delivering the radiation beam from the radiation source to the subject comprises:

varying at least one of an intensity of the radiation beam and a shape of the treatment radiation beam over at least a portion of the trajectory;

deactivating delivery of the radiation beam upon sensing that the position of the subject is outside of an acceptable range; and

reactivating delivery of the radiation beam upon sensing that the position of the subject is within the acceptable range; and

while effecting relative movement between the radiation source and the subject along the trajectory, obtaining two-dimensional projection images of the target area at a plurality of locations along the trajectory.

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

defining a set of one or more optimization goals, the set of one or more optimization goals comprising a desired dose distribution in the subject;

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

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

upon reaching one or more initial termination conditions:

adding one or more additional control points to obtain an increased plurality of control points;

iteratively optimizing the simulated dose distribution relative to the set of optimization goals to determine one or more radiation delivery

parameters associated with each of the increased plurality of control points.

JX-0005 ('770 Patent) at col. 35, ln. 63 – col. 36, ln. 12; col. 36, ln. 58 – col. 37, ln. 39.

A. Claim Construction

1. Applicable Law

Claim construction begins with the plain language of the claim.[80] Claims should 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.[81] *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

[80] 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).

[81] 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).

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).

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 312-13; Resps. Br. at 207; Staff Br. at 134.

The parties jointly propose that the construction of "initial termination conditions" should be "criteria indicating termination of initial optimization." *See* Compls. Br. at 312-13; Resps. Br. at 207; Staff Br. at 134.

Examples of "termination conditions" appear in the specification. For instance, "[b]y way or 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-0005 ('770 Patent) at col. 20, lns. 1-9; *see also id.* at column 20 (generally); col. 2, lns. 61-64 ("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. "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 312-13; Resps. Br. at 207; Staff Br. at 135.

The parties jointly propose that "iteratively optimizing" should be construed as "repeatedly modifying parameters to achieve an optimization goal." *See* Compls. Br. at 312-13; Resps. Br. at 207; Staff Br. at 135.

The '770 patent states that "[t]he method comprises iteratively optimizing a simulated dose distribution relative to the set of optimization goals lo determine one or more radiation delivery parameters associated with each of the initial plurality of control points." *See* JX-0005 ('770 Patent) at col. 2, lns. 61-64. The '770 patent explains that "[w]hen the optimization relating to the initial plurality of control points reaches one or more initial termination conditions, the method comprises: adding one or more additional control points to obtain an increased plurality or control points; and iteratively optimizing the simulated dose distribution relative to the set of optimization goals to determine one or more radiation delivery parameters associated with each of the increased plurality of control points." *See id.* at col. 2, ln. 64 – col. 3, ln. 5; *see also id.* at col. 3, lns. 40-45; col. 3, ln. 58 – col. 4, ln. 3; col. 11, lns. 39-51 ("The quality of the dose distribution

resulting from the modified optimization variable(s) is evaluated in relation to a set of one or more optimization goals. The modification is then accepted or rejected. Optimization process 54 continues until it achieves an acceptable set of beam shapes and intensities or foils.").

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."

5. "sensing a positional state of the subject" and "sensing that the position of the subject"

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

"sensing a positional state of the subject" and "sensing that the position of the subject"		
Complainants' Construction	**Respondents' Construction**	**Staff's Construction**
"collecting data on the location of the subject at a particular time"		

See Compls. Br. at 312-13; Resps. Br. at 207; Staff Br. at 136.

The parties jointly propose that claim terms "sensing a positional state of the subject" and "sensing that the position of the subject" should be construed as "collecting data on the location of the subject at a particular time." *See* Compls. Br. at 312-13; Resps. Br. at 207; Staff Br. at 136; *see* JX-0005 ('770 Patent) at col. 4, lns. 41-52 (one aspect of the claimed invention is "deactivating delivery of the radiation beam upon sensing that the position of the subject is outside of an acceptable range; and reactivating

delivery of the radiation beam upon sensing that the position of the subject is within the acceptable range.").

Accordingly, as proposed by the parties, the administrative law judge adopts the joint proposed claim construction has determined that the claim terms "sensing a positional state of the subject" and "sensing that the position of the subject" should be construed to mean "collecting data on the location of the subject at a particular time."

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 313-14; Resps. Br. at 208-12; Staff Br. at 133.

For the reasons discussed above in the claim construction section for the term "control point" with respect to the '538 patent, 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." *See* Compls. Br. at 313 ("The 'control point' claim construction arguments and supporting evidence above with respect to the '538 patent apply with equal force with respect to the '770 patent"); Resps. Br. at 208-12 (proposing same claim construction for "control point" as proposed for the '538 patent); Staff Br. at 133 ("As

explained above with regard to the term 'control point' in the '538 patent, the evidence has shown that "control point" should be construed as 'a set of one or more radiation delivery parameters associated with a point along the trajectory of the radiation source.'").

B. Infringement Analysis of the '770 Patent

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

Respondents argue that the accused products do not infringe the asserted claims of the '770 patent. *See* Resps. Br. at 318-27.

The Staff argues that the accused products infringe the asserted claims of the '770 patent. *See* Staff Br. at 137-39. However, with respect to direct infringement, the Staff argues:

> Elekta argues that claims 61 and 67, which are method claims, are not directly infringed by Elekta. As the Staff explained with regard to the potential infringement of the method claims in the '154 patent, the Commission has previously determined that performance of a claimed method directly by a respondent is not a violation of Section 337.
>
> In addition, Elekta also argues that claims 61 and 67 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. For the same reasons as given with regard to the '154 patent, the Staff agrees with Elekta.

See Staff Br. at 138 (citations omitted).

Regarding indirect infringement, the Staff argues that "the evidence showed indirect infringement by Elekta's customers." Staff Br. at 139.

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.[82] *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

[82] 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).

determination of equivalence should be applied as an objective inquiry on an element-by-element basis."[83] *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.[84]

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:

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[83] "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).

[84] "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.

> The Accused '770 Products for claim 61 are the Accused Linacs when used in combination with a treatment planning system such as Elekta's Monaco treatment planning software, and XVI with kV imaging. As discussed above, the Accused Linacs include Versa HD, Infinity, Axesse, and Synergy/Synergy S linac systems. The Accused '770 Products for claim 67 are the Accused Linacs when used in combination with a treatment planning system such as Elekta's Monaco treatment planning software, XVI with kV imaging, and Response MV Beam Gating, or the Accused Linacs when used in combination with a treatment planning system such as Elekta's Monaco treatment planning software, XVI with kV imaging, Response MV Beam Gating, and Active Breathing Coordinator.

Compls. Br. at 312 (citations omitted).

3. Direct Infringement of Accused Products

Complainants argue: "The record evidence shows that Elekta's products practice claims 61 and 67; Elekta both directly and directly and indirectly infringes claim 61 and 67." *See* Compls. Br. at 311-12, 314-29.

Respondents argue that the accused products do not directly infringe the asserted claims of the '770 patent. *See* Resps. Br. at 318-27.

The Staff argues that the accused products infringe the asserted claims of the '770 patent. *See* Staff Br. at 137-39. However, with respect to direct infringement, the Staff argues:

> Elekta argues that claims 61 and 67, which are method claims, are not directly infringed by Elekta. As the Staff explained with regard to the potential infringement of the method claims in the '154 patent, the Commission has previously determined that performance of a claimed method directly by a respondent is not a violation of Section 337.
>
> In addition, Elekta also argues that claims 61 and 67 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. For the same reasons as given with regard to the '154 patent, the Staff agrees with Elekta.

See Staff Br. at 138 (citations omitted).

a. Claim 61

Complainants argue: "The record evidence establishes that the combination of treatment planning software such as Monaco, the Accused Linacs, and XVI with kV practice every limitation of claim 61 of the '770 patent." *See* Compls. Br. at 314, 314-27.

Respondents argue:

> Varian admits that a single element, "Element F of claim 61 [of the '770 patent, JX-0005] is the **only element** that is different than the elements of Claim 19 of the '154 patent [JX-0004]." Element F, according to Varian, corresponds to "obtaining two-dimensional projection images of the target area at a plurality of locations along the trajectory."
>
> Varian has failed to prove infringement of claim 61 of the '770 patent, at least for reasons explained above with respect to claim 19 of the '154 patent. For example, for reasons similar to those explained above, Elekta does not infringe limitation 61B ("defining a trajectory for relative movement between a treatment radiation source and the subject") or 61C ("determining a radiation delivery plan").

Resps. Br. at 318 (citations omitted) (emphasis in original).

The Staff argues that the accused products infringe asserted claim 61 of the '770 patent. *See* Staff Br. at 137. However, with respect to direct infringement, the Staff argues:

> Elekta argues that claims 61 and 67, which are method claims, are not directly infringed by Elekta. As the Staff explained with regard to the potential infringement of the method claims in the '154 patent, the Commission has previously determined that performance of a claimed method directly by a respondent is not a violation of Section 337.
>
> In addition, Elekta also argues that claims 61 and 67 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. For the same reasons as given with regard to the '154 patent, the Staff agrees with Elekta.

See Staff Br. at 138 (citations omitted).

Asserted independent method claim 61 reads 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.

JX-0005 ('770 Patent) at col. 35, ln. 63 – col. 36, ln. 12.

As discussed below, the evidence shows that the combination of treatment planning software such as Monaco, the Accused Linacs, and XVI with kV practice every limitation of claim 61 of the '770 patent.

Dr. Bergeron testified that only one limitation of claim 61 is different from claim 19 of the '154 patent, the infringement of which has already been discussed above (as a predicate to showing infringement of its asserted dependent claim 23). *See* CX-3835C (Bergeron WS) Bergeron WS) at Q517-22. Specifically, "while effecting relative movement between the treatment radiation source and the subject along the trajectory: obtaining two-dimensional projection images of the target area at a plurality of locations

along the trajectory" is a limitation of claim 61 of the '770 patent but not claim 19 of the '154 patent. *See* CX-3835C (Bergeron WS) at Q522. Dr. Bergeron explained that the remaining limitations of claim 61 are identical or not materially different from the limitations of claim 19 of the '154 patent. CX-3835C (Bergeron WS) at Q517-521. Accordingly, as Dr. Bergeron testified, the same evidence which shows that the accused products practice those limitations of claim 19 of the '154 patent also shows that the accused products practice the limitations which are identical or materially the same in claims 61 and 67 of the '770 patent. *Id.*

Dr. McNutt agrees with Dr. Bergeron that the limitations of claim 19 of the '154 patent and claim 61 of the '770 patent overlap in this way. *See* RX-0495C (McNutt RWS) at Q429-31; McNutt Tr. 761. Elekta's only noninfringement arguments with respect to claim 61 are directed to limitations that it also challenged with respect to claim 19 of the '154 patent. RX-0495C (McNutt RWS) at Q430-33; McNutt Tr. 761. For the same reasons discussed above regarding claim 19 of the '154 patent, the evidence shows that the shared limitations are met by the Accused '770 Products. Elekta does not dispute that XVI with kV imaging satisfies the limitation in claim 61 that is not identical or materially the same as claim 19 of the '154 patent, *i.e.*, Limitation F. Infringement analysis of Limitation F follows:

> **(Limitation F) while effecting relative movement between the treatment radiation source and the subject along the trajectory: obtaining two-dimensional projection images of the target area at a plurality of locations along the trajectory**

Dr. Bergeron testified that based on his review of the documentation for Monaco, the Accused Linacs, and XVI with kV, this limitation was met because (1) XVI with kV

imaging, a component of the Accused Linacs, obtains two-dimensional projection images; (2) the obtaining step occurs at a plurality of locations along the trajectory; and (3) the projection images are obtained "while effecting relative movement between the treatment radiation source and the subject along the trajectory." *See* CX-3835C (Bergeron WS) at Q527.

Regarding the ability of XVI to obtain two-dimensional project images, Elekta Global Vice President, Kevin Brown, testified that XVI with kV imaging performs acquisition of cone-beam CT images. *See* CX-3835C (Bergeron WS) at Q527; JX-0025C (Brown Dep. Tr.) at 116. Elekta's Chief Engineer, Adrian Smith, also testified that the images obtained by XVI with kV are two-dimensional images. *See* CX-3835C (Bergeron WS) at Q527; JX-0055C (Smith Dep. Tr.) at 110-111. Two-dimensional image capture is also highlighted in Elekta's internal documentation. *See* CX-3835C (Bergeron WS) at Q527; CX-0251C.017-018. Evidence in Elekta's source code for XVI further proves two-dimensional image capture. *See* CX-3835C (Bergeron WS) at Q527; CPX-0028 (printed as CX-3686C) at [

] at lines 401-403.

Dr. Bergeron also explained that two-dimensional images are obtained "at a plurality of locations along the trajectory" when using XVI with kV imaging. In particular, Elekta's technical documentation revealed that [ ] are captured in one full 360-degree rotation of the linac gantry in the Accused Linacs. *See* CX-3835C (Bergeron WS) at Q527; CX-0251C.18. The projection images are obtained while the radiation is being delivered. *See* CX-3835C (Bergeron WS) at Q527; CPX-

0033 at 4:10; JX-0025C (Brown Dep. Tr.) at 116, 141-142. Accordingly, evidence shows that the combination of treatment planning software such as Monaco, the Accused Linacs, and XVI with kV imaging practices Limitation F of claim 61.

Elekta's expert, Dr. McNutt does not dispute that the accused products practice Limitation F. Nor has Elekta put forth any evidence to show that the accused products do not practice Limitation F. Thus, the evidence shows that the combination of treatment planning software such as Monaco, each of the Accused Linacs, and XVI with kV imaging meets each limitation of claim 61 of the '770 patent.

b. Claim 67

Complainants argue: "The record evidence further establishes that the combination of treatment planning software such as Monaco, the Accused Linacs, Response MV Beam Gating, and one or both of XVI with kV imaging and Active Breathing Coordinator practice every limitation of claim 67 of the '770 patent." Compls. Br. at 317.

Respondents argue:

> Just like with claim 61, Varian admits that three elements, "Elements D, G, and H of Claim 67 are the **only elements** that are different than the elements of claim 61 of the '770 patent [JX-0005]."[85] Varian has failed to prove infringement of claim 67 of the '770 patent, at least for reasons similar to those explained above with respect to claim 19 of the '154 patent, JX-0004 as well as those explained above with respect to claim 61 of the '770 patent. For example, Elekta does not infringe limitations 67B ("defining a trajectory for relative movement between a

[85] Element D (limitation 67D) is "sensing a positional state of the subject," Element G (limitation 67G) is "deactivating delivery of the radiation beam upon sensing that the position of the subject is outside of an acceptable range," and Element H (limitation 67H) is "reactivating delivery of the radiation beam upon sensing that the position of the subject is within the acceptable range."

> treatment radiation source and the subject") or 67C ("determining a radiation delivery plan"). Moreover, Elekta does not infringe limitations 67D, 67G, or 67H.

Resps. Br. at 318-19 (citations omitted) (emphasis in original).

The Staff argues that the accused products infringe asserted claim 67 of the '770 patent. *See* Staff Br. at 137-38. However, with respect to direct infringement, the Staff argues:

> Elekta argues that claims 61 and 67, which are method claims, are not directly infringed by Elekta. As the Staff explained with regard to the potential infringement of the method claims in the '154 patent, the Commission has previously determined that performance of a claimed method directly by a respondent is not a violation of Section 337.
>
> In addition, Elekta also argues that claims 61 and 67 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. For the same reasons as given with regard to the '154 patent, the Staff agrees with Elekta.

See Staff Br. at 138 (citations omitted).

Asserted independent method claim 67 of the '770 patent reads as follows:

> **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 delivering the radiation beam from the radiation source to the subject comprises:

> varying at least one of an intensity of the radiation beam and a shape of the treatment radiation beam over at least a portion of the trajectory;
>
> deactivating delivery of the radiation beam upon sensing that the position of the subject is outside of an acceptable range; and
>
> reactivating delivery of the radiation beam upon sensing that the position of the subject is within the acceptable range; and
>
> while effecting relative movement between the radiation source and the subject along the trajectory, obtaining two-dimensional projection images of the target area at a plurality of locations along the trajectory.

JX-0005 ('770 Patent) at col. 36, ln. 58 – col. 37, ln. 17.

As discussed below, the evidence shows that the combination of treatment planning software such as Monaco, the Accused Linacs, Response MV Beam Gating, and one or both of XVI with kV imaging and Active Breathing Coordinator practice each limitation of claim 67 of the '770 patent.

Dr. Bergeron testified that only three elements of claim 67 are different from claim 61 of the '770 patent, the infringement of which has already been discussed above. Specifically, Dr. Bergeron testified that Limitations D, G, and H of claim 67 are the limitations that differ from claim 61. *See* CX-3835C (Bergeron WS) at Q535. The remaining limitations of claim 67, Limitations A-C, E and F are identical or not materially different from the limitations of claim 61 of the '770 patent. *See* CX-3835C (Bergeron WS) at Q536. Thus, Dr. Bergeron opined that the same evidence discussed above which shows that the treatment planning software such as Monaco, in combination with the Accused Linacs and XVI with kV imaging practices Limitations A-F of claim 61, also shows that treatment planning software such as Monaco, in combination with the

Accused Linacs and XVI with kV imaging practices Limitations A-C, E, F and I of claim 67. *See id.*

Dr. McNutt agrees with Dr. Bergeron that the limitations of claims 61 and 67 of the '770 patent overlap in this way and that limitations of claim 67 overlap with claim 19 of the '154 patent. *See* RX-0495C (McNutt RWS) at Q429-31. Elekta's noninfringement arguments with respect to claim 19 of the '154 patent are also directed to claim 67 of the '770 patent. RX-0495C (McNutt RWS) at Q430-33. For the same reasons discussed above with respect to claim 19 of the '154 patent, the evidence shows that the shared limitations are met by the accused products.

The evidence also demonstrates that XVI with kV imaging in combination with Response MV Beam Gating practices Limitations D, F, and G of the '770 patent. The evidence shows that Active Breathing Coordinator in combination with Response MV Beam Gating also practices Limitations D, F, and G of the '770 patent.

(Limitation D) (Claim 67) sensing a position state of the subject

Dr. Bergeron testified that based on his review of the documentation for Monaco, the Accused Linacs, Response MV, XVI with kV and Active Breathing Coordinator, this limitation was met because the Accused Linacs—when used (1) in combination with treatment planning systems such as Monaco and XVI with kV or (2) in combination with treatment planning systems such as Monaco and Active Breathing Coordinator—sense a positional state of the subject. *See* CX-3835C (Bergeron WS) at Q541.

Dr. Bergeron explained, and Elekta's internal documentation and the deposition testimony of Elekta witnesses show, that XVI with kV imaging is used in combination with Accused Linacs to obtain two-dimensional images and reconstruct a target volume

to sense the positional state of the subject. *See* CX-3835C (Bergeron WS) at Q541-42; *see also, e.g.*, JX-0055C (Smith Dep. Tr.) at 103; CX-0251C.018. For example, Elekta's System Submission—Overall Navigation Document states that XVI "[

]" and even states that this "[

]." CX-0251C.004, 018. The relevant excerpt is reproduced below:

[

]

Id. Accordingly, the evidence shows that XVI with kV imaging practices Limitation D of claim 67.

Regarding the combination with Active Breathing Coordinator, descriptions of the product indicate that it senses the position of a patient by digitally monitoring the patient's respiratory cycle. *See* CX-3835C (Bergeron WS) at Q541; CX-3869.1. Adrian

Smith, an Elekta employee, testified that Active Breathing Coordinator senses a patient's breathing cycle as a surrogate for position of the patient and the tumor within the patient. *See* CX-3835C (Bergeron WS) at Q541; JX-0055C (Smith Dep. Tr.) at 66-67, 69. Mr. Smith characterized Active Breathing Coordinator as a patient position monitoring system that detects position based on breathing. *See* CX-3835C (Bergeron WS) at Q541; JX-0055C (Smith Dep. Tr.) at 112, 115. Accordingly, the evidence shows that Active Breathing Coordinator practices *Limitation D* of claim 67.

> **(Limitations G and H) (Claim 67) deactivating delivery of the radiation beam upon sensing that the position of the subject is outside of an acceptable range [and] reactivating delivery of the radiation beam upon sensing that the position of the subject is within the acceptable range.**

Dr. Bergeron characterized *Limitations G* and *H* as interrelated because both elements concern controlling delivery of radiation in response to sensing the position of a subject relative to an "acceptable range." *See* CX-3835C (Bergeron WS) at Q544-45. Dr. Bergeron testified that based on his review of the documentation for Monaco, the Accused Linacs, Response MV, XVI with kV and Active Breathing Coordinator, this limitation was met because the Accused Linacs—when used (1) in combination with treatment planning systems such as Monaco, Response MV and XVI with kV or (2) in combination with treatment planning systems such as Monaco, Response MV and Active Breathing Coordinator—deactivate delivery of a therapeutic radiation beam upon sensing that the position of a subject is outside of an acceptable range and reactivate delivery of the beam upon sensing that the position of a subject is within the acceptable range.

Regarding the combination with Active Breathing Coordinator, descriptions of Active Breathing Coordinator reveal that it specifically detects whether a patient is in an

optimal or most favorable phase of his or her respiratory cycle for the purposes of administering optimal treatment. *See* CX-3835C (Bergeron WS) at Q548; CX-3869. Response MV is linked to Active Breathing Coordinator specifically to "gate" treatment radiation in response to patient position. *See* CX-3835C (Bergeron WS) at Q548; CX-3868C.1; CX-3869.1. Elekta's documents show that "gating" means a procedure to effect a pause in radiation delivery in response to patient position information. *See* CX-3835C (Bergeron WS) at Q548; CX-0277C at 42, 181. Specifically, Response MV gating has three modes of gating operation: (1) breath-hold, where there are long periods of alternating beam deactivation and reactivation; (2) free breathing, wherein a patient breathes normally and there are shorter periods of beam deactivation and reactivation; and (3) exception gating, where a treatment beam may be deactivated for certain exceptional circumstances, such as patient coughing. *See* CX-3835C (Bergeron WS) at Q548; CX-0251C at 4, 8. Dr. Bergeron opined that all three modes meet Limitations G and H. *See id.* Adrian Smith, Elekta's Chief Engineer, also confirmed that Response MV and Active Breathing Coordinator serve this gating function. *See* CX-3835C (Bergeron WS) at Q548; JX-0055C (Smith Dep. Tr.) at 66-67, 69, 111-115. Based on the foregoing evidence, Dr. Bergeron concluded that the Accused Linacs, in combination with treatment planning systems such as Monaco, Response MV and Active Breathing Coordinator meet Limitations G and H.

Regarding the combination with XVI with kV imaging, the accused XVI product is also a patient position monitoring system that can work in combination with Response MV Beam Gating. Elekta's documents explain that XVI with kV imaging provides patient position information and that kV patient imaging may be used in combination

with gating of a treatment radiation beam. *See* CX-3835C (Bergeron WS) at Q549; CX-0251C at 4, 18-19. Adrian Smith also confirmed that XVI is a patient position monitoring system, and that patient position monitoring systems that work with Response MV can be a "variety of things." *See* CX-3835C (Bergeron WS) at Q549; JX-0055C (Smith Dep. Tr.) at 108, 111-112. The source code for Elekta's Integrity and XVI with kV imaging further shows that XVI with kV imaging can detect patient position and that Response MV Beam Gating can deactivate and reactivate the treatment radiation beam in response to external stimulus such as XVI with kV imaging patient positioning information. *See* CX-3835C (Bergeron WS) at Q549. Based on the foregoing evidence, Dr. Bergeron concluded that the Accused Linacs, in combination with treatment planning systems such as Monaco, Response MV Beam Gating, and XVI with kV imaging meet Limitations G and H. Accordingly, the evidence shows that Active Breathing Coordinator practices Limitations G and H of claim 67.

In sum, the evidence shows that the combination of treatment planning software such as Monaco, each of the Accused Linacs and XVI with kV imaging, and Response MV Beam Gating meets each limitation of claim 67 of the '770 patent. The evidence also demonstrates that the combination of treatment planning software such as Monaco, each of the Accused Linacs and XVI with kV imaging, Response MV Beam Gating and Active Breathing Coordinator meets each limitation of claim 67 of the '770 patent.

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

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. Because Elekta makes this same argument with respect to all of the Otto patents, Section IX.D.3—which fully explains why Dr. McNutt is incorrect about the meaning of the term "subject"—is incorporated by reference.
>
> Finally, Dr. McNutt again makes the incorrect legal argument that Elekta cannot directly infringe because, while the Accused Linacs are imported, Monaco software is not; therefore, direct infringement has not occurred. But Dr. McNutt makes the same argument with respect to the '154 patent and is wrong on the law for the same reasons.

Compls. Br. at 328-29 (citations omitted) (emphasis in original).

Respondents argue: "Varian has failed to prove infringement of claim 61 of the '770 patent, at least for reasons explained above with respect to claim 19 of the '154 patent." Resps. Br. at 318 (citations omitted). Respondents argue: "Varian has failed to prove infringement of claim 67 of the '770 patent, at least for reasons similar to those explained above with respect to claim 19 of the '154 patent, JX-0004 as well as those explained above with respect to claim 61 of the '770 patent." Resps. Br. at 318-19 (citations omitted).

As discussed above, with respect to the '154 patent, respondents argued:

> "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 accused products infringe the asserted claims of the '770 patent. *See* Staff Br. at 137-39. However, with respect to direct infringement, the Staff argues:

> Elekta argues that claims 61 and 67, which are method claims, are not directly infringed by Elekta. As the Staff explained with regard to the potential infringement of the method claims in the '154 patent, the Commission has previously determined that performance of a claimed method directly by a respondent is not a violation of Section 337.
>
> In addition, Elekta also argues that claims 61 and 67 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. For the same reasons as given with regard to the '154 patent, the Staff agrees with Elekta.

See Staff Br. at 138 (citations omitted).

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 claims 61 and 67 by respondents, whether on a patient or a dummy, is not sufficient to prove a violation under section 337. Additionally, as discussed above in the infringement section of the '154 patent, the administrative law judge agrees with respondents and the Staff that the "subject" in claims 61 and 67 of the '770 patent who is receiving the "radiation dose" must be a living person. Thus, there is no direct infringement by respondents.

3. Indirect Infringement

Complainants argue that "the record evidence establishes that Elekta indirectly infringes claims 61 and 67 of the '770 patent by actively inducing customers in the United States to use the Accused Products," and "[t]he record evidence establishes that Elekta contributes to customers' infringement of claims 61 and 67 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 to practice claims 61 and 67 of the '770 patent." *See* Compls. Br. at 333-34, 329-37.

Respondents argue that the accused products do not infringe the asserted claims of the '770 patent. *See* Resps. Br. at 318-27.

The Staff argues that "the evidence showed indirect infringement by Elekta's customers." Staff Br. at 139.

As discussed below, the evidence shows that Elekta's customers directly infringe claims 61 and 67 of the '770 patent in the United States when: (a) testing the accused products; (b) receiving training from Elekta on how to use the accused products; and (c) treating patients with the accused products.

Testing

As discussed above, and as Dr. Bergeron explains, Elekta performs testing of the Accused Linacs in combination with other infringing instrumentalities that a customer has purchased at the customer site, including the delivery of a VMAT treatment plan and obtaining 2D projection images with XVI with kV. *See* CX-3835C Bergeron WS) at Q570. Elekta performs this testing in concert with the customer's own personnel, as confirmed by [ ]. *See* CX-3835C (Bergeron WS) at Q570; JX-0034C [ ] Dep. Tr.) at 100-101. Accordingly, there is substantial evidence establishing that Elekta's customers directly infringe claims 61 and 67 of the '770 patent in the United States when they perform testing of the creation and delivery of a treatment plan after purchasing the accused products.

Training

As discussed above, and as Dr. Bergeron testified, Elekta provides training to its customers in the United States on using XVI with kV and Active Breathing Coordinator. *See* CX-3835C (Bergeron WS) at Q574. As discussed above, Elekta witness Mark Symons testified that training is included with every purchase of an Accused Linac, including actual delivery of radiation. *See* JX-0056C (Symons Dep. Tr.) at 208, 244-245, 250-251. [ ] show that [

]. *See* CX-1109C; CX-3706C; CX-1125C; CX-1113C. Further, [ ] testified that its employees actually did receive training in the United States on how to deliver a VMAT plan on the Accused Linacs. *See* JX-0034C [ ] Dep. Tr.) at 82-84, 86-87, 89.

On June 22, 2016, Elekta stipulated that it has trained at least one customer in the United States in accordance with the training instructions set forth on pages 115-121 of the XVI R5.0 Applications Training Guide (CX-3779C) and performed each of the steps detailed in the Training Guide using an Accused Linac in the United States. *See* JX-0061C (Stipulation Regrarding Intrafractional Imaging and ABC Training) at 1. Elekta also stipulated that it has trained at least one customer in the United States in accordance with the training instructions set forth on pages 60-61 of the Active Breathing Coordinator R3.0 Applications Training Guide (CX-3776C) and has performed each of the steps detailed in the Training Guide in the United States. *See* JX-0061C (Stipulation Regrarding Intrafractional Imaging and ABC Training) at 2.

Accordingly, the evidence shows that Elekta trained customers to use XVI with

kV and Active Breathing Coordinator in the accused manner in the United States. Elekta's customers directly infringed claims 61 and 67 of the '770 patent in the United States when they received such training on how to use the accused products.

Treating Patients

As discussed above, [

]. *See* CX-1109C; CX-3706C; CX-1125C; CX-1113C. As Dr. Bergeron testified, it is highly unlikely they would have [

], and not have used the purchased products. *See* CX-3835C (Bergeron WS) at Q578.

Moreover, [ ], one of Elekta's customers that had purchased Monaco and a number of Accused Linacs, admitted to delivering VMAT plans on an Accused Linac in order to treat patients at their facilities. *See* JX-0034C [ ] Dep. Tr.) at 25-26, 33, 40-43, 103, 104-105, 112-114, 116-119; CX-3835C (Bergeron WS) at Q578; *see also, e.g.*, [

] are actively using Active Breathing Coordinator to gate radiation treatment as described above. *See* CX-3869. Accordingly, there is substantial evidence establishing that Elekta's customers directly infringed claims 61 and 67 in the United States when delivering a VMAT treatment plan to a patient using an Accused Linac with the infringing instrumentalities.

Accordingly, the evidence shows that Elekta's customers directly infringe claims 61 and 67 of the '770 patent when they perform test, train customers or actually treat

patients by delivering VMAT plans using the accused products in the United States and use the other infringing instrumentalities as intended.

Inducement

Dr. Bergeron cited evidence showing that Elekta encourages its customers to deliver VMAT treatment plans with an Accused Linac in a manner that practices each limitation of claims 61 and 67, including through advertisements on its website, marketing materials and presentations; videos and animations, white papers, user guides, training guides, Instructions for Use, customer walkthroughs, FDA regulatory documentation, other technical references, and a variety of other evidence. *See* CX-3835C (Bergeron WS) at Q585; *see also, e.g.*, CX-3684C; CX-1135C; CX-3691; CX-3589; CX-3584; CX-3667; CPX-0008; CPX-0009; CPX-0030 through CPX-0038; CPX-0044 through CPX-0046; CX-0299C; CPX-0037; CPX-0039; CPX-0043; CX-0871C; CX-3622C; CX-1135C; CX-0308C; CX-1148C; CX-0888C; CX-3680; CX-0251C; CX-0279C; CX-0233C; CX-3620C; CX-3690C; CX-3697C; CX-0299C; CX-1133C; CX-3689C; CX-3685C; CX-0246C; CX-3768C; CX-0308C; CX-0233C; CX-0357C; CX-1113C; JX-0031C (Hedges Dep. Tr.) at 93-94; JX-0025C (Brown Dep. Tr.) at 167-168; JX-0056C (Symons Dep. Tr.) at 215-217, 223, 229-231, 256; JX-0048C (Sankey Dep. Tr.) at 29-30; JX-0023C ([ ] Dep. Tr.) at 36-38, 61, 75-76, 80-86; JX-0035C ([ ] Dep. Tr.) at 34-39, 54, 58-60.

Further, Elekta knew that it was encouraging its customers to infringe, and thus had the requisite specific intent. In particular, Dr. Bergeron opined that Elekta had knowledge of its infringement of the '770 patent as early as August 27, 2012, which was admitted by Elekta. *See* Response to Complaint, ¶ 72. Elekta was informed of the '770

patent yet again when it received the Complaint in this Investigation. *See* Complaint, ¶ 77. Yet, Elekta continued to encourage customers to use the accused functionality, and continues to do so today. *See* CX-3835C (Bergeron WS) at Q586. In sum, the evidence shows that Elekta indirectly infringes claims 61 and 67 of the '770 patent by inducing customers in the United States to use the accused products as described above.

Contributory Infringement

As discussed below, the evidence shows that Elekta contributes to customers' infringement of claims 61 and 67 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 to practice claims 61 and 67 of the '770 patent.

As explained above, customers use the Accused Linacs that are imported into the United States and thereby infringe claims 61 and 67. Dr. Bergeron 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 "(1) deliver VMAT treatment plans as set forth in the '770 patent (*see* JX-0025C (Brown Dep. Tr.) at 17; JX-0055C (Smith Dep. Tr.) at 52-53, 138-139); (2) take two dimensional images of the patient as radiation is being delivered along a portion of the trajectory as set forth in the asserted claims of the '770 patent (*see* JX-0055C (Smith Dep. Tr.) at 108, 110); and gate the radiation beam on and off in response to a patient position monitoring system as set forth in the asserted claims of the '770 patent. *See* JX-0055C (Smith Dep. Tr.) at 66-67, 69, 112, 115. Additionally, Kevin Brown suggested that a major reason Elekta customers buy the Accused Linacs is for their VMAT treatment delivery functions and capabilities. *See* JX-0025C (Brown Dep. Tr.) at 54-56, 57-58.

In sum, the evidence shows that Elekta indirectly infringes claims 61 and 67 of the '770 patent by contributing to its customers' infringement of claims 61 and 67. Specifically, Elekta sells Accused Linacs which are especially adapted to be combined with VMAT treatment plans and the other infringing instrumentalities, all of which individually and collectively are specially designed to infringe as described above.

C. Domestic Industry (Technical Prong)

Complaints argue that they have a domestic industry based on claim 61 and independent apparatus claim 68. *See* Compls. Br. at 337-39.

Respondents argue:

> With respect to claim 61 of the '770 patent, JX-0005, Varian cannot satisfy the technical prong of the domestic industry requirement because claim 61 is invalid for the reasons set forth below.
>
> Similarly, claim 68 of the '770 patent is invalid for the reasons set forth below. Moreover, like claims 26 and 41 of the '538 patent, claim 68 of the '770 patent recites specifying "an increased plurality of control points." For the same reasons provided above for claims 26 and 41 of the '538 patent, the Domestic Industry Products also fail to perform all of the limitations in claim 68 of the '770 patent.

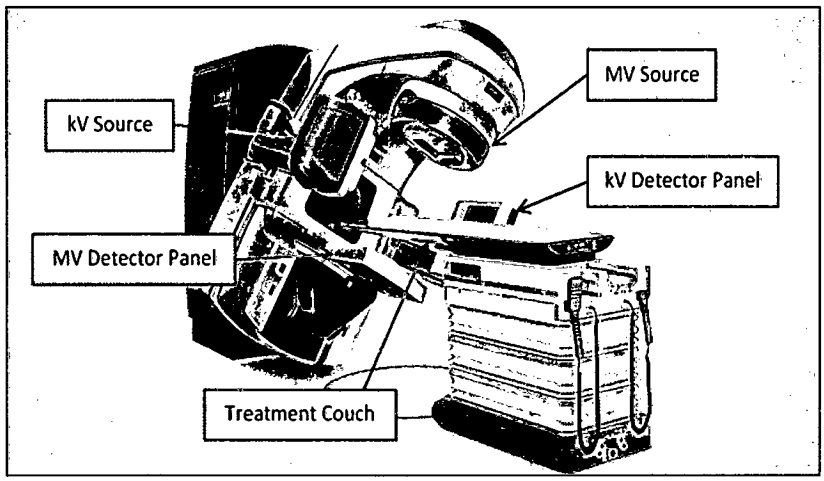
Resps. Br. at 327-28 (citations omitted).

The Staff argues that "the evidence has shown that Varian has satisfied the technical prong of the domestic industry requirement based on claims 61 and 68 of the '770 patent." Staff Br. at 140.

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.

Asserted independent method claim 61 and independent apparatus claim 68 of the '770 patent 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.

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

defining a set of one or more optimization goals, the set of one or more optimization goals comprising a desired dose distribution in the subject;

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

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

upon reaching one or more initial termination conditions:

adding one or more additional control points to obtain an increased plurality of control points;

iteratively optimizing the simulated dose distribution relative to the set of optimization goals

> to determine one or more radiation delivery parameters associated with each of the increased plurality of control points.

JX-0005 ('770 Patent) at col. 35, ln. 63 – col. 36, ln. 12; col. 37, lns. 18-39.

As discussed below, the evidence shows that Varian's Domestic Industry Products practice claims 61 and 68 of the '770 patent. The Domestic Industry Products for the '770 patent include the Varian's TrueBeam and Clinac linear accelerators in combination with Varian's Eclipse treatment planning software. Compls. Br. at 312 (citing CX-3835C (Bergeron WS) at Q11). These systems work together to allow clinicians to create and deliver Varian's RapidArc VMAT treatment plans, and to acquire two-dimensional projection images of a patient target volume during treatment. *See* CX-0855C (Zankowski WS) at Q29-30, 44-58.

Claim 61

The Domestic Industry Products meet *Limitations A, B, C, D,* and *E* of claim 61 of the '770 patent for the same reasons that they meet *Limitations A, B, C, D,* and *E* of claim 19 of the '154 patent, discussed above. CX-3835C (Bergeron WS) at Q599-603. Claim 61 of the '770 patent includes the additional requirement of "obtaining two-dimensional projection images of the target area at a plurality of locations along the trajectory." Elekta does not dispute that the Domestic Industry Products meet this requirement.

The TrueBeam and Clinac linear accelerators perform imaging of the patient target volume during delivery of RapidArc treatment plans. The TrueBeam imaging system performs kV and MV imaging during treatment. Each technique acquires two-dimensional projection images of the patient target volume and surrounding structures by

projecting x-ray beams through the patient target volume and onto a photodetector positioned behind the patient target volume. For MV imaging, the treatment beam source acts as the imaging source such that images are acquired from the beam's eye perspective. For kV imaging, the imaging source is positioned on an arm that is positioned 90 degrees from the treatment beam source and aligned with the treatment isocenter. For both types of imaging, the TrueBeam control system synchronizes image acquisition with delivery of the treatment beam. CX-3835C (Bergeron WS) at Q604-606; CX-0419.13; CX-1021C.27-32, 44-48, 55-63, 141; CX-1664C.1-2; CX-3050C.72-73, 82-85; CPX-0013.

The Clinac linear accelerators include an On-Board Imager (OBI) that obtains two-dimensional projection images of the target area at a plurality of locations along a treatment trajectory. OBI provides kV imaging capability similar to TrueBeam's kV imager. The system includes a kV imaging source and kV detector positioned 90 degrees from the treatment beam source and aligned with the treatment isocenter. The system produces fluoroscopic imaging and triggered images during treatment to manage intrafraction patient movement. CX-3835C (Bergeron WS) at Q607; CX-3754C.74-75; CX-3757C.14; CX-3787C.50-51, 62-69. Accordingly, the Domestic Industry Products meet every limitation of claim 61.

Claim 68

The Domestic Industry Products meet *Limitations A* through *G* of claim 68 of the '770 patent for the same reasons that they meet *Limitations A* through *G* of claim 26 of the '538 patent, discussed above. CX-3835C (Bergeron WS) at Q608-623. As with the '538 patent, Elekta disputes only that (1) certain data structures in the PRO algorithm are

not "control points," and (2) that the PRO algorithm does not add "control points" as it progresses from one optimization level to the next. These arguments contradict the evidence discussed above, including the testimony of Dr. Pyyry and Dr. Bergeron, and documentation and source code for the Domestic Industry Products. CX-0853C Pyyry WS) at Q21-30, 49-54; CX-3835C (Bergeron WS) at Q276-285, 290-317, 612-623; CX-0378C.204-205; CX-0379C.2-4. Accordingly, the Domestic Industry Products meet every limitation of claim 68.

C. Validity of the '770 Patent

Respondents argue that claim 68 of the '770 patent is anticipated by Otto '530. *See* Resps. Br. at 346-51. Respondents argue that six references, in six combinations of between two and three references each, render claims 61, 67, and 68 of the '770 patent obvious. *See* Resps. Br. at 328-51. Respondents argue that asserted claims 61 and 67 are invalid under 35 U.S.C. § 112, ¶ 2 because certain claim terms are indefinite. *See* Resps. Br. at 351-55.

Complainants disagree. *See* Compls. Br. at 340-45. The Staff argues that claims 67 and 68 are not invalid. The Staff, however, argues that claim 61 is rendered obvious by a certain combination of prior art. *See* Compls. Br. at 340-45; Staff Br. at 140-44.

For the reasons set forth below, respondents have not shown by clear and convincing evidence that claim 68 is anticipated; that claims 67 and 68 are rendered obvious; and that claims 61 and 67 are invalid under 35 U.S.C. § 112, ¶ 2. Respondents have shown by clear and convincing evidence that claim 61 is rendered obvious by a certain combination of prior art.

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."[86] 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

[86] 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).

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 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).[87]

c. Indefiniteness

The definiteness requirement of 35 U.S.C. § 112 ensures that the patent claims particularly point out and distinctly claim the subject matter that the patentee regards to be the invention. *See* 35 U.S.C. § 112, ¶ 2; *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366 (Fed. Cir. 2004). If a claim's legal scope is not clear enough so that a person of ordinary skill in the art could determine whether or not a particular product infringes, the claim is indefinite, and is, therefore, invalid. *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003).[88]

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[87] 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)).

[88] Indefiniteness is a question of law. *IGT v. Bally Gaming Int'l, Inc.*, 659 F.3d 1109

Thus, it has been found that:

> When a proposed construction requires that an artisan make a separate infringement determination for every set of circumstances in which the composition may be used, and when such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not), that construction is likely to be indefinite.

Halliburton Energy Servs. v. M-I LLC, 514 F.3d 1244, 1255 (Fed. Cir. 2008).

The Supreme Court addressed the issue of indefiniteness, and stated that a finding of indefiniteness should not be found if the claims, "viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014).

A patent is not indefinite if the claims, "viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). "If, after a review of the intrinsic and extrinsic evidence, a claim term remains ambiguous, the claim should be construed so as to maintain its validity." *Certain Consumer Electronics And Display Devices With Graphics Processing And Graphics Processing Units Therein*, Inv. No. 337-TA-932, Order No. 20 (Apr. 2, 2015) (quoting *Phillips*, 415 F.3d at 1327).

The burden is on the accused infringer to come forward with clear and convincing evidence to prove invalidity. *See Young v. Lumenis, Inc.*, 492 F.3d 1336, 1344 (Fed. Cir.

(Fed. Cir. 2011).

2007) ("A determination that a patent claim is invalid for failing to meet the definiteness requirement in 35 U.S.C. § 112, ¶ 2 is a legal question reviewed de novo.").

2. Anticipation (Claim 68)

Respondents argue that claim 68 of the '770 patent is anticipated by Otto '530. *See* Resps. Br. at 346-51. Complainants and the Staff disagree. *See* Compls. Br. at 343-44; Staff Br. at 140.

Respondents have not shown by clear and convincing evidence that claim 68 is anticipated. For the same reasons discussed above in the context of the '538 patent, the evidence does not show that *Otto '530* anticipates claim 68 of the '770 patent. *See* CX-3880C (Verhey RWS) at Q192, 195, 198-204 (Varian alleges Elekta does not contest validity of claim 68 but opining that claim 68 is not anticipated by Otto '530).

3. Obviousness[89]

Respondents argue that six references, in six combinations of between two and three references each, render claims 61, 67, and 68 of the '770 patent obvious. *See* Resps. Br. at 328-51. Complainants disagree. *See* Compls. Br. at 340-45. The Staff argues that claims 67 and 68 are not invalid. The Staff, however, argues that claim 61 is rendered obvious by a certain combination of prior art. *See* Compls. Br. at 340-45; Staff Br. at 140-44.

[89] 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.

Each of the six combinations are discussed below.

a. *Earl Article* and *Mosleh* (Claim 61)

As discussed above, the *Earl Article* fails to disclose claim 61(e), which requires "while effecting relative movement between the treatment radiation source and the subject along the trajectory: . . .obtaining two-dimensional projection images of the target area at a plurality of locations along the trajectory." Instead, Dr. McNutt relies on *Mosleh* (RX-0233), a paper titled "A cone beam megavoltage CT scanner for treatment verification in conformal radiotherapy," for this limitation. *Mosleh* discloses an experimental imaging system and does not render claim 61 obvious when combined with the *Earl Article*. CX-3880C (Verhey RWS) at Q169-70.

Dr. McNutt's purported reasons for motivations to combine are unpersuasive, are not based on the disclosures of these references (or any other factual evidence), and improperly ignores the secondary considerations. CX-3880C (Verhey RWS) at Q170. The *Earl Article* never mentions imaging, and does not disclose the need for some way of "obtaining two- dimensional projection images of the target area." Likewise, *Mosleh* does not reference the *Earl Article* or IMAT. Dr. McNutt provides no reason why a person of ordinary skill in the art would have been motivated to combine these two disparate references. *Id.*

Moreover, Dr. McNutt's purported motivations are not actually based on the disclosures of the *Earl Article* and *Mosleh*. Rather, Dr. McNutt merely states that both "relate to radiation therapy," RX-0434C (McNutt WS) at Q275, and both "refer[] to the general desire to minimize delivering radiation to critial, that is, non-tumorous organs during treatment.," *id.* at Q274, providing no insight into why a person of ordinary skill

might be motivated to combine the references. Nor does Dr. McNutt explain his opinion that combining the references would have been "desirable" or "straightforward." RX-0434C (McNutt WS) at Q275. As Dr. Verhey explains, these arguments support the secondary indicia of non-obviousness of the claimed inventions—that it would have been desirable to achieve the results of the Otto patents. Such shared goals do not indicate that a person of skill in the art would have known to combine the two references. In any event, "[d]efining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness." *Monarch Knitting Mach. Corp*, 139 F.3d at 881. As previously discussed, the *Earl Article* actually teaches away from the innovations of Dr. Otto's patented solution by using multiple overlapping arcs.

Moreover, as Dr. Verhey explains, a person of ordinary skill in the art would not have been motivated to combine these two references for at least two reasons: (1) at that time, a person of ordinary skill in the art would have sought a fast and accurate way to administer IMRT, a technology that is entirely different from the subject matter of the *Earl Article*, (2) and *Mosleh*, the latter of which only describes a very early experimental megavoltage CT imaging system, not a proven clinical solution. *See* CX-3880C (Verhey RWS) at Q170. As previously discussed, the *Earl Article* teaches away from the innovations of Dr. Otto's patented solution by using multiple overlapping arcs.

b. *Earl Article* and *Jaffray WIPO* (Claim 61)

The sole reason that Varian argues that the combination of the *Earl Article* (RX-0233) and *Jaffray WIPO* (RX-0270) do not invalidate claim 61 of the '770 patent is that there was no motivation to combine them because they do not cite each other. *See* Compls. Br. at 342 (citing CX-3880C (Verhey RWS) at Q175-77). As argued by

respondents, the evidence shows that there was sufficient motivation to combine these two references. *See* Resps. Br. at 336-39; RX-0434C (McNutt WS) at Q335-36. However, as noted above, 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.

c. *Earl Article* and *Mosleh* (or *Jaffray*) and *Mostafavi* (Claim 67)

Elekta has not shown that claim 67 is obvious in light of the *Earl Article*, *Mosleh*, and *Mostafavi* because a person of ordinary skill in the art would not have been motivated to combine these three, disparate references. During the hearing, Dr. McNutt admitted that he failed to consider relevant evidence describing Elekta's difficulty combining arc therapy (similar to the *Earl Article*) and gating technology (similar to *Mostafavi*). *See* McNutt Tr. 747-752. Indeed, as to this specific combination, Dr. McNutt admits that "[he] didn't know how challenging that is from an engineering perspective[.]" *See* McNutt Tr. 749.

Mostafavi (RX-0240) (U.S. Patent Application Publication No. 2004/0116804) describes a "gating" system that tracks patient movement. Dr. McNutt's opinion that these three references would have been obvious to combine merely because all three

discuss delivering minimal doses of radiation to critical structures is unpersuasive, as it is not specific to or based on the disclosures of these specific references.

Likewise, Dr. McNutt's opinion that a person of ordinary skill in the art would have been motivated to combine these three references because it would have been desirable is uninformative as to any motivation to combine. *See* CX-3880C (Verhey RWS) at Q184. As previously discussed, the *Earl Article* actually teaches away from the innovations of Dr. Otto's VMAT solution by using multiple overlapping arcs, rendering any obviousness argument futile. The same opinions are recited again for the combination of *Earl Article*, Jaffray, and *Mostafavi*, and those opinions are unpersuasive as to those combinations as well. *See* CX-3880C (Verhey RWS) at Q186-91.

For the reasons discussed above with respect to the combination of the *Earl Article*, *Mosleh*, and *Mostafavi*, Elekta has failed to prove that claim 67 is obvious in light of the *Earl Article*, Jaffray, and *Mostafavi*.

d. *Otto '530* and *Earl '261* (Claim 68)

Elekta argues that the combination of *Otto '530* and *Earl '261* renders claim 68 of the '770 patent invalid as obvious. *See* Resps. Br. at 346-51. Varian argues that Elekta's expert does not discuss the validity of claim 68. *See* Compls. Br. at 344, 340; CX-3880C (Verhey RWS) at Q192. Nonetheless, Varian's expert did discuss this in his witness statement and opined that Otto '530 and Earl '261 does not render claim 68 obvious because the combinations lack various limitations, there was no motivation to combine them, and the commercial success of products than embody Dr. Otto's inventions are secondary indicia of non-obviousness. *See id.* at Q196-97, 205-219; *see also 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). Thus, the evidence does not show that this combination renders claim 68 obvious.

e. *Duthoy* and *Otto '530* (Claim 68)

Elekta argues that the combinations of *Otto '530* and *Duthoy* renders claim 68 of the '770 patent invalid as obvious. *See* Resps. Br. at 346-51. Varian argues that Elekta's expert does not discuss the validity of claim 68. *See* Compls. Br. at 344-45, 340; CX-3880C (Verhey RWS) at Q192. Nonetheless, Varian's expert did discuss this in his witness statement and opined that Otto '530 and Duthoy does not render claim 68 obvious because the combinations lack various limitations, there was no motivation to combine them, and the commercial success of products than embody Dr. Otto's inventions are secondary indicia of non-obviousness. *See id.* at Q196-97, 205-219; *see also Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d 1356 (2013). Thus, the evidence does not show that this combination renders claim 68 obvious.

4. Indefiniteness (Claims 61 and 67)

Respondents argue that asserted claims 61 and 67 of the '770 patent are invalid under 35 U.S.C. § 112, ¶ 2 because certain claim terms are indefinite. *See* Resps. Br. at 351-55.

Respondents argue:

> As evidenced during the hearing, both the term "intensity" and the phrase "obtaining two-dimensional projection images" are indefinite. First, a person of ordinary skill could not be reasonably certain as to the scope of the term "intensity" in claims 61 and 67 of the '770 patent and claims 23 and 26 of the '154 patent, thus rendering these claims invalid. Second, a person of ordinary skill in the art could not be reasonably certain whether the step of "obtaining two-dimensional projection images"

> required by claim 61 of the '770 patent is performed "while effecting relative movement between the treatment radiation source and the subject along the trajectory," or whether the "while effecting relative movement" phrase refers only to the "delivering a treatment radiation beam," rendering this claim invalid.

Resps. Br. at 351.

Complainants and the Staff disagree. *See* Compls. Br. at 345-50; Staff Br. at 143-44.

As discussed below, respondents have not shown by clear and convincing evidence that claims 61 and 67 are invalid under 35 U.S.C. § 112, ¶ 2.

Claim 61

Elekta argues that claim 61 of the '770 patent is indefinite because a person of ordinary skill in the art could not be reasonably certain whether the step of obtaining two-dimensional projection images is performed "while effecting relative movement between the treatment radiation source and the subject along the trajectory." *See* Resps. Br. at 351. However, this conclusion is contrary to the plain language of the claims and the specification. Claim 61 recites:

> **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.

JX-0005 ('770 Patent) at col. 35, ln. 63 – col. 36, ln. 12 (emphasis added).

Dr. McNutt's analysis ignores that the colon, emphasized above in the third element ("while effecting relative movement between the treatment radiation source and the subject along the trajectory:"), would be interpreted by a person of ordinary skill as modifying the remainder of the claim, and cannot overcome the presumption that the claim complies with this requirement of ¶ 112. *See generally, Microsoft Corp.*, 564 U.S. at 95. Thus, the "obtaining . . ." step that Dr. McNutt challenges as indefinite is plainly modified by "while effecting relative movement between the treatment radiation source and the subject along the trajectory." *See* CX-3880C (Verhey RWS) at Q140-41; Verhey Tr. 1108-1112. This interpretation is supported, verbatim, by the specification. *See id.*; JX-0005 at col. 4, lns. 25-36. As Dr. Verhey testified, "[t]here is nothing indefinite about that." *See* CX-3880C (Verhey RWS) at Q141; *Nautilus, Inc.*, 134 S. Ct. at 2129-30 (a claim is *only* indefinite if , read in light of the specification and file history, fails to inform those skilled in the art about the scope of the invention with reasonable certainty.

Claims 61 and 67: "intensity"

Elekta argues that claims 61 and 67 are indefinite because a person of ordinary skill in the art would not know the meaning of the word "intensity." *See* RX-0434C (McNutt WS) at Q229-33, 37. However, such conclusions are counter to Dr. McNutt's

analysis in other parts of his testimony. Dr. McNutt admitted during the hearing that varying the intensity in claim 19 of the '154 refers to changing the dose rate (McNutt Tr. 797-798), he had no difficulty interpreting the term "intensity" in performing his invalidity analysis (McNutt Tr. 729-731), and had no problem answering questions from his own counsel regarding passages from the '154 patent describing intensity and radiation output rate, as well as the claim limitation from claim 19 of the '154 patent describing varying the intensity of treatment radiation beam. *See* McNutt Tr. 784-786.

Dr. McNutt's only purported evidence is that, according to Dr. McNutt, two fact witnesses had difficulty providing a specific definition of the term. *See id.* However, as Dr. Verhey explained and is evident from the transcripts of those depositions, Dr. McNutt's characterizations are inaccurate. As Dr. McNutt admits, Mr. Archambault, a fact witness, testified that the word "intensity" could have different meanings in different contexts. *See* RX-0434C (McNutt WS) at Q233. Mr. Archambault did not testify that he was unable to determine the meaning of the word "intensity" within the context of the '770 patent or any other patent. Indeed, he was fully capable of answering questions about "intensity" in the context of the '770 patent invention. *See* JX-0022C (Archambault Dep. Tr.) at 36-37. Likewise, Adrian Smith, Elekta's Chief Engineer, testified that there were "reasonable" uses of the term "intensity" in the art, directly contradicting Dr. McNutt's characterization of the testimony. *See* JX-0055C (Smith Dep. Tr.) at 138.

Additional testimony from other witnesses reinforce that the term "intensity" as used in the Otto patents is well understood. During the hearing, the inventor Dr. Otto stated that changing the intensity of the source refers to changing the dose rate Otto Tr.

143-145. Dr. Bergeron testified during the hearing that "varying the intensity of the treatment radiation beam" in claim 19 of the '154 patent refers to varying the dose rate. Bergeron Tr. 315-317, 351-352. Dr. Verhey also opined that varying the intensity of the treatment radiation beam in claim 19 refers to changing the output of the radiation source. Verhey Tr. 1088-1092, 1119-1123.

Thus, Elekta has not shown that the claims fail to inform those skilled in the art about the scope of the invention with reasonable certainty with respect to the term "intensity." *See Nautilus, Inc.*, 134 S. Ct. at 2129-30 (a claim is only indefinite if, read in light of the specification and file history, it fails to inform those skilled in the art about the scope of the invention with reasonable certainty).

X. Domestic Industry (Economic Prong)

Complainants argue:

> Founded in 1948 in Palo Alto, California by Stanford graduates, Varian is the world's leading manufacturer of medical devices and software for treating cancer and other medical conditions with radiotherapy, radiosurgery, proton therapy and brachytherapy. With its headquarters still in Palo Alto, Varian is an American company employing over 3,800 people in the United States. Varian currently has 18 offices and factories located throughout the United States. Varian manufactures its TrueBeam, Edge, Trilogy, Clinac iX, and other DI Products in its Palo Alto facility.
>
> Varian remains one of the few companies in Silicon Valley that conducts extensive manufacturing operations, producing [ ] of the domestic industry radiotherapy systems per year at its factory in Palo Alto, California. As detailed below, the evidence presented at the hearing shows that Varian's investments in plant, equipment, labor and capital related to domestic manufacturing are immense. Between 2012-2015, Varian invested [ ] in manufacturing the DI Products at its Palo Alto facility.
>
> Additionally, Varian maintains a state-of-the-art training facility in Las Vegas, Nevada and a domestic service center in Atlanta, Georgia. At

the Las Vegas facility, Varian employs a staff of several dozen highly qualified instructors who provide training to Varian staff and customers. Varian also staffs and operates a call-center to provide technical support to Varian customers, and employs highly-trained workers around the country who travel to customer facilities in order to conduct installation, to provide on-site support and repairs, and to provide on-site training to Varian's customers. Between 2012-2015, Varian invested [ ] in installation, [ ] in customer support, and [ ] in customer training and education, all in support of the DI Products.

These expenditures, which are summarized in CDX-0033C below, represent significant investments that establish the existence of domestic industry under 19 U.S.C. § 1337(a)(3), subparagraphs (A) or (B).

[

]

Accordingly, Varian's investments in manufacturing, installation, service, support, training and education clearly establish the existence of a domestic industry. Neither Elekta nor its experts have challenged Varian's accounting or allocation of these expenditures. Indeed, as the Staff predicted in its Pre-Hearing Brief, the evidence at the hearing has shown that Varian has satisfied the economic prong of the domestic industry requirement.

Compls. Br. at 350-52 (citations and footnotes omitted); *see id.* at 350-77.

Respondents argue:

> Varian presented only carefully selected information regarding its domestic industry, while ignoring other important, relevant facts which could put the significance of Varian's domestic investiments in the appropriate context. In truth, Varian is a global company with activities and investments around the world. Varian has a global manufacturing chain, and extensive global activities focused on very features that are the focus of the Shapiro and Otto patents. But the full extent of Varian's foreign activities, or how they compare to the U.S. activities, is unknown, due to Varian's carefully edited data. Varian also relies on summary investments for certain of its linacs as a whole, ignoring the limited significance of the technology claimed in the patents-in-suit in the context of the linacs and this particular industry. Varian cannot establish economic prong of domestic industry based on the distorted record of evidence, which fails to demonstrate the significance of its investments in context. Varian has presumed its domestic activities are significant, while strategically relying on dependent claims for its domestic industry to obscure the fact that some unknown quantity of manufacturing-related activities related to the most significant aspects of the Shapiro and Otto Patents take place outside the United States.

Resps. Br. at 359 (citations omitted); *see id.* at 359-68.

The Staff argues that "the evidence has also shown that Varian has satisfied the economic prong of the domestic industry requirement under 19 U.S.C. §§ 1337 (a)(3)(A) and (B)." Staff Br. at 144; *see id.* at 144-51.

A violation of section 337(a)(1)(B), (C), (D), or (E) can be found "only if an industry in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Section 337(a) further provides:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned—
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or

> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

These statutory requirements consist of an economic prong (which requires certain activities)[90] and a technical prong (which requires that these activities relate to the intellectual property being protected). *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 13 (May 16, 2008) ("*Stringed Musical Instruments*"). The burden is on the complainant to show by a preponderance of the evidence that the domestic industry requirement is satisfied. *Certain Multimedia Display and Navigation Devices and Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-694, Comm'n Op. at 5 (July 22, 2011) ("*Navigation Devices*").

With respect to the economic prong, and whether or not section 337(a)(3)(A) or (B) is satisfied, the Commission has held that "whether a complainant has established that its investment and/or employment activities are significant with respect to the articles protected by the intellectual property right concerned is not evaluated according to any

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[90] The Commission practice is usually to assess the facts relating to the economic prong at the time that the complaint was filed. *See Certain Coaxial Cable Connectors and Components Thereof and Products Containing Same*, Inv. No. 337-TA-560, Comm'n Op. at 39 n.17 (Apr. 14, 2010) ("We note that only activities that occurred before the filing of a complaint with the Commission are relevant to whether a domestic industry exists or is in the process of being established under sections 337(a)(2)-(3).") (citing *Bally/Midway Mfg. Co. v. U.S. Int'l Trade Comm'n*, 714 F.2d 1117, 1121 (Fed. Cir. 1983)). In some cases, however, the Commission will consider later developments in the alleged industry, such as "when a significant and unusual development occurred after the complaint has been filed." *See Certain Video Game Systems and Controllers*, Inv. No. 337-TA-743, Comm'n Op., at 5-6 (Jan. 20, 2012) ("[I]n appropriate situations based on the specific facts and circumstances of an investigation, the Commission may consider activities and investments beyond the filing of the complaint.").

rigid mathematical formula." *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 27 (Feb. 17, 2011) ("*Printing and Imaging Devices*") (citing *Certain Male Prophylactic Devices*, Inv. No. 337 TA-546, Comm'n Op. at 39 (Aug. 1, 2007)). Rather, the Commission examines "the facts in each investigation, the article of commerce, and the realities of the marketplace." *Id.* "The determination takes into account the nature of the investment and/or employment activities, 'the industry in question, and the complainant's relative size.'" *Id.* (citing *Stringed Musical Instruments* at 26).

As discussed above for each of the asserted patents, the evidence shows that Varian has established the technical prong of the domestic industry requirement with regard to at least one claim of each asserted patent. For the reasons discussed below, the evidence shows that Varian has satisfied the economic prong of the domestic industry requirement under 19 U.S.C. §§ 1337 (a)(3)(A) and (B).[91]

A. Articles Protected by the Patent

Whether an industry exists in the United States depends on whether the requisite investments have been made with regard to "articles protected" by the asserted intellectual property. 19 U.S.C. § 1337(a)(2). Whether a product can be an article of commerce under section 337 when it includes components that are both within and outside of the scope of the intellectual property right in dispute depends on the realities of the marketplace in which it exists. *See Certain Double-Sided Floppy Disk Drives and*

[91] The administrative law judge precluded Varian from arguing that it has a domestic industry under prong (C). *See* Order No. 32 at 5-6 (granting Elekta's motion *in limine* No. 4).

Components Thereof, Inv. No. 337-TA- 215, Comm'n Op. at p. 23 (Nov. 1985) ("*Floppy Disk Drives*") ("The Commission does not adhere to any rigid formula in determining the scope of the domestic industry as it is not precisely defined in the statute, but will examine each case in light of the realities of the marketplace."); *Certain Video Game Systems and Wireless Controllers and Components Thereof*, Inv. No. 337-TA-770, Comm'n Op. at p. 66 (Oct. 28, 2013) ("The Commission has held that in certain circumstances, the realities of the marketplace require a modification of the principle that the domestic industry is defined by the patented article.").

In *Floppy Disk Drives*, the Commission explained that while a product (in that case the patented head assembly for floppy disk drives) "may be in and of itself an article of commerce," the inquiry does not end there. *See Floppy Disk Drives* at p. 27. Rather, "when viewed according to the competitive realities of the marketplace" the entire floppy disk drives, not just their patented head assemblies, were "the actual articles of commerce at issue" under section 337. *Id.*

In more recent investigations, the Commission continued to follow the view that unpatented components can be included as part of a domestic industry. *See Certain Product Containing Interactive Program Guide and Parental Control Technology*, Inv. No. 337-TA-845, Initial Determination (unreviewed in relevant part) at p. 304 (June 7, 2013) (the Commission "evaluates whether the complainant has made investments in particular products, rather than evaluating whether the investment relates to the specific features of an asserted patent"); *see also Video Game Systems*, Inv. No. 337-TA-770, Comm'n Op'n at p. 70 (unpatented game park technology related to the patented magic wands could have been a domestic industry expenditure upon a showing of adequate

factual proof because it was "central to enabling [complainant] to exploit the technology of the claimed toy wands."). *See id.* at 70.

In this context, Varian's domestic industry products are its radiotherapy systems as a whole, not just the software treatment system, or the "OBI," which has no use unless it is run on a compatible radiotherapy device with a linear accelerator. *See Motorola Mobility, LLC v. Int'l Trade Comm'n*, 737 F.3d 1345, 1351 (Fed. Cir. 2013) ("nothing in § 337 precludes a complainant from relying on investments or employment directed to significant components, specifically tailored for use in an article protected by the patent. The investments or employment must only be 'with respect to the articles protected by the patent.' 19 U.S.C. § 1337(a)(3). An investment directed to a specifically tailored, significant aspect of the article is still directed to the article.").

Thus, while the evidence shows that [

], it would be improper to weigh the expense of the development of the software, which is a component of the overall system, overseas versus domestically. *See e.g.* Resps. Br. at 362, 364-65. Rather, Varian's total allocable expenses for the manufacture of the domestic industry systems must be considered. As Varian argues, "[t]he vast majority of the work performed on each linac is undertaken in Palo Alto." *See* Compls. Br. at 356 (citing CX-0847C (Haines WS) at Q25, 30-33); *see also* CX-0847C (Haines WS) at Q29, 40-42. The evidence shows that it takes [ ] to assemble and test each linac, where each linac contains dozens of subassemblies. This work is performed in Palo Alto. *See id.*

Thus, Varian's expenses in plant and equipment and labor or capital are qualitatively significant. Further, the evidence shows that Varian's expenses in plant and

equipment and labor or capital are both qualitatively and quantitatively significant, as discussed below. *See Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Products Containing the Same*, Inv. No. 337-TA-921, Comm'n Op. at 62-64 (Dec. 1, 2015) ("*Marine Sonar*") (requiring qualitative and quantitative analysis).

B. Exclusive License and Ownership of the Otto Patents

Elekta argued in its opposition to Varian's motion for summary judgment that Varian did not own the patents until 10 days before the filing of its original complaint. *See* Order No. 30 at 5-6. Indeed, Varian acknowledged this in the original complaint. *See* Ex. 18 to the Complaint. However, Varian (in particular Varian Medical Systems, Inc.) has been the exclusive licensee to the Otto patents (and their priority applications) since 2006, as shown in [ ]:

[

]

See CX-1628.01, .02C ([

]); *see also* CX-0852C (Otto WS) at Q19, 62; Otto Tr. 135-

137. Whether as the exclusive licensee or the assignee of the Otto patents, Varian's expenses toward exploiting the patents are allowable as domestic industry expenses.

C. Significant Investment in Plant and Equipment

The evidence shows that Varian has made significant investments in its plant and equipment for its manufacturing facilities at its Palo Alto headquarters. Varian has a [ ] for the land in Palo Alto where its campus is located. Varian currently uses about [ ] on this property for linac manufacture and testing. *See* Compls. Br. at 359 (citing CX-0847C (Haines WS) at Q29).

The evidence shows that Varian's plant and equipment costs (including tooling costs) relating to manufacturing in Palo Alto are as follows:

Shapiro Patents						
	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	Total
TrueBeam	[					]

Otto Patents						
	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	Total
RapidArc	[					]
Eclipse	[					]
TrueBeam	[					]
Total	[					]

See Compls. Br. at 366 (citing CX-0846C (Bakewell DWS) at Q85-86; CDX-0016C).

Thus, the evidence shows that Varian has made qualitatively and quantitatively significant investments in its plant and equipment for its manufacturing facilities at its Palo Alto headquarters. *See Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Products Containing the Same*, Inv. No. 337-TA-921, Comm'n Op. at 62-64 (Dec. 1, 2015) ("*Marine Sonar*") (requiring qualitative and quantitative analysis).

D. Significant Employment of Labor or Capital

The evidence shows that Varian argues that it has also made significant investments in labor at its Palo Alto factory. The plant had approximately [ ] in 2015. Varian tracks "Direct Labor" costs, which reflect "hands on" labor (*i.e.*, work done to physically produce and assemble products) as well as "Indirect Labor" costs which reflect non-hands on work (*e.g.*, management, materials procurement, and other work done to support production) for the two cost pools discussed above. *See* Compls. Br. at 360-61 (citing CX-0847C (Haines WS) at Q26, 28, 43; CX-0590C; CX-0591C).

Varian allocates its total labor expenses to the domestic industry products that practice the Shapiro and Otto patents, as show in the following table:

Shapiro Patents						
	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	Total
TrueBeam	[					]

Otto Patents						
	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	Total
TrueBeam	[					]
C-Series	[					]
Eclipse	[					]
Total	[					]

See Compls. Br. at 367 (citing CX-0846C (Bakewell DWS) at Q96-97; CDX-0020C). Varian states that its total labor costs attributable to its linac manufacturing for FY 2012 through 2015 are [ ]. *See* Compls. Br. at 361 (citing CX-0794C; CX-0847C (Haines WS) at Q43).

The evidence shows that Varian's plant and equipment and labor or capital expenses that are attributable to the manufacture, installation and customer support (service technicians, help desk, and training) relating to the domestic industry products are part of Varian's domestic industry. *See, e.g.*, Amacker Tr. 174, 179-180; CX-0846C (Bakewell WS) at Q85-86, 127; CX-0850C (Amacker WS) at Q9, 15; CX-0430C, CX-0431C, CX-0432C, CX-0429C, CX-0606C, CX-0604C, CX-0605C, CX-0607C, CX-0793C, CX-0794C, CX-0704C, CX-0795C.

However, Varian's expert Mr. Bakewell admitted at the hearing that Varian's "help desk" expenses were in his opinion more like prong (C) engineering expenses than prong (B) labor expenses. *See* Bakewell Tr. 526-527. While customer support expenses like a help desk have typically been included in domestic industry expenses, here Varian is not alleging a domestic industry under prong (C). *See* Order No. 32 at 5-6 (granting

Elekta's motion *in limine* No. 4). Thus, the evidence does not support including Varian's helpdesk expenses in its domestic industry. Likewise, the record does not support Varian's argument that its expenses related to conferences (such as the ASTRO conference) are prong (B) expenses as opposed to prong (C). *See* Bakewell Tr. 528-529, 548-549.

In addition, Varian's expenses with respect to marketing and sales (albeit it "technical marketing and sales," as Varian describes these expenses) or the Atlanta facility (which currently is not used to exploit the asserted patents) are not properly allocable under either prong (A) or (B). *See* Bakewell Tr. 529, 549-550; *see also* Resps. Br. at 367-68 (regarding sales team).

Yet, even without the excluded expenses, Varian's investments, as discussed above, are both qualitatively and quantitatively significant. The evidence shows that Varian has satisfied the economic prong of the domestic industry requirement.

XI. Public Interest

The Commission delegated the taking of evidence or other information with respect to the public interest in this investigation to the administrative law judge. *See* 80 Fed. Reg. 66934 (October 30, 2015); 19 C.F.R. §210.10(b). Before issuing any remedial order for a violation of section 337, the Commission must weigh the effects of the remedy on the public interest by considering four factors. *Certain Inclined-Field Acceleration Tubes*, Inv. No. 337-TA-67, Comm'n. Op. (Dec. 29, 1980). These public interest factors are: (1) the public health and welfare; (2) the competitive conditions in the United States economy; (3) the production of like or directly competitive articles in the United States; and (4) the United States consumers. 19 U.S.C. § 1337(d)(1). The

Commission must then balance any potentially adverse impact on the public interest against the public's interest in protecting and enforcing intellectual property rights. *See id.* If the negative impact of the remedial order outweighs its benefit, the Commission must deny the requested relief. *Id.*

In the few instances in which the Commission has found a public interest impact significant enough to deny relief, "the exclusion order was denied because inadequate supply within the United States—by both the patentee and domestic licensees—meant that an exclusion order would deprive the public of products necessary for some important health or welfare need...." *Spansion, Inc. v. ITC*, 629 F.3d 1331, 1360 (Fed. Cir. 2010) (citing *Certain Fluidized Supporting Apparatus*, Inv. No. 337-TA-182/188, Comm'n. Op. (Oct. 1984), *Inclined-Field Acceleration Tubes*, (Dec. 1980); and *Certain Automatic Crankpin Grinders*, Inv. No. 337-TA-60, Comm'n. Op. (Dec. 1979)).

Complainants argue:

> The issuance of limited exclusion orders and/or cease-and-desist orders in this Investigation would not adversely affect public health and welfare or U.S. consumers because: (1) there are substitute radiotherapy and treatment planning systems available in the U.S.; (2) Varian has capacity to supply the U.S. market with substitute radiotherapy and treatment planning systems; and (3) Varian's requested remedy contains a proposed "carve-out" to allow continued operation of Elekta's installed base in the U.S. These factors, combined with the strong public interest in enforcing intellectual property rights and providing patent owners with an effective remedy for infringement, counsel that Varian's requested remedial orders in this Investigation are warranted. Further, Varian has been and remains amenable to offering a license to Elekta, which would eliminate any potential public interest concerns raised by Elekta.

Compls. Br. at 383 (citations omitted); *see id.* at 383-99.

Respondents argue:

> There is no real dispute that the public interest would be adversely impacted if a limited exclusion order and a cease and desist order were entered barring all the accused radiotherapy products and Elekta's U.S. activities related to those products. From the outset, Varian agreed it would not seek "remedial orders precluding U.S. hospitals or customers from servicing existing Elekta linacs or from buying replacement parts for those machines," nor would it seek "remedial orders precluding U.S. hospitals or customers from receiving bug fixes or critical software updates." However, as discussed below, Varian's vague "carve-out" does not adequately address the impact on the public interest.
>
> The potential remedial orders in this Investigation, even as limited by Varian, would adversely impact every one of the four factors set out in 19 U.S.C. § 1337(d)(1). Such remedial orders would harm consumers by reducing their access to and increasing the cost of life-saving health care treatments. Should any remedial orders issue, it is imperative that they protect the public interest by providing patients access to up-to-date, accurate radiotherapy equipment, administered by qualified, trained professionals, at a reasonable cost. Such orders should also protect access to Elekta's accused products by institutions involved in collaborative research that is crucial for future developments in cancer treatment. To protect the public interest, any remedial order should permit service, maintenance, repair, and upgrades of existing Elekta equipment. In addition, should an exclusion order be issued blocking importation of any accused products to be delivered to customers, customers should be provided with a transition period to ameliorate issues caused by additional training, economic investments in existing orders, and Varian's inability to supply the market. Finally, any such order should allow the importation of the Gamma Knife Icon, the newest product in Elekta's flagship Gamma Knife product line.

See Resps. Br. at 376-77 (citations omitted); *see id.* at 376-88.

The Staff argues: "Thus, although the evidence has not shown that public interest concerns should preclude a remedy in this investigation, some form of tailoring of the remedy (in particular, the type of carve-out proposed by Varian) may be appropriate." Staff Br. at 152; *see id.* at 151-52.

The administrative law judge was especially interested in weighing evidence relating to the first and fourth of the enumerated public interest factors, *i.e.*, the effects that a remedy might have on public health and welfare, and on domestic consumers. In particular, questions were raised as to whether the quality of treatment that patients receive depends on whether the accused or other products are used, and whether the issuance and implementation of Commission remedial orders would disrupt patients' treatment. As discussed below, the evidence adduced by the parties does not show that the accused devices must be imported in order for patients to receive the same level of care. In fact, in the case of the Gamma Knife, Elekta itself has available a substitute, non-accused product. Furthermore, the evidence adduced by the parties does not show that there would be disruption in patients' treatment, provided that certain exceptions, or "carve outs," are present in Commission remedial orders. Indeed, having considered all of the public interest factors, the evidence does not show that public interest concerns should preclude a remedy in this investigation.

Availability of Substitutes for Elekta's Accused Linacs

The evidence shows that substitutes for Elekta's accused linacs are available in the United States. Varian's linacs, such as TrueBeam, are direct substitutes for Elekta's Accused Linacs, such as Versa HD. *See* Reed Tr. 941 (agreeing that Varian and Elekta linacs are directly competitive); CX-0300C; CX-0846C (Bakewell WS) at Q159; CDX-0039C, citing JX-0025C (Brown Dep. Tr.) at 34 and JX-0035C ([ ] Dep. Tr.) at 74; CX-3835C (Bergeron WS) at Q11, 624-629. Varian and Elekta make linacs that are capable of treating the same range of indications; the choice of vendor does not impact efficacy or clinical outcome. As a result, some hospitals and clinics employ both Varian and Elekta

linac systems side-by-side, and do not opt to treat patients on one manufacturer's machine versus another for any clinically based reason. *See* CX-0848C (Mutic WS) at Q393-397; CX-0425C; CX-0843; CX-0844; CX-1031; Quon Tr. 853 (Elekta's expert, Dr. Quon, testifying that Varian and Elekta products sometimes replace each other, and that there are a number of hospitals throughout the U.S. operating both Elekta and Varian linacs). [ ] testified that [

]." *See* JX-0034C ([ ] Dep. Tr.) at 138-139. Similarly, [

], testified during his deposition that "[

]." JX-0035C ([ ] Dep. Tr.) at 28.

In addition, there are products offered by third parties such as Accuray that are also direct substitutes for Elekta's Accused Linacs. *See* CX-0848C (Mutic WS) at Q397-401; CX-0842C; CX-0855C; CX-0887C. Elekta acknowledges that Varian, Accuray and others compete in the linac space. For example, [

]." *See* CX-0300C at 26; *see also* CX-0846C (Bakewell WS) at Q165-68 (noting that various industry analysts view the radiotherapy market as a three player market – *i.e.,* Elekta, Varian, and Accuray, and that Accuray is a direct competitor to both Elekta's linacs and to Gamma Knife). Mr. Sedihn, Chief Operating Officer at Elekta, testified that, "in general linear accelerators can replace each other." JX-0051C (Sedihn Dep. Tr.) at 186. Dr. Quon, Elekta's expert in

radiation oncology does not dispute that Varian and other manufacturers sell linacs in the U.S. that are "like or directly competitive" to Elekta's Accused Linacs. *See* CX-0848C (Mutic WS) at Q402.

The evidence shows that Varian has been the longstanding leader for linacs in the United States. Companies such as Elekta, Accuray, BrainLab, and others are targeting Varian competitively. *See* CDX-0037C; CX-0846C (Bakewell WS) at Q175; CX-0579C; CX-0859C; CX-3546C. While there are some price differences between the various linacs, these price differences do not create distinct market segments, and hospitals and clinics are generally relatively price insensitive. *See* CX-0846C (Bakewell WS) at Q163. Elekta's witnesses agree. For example, Mr. Symons testified that while "[

]." JX-0056C (Symons Dep. Tr.) at 111-112. Similarly, Mr. Sedihn testified that [

]." JX-0051C (Sedihn Dep. Tr.) at 133. This relative price insensitivity is not only a function of a desire to focus on patient care, but also because the products at issue in this case have relatively lengthy life cycles. Thus, while the initial investment may be sizeable, it is an investment that is made for a time horizon that spans one or two decades. *See* CX-0846C (Bakewell WS) at Q163.

Substitutes for Elekta's Gamma Knife Icon

Elekta's Gamma Knife Perfexion, which is not an accused product in this investigation, is a direct substitute for the accused Gamma Knife Icon. *See* CX-0848C (Mutic WS) at Q409-412. This is consistent with [

]." *See* JX-0034C ([ ] Dep. Tr.) at 132, 134-135. It is also consistent with the hearing testimony of Dr. Quon, who conceded that "from a clinical and operational perspective … Perfexion and Icon are the same." Quon Tr. 855. Dr. Quon also admitted that his opinion that "Gamma Knife is the standard for SRS treatment" is based on his experience with Gamma Knife Perfexion not Gamma Knife Icon. Quon Tr. 863-864. Inasmuch as Gamma Knife Perfexion is not an accused product, Varian's requested remedy would not impact the ability of U.S. consumers to purchase Gamma Knife Perfexion, nor would Varian's requested relief impact U.S. consumers' ability to receive treatment from a Gamma Knife Perfexion. Further, due to Varian's proposed "carve-out," Varian's requested remedy would not impact U.S. consumers' ability to receive treatment on a Gamma Knife Icon already installed in the United States.

In addition to Gamma Knife Perfexion, there are several linac-based radiotherapy systems that are "like or directly competitive" to Gamma Knife Icon. As Elekta's expert Mr. Reed admitted during the hearing, substitutable products do not need to be identical to the excluded products. Reed Tr. 942. Gamma Knife Icon competes in the same market as linacs, and in particular those manufactured by Varian, Accuray, and BrainLab. *See* CX-0262C; CX-3565; JX-0051C (Sedihn Dep. Tr.) at 137, 183-184; JX-0056C (Symons Dep. Tr.) at 102-103, 173; JX-0025C (Brown Dep. Tr.) at 35, 186-187. For example, Accuray's CyberKnife, Varian's TrueBeam and Edge, and BrainLab's Novalis are able to treat the same indications as the Gamma Knife Icon. *See* CX-0848C (Mutic WS) at Q409, 413. Dr. Carlsson, Director of System Design at Elekta, testified during his deposition that the Gamma Knife Icon can be replaced by other products at least "for

certain indications." JX-0026C (Carlsson Dep. Tr.) at 89. In addition, Dr. Quon testified at the hearing that Johns Hopkins replaced its Gamma Knife with an Accuray CyberKnife (*i.e.,* a linac-based system), and that Accuray's CyberKnife and Varian's TrueBeam can be used to perform stereotactic radiosurgery ("SRS") and are "roughly equivalent" to Gamma Knife in terms of attacking the cancer target. *See* Quon Tr. 858; *see also* CX-0848C (Mutic WS) at Q414. This is also consistent with [

]." *See* JX-0035C ([ ] Dep. Tr.) at 67-68; JX-0034C ([ ] Dep. Tr.) at 133.

As Dr. Mutic testified, multiple clinical studies have shown that there is no difference in clinical efficacy or patient outcome between Gamma Knife and linac-based solutions. *See* CX-0848C (Mutic WS) at Q409. Dr. Mutic explained that Dr. Quon based his opinions on technical studies, examining only dosimetry. While these technical studies may identify differences in the technical performance of radiotherapy systems, clinical studies, such as those relied on by Dr. Mutic, demonstrate that there is no evidence that these technical differences result in differences in clinical efficacy or patient outcomes. *See* CX-0848C (Mutic WS) at Q416-22 (citing CX-0862, CX-0142 through CX-0152). Indeed, at the hearing Dr. Quon was forced to admit that there have not been any clinical studies concluding that Gamma Knife is "any better" than linac-based treatment. *See* Quon Tr. 861-862. Further, Dr. Quon acknowledged that the studies he cited were conducted on *Gamma Knife Perfexion* or other, older models of Gamma Knife, and not on Gamma Knife Icon. *See* Quon Tr. 859; *see also* CX-0848C (Mutic WS) at Q412.

Additionally, as Dr. Mutic explained, Dr. Quon's claims regarding the "faster rate" of radiation delivery for Gamma Knife are in many cases incorrect. The rate of radiation delivery is dependent on several factors, including the collimator (which controls the size and shape of the radiation beam) and the parameters of the treatment plan. In the case of Gamma Knife, the rate at which the radiation dose can be delivered also depends on the age of the cobalt-60 source. The cobalt-60 source in a Gamma Knife degrades over time (due to the natural radioactive decay of cobalt-60). Thus, as the source ages, the rate at which it can deliver radiation decreases. The cobalt-60 source in a Gamma Knife must be replaced approximately every five years, and clinicians are generally aware that using a Gamma Knife with a cobalt-60 source near the end of its usable life can result in long treatment times. *See* CX-0848C (Mutic WS) at Q423; CX-0147; CX-0152.

Dr. Mutic explained that Gamma Knife products have several disadvantages as compared to linacs. For example:

- As mentioned above, the cobalt-60 sources in a Gamma Knife need to be replaced approximately every five years. Replacement costs can be as much as 1/5 of the initial purchase price of the Gamma Knife system. *See* CX-0848C (Mutic WS) at Q427; CX-0152.

- The United States Nuclear Regulatory Commission ("NRC") regulates "the medical use of radioactive materials in the fields of nuclear medicine, radiation therapy, and research." In recent years, there have been efforts to further tighten regulatory controls regarding medical use of cobalt-60. These efforts are driven by the concern that "high risk radiological material," such as the cobalt-60 sources in Gamma Knife, could be used by terrorists to make a "dirty bomb." Increased regulation (*e.g.*, licensing requirements including background checks, regulation over the transport and storage of cobalt-60, and regulation of the disposal of retired cobalt-60 sources) results in increased costs to hospitals and/or clinics operating Gamma Knife systems. *See* CX-0848C (Mutic WS) at Q426.

- Gamma Knife is only capable of delivering treatment to the head and upper portion of the neck. *See* CX-0848C (Mutic WS) at Q408. Unlike a Gamma Knife, linacs are capable of delivering treatment to various parts of the body. In this regard, linacs are more versatile and can be used to treat a wider range of indications and patients. This means that a linac is less likely to remain idle for long periods of time. *See* CX-0846C (Bakewell WS) at Q177.

Given these disadvantages, Mr. Carlsson testified that [

]. *See* JX-0026C (Carlsson Dep. Tr.) at 91-92, 96-98; *see also* JX-0024C, Börjesson at 104. Mr. Carlsson explained that in part, this is because the [

]. The fact that Elekta [

], provides further evidence that demand for Gamma Knife Icon, if excluded, could be met by linacs. *See* CX-0846C (Bakewell WS) at Q176 (citing JX-0026C (Carlsson Dep. Tr.) at 98-101 ("[

]") and JX-0051C (Sedihn Dep. Tr.) at 249-250); CX-0848C (Mutic WS) at Q427.

Further, there have been [ ] Icon sales, with [ ] of the Gamma Knife Icon as of October 2015. *See* CX-0846C (Bakewell WS) at Q174; CX-0848C (Mutic WS) at Q424 (citing Sedihn Dep., JX-0051C at 177); *see also* CX-0262C (Elekta ASTRO Capital Markets presentation). Icon's low sales have continued in 2016 with Elekta disclosing that "delivery volumes for Leksell Gamma Knife were significantly below plan." *See* CX-1088 (Elekta interim financial report). In addition, Elekta stated that "[ ]." *See* CX-0537C (internal Elekta document). This was acknowledged by Tomas Puusepp, the recent former President and Chief

Executive Officer of Elekta, when he stated during an earnings call that "Q3 was clearly a disappointment to me and my colleagues, and also weaker than forecasted" and that Elekta's challenges in this timeframe included "new sales of Leksell Gamma Knife." *See* CX-3593 (earnings call). Indeed, Elekta's expert Dr. Quon admitted that he has never used a Gamma Knife Icon nor does he know anyone who has. *See* Quon Tr. 855-856.

Varian's treatment planning systems

Elekta's linacs and Varian's linacs are compatible with treatment planning systems from Elekta and Varian. *See* Quon Tr. 853-854; CX-0848C (Mutic WS) at Q404; Sedihn Dep., JX-0051C at 134-135; CX-0579C; CX-0304C. Specifically, Varian RapidArc and Eclipse treatment planning systems have the same features and functionality related to VMAT treatment planning as Monaco. *See* CX-3835C (Bergeron WS) at Q627.

For example, the Monaco software is compatible with Varian's linacs in addition to being compatible with the Accused Linacs. In fact, the Monaco Training Guide provides explicit instructions on how to tailor Monaco for use with Varian linacs instead of the Elekta linacs. *Id.* In addition, the Monaco [

]. *See* CX-3835C (Bergeron WS) at Q627 (citing CPX-0023C, CPX-0024C, CPX-0025C).

As a result of these compatibilities, a current Elekta customer seeking to upgrade its linacs with VMAT functionality could use Varian's treatment planning systems. Similarly, a customer who replaces an Elekta linac with a Varian linac would not necessarily need to replace its current treatment planning system.

Costs related to switching equipment from one vendor to another

Moving from one manufacturer to another can be accomplished without incurring unreasonable costs. This is because the "siting" (*i.e.*, required vault size and design elements for the building/room housing a linac) does not vary greatly between linac manufacturers, and because there are options for interoperability between treatment planning products and linacs from different manufacturers. Especially relative to the overall cost of the system, the potential switching costs would not be material. *See* CX-0848C (Mutic WS) at Q434-436; CX-0846C (Bakewell WS) at Q170. Indeed, at the hearing, Dr. Quon admitted that Varian and Elekta products replace each other, and that he knows of a number of hospitals throughout the U.S. that have both Varian and Elekta linacs. *See* Quon Tr. 853.

Nor is clinician training time a barrier to switching manufacturers for external beam therapy equipment and/or treatment planning systems. Training courses are often included in the purchase price of a radiotherapy or treatment planning system, and training can be completed in a matter of weeks or months, depending on the clinician's schedule and pace at which they take the offered courses. *See* CX-0848C (Mutic WS) at Q437. This is consistent with [ ] deposition testimony that [

].

See JX-0035C (Liu Dep. Tr.) at 120 (explaining that [

].").

Capacity to increase production

Varian has the capacity to increase linac production at its Palo Alto factory in order to replace Elekta products excluded from the market, as well as capacity to increase production and support for its treatment planning systems, and to increase its capacity to perform support services such as installation, upgrades, service, support, training and education. Varian's capacity to provide substitute products is sufficient to override any public interest concerns.

Elekta's expert Mr. Reed estimated the total annual supply of Elekta systems in the U.S. to be "[ ] Elekta linacs in the U.S., along with [ ] Gamma Knife replacements," for a total of [ ] per year [ ]. *See* RX-0469C (Reed WS) at Q100; *see also* JX-0056C (Symons Dep. Tr.) at 62, 125, 132, 133-134; CX-0304C (internal Elekta document); JX-0051C (Sedihn Dep. Tr.) at 220. Varian's expert Mr. Bakewell agrees that given Elekta's sales projections [ ], even with an optimistic view of Elekta's contribution to the U.S. radiotherapy market, it is reasonable to assume that, without an exclusion order, Elekta's expected sales of radiotherapy treatment systems in the United States will be [ ]. *See* CX-0846C (Bakewell WS) at Q184; CDX-0046C.

Varian is capable of increasing TrueBeam (including Edge) and/or Clinac (including Trilogy and Clinac iX) production to compensate for the [ ] that Elekta would be prevented from selling in the United States. In fact, Varian's capacity to increase linac production is significantly greater than [ ] per year. As Mr. Haines testified at the hearing, Varian could ramp-up production "almost immediately" by "[ ]. *See* Haines Tr.

1203, 1200-1201. Mr. Haines, Varian's Senior Director of Production in Palo Alto, has over 40 years of experience in production at Varian (CX-0847C (Haines WS) at Q2), and Elekta's expert Mr. Reed admitted that Mr. Haines "would be more informed" about the specifics of Varian's ability to increase production in Palo Alto. *See* Reed Tr. 949-950 (Mr. Reed testifying that he has not analyzed any specific limitations that would prevent Varian from manufacturing enough linacs to supply Elekta customers if an exclusion order is put into place). Even prior to this investigation, Varian examined various scenarios for increasing production – [

] in FY 2016. *See* CX-0847C (Haines WS) at Q59-63; CX-0413C; CX-3555C; CX-0846C (Bakewell WS) at Q187; CDX-0047C. Per this plan, Varian has [

]. *See* CX-3555C at 4 (Chart examining "[

]).

As Mr. Haines testified, he has studied the factors impacting production capacity at Varian's Palo Alto facility, and has analyzed changes to operations in the Palo Alto facility that could be made in order to increase production. There are three main variables impacting Varian's capacity: (1) test time; (2) number of available test cells; and (3) utilization. *See* Haines Tr. 1200. Decreasing test time and increasing the number of test cells increases the number of linacs that can move through the System Test phase in Palo Alto, and thus ultimately increases production. "Utilization" refers to the amount of time workers are actually working on a linac while it is being built or tested in the Palo Alto facility – *i.e.*, it is basically a measure of how long the linac sits idle with no one

working on it. By making changes to staffing (*e.g.*, hiring additional staff, changing the number of shifts, increasing second and third shift staffing, etc.), Varian can increase utilization and in turn increase production in Palo Alto. By studying these factors, Mr. Haines determined that Varian could reasonably increase production of TrueBeam in its Palo Alto factory to as many as [ ]. *See* CX-0847C (Haines WS) at Q49-57; CX-3481C; CX-0846C (Bakewell WS) at Q193; CDX-0049C.

In addition, in 2006, Accuray announced that it had opened a manufacturing facility in Sunnyvale, California. This facility was said to double Accuray's production capacity and was "sized to support the company's growth over the next decade" *See id.* (citing CX-0820 (Accuray press release)). Accordingly, Accuray also has capacity to increase production to replace excluded Elekta linacs and Gamma Knife Icon.

Varian has capacity to make similar increases to its production and support of treatment planning systems, and to its support services including installation, upgrades, support, training, and education. Increasing capacity for these services would not require any change to Varian's business model and would be easy to accomplish relatively quickly. *See* CX-0850C (Amacker WS) at Q20; CX-0846C (Bakewell WS) at Q195.

Varian's proposed "carve-out"

Varian's requested remedy includes a proposed "carve-out" to allow patients to continue receiving treatment from Elekta's installed base of radiotherapy equipment. This "carve-out" further minimizes any potential impact on the public health and welfare or U.S. consumers. *See* CX-0846C (Bakewell WS) at Q152, 200.

As Elekta's expert Mr. Reed admitted, the U.S. market for radiotherapy systems is relatively mature. *See* Reed Tr. 940; *see also* JX-0056C (Symons Dep. Tr.) at 53-54; JX-

0051C (Sedihn Dep. Tr.) at 165. As of September 2014, market analysts IMV found that there were [ ] already installed in the United States, and that linacs were installed in every state in the United States. *See* CX-0579C at 65; *see also* CX-0300C at 15. Mr. Reed acknowledged that most facilities in the United States have adequate radiotherapy equipment. *See* Reed Tr. 941. Moreover, the average lifespan for linacs is normally around ten years, and it can be extended for up to 20 years or more. *See* CX-0846C (Bakewell WS) at Q203; CX-3606 at 7; CX-3613 at 44; CX-0300C at 20. Elekta's oldest installed units (specifically, those more than ten years old) comprise [ ] of Elekta's total installed base. *See* CX-0300C; CX-3565; CDX-0051C. This means that [ ] Elekta's installed base of linacs could remain in operation, and may not need to be replaced until after the Shapiro patents expire in 2022. The Otto patents expire in 2027, and many of Elekta's linacs could remain in operation until then, as well. Thus, over the term of an exclusion and/or cease and desist order, much of Elekta's installed base would still be available to treat patients. *See* CX-0846C (Bakewell WS) at Q204.

Additionally, there is capacity for the existing linacs in the U.S. to be used to treat more patients. *See* CX-3609 at 3 (explaining that radiotherapy equipment installed in U.S. hospitals and clinics experience "15% lower capacity utilization" relative to European institutions, meaning that each installed unit in the U.S. is being utilized 15% less than installed units in Europe, and indicating that there is capacity to treat additional patients using currently installed units in the U.S). Elekta's economist, Mr. Reed agrees, testifying at the hearing that the market research indicates that compared to areas outside the U.S., radiotherapy equipment in the U.S. is utilized to a lesser degree, and that there is

no expectation for growth (*i.e.*, increase in number of overall installed units) in the U.S. *See* Reed Tr. 941. Thus, if hospitals and clinics more fully utilize their installed base of radiotherapy treatment systems, it would further minimize any potential impact from an exclusion order and/or cease and desist order. *See* CX-0846C (Bakewell WS) at Q205 (explaining that increasing the utilization of linacs in the U.S., for example to levels consistent with what is seen in Europe, would alleviate some of the need to purchase additional linacs).

Limiting Elekta's ability to provide "upgrades" to existing Elekta customers

Elekta argues that limiting its ability to provide "upgrades" to existing Elekta customers will harm the public interest. *See* Resps. Br. at 385-87. However, Elekta did not provide evidence from which the Commission could gain an understanding of exactly what constitutes an "upgrade" (versus a repair or update to preserve existing functionality, which Varian has agreed should be "carved-out" from any remedy in this Investigation). *Id.* For example, Mr. Reed has not clearly defined what he means by "upgrade," he has not explained what benefits would be unavailable without the ability to upgrade, he has not explained why Varian or others would be unable to provide these upgrades, and he did not provide evidence regarding how many of Elekta's currently installed linacs are upgradeable. Rather, Mr. Reed has provided vague and conclusory opinions that "upgrades" are valuable to Elekta customers. However, contrary to this opinion, Mr. Reed admitted that Elekta's most popular linac model (Versa HD) is not upgradable. *See* Reed Tr. 945-946. Further, Mr. Reed was unable to provide any certain data on the number of Elekta linacs that have been upgraded. *See* Reed Tr. 944. Nor did he provide evidence regarding how long an upgrade would take (*i.e.*, whether it would be

quicker to install than a new system), nor did he demonstrate that upgrading is technically feasible. *See* CX-0846C (Bakewell WS) at Q207-210. Indeed, Mr. Reed conceded that "not every customer and not every customer's particular installed equipment would require an upgrade" and that he has not seen any evidence that patients who receive treatment from Elekta linacs that have not been upgraded are receiving substandard care. *See* Reed Tr. 943, 948. Mr. Reed's unsupported opinion about the "value" of upgrades to Elekta customers is not sufficient to demonstrate that limiting "upgrades" would harm the public interest.

Further, the evidence shows that Elekta's installed base of linacs is [ ]. For example, as of January 2016, upgrades comprised [ ] of Elekta's U.S. orders in oncology and software products. *See* CX-0846C (Bakewell WS) at Q207; CX-0537C; CX-1088; CX-3593. Elekta believes that "[ ]." *See* CX-0300C. Given the [ ], the evidence does not show that there would be any significant impact on the public interest from excluding upgrades of Elekta's accused products.

Therefore, Elekta has failed to articulate any appropriate exception, or carve out, for upgrades. If later the parties are able to propose an exception for any genuine upgrades, as rare as they may be, that are necessary for patients' treatment, and are not used to flout any remedial orders, the Commission in its discretion could entertain such a proposal.

Competitive conditions in the U.S. market

Remedial orders in this investigation will not negatively impact competitive

conditions in the U.S. market for radiotherapy equipment and treatment planning systems. Healthcare innovation is costly and requires significant long-term investments. The U.S. patent system is designed to encourage innovation by creating incentives to make the types of significant, long-term investments that serve the public interest. *See Digital Televisions*, Comm'n Op. at 9 ("[P]rotection of intellectual property rights in the United States provides foreign and domestic businesses alike with a climate of predictability that fosters investment, innovation and the exchange of technology."); *Certain Display Controllers and Products Containing Same*, Inv. No. 337-TA-491/481, Comm'n Op. at 66 (Feb. 2005) (Denying remedial relief "would discourage investment in the development of technological innovations, which, in turn, would have a negative effect on competition."). In exchange for "laying open" its invention to the public, a patent provides the patentee with the legal right to collect royalties or exclude others from the marketplace for the statutory life of the patent right. Elekta's economist agrees, testifying at the hearing that it is "absolutely" important to protect intellectual property rights. *See* Reed Tr. 950-951.

Elekta argues that excluding future products from the U.S. market will harm competitive conditions. However, Elekta's arguments about potential harm to competitive conditions are speculative. As Varian's expert economist Mr. Bakewell explained, purchasing departments in clinics, like many purchasers that have significant influence, can foster competition even in situations where there are only a handful of suppliers. *See* CX-0846C (Bakewell WS) at Q218-220. This is consistent with the fact that analysts often refer to Accuray as a prominent third market participant, despite its smaller market share relative to Varian and Elekta. *See id.* (citing CX-3613 (RBC

Capital Markets report); CX-0859C (RBC Capital Markets report); CX-1131C (KLAS Research report); CX-0300C (internal Elekta document); CX-0262C (Elekta ASTRO Capital Markets presentation). As Mr. Bakewell testified, the availability of substitute products from multiple suppliers, as well as the purchasing influence of hospitals and clinics, negates Elekta's claim that competitive conditions would be harmed by removal of Elekta's infringing products from the U.S. market. *See id.* (testifying that "the statements made by Elekta about monopolization are simply unsubstantiated, unmeasured and speculative" and that "that the type of relief that Varian seeks is reasonable and consistent with the public interest.")); *see also Digital Televisions*, Comm'n Op. at 16-17 (holding that speculation that an exclusion order will cause prices to increase is insufficient to justify denying relief because "the Commission has consistently held that the benefit of lower prices to consumers does not outweigh the benefit of providing complainants with an effective remedy for an intellectual property-based section 337 violation.").

Likelihood of manufacturing in the U.S. of competitive products

Excluding Elekta (who manufactures products abroad) from importing products into the U.S. would likely provide an opportunity for increased U.S. manufacturing activities, performed by companies such as Varian and Accuray. As discussed above, Varian has the capacity to increase production in Palo Alto to satisfy increased demand due to any remedy in this investigation, and each additional linac produced by Varian in Palo Alto could result in [ ] of Varian investments in manufacturing in the United States. Elekta's economist, Mr. Reed, acknowledged at the hearing that exclusion of Elekta products from the U.S. could result in additional production of Varian's linacs

in California. *See* Reed Tr. 948. As noted, Accuray also produces its linacs in the U.S. *See* CX- 0846C (Bakewell WS) at Q212-213.

* * *

Accordingly, the public interest factors, when evaluated individually or evaluated as a whole, do not weigh against the issuance of a remedy in this investigation, provided that any Commission remedial orders contain the exceptions, discussed above.

XII. Remedy and Bonding

This is the recommended determination of the administrative law judge on remedy and bonding.

The administrative law judge must issue a recommended determination concerning the appropriate remedy in the event that the Commission finds a violation. *See* 19 C.F.R. § 210.42(a)(1)(ii). That recommendation is contained herein below.

Complainants argue:

> Varian seeks a permanent exclusion order directed to Elekta and excluding from entry into the United States certain radiotherapy systems and treatment planning software, and components thereof, that infringe one or more asserted claims of the Shapiro and/or Otto patents. Varian also seeks a permanent cease and desist order prohibiting Elekta from engaging in the importation, sale for importation, use, marketing, and/or advertising, distribution, offering for sale, sale, sale after importation, or other transfer within the United States of certain radiotherapy systems and treatment planning software, and components thereof, that infringe one or more asserted claims of the Shapiro and/or Otto patents. Varian's requested cease and desist order includes prohibiting Elekta from providing "upgrades" to existing (*i.e.* previously installed) Elekta linacs, Gamma Knifes, and treatment planning systems in the United States. For example, Varian seeks to prohibit Elekta from providing "upgrades" to existing linacs including but not limited to "upgrading" previously installed Infinity systems with Agility. Similarly, Varian seeks to preclude

> Elekta from "upgrading" existing Gamma Knife Perfexion systems to Gamma Knife Icon. Varian also seeks to preclude Elekta from providing upgrades to existing/installed treatment planning systems that provide improvements to functionality, for example the addition of VMAT capability to an existing software license.
>
> However, Varian does not seek any remedial order precluding U.S. hospitals or customers from servicing existing Elekta linacs or Gamma Knife systems, or from buying replacement parts for those machines. Further, Varian does not seek remedial orders precluding U.S. hospitals or customers from receiving bug fixes or critical software updates for existing functionality. Under Varian's requested remedy, patients in the U.S. could continue to receive treatments on Elekta machines without interruption.

Compls. Br. at 377-78 (citations omitted); *see id.* at 377-83, 399-400.

Respondents argue:

> Varian's requested remedy is particularly troublesome in view of the facts of this Investigation. With respect to the Otto patents, Varian accuses Elekta's Monaco software, which is developed in the United States and not imported, of infringement. Notably, Varian's Eclipse software, which it relies on for domestic industry of the Otto patents, [
>
>], yet comes to the ITC to exclude Elekta's U.S.-produced software product. Varian should not be permitted to obtain this incongruous result, which turns the ITC's jurisdiction on its head. No remedial order in this Investigation should impact Elekta's ability to continue to sell the Monaco software, which is not an imported product. Nor should any remedial order based on the Otto patents alone prevent importation of Elekta's linacs which are used with treatment planning software other than the accused Monaco software.
>
> To the extent a remedy issues in this Investigation, it should be limited to a limited exclusion order directed to imported Elekta products specifically found to infringe a valid asserted claim. A cease and desist order is not appropriate, because Elekta maintains no inventory of imported accused products in the United States. Further, there should be no bond set during the Presidential review period.

Resps. Br. at 369 (citations omitted); *see id.* at 369-75.

The Staff argues that "if a violation of section 337 is found, the appropriate remedy in this investigation will include a limited exclusion order, as well as cease and desist orders directed to the domestic Respondents." Staff Br. at 153-54.

A. Limited Exclusion Order

The Commission has broad discretion in selecting the form, scope, and extent of the remedy in a section 337 proceeding. *Viscofan, S.A. v. United States Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986). A limited exclusion order directed to respondents' infringing products is among the remedies that the Commission may impose. *See* 19 U.S.C. § 1337(d).

As discussed above, "Varian seeks a permanent exclusion order directed to Elekta and excluding from entry into the United States certain radiotherapy systems and treatment planning software, and components thereof, that infringe one or more asserted claims of the Shapiro and/or Otto patents." Compls. Br. at 377.

Respondents argue that "[t]o the extent a remedy issues in this Investigation, it should be limited to a limited exclusion order directed to imported Elekta products specifically found to infringe a valid asserted claim." Resps. Br. at 369.

The Staff argues that "a limited exclusion order directed against Elekta's infringing products" is appropriate. Staff Br. at 153.

The administrative law judge recommends that in the event the Commission determines that a violation of section 337 has occurred, and if consideration of the statutory public interest factors does not require that remedies be set aside or modified,[92]

[92] As discussed above, after considering the public interest factors, the administrative law judge determined that those factors do not require that remedies be set aside.

the Commission should issue a limited exclusion order covering all of the infringing articles imported, sold for importation, or sold after importation by respondents and should apply to respondents' affiliated companies, parents, subsidiaries or other related business entities, or their successors or assigns.

Further, in the event the Commission does issue a limited exclusion order in this investigation, the exclusion order should include a provision that allows the respondents to certify, pursuant to procedures to be specified by U.S. Customs and Border Protection, that they are familiar with the terms of the order, that they have made appropriate inquiry, and that, to the best of their knowledge and belief, the products being imported are not excluded from entry under the order.

B. Cease and Desist Order

Section 337 provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a cease and desist order as a remedy for a violation of section 337. 19 U.S.C. § 1337(f)(1). The Commission "generally issues a cease and desist order only when a respondent maintains a commercially significant inventory of infringing products in the United States." *Certain Ground Fault Circuit Interrupters and Products Containing Same*, Inv. No. 337-TA-615, Comm'n Op. at 24 (Mar. 26, 2009); *Certain Video Game Systems, Accessories, and Components Thereof*, Inv. No. 337-TA-473, Comm'n Op. at 2 (Dec. 24, 2002).

Complainants argue that it "demonstrated at the hearing that a cease and desist order is appropriate because Elekta maintains commercially significant inventory of infringing products in the United States." *See* Compls. Br. at 381.

Respondents argue that "Varian has failed to make any showing in this Investigation that Elekta maintains commercially significant inventory meriting a cease and desist order." Resps. Br. at 372. Respondents argue: "The evidence of record shows that Elekta maintains [ ]— of accused imported products in the United States." *Id.* (emphasis in original).

The Staff argues: "For the reasons set forth by Varian, the evidence has shown that Elekta maintains a commercially significant inventory in the United States. A cease and desist order is thus appropriate if it is determined that there has been a violation of Section 337." *See* Staff Br. at 153.

As discussed below, the evidence shows that a cease and desist order is appropriate. Elekta maintains commercially significant inventory of infringing products in the United States. In the ordinary course of business, Elekta [

]. *See* JX-0050C (Seddon Dep. Tr.) at 32-34. Elekta [

], a fact to which Mr. Schoettelkotte admitted during the hearing. *See* Schoettelkotte Tr. 560 ("[ ]."); JX-0050C (Seddon Dep. Tr.) at 80-82; JX-0056C (Symons Dep. Tr.) at 95-96, 123; CX-1113C (Elekta Purchase and License Agreement with [ ]) at 25 ("[

].").

Elekta argues that its [ ] are not "inventory" because they are subject to existing purchase orders. Resps. Br. at 373 ("[

].'").[93] Elekta's fact witnesses testified, however, that if purchase orders are cancelled, [ ]. *See* JX-0050C (Seddon Dep. Tr.) at 38-40. Mr. Seddon testified that [ ]. *Id.* Inasmuch as a single Elekta linac can cost several million dollars, maintaining even a single unit in the United States constitutes commercially significant inventory and warrants a cease and desist order. *See* CX-0846C (Bakewell WS) at Q142.

The evidence shows that Elekta [ ] in the United States. *See* JX-0050C (Seddon Dep. Tr.) at 64; JX-0051C (Sedihn Dep. Tr.) at 115-116. For example, as of January 2016, Elekta had more than [ ] in inventory in the United States. *See* CX-3604C (Elekta - Inventory Spreadsheet). Although Elekta argues that this inventory consists [ ], Mr. Seddon's testimony was unclear as to whether the inventory is only used [ ], or whether the inventory may also be used to provide Elekta customers with "upgrades" or improvement in the functionality of their previously installed Elekta equipment. *See* JX-0050C (Seddon Dep. Tr.) at 90-92. Elekta did not provide any testimony to clarify this issue at the hearing (*e.g.*, Elekta did not provide witness statements for Mr. Seddon or Mr. Symons), nor was Elekta's expert able to testify as to [ ]."

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[93] The Commission has rejected similar arguments in the past. *See, e.g., Certain Electronic Devices, Including Mobile Phones and Tablet Computers, and Components Thereof*, Inv. No. 337-TA-847, Initial Determination at 221-222 (Sept. 23, 2013) (finding evidence of commercially significant inventory based on "in-transit" inventory over which respondent retains title until contractual acceptance of the accused products by respondent's customers).

See Schoettelkotte Tr. 562 ("[ ]."). Thus, to the extent that any of Elekta's inventory in the U.S. may be used to provide "upgrades" to Elekta customers (as opposed to merely repairing previously installed Elekta radiotherapy systems), a cease and desist order is warranted. Any cease and desist order should contain the exception discussed above to allow patients to continue receiving treatment from Elekta's installed base of radiotherapy equipment.[94]

Elekta argues that a cease and desist order should not apply to the use and sale of software purportedly developed in the United States. *See* Resps. Br. at 373. Yet, any cease and desist order should be broad enough to prevent Elekta from circumventing any exclusion order by using, distributing, marketing, or selling software and components that that can be combined with imported linacs to be used in an infringing manner. *See, e.g.*, *Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chips, Power Control Chips, and Products Containing Same, Including Cellular Telephone Handsets*, Inv. No. 337-TA-543, Comm'n Op. at 135-136 (June 7, 2007) (issuing cease and desist order to prevent Respondent from converting accused products into infringing articles and stating that "[i]n the present investigation, a cease and desist order that does not prohibit Qualcomm from programming the accused chips after importation into the United States would allow for an obvious method of circumvention of the Commission's remedial orders such that the remedial orders would be rendered meaningless.") (internal quotations and citations omitted).

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[94] As discussed above in the public interest section, if later the parties are able to propose an exception for any genuine upgrades, as rare as they may be, that are necessary for patients' treatment, and are not used to flout any remedial orders, the Commission in its discretion could entertain such a proposal.

Accordingly, should a violation be found, the administrative law judge recommends that the Commission issue a cease and desist order as to respondents.

C. Bond

Pursuant to section 337(j)(3), the administrative law judge and the Commission must determine the amount of bond to be required of a respondent, during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to issue a remedy. The purpose of the bond is to protect the complainant from any injury. 19 U.S.C. § 1337(j)(3); 19 C.F.R. §§ 210.42(a)(1)(ii), 210.50(a)(3).

When reliable price information is available, the Commission has often set bond by eliminating the differential between the domestic product and the imported, infringing product. *Certain Microsphere Adhesives, Processes for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 24 (1995). In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *Certain Integrated Circuit Telecommunication Chips and Products Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Comm'n Op. at 41 (1995). A 100 percent bond has been required when no effective alternative existed. *Certain Flash Memory Circuits and Products Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 26-27 (July 1997) (a 100% bond imposed when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimis* and without adequate support in the record).

Complainants argue:

> Here, there are indications that Respondents are pricing the Accused Products to undercut Varian's prices. However, while Respondents have produced some information concerning various list prices and contract prices for sales of the accused products, Respondents have failed to provide any documentation showing prices actually paid by customers. In fact, Elekta withheld responsive documents regarding Elekta's sales (*e.g.*, purchase orders) until after the close of fact discovery, producing some sales documents on April 6, 2016. However, to date, Elekta has failed to produce documents sufficient to show pricing information from which the price differential between Varian's DI Products and the Accused Products could be determined. Accordingly, a price comparison is not clear and bond in the amount of 100 percent is appropriate. To the extent Respondents set forth evidence of their actual sales before the Commission during the remedy phase, Varian will respond accordingly.

Compls. Br. at 400 (citations omitted).

Respondents argue:

> The purpose of the bonding requirement is to protect the complainant from injury during the Presidential review period. The complainant bears the burden of supporting the amount of a bond. Here, Varian has failed to meet that burden and has simply presented no evidence, hoping to be awarded a windfall of 100% bond by claiming a lack of price information. Further, because Varian failed to even attempt to make a price comparison in its Prehearing Brief, it is foreclosed from doing so now.
>
> When parties' products compete directly, the Commission typically sets the bond by attempting to eliminate any difference in sales prices between the products. Here, Varian's economic expert, Mr. Bakewell, considered pricing information, and opined that products by Varian and Elekta compete directly against each other. Yet Mr. Bakewell offered no opinion regarding the appropriate bond. Varian's responses to contention interrogatories similarly failed to provide any analysis of price differentials on which to base a bond request as did Varian's pre-hearing brief.
>
> Nor did Varian lack for reliable pricing information. Indeed, the record is replete with information regarding pricing of Elekta's and Varian's products, which Varian simply failed to analyze or assert in any way. For instance, Varian's own documents show extensive pricing and

> features comparisons between Elekta and Varian linacs. *See, e.g.,* RX-114C. Additionally, Elekta produced in this Investigation documents showing both list and actual-paid prices for Elekta's products. *See, e.g.,* CX-3679C; CX-3703C–CX-3752C. Varian chose, however, to ignore this information and attempt no price comparison whatsoever between the parties' competing products.

Resps. Br. at 374-75 (certain citations omitted).

The Staff argues:

> Here, Varian argues that it was not able to perform a price differential analysis because certain sufficient pricing information was not produced by Elekta during discovery. The Staff notes that Varian did not move to compel such information from Elekta.
>
> The Staff is of the view that if Varian can proint [sic] to record evidence demonstrating that it was impossible to determine a price differential (the Staff is of the view that a reasonably royalty determination cannot be done in this case because the patents have not been licensed outside of Varian) then a 100% bond may be appropriate. Otherwise, in the absence of adequate price differential information, no bond should be entered.

Staff Br. at 154 (citations omitted).

Contrary to Varian's arguments, the evidentiary record includes information regarding pricing of Elekta's and Varian's products.[95] As noted by Elekta, Varian's own documents show pricing and features comparisons between Elekta and Varian linacs. *See*

[95] Complainants argue in their reply brief that the data contained in RX-0114C, which is a Varian document entitled "Varian and Elekta Linac Comparison," "merely represents Varian's best estimate of Elekta sales prices for use by Varian's sales team in comparing Varian and Elekta products. It is not information provided or verified by Elekta, and cannot be used to reliably calculate bond amount." Compls. Reply Br. at 149. Complainants argue that CX-3679C, an Elekta spreadsheet entitled "[ ]," "has some sales information for Elekta products, but not sufficient information for Varian to make a reasonable price comparison." *Id.* at 149 n.23. Complainants argue: "Similarly, CX-3703 through CX-3752 are bids or sales proposals to potential Elekta customers, or contain invoices from Elekta to its customers." *Id.* Complainants' arguments are not persuasive. While the current record may not have been ideal in complainants' view, complainants should have performed an analysis of price differential information based on the record.

RX-0114C (Varian and Elekta Linac Comparison). According to Elekta, Elekta produced in this investigation "documents showing both list and actual-paid prices for Elekta's products." *See* Resps. Br. at 375 (citing CX-3679C; CX-3703C–CX-3752C). Yet, it appears that Varian did not analyze the data, and did not attempt any type of price comparison. *See* Compls. Br. at 400; Compls. Reply Br. at 149. Under these circumstances, a bond of 100 percent is inappropriate.

Accordingly, based on the current record, it is the recommendation of the administrative law judge that no bond should be imposed during the Presidential review period.

* * *

It is the RECOMMENDED DETERMINATION ("RD") of the administrative law judge that in the event a violation of section 337 is found, the Commission should issue a limited exclusion order, and a cease and desist order subject to the exception discussed above to allow patients to continue receiving treatment from Elekta's installed base of radiotherapy equipment. Further, should the Commission impose a remedy that prohibits importation, it is recommended that no bond be imposed during the Presidential review period.

* * *

XIII. Conclusions of Law

1. The Commission has subject matter, personal, and *in rem* jurisdiction in this investigation.

2. The accused products have been imported or sold for importation into the United States.

3. U.S. Patent No. 7,945,021:

   - Accused Linacs products infringe the asserted claims.
   - Gamma Knife Icon products do not infringe the asserted claims.
   - The domestic industry requirement has been satisfied.
   - It has been shown by clear and convincing evidence that the asserted claims are invalid.

4. U.S. Patent No. 8,116,430:

   - Accused Linacs products infringe asserted claim 6.
   - Accused Linacs products do not infringe asserted claim 18.
   - Gamma Knife Icon products do not infringe the asserted claims.
   - The domestic industry requirement has been satisfied.
   - It has been shown by clear and convincing evidence that the asserted claim 6 is invalid.
   - It has not been shown by clear and convincing evidence that asserted claim 18 is invalid.

5. U.S. Patent No. 8,867,703:

   - Accused Linacs products do not infringe asserted claim 1.
   - Gamma Knife Icon products do not infringe asserted claim 1.
   - The domestic industry requirement has been satisfied.

- It has not been shown by clear and convincing evidence that asserted claim 1 is invalid.

6. U.S. Patent No. 7,880,154:

   - Accused '154 Products infringe the asserted claims.
   - The domestic industry requirement has been satisfied.
   - It has not been shown by clear and convincing evidence that the asserted claims are invalid.

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

   - Accused '770 Products infringe the asserted claims.
   - The domestic industry requirement has been satisfied.
   - It has been shown by clear and convincing evidence that asserted claim 61 is invalid.
   - It has not been shown by clear and convincing evidence that asserted claim 67 is invalid.

8. U.S. Patent No. 8,696,538:

   - Accused '538 Products infringe the asserted claims.
   - The domestic industry requirement has been satisfied.
   - It has not been shown by clear and convincing evidence that the asserted claims are invalid.

XIV. Initial Determination and Order

Accordingly, it is the INITIAL DETERMINATION of the undersigned that a violation of section 337 (19 U.S.C. § 1337) has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain radiotherapy systems and treatment planning software, and components thereof that infringe the asserted claims of U.S. Patent No. 7,880,154; U.S. Patent No. 7,906,770; and U.S. Patent No. 8,696,538.

Further, this Initial Determination, together with the record of the hearing in this investigation consisting of (1) the transcript of the hearing, with appropriate corrections as may hereafter be ordered, and (2) the exhibits received into evidence in this investigation, is CERTIFIED to the Commission.

In accordance with 19 C.F.R. § 210.39(c), all material found to be confidential by the undersigned under 19 C.F.R. § 210.5 is to be given *in camera* treatment.

The Secretary shall serve a public version of this ID upon all parties of record and the confidential version upon counsel who are signatories to the Protective Order, as amended, issued in this investigation.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to § 210.43(a) or the Commission, pursuant to § 210.44, orders on its own motion a review of the ID or certain issues herein.

To expedite service of the public version, each party is hereby ordered to file with the Commission Secretary no later than November 9, 2016, a copy of this initial determination with brackets to show any portion considered by the party (or its suppliers of information) to be confidential, accompanied by a list indicating each page on which such a bracket is to be found. At least one copy of such a filing shall be served upon the office of the undersigned, and the brackets shall be marked in red. If a party (and its suppliers of information) considers nothing in the initial determination to be confidential,

and thus makes no request that any portion be redacted from the public version, then a statement to that effect shall be filed.[96]

David P. Shaw
Administrative Law Judge

Issued: October 27, 2016

[96] Confidential business information ("CBI") is defined in accordance with 19 C.F.R. § 201.6(a) and § 210.5(a). When redacting CBI or bracketing portions of documents to indicate CBI, a high level of care must be exercised in order to ensure that non-CBI portions are not redacted or indicated. Other than in extremely rare circumstances, block-redaction and block-bracketing are prohibited. In most cases, redaction or bracketing of only discrete CBI words and phrases will be permitted.

CERTAIN RADIOTHERAPY SYSTEMS AND TREATMENT PLANNING SOFTWARE, AND COMPONENTS THEREOF

INV. NO. 337-TA-968

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **Final Initial Determination** has been served by hand upon the Commission Investigative Attorney, **Peter J. Sawert, Esq.**, and the following parties as indicated, on NOV 28 2016.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street SW, Room 112A
Washington, DC 20436

FOR COMPLAINANTS VARIAN MEDICAL SYSTEMS, INC. AND VARIAN MEDICAL SYSTEMS INTERNATIONAL AG:	
Stephen R. Smith, Esq. **COOLEY LLP** 1299 Pennsylvania Avenue, NW Suite 700 Washington, DC 20004	( ) Via Hand Delivery (X) Express Delivery ( ) Via First Class Mail ( ) Other: _____
FOR RESPONDENTS ELEKTA AB; ELEKTA LTD.; ELEKTA GMBH; ELEKTA INC.; IMPAC MEDICAL SYSTEMS, INC.; ELEKTA INSTRUMENT (SHANGHAI) LIMITED; AND ELEKTA BEIJING MEDICAL SYSTEMS CO. LTD.:	
James R. Barney, Esq. **FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER L.L.P.** 901 New York Avenue, NW Washington, DC 20001-4413	( ) Via Hand Delivery (X) Express Delivery ( ) Via First Class Mail ( ) Other: _____