

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ELEKTA LTD.,	)	
	)	
Plaintiff/Counterclaim-Defendant,	)	C.A. No. 16-82-RGA
	)	
v.	)	<b>JURY TRIAL DEMANDED</b>
	)	
VARIAN MEDICAL SYSTEMS, INC.,	)	<b>PUBLIC VERSION</b>
	)	
Defendant/Counterclaim-Plaintiff.	)	

**SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

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**SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Elekta Limited (“Plaintiff” or “Elekta”), by and through its undersigned counsel, alleges as follows:

**NATURE OF THE ACTION**

1. This action seeks to redress defendant Varian Medical Systems, Inc.’s (“Defendant” or “Varian”) infringement of Elekta’s U.S. Patent No. 7,961,843 (“the ’843 Patent”) and Elekta’s U.S. Patent No. 8,503,608 (“the ’608 Patent”). As pled below, Varian has infringed and continues infringing the ’843 Patent through its TrueBeam™ Radiotherapy System and its equivalent products sold under different names<sup>1</sup> (“TrueBeam”) and VitalBeam™ Radiotherapy System (“VitalBeam”), and any substantially equivalent product, whether used alone or with Varian’s 4pi technology, now known as “HyperArc high-definition radiotherapy” or “HyperArc HDRT” (“HyperArc”), and through Varian’s treatment planning software, the Eclipse™ Treatment Planning System including RapidArc® Radiotherapy Technology (“RapidArc”). Varian has infringed and continues infringing the ’608 Patent through its TrueBeam and

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<sup>1</sup> Elekta is informed and believes and therefore alleges that from as early as July 18, 2010, Varian has offered to sell and has sold its TrueBeam apparatus in several packages and sometimes using different names. Because such apparatuses are essentially the same TrueBeam apparatus, no matter how outfitted or named, all are included as “TrueBeam” for purposes of this Complaint.

VitalBeam products, and any substantially equivalent product, whether used alone or with Varian's HyperArc technology.

### **THE PARTIES**

2. Elekta is a foreign entity organized and existing under the laws of the United Kingdom, with a principal place of business at Linac House, Fleming Way, Crawley, West Sussex RH10 9RR, United Kingdom. Elekta Limited is a subsidiary of Elekta AB, Stockholm, Sweden, a pioneering biomedical-engineering company that has developed significant innovations and clinical solutions for treating cancer and brain disorders since its founding in 1972. The Elekta companies develop state-of-the-art tools and treatment planning systems for radiation therapy, including brachytherapy and radiosurgery, and workflow enhancing software systems across the spectrum of cancer care.

3. Varian is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 3100 Hansen Way, Palo Alto, California. Varian's registered agent for service is Corporation Service Company, 2711 Centerville Road Suite 400, Wilmington, Delaware 19808.

### **JURISDICTION AND VENUE**

4. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. A Delaware corporation, Varian is subject to the Court's general personal jurisdiction.

6. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400 because Varian is incorporated and subject to personal jurisdiction in this District, and because it has committed acts of patent infringement and/or contributed to or induced acts of patent infringement by others in this District.

## **BACKGROUND**

### **ELEKTA'S PATENTED TECHNOLOGY**

7. Elekta devotes a substantial amount of its business to oncology treatment research and development ("R&D"). Elekta R&D is responsible for innovating many of the critical technological advances in radiotherapy cancer treatment over the past thirty years. Elekta's R&D innovations include treatment delivery systems, such as its Versa HD<sup>TM</sup>, Axesse<sup>TM</sup>, Infinity<sup>TM</sup>, and Synergy<sup>®</sup> Linear Accelerator Systems, and treatment solutions, such as techniques for volumetric modulated arc radiotherapy (VMAT) and related software systems.

8. Elekta seeks to protect its innovations by applying for patent protection when possible and appropriate. For example, the '843 Patent protects Elekta's Versa HD<sup>TM</sup>, Axesse<sup>TM</sup>, Infinity<sup>TM</sup>, and Synergy<sup>®</sup> Linear Accelerator Systems, as well as Elekta's Monaco<sup>TM</sup> with VMAT treatment planning solutions.

9. Elekta employees Kevin Brown, Ralph Streamer, Paul Boxall, and Duncan Bourne filed an application for the '843 Patent on April 27, 2006. On June 14, 2011, after fully examining the application, the United States Patent and Trademark Office ("USPTO") duly issued the '843 Patent, entitled "Radiotherapeutic Apparatus." A true and correct copy of the '843 Patent is attached as Exhibit A.

10. Elekta is the record assignee and owner of all right, title, and interest in the '843 Patent, including the rights to sue, recover damages and obtain equitable relief for the patent's infringement.

11. Elekta employees Kevin Brown, Ralph Streamer, Paul Boxall, Duncan Bourne, and Christopher Gibson filed an application for the '608 Patent on October 24, 2007. On August 6, 2013, after fully examining the application, the USPTO duly issued the '608 Patent, entitled "Radiotherapeutic Apparatus." A true and correct copy of the '608 Patent is attached as Exhibit B.

12. Elekta is the record assignee and owner of all right, title, and interest in the '608 Patent, including the rights to sue, recover damages and obtain equitable relief for the patent's infringement.

**VARIAN'S RADIOTHERAPY SYSTEMS AND TREATMENT PLANNING SOFTWARE**

13. The facts chronicled below show that Varian makes, uses, sells, and offers to sell in the U.S. products that infringe one or more claims of the '843 Patent and/or one or more claims of the '608 Patent. Varian's infringing products are TrueBeam (top photo below) and VitalBeam (bottom photo below), with and without Varian's HyperArc technology, and RapidArc (collectively the "Accused Products").



Varian's TrueBeam



Varian's VitalBeam

14. TrueBeam and VitalBeam generally work by delivering therapeutic radiation to specific regions of a patient's body. Radiation is beamed from a source traveling along an arc-shaped path according to a treatment plan. In delivering radiation according to the treatment plan, TrueBeam and VitalBeam can, among other things, adjust the rotational speed of the gantry and the delivery dose rate to minimize the time of treatment for the particular treatment plan.

15. On September 26, 2016, Varian issued a press release regarding its "new HyperArc High Definition Radiotherapy (HDRT) technology, stating that "HyperArc is the first step into our OnComand ecosystem . . . . It is designed to automate and simplify sophisticated treatments such as Stereotactic Radiosurgery (SRS) . . . [and] to capitalize on the unique capabilities of Varian's TrueBeam and EDGE treatment platforms including the PerfectPitch couch." (<http://newsroom.varian.com/2016-09-26-Varian-Exhibiting-New-HyperArc-Technology-for-High-Definition-Radiotherapy-and-Radiosurgery>)

16. Varian exhibited its HyperArc technology at the 2016 American Society for Radiation Oncology (ASTRO) Annual Meeting, which took place from September 25-27, 2016.

17. RapidArc is Varian's radiotherapy treatment planning system software. It produces radiotherapy treatment plans for use with Varian linear accelerator delivery platforms including TrueBeam and VitalBeam. RapidArc uses an algorithm to determine the treatment aperture shape (*i.e.*, beam size), the rotational speed of the gantry, and the delivery dose rate to minimize the time of treatment. According to Varian's promotional materials, "RapidArc radiotherapy technology is a major advance from Varian Medical Systems that improves dose conformity while shortening treatment times. RapidArc is available for Varian linear accelerators including the Edge™, TrueBeam®, Trilogy® and many Clinac® linear accelerators. RapidArc uses a dynamic multileaf collimator (MLC), variable dose rate, and variable gantry speed to generate [Intensity Modulated Radiation Therapy]-quality dose distributions."

18. Varian claims to have provided training and instructional materials to use the Accused Products to "thousands of, physicists, dosimetrists, physicians, radiation therapists and administrative personnel at customers' clinics and key Varian education centers worldwide." Indeed, Varian actively promotes its on-site and classroom training for the Accused Products. The U.S. training courses that it provides for Accused Products include "EC102 Eclipse Inverse Planning: IMRT and RapidArc (v13);" "EC112 Eclipse Inverse Planning: RapidArc Only (v13);" "EC202 Eclipse Commissioning II: IMRT and RapidArc;" "TB100 TrueBeam Operations with Imaging Foundations;" "TB101 TrueBeam Operations;" and "TB201 TrueBeam for Physicists."

19. Varian offers for sale, sells, and/or uses the Accused Products throughout the United States, including in this District.

#### **VARIAN'S EXISTING KNOWLEDGE ABOUT THE '843 AND '608 PATENTS**

20. Varian has known about the '843 and '608 Patents since at least February 20, 2014. On that date the USPTO sent Varian official correspondence regarding Varian's U.S. patent

application No. 13/676,370, directed toward the use of radiotherapy to treat moving targets.<sup>2</sup> The USPTO correspondence expressly referenced the '843 and '608 Patents, providing Varian with actual knowledge of the patents as of that date.

21. In Spring 2015, Elekta told Varian that the Accused Products infringe the '843 Patent. Varian has thus known since at least then that it would be infringing the '843 Patent by making, using, selling, or offering to sell the Accused Products.

22. Despite its actual knowledge of the '843 and '608 Patents, Varian continues its infringement. Its actions belie any intention of ceasing its infringement or seeking a license to the '843 and/or '608 Patents from Elekta.

### **CLAIM FOR RELIEF**

#### **INFRINGEMENT OF THE '843 PATENT [35 U.S.C. § 271(a)]**

23. Elekta re-alleges each and every allegation set forth in the preceding paragraphs.

24. Varian has infringed, and continues its infringement under 35 U.S.C. § 271(a) of claims 1-14 of the '843 Patent (the "Asserted Claims"), either literally or under the doctrine of equivalents, by making, using, selling, or offering to sell the Accused Products in the United States without license or authority. Attached are charts showing that:

- Varian's TrueBeam infringes claims 1-5 of the '843 Patent, and Varian's TrueBeam, both without and with HyperArc, infringes claim 6 of the '843 Patent (**Exhibit C**); and
- Varian's RapidArc infringes claims 7-11 and 14 of the '843 Patent, and Varian's RapidArc with HyperArc infringes claims 12-13 of the '843 Patent (**Exhibit D**).

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<sup>2</sup> The application issued as U.S. Pat. No. 8,744,045, on June 3, 2014.



Varian's FDA submissions and press releases admit that VitalBeam is equivalent to TrueBeam in every respect material to the '843 Patent. Exhibit C, showing how Varian infringes claims 1-6 of the '843 Patent with TrueBeam, either alone or with HyperArc, thus shows how Varian also infringes claims 1-6 of the '843 Patent with VitalBeam, either alone or with HyperArc.

25. Varian has infringed and continues to infringe these claims by making, using, selling, and/or offering to sell in the U.S. TrueBeam, TrueBeam with HyperArc, VitalBeam, VitalBeam with HyperArc, RapidArc, and RapidArc with HyperArc.

26. For example,

a. On October 1, 2011, Varian provided Bayhealth Medical Center in Dover with a TrueBeam System, becoming the first clinic in Delaware to install TrueBeam, with Eclipse with RapidArc.

b. Varian has provided and used the HyperArc technology at UCLA.

c. Medical Physics Services LLC commissioned the following Accused Products from Varian for hospitals and clinics in the U.S.:

Clinic	Location	Varian Products Commissioned
Alan B. Pearson Regional Cancer Center	Lynchburg, VA	TrueBeam with Eclipse, IMRT, Rapid Arc, and Portal Dosimetry
Fresno Cancer Center	Fresno, CA	TrueBeam with Eclipse, Rapid Arc, IMRT, and FFF
Kaiser NW Permanente	Portland, OR	TrueBeam with Eclipse, IMRT, and Rapid Arc
Nevada Cancer Institute	Las Vegas, NV	TrueBeam with Eclipse Rapid Arc, IMRT, and FFF
Rohnert Park Cancer Center	Rohnert Park, CA	Clinac iX and TrueBeam with Eclipse, Rapid Arc, IMRT, and FFF
South Sacramento Cancer Center	Sacramento, CA	TrueBeam with Eclipse, Rapid Arc, IMRT, FFF, and Portal Dosimetry

Clinic	Location	Varian Products Commissioned
Space Coast Cancer Center	Viera, FL	TrueBeam with Eclipse, Rapid Arc, IMRT, and FFF
Vanderbilt-Ingram Cancer Center, Vanderbilt University	Franklin, TN	TrueBeam with Eclipse

***Varian's Infringement is Willful and Continues to Harm Elekta***

27. Because the Accused Products meet each limitation of the Asserted Claims in the manner alleged above and as shown in Exhibits C and D, and because Varian has had actual knowledge of the '843 Patent as of at least February 2014, Varian's infringement has been willful since then, if not before.

28. Varian's infringement of the '843 Patent has damaged Elekta by violating Elekta's right to exclude others from making, using, selling or offering to sell covered apparatuses in the U.S. and importing them into the U.S. That damage is more keenly felt because Elekta and Varian compete head-to-head in the U.S. in the field of radiotherapy systems. For example, Elekta's Versa HD™ competes with Varian's TrueBeam and VitalBeam, and RapidArc competes with Elekta's Monaco™ with VMAT treatment planning solutions. Because no other comparable solutions are available, every infringing sale or lease of TrueBeam, VitalBeam or RapidArc represents a sale or lease that Elekta should otherwise have made or make.

29. For the reasons set forth in the preceding paragraph, Varian's continuing infringement of the '843 Patent irreparably harms Elekta. Elekta will continue to suffer irreparable harm absent entry of a permanent injunction enjoining Varian and its agents, servants, employees, representatives, affiliates, and all others acting with them, from infringing the '843 Patent.

**INFRINGEMENT OF THE '608 PATENT [35 U.S.C. § 271(a)]**

30. Elekta re-alleges each and every allegation set forth in the preceding paragraphs.

31. Varian has infringed, and continues its infringement under 35 U.S.C. § 271(a) of at least claims 1-2 and 6-10 of the '608 Patent (the "Asserted Claims"), either literally or under the doctrine of equivalents, by making, using, selling, or offering to sell the Accused Products in the United States without license or authority. In particular, and as shown in **Exhibit E**, Varian's TrueBeam infringes claims 1-2 and 6-9 of the '608 Patent, while Varian's TrueBeam, both without and with HyperArc, infringes claim 10 of the '608 Patent. Varian's FDA submissions and press releases admit that VitalBeam is equivalent to TrueBeam in every respect material to the '608 Patent. Consequently, Exhibit E, showing how Varian infringes claims 1-2 and 6-9 of the '608 Patent with TrueBeam, either alone or with HyperArc, also shows how Varian infringes claims 1-2 and 6-9 of the '608 Patent with VitalBeam, either alone or with HyperArc.

32. As detailed above, Varian has infringed and continues to infringe these claims by making, using, selling, and offering to sell in the U.S. TrueBeam, TrueBeam with HyperArc technology, VitalBeam, and VitalBeam with HyperArc technology, and RapidArc.

***Varian's Infringement is Willful and Continues to Harm Elekta***

33. Because the Accused Products meet each limitation of the Asserted Claims in the manner alleged above and as shown in Exhibit E, and because Varian has had actual knowledge of the '608 Patent as of at least February 2014, Varian's infringement has been willful since then, if not before.

34. Varian's infringement of the '608 Patent has damaged Elekta, both by violating Elekta's right to exclude others from making, using, selling or offering to sell covered apparatuses in the U.S. and importing them into the U.S., but also because Elekta and Varian compete head-to-head in the U.S. in the field of radiotherapy systems. For example, Elekta's Versa HD™ competes with Varian's TrueBeam and VitalBeam. Because no other comparable solutions are

available, every infringing sale or lease of TrueBeam and VitalBeam represents a sale or lease that Elekta should otherwise have made or make.

35. For the reasons set forth in the preceding paragraph, Varian's continuing infringement of the '608 Patent irreparably harms Elekta. Elekta will continue to suffer irreparable harm absent entry of a permanent injunction enjoining Varian and its agents, servants, employees, representatives, affiliates, and all others acting with them, from infringing the '608 Patent.

### **PRAYER FOR RELIEF**

WHEREFORE, Elekta respectfully requests that the Court enter judgment in favor of Elekta and against Varian as follows:

- A. Finding that Varian is and has been infringing the '843 and '608 Patents;
- B. Permanently enjoining Varian and its affiliates, employees, agents, officers, directors, attorneys, successors, and assigns, and all those acting on behalf of or in active concert or participation with any of them, from infringing the '843 and '608 Patents;
- C. Requiring that Varian render a full and complete accounting to Elekta for Varian's profits, gains, advantages or the value of business opportunities received from its acts of infringement;
- D. Requiring that Varian pay Elekta damages, together with interest and costs as fixed by the court, to compensate Elekta for Varian's infringement of the '843 and '608 Patents;
- E. Enhancing by three-fold the damages that Varian must pay Elekta pursuant to 35 U.S.C. § 284;
- F. Finding the case exceptional under 35 U.S.C. § 285 and requiring that Varian pay to Elekta all of its attorneys' fees and costs and expenses in this action;
- G. Awarding Elekta prejudgment interest, post-judgment interest, and costs; and

H. Such other and further relief as the Court may deem appropriate.

**JURY DEMAND**

Elekta respectfully demands a trial by jury on all issues raised by this Complaint that are properly triable by a jury.

Respectfully submitted,

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