Donohue*, 766 F.2d 531, 533 (Fed.Cir.1985). This is so despite the fact that the description provided in the anticipating reference might not otherwise entitle its author to a patent. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed.Cir.1991) (discussing the "distinction between a written description adequate to support a claim under § 112 and a written description sufficient to anticipate its subject matter under § 102(b)").

In re Gleave, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

b. Obviousness

Under section 103 of the Patent Act, a patent claim is invalid "if the differences

between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[67] 35 U.S.C. § 103. While the ultimate determination of whether an invention would have been obvious is a legal conclusion, it is based on "underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness." *Eli Lilly and Co. v. Teva Pharmaceuticals USA, Inc.*, 619 F.3d 1329 (Fed. Cir. 2010).

The objective evidence, also known as "secondary considerations," includes commercial success, long felt need, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 13-17 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006). "[E]vidence arising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). Secondary considerations, such as commercial success, will not always dislodge a determination of obviousness based on analysis of the prior art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007) (commercial success did not alter conclusion of obviousness).

"One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an

[67] The standard for determining whether a patent or publication is prior art under section 103 is the same as under 35 U.S.C. § 102, which is a legal question. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987).

obvious solution encompassed by the patent's claims." *KSR*, 550 U.S. at 419-20. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.*

Specific teachings, suggestions, or motivations to combine prior art may provide helpful insights into the state of the art at the time of the alleged invention. *Id.* at 420. Nevertheless, "an obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way." *Id.* "Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* A "person of ordinary skill is also a person of ordinary creativity." *Id.* at 421.

Nevertheless, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); *see KSR*, 550 U.S. at 416 (a combination of elements must do more than yield a predictable result; combining elements that work together in an "unexpected and fruitful manner" would not have been obvious).[68]

[68] Further, "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious."

2. Anticipation

Respondents argue that the article "Inverse planning for intensity-modulated arc therapy using direct aperture optimization," Phys. Med. Biol. 48 1075-1089 by Earl, Shepard, Naqvi, Li and Yu (2004) (RX-0233, the "*Earl Article*") anticipates claim 23 (and thus claim 19, from which it depends) of the '154 patent. *See* Resps. Br. at 239-52.

Complainants and the Staff disagree that the Earl Article anticipates claim 23. *See* Compls. Br. at 217, 220-25; Staff Br. at 104-05.

For the reasons discussed below, respondents have not shown by clear and convincing evidence that asserted claim 23 of the '154 patent is anticipated.

Claim 23 requires delivering a radiation delivery plan that was optimized using the techniques recited in claim 19. *See* McNutt Tr. 795-796; Verhey Tr. 1089-1090. As to claim 23, Dr. McNutt admits that the plain language of the claim requires varying the dose rate of the linac. *See, e.g.*, RX-0434C (McNutt WS) at Q362; McNutt Tr. 797-798. However, Dr. McNutt opines that *Earl Article's* reference to varying the gantry speed and claim 23's requirement of varying the dose rate of the linac, are both related to the "total amount of radiation delivered over a portion of an arc or trajectory." *See* RX-0434C (McNutt WS) at Q363.

As Dr. Verhey explained, the "radiation source" in claim 23 is not related to either the multileaf collimator or the speed of the gantry. *See* Verhey Tr. 1089-1091. Rather, Dr. Verhey testified, claim 23 requires measuring the dose rate of the linac, the source of the radiation. *See id.* When questioned on this issue, Dr. McNutt admitted during the evidentiary hearing that varying the gantry speed and varying the dose rate are two

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KSR, 550 U.S. at 416 (citing *United States v. Adams*, 383 U.S. 39, 52 (1966)).

different techniques, and that one "can have variable gantry speed and at a constant dose rate." *See* McNutt Tr. 737, 742-743.

Dr. McNutt opines that the *Earl Article*'s "beam weight" is the dose rate of the linac, but in doing so contradicts Dr. Yu's later description of his own work. *See* RX-0434C (McNutt WS) at Q360. On cross examination, Dr. McNutt admitted that "beam weight" does not measure the "rate" of radiation (measured per unit of time), but rather describes only the relative amount of radiation delivered over the course of a portion of an arc, as compared to the radiation entire length of the arc. *See* McNutt Tr. 737 ("the beam weight is the relative contribution of a beam, yes"); CX-3880C (Verhey RWS) at Q225 ("beam weight [is the] relative amount of radiation delivered over the course of a portion of an arc"); *see also* CX-3802.10 at R40; CDX-0851C; RX-233 at Abstract.

Dr. McNutt admitted that no prior art reference that he has seen, including the *Earl Article*, optimizes the dose rate of the linac:

> Q All right. The algorithm that is described here on ELEKTA_ITV968-105518 does not use dose rate of the linac as an optimization parameter; correct?
> A It – it use – it can optimize the control point weights, the overall arc weights and the leaf positions. ***None of the algorithms we're talking about optimize dose rate.***

McNutt Tr. 735 (emphasis added).

> Q Okay. And page 226 of your deposition, line 14 through 18, let's just have this on the screen, Mr. Kelly. Question 14, "Dr. McNutt, the algorithm that is disclosed in the ***Earl articles does not explicitly specify the dose rate of the linac*** as an optimization parameter? Yes or no? "Answer: ***That is true.***"

McNutt Tr. 736 (emphasis added).

This lack of disclosure in the *Earl Article* was explained by Dr. Verhey at the evidentiary hearing:

Q Dr. Verhey, can you explain why you believe the Earl article does not disclose or describe an algorithm that optimizes dose rate?
A Yes, I can try to do that. Actually, if you would look at the second sentence of what's projected here, it says about the constant dose rate, constant gantry rotation speed, the delivery of IMAT plans, and this constraint is imposed in the optimization by requiring that all angles composing the arc have the same relative weight. And whatever you call it, that is a fact that is created by the constraints on the accelerator. And if you -- if you just do away with that constraint and let each control point have a different weight, whether you call it arc weight or beam weight, then you have the option of displaying something which at least they claim is a simulation of having the variable dose rate as part of their planning program, as part of the accelerator. So they often use that, in my opinion, to confuse the reader as to what they are talking about, because ***they're not talking about changing dose rate***. They talk about changing the relative weights of different portions of the arc.
Q When you say "changing the relative weights of different portions of the arc," how is that different than dose rate?
A Well, ***it's very different than dose rate, because as we know, as long as we're in the patient, we can't vary the dose rate from the accelerator***. That's not one of the things that we can do. Once you're in the patient, all you can do is redistribute the dose in the patient in such a way that it gives you a better fit until your desired dose distribution. And one of the ways of doing that, in the case of a rotational plan, is to vary the weights of the doses, which were delivered by the constant option, and then give a dose distribution which varies from one place along the arc to another. And that is what they would like to say simulates variable dose rate. But I, for one, disagree with that characterization of this portion of the article.
Q And just to be clear, whether you have a disagreement or not with the wording of "simulate," did

you, in fact, find any optimization algorithm that actually varied the dose rate in the Earl article?
A Well, no. In fact, even the optimization algorithm prior to trying to insert the dose rate is not disclosed, and certainly the ***way that they add in the variable dose rate, as they claim they do, is not disclosed.***

Verhey Tr. 1144-1146 (emphasis added).

As Dr. Verhey testified, the IMAT treatment plan described by the *Earl Article* controls the amount of radiation delivered to a target site by using different numbers of overlapping arcs with constant dose rate to increase or decrease the amount of radiation that is delivered to a target site. This view is consistent with Dr. Yu's later description of the *Earl Article*'s disclosure. *See* Verhey Tr. 1144-1145; CX-3880C (Verhey RWS) at Q97-99; CX-3802.10, Yu 2011 Article at R40. As a result, the authors admit that one effect of the additional arcs was the "additional delivery time required to deliver the additional arcs." *Id.* In contrast, Dr. Otto's patented VMAT solution creates, optimizes, and delivers a treatment plan that varies the dose rate while the gantry is moving, allowing for single arc delivery.

Claim 23 requires planning and delivering an optimized treatment plan that varies the dose rate of the linac, a disclosure not found anywhere in the *Earl Article*. As Dr. Verhey testified, the authors of the *Earl Article* expressly disclaimed the ability to optimize and deliver a treatment plan that could "vary[] a rate of radiation output of the radiation source while effecting continuous relative movement between the treatment radiation source and the subject along the trajectory." Verhey Tr. 1144-1146. Rather, the authors were forced to "simulate the effect of" varying the dose rate of the linac. *See* RX-0233, *Earl Article* at 1086; CX-3880C (Verhey RWS) at Q97, 99, and 225; Verhey

Tr. 1134-1135 (explaining the difference between simulating a dose distribution and simulating a dose rate).

Additionally, inasmuch as they did not have a linac that was capable of varying the intensity of the treatment beam while the gantry is moving, the authors of the *Earl Article* could not have been in possession of an optimization algorithm to generate a treatment plan that requires varying the dose rate of the linac. *Id.*; Verhey Tr. 1139 (confirming the Earl Article only discloses constant dose rate delivery). This was later confirmed by Dr. Yu, one of the co-authors of the *Earl Article*, who admitted that the *Earl Article* described an IMAT treatment planning process that "us[es] ***constant*** dose rate[.]" *See* CX-3802, Yu 2011 Article at R40 (emphasis added); CX-3880C (Verhey RWS) at Q221.

The *Earl Article* cannot anticipate claim 23 because the IMAT treatment planning and delivery technique described by the *Earl Article* cannot meet the variable dose rate limitations of claim 23, which depends from claim 19, as confirmed by Dr. McNutt's own description of the claim requirements:

> Dr. Bergeron correctly admits that VMAT treatment plans where the intensity of the radiation beam is varied over at least a portion of the trajectory are the only kind of treatment plan that could possibly infringe upon claim 19. This is because claim 19 requires, in part, varying an intensity of the treatment radiation beam over at least a portion of the trajectory. ***Indeed, this is what distinguishes variable dose rate VMAT from other types of treatment such as IMRT and IMAT.***

McNutt Tr. 712 (emphasis added); RX-0434C (McNutt WS) at Q83-85.

Moreover, the *Earl Article* cannot be anticipatory prior art because it merely contains aspirational statements that would require undue experimentation. *See* CX-

3880C (Verhey RWS) at Q104 and 225; *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1085 (Fed. Cir. 2008). In *Sanofi-Synthelabo*, the Federal Circuit expressly rejected the argument that a general description of an allegedly invalidating technique was sufficient because "a person of ordinary skill in this field would know all of the existing techniques." *Id.* Here too, the *Earl Article* describes aspirational goals and admits that its disclosure "***simulates*** the effect of allowing the gantry speed to vary or the dose rate to change during delivery" (RX-233.0006 at 1086 (emphasis added)), and that it is describing the possibility of "relaxing" the constant weight constraint during the optimization process. *Id.* at 1085-86; CX-3880C (Verhey RWS) at Q104, 106-07, and 225. Indeed, Dr. McNutt does not point to an actual treatment planning optimization algorithm or corresponding treatment delivery system in which the dose rate of the linac varies while the gantry is moving along a trajectory, nor could he do so because the Elekta linac used by the authors of the *Earl Article* did not have this capability. *Id.* There is no disclosure in this article that would allow one skilled in the art to accomplish the patented treatment planning and delivery features and benefits of Dr. Otto's VMAT inventions. *See* CX-3880C (Verhey RWS) at Q104, Q221.

3. Obviousness[69]

Respondents argue that five combinations of between two and three references

[69] As an initial matter, Elekta cannot meet its burden on any obviousness combinations because Dr. McNutt did not analyze any facts relating to the secondary considerations of non-obviousness. *See* McNutt Tr. 731-734. Thus, Elekta's *Graham* analysis for each prior art combination is incomplete. *See Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d 1356 (2013) (vacating determination of obviousness that was otherwise supported by substantial evidence for failure to consider secondary considerations). *See* Staff Br. at 105-06; Compls. Br. at 217-20.

render both asserted claims 23 and 26 invalid as obvious. *See* Resps. Br. at 252-57.

Complainants and the Staff disagree. *See* Compls. Br. at 217-20, 226-35; Staff Br. at 105-11.

For the reasons set forth below, respondents have not shown by clear and convincing evidence that asserted claims 23 and 26 of the '154 patent are rendered obvious.

a. Earl Article and Tobler (Claim 23)

As discussed below, the evidence does not show that the combination of the *Earl Article* and *Tobler* renders claim 23 obvious. Elekta cannot meet its burden because the combination fails to disclose varying the dose rate of the linac during the planning and delivery stages, and Dr. McNutt's motivations to combine analysis lacks evidentiary support.

Tobler, which only describes treatment planning, does not disclose delivering a treatment plan wherein the intensity of the treatment radiation beam varies over at least a portion of the trajectory. *See* McNutt Tr. 745-746 (Dr. McNutt admits that claim 19 requires delivery of a variable dose rate VMAT plan; *id.* at 795-796. Indeed, Dr. McNutt does not point to any disclosure that describes an actual delivery of a treatment plan. CX-3880C (Verhey RWS) at Q232. Rather, Dr. McNutt opines that *Tobler*'s mere mention of a linac (a Varian 2100 CD) that could change the shape of the treatment beam is sufficient to infer delivery. RX-0434C (McNutt WS) at Q376; CX-3880C (Verhey RWS) at Q232. However, as Dr. Verhey testified, at the time of the Otto patents, Varian linacs were not able to treat patients by varying the intensity of the beam while the gantry

is moving. CX-3880C (Verhey RWS) at Q233; Verhey Tr. 1099-1101 (claim 19 requires delivering "according" to a treatment plan, as claimed).

Like the *Earl Article*, *Tobler* does not disclose optimizing (as required by claim 19, from which claim 23 depends) or delivering (as required by claim 23) a treatment plan where the dose rate of the linac varies along the trajectory around the patient, and in fact, Dr. McNutt's witness statement ignores the planning aspect of claim 19, which is part of claim 23. Moreover, *Tobler* would not have enabled a person of skill in the art at the time of Dr. Otto's invention to create and deliver such a treatment plan. Dr. McNutt does not provide any factual evidence to support his opinion that a person of ordinary skill in the art would have been motivated to combine the *Earl Article* and *Tobler*.

Dr. McNutt's analysis of this combination does not consider creating and optimizing a treatment plan, as required by claim 19(b) and 19(c) ("according to the radiation delivery plan"), that "var[ies] an intensity of the treatment radiation beam over at least a portion of the trajectory[,]" as required by claim 19(d). CX-3880C (Verhey RWS) at Q229. At the hearing, Dr. McNutt admitted that claim 19, and thus claim 23, required delivering a "variable dose rate VMAT" treatment plan. McNutt Tr. 715. Inasmuch as neither the *Earl Article*, nor *Tobler*, discloses creating and delivering a VMAT treatment plan, Dr. McNutt's analysis is incorrect.

Moreover, *Tobler* cannot describe a treatment plan optimization algorithm that varies the dose rate of the linac. Indeed, as Dr. McNutt admitted, *Tobler* expressly describes that then-contemporary treatment planning systems were incapable of optimizing the dose rate. McNutt Tr. 745-746; CX-3880C (Verhey RWS) at Q230; RX-234.0002 at 252 ("[c]urrently, treatment planning systems are ***unable to represent the***

dynamic dose rate control option that will be required for this dynamic conformal rotational treatment technique.") (emphasis added). As a consequence, *Tobler* merely describes "simulat[ing] that exact type of delivery." McNutt Tr. 746.

Dr. Verhey testified that rather than rendering claim 23 obvious, simulating the ability to vary the intensity of the treatment beam teaches away from the novel aspects of Dr. Otto's invention. CX-3880C (Verhey RWS) at Q230. In particular, Dr. Verhey explained the lack of disclosure in *Tobler* with respect to the variable dose rate limitations of claim 23:

Q And I want to focus in -- first of all, again just to be clear on the record, did you find any type of optimization algorithm in Tobler that varied the dose rate and actually delivered a variable dose rate plan to a subject?
A No. ***In fact, they claim they don't have an optimization algorithm. Period.***
Q And let's take a look at 252, page 252 of Tobler. I don't believe counsel showed you this section but asked you questions about describing varying of the dose rate. Here it says, and Mr. Kelly, if we could blow up "currently the treatment planning systems are unable to represent."
Dr. Verhey, can you read that first sentence into the record, please?
A Yes. "Currently treatment planning systems are unable to represent the dynamic dose rate control option that will be required for this dynamic conformal rotational treatment technique."
Q And what does that tell you in terms of whether the authors of the Tobler reference had, in fact, developed an algorithm for optimizing dose rate?
A Well, they just throw up their hands and say even if we tried to get it or if we tried to simulate it the correct way, ***we aren't able to do that, because the treatment planning systems that we're using at least don't have any way of dealing with that option.***
Q And then it goes on to say, "to simulate this technique."

Do you see that?
A Right.
Q Now, here is this talking about simulation of dose distribution, as in the context of the patent?
A No, again, it's a simulating of a technology.
Q What is your understanding when they simulate this technique, what are they referring to here?
A They're trying to simulate the variation of dose at one portion of the treatment, namely the lateral portion of the treatment. This is a prostate case.
So they develop a large number of multiple rotational fields created at intervals of 12 degrees of rotation, and then they weight these separately so they have more weight where they need it when the patient is thick and they need -- and less weight when they don't need it where the patient is thin.
So they claim that is a way of simulating the variability of dose rate.
Q He but now, just to be clear in the record, is there any algorithm here for actually optimizing the variable dose rate and delivering an optimization plan that has variable dose rate in it?
A ***Absolutely not.***

Verhey Tr. 1146-1148 (emphasis added).

Thus, *Tobler* would not have enabled a person of ordinary skill in the art at the time of the Otto patents to create and deliver a treatment plan that requires varying the intensity of the beam while the gantry is moving. *See* CX-3880C (Verhey RWS) at Q235- Q236.

Additionally, Dr. McNutt's purported motivations to combine are unpersuasive, and are not based on the disclosures of these references. CX-3880C (Verhey RWS) at Q237-8; *Certain Multimedia Display And Navigation Devices And Systems, Components Thereof, And Products Containing Same*, Inv. No. 337-TA-694, Initial Determination, 2010 WL 5676536, at *73; *Transocean*, 699 F.3d at 1349. Dr. McNutt offers vague reasons for combining these two references, such as that they both share a goal of

delivering radiation to the tumor while sparing healthy tissues. *See* RX-0434C (McNutt WS) at Q383. These conclusory opinions are the kind of hindsight reasoning that the Federal Circuit has rejected. *See Monarch Knitting Mach. Corp.*, 139 F.3d at 881 ("[d]efining the problem in terms of its solution reveals improper hindsight.") After all, almost any technique in the field of radiation therapy has a goal of minimizing the radiation dose to healthy tissue.

Dr. McNutt opines that a person of skill in the art would have been motivated to combine these two references because they both describe prostate therapy. *See* RX-0434C (McNutt WS) at Q383. As Dr. Verhey explains, this does not speak to any motivation to combine the specific technological solutions purportedly described by these references. *See* CX-3880C (Verhey RWS) at Q237-38.

Likewise, Dr. McNutt's reasoning that a person of ordinary skill in the art would have been motivated to combine the references because the results would have led to a more desirable radiation therapy system provides no insight into actual motivations to combine. *See* RX-0434C (McNutt WS) at Q383. Neither reference refers to the other, and such shared goals do not indicate that a person of skill in the art would have known or have been motivated to combine these two references to achieve a more desirable system.

Moreover, the *Earl Article* describes the creation of treatment plans for delivery with Elekta linacs using overlapping arcs (RX-233.0007 at 1080), while *Tobler* describes the creation of treatment plans with treatment beam shaping for Varian linacs. *See* RX-234.0003 at 253. As Dr. Verhey explains, inasmuch as treatment plans at that time generally could only be delivered on the brand of linear accelerator for which they were

designed, a person of skill in the art would not have thought to combine a planning method for Elekta machines with a planning method for Varian machines. *See* CX-3880C (Verhey RWS) at Q237-38.

b. Yu '902 and Tobler (Claim 23)

Respondents argue that U.S. Patent No. 5,818,902 "Intensity Modulated Arc Therapy with Dynamic Multi-leaf Collimation," to Cedric Yu, which was filed on March 1, 1996 and issued on October 6, 1998 (RX-0230 ("Yu '902")), in combination with Tobler rendered claim 23 invalid as obvious. *See* Resps. Br. at 255-57. Yu '902 was considered by the examiner during prosecution of the '154 patent. *See* JX-0014.427.

Claim 23 requires delivering a radiation delivery plan that was optimized using the techniques of in claim 19 (McNutt Tr. 795-796; Verhey Tr. 1089-1090), and while varying the dose rate of the linac. *See, e.g.*, RX-0434C (McNutt WS) at Q362; McNutt Tr. 797-798. However, Dr. McNutt admits that *Yu '902* describes an IMAT technique that does not vary the dose rate of the linac and thus, under his own analysis, cannot meet the delivery requirements of claim 23. McNutt Tr. 738-739 (*Yu '902* discloses IMAT); 712-715 (claim 19 requires "variable dose rate VMAT"); and 715 ("delivery of a nonvariable dose rate VMAT treatment plan...does not satisfy the requirement of varying an intensity of the radiation beam over at least a portion of the trajectory."). Moreover, as discussed above, *Tobler* fails to disclose any form of delivery, as required by claim 23. Thus, neither *Yu '902* nor *Tobler* discloses the limitations of claim 23.

In addition, as discussed above with respect to *Earl Article* and *Tobler*, Dr. McNutt admits that none of his prior art references, including *Tobler*, discloses optimizing the dose rate of a treatment plan and delivering radiation according to such a

plan. McNutt Tr. 735-736 (A: "I explained very clearly that none of the algorithms optimize the dose rate."); Verhey Tr. 1137 (confirming that none of the prior art shows or teaches an algorithm for optimizing dose rate) and 1137 (confirming that none of the prior art discloses delivering a variable dose rate treatment plan).

Additionally, Dr. McNutt's purported motivations to combine are unpersuasive, and are not based on the disclosures of these references. *See* CX-3880C (Verhey RWS) at Q258. As Dr. Verhey testified, the references lack a specific connection between them that would provide a reason to combine. *Tobler*, the newer of the two references, does not cite or discuss *Yu '902*. CX-3880C (Verhey RWS) at Q258. Dr. McNutt does not point to any specific connection between these two references that would motivate a person of ordinary skill in the art to combine them because none exists.

c. Earl Article and Yu '902 (Claim 26)

As discussed above, neither the *Earl Article* nor *Yu '902* disclose varying the intensity of the radiation beam, as is claimed in both claim 23 and claim 19, from which claim 26 depends. Thus, the evidence does not show that the combination of the *Earl Article* and *Yu '902* renders claim 26 of the '154 patent as obvious.

d. Earl Article, Tobler and Yu '902 (Claim 26)

As discussed above, neither the *Earl Article*, *Tobler*, nor *Yu '902* discloses varying the intensity of the radiation beam, as is claimed in both claim 23 and claim 19, from which claim 26 depends. Thus, the evidence does not show that the combination of these three references renders claim 26 of the '154 patent as obvious. *See* CX-3880C (Verhey RWS) at Q270.

e. Yu '902 and Tobler (Claim 26)

As discussed above, neither *Yu '902* nor *Tobler* discloses varying the intensity of the radiation beam, as is claimed in both claim 23 and claim 19, from which claim 26 depends. Thus, the evidence does not show that the combination of these two references renders claim 26 of the '154 patent as obvious.

However, as the Staff argues, unlike the other combinations of prior art, the evidence shows that there would have been sufficient motivation to combine Yu '902 and Tobler. One author of Tobler is Dennis D. Leavitt. *See* RX-234.001 (*Tobler*). Dennis Leavitt is also the named inventor on U.S. Patent No. 5,160,847, which is the first reference listed as prior art on the face of *Yu '902*. *See* RX-0230 (Yu '902). This would have provided sufficient motivation to a person of ordinary skill to combine the two references. *See also* RX-0434C (McNutt WS) at Q397.

Nonetheless, given that Yu '902 and Tobler do not disclose every limitation of claim 26, the evidence does not show that the combination renders claim 26 obvious.

VIII. U.S. Patent No. 8,696,538[70]

United States Patent No. 8,696,538 ("the '538 patent"), entitled "Methods and apparatus for the planning and delivery of radiation treatments," issued on April 15,

[70] It is noted that on September 29, 2016, respondents filed a letter requesting the administrative law judge to take judicial notice of "USPTO Institution Decisions, indicating that all asserted claims from the Otto Patents in this Investigation are now currently under review by the Patent Trial and Appeal Board (PTAB) at the U.S. Patent and Trademark Office in four separate *inter partes* review (IPR) proceedings." *See* Letter to Administrative Law Judge re Otto IPRs (emphasis in original) (EDIS Doc. ID No. 591647). On October 4, 2016, complainants filed a "Letter to Judge Shaw regarding Elekta's Request for Judicial Notice" in response to respondents letter. *See* Letter to Judge Shaw regarding Elekta's Request for Judicial Notice (EDIS Doc. ID No. 591922).

2014, to named inventor Karl Otto. JX-0006 ('538 Patent). The '538 patent issued from Application No. 12/986,420, filed on January 7, 2011, which a continuation of Application No. 12/132,597 (now the '154 patent), which is a continuation-in-part of Application No. 11/996,932 (now the '770 patent). *Id.* The '538 patent relates to "radiation treatment," and "particularly to methods and apparatus for planning and delivering radiation to a subject to provide a desired three-dimensional distribution of radiation dose." JX-0006 ('538 Patent) at col. 1, lns. 22-25. The '538 patent has a total of 50 claims.

Complainants allege infringement of, and a domestic industry based on, dependent method claims 26 (which depends from dependent claim 25, which in turn depends from independent claim 23) and 41 (which depends from dependent claim 40, which in turn depends from independent claim 39) of the '538 patent. *See* Compls. Br. at 239-96.

As noted, complainants assert dependent method claims 26 (which depends from dependent claim 25, which in turn depends from independent claim 23) and 41 (which depends from dependent claim 40, which in turn depends from independent claim 39). Those claims read as follows:

> **23**. A method for planning delivery of radiation dose to a target region within a subject, the method comprising:
>
> iteratively optimizing, by a processor, a simulated dose distribution relative to a set of one or more optimization goals comprising a desired dose distribution in the subject over an initial plurality of control points along a trajectory which involves relative movement between a radiation source and the subject;

reaching one or more initial termination conditions, and after reaching the one or more initial termination conditions:

specifying, by the processor, an increased plurality of control points along the trajectory, the increased plurality of control points comprising a larger number of control points than the initial plurality of control points; and

iteratively optimizing, by the processor, a simulated dose distribution relative to the set of one or more optimization goals over the increased plurality of control points to thereby determine a radiation delivery plan;

the radiation delivery plan capable of causing a radiation delivery apparatus to deliver radiation in accordance with the radiation delivery plan;

wherein iteratively optimizing, by the processor, the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points comprises performing, by the processor, the iterative optimization using a set of optimization parameters, the set of optimization parameters representative of one or more of: a beam shape of the radiation source; and a beam intensity of the radiation source.

25. A method according to claim **23** comprising providing the radiation delivery plan to the radiation delivery apparatus.

26. A method according to claim **25** comprising delivering, by the radiation delivery apparatus, radiation in accordance with the radiation delivery plan.

39. A method for planning delivery of radiation dose to a target region within a subject, the method comprising:

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

reaching one or more initial termination conditions, and after reaching the one or more initial termination conditions:

specifying, by the processor, an increased plurality of control points along the trajectory, the increased plurality of control points comprising a larger number of control points than the initial plurality of control points; and

iteratively optimizing, by the processor, a simulated dose distribution relative to the set of one or more optimization goals over the increased plurality of control points to thereby determine a radiation delivery plan;

the radiation delivery plan capable of causing a radiation delivery apparatus to deliver radiation in accordance with the radiation delivery plan;

wherein a start of the trajectory and an end of the trajectory comprise the same relative position between the radiation source and the subject and the trajectory is otherwise non-self overlapping.

40. A method according to claim **39** comprising providing the radiation delivery plan to the radiation delivery apparatus.

41. A method according to claim **40** comprising delivering, by the radiation delivery apparatus, radiation in accordance with the radiation delivery plan.

JX-0006 ('538 Patent) at col. 34, lns. 35-65; col. 35, lns. 8-12; col. 37, lns. 25-58.

A. Claim Construction

1. Applicable Law

Claim construction begins with the plain language of the claim.[71] Claims should be given their ordinary and customary meaning as understood by a person of ordinary

[71] Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vanderlande Indus. Nederland BV v. Int'l Trade Comm.*, 366 F.3d 1311, 1323 (Fed. Cir. 2004); *Vivid Tech., Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

skill in the art, viewing the claim terms in the context of the entire patent.[72] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006).

In some instances, claim terms do not have particular meaning in a field of art, and claim construction involves little more than the application of the widely accepted meaning of commonly understood words. *Phillips*, 415 F.3d at 1314. "In such circumstances, general purpose dictionaries may be helpful." *Id.*

In many cases, claim terms have a specialized meaning, and it is necessary to determine what a person of skill in the art would have understood the disputed claim language to mean. "Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.'" *Phillips*, 415 F.3d at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). The public sources identified in *Phillips* include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* (quoting *Innova*, 381 F.3d at 1116).

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[72] Factors that may be considered when determining the level of ordinary skill in the art include: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

In cases in which the meaning of a claim term is uncertain, the specification usually is the best guide to the meaning of the term. *Phillips*, 415 F.3d at 1315. As a general rule, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). The specification is, however, always highly relevant to the claim construction analysis, and is usually dispositive. *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Moreover, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316.

Claims are not necessarily, and are not usually, limited in scope to the preferred embodiment. *RF Delaware, Inc. v. Pacific Keystone Techs., Inc.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003); *Decisioning.com, Inc. v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1314 (Fed. Cir. 2008) ("[The] description of a preferred embodiment, in the absence of a clear intention to limit claim scope, is an insufficient basis on which to narrow the claims."). Nevertheless, claim constructions that exclude the preferred embodiment are "rarely, if ever, correct and require highly persuasive evidentiary support." *Vitronics*, 90 F.3d at 1583. Such a conclusion can be mandated in rare instances by clear intrinsic evidence, such as unambiguous claim language or a clear disclaimer by the patentees during patent prosecution. *Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc.*, 214 F.3d 1302, 1308 (Fed. Cir. 2000); *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319 (Fed. Cir. 2002).

If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence consists of all evidence external to the

patent and the prosecution history, and includes inventor testimony, expert testimony, and learned treatises. *Phillips*, 415 F.3d at 1317. Inventor testimony can be useful to shed light on the relevant art. In evaluating expert testimony, a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent. *Id.* at 1318. Extrinsic evidence may be considered if a court deems it helpful in determining the true meaning of language used in the patent claims. *Id.*

2. A Person of Ordinary Skill in the Art

Complainants argue:

> In the context of the Otto patents, a person of ordinary skill in the art as of July 2005 would have: (a) at least a post-graduate degree in medicine or at least two years of experience in the field of radiation therapy; and (b) at least a Bachelors of Science in computer science, applied physics, or electrical engineering; or the equivalent to all of the above.
>
> Elekta disagrees, contending that a person of ordinary skill with respect to the Otto patents would require a graduate degree, specifically an M.S. or Ph.D., in medical physics or a related field, for example, Physics or Engineering, and three years of work in radiation oncology beyond the completion of their degree, including at least three years of experience with programming of treatment planning software systems and programming of optimization processes. Elekta's definition requires a person of ordinary skill in the art to have extraordinary and highly specialized skill, and it is inflexible in how that skill is acquired. Both are unnecessary. Physicians or engineers with a Bachelors of Science in computer science, applied physics or electrical engineering and a post-graduate degree in medicine or two years of experience in radiation therapy, or equivalent experience, would have a deep understanding of all the underlying technologies necessary to understand the Otto patents from their education and practical experience in medicine, including knowledge of applied physics, electrical engineering, computer science, radiation medicine, and radiotherapy concepts.

> Elekta's argument for an inflexible, extraordinarily high level of skill is inspired by this litigation rather than by a reasonable interpretation of the Otto patents. Elekta's purpose simply is to attempt to disqualify Varian's infringement expert, Dr. Bergeron. Elekta has failed, however, to identify ***any aspects*** of Dr. Bergeron's opinions or testimony that are unreliable because of his lack of qualifications. Indeed, Dr. Bergeron's witness statement was admitted without objection, and Elekta's own expert (Dr. McNutt) even admitted that he had no technical disagreement with Dr. Bergeron's detailed source code analysis of the accused Elekta systems. Elekta cannot square its inflexible standards for a person of ordinary skill with its failure to identify any substantive deficiencies in Dr. Bergeron's expert analysis.

Compls. Br. at 31-33 (citations omitted) (emphasis in original).

Respondents argue:

> A person of ordinary skill in the art for the Otto patents would be a person with a Master's degree or PhD in medical physics or a related field, such as, physics or engineering. In addition, a skilled person would need to have three years of work in radiation oncology beyond the completion of their degree, including at least three years of experience with programming of treatment planning software systems and programming of optimization processes. A person of skill would need this additional work experience in order to analyze and apply the terms of art that appear in the patents, technical documents, and prior art.

Resps. Br. at 205 (citations omitted).

The Staff argues:

> The Staff agrees with Elekta's definition of a person of ordinary skill in the art. In particular, the Staff is of the view that Varian's proposed level of skill is too low, given the complex algorithms, mathematics, functionality of radiotherapy devices and clinical radiation oncology that one would need understand in order to understand the Otto patents. For example, combinations of Varian's criteria result in level of skill that is simply too low, such as (1) a person with a undergraduate degree in physics and two years or work in "the field of radiation therapy" (which could include many supporting roles that do not involve developing radiation treatment technologies) or (2) a person with a computer science degree and an MD, but no experience in radiation oncology.

> Nevertheless, the Staff is of the view that the differences in the proposed levels of ordinary skill in the art do not significantly impact the substantive issues of the investigation; for example, the parties have not argued that persons of the respective proposed levels of skill in the art would interpret the claims or prior art, or apply the claims to the accused products or domestic industry products differently.

Staff Br. at 90-91 (citations omitted).

As argued by complainants, respondents' proposed definition requires a person of ordinary skill in the art to have extraordinary and highly specialized skill which is not necessary. Physicians or engineers with a bachelor's of science degree in computer science, applied physics or electrical engineering and a post-graduate degree in medicine or two years of experience in radiation therapy, or equivalent experience, would understand the Otto patents.

Thus, as proposed by complainants, the administrative law judge finds that with respect to the Otto patents, a person of ordinary skill in the art as of July 2005 would have: (a) at least a post-graduate degree in medicine or at least two years of experience in the field of radiation therapy; and (b) at least a bachelor's of science degree in computer science, applied physics, or electrical engineering; or the equivalent to all of the above.

3. "initial termination conditions"

Below is a chart showing the parties' proposed claim constructions.

"initial termination conditions"		
Complainants' Construction	**Respondents' Construction**	**Staff's Construction**
"criteria indicating termination of initial optimization"		

See Compls. Br. at 235-36; Resps. Br. at 207; Staff Br. at 112.

The parties have jointly proposed that the construction of "initial termination conditions" should be "criteria indicating termination of initial optimization." Examples of "termination conditions" appear in the specification. For example, "[b]y way of non-limiting example, the termination conditions for block 174 may comprise any one or more of: successful achievement of optimization goals 61 to within a tolerance level which may be particular to the current level; successive iterations not yielding optimization results that approach optimization goals 61: and operator termination of the optimization process." *See* JX-0006 ('538 Patent) at col. 19, lns. 57-65; *see also id.* at column 20 (generally); col. 2, ln. 65 – col. 3, ln. 1 (the method comprises "iteratively optimizing a simulated dose distribution relative to the set of optimization goals to determine one or more radiation delivery parameters associated with each of the initial plurality of control points").

Accordingly, as proposed by the parties, the administrative law judge adopts the joint proposed claim construction and has determined that the claim term "initial termination conditions" should be construed to mean "criteria indicating termination of initial optimization."

4. "radiation delivery apparatus"

Below is a chart showing the parties' proposed claim constructions.

"radiation delivery apparatus"		
Complainants' Construction	**Respondents' Construction**	**Staff's Construction**
"apparatus for delivering therapeutic radiation"		

See Compls. Br. at 235-36; Resps. Br. at 208; Staff Br. at 113.

The parties jointly propose that the construction of "radiation delivery apparatus" should be "apparatus for delivering therapeutic radiation." In this respect, the phrase "radiation delivery apparatus" appears in the specification of the '538 patent. *See* JX-0006 ('538 Patent) at col. 1, lns. 54-46 ("[a] typical radiation delivery apparatus has a source of radiation, such as a linear accelerator, and a rotatable gantry"); col. 2, ln. 42 ("radiation treatment apparatus"); col. 5, lns. 12-21; Fig. 1.

Accordingly, as proposed by the parties, the administrative law judge adopts the joint proposed claim construction and has determined that the claim term "radiation delivery apparatus" should be construed to mean "apparatus for delivering therapeutic radiation."

5. "iteratively optimizing"

Below is a chart showing the parties' proposed claim constructions.

"iteratively optimizing"		
Complainants' Construction	**Respondents' Construction**	**Staff's Construction**
"repeatedly modifying parameters to achieve an optimization goal"		

See Compls. Br. at 235-36; Resps. Br. at 207; Staff Br. at 113.

The parties jointly propose that "iteratively optimizing" should be construed as "repeatedly modifying parameters to achieve an optimization goal." The '538 patent states that "[t]he method comprises ... iteratively optimizing a simulated dose distribution relative to the set of optimization goals to determine one or more radiation delivery parameters associated with each of the initial plurality of control points." *See* JX-0006 ('538 Patent) at col. 2, ln. 58 – col. 3, ln. 1; *see also id.* at col. 11, lns. 28-31 ("In

the illustrated embodiment of method 50, optimization process 54 involves iteratively selecting and modifying one or more optimization variables affecting the beam shape 30 or the beam intensity."); col. 32, lns. 4-8 (claim 1: "iteratively optimizing, by the processor, a simulated dose distribution relative to the set of one or more optimization goals over the increased plurality of control points to thereby determine a radiation delivery plan").

Accordingly, as proposed by the parties, the administrative law judge adopts the joint proposed claim construction and has determined that the claim term "iteratively optimizing" should be construed to mean "repeatedly modifying parameters to achieve an optimization goal."

6. "control point"

Below is a chart showing the parties' proposed claim constructions.

"control point"		
Complainants' Construction	**Respondents' Construction**	**Staff's Construction**
"one or more radiation delivery parameters associated with a portion of the trajectory of the radiation source"	"a set of one or more radiation delivery parameters associated with a point along the trajectory of the radiation source"	"a set of one or more radiation delivery parameters associated with a point along the trajectory of the radiation source"

See Compls. Br. at 236-39; Resps. Br. at 208-12; Staff Br. at 114-17.

For the reasons discussed below, the administrative law judge has determined that the claim term "control point" should be construed to mean "a set of one or more radiation delivery parameters associated with a point along the trajectory of the radiation source."

The parties dispute the construction of the term "control point," which appears extensively throughout the '538 patent. *See* Compls. Br. at 236-39; Resps. Br. at 208-12; Staff Br. at 114-17. The term "control point" appears in claim 68 of the '770 patent and claims 23 (from which asserted claim 26 depends) and 39 (from which asserted claim 41 depends) of the '538 patent. All parties agree that the definition of "control point" should include "one or more radiation delivery parameters." The parties disagree as to whether those parameters are part of a "set" and whether they are associated with a "point" along the trajectory as opposed to a "portion" of the trajectory. *See* RX-495C at Q30.

The terms of a claim are typically given their ordinary and customary meaning as understood by a person of ordinary skill in the art when considered in light of the intrinsic record. *Phillips*, 415 F.3d at 1312-13. The intrinsic record (the claims themselves, the specification, and the prosecution history) is "the most significant source of the legally operative meaning of [the] disputed claim language." *Vitronics*, 90 F.3d at 1582. The intrinsic record of the Otto patents (as well as the extrinsic evidence) supports Elekta's and the Staff's proposed construction.

The intrinsic record supports Elekta's and the Staff's requirements that the radiation delivery parameters be part of "a set." The specification of each of the Otto patents discloses that "[f]or 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." JX-0005 ('770 Patent) at col. 6, lns. 4-7; JX-0006 ('538 Patent) at col. 5, lns. 7-10 (emphasis added). The specification thus uses the term "set" to clarify that a "control point" refers to a collection of one or more parameters as opposed to a random sampling of parameters that are disassociated with one another.

RX-0434C (McNutt WS) at Q211. The term "set" also reflects the requirement of the '538 patent that, even if a control point is a single parameter, other parameters for that control point must be specified and remain constant throughout the duration of delivery. *See* JX-0006 ('538 Patent) at col. 7, ln. 64 – col. 8, ln. 3; RX-0495C (McNutt RWS) at Q48. In other words, the term "set" clarifies that the "one or more radiation delivery parameters" are sufficient to control the machine at that point along the trajectory during delivery.

The specification describes the "control points" as points along a trajectory. For instance, the '770 and '538 patents state 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." JX-0005 ('770 Patent) at col. 7, lns. 50-52; JX-0006 ('538 Patent) at col. 6, lns. 54-56. These "locations" correspond to "points" along the trajectory, not "portions" of the trajectory. RX-0434C (McNutt WS) at Q211. Figure 2 of the '770 and '538 patents further compels this construction. In Figure 2, control points are depicted as points 32. RX-0434C (McNutt WS) at Q211, RX-495C at Q30. Indeed, arrows are used to identify a specific "point" or location on trajectory 30 as corresponding to each control point 32. RX-0434C (McNutt WS) at Q211, RX-495C at Q30.

Construing "control point" to be associated with a "portion" of a trajectory, as Varian propounds, flatly contradicts Figure 2. RX-0434C (McNutt WS) at Q212. Dr. McNutt explained that one of skill in the art would understand the term "portion," unlike the term "point," describes the part of a trajectory existing between control points. *Id.* This understanding flows from the Otto patents, stating that "[i]n other embodiments, the

set of control points 32 are used to define trajectory 30. In such embodiments, ***the portions of trajectory 30 between control points 32*** may be determined." JX-0006 ('538 Patent) at col. 7, lns. 14-18 (emphasis added); JX-0005 ('770 Patent) at col. 8, lns. 10-14 (emphasis added). The intrinsic record thus identifies "control points" as distinct from "portions of [the] trajectory." RX-0434C (McNutt WS) at Q205-12.

Furthermore, Elekta's and the Staff's proposed construction is consistent with the understanding of a person of ordinary skill regarding the meaning of "control points." RX-0434C (McNutt WS) at Q205-212. The term "control point" was, and still is, a standardized term in the radiation therapy field used to refer to the set of radiation delivery parameters, meaning the parameters used to control a therapy machine during radiation delivery at a point along the source's trajectory. RX-0434C (McNutt WS) at Q209; *see also* Otto Tr. 137 (testifying "control point" was a term of art). In other words, a control point is the state of the machine's delivery parameters at a particular instant of the delivery, e.g., an angular point along the rotational trajectory. *Id.* The DICOM RT standard, for example, explains that applicable treatment parameters are specified at a given control point ("Control Point 0"). RX-259.

Similarly, a person of ordinary skill would understand that a control point is not a "portion" of the trajectory. It takes two control points to form a portion (a start point and an end point), and if those points are different, the radiation field may change from one to the next. RX-0434C (McNutt WS) at Q212. *Id.* If a control point was to define a "portion" of the trajectory, that entire "portion" would be static because a single control point only defines one desired state of the machine. *Id.* For example, it takes two control points for the leaves of the MLC, the multileaf collimator, to change the shape of the

treatment beam along a portion of the trajectory. *Id.* Because the shape of the MLC leaves in fact changes over a portion of the trajectory, a control point must be associated with a point along the trajectory rather than a portion. *Id.*; JX-0006 ('538 Patent) at col. 11, lns. 31-36; col. 12, lns. 22-24; col. 7, ln. 66, col. 8, ln. 3; col. 16, lns. 51-53. Multiple control points are required to change the beam shape. *Id.*; RX-0495C (McNutt RWS) at Q34.

In addition, all parties agree that the construction of "control point" should include "one or more radiation delivery parameters." Varian argues that a single radiation delivery parameter is sufficient to control delivery in the recited radiation therapy apparatus. While one parameter alone may constitute a control point, it cannot control delivery. RX-0495C (McNutt RWS) at Q48; Bergeron Tr. 249-254. This is also discussed in more detail below. While there may be instances with only one varying parameter, it must then be assumed that other parameters are specified and just remain constant throughout the duration of delivery. RX-0495C (McNutt RWS) at Q48; McNutt Tr. 776.

As an example, the gantry angle may be the only changing parameter, and so that gantry angle would have to be specified. In that case, all of the other radiation delivery parameters would have been initialized to a desired constant value. RX-0495C (McNutt RWS) at Q48. Even though only one varying parameter is specified, other parameters are present and preset. One of skill in the art would know that for any given couch angle or gantry angle, there necessarily will be an associated treatment amount of radiation that is being delivered to the patient for that couch or gantry angle and/or a beam shape at that angle. RX-0495C (McNutt RWS) at Q48. In other words, there would be at least three

parameters. RX-0495C (McNutt RWS) at Q48. This is confirmed in the Otto patents themselves. JX-0006 ('538 Patent) at Fig. 11A, 11B, col. 4, lns. 29-31, col. 24, ln. 66 – col. 25, ln. 3. Varian's overbroad application of the proposed constructions is contrary to the plain and ordinary meaning in light of the intrinsic record.

B. Infringement Analysis of the '538 Patent

Complainants allege infringement of dependent method claims 26 (which depends from dependent claim 25, which in turn depends from independent claim 23) and 41 (which depends from dependent claim 40, which in turn depends from independent claim 39) of the '538 patent. *See* Compls. Br. at 239-82.

Respondents argue that the accused products do not infringe the asserted claims of the '538 patent. *See* Resps. Br. at 257-85.

The Staff argues that the accused products infringe the asserted claims of the '538 patent. *See* Staff Br. at 119-26.

1. Applicable Law

Under 35 U.S.C. §271(a), direct infringement consists of making, using, offering to sell, or selling a patented invention without consent of the patent owner. The complainant in a section 337 investigation bears the burden of proving infringement of the asserted patent claims by a "preponderance of the evidence." *Certain Flooring Products*, Inv. No. 337-TA-443, Comm'n Notice of Final Determination of No Violation of Section 337, 2002 WL 448690, at *59, (Mar. 22, 2002); *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376 (Fed. Cir. 1998).

Literal infringement of a claim occurs when every limitation recited in the claim appears in the accused device, *i.e.*, when the properly construed claim reads on the accused device exactly.[73] *Amhil Enters., Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1562 (Fed. Cir. 1996); *Southwall Tech. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed Cir. 1995).

If the accused product does not literally infringe the patent claim, infringement might be found under the doctrine of equivalents. "Under this doctrine, a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 21 (1997) (citing *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 609 (1950)). "The determination of equivalence should be applied as an objective inquiry on an element-by-element basis."[74] *Id.* at 40.

"An element in the accused product is equivalent to a claim limitation if the differences between the two are insubstantial. The analysis focuses on whether the element in the accused device 'performs substantially the same function in substantially the same way to obtain the same result' as the claim limitation." *AquaTex Indus. v.*

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[73] Each patent claim element or limitation is considered material and essential. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). If an accused device lacks a limitation of an independent claim, the device cannot infringe a dependent claim. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).

[74] "Infringement, whether literal or under the doctrine of equivalents, is a question of fact." *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1130 (Fed. Cir. 2011).

Techniche Solutions, 419 F.3d 1374, 1382 (Fed. Cir. 2005) (quoting *Graver Tank*, 339 U.S. at 608); *accord Absolute Software*, 659 F.3d at 1139-40.[75]

Prosecution history estoppel can prevent a patentee from relying on the doctrine of equivalents when the patentee relinquished subject matter during the prosecution of the patent, either by amendment or argument. *AquaTex*, 419 F.3d at 1382. In particular, "[t]he doctrine of prosecution history estoppel limits the doctrine of equivalents when an applicant makes a narrowing amendment for purposes of patentability, or clearly and unmistakably surrenders subject matter by arguments made to an examiner." *Id.* (quoting *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1344 (Fed. Cir. 2005)).

2. Accused Products

Complainants argue: "The record evidence establishes that the combination of the Accused Linacs and treatment planning software such as Monaco practices every limitation of claim 26, which include all of the limitations of parent claims 23 and 25, as well the limitation particular to claim 26." Compls. Br. at 239-40. Complainants argue: "The record evidence establishes that the combination of the Accused Linacs and treatment planning software such as Monaco practices every limitation of claim 41, which include all of the limitations of parent claims 39 and 40 as well the limitation particular to claim 41." *See* Compls. Br. at 268.

[75] "The known interchangeability of substitutes for an element of a patent is one of the express objective factors noted by *Graver Tank* as bearing upon whether the accused device is substantially the same as the patented invention. Independent experimentation by the alleged infringer would not always reflect upon the objective question whether a person skilled in the art would have known of the interchangeability between two elements, but in many cases it would likely be probative of such knowledge." *Warner-Jenkinson*, 520 U.S. at 36.

3. Direct Infringement of Accused Linacs

Complainants argue: "The record evidence establishes that the combination of the Accused Linacs and treatment planning software such as Monaco practices every limitation of claim 26, which include all of the limitations of parent claims 23 and 25, as well the limitation particular to claim 26." Compls. Br. at 239-40. Complainants argue: "The record evidence establishes that the combination of the Accused Linacs and treatment planning software such as Monaco practices every limitation of claim 41, which include all of the limitations of parent claims 39 and 40 as well the limitation particular to claim 41." Compls. Br. at 268.

Respondents argue that the accused products do not infringe the asserted claims of the '538 patent. *See* Resps. Br. at 257-85.

The Staff argues that the accused products infringe the asserted claims of the '538 patent. *See* Staff Br. at 119-26.

As noted, complainants assert dependent method claims 26 (which depends from dependent claim 25, which in turn depends from independent claim 23) and 41 (which depends from dependent claim 40, which in turn depends from independent claim 39). Those claims read as follows:

> **23**. A method for planning delivery of radiation dose to a target region within a subject, the method comprising:
>
> iteratively optimizing, by a processor, a simulated dose distribution relative to a set of one or more optimization goals comprising a desired dose distribution in the subject over an initial plurality of control points along a trajectory which involves relative movement between a radiation source and the subject;

reaching one or more initial termination conditions, and after reaching the one or more initial termination conditions:

specifying, by the processor, an increased plurality of control points along the trajectory, the increased plurality of control points comprising a larger number of control points than the initial plurality of control points; and

iteratively optimizing, by the processor, a simulated dose distribution relative to the set of one or more optimization goals over the increased plurality of control points to thereby determine a radiation delivery plan;

the radiation delivery plan capable of causing a radiation delivery apparatus to deliver radiation in accordance with the radiation delivery plan;

wherein iteratively optimizing, by the processor, the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points comprises performing, by the processor, the iterative optimization using a set of optimization parameters, the set of optimization parameters representative of one or more of: a beam shape of the radiation source; and a beam intensity of the radiation source.

25. A method according to claim **23** comprising providing the radiation delivery plan to the radiation delivery apparatus.

26. A method according to claim **25** comprising delivering, by the radiation delivery apparatus, radiation in accordance with the radiation delivery plan.

39. A method for planning delivery of radiation dose to a target region within a subject, the method comprising:

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

reaching one or more initial termination conditions, and after reaching the one or more initial termination conditions:

specifying, by the processor, an increased plurality of control points along the trajectory, the increased plurality of control points comprising a larger number of control points than the initial plurality of control points; and

iteratively optimizing, by the processor, a simulated dose distribution relative to the set of one or more optimization goals over the increased plurality of control points to thereby determine a radiation delivery plan;

the radiation delivery plan capable of causing a radiation delivery apparatus to deliver radiation in accordance with the radiation delivery plan;

wherein a start of the trajectory and an end of the trajectory comprise the same relative position between the radiation source and the subject and the trajectory is otherwise non-self overlapping.

40. A method according to claim **39** comprising providing the radiation delivery plan to the radiation delivery apparatus.

41. A method according to claim **40** comprising delivering, by the radiation delivery apparatus, radiation in accordance with the radiation delivery plan.

JX-0006 ('538 Patent) at col. 34, lns. 35-65; col. 35, lns. 8-12; col. 37, lns. 25-58.

a. Claim 26

As discussed below, the evidence shows that the combination of the Accused Linacs and treatment planning software such as Monaco practices every limitation of claim 26, which includes all of the limitations of parent claims 23 and 25, as well as the limitation particular to claim 26.

(Limitation A) (Claim 23): A method for planning delivery of radiation dose to a target region within a subject, the method comprising

The evidence shows that the combination of Monaco and the Accused Linacs practice a method for planning delivery of radiation dose to a target region within a subject such as a patient or phantom. Dr. Bergeron explained how Monaco can be used to generate a VMAT treatment plan that targets an area of a subject such as a tumor within a patient's body, which can subsequently be delivered to an Accused Linac. *See* CX-3835C (Bergeron WS) at Q77, Q98-100. Dr. Bergeron's opinion is supported by Elekta's [ ] and marketing materials for the Monaco software, which show that Monaco is used to generate a VMAT treatment plan that targets an area within a subject, such as a tumor within a patient's body. *See* CX-1133C.0001 (2013 Premarket Notification 510(k) Monaco RTP System - Executive Summary - Description of Device); CX-3688C.0002 (Monaco 5 Brochure) and CX-3688C.0005. Once a VMAT treatment plan is generated with Monaco it can be transferred to a record and verify system, such as Elekta MOSAIQ, which will then push the plan to the Integrity software on an Accused Linac such as a Versa HD. The Integrity software instructs the Accused Linac to deliver the radiation to the targeted area of the subject according to the plan that was generated with Monaco. *See* CX-3688C.0002 and CX-3688C.005; CX-3686; CX-0279C. Accordingly, the evidence shows that the combination of Monaco and the Accused Linacs practice *Limitation A* of claim 26. Elekta's expert, Dr. McNutt, has not disputed that the Accused '538 Products practice *Limitation A.* Nor has Elekta put forth any evidence to show that the Accused '538 Products do not practice *Limitation A.*

(Limitation B) (Claim 23): iteratively optimizing, by a processor, a simulated dose distribution relative to a set of one or more optimization goals comprising a desired dose distribution in the subject over an initial plurality of control points along a trajectory which involves relative movement between a radiation source and the subject.

The evidence shows that Monaco iteratively optimizes a simulated dose distribution relative to a set of optimization goals, including a desired dose distribution entered by a user, over an initial set of control points along a trajectory. In particular, Dr. Bergeron explained that based on his review of the Monaco documentation and [ ], *Limitation B* is performed by Monaco stage one optimization. *See* CX-3835C (Bergeron WS) at Q77, Q101.

In establishing that *Limitation B* is satisfied, Dr. Bergeron analyzed all of the tasks that are taken by the Monaco software in preparation for stage one optimization, which together show how each of the elements within *Limitation B* are specified, including "one or more optimization goals comprising a desired dose distribution," "the trajectory involving relative movement between the radiation source and the subject," "the initial plurality of control points," and the "simulated dose distribution" that must be iteratively optimized by a processor. *See* CX-3835C (Bergeron WS) at Q101.

Dr. Bergeron analyzed the Monaco documentation showing how a user of the Monaco software can specify "one or more optimization goals, including a desired dose distribution" by creating a [ ] for the patient through the [ ], and inputting a [ ] and [ ] in an attempt to target the tumor while avoiding healthy tissue. *See* CX-3835C (Bergeron WS) at Q78, Q101; *see also, e.g.*, CX-3620.0253, 0585; CX-3690C.469, 1022; CX-3863C.0011.

Dr. Bergeron analyzed the Monaco documentation and source code showing how after selecting VMAT as the delivery mode for the treatment plan, the user specifies a "trajectory" by specifying one or more circular arcs using the Monaco software, each arc up to 360 degrees, that is a full circle or a partial circle that represents the path along which radiation is to be continuously delivered relative to the radiation source and the patient. *See* CX-3835C (Bergeron WS) at Q39, Q78, Q101; *see also, e.g.,* CX-3620.218, 237 to 239; CX-3690C.334, 357-358; CPX-0025C (printed as CX-3683C) at [ ] at lines 140-260, 262-286, [ ] at lines 44-512.

Dr. Bergeron showed how the "initial plurality of control points" and "simulated dose distribution" are specified before iterative optimization begins. In particular, to specify the "initial plurality of control points," Monaco divides the [

], and

[

]. *See* CX-3835C (Bergeron WS) at Q78, Q101; *see also, e.g.*, CX-3620.230, 240-241, 323; CX-3690C.346, 358-361, 538; CX-3862C.002; CX-3861C.046; CX-1135C.137; CX-0308C.106; JX-0047C (Rodriguez Dep. Tr.) at 174-175; CPX-0025C (printed as CX-3683C) at [ ] at lines 114-120, 163-195. Monaco then [ ] "simulated dose distribution" by dividing the [

] and [ ], which Dr. Bergeron explains is a form of dose calculation, [ ]. *See* CX-3835C (Bergeron WS) at Q78-79, Q87, Q101; *see also, e.g.*, CX-3620, 240-242, 323; CX-3690C.360-362, CX-3862C.002-003; CX-3861C.046-047; CX-1135C.137; CX-0308C.106; CPX-0025C (printed as CX-3683C) at [ ] at lines 44- 512,

[ ] at lines 27-93, 221-312, 410-629, tp.h at lines 317-329, [ ] at lines 1126-1152, [ ]. Accordingly, in addition to couch angle, collimator angle and gantry angle, a fluence is associated with the [ ] as well. *Id.*

As Dr. Bergeron explained, the initial plurality (two or more) of control points satisfies the correct claim construction (Elekta and Staff's proposed construction) of "control point." Each of Monaco's initial plurality of control points are "a set of one or more radiation delivery parameters associated with a point along the trajectory of the radiation source" because the same [ ] are also [ ] where Monaco has [ ]. *See* CX-3835C (Bergeron WS) at Q104. Dr. Bergeron analyzed the [ ], which shows that the [ ] associated with a [ ], are further associated with the [ ] when they are [ ] into an [ ]. *See* CX-3835C (Bergeron WS) at Q87-88; CPX-0025C (printed as CX-3683C) at [ ] at line 187. Dr. Bergeron further discussed the [ ], which shows that the [ ] associated with a [ ], when [ ]. Monaco [ ] by [ ]—for each [ ]. *See* CX-3835C (Bergeron WS) at Q89; CPX-0025C (printed as CX-3683C) at [ ] at lines

27-93, 221-312, 410-659, [ ] at lines 317-329, [ ] at lines 1126-1152, [ ].

The evidence shows that the simulated dose distribution is iteratively optimized by Monaco's stage one optimization process over the initial plurality of control points. In particular, Dr. Bergeron analyzed the Monaco documentation showing that Monaco stage one optimization uses a [ ] to iteratively optimize the simulated dose distribution over the [ ] containing the radiation delivery parameters until all the optimization goals have been met or the number of iterations have reached a predefined threshold, thereby [ ] at each of the [ ]—that is, the [ ]. *See* CX-3835C (Bergeron WS) at Q80, Q101; *see also, e.g.*, CX-3620.323, 556; CX3690C.538, 1009. Dr. Bergeron also analyzed the [ ], showing the [ ] that iteratively optimize the dose distribution, executing the [ ]. *See* CX-3835C (Bergeron WS) at Q90; *see also, e.g.*, CPX-0025 (printed as CX-3683C) at [ ] at line 677, [ ], at lines 99-170, [ ] at lines 162-480, [ ] at lines 1530-75.

In addition, Dr. Bergeron, as well as Elekta witness Kevin Brown, and the Monaco documentation and [ ] show that the Accused Linacs are part and parcel of Monaco's stage one iterative optimization process that performs *Limitation B*. In particular, a user or physician can obtain images of the subject using an Accused Linac and import the images into the Monaco software, using them to determine the areas of the subject to target, and thus the "desired dose distribution" for the subject. *See* CX-3835C

(Bergeron WS) at Q80, Q101, CX-0277C.051; CX-3620.785-787, CX-3690C.1172-1173, JX-0025C (Brown Dep. Tr.) at 110-112, 116. In addition, the user must select the Accused Linac on which the radiation treatment plan is intended to be delivered prior to treatment—the particularized parameters of which are used as inputs and constraints on the stage one optimization process. *Id.*; *see also* CX-3620.218, CX-3690C.1144, CX-3862C.002-003, 007-008, CX-3861C.053-054. Dr. Bergeron also analyzed the particular [ ], which repeatedly use the parameters of the linac machine selected for delivery as [ ]. *See* CX-3835C (Bergeron WS) at Q87, Q89; CPX-0025C (printed as CX-3683C) at [ ] at lines 114-120, 147-148, 163-195, 270, [ ] at lines 221-312, 410-659; [ ].

Accordingly, the evidence shows that the combination of Monaco and the Accused Linacs practice *Limitation B* of claim 26.

(Limitation C) (Claim 23): reaching one or more initial termination conditions, and after reaching the one or more initial termination conditions

The evidence shows that Monaco reaches one or more initial termination conditions. As discussed above with respect to *Limitation B*, Dr. Bergeron analyzed the Monaco documentation, deposition testimony from Elekta witnesses, and the [ ] showing that the iterative optimization of the simulated dose distribution will terminate upon particular conditions: either when all the optimization goals specified in the patient's prescription have been met, or after a pre-defined number of iterations of the optimization algorithm have occurred. *See* CX-3835C (Bergeron WS) at Q80, 113;

see also, e.g., CX-3620.323, 556; CX-3690C.538, 1009; CPX-0025C (printed as CX-3683C) at [ ] at lines 99-170, [ ] at lines 162-480.

Accordingly, the evidence shows that the combination of Monaco and the Accused Linacs practices *Limitation C* of claim 26. Dr. McNutt, has not disputed that the accused products practice *Limitation C.* Nor has Elekta put forth any evidence to show that the accused products do not practice *Limitation C.*

(Limitation D) (Claim 23): specifying, by the processor, an increased plurality of control points along the trajectory, the increased plurality of control points comprising a larger number of control points than the initial plurality of control points; and

The evidence shows that after Monaco stage one optimization is complete, Monaco specifies an increased plurality of control points along the one or more arcs defining the trajectory, and thus more control points than were optimized over during Monaco stage one optimization.

In his witness statement Dr. Bergeron analyzed the Monaco documentation and [ ] showing that after Monaco [ ], Monaco then starts to prepare for a second stage of optimization by [ ]. In particular, Monaco divides [ ]. Monaco then assigns a control point to the [ ], thus associating these radiation delivery parameters with [ ] as well as the control points at the

[ ]. *See* CX-3835C (Bergeron WS) at Q80, 91, 118; *see also, e.g.*, CX-3620C.233, 324, 329-330; CX-3690C.363, 539, 546-547; CPX-0025C (printed as CX-3683C) at [ ] at lines 900-925, [ ] at lines 64-182, 480-700, [ ] at lines 67-198, [ ].

As Dr. Bergeron explained, the control points that are specified by Monaco's [ ] contains a larger number of control points than the control points which were part of stage one optimization because the number of control points during stage one directly corresponded to the [ ]. *See* CX-3835C (Bergeron WS) at Q122. After the first stage of optimization, those [ ]. As Dr. Bergeron testified, the [ ] specifically ensures that there are a [ ]. *See* CX-3835C (Bergeron WS) at Q118; CPX-0025C (printed as CX-3683C) at [ ], at lines 171-179. In addition, as discussed above, the user specifies the [ ], which is used to [ ], and thus the number of control points for stage one optimization, and further specifies [ ], which determines the [ ], and thus the number of control points for stage two optimization. Monaco's documentation explicitly recommends [ ] (resulting in 8 to 14 control points) for stage one, but recommends [ ], thus recommending a number of control points for stage one that is an order of magnitude lower than stage two. *See* CX-3835C (Bergeron WS) at Q122; CX-3620.242-243, 329-330; CX-3690C.362-363, 546-547.

Dr. Bergeron also analyzed the Monaco documentation showing that the Accused Linacs are involved in the specification of the increased plurality of control points

because the [ ] setting for the Accused Linac selected for delivery of the VMAT treatment plan is used as a constraint on the [ ], and thus the total number of control points allowed. *See* CX-3835C (Bergeron WS) at Q118; CX-3862C.007; 3681C.0051.

Accordingly, the evidence shows that the combination of Monaco and the Accused Linacs practice *Limitation D* of claim 26.

(Limitation E) (Claim 23): iteratively optimizing, by the processor, a simulated dose distribution relative to the set of one or more optimization goals over the increased plurality of control points to thereby determine a radiation delivery plan.

The evidence shows that after [ ] occurs, Monaco's stage two optimization process will optimize the simulated dose distribution relative to the one or more optimization goals over the increased plurality of control points, *i.e.*, [ ] in order to determine a radiation delivery plan.

In his witness statement, Dr. Bergeron analyzed the Monaco documentation and [ ] showing how—after [ ] is complete, after the creation of the increased plurality of control points has occurred, and prior to stage-two optimization—another "simulated dose distribution" is generated. *See* CX-3835C (Bergeron WS) at Q125; CX-3620.324; CX-3690C.539; CX-1136C.043-049; CPX-0025C (printed as CX-3683C) at [ ] at lines 85-9, 936-951, [ ] at lines 333-428, [ ] at lines 317-329, [ ] at lines 1126-1152, [ ].

Dr. Bergeron explained that Monaco begins the second stage of optimization by

optimizing the dose distribution using the same [ ] that was used for stage one optimization and one or more of the optimization goals specified by the user as [ ], but this time optimizing the dose distribution over the increased set of control points, i.e., [ ] that are associated with each [ ], until the optimization goals are met or the predefined number of iterations are reached. *See* CX-3835C (Bergeron WS) at Q125-127. The Monaco documentation and source [ ] Dr. Bergeron's analysis. *See* CX-3620.324, 610; CX-3690C.539, 1046; CX-3861C.0036, CX-0254.008, CPX-0025C (printed as CX-3683C) at [ ] at lines 99-170, [ ] at lines 34-54, 162-480, [ ] at lines 548-563.

In addition, as Dr. Bergeron, the Monaco documentation, and the [ ] show, just as with stage one optimization, the parameters of the Accused Linac selected for delivery of the VMAT treatment plan are [ ] the stage two optimization process. *See* CX-3835C (Bergeron WS) at Q125; CX-3620.847-848; CX3690C.1144-1145; CX-3862C.007-008; CX-3861C.0051-0052; CPX-0025C (printed as CX-3683C) at [ ] at lines 64-182, [ ] at lines 162-460, [ ].

Accordingly, the evidence shows that the combination of Monaco and the Accused Linacs practice *Limitation E* of claim 26.

(Limitation F) (Claim 23): the radiation delivery plan capable of causing a radiation delivery apparatus to deliver radiation in accordance with the radiation delivery plan

The evidence shows that a VMAT radiation delivery plan generated by Monaco is

capable of causing an Accused Linac to deliver radiation in accordance with that plan. Dr. Bergeron explained in his witness statement how the evidence shows that after VMAT plans generated by Monaco can be pushed to a linac using a record and verify system such as MOSAIQ. A user can then transfer the plan from the record and verify system to the Integrity software on an Accused Linac, which ensures that the Accused Linac delivers the radiation in accordance with the VMAT treatment plan generated by Monaco. *See* CX-3835C (Bergeron WS) at Q131; *see also, e.g.,* CX-3688C.002, 005; CPX-0036.0:51; CX-3680C.48; JX-0025C (Brown Dep. Tr.) 17, 20; JX-0055C (Smith Dep. Tr.) at 73-74. Accordingly, the evidence shows that the combination of Monaco and the Accused Linacs practice *Limitation F* of claim 26. Dr. McNutt has not disputed that the Accused '538 Products practice *Limitation F.* Nor has Elekta put forth any evidence to show that the Accused '538 Products do not practice *Limitation F.*

(Limitation G) (Claim 23): wherein iteratively optimizing, by the processor, the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points comprises performing, by the processor, the iterative optimization using a set of optimization parameters, the set of optimization parameters representative of one or more of: a beam shape of the radiation source; and a beam intensity of the radiation source

The evidence shows that Monaco's stage one optimization process, which as discussed above iteratively optimizes the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points, uses a set of optimization parameters representative of a beam shape as well as a beam intensity.

As Dr. Bergeron explained in his witness statement, and the Monaco documentation shows, the stage one optimization process [

], the [

]. One of the parameters that is input into the stage one optimization process is the [ ]. Monaco defines the [ ] based on the MLC of the Accused Linac selected for delivery—the MLC determines the shape of the beam when it is actually delivered. Thus, as Dr. Bergeron concluded and the Monaco documentation shows, the optimization parameter of [ ] used for stage one iterative optimization over the initial plurality of control points is representative of beam shape. *See* CX-3835C (Bergeron WS) at Q134; *see also, e.g.,* CX-3620.323, 570; CX-3690C.538, 1014.

Separately, as discussed above, and the record evidence shows, [ ] and optimized during Monaco stage one optimization. *See* CX-3835C (Bergeron WS) at Q134; *see also, e.g.,* CX-3620.323, 570; CX-3690C.538, 1014; CPX-0025C (printed as CX-3683C) at [ ] at lines 34-54, [ ] at lines 548-563, [ ] at lines 863-879. Dr. Bergeron explained that a fluence is a form of dose calculation that is representative of beam shape and beam intensity. CX-3835C (Bergeron WS) at Q134.

Accordingly, the evidence shows that the combination of Monaco and the Accused Linacs practice *Limitation G* of claim 26.

Limitation H (Claim 25). A method according to claim 23 comprising providing the radiation delivery plan to the radiation delivery apparatus

The evidence shows that a VMAT radiation delivery plan generated by Monaco is provided to an Accused Linac, which is the radiation delivery apparatus.

In particular, Dr. Bergeron analyzed the evidence showing that VMAT plans generated by Monaco are packaged up in the DICOM file format, then pushed to a linac

using a record and verify system such as MOSAIQ. A user can then transfer the plan from the record and verify system to the Integrity software on an Accused Linac. *See* CX-3835C (Bergeron WS) at Q138; *see also, e.g.,* CX-3688C.005; CX-3620.791; CX-3690C.1176; CX-0279C.0002-0003; CPX-0027C (printed as CX-3683C) at [ ]; JX-0025C (Brown Dep. Tr.) at 27-28; JX-0055C (Smith Dep. Tr.) at 52-53, 73-74. Accordingly, the evidence shows that the combination of Monaco and the Accused Linacs practices *Limitation H* of claim 26. Dr. McNutt does not offer any additional noninfringement arguments for *Limitation H.*

Limitation I (Claim 26). A method according to claim 25 comprising delivering, by the radiation delivery apparatus, radiation in accordance with the radiation delivery plan.

The evidence shows that once a VMAT treatment plan generated by Monaco has been delivered to an Accused Linac, the Accused Linac will deliver radiation in accordance with that VMAT treatment plan. Dr. Bergeron analyzed documentation and video demonstrations for Monaco and the Accused Linacs, the [ ] for the Accused Linac Integrity software, and deposition testimony of Elekta witnesses, showing that the Accused Linacs will deliver radiation according to VMAT treatment plans generated by Monaco. *See* CX-3835C (Bergeron WS) at Q142; *see also, e.g.,* CX-3688C.005; CX-0279C.0002-0003; CPX-0044; CPX-0027C (printed as CX-3683C) at [ ]; JX-0025C (Brown Dep. Tr.) 17, 27-28; JX-0055C (Smith Dep. Tr.) at 52-53, 73-74. Accordingly, the evidence shows that the combination of Monaco and the Accused Linacs practice *Limitation I* of claim 26. Dr. McNutt does not offer any additional noninfringement arguments for *Limitation I.*

Accordingly, the evidence shows that the combination of the Monaco treatment planning software and each of the Accused Linacs meets each limitation of Claim 26 of the '538 patent.

b. Claim 41

For the reasons discussed below, the evidence shows that the combination of the Accused Linacs and treatment planning software such as Monaco practices every limitation of claim 41, which include all of the limitations of parent claims 39 and 40 as well the limitation particular to claim 41.

All of the *Limitations A* through *I* of claim 41 are verbatim the same as the *Limitations A* through *I* of claim 26 of the '538 patent except for *Limitation G*. *See* CX-3835C (Bergeron WS) at Q209-210. Accordingly, the same evidence discussed above establishing that the combination of the Monaco treatment planning software and the Accused Linacs practices *Limitations A* through *F* and *H* through *I* of claim 26, also establishes that the combination of the Monaco treatment planning software and the Accused Linacs practices *Limitations A* through *F* and *H* through *I* of claim 41. *See* CX-3835C (Bergeron WS) at Q40, Q147-152; *see also* CX-3875C.

The only limitation that differs between claim 26 and claim 41 is *Limitation G* of claim 41, which appears in unasserted claim 39 upon which claim 41 depends. The evidence shows that the combination of the Monaco treatment planning software and the Accused Linacs practices *Limitation G* of claim 41.

(Limitation G) (Claim 39): wherein a start of the trajectory and an end of the trajectory comprise the same relative position between the radiation source and the subject and the trajectory is otherwise non-self overlapping

The evidence shows that the trajectory that is defined by Monaco may be a single 360-degree arc, that is a full circle that overlaps only at the ends such that the start and end of the trajectory will be at the same position between the radiation source and the subject, but the trajectory is otherwise non-self overlapping.

As Dr. Bergeron testified in his witness statement, the ability of a user to define a full 360-degree circle as a trajectory is exemplified in the Monaco documentation and [ ], which clearly shows that a user can create a single arc that is exactly 360 degrees. That documentation even recommends a [ ]. *See* CX-3835C (Bergeron WS) at Q153; CX-3620.238-239; CX-3690.357-358; CPX-0025C (printed as CX-3683C) at [ ], at lines 197-201. [ ]. *See, e.g.*, JX-0047C ([ ] Dep. Tr.) at 155-157; JX-0023C ([ ] Dep. Tr.) at 116-117; JX-0034C ([ ] Dep. Tr.) at 59, 64. Dr. Bergeron also analyzed the documentation, videos and deposition testimony from Elekta witnesses regarding the Accused Linacs, which shows that the Accused Linacs can execute VMAT treatment plans that deliver radiation in a single 360-degree arc. *See* CX-3835C (Bergeron WS) at Q153; *see also, e.g.,* CX-3680C.131, 236; CX-0279C.002; CPX-0008C.4:28; JX-0055C (Smith Dep. Tr.) at 73, 80, 82. Accordingly, the evidence shows that the combination of Monaco and the Accused Linacs practice *Limitation G* of claim 41.

Accordingly, the evidence shows that the combination of the Monaco treatment planning software and each of the Accused Linacs meet each limitation of Claim 41 of the '538 patent.

c. Direct Infringement of Accused Products by Respondents: Claim Term "subject"

As discussed above in the infringement section of the '154 patent, the Commission has previously determined that performance of a claimed method directly by a respondent is not proof of a violation under section 337. *See Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, 337-TA-724, Comm'n Op. at 14, 17-19 (Nov. 21, 2011). Thus, performance of claim 19 by respondents, whether on a patient or a dummy, is not sufficient to prove a violation under section 337.

Elekta argues that claims 26 and 41 are not infringed because they are directed to a method "within a subject," but Varian has no proof that Elekta ever performed the claimed methods "within a subject," that is, on an actual patient. *See* Resps. Br. at 283-84. The administrative law judge agreed with Elekta's similar argument with respect to the '154 patent. However, as to the '538 patent, the administrative law judge disagrees with Elekta. Claim 19 of the '154 patent was for "[a] method for *delivering* a radiation dose to a target area within a subject," whereas claims 26 and 41 of the '538 are for "[a] method for *planning* delivery of a radiation dose to a target region within a subject." Inasmuch as the claims of the '538 patent are for planning, rather than delivery, direct infringement could be shown without actual treatment of a patient.

4. Indirect Infringement

As discussed below, the evidence shows that Elekta's customers directly infringes claims 26 and 41 of the '538 patent in the United States when: (a) testing how to create and deliver VMAT treatment plans using a combination of the Monaco software and an Accused Linac; (b) receiving training from Elekta on how to create and deliver VMAT treatment plans using Monaco and an Accused Linac; and (c) treating patients by creating and delivering VMAT treatment plans using Monaco and an Accused Linac.

Testing

As discussed above, and as Dr. Bergeron explained, Elekta performs testing of Monaco and the Accused Linacs that a customer has purchased at the customer site, including the creation and delivery of a VMAT treatment plan – but Elekta performs this testing in concert with the customer. *See* CX-3835C (Bergeron WS) at Q171. For example, [ ] testified that an [ ] performed the [ ]. *See* JX-0034C [ ] Dep. Tr.) at 100. Accordingly, the evidence shows that Elekta's customers directly infringe claims 26 and 41 in the United States when they perform testing of the creation and delivery of a treatment plan after purchasing Monaco and one or more Accused Linacs.

Training

As discussed above, and as Dr. Bergeron testified, Elekta provides training to its customers in the United States on Monaco, MOSAIQ, VMAT planning and VMAT delivery on a linear accelerator, either at the customer site or at Elekta's training facilities in Atlanta, Georgia. *See* CX-3835C (Bergeron WS) at Q175; *see also, e.g.*, CX-

3768C.013, 018, 024-025; JX-0056C (Symons Dep. Tr.) at 208, 244-245, 246-248, 250-251. [ ] show that [ ]. *See* CX-1109C [ ]; CX-1110C ([ ]); CX-1113C ([ ]); CX-1125C ([ ]); CX-1127C ([ ]); CX-3706C ([ ]). Further, [ ] testified that its employees actually received training in the United States on how to create a VMAT treatment plan with Monaco and how to deliver that treatment plan on the Accused Linacs. *See, e.g.*, JX-0034C ([ ] Dep. Tr.) at 82-84, 86-87, 89.

Accordingly, the evidence shows that Elekta's customers directly infringed claims 26 and 41 of the '538 patent in the United States when receiving training on how to use the combination of Monaco and the Accused Linacs in the United States to create and deliver VMAT treatment plans.

Treating Patients

As discussed above, [ ]. *See* CX-1109C; CX-1110C; CX-1113C; CX-1125C; CX-1127C; CX-3706C. As Dr. Bergeron testified, it is highly unlikely customers would have [ ], and not have used that functionality. *See* CX-3835C (Bergeron WS) at Q179. Moreover, [ ], one of Elekta's customers that had purchased Monaco and a number of Accused Linacs, admitted to repeatedly creating VMAT treatment plans using Monaco and delivering them on an Accused Linac in order to treat patients at their facilities. CX-3835C

(Bergeron WS) at Q179; *see also, e.g.,* JX-0034C ([ ] Dep. Tr.) at 24, 26- 29, 103-105. Accordingly, the evidence shows that Elekta's customers directly infringed claims 26 and 41 in the United States when creating a VMAT treatment plan using Monaco and delivering that treatment plan to a patient using an Accused Linac.

Accordingly, the evidence shows that Elekta's customers directly infringe claims 26 and 41 of the '538 patent when they perform testing, training, or actually treat patients by creating and delivering VMAT plans using the accused products in the United States.

Inducement

Dr. Bergeron cited substantial evidence showing that Elekta encourages its customers to create and deliver VMAT treatment plans using a combination of Monaco software and an Accused Linac – that is, encouraging its customers to practice each limitation of claims 26 and 41, including through advertisements on its website, marketing materials and presentations; white papers, user guides, training guides, Instructions for Use and other technical manuals; live and video demonstrations and animations; [ ]; technical support for customers, training for customers, and warning customers that it will disclaim liability for damages from the customers' failure to follow Elekta's guidance. *See* CX-3835C (Bergeron WS) at Q186; *see also, e.g.*, CX-3684C; CX-1135C; CX-3589; CX-3872; CX-3870; CX-3584; CX-3622C; CX-1135C; CX-1148C; CX-3680C; CX-0251C; CX-0279C; CX-0233C; CPX-0008; CPX-0009; CPX-0030 to CPX-0031; CPX-0033; CX-0036 to CPX-0039; CPX-0042 to CPX-0043; CPX-0046; CX-0299C; CX-3620.469-85, 487-89, 536; CX-3690C.612-632, 730; CX-3697C; CX-0299C; CX-1133C; CX-3689; CX-3685; CX-3768C; CX-0308C.3; CX-0233C; CX-0357C; CX-1113C; JX-0025C (Brown Dep. Tr.) at

167-168; JX-0056C (Symons Dep. Tr.) at 215-217; 223, 229-231, 256. Neither Elekta nor Dr. McNutt dispute that these materials encourage customers to perform the functionality discussed above that practices claims 26 and 41 of the '538 patent.

Further, Elekta knew that it was encouraging customers to infringe, and thus had the requisite specific intent. In particular, Dr. Bergeron testified that Elekta had knowledge of its infringement of the '538 patent as early as March 3, 2015 when Varian informed Elekta of its infringement of the '538 patent, and was informed yet again when it received the Complaint in this Investigation. Yet, Elekta continued to encourage customers to use the accused functionality, and continues to do so today. *See* CX-3835C (Bergeron WS) at Q187. Thus, the evidence shows that Elekta indirectly infringes claims 26 and 41 of the '538 patent by actively inducing customers in the United States to create VMAT treatment plans and deliver them using a combination of the Monaco software and an Accused Linac.

Contributory Infringement

The evidence shows that Elekta contributes to customers' infringement of claims 26 and 41 in the United States by importing the Accused Linacs into the United States, which as discussed above, are used by Elekta's customers in the United States, in combination with the Monaco treatment planning software, to practice claims 26 and 41 of the '538 patent.

As explained by Dr. Bergeron, customers use the Accused Linacs that are imported into the United States in combination with Monaco to create and deliver VMAT treatment plans in the United States. Dr. Bergeron further concluded that the Accused Linacs do not have a substantial noninfringing use after they are imported into the United

States because they are specifically designed and adapted to deliver VMAT treatment plans – which is one of the major reasons Elekta's customers purchase the Accused Linacs. *See* CX-3835C (Bergeron WS) at Q191-195; *see also, e.g.*, JX-0025C (Brown Dep. Tr.) at 17; JX-0055C (Smith Dep. Tr.) at 52-53, 138-139.

Dr. McNutt opines that the accused products are staple articles of commerce suitable for substantial noninfringing use for three reasons: (a) the Accused Linacs can be used to deliver non-VMAT treatment plans; (b) Monaco is not imported, only the Accused Linacs are imported; and (c) the Accused Linacs can be used with Varian's treatment planning software and Monaco's treatment planning software can be used with the Elekta linacs. RX-0495C (McNutt RWS) at Q260-65. Dr. McNutt is incorrect.

The contributory infringement inquiry focuses on whether there are substantial noninfringing uses for the particular functionality that practices the claims at issue, not the functionality of the device as a whole. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1312 (Fed. Cir. 2005) ("In order to succeed on a claim of contributory infringement, in addition to proving an act of direct infringement, plaintiff must show that defendant knew that the combination for which its components were especially made was both patented and infringing and that defendant's components have 'no substantial non-infringing uses.'") (quotations omitted); *see also Lucent Techs., Inc. v. Gateway, Inc.*, 580 F. 3d 1301, 1321 (Fed. Cir. 2009) (holding that inclusion of an accused feature within a larger device does not change the accused functionality's ability to infringe). Accordingly, Dr. McNutt is incorrectly focusing on the linac and Monaco as a whole, instead of the functionality that practices claims 26 and 41 of the '538 patent: the creation and delivery of VMAT treatment plans using Monaco and the Accused

Linacs. As discussed above in connection with Elekta's contributory infringement of the '154 patent, Monaco is also developed to work with and has specific documentation and [ ] tied to the Accused Linacs, using the parameters specific to the Accused Linacs as inputs into its multi-stage optimization process for VMAT plans. In turn, the Accused Linacs are adapted to work with the Monaco software because their parameters have been [ ]. *See* CX-3835C (Bergeron WS) at Q101, 118, 125; *see also, e.g.*, CX-3862C.007; CX-3861C.0051; CPX-0025C (printed as CX-3683C) at [ ] at lines 114-120, 147-148, 163-195, 270, [ ] at lines 221-312, 410-659, [ ] at lines 64-182, [ ] at lines 162-460, [ ].

Accordingly, the evidence shows that Elekta indirectly infringes claims 26 and 41 of the '538 patent by contributing to its customers' infringement of claims 26 and 41 when selling Accused Linacs which are especially adapted to be combined with Monaco to create VMAT treatment plans and deliver them.

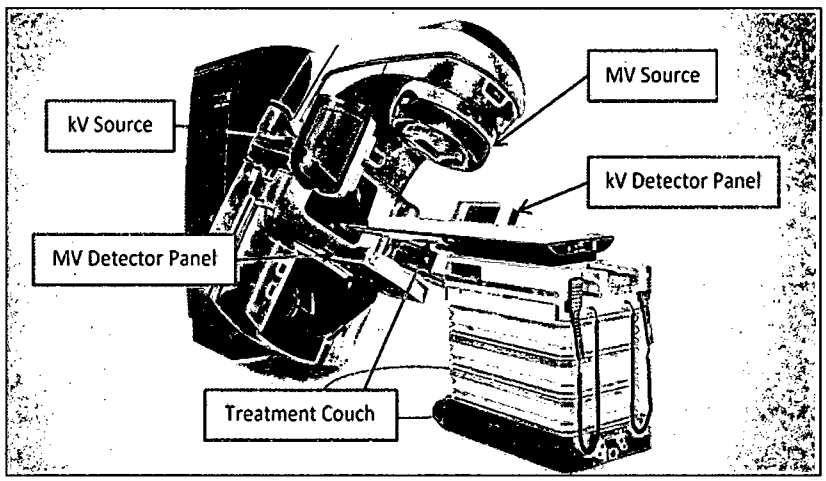
C. Domestic Industry (Technical Prong)

Complainants allege domestic industry based on dependent method claims 26 (which depends from dependent claim 25, which in turn depends from independent claim 23) and 41 (which depends from dependent claim 40, which in turn depends from independent claim 39) of the '538 patent. *See* Compls. Br. at 282-96.

Varian's Clinac iX and TrueBeam Linacs

Varian's domestic industry products include the Clinac iX and Trilogy linac systems when used with the On-Board Imager system, and the TrueBeam and Edge linac

systems. *See, e.g.*, CX-0848C (Mutic WS) at Q289. Varian's linacs are integrated and networked computer-controlled systems used to perform imaging and implement radiotherapy treatments, such as treatment plans generated by Varian's RapidArc VMAT planning software. *See, e.g.*, CX-0848C (Mutic WS) at 289; CX-3835C (Bergeron WS) at Q11. They all function similarly and their basic configuration is the same: a rotatable gantry with a high-energy MV source and opposing MV flat-panel imager and an orthogonal kV source and opposing kV flat-panel imager coupled to the gantry, as shown with respect to the Clinac iX. *See, e.g.*, CX-3835C (Bergeron WS).



The Clinac iX and Trilogy systems optionally include the "On-Board Imager," a kV imaging system used with the linacs. *See, e.g.*, CX-0848C (Mutic WS) at 298-300, 312-14. The integrated kV imaging system of the TrueBeam and Edge systems is called the "X-Ray Imaging System." *See, e.g.*, CX-0848C (Mutic WS) at 331-33, 366-67, 377-79.

RapidArc

RapidArc is a VMAT treatment technology sold by Varian. It includes both

treatment planning and treatment delivery components. For treatment planning, it consists of optimization algorithms used within Eclipse for developing VMAT treatment plans. For treatment delivery, it consists of hardware modifications to TrueBeam (including Edge) and Clinac (including Clinac iX and Trilogy) treatment delivery platforms to enable delivery of VMAT treatment plans. During these VMAT treatments, the delivering linac varies both the dose rate and beam shape while moving in a trajectory around the patient and delivering radiation. *See* CX-3835C (Bergeron WS) at Q224.

Claims 26 and 41

Varian's Domestic Industry Products practice claims 26 and 41 of the '538 patent. As with the '154 patent, the Domestic Industry Products for the '538 patent include Varian's TrueBeam and Clinac linear accelerators in combination with Varian's Eclipse treatment planning software that is used to create and deliver RapidArc treatment plans. *See* CX-855C, Zankowski at Q29-30, 44-58. RapidArc plans are optimized using the Progressive Resolution Optimization (PRO) algorithm, based directly on Dr. Otto's work. *See* CX-0853C, Pyyry at Q17; CX-3835C (Bergeron WS) at Q241-242; CX-0378C.204; CX-0379.2; CDX-0495C; CX-0496. Two versions of the PRO algorithm are used in Varian's Domestic Industry Products: PRO2 and PRO3. *See* CX-3835C (Bergeron WS) at Q243.

Claim 26

(Limitation A) (Claim 23)

The Domestic Industry Products perform a method for planning delivery of radiation dose to a target region within a subject. The Eclipse treatment planning

software allows an operator to create and optimize radiation treatment plans to irradiate specific patient target volumes. RapidArc treatment plans use the PRO algorithm to optimize the dose distribution delivered to the patient target volume. After a RapidArc treatment plan is optimized and approved for delivery, it is exported to a DICOM file. The DICOM files are provided to the TrueBeam and Clinac linear accelerators, which read the DICOM files and generate instructions to implement the treatment plans. *See* CX-3835C (Bergeron WS) at Q288; CX-1661C.130-144; CX-0378C.204-205.

(Limitation B) (Claim 23)

The Domestic Industry Products perform the step of "iteratively optimizing, by a processor, a simulated dose distribution relative to a set of one or more optimization goals comprising a desired dose distribution in the subject over an initial plurality of control points along a trajectory which involves relative movement between a radiation source and the subject." The Eclipse treatment planning software executes on a computer processor. When creating a RapidArc treatment plan, the Eclipse software receives as input a set of one or more optimization goals comprising a desired dose distribution for a patient target volume and surrounding healthy tissue. The goals include maximum and minimum radiation limits for patient target volumes including tumors and surrounding healthy tissue. The software also receives as an input an "arc geometry" defining a trajectory that the radiation source will follow relative to the patient during treatment. *See* CX-3835C (Bergeron WS) at Q290; CX-1661C.130-144; CX-1683C.7-8; CDX-0485C-0490C.

After the arc geometry is defined, the software causes the processor to optimize the treatment plan using the PRO algorithm. The PRO algorithm optimizes a simulated

dose distribution along the treatment trajectory relative to the clinical objectives input into the Eclipse software, including the desired dose distribution. The clinical objectives are embodied in a cost function. The PRO algorithm includes multiple levels of optimization, called MR levels, and each MR level includes a series of iterations where the simulated dose distribution is optimized. At each iteration, the PRO algorithm attempts to improve the cost function by adjusting dose amounts and MLC leaf positions at different points along the trajectory. *See* CX-0853C, Pyyry at Q21, 31; CX-3835C (Bergeron WS) at Q290; CX-0378C.204-05; CX-0379.2-4; CX-1661C.95, 137-145; CDX-0491C-0493C.

There are two versions of the PRO algorithm in the Domestic Industry Products: PRO2 and PRO3. The PRO2 algorithm includes five levels of optimization, referred to as "MR levels." In the first MR level, the trajectory is divided into a number of Dose Calculation Sectors, each defining a dose amount, or intensity, for the portion of the trajectory represented by the sector. The trajectory also contains a number of Fluence Control Points defining MLC leaf positions for a point along the trajectory. Within the first MR level, the PRO2 algorithm [

]. It then calculates a dose distribution and compares it to the cost function. When convergence of the cost function is reached within the first MR level, or when a predetermined number of iterations has occurred, the algorithm progresses to the second MR level. *See* CX-0853C, Pyyry at Q21-26; CX-3835C (Bergeron WS) at Q243-256, 290; CX-0379.2-4.

The PRO3 algorithm includes four MR levels of optimization. In the first MR level, the treatment trajectory is divided into a number of Dose Calculation Sectors, each

having a dose amount for the portion of the trajectory represented by the sector. The treatment trajectory also includes a fixed number of Fluence Control Points defining MLC leaf positions associated with a point along the trajectory. The treatment trajectory also includes by a number of Dose Control Points positioned at the center of each Dose Calculation Sector. Each Dose Control Point stores a dose distribution that is calculated as a function of the dose amount of the Dose Calculation Sector and the sequence of MLC leaf positions stored in the Fluence Control Points within the sector. Within the first MR level, the PRO3 algorithm [

]. It then calculates a dose distribution at the Dose Control Points, and compares the dose distribution to the cost function. When convergence of the cost function is reached within the first MR level, or when a predetermined number of iterations has occurred, the algorithm progresses to the second MR level. *See* CX-0853C, Pyyry at Q39-51; CX-3835C (Bergeron WS) at Q261-272, 290; CX-0378C.204-205; CX-0379.2-4; CX-1661C.24-27 and 95.

Dr. Bergeron testified that the Fluence Control Points and Dose Calculation Sectors in PRO2 are each an "initial plurality of control points" under each party's proposed construction of the term "control point." *See* CX-3835C (Bergeron WS) at Q290-302. He also testified that, in PRO3, the Dose Calculation Sectors and Dose Control Points are each an initial plurality of control points under each party's construction. *Id.* at Q303-312.

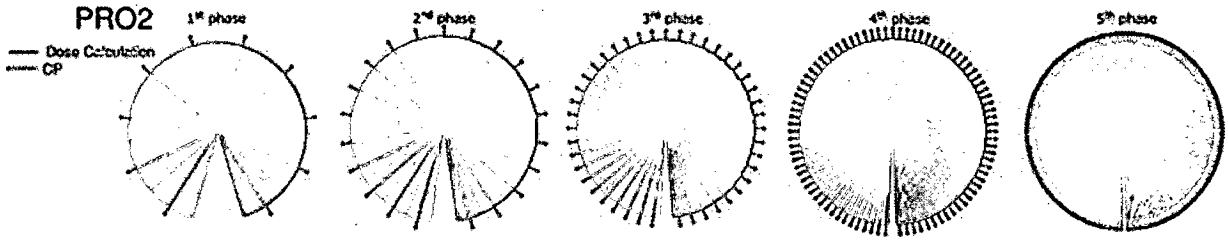
(Limitation C) (Claim 23)

The Domestic Industry Products perform the step of "reaching one or more initial

termination conditions, and after reaching the one or more initial termination conditions." In both PRO2 and PRO3, the optimization algorithm calculates a three-dimensional dose distribution and compares it to the cost function to determine whether the iterative adjustments to dose amounts and MLC leaf positions have moved the treatment plan closer to or further away from the clinical objectives. If several adjustments in a row do not lower the cost function by a sufficient amount, the cost function is determined to have converged. If the cost function has converged, or if the algorithm has progressed through a specified number of iterations, then the algorithm moves to the next MR level. *See* CX-0853C, Pyyry at Q23-26, 49-52; CX-3835C (Bergeron WS) at Q313; CX-0378C.204-205; CX-0379.3-4; CX-1661C.24-27, 95.

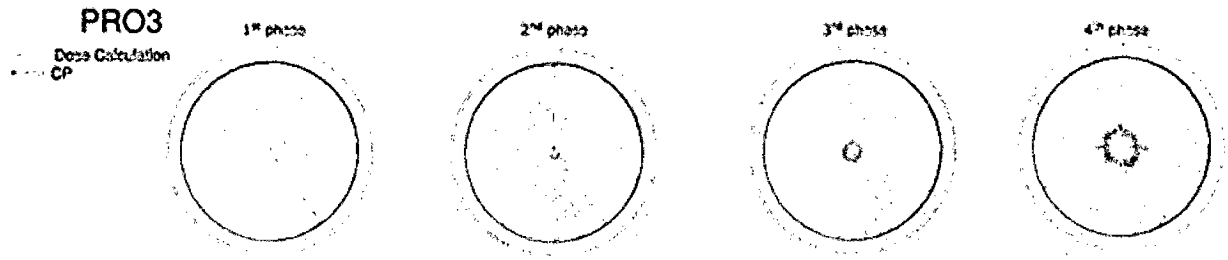
(Limitation D) (Claim 23)

The Domestic Industry Products perform the step of "specifying, by the processor, an increased plurality of control points along the trajectory, the increased plurality of control points comprising a larger number of control points than the initial plurality of control points." Starting with PRO2, the Dose Calculation Sectors and Fluence Control Points are "control points" under the correct claim construction. When the PRO2 algorithm progresses from one MR level to the next MR level, it increases both the number of Dose Calculation Sectors and Fluence Control Points. The progression is depicted in the PRO2 diagram of CX-0379.3, which shows both the number of Dose Calculation Sectors and Fluence Control Points increasing at each MR level:



The Dose Calculation Sectors are depicted in yellow and green, and the Fluence Control Points are represented by the blue dots with lines that extend to the center of the circle. As shown, the algorithm specifies an increased plurality of Dose Calculation Sectors and Fluence Control Points at each optimization phase. *See* CX-0853C, Pyyry at Q27-34; CX-3835C (Bergeron WS) at Q254-256, 315; CX-0379.3-4.

With respect to PRO3, the Dose Calculation Sectors and Dose Control Points are "control points" under each party's proposed construction as discussed above. When the PRO3 algorithm progresses from one MR level to the next MR level, it increases both the number of Dose Calculation Sectors and Dose Control Points. The progression is depicted in the PRO3 diagram of CX-0379.3, which shows both the number of Dose Calculation Sectors and Dose Control Points increasing at each MR level:



The Dose Calculation Sectors are shown in blue and green, and the Dose Control Points are represented by the lines labeled "Dose Calculation." As shown, the algorithm specifies an increased plurality of Dose Calculation Sectors and Dose Control Points at each MR level. *See* CX-0853C, Pyyry at Q52-54; CX-3835C (Bergeron WS) at Q270-

272, 315; CX-0378C.204; CX-0379.3-4.

(Limitation E) (Claim 23)

The Domestic Industry Products perform the step of "iteratively optimizing, by the processor, a simulated dose distribution relative to the set of one or more optimization goals over the increased plurality of control points to thereby determine a radiation delivery plan." In PRO2, after the algorithm progresses from one MR level to the next and increases the number of Dose Calculation Sectors and Fluence Control Points, it then causes the processor to iteratively optimize the dose distribution over the increased number of Dose Calculation Sectors and Fluence Control Points. The iterative process repeats until convergence of the cost function, or until a predetermined number of iterations has occurred. The cost function embodies the clinical objectives input by a user, including the desired dose distribution. When one of these termination conditions is met, the algorithm progresses to the next phase of optimization, provided the algorithm is not currently in the fifth and final phase. When the algorithm is in the fifth and final phase and one of the termination conditions occurs, the optimization algorithm is complete and the treatment plan is deliverable. *See* CX-853C, Pyyry at Q30, 35; CX-3835C (Bergeron WS) at Q318; CX-0379.3-4.

In PRO3, after the algorithm progresses from one MR level to the next and increases the number of Dose Calculation Sectors and Dose Control Points, it then causes the processor to iteratively optimize the dose distribution over the increased number of Dose Calculation Sectors and Dose Control Points. The iterative process repeats until convergence of the cost function, or until a predetermined number of iterations has occurred. As discussed above, the cost function embodies the clinical objectives input by

a user, including the desired dose distribution. When one of these termination conditions is met, the algorithm progresses to the next phase of optimization, provided the algorithm is not currently in the fourth and final phase. When the algorithm is in the fourth and final phase and one of the termination conditions occurs, the optimization algorithm is complete and the treatment plan is deliverable. *See* CX-853C, Pyyry at Q52-55; CX-3835C (Bergeron WS) at Q318; CX-0378C.204-205; CX-0379.3-4; CX-1661C.24-27, 95,130-140.

(Limitation F) (Claim 23)

In the Domestic Industry Products, "the radiation delivery plan [is] capable of causing a radiation delivery apparatus to deliver radiation in accordance with the radiation delivery plan." After a RapidArc treatment plan is optimized and approved for delivery, it is exported to a DICOM file. The DICOM files are provided to linear accelerators including the TrueBeam and Clinac linear accelerators, which read the DICOM files and generate instructions to implement the treatment plans. In TrueBeam, the Supervisor node of the control system unpacks the data from the DICOM file and prepares instructions that direct the other machine nodes, including the gantry, MLC, and beam generation components, to deliver the radiation dose to the patient target volume. In Clinac, the Clinac Controller and MLC Controller extract the DICOM control point data and implement the treatment plan to deliver the radiation dose to the patient target volume. *See* CX-853C, Pyyry at Q36-38; CX-3835C (Bergeron WS) at Q320; CX-0378C.204-205; CX-1661C.24.

(Limitation G) (Claim 23)

The Domestic Industry Products perform the step of "wherein iteratively optimizing, by the processor, the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points comprises performing, by the processor, the iterative optimization using a set of optimization parameters, the set of optimization parameters representative of one or more of: a beam shape of the radiation source; and a beam intensity of the radiation source." The PRO algorithm optimizes a set of optimization parameters, including those representative of intensity of the radiation source. The varying intensity results from the PRO algorithm optimization process, which [ ] as discussed above. When optimization is complete, the plan is exported to a DICOM file that stores the dose amounts as a function of gantry angle. This information is transferred to the TrueBeam or Clinac treatment machines, and the machine control systems determine how intensity of the radiation beam and gantry speed should be modulated to deliver the plan. *See* CX-853C, Pyyry at Q13; CX-3835C (Bergeron WS) at Q322; CX-0378C.204-205; CX-0379C.3-4; CX-1661C.24-27, 95; CX-1664C.1; CX-1683C.14.

(Limitation H) (Claim 25)

The Domestic Industry Products perform "A method according to claim 23 comprising providing the radiation delivery plan to the radiation delivery apparatus." As discussed above with respect to Limitation F, the TrueBeam and Clinac linear accelerators deliver RapidArc treatment plans by reading DICOM files that encapsulate the plans. *See* CX-853C, Pyyry at Q13; CX-3835C (Bergeron WS) at Q324; CX-0378C.204-205; CX-0379C.3-4; CX-1661C.24-27, 95; CX-1664C.1; CX-1683C.14.

(Limitation I) (Claim 26)

The Domestic Industry Products perform "A method according to claim 25 comprising delivering, by the radiation delivery apparatus, radiation in accordance with the radiation delivery plan." As discussed above with respect to Limitation F, the TrueBeam and Clinac linear accelerators deliver RapidArc treatment plans by reading DICOM files that encapsulate the plans. *See* CX-853C, Pyyry at Q13; CX-3835C (Bergeron WS) at Q324; CX-0378C.204-205; CX-0379C.3-4; CX-1661C.24-27, 95; CX-1664C.1; CX-1683C.14.

Claim 41

As discussed above with respect to the Accused '538 Products, *Limitations A-F* and *H-I* of claim 41 are the same as in claim 26. The evidence discussed with respect to those limitations demonstrates that the Domestic Industry Products practice Limitations A-F and H-I of claim 41. *See* CX-3835C (Bergeron WS) at Q326-328. The evidence shows that the Domestic Industry Products practice Limitation G of claim 41.

(Limitation G) (Claim 41)

The Domestic Industry Products perform the step of "wherein a start of the trajectory and an end of the trajectory comprise the same relative position between the radiation source and the subject and the trajectory is otherwise non-self overlapping." The Arc Geometry tool in the Eclipse treatment planning software allows an operator to define a RapidArc treatment trajectory as a continuous, 360° arc where the starting point and ending point of the trajectory comprise the same relative position between the radiation source and subject without overlapping. *See* CX-3835C (Bergeron WS) at

Q327; CX-1661C.137. Dr. Bergeron confirmed this functionality in the Eclipse source code. *See* CX-3835C (Bergeron WS) at Q327. Gantry motion in the TrueBeam and Clinac delivery systems allow for implementation of the delivery plan across the range of 360°. *Id.*

C. Validity of the '538 Patent

Respondents argue that claim 26 of the '538 patent is anticipated by U.S. Patent Application Publication No. 86,530 (RX-0146), which names Karl Otto as the inventor. The application was filed on September 25, 2002 and published on May 8, 2003. *See* Resps. Br. at 292-303; RX-0146 (hereinafter, "Otto '530"). Respondents argue that five references, in six combinations of between two and four references each, render claims 26 and 41 of the '538 patent obvious. *See* Resps. Br. at 303-15. Respondents argue that asserted claims 26 and 41 do not claim patentable subject matter under 35 U.S.C. § 101. *See* Resps. Br. at 315-17.

Complainants and the Staff disagree. *See* Compls. Br. at 296-311; Staff Br. at 127-32.

For the reasons set forth below, respondents have not shown by clear and convincing evidence that the asserted claims of the ''538 patent are invalid.

1. Applicable Law

One cannot be held liable for practicing an invalid patent claim. *See Pandrol USA, LP v. AirBoss Railway Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003). Nevertheless, each claim of a patent is presumed to be valid, even if it depends from a claim found to be invalid. 35 U.S.C. § 282; *DMI Inc. v. Deere & Co.*, 802 F.2d 421 (Fed. Cir. 1986).

A respondent that has raised patent invalidity as an affirmative defense must overcome the presumption by "clear and convincing" evidence of invalidity. *Checkpoint Systems, Inc. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995).

a. Anticipation

Anticipation under 35 U.S.C. § 102 is a question of fact. *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1347 (Fed. Cir. 2007). Section 102 provides that, depending on the circumstances, a claimed invention may be anticipated by variety of prior art, including publications, earlier-sold products, and patents. *See* 35 U.S.C. § 102 (*e.g.*, section 102(b) provides that one is not entitled to a patent if the claimed invention "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States").

The general law of anticipation may be summarized, as follows:

> A reference is anticipatory under § 102(b) when it satisfies particular requirements. First, the reference must disclose each and every element of the claimed invention, whether it does so explicitly or inherently. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed.Cir.2006). While those elements must be "arranged or combined in the same way as in the claim," *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1370 (Fed.Cir.2008), the reference need not satisfy an *ipsissimis verbis* test, *In re Bond*, 910 F.2d 831, 832-33 (Fed.Cir.1990). Second, the reference must "enable one of ordinary skill in the art to make the invention without undue experimentation." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed.Cir.2008); *see In re LeGrice*, 49 C.C.P.A. 1124, 301 F.2d 929, 940-44 (1962). As long as the reference discloses all of the claim limitations and enables the "subject matter that falls within the scope of the claims at issue," the reference anticipates -- no "actual creation or reduction to practice" is required. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1380-81 (Fed.Cir.2003); *see In re Donohue*, 766 F.2d 531, 533 (Fed.Cir.1985). This is so despite the

> fact that the description provided in the anticipating reference might not otherwise entitle its author to a patent. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed.Cir.1991) (discussing the "distinction between a written description adequate to support a claim under § 112 and a written description sufficient to anticipate its subject matter under § 102(b)").

In re Gleave, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

b. Obviousness

Under section 103 of the Patent Act, a patent claim is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[76] 35 U.S.C. § 103. While the ultimate determination of whether an invention would have been obvious is a legal conclusion, it is based on "underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness." *Eli Lilly and Co. v. Teva Pharmaceuticals USA, Inc.*, 619 F.3d 1329 (Fed. Cir. 2010).

The objective evidence, also known as "secondary considerations," includes commercial success, long felt need, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 13-17 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006). "[E]vidence arising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of

[76] The standard for determining whether a patent or publication is prior art under section 103 is the same as under 35 U.S.C. § 102, which is a legal question. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987).

obviousness." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). Secondary considerations, such as commercial success, will not always dislodge a determination of obviousness based on analysis of the prior art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007) (commercial success did not alter conclusion of obviousness).

"One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *KSR*, 550 U.S. at 419-20. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.*

Specific teachings, suggestions, or motivations to combine prior art may provide helpful insights into the state of the art at the time of the alleged invention. *Id.* at 420. Nevertheless, "an obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way." *Id.* "Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* A "person of ordinary skill is also a person of ordinary creativity." *Id.* at 421.

Nevertheless, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would

have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); *see KSR*, 550 U.S. at 416 (a combination of elements must do more than yield a predictable result; combining elements that work together in an "unexpected and fruitful manner" would not have been obvious).[77]

2. Anticipation (Claim 26)

Respondents argue that claim 26 of the '538 patent is anticipated by U.S. Patent Application Publication No. 86,530 (RX-0146), which names Karl Otto as the inventor. The application was filed on September 25, 2002 and published on May 8, 2003. *See* Resps. Br. at 292-303; RX-0146 ("Otto '530"). Complainants and the Staff disagree. *See* Compls. Br. at 296-98; Staff Br. at 128.

The evidence does not show that claim 26 of the '538 patent is anticipated by *Otto '530*. As Dr. McNutt admitted on cross-examination, treatment planning optimization of *Otto '530* does not take the trajectory into account, McNutt Tr. 744-745, and thus this reference cannot disclose at least the three "control points along a trajectory" limitations of claim 23, on which claim 26 indirectly depends. Claim 23, below, recites (emphasis added):

> 23. A method for planning delivery of radiation dose to a target region within a subject, the method comprising:
>
> (a) iteratively optimizing, by a processor, a simulated dose distribution relative to a set of one or more optimization goals comprising a desired dose distribution in the subject over ***an initial plurality of control***

[77] Further, "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 550 U.S. at 416 (citing *United States v. Adams*, 383 U.S. 39, 52 (1966)).

points along a trajectory which involves relative movement between a radiation source and the subject;

(b) reaching one or more initial termination conditions, and after reaching the one or more initial termination conditions:

(c) specifying, by the processor, ***an increased plurality of control points along the trajectory, the increased plurality of control points comprising a larger number of control points than the initial plurality of control points***; and

(d) iteratively optimizing, by the processor, a simulated dose distribution relative to the set of one or more optimization goals over the ***increased plurality of control points*** to thereby determine a radiation delivery plan;

(e) the radiation delivery plan capable of causing a radiation delivery apparatus to deliver radiation in accordance with the radiation delivery plan;

(f) wherein iteratively optimizing, by the processor, the simulated dose distribution relative to the set of one or more optimization goals over ***the initial plurality of control points*** comprises performing, by the processor, the iterative optimization using a set of optimization parameters, the set of optimization parameters representative of one or more of: a beam shape of the radiation source; and a beam intensity of the radiation source.

Although Dr. McNutt contends that *Otto '530* discloses the claimed trajectory dependent control points (RX-0434C (McNutt WS) at.0096 at Q443 and 450), he admits that the disclosures of *Otto '530* are in the context of static, fixed angle IMRT—a technology that does not plan for, or contemplate, delivering treatment while the gantry is moving, (McNutt Tr. 743-744; RX-0434C (McNutt WS) at Q93) Thus, Dr. McNutt's argument that the "subfields" described by *Otto '530* are analogous to "control points" is directly contradicted by his own admission that *Otto '530* ***does not contemplate any form of trajectory-based treatment planning***, which requires administering treatment while the gantry is moving along a trajectory. *See* McNutt Tr. 743-744; RX-0434C (McNutt WS)

at Q451; Verhey Tr. 1150 (***"no, there's no trajectory here"***) (emphasis added).

As Dr. Verhey explained, and as described by *Otto '530*, sub-fields are divisions of a single radiation field that represents a single, fixed gantry angle. *See* Verhey Tr. 1150-1151; CX-3880C (Verhey RWS) at Q112-15. Thus, like all IMRT solutions, even if "sub-fields" were analogous to control points (which they are not), *Otto '530* lacks any notion of planning or delivering treatment while the gantry is moving along a trajectory, making it impossible for *Otto '530* to disclose "control points along a trajectory," as required by claim 26. *See* McNutt Tr. 743-744; CX-3880C (Verhey RWS) at Q199 and 324.

3. Obviousness[78]

Respondents argue that five references, in six combinations of between two and four references each, render claims 26 and 41 of the '538 patent obvious. *See* Resps. Br. at 303-15. Complainants and the Staff disagree. *See* Compls. Br. at 296, 298-306; Staff Br. at 129-32.

a. Otto '530 and Earl '261 (Claim 26)

The evidence does not show that the combination of *Otto '530* and *Earl '261* renders claim 26 of the '538 patent obvious. Dr. McNutt does not explain which limitations are purportedly disclosed by *Earl '261* and which are purportedly disclosed by

[78] As an initial matter, Elekta cannot meet its burden on any obviousness combinations because Dr. McNutt did not analyze any facts relating to the secondary considerations of non-obviousness. *See* McNutt Tr. 731-734. Thus, Elekta's *Graham* analysis for each prior art combination is incomplete. *See Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d 1356 (2013) (vacating determination of obviousness that was otherwise supported by substantial evidence for failure to consider secondary considerations). *See* Staff Br. at 105-06; Compls. Br. at 217-20; Compls. Reply Br. at 112-13.

Otto '530, or how that combination differs in any way from *Earl '261* and *Otto '530*. Instead, Dr. McNutt relies on portions of *Earl '261* describing different user inputs and selections, as well as a description of gantry rotation. *See* RX-0434C (McNutt WS) at Q467. Dr. McNutt's position, leaving one to guess which limitation(s) of claims 23, 25, or 26 are disclosed by *Earl '261* and which are disclosed by *Otto '530*, falls well short of meeting Elekta's burden to overcome the presumption of validity. Moreover, as described above, Elekta cannot meet its burden on any obviousness combinations because Dr. McNutt failed to analyze any facts relating to the secondary considerations of non-obviousness.

Earl '261 fails to disclose increasing the number of control points along a trajectory in a multi-stage optimization process, as required by claim 23, and indeed Dr. McNutt admits that his analysis of this reference is based entirely on his own alteration of *Earl '261* (McNutt Tr. 740-741), and his unsupported theory that *Earl '261* does not preclude adding control points—reasoning that cannot meet Elekta's burden and an implicit admission that *Earl '261* fails to disclose this limitation. *See* RX-0434C (McNutt WS) at Q504.

Elekta's purported motivation to combine these distinct references is unpersuasive and driven by hindsight. It is not based on the disclosures of these references (or any other factual evidence), and it ignores the secondary considerations. *See* CX-3880C (Verhey RWS) at Q206-07.

Dr. McNutt opines that "it would have been obvious to a person of ordinary skill in the art at the time of the alleged invention to apply the iterative optimization process disclosed by *Otto '530* so that the control points are 'along an initial trajectory which

involves relative movement between a radiation source and the subject,' as taught by Earl'261[.]" *See* CX-0161C.87 at ¶192. However, Dr. McNutt did not provide any facts supporting his purported "obvious" motivation. *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F. 3d 1043, 1051 (Fed. Cir. 2001) (citing *Shaw v. Strackhouse,* 920 F.2d 1135, 1142 (3d Cir. 1990) ("where an expert's opinion is predicated on factual assumptions, those assumptions must also find some support in the record") (citing *Shaw*, 920 F.2d at 1142 (3d Cir. 1990))). Rather, as Dr. Verhey explained, a person of skill in the art would not have been motivated to combine *Otto '530* with *Earl '261* because the two involve different types of radiation treatment delivery and address different problems. *See* CX-3880C (Verhey RWS) at Q206-07.

b. Duthoy and Otto '530 (Claim 26)

The evidence does not show that the combination of *Duthoy* and *Otto '530* renders claim 26 obvious. *Duthoy* (RX-232), an article by Wim Duthoy, M.D. et al., titled "Whole Abdominopelvic Radiotherapy (WAPRT) Using Intensity-Modulated Arc Therapy (IMAT): First Clinical Experience," is another paper that describes an IMAT treatment solution. *See* McNutt Tr. 717-719; CX-3880C (Verhey RWS) at Q125-28. As Dr. Verhey explained, and as with the *Earl Article*, *Duthoy* illustrates the shortcomings of merely simulating the ability to vary the intensity of the beam while the gantry is moving—a technique that teaches away from Dr. Otto's VMAT solution. *See id.* Moreover, as described above, Elekta cannot meet its burden on *any* obviousness combinations because Dr. McNutt failed to analyze any facts relating to the secondary considerations of non-obviousness.

This combination fails to disclose limitations 23(c) and 23(d), which require increasing the number of control points along a trajectory through a multi-stage process. As with the prior combination, Dr. McNutt's witness statement does not identify any disclosure in *Duthoy* relating to a multi-stage process that increases the number of control points, and separately does not identify any disclosure in *Otto '530* of control points along a trajectory. As with *Earl '261*, Dr. McNutt merely posits that *Duthoy* does not preclude adding control points *(see* McNutt, RX-0434C (McNutt WS) at Q561), an implicit admission that *Duthoy* does not actually disclose the feature of adding control points and far from meeting Elekta's burden to show by clear and convincing evidence that *Duthoy* discloses the claimed multi-stage optimization process that increases the number of control points along a trajectory.

Dr. McNutt merely recites the same purported motivation to combine as *Otto '530* and *Earl '261*, and thus for the same reasons described above, even if the combination of *Duthoy* and *Otto '530* disclosed every limitation of claim 26, which it does not, Dr. McNutt has failed to provide a motivation to combine these discrete references.

c. Otto '530 and the Earl Article (Claim 41)

The evidence does not show that the combination of *Otto '530* and the *Earl Article* renders claim 41 obvious. As discussed above, claim 41 is similar in scope to claim 26 and contains only one additional limitation. Thus, for the reasons described above, neither *Otto '530* nor the *Earl Article* disclose the claimed control point limitations. Moreover, claim 39, on which claim 41 depends, replaces claim 23(f), on which claim 26 depends, with the limitation: "wherein a start of the trajectory and an end of the trajectory comprise the same relative positions between the radiation source and

the subject and the trajectory is otherwise non-self overlapping." This limitation, along with claim 41, requires planning and delivering treatment in a single 360° arc around the patient. This feature is not disclosed by any of the prior art combinations that Dr. McNutt relies on.

Dr. McNutt implicitly admits that *Otto '530* does not disclose this limitation, but opines that *Earl Article* discloses this limitation during the treatment planning process. However, the evidence Dr. McNutt relies on in the *Earl Article* is in a different section of the *Earl Article* that describes calculating the desired dose distribution, completely separate from the treatment plan optimization process. *See* CX-3880C (Verhey RWS) at Q341; CDX-0879C. As the *Earl Article* describes, the treatment planning process uses multiple overlapping arcs, not a single arc that overlaps only at the start and stop points. *See* CX-3880C (Verhey RWS) at Q341; RX-233.0003 at 1076.

Dr. McNutt's purported motivations to combine are unpersuasive, are not based on the disclosures of these references (or any other factual evidence), and improperly ignore secondary considerations. *See* CX-3880C (Verhey RWS) at Q335-56.

As to these prior art combinations, Dr. McNutt does not provide any practical reason why a person of skill in the art would combine the *Earl Article* (which used IMAT) and *Otto '530* (which used IMRT) in the way that he suggests. Dr. McNutt also contends that a person of skill in the art would have been motivated to combine the *Earl Article* with *Otto '530* because the result would have been a more desirable radiation therapy system. Such shared goals do not indicate that a person of skill in the art would have known to combine the two references to achieve a more desirable system, but rather are a strong indicator that the claim is non-obvious. *See ActiveVideo Networks, Inc.*, 694

F.3d at 1328 (Fed. Cir. 2012) (holding that generic testimony that "[t]he motivation to combine would be because you wanted to build something better" and which bears no relation to any specific combination of prior art elements "fails to explain why a person of ordinary skill in the art would have combined elements from specific references ***in the way the claimed invention does***.") (emphasis in original).

Moreover, the *Earl Article* does not mention rotating the MLC to avoid "hot spots," which Dr. Verhey explains is an issue for IMRT (the technology of *Otto '530*), but not for IMAT (the technology of the *Earl Article*).

d. Otto '530, the Yu Article, and Podgorsak (Claim 41)

The evidence does not show that claim 41 is obvious in light of the four-part combination of *Otto '530*, *Yu Article*, and *Podgorsak.* All three pieces of prior art fail to disclose limitation 39(f) and Dr. McNutt does not provide any evidence to support his purported motivations to combine these three disparate references. Moreover, as described above, Elekta cannot meet its burden on *any* obviousness combinations because Dr. McNutt failed to analyze any facts relating to the secondary considerations of non-obviousness.

As described in the sections above, *Otto '530,* like *Earl '261* fails to disclose the claimed control points, and Dr. McNutt implicitly admits that *Otto '530* fails to disclose claim 39(f). Likewise, Dr. McNutt's analysis implicitly admits that *Earl '261* fails to disclose this single-arc limitation, leaving only the *Yu Article* and *Podgorsak* in this combination.

Dr. McNutt opines that the *Yu Article* discloses the single-arc limitation, 39(f),

based on a passage stating that in half of the treatment cases, overlapping arcs must be used. *See* RX-0434C (McNutt WS) at Q479. However, Dr. McNutt's analysis is based on an erroneous interpretation of what claim 39(f) requires, *i.e.*, that the trajectory overlaps at its start and end points. Moreover, this lone statement that overlapping arcs must be used, by itself, is far from the clear and convincing evidence that non-self overlapping arcs must be used as well. Indeed, the *Yu Article* expressly states the use of multiple overlapping arcs as a method of controlling the amount of radiation that is administered: "We have implemented…IMAT...intensity distributions at all angles around the patient are ***achieved with multiple overlapping arcs***, with each arc having a different set of field apertures." *See* RX-236.0002 at 454 (emphasis added).

As to *Podgorsak*, Dr. McNutt's analysis is based entirely on a figure (Figure 5) that he interprets in a manner that is not supported by, and is arguably even contrary to, *Podgorsak*'s own description of that figure. *See* RX-0434C (McNutt WS) at Q480; RX-255.0008 at Fig. 5. Indeed, the claimed limitation, *e.g.*, start and stop points and the number of arcs around the patient, are not actually described by *Podgorsak*, and the annotation on Figure 5 (point C) that Dr. McNutt relies on is related to dynamic rotation. Contrary to Dr. McNutt's assertion, it does not signify or even describe the start or stop position of a single arc. *See* RX-0255.0008 at Fig. 5; CX-3880C (Verhey RWS) at Q340. Thus, this reference, like the others in this combination, cannot meet Elekta's clear and convincing burden.

Dr. McNutt merely offers overbroad reasons for combining these references, such as the ability to "treat targets located in anatomically complex positions." *See* RX-0434C (McNutt WS) at Q483-84. As Dr. Verhey explains, Dr. McNutt's purported motivation

merely parrots the advantages of Dr. Otto's invention and tends to support the secondary considerations of non-obviousness. *See* CX-3880C (Verhey RWS) at Q343. The *Yu Article* does not actually recite these purported motivations or benefits. *See* RX-0434C (McNutt WS) at Q483; CX-3880C (Verhey RWS) at Q343. Dr. McNutt does not provide insight into whether a person of ordinary skill in the art would have been motivated to combine *Otto '530*, the *Yu Article*, *Podgorsak,* and *Earl '261*. *Id.*

e. Duthoy, Otto '530 and the Earl Article (Claim 41)

The evidence does not show that claim 41 is obvious in light of the three-part combination of *Duthoy*, *Otto '530*, and *Earl Article*. All three pieces of prior art fail to disclose limitation 39(f) and Dr. McNutt does not provide any evidence to support his purported motivations to combine these three disparate references. Moreover, as described above, Elekta cannot meet its burden on any obviousness combinations because Dr. McNutt failed to analyze any facts relating to the secondary considerations of non-obviousness.

Duthoy and *Otto '530* fail to disclose the control point limitations for the same reason described in context of claim 26. As described in the section above, Dr. McNutt admits that *Otto '530* and *Duthoy* fail to disclose claim 39(f), CX-3880C at Q355, and the *Earl Article* fails to disclose claim 39(f). Thus, this combination cannot render claim 41 obvious.

For the reasons discussed above with respect to claim 26 of the '538 patent, Dr.

f. Duthoy, Otto '530, the Yu Article and Podgorsak (Claim 41)

The evidence does not show that claim 41 is obvious in light of the four-part

combination of *Duthoy, Otto '530*, the *Yu Article*, and *Podgorsak*. As discussed in the prior sections, all four pieces of prior art fail to disclose limitation 39(f), and Dr. McNutt does not provide any evidence to support his purported motivations to combine these four references. Moreover, as described above, Elekta cannot meet its burden on any obviousness combinations because Dr. McNutt failed to analyze any facts relating to the secondary considerations of non-obviousness.

4. Patent Eligible Subject Matter

Respondents argue that asserted claims 26 and 41 of the '538 patent do not claim patentable subject matter under 35 U.S.C. § 101. *See* Resps. Br. at 315-17. Complainants and the Staff disagree. *See* Compls. Br. at 306-11; Staff Br. at 127-28.

Respondents argue:

> Claims 26 and 41 of the '538 patent are ineligible for patenting under 35 U.S.C. § 101, and are thus invalid. Claims 26 and 41 are directed to methods or software for "planning delivery of radiation dose to a target region within a patient." Each of these claims recites steps relating to methods of calculation. These steps are nothing more than a mathematical calculation or data processing step, and are thus ineligible subject matter. The remaining limitations in the claims do not add any elements that would transform this unpatentable subject matter into patentable subject matter, rendering the claim invalid.

Resps. Br. at 315.

Elekta's allegations that claims 26 and 41 of the '538 patent are not directed toward patent eligible subject matter are unsupported by the evidence. Elekta's allegations are based solely on the conclusory opinions of Dr. McNutt. His opinions ignore key elements of the claims and specification, and should be given little weight. *Davis v. Brouse McDowell, LPA*, 596 F. 3d 1355, 1364 (Fed. Cir. 2010) ("His expert report contains no affirmative analysis supporting his opinion . . . . An unsupported

opinion such as this cannot and does not create a genuine issue of material fact."). Elekta has failed to present any evidence that the '538 patent is abstract.

Claims 26 and 41

Elekta's arguments that claims 26 and 41 are directed toward patent ineligible subject matter under § 101 are substantially the same. Elekta alleges that claims 26 and 41 are invalid because the independent claims they rely on, claims 23 and 39, are directed to an abstract idea.

Under the first step of § 101 analysis, one must determine if the claims are directed toward abstract ideas or purely mental processes. *Id.* Dr. McNutt merely assumes the conclusion that claims 23 and 39, from which claims 26 and 41 depend, recite steps that are nothing more than a mathematical calculation or data processing step. *See* RX-0434C (McNutt WS) at Q217-24; CX-3880C (Verhey RWS) at Q134. From three portions of claim 23 (on which claim 26 depends), Dr. McNutt characterizes the claimed process as "very simple" and "trial-and-error." RX-0434C (McNutt WS) at Q220. Claim 23 of the '538 patent, from which claim 26 depends, recites a method with a large number of steps and Dr. McNutt's analysis is based only on the emphasized parts of claim 23:

> **23.** A method for planning delivery of radiation dose to a target region within a subject, the method comprising:
>
> ***iteratively optimizing***, by a processor, ***a*** simulated ***dose distribution*** relative to a set of one or more optimization goals comprising a desired dose distribution in the subject over an ***initial plurality of control points*** along a trajectory which involves relative movement between a radiation source and the subject;

reaching one or more initial termination conditions, and after reaching the one or more initial termination conditions:

specifying, by the processor, ***an increased*** plurality of ***control points*** along the trajectory, the increased plurality of control points comprising a larger number of control points than the initial plurality of control points; and

iteratively optimizing, by the processor, a simulated dose distribution relative to the set of one or more optimization goals over the increased plurality of control points to thereby determine a radiation delivery plan;

the radiation delivery plan capable of causing a radiation delivery apparatus to deliver radiation in accordance with the radiation delivery plan;

wherein iteratively optimizing, by the processor, the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points comprises performing, by the processor, the iterative optimization using a set of optimization parameters, the set of optimization parameters representative of one or more of: a beam shape of the radiation source; and a beam intensity of the radiation source.

JX-0006 ('538 Patent) at col. 34, lns. 35-65 (emphasis added); *see* CX-3880C (Verhey RWS) at Q134.

At the hearing, Dr. McNutt admitted that his § 101 analysis did not apply to claim 23 as a whole, but only to the iterative optimization step. *See* McNutt Tr. 777-778. By focusing only on 15 of claim 23's words, Dr. McNutt fails to consider the claim as a whole and ignores claim language that ties the algorithm to constraints of the linear accelerator. *See* CX-3880C (Verhey RWS) at Q134-35. This is also true of claim 39. Dr. McNutt's analysis does not consider the claims as a whole, leading to an erroneous, improper conclusion. *See Diamond v. Diehr*, 450 U.S. 175, 176 (1981) ("claims must be

considered as a whole").

Likewise, Dr. McNutt reads the specification out of context and concludes that claims 26 and 41 are directed to nothing beyond the steps of selecting a change, calculating a dose distribution, and deciding whether to keep the change, each of which can be performed manually. *See* RX-0434C (McNutt WS) at Q220. As Dr. Verhey explained, this characterization is not supported by evidence, nor is it tied to the claim language. *See* CX-3880C (Verhey RWS) at Q134.

As Dr. Verhey explained, the claimed treatment optimization process, which is built upon very complex computer simulations and projections, is a uniquely computerized solution that has no manual analogue and cannot be performed by hand. *Earl '261* expressly notes that that even for simpler IMRT algorithms, "[b]ecause of the complexity of the treatment plans for IMRT, an automated system is required" to generate the optimal plan. *See Earl '261* (RX-0360) at [11]; *see also* CX-3880C (Verhey RWS) at Q134. Likewise, *Tobler* expressly notes that then-modern "treatment planning systems are unable to represent the dynamic dose rate control option that will be required for this dynamic conformal rotational treatment technique." *See Tobler* (RX-0234) at 252; McNutt Tr. 745-747.

Dr. McNutt agrees that the algorithms cannot be performed manually. During the hearing, he testified that the algorithm could not be performed manually "in practice," and that attempting to optimize a VMAT treatment plan by hand is something he "would not do." *See* McNutt Tr. 779. In fact, Dr. McNutt has never tried to perform either the treatment plan optimization or the delivery steps of claim 23 and 39 manually, and does not know if anyone in the field has ever attempted to do so. *See* McNutt Tr. 779

(optimization) and 781 (delivery). Inasmuch as Dr. McNutt fails to provide any evidence that the claimed optimization process can be or is performed manually, his unsupported expert opinion is entitled to little weight. *See Davis*, 596 F.3d at 1364.

Moreover, the claimed VMAT optimization process represents a specific and unique technique for creating a treatment plan that takes into account all of the parameters and constraints for the plan to be executed and delivered on modern linacs. *Id.* According to Dr. Verhey, VMAT is a giant leap within the art of automated treatment planning and delivery, and is ultimately directed to a dramatic increase in the efficiency and speed of delivery on a corresponding physical apparatus, which, as explained through the exemplary embodiment in the '538 patent, is a specialized radiation treatment apparatus for delivering the treatment plan. *See* JX-0006 ('538 Patent) at Fig. 4A; col. 9, ln. 55 – col. 14, ln. 56. This embodiment expressly depends on the specialized radiation treatment apparatus and takes into account its physical characteristics and constraints, including: the maximum and minimum gantry speeds, the maximum and minimum dose rates, the configuration of the MLC, including leaf speed constraints, maximum leaf extensions relative to neighbors, constraints on gantry angle based on potential interference with portions of the patient couch, and speed of dose rate change. These are all undisputed disclosures that Dr. McNutt fails to consider in his flawed § 101 analysis. *See* JX-0006 ('538 Patent) at col. 2, lns. 1-10, 65-66; col. 11, lns. 15- 25; col. 11, ln. 48 – col. 13, ln. 3; col. 21, lns. 22-38; CX-3880C (Verhey RWS) at Q134. Thus, under the first step of the *Alice* analysis, claims 26 and 41 are not directed toward abstract ideas or purely mental processes.

Under the second step of the *Alice* analysis, courts must evaluate whether a patent

directed towards an abstract idea reflects a technological innovation. *See Enfish, LLC v. Microsoft Corp.*, No. 2015-1244, 2016 WL 2756255, at *4-5 (Fed. Cir. May 12, 2016). Even if Elekta were correct that claims 26 and 41 are directed toward abstract ideas, they are still directed toward patent eligible subject matter because they represent inventive concepts. *Id.* at *5 (a patent directed towards an abstract idea is valid "if nevertheless there is some inventive concept in the application of the abstract idea").

The multi-stage optimization process described by claims 23 and 39, from which claims 26 and 41 depend, was a novel technology that dramatically improved safety and efficiency in treatment planning and treatment delivery. Though some clinical linear accelerators were capable of changing the treatment beam dose rate prior to Dr. Otto's inventions in non-clinical modes, manufacturers did not allow clinicians to utilize these capabilities because it would have compromised patient safety; without a safe, proven algorithm capable of varying dose rate during treatment planning, the risk of "terrible error" resulting in "destruction of human tissue" was too great. *See* Verhey Tr. 1137-1138. Dr. Otto's inventions allowed clinicians, for the first time, to safely vary dose rate during treatment. *See* Verhey Tr. 1137-1139. Dr. Otto's innovations also significantly reduced the calculation time for treatment optimization. During the hearing, Dr. Verhey testified that he was "amazed" and "astonished" by the Otto patents' reduction of total treatment planning time from hours to minutes. *See* Verhey Tr. 1130.

Dr. McNutt did not dispute that Dr. Otto's inventions allowed clinicians to vary dose rate for the first time, or that his inventions significantly reduced planning and treatment times. *See* Verhey Tr. 798-799. Instead, his analysis misses the technological innovations of claims 23 and 39, from which claims 26 and 41 depend, skipping the

second step of the *Alice* inquiry entirely. Under a full *Alice* inquiry, it is apparent that the '538 patent improves the efficiency of use of the treatment planning system and linear accelerator hardware, and claims a patent eligible invention under the second step of the *Alice* inquiry.

Accordingly, the evidence shows that the asserted claims 26 and 41 of the '538 patent claim patentable subject matter under 35 U.S.C. § 101.

IX. U.S. Patent No. 7,906,770[79]

United States Patent No. 7,906,770 ("the '770 patent), entitled "Methods and apparatus for the planning and delivery of radiation treatments," issued on March 15, 2011, to named inventor Karl Otto. JX-0005 ('770 Patent). The '770 patent issued from Application No. 11/996,932, filed on July 25, 2006. *Id.* The '770 patent relates to "radiation treatment," and "particularly to methods and apparatus for planning and delivering radiation to a subject to provide a desired three-dimensional distribution of radiation dose." JX-0005 ('770 Patent) at col. 1, lns. 19-22. The '770 patent has a total of 70 claims.

Complainants allege infringement of independent method claims 61 and 67 of the '770 patent. *See* Compls. Br. at 311-12, 314-37. Complaints argue that they have a

[79] It is noted that on September 29, 2016, respondents filed a letter requesting the administrative law judge to take judicial notice of "USPTO Institution Decisions, indicating that all asserted claims from the Otto Patents in this Investigation are now currently under review by the Patent Trial and Appeal Board (PTAB) at the U.S. Patent and Trademark Office in four separate *inter partes* review (IPR) proceedings." *See* Letter to Administrative Law Judge re Otto IPRs (emphasis in original) (EDIS Doc. ID No. 591647). On October 4, 2016, complainants filed a "Letter to Judge Shaw regarding Elekta's Request for Judicial Notice" in response to respondents letter. *See* Letter to Judge Shaw regarding Elekta's Request for Judicial Notice (EDIS Doc. ID No. 591922).

domestic industry based on claim 61 and independent apparatus claim 68. *See* Compls. Br. at 311-12, 337-39.

As noted, complainants assert independent method claims 61 and 67, and independent apparatus claim 68 of the '770 patent. Those claims read as follows:

> **61**. A method for delivering radiation dose to a target area within a subject, the method comprising:
>
> defining a trajectory for relative movement between a treatment radiation source and the subject;
>
> determining a radiation delivery plan;
>
> while effecting relative movement between the treatment radiation source and the subject along the trajectory:
>
> delivering a treatment radiation beam from the treatment radiation source to the subject according to the radiation delivery plan to impart a dose distribution on the subject, wherein delivering the treatment radiation beam from the treatment radiation source to the subject comprises varying at least one of an intensity of the treatment radiation beam and a shape of the treatment radiation beam over at least a portion of the trajectory;
>
> obtaining two-dimensional projection images of the target area at a plurality of locations along the trajectory.
>
> **67**. A method for delivering radiation dose to a target area within a subject, the method comprising:
>
> defining a trajectory for relative movement between a radiation source and the subject;
>
> determining a radiation delivery plan;
>
> sensing a positional state of the subject;
>
> while effecting relative movement between the radiation source and the subject along the trajectory, delivering a radiation beam from the radiation source to the subject according to the radiation delivery plan to impart a dose distribution on the subject, wherein