

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNIVERSITY OF PITTSBURGH OF THE
COMMONWEALTH SYSTEM OF HIGHER
EDUCATION,

Plaintiff,

v.

VARIAN MEDICAL SYSTEMS, INC.,

Defendant.

08cv01307

**ELECTRONICALLY
FILED**

Memorandum Opinion on Cross-Motions for Summary Judgment

I. Introduction

This is an action in patent infringement. Plaintiff, University of Pittsburgh of the Commonwealth System of Higher Education (hereinafter “Pitt” or “plaintiff”), alleges that defendant Varian Medical Systems, Inc. (hereinafter “Varian” or “defendant”) has infringed its patent (U.S. Patent No. 5,727,554) (hereinafter “the patent,” or “the ‘554 Patent”) by making and selling the RPM Respiratory Gating System (hereinafter “the RPM System”). Varian denies that its product (and/or modified product) infringes Pitt’s patent,¹ and further argues that Pitt cannot establish willful infringement. Defendant also contends that the asserted patent is invalid, for lack of enablement, and that Pitt’s measure of damages is improper.²

¹ Defendant filed an Answer and Counterclaim, seeking a declaration that the claims of the ‘554 Patent are invalid, and that the products of Varian do not infringe any of the asserted claims of the ‘554 Patent, and asserted numerous defenses including failure to state a claim, patent invalidity, estoppel, laches, and authorization and consent of the United States Government. Doc. No. 355.

² This Court previously granted Pitt’s Motion to Strike Varian’s Untimely Non-Infringement Defense regarding its Non-Treatment RPM’s (doc. no. 403). Pitt argues, and this Court agrees, that after nearly six (6) years of protracted discovery and litigation, it would be unfair and overly

Before this Court is Pitt's Motion for Partial Summary Judgment, and Varian's Motion for Summary Judgment, respectively (doc. nos. 363 and 364). After careful consideration of the voluminous summary judgment records, and the legal arguments of the parties, the Court has GRANTED and entered partial summary judgment in Pitt's favor, finding as a matter of law that Varian's RPM System (and The Modified RPM System) infringes the '554 Patent. See Doc. No. 425. The Court has DENIED Defendant's Motion for Summary Judgment with respect to invalidity, damages, and willful infringement. This issue of willfulness will be the sole subject of the jury trial set to commence on January 23, 2012. See Doc. No. 426.

II. Procedural History

This particular lawsuit has a lengthy procedural history dating back to June 16, 2008, when Pitt filed the instant action against Varian alleging that Varian's product, the RPM Gating System, which is radiotherapy equipment for the treatment of cancer, infringes Pitt's '554 Patent,

prejudicial to Pitt to allow Varian to set forth a new theory of non-infringement, which would in turn require a reopening of both fact and expert discovery. Local Patent Rule 3.4 obligated Varian to identify its reasons for claiming non-infringement by the accused products, including Non-Treatment RPMs, on July 6, 2010 (later amended on July 26, 2010). Doc. No. 57-8. Varian made no such mention of this defense, and so no discovery occurred with respect to this defense. At this late juncture, the Court will not countenance Varian's attempt to side-step the Local Patent Rules, and Federal Rules of Civil Procedure 16(f) and 37(c)(1) which mandate that discovery should have occurred within a preset time table. In the interests of completeness of the record, however, the Court has included Varian's counter-factual allegations regarding this belated defense, but the Court has not based its decision on them, because discovery closed on December 8, 2010, and it would give Varian an unfair advantage to allow it to present a defense that was not disclosed in a timely and fair manner. Given the protracted history of this case, the Court declines any request for further discovery and or expert discovery, as untimely. See *AstraZeneca AB v. Mutual Pharm. Co., Inc.* 278 F. Supp. 491, 507 (E.D. Pa. 2003)(citations omitted) (excluding untimely submission of prior art, testing results, and expert testimony offered during summary judgment proceedings).

which also concerns an application for radiation therapy. This lawsuit (“*Varian II*”) is the second action which Pitt has commenced against Varian claiming an alleged infringement of the ‘554 patent. This Court dismissed the first action (“*Varian I*”) for lack of standing. See Civil Action 07-cv-491. During the pendency of the appeal to the United States Court of Appeals for the Federal Circuit in *Varian I*, Pitt filed the instant action (*Varian II*). This Court dismissed *Varian II* on *res judicata* grounds (doc. no. 106). Pitt then appealed this decision (doc. no. 120). While *Varian II* was on appeal, the Court of Appeals reversed this Court’s judgment and remanded *Varian I*. (07-cv-491, doc. no. 344). The parties then reached an agreement pursuant to which the dismissal of *Varian II* would be vacated, the appeal in *Varian II* would be dismissed, and this case would proceed on the merits (doc. no. 152).

During the pendency of the appeals in *Varian I* and *II*, Varian filed an *ex parte* request with the United States Patent and Trademark Office (“PTO”) requesting a reexamination of all of the “disputed” claims. The PTO reexamined the ‘554 Patent in light of the prior art, which Varian claimed rendered the disputed patent claims invalid. The PTO issued a reexamination certificate confirming the claims that were under reexamination, and added additional patent claims (Claims 23-28) that Pitt had submitted during the reexamination proceedings. At the conclusion of the reexamination proceedings, Claims 20-22 of the ‘554 Patent were deemed valid.

By Order of this Court of June 18, 2010 (doc. no. 182), pursuant to Fed. R. Civ. Pro. 53, this Court appointed the Honorable Donald E. Ziegler as Special Master in this action to conduct a claim construction hearing, and to set forth his findings in a Report and Recommendation, which the Court received on April 6, 2011 (doc. no. 283). After hearing the objections of the parties, and the motions to adopt/modify the Report and Recommendation, on May 16, 2011, this

Court issued a Memorandum Opinion and Order thereon (doc. nos. 302 and 303). This Court affirmed and adopted the Report and Recommendation of the Special Master as the Opinion of the Court with only three (3) modifications (doc. no. 303). The Court then set a status conference to discuss scheduling matters, and the parties elected that this Court, rather than a Special Master (in the first instance), hear the instant summary judgment motions. During the status conference, in addition to setting deadlines for the instant motions, the Court asked the parties to brief the issue of whether a ruling on the liability aspects of the summary judgment motions would compel an appeal to the Federal Circuit as a final order, and/or whether any such ruling would constitute an Interlocutory Order (which the Court would need to “certify” as interlocutory, and would be subject to the discretion of the Federal Circuit) (doc. no. 307). Following the status conference, the parties submitted a joint brief (doc. no. 315), essentially concluding the following:

The Court’s ruling on the parties’ summary judgment motions *could* result in an appealable judgment, either because it is final (in favor of Varian) or final except for damages issues (in favor of Pitt) within the meaning of 28 U.S.C. § 1292(c)(2). The Court has the power to certify other interlocutory orders for appeal under 28 U.S.C. § 1292(b), but the Federal Circuit is unlikely to accept such a certified order for appeal. In any event, the Court’s ruling on motions related to damages will not hinder either party’s ability to appeal any of the Court’s rulings.

The parties then filed a stipulation setting forth the briefing schedule for the pending motions for summary judgment (doc. no. 316), and the motions were ordered to be fully briefed as of December 19, 2011. However, all replies were not received until December 20, 2011.

III. Factual Background

A summary of the factual and technical background of this case can be found in the Special Master’s Report and Recommendation on Claim Construction (doc. no. 283) and this

Court's Opinion affirming the Report and Recommendation. Doc. No. 302. The parties have amassed over 100 pages of facts, but the factual background may be fairly stated as follows. See Doc. Nos. 380, 389, 401, 421.

The '554 Patent

On March 17, 1998, U.S. Patent No. 5,727,554 (the '554 Patent) was duly issued by the Patent and Trademark Office. Plaintiff, Pitt, owns the '554 Patent which is the subject of this lawsuit.

The '554 Patent claims an apparatus for turning on and off a radiation treatment beam synchronously with a patient's breathing. The claimed apparatus comprises a system that uses a video camera and imaging process equipment to monitor patient movement, including breathing. The system identifies and tracks in a video image certain markers on a patient's body ("fiducials"). The markers, or fiducials, may be reference markers placed on the patient ("artificial fiducials") or natural features on the patient's body ("natural fiducials"). The invention claimed by the '554 Patent turns off a radiation treatment beam when the cancerous tumor that is the subject of treatment moves out of the beam's path, as a result of breathing, and turns back on when the tumor re-enters the path of the beam.

The RPM System

Varian manufactures, sells, and services equipment and software for the medical use of radiation for treatment and diagnosis. The alleged infringing system, entitled the Real-Time Position Management ("RPM") Respiratory Gating System ("RPM System"), has been sold by Varian in the United States and abroad since approximately June 10, 1999. Varian's RPM Respiratory Gating System has been manufactured and partially assembled at Varian's manufacturing plant in Palo Alto, CA from 2001, until the present. The remaining assembly

occurs at the customer sites, including abroad (there appears to be no genuine dispute that the Systems are made and sold in the United States). See Doc. No. 400-31 at 48 (“RPM System manufactured and assembled in Palo Alto, CA.”)

Varian’s RPM System is a video-based system that monitors and tracks patient respiratory movement during radiotherapy treatment. It generates gating signals that turn on and off a radiotherapy treatment beam in synchronization with respiratory motion. Non-Treatment RPM Systems are used with CT and PET scanners to locate and identify a tumor to be subjected to radiotherapy treatment. Treatment RPMs are used with beam generators, one component of linear accelerator systems, in the radiotherapy treatment process itself.

Specifically, the RPM System (designed for use with Varian’s Clinac and Trilogy radiotherapy treatment machines) using an infrared tracking camera, infrared illuminator rings, and reflective markers on the marker block system, measures the patient’s respiratory pattern and range of motion and displays them as a waveform on a work station monitor. The parties contest whether the Non-Treatment RPMs infringe the ‘554 Patent because, unlike the Treatment RPMs, they are not used for radiotherapy treatment.

Nonetheless, the parties agree that the RPM System (at least the Treatment RPMs) is used to obtain tracking of the subject respiratory pattern for respiratory image acquisition, and radiation therapy treatment. The RPM System can also be used to monitor the patient position during the image acquisition, simulation, and treatment.

The RPM System includes a charge-coupled device (“CCD”) camera referred to as a tracking camera, which is sensitive to infrared and visible light. Although the parties dispute whether the use of a marker is inherent to, or only one feature of, the RPM System, they agree that a marker block is placed on the patient’s chest or abdomen and the video camera generates

images of the patient with the marker block. The parties agree that the RPM System tracks patient respiration motion using a video camera connected to a PC workstation. However, the parties dispute whether movement of the marker block serves as a surrogate for movement of the tumor. While Pitt claims that it does, Varian contends that the marker block can only be considered a surrogate for movement of the tumor if additional equipment beyond the RPM System is used to correlate marker block motion with tumor motion.

The parties agree that the RPM System includes a video-frame grabber board, which is a digitizer that functions to digitize the incoming video signal and generates a “digital image.” The frame-grabber generates a digitized video signal having an array of 640 x 480 pixels, with each pixel represented in eight (8) bits. The RPM System includes a Windows-based workstation with an Intel Pentium processor. The RPM workstation runs software that processes the digitized video signal from the video camera and generates a signal, albeit they dispute that it is termed a “gating signal.”

The RPM System is programmed to identify fiducials in the “image signals.” Varian disputes use of the term “image signals” to the extent that the term is intended to include digital images of the patient, and claims that the RPM System does not use images of the patient, and instead uses coordinates of the marker centroids, whereby only the reflective markers remain.

The parties agree that the RPM System includes a marker block having multiple two (2) or six (6) reflective markers on a plastic base, and these markers are “artificial” reflective markers. The retroreflective markers on the marker block are fiducials. The parties, however, dispute whether the marker block itself is a fiducial. The marker block, including the markers, is placed on the patient, the patient is positioned on the couch in the field of view of the camera and the marker block is placed on the patient and moves with the patient’s breathing.

The RPM System tracks the motion of the (conceptualized) marker block to determine breathing motion of the patient. While Pitt contends that the RPM System determines the coordinates of the marker block, Varian denies that statement and claims that the RPM System “merely determines the coordinates of individual marker centroids and uses that information to calculate the coordinates of a single point.” Doc. No. 389 at 7, ¶ 26. The images captured by the camera of the RPM System include the markers placed on the patient, and the reflective markers appear in the video signals that the camera sends to the workstation computer. The parties debate whether all patient motion data is calculated based on the motion of the markers. The RPM System displays the patient’s breathing motion in the amplitude-based display, which provides a real-time graph of the patient’s breathing. While Pitt contends that the RPM System determines patient breathing by using the movement of the marker as a surrogate, Varian argues that the System determines the position of a single calculated point at different points in time based on coordinates of the marker centroid. The parties also debate whether or not the RPM System senses the respiration motion of the patient by tracking two or six passive reflective markers on a marker block.

In gated radiotherapy, the RPM Respiratory Gating System sends a signal to the Clinac accelerator to stop the radiation beam (Varian admits this statement only with respect to Treatment RPM’s not with respect to Non-Treatment RPM’s such as those used with PET and CT scanners (RPM-PET/CT)). While Pitt claims that this switching on and off of the treatment beam with respiration motion synchronizes treatment delivery with respiration, Varian denies this alleged fact on the basis that the RPM does not “switch on” the treatment beam. According to Pitt, the RPM System includes run by the PC workstation that generates “gating signals” synchronized to actuate the treatment beam of the Clinac accelerator in synchronism with patient

breathing. Varian denies that the RPM generates “gating signals,” and argues that there are no RPM signals that “actuate” the treatment beam of the Clinac accelerator.

Again, the parties debate whether the technique of respiratory gating “starts and stops” a treatment beam - - metaphorically speaking, opening and shutting a gate that holds in radiation according to a pattern of breathing. While Pitt contends that the “gating signal” created by the RPM System is the signal from which the RPM Respiratory Gating System to Varian’s Clinac machine turns the radiation beam on or off, Varian counters that the RPM System does not create a “gating signal” and RPM does not send a signal to the Clinac machine which turns on the radiation beam. In addition, according to Varian, RPM-PET/CT lacks hardware needed to enable it to operate together with a treatment beam. Nonetheless, through an interface provided by the workstation, the clinician is able to set a threshold that, if exceeded, will generate a beam hold signal (again, Varian denies this as a “gating signal”) to turn off the treatment beam produced by the beam generator.

According to Pitt, if the patient returns to the proper position within the threshold, the RPM will generate a signal to turn “on” the treatment beam, and the RPM System can turn the treatment beam on and off. Varian disagrees with Pitt and claims that the RPM does not generate a signal to turn “on” the beam. Once gating is enabled, the system begins sending beam-on and beam-off signals to the Clinac machine according to the thresholds established in the reference session; but again, Varian claims that the RPM does *not* send signals to the Clinac that turn *on* the radiation beam. Pitt contends that if the other safety or operation features of the Clinac accelerator are not causing a beam hold, the RPM System will act to both turn the beam on and off. Varian posits that the RPM does not “turn on” the beam “but merely asserts or does not assert a beam hold.” Doc. No. 389 at 12, ¶ 40.

Enabling gating makes the RPM Respiratory Gating System send a pre-established signal to Varian's Clinac to trigger beam-enable at the start of the specified respiratory phase and a signal to either "trigger beam-hold" (as Pitt claims) or "stop asserting beam hold" (as Varian claims) during the part of the respiration cycle that is outside the gated interval.

All versions of the RPM System had the same basic functionality - - to identify and track markers and set thresholds for gating. The RPM System is used during treatment of the patient with Varian's Clinac accelerator. The RPM workstation includes two monitors. According to Pitt, the workstation computer causes the in-room monitor to display a section of green light when the movement of the markers, due to the patient's breathing, is within a preferred tolerance. The workstation computer turns off the green light when the movement of the marker, due the patient's breathing, is outside a preferred tolerance. Varian disputes these facts and claims that any green light on the monitor is based upon the position of a single calculated point, not "movement of the marker," and that, in any event, defendant does not "supply the monitor to which Pitt refers." Doc. No. 389. at 13, ¶¶ 45-46.

Varian's Clinac and Trilogy Systems

Varian has sold (in the United States and abroad) its Clinac linear accelerator at least as long as it has been selling its RPM Respiratory Gating System. The Clinac beam generator is manufactured and partially assembled in Palo Alto, CA, and, like the RPM System, requires further assembly at the customer site.

Varian's Trilogy Systems is composed of a suite of Varian products including the Clinac iX linear accelerator. The RPM System and beam generator "component" of Trilogy (as "bundled with Trilogy at one time") are manufactured and partially assembled in Palo Alto, CA, and also require further "final" assembly at the customer site. Varian's Clinac and Trilogy

devices are designed to deliver radiation therapy to treat tumors, and according to Varian, “is just one component of the complete Clinac and Trilogy systems.” Doc. No. 389 at 15, ¶ 51.

Varian’s Clinac and Trilogy devices are used with the RPM System, but they can also be purchased and/or used without an RPM system. Varian’s RPM System is sold as an option to Varian’s Clinac devices, but Varian denies that statement with respect to Non Treatment RPM Systems (those used with PET/CT scanners), which Varian claims lacks the hardware needed to enable it to operate together with Clinac or Trilogy. Varian’s RPM Respiratory Gating System (minus Non Treatment RPM-PET/CT) was bundled with Trilogy between 2005 and 2007, but also has been available as “an option” with Trilogy.

Varian’s Clinac accelerator is a medical linear accelerator used to provide radiotherapy treatment to patients. Accelerators include beam generators. Other components of the Clinac accelerators include a workstation, console computer, electronics cabinet, gantry, collimator, and multi-leaf collimator, and treatment couch. C-series, Clinac iX, and Trilogy accelerators are controlled using C-series control software.

Clinac accelerators operate with the RPM System to turn the treatment beam on and off based on respiratory motion (with respect to “Treatment RPMs”). At least with respect to Treatment RPMs, the RPM System is physically connected to the Clinac accelerator during installation. As part of the system verification procedure, according to Pitt, the installer will operate the RPM System causing the Clinac accelerator to turn the treatment beam on and off. As noted above, Varian debates the contention that the accelerator turns “on and off,” and it claims that the RPM System does not cause the Clinac to turn the treatment beam on, rather it merely stops asserting beam hold. Nonetheless, the parties agree that the Clinac accelerator includes a beam hold icon that indicates when the treatment beam is being held, and the beam

hold icon is displayed on the monitor of the Clinac console. A black-on-yellow “beam hold” message is displayed instead of the “beam on” message to indicate when the RPM System is being held (according to Varian), or withholding the beam (according to Pitt).

Clinac accelerators are generally equipped with a multileaf collimator (hereinafter “MLC”). The Trilogy systems generally include the Millennium MLC. The MLC is a device that shapes the treatment beam to conform to the shape of the tumor. Treatment that conforms to the shape of the tumor is referred to as conformal radiotherapy. Clinac accelerators are capable of operating with the RPM System while providing conformal radiotherapy. Clinac accelerators are capable of generating multiple beams from different directions in a conformal therapy.

During installation (at least with respect to Treatment RPMs) the technician ensures that the dynamic MLC mode of the Clinac is enabled so that the RPM System will operate to hold the treatment beam or not hold the beam. With version 8.0 of the C-series control software (at least with respect to Treatment RPMs), the Clinac accelerator can implement Gated RapidArc treatment deliveries in which RapidArc treatment deliveries are gated using the RPM System. Gated RapidArc Treatment is a computer-controlled conformal treatment that involves movement of the gantry to deliver different treatment beams to the patient from different angles.

Clinac accelerators are capable of operating with the RPM System to work with intensity-modulated radiotherapy (“IMRT”). IMRT is a type of conformal radiotherapy. IMRT is a treatment modality that better conforms to the shape of the tumor by modulating the intensity of the radiation beam. The Clinac accelerator may be operated in a segmental IMRT treatment mode, also known as “step-and-shoot.” In the “step-and-shoot” mode, the MLC is moved in a series of positions while the treatment beam is off, and when a position is reached, the treatment beam is turned on. While Pitt contends that Clinac accelerators are also capable of operating

with the RPM System to provide dose dynamic radiotherapy, Varian denies that contention and claims that Clinac independently provides dose dynamic radiotherapy and the RPM System merely offers the option of gating the beam during dose dynamic radiotherapy.

Dose dynamic treatment is a type of dynamic therapy in which the leaves of the MLC move while the beam is being generated, but Varian emphasizes that dynamic treatment does not always operate in that manner. While Pitt argues that dose dynamic therapy is a form of IMRT, Varian denies that statement on the basis that there is an “intersection” between dose dynamic therapy and IMRT, but one is not a subset of the other. Clinac accelerators are configured to provide radiation therapy treatment under computer control, and are capable of generating multiple beams from different directions in a conformal therapy. Although not all Clinac systems include a MLC, Clinac accelerators include a gantry that contains the MLC for shaping the beam and can rotate around the treatment couch to deliver treatments.

IV. Standard of Review

The summary judgment standard in a patent case is the same as in other civil cases. Summary Judgment is appropriate when it is apparent from the entire record, viewed in the light most favorable to the non-moving party, that there are no genuine issues of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-24 (1986). One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses. Therefore, summary judgment is required, “against a party who fails to make a sufficient showing to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Id.* at 322. The summary judgment inquiry asks whether there is a need for trial – “whether, in other words, there are any genuine factual issues

that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986).

A. Infringement

1. *Literal Infringement*

Patent infringement analysis involves a two-step process: first, the claims are construed, as a matter of law, and second, the properly construed claims are compared to the allegedly infringing device to determine, as a matter of fact, whether all of the limitations of at least one claim are present in the accused device. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

Summary judgment is appropriate where there is no genuine issue of material fact as to whether the asserted claims read on the accused device, or where no reasonable jury could find that every limitation from an asserted claim is or is not found in the accused device, either literally or under the doctrine of equivalents. *PC Connector Solutions LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1364 (Fed. Cir. 2005); *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998); *Lifescan, Inc. v. Home Diagnostics, Inc.* 76 F.3d 358, 359 (Fed. Cir. 1996).

2. *Doctrine of Equivalents Infringement*

Even where an accused device does not infringe literally, it may still be found to infringe under the doctrine of equivalents. An infringement under this doctrine occurs when the differences between the accused device and the claim limitation are “insubstantial,” meaning that “the element performs substantially the same function in substantially the same way to obtain substantially the same result as the claim limitation.” *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1316-17 (Fed. Cir. 1999) (citations omitted). This doctrine prohibits a party from avoiding infringement liability by making only “insubstantial” changes and substitutions which, though

adding nothing, would be sufficient to make the copy fall outside the claim, and therefore, outside the reach of the law. *American Calcar, Inc. v. American Honda Motor Co., Inc.*, 651 F.3d 1318, 1340 (Fed. Cir. 2011).

The United States Court of Appeals for the Federal Circuit has reiterated that in the context of summary judgment, a patent holder must provide particularized testimony, and a linking argument setting forth the “insubstantiality of the difference” between the claimed invention, and the accused device on a limitation-by-limitation basis. *Network Commerce, Inc. v. Microsoft Corp.*, 422 F.3d 1353 (Fed. Cir. 2005) (citing cases). Where the evidence is such that no reasonable jury could determine that an accused device includes an equivalent of each and every one of the limitations of an asserted claim, it is appropriate to enter judgment as a matter of law on this theory of infringement. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1017 (Fed. Cir. 2006).

B. Invalidity

An issued patent is presumed to be valid. 35 U.S.C. § 282; *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1378 (Fed. Cir. 2005). Indeed, a party that is “otherwise an infringer who assails the validity of a patent fair upon its face bears a heavy burden of persuasion, and fails unless his evidence has more than a dubious preponderance.” *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984)(citation omitted). In other words, in order to overcome the presumption of validity, the party challenging the patent must prove invalidity by clear and convincing evidence. *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315 (Fed. Cir. 2002).

In addition, the attacking party must overcome the deference that is due to the PTO examiner, who is presumed to have properly done his or her job in issuing the patent. *Am. Hoist*

& Derrick Co., 725 F.2d at 1359. Notably, however, no deference is due the examiner’s decision with respect to new evidence that was not before the PTO, and therefore, was not considered by the examiner in issuing the patent. *Id.* at 1360. Nevertheless, and regardless of whether the PTO’s decision is entitled to deference, the burden of proof remains “constant and never changes” and requires the attacking party to “convince the court of invalidity by clear evidence.” *Id.*

C. Written Description/Enablement

The written description requirement is set forth at 35 U.S.C.A. § 112, which states:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

In other words, if the patent specification teaches those skilled in the art how to make and use the full scope of the claim invention without undue experimentation, the enablement requirement is met. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (citing cases). The fact that some experimentation is needed in order to practice the claim invention is permissible, as long as it is not undue. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). Enablement is a question of law based on the underlying facts, and the issue is to be determined as of the filing date of the patent application. *E.g., Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). Summary judgment may be granted where the full scope of the claimed invention is not enabled. *See Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999-1001 (Fed. Cir. 2008) (affirming grant of summary judgment on non-

enablement). (See Section (V)(H) below, discussing *Powell v. Home Depot*, ___ F.3d. ___, 100 U.S.P.Q. 1742 (Fed. Cir. November 14, 2011), and other applicable cases).

D. Willful Infringement

When it is found that an infringer acted without a reasonable belief that its actions would avoid infringement, the patentee has established “willful infringement,” which may be accompanied by enhanced damages. *Vulcan Engineering, Co. Inc. v. Fata Aluminium, Inc.*, 278 F.3d 1366, 1378 (Fed. Cir. 2002). Whether infringement is willful is a question of fact, and is determined from totality of the circumstances. *See Gustafson, Inc. v. Intersystems Indus. Products, Inc.*, 897 F.2d 508, 510 (Fed. Cir. 1990). A finding of willful infringement is made where there is clear and convincing evidence to show that: (1) “the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent,” and (2) “this objectively-defined risk was either known or so obvious that it should have been known to the accused infringer.” *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007). The inquiry focuses on the infringer’s pre-litigation conduct. *Id.* at 1373.

V. Discussion

Pitt has moved for partial summary judgment (as to liability) on the basis that: (1) Varian’s RPM System infringes Claim 20 of the ‘554 Patent as a matter of law; (2) the RPM System infringes Claims 21, 25, 26 and 36 of the ‘554 Patent as a matter of law; and (3) the combination of the RPM System and Clinac and Trilogy Linear Accelerators infringes Claims 38 and 22 of the ‘554 Patent. Doc. No. 363.

Varian, on the other hand, has moved for summary judgment on the grounds of invalidity for lack of enablement, lack of damages (Entire Market Value Rule allegedly precludes Pitt from obtaining royalties on sales of linear accelerators), non-infringement due to “incapacity” (which

was subject of Pitt's previously granted Motion to Strike), non-infringement of the redesigned (or modified) RPM System, and willfulness. Doc. No. 364.

For the reasons that follow, the Court has granted Pitt's Motion for Partial Summary Judgment, denied Varian's Motion for Summary Judgment regarding invalidity, denied Varian's Motion for Summary Judgment regarding damages, found the redesigned RPM System infringes as a matter of law (literally and under the doctrine of equivalents), and stricken Varian's belated defense of non-infringement due to "incapacity." See Doc. No. 425. The Court finds that the issue of willfulness must proceed before a jury, and thus the Court denied Varian's Motion for Summary Judgment as to the issue of willfulness. See Doc. No. 425.

A. Varian Infringes Claim 20 By Making and Selling The RPM System

Plaintiff has moved for partial summary judgment on the basis that there is no genuine dispute of material fact that the RPM System satisfies each of the elements of Claim 20, as construed by the Court.

Claim 20 recites:

20. Apparatus responsive to movement of a patient positioned on a patent positioning assemble, said apparatus comprising:

Camera means generating digital images signals representative of an image of said patient; and

Processing means comprising

Meaning determining movement of said patient from said digital image signals, including movement associated with breathing by said patient, and

Gating means generating gating signals synchronized with said movement associated with breathing by said patient.

(Emphasis added).

According to Pitt, based upon the claim construction of this Court, the RPM system meets each of the elements of Claim 20. Pitt attaches as an exhibit a claim chart, compiled by

Dr. R. Alredo Siochi (upon which Varian does not object to his declaration at present, but intends to object to his qualifications/analysis during trial, if any) matching each element of Claim 20 to corresponding elements of the RPM System that uses a marker block with two fiducials, and with six fiducials.

The parties do not dispute that each version of the RPM System that Varian made and sold satisfies the preamble, and the “camera means” element, nor do they dispute that the RPM System contains a “processing means.” Furthermore, the parties do not contest that the RPM Systems, used with beam generators (“Treatment RPM’s”) meet the “gating means” element of Claim 20.

It appears that the parties only dispute the means determining movement element highlighted in the quoted section hereinabove. The means determining movement element is a means-plus-function term within the meaning of 35 U.S.C. § 112 (doc. no. 302 at 3-4). During the claim construction process, this Court construed the function of this element to be “determining movement of the patient from digital image signals of the patient, including movement associated with breathing by the patient.” Doc. No. 302 at 3, 5-6.

This Court construed the corresponding structure to be “a computer processor programmed as a patient motion detector that (1) identifies at least one marker from the image signals, and (2) tracks its movement, and equivalents.” Doc. No. 302 at 4-6.

According to Pitt, there is uncontroverted evidence in the form of expert testimony by one of a Varian’s experts, and an article written by Varian employees (see doc. no. 325 and Exhibit 10 thereof), that the RPM System performs the function of the “means determining movement” element.

Varian counters with two main arguments: (1) the RPM System lacks the corresponding structures of the “means determining movement” because the RPM algorithm does not track fiducials, and (2) the RPM does not perform the function of the “means determining movement” because it does not use any image “of the patient” to determine movement.

In support of its first argument (that the RPM algorithm does not track fiducials), Varian contends that the RPM tracks the position of a single calculated point, not the movement of individual markers, and analogizes that the RPM approach is like tracking a flock of geese, in contrast with the ‘554 Patent’s approach of tracking individual geese in the flock. Varian argues that the RPM algorithm is not identical to the corresponding structure of the “means determining movement” of Claim 20, and the RPM System’s approach of tracking a single, calculated point is a novelty and that is shown by the fact that Varian obtained its own patent on the marker block, with the ‘554 patent cited as prior art over which the Varian invention was found to be patentable. Therefore, according to Varian, any arguments of infringement by equivalents would be defeated.

Pitt counters, and this Court agrees, that Varian’s arguments in this regard are without merit for the following reasons: First, it is indisputable that the RPM System’s video camera captures an image of the patient and processes that image in order to locate and track the individual markers (fiducials) contained within it. Varian’s own expert on the issue of infringement agreed with this conclusion. Indeed, he explained that the initial image captured by the RPM camera includes an image of the patient and that the RPM software uses that image to locate within it the pixels that represent each of the markers. Doc. No. 325 at 17-20, ¶¶ 44, 48. Second, the distinction Varian draws between determining movement from the patient’s image, and determining movement from the fiducials contained within that image defies logic because

there is no meaningful difference between using the image of the patient and using a particular portion of that image (*i.e.* the portion representing the fiducials located on the patient's body to determine the patient's movement). Thirdly, Varian's current position requires that the Court deem that the digital image signals "of the patient" excludes the markers (or artificial fiducials) placed on the patient. However, as Pitt correctly notes, the Court already rejected this interpretation in its Memorandum Opinion on Claim Construction, and like the Special Master, found that the "means determining movement" *does not exclude* determining movement from artificial markers in the image of the patient. Thus, this Court found that the image of the patient in Claim 20 "may include both natural and artificial fiducials." Doc. No. 302 at 6.

Varian does not dispute that its markers are artificial fiducials consistent with the '554 Patent. Rather, Varian argues that the marker block is not a fiducial or marker because it is a block on which individual markers are mounted. However, as Pitt emphasizes, this is precisely the same arrangement as the preferred fiducial disclosed in its '554 Patent specification - - "a reflective sphere mounted non-reflective base." See '554, 3:58-64. Because the preferred fiducial is not limited to the reflector only, but also includes the base on which the reflector is mounted, the Court finds that the RPM marker block is not excluded from being a "fiducial" for the '554 Patent because it includes both markers and a base.

As Pitt correctly notes, this Court supported its claim construction by finding that the preferred fiducial disclosed in the '554 Patent is an artificial one. Doc. No. 302 at 7. The '554 Patent specification discloses determining movement solely from preferred artificial markers. The Court is mindful of the fact that it is well settled that "a claim construction that excludes a preferred embodiment is 'rarely, if ever, correct.'" *See Dow Chem. Co. v. Sumitomo Chem. Co., Ltd.*, 257 F.3d 1364 (Fed Cir. 2001), and "would require highly persuasive evidentiary support."

Vitronics Corp. v. Conceptronic Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996). The Court determined that Claim 20 does not exclude determining movement from artificial fiducials, and therefore, the phrase “of the patient” in the Court’s claim construction certainly covers devices, including the RPM System, that determine patient movement from artificial markers in the digital image of the patient. Varian’s arguments that the RPM System does not use any digital image signals of the patient but rather uses only digital image signals of the circular markers on the marker block to determine the patient’s position is not convincing, and lacks any proper evidentiary support.

Accordingly, because this Court found that the “means determining movement” does not exclude determining movement from artificial markers in the patient image, there is no genuine factual dispute that the RPM System satisfies the function of the “means determining movement” element.

The parties further dispute whether the structure of the RPM System determines movement by tracking the markers in the digital image of the patient. Pitt has presented credible and unrefuted evidence that the RPM System includes “a computer processor programmed as a patient motion detector that: (1) identifies at least one marker from the image signals and (2) tracks its movement, and equivalents.”

Specifically, Pitt cites Varian’s technical documents which explicitly state that the RPM Systems track the markers. According to Varian’s own RPM Reference Guide Ver. 1.6 (381-15, Ex. 9, at p.1-11), “[t]he RPM systems senses respiration motion of the patient by tracking a pair of passive reflective markers on a marker block.” Also, the RPM Reference Guide (at 1-6) states: “[t]he video camera and PC workstation (or RPM application installed on the workstation) tracks markers attached to a synthetic block which, in turn, is placed on the patient’s chest or

abdomen.” Also, according to Ver. 1-7 (381-11, Ex. 5, at 67) “[t]he RPM system senses the respiration motion of the patient by tracking two or six passive reflective markers (dots) on a marker block.”

In response to this competent evidence demonstrating that the RPM System determines movement by tracking the markers in the digital image of the patients, which was contained in Varian’s own product manuals, Varian attempts to distance itself from its own statements by arguing that “these statements are not conclusive because they are only intended by Varian to provide a general description of the RPM [S]ystem for customer reference.” Doc. No. 387 at 19-20. This Court finds that argument unpersuasive.

As further support for its assertion, Pitt provides the deposition testimony of Varian’s witness, Hassan Mostafavi, Ph.D., who was a corporate designee pursuant to Fed. R. Civ. Pro. 30(b)(6). Doc. No. 381-14, Ex. 8. Dr. Mostafavi was designated on behalf of Varian, and thus, binds the company, with respect to technical information about Varian products related to the ‘554 Patent, including the RPM, and the release date, and the technical distinctions between versions of Varian products related to the ‘554 Patent. In response to the question, “Does the RPM systems actually identify the markers on the marker block?” Dr. Mostafavi answered as follows: “The – the - it tracks the - - the markers, which are – have a rigid relationship relative to each other because of the marker block.” When questioned again, “So you’re actually tracking the motion of the markers?”, he answered, “Yes.” Doc. No. 381-14, Ex. 8 at p. 46.

It is the view of this Court, that the above testimony, albeit further clarified by answers at the deposition which are cited by Varian in its Response in Opposition (doc. no. 387 at 20), constitutes an admission by Varian that the RPM System determines movement by tracking the markers in the digital image of the patients. *See Custer v. Penn State Geisinger Health System,*

2005 WL 2860540 (M.D. Pa. 2005) (discussing effect of “binding admissions”); *See generally*, *Resolution Tr. Corp. v. Farmer*, No. 92-3310, 1994 WL 317458, at *1 (E.D. Pa. June 24, 1994) (discussing that purpose of Rule 30(b)(6) is to create testimony that binds the corporation).³

Additionally, to the extent that Varian’s non-infringement expert, Martin Murphy, Ph.D. argues that the RPM System does not “track” the markers, his testimony is based on an overly narrow definition of the word “track” that is not supported by the ‘554 Patent. Dr. Murphy testified that he defines “tracking” to require reporting the trajectory of the object to the user. Doc. No. 381-21 at p. 125:15-127:5 and 137:7-25. However, this definition of tracking will be disregarded as a matter of law because the ‘554 Patent does not require, much less describe, tracking as reporting the trajectory of markers to the user. Instead, the ‘554 patent specification describes tracking separately from the information displayed to the user. It is well settled that claim construction is a matter of law for the Court to determine, and this Court construed the claim terms in view of the claim language itself, the ‘554 Patent specification, and its prosecution history. *See Markman v. Westview Industries, Inc.* 52 F.3d 967, 979 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996). Varian may not attempt to avoid liability by inviting the Court to re-interpret its own claim construction in a manner which is inconsistent with the patent and its prosecution history.

For all of these reasons, this Court finds that there is no genuine dispute of material fact that the RPM System satisfies each of the elements of Claim 20, as construed by the Court.

³ The Court finds *Resolution Tr. Corp.*, 1994 WL 317458, to be persuasive on this issue, but notes that at least one other District Court in this Circuit has held that Federal Rule of Civil Procedure 30(b)(6) testimony is an admissible admission, although not a binding judicial admission. *State Farm Mut. Auto. Ins. Co. v. New Horizon Inc.*, 2008 US Lexis 37571 (E.D. Pa. May 7, 2008). The United States Court of Appeals for the Third Circuit has not yet addressed this issue.

Accordingly, the RPM System indisputably, and as a matter of law, infringes Claim 20 of the subject patent.

B. Varian’s RPM System Infringes Claims Dependent Claims 21, 25, 26 and 36 of the ‘554 Patent

1. Claim 21

Pitt argues, and this Court agrees, that the RPM System satisfies the elements of Claim 21, literally. The only evidence upon which Varian relies for the contention that RPM System does not infringe Claim 21, is Varian’s non—infringement expert’s (Dr. Murphy’s) opinion that it does not infringe Claim 20 (from which Claim 21 depends). Doc. No. 325 at ¶ 89. For the reasons set forth hereinabove, the RPM System infringes Claim 20 as a matter of law, and therefore, it follows that it also indisputably infringes Claim 21.

2. Claim 25

Pitt argues, and this Court agrees, that the RPM System satisfies the elements of Claim 25, literally. The only evidence upon which Varian relies for the contention that the RPM System does not infringe Claim 25, is Dr. Murphy’s opinion that it does not infringe Claim 21 (from which Claim 25 depends). Doc. No. 325 at ¶ 101. For the reasons set forth hereinabove, the RPM System infringes Claims 20 and 21 as a matter of law, and therefore, it follows that it also indisputable infringes Claim 25.

3. Claim 26

Pitt argues, and this Court agrees, that the RPM System satisfies the elements of Claim 26, literally. The only evidence upon which Varian relies for the contention that the RPM System does not infringe Claim 26, is Dr. Murphy’s opinion that it does not infringe Claim 21 (from which Claim 26 depends). Doc. No. 325 ¶ 103. For the reasons set forth hereinabove, the

RPM System infringes Claims 20, 21 and 25 as a matter of law, and therefore, it follows that it also indisputably infringes Claim 26.

4. Claim 36

Pitt argues, and this Court agrees, that the RPM System satisfies the elements of Claim 36, literally. The only evidence upon which Varian relies for the contention that the RPM System does not infringe Claim 36, is Dr. Murphy's opinion that it does not infringe Claim 20 (from which Claim 36 depends). Doc. No. 325 at ¶ 134. For the reasons set forth hereinabove, the RPM System infringes Claim 20 as a matter of law, and therefore, it follows that it also indisputably infringes Claim 36.

C. The Combination of Varian's RPM System and Clinac and Trilogy Linear Accelerators Infringes Claims 38 and 22 of the '554 Patent

Pitt argues, and this Court agrees, that Claim 38 depends from Claim 20, and as explained above, the RPM System satisfies each of the elements of Claim 38 as a matter of law. The only evidence upon which Varian relies for the contention that the combination of the RPM System and the Clinac and Trilogy linear accelerators does not infringe Claim 20, is Dr. Murphy's opinion that it does not infringe Claim 20 (from which Claim 38 depends). For the reasons set forth hereinabove, the combination of the RPM System and the Clinac and Trilogy Linear Accelerators infringe Claim 38 as a matter of law.

With respect to Claim 22, it also depends from Claim 20, which recites:

The apparatus of claim 20 adapted for use during treatment of said patient with a radiation beam generated by a beam generator, wherein said gating means comprises means generating gating signals synchronized to actuate said beam generator in synchronism with patient breathing.

Pitt argues, and this Court agrees, that Claim 22 varies from Claim 20 in the following two ways. First, in order to be covered by Claim 22, the apparatus of Claim 20 must be "adapted

for use during treatment of said patient with a radiation beam generated by a beam generator.”
Second, the gating means of Claim 22 varies from the gating means of Claim 20. The gating means of Claim 22 requires gating signals synchronized “to actuate said beam generator in synchronism with patient breathing.”

“A claim construction analysis must begin and remain centered on the claim language itself.” *Innova/Pure Water Inc., v. Safari Water Filtration Sys., Inc.* 381 F.3d 1111, 1116 (Fed. Cir. 2004). With that precept in mind, Pitt argues, and this Court agrees, that the phrase “said gating means” in Claim 20 refers to the “gating means” of Claim 20, and in particular, “gating means generating gating signals synchronized with said movement associated with breathing said patient.” Unlike Claim 20, Claim 22 specifically recites the “beam generator” and states that the beam generator is actuated by the gating signals. Accordingly, Claim 22 encompasses the beam generator (a Clinac or Trilogy Linear Accelerator).

With the exception of Dr. Murphy’s bold conclusion that “the Clinac linear accelerator does not come from within [Claim 22’s] scope,” Doc. No. 325 at ¶ 89-92, Varian offers no competent evidence from which a reasonable fact finder could determine that the combination of the RPM System and the Clinac or Trilogy Linear Accelerators, does not infringe Claim 22. Because the RPM System satisfies each of the elements of Claim 20, the combination of the RPM System and the Clinac and Trilogy Linear Accelerators infringes Claim 22 as a matter of law.

D. The Asserted Claims Are Not Invalid for Lack of Enablement

In its Motion for Summary Judgment, Varian argues that all of the asserted claims of the ‘554 Patent are invalid for lack of enablement because they improperly claim more than Pitt invented. In support thereof, Varian contends that “independent” Claim 20 covers embodiments

that determine patient movement from a single image of the patient, and that the '554 Patent specification does not explain or teach how to determine movement from “an image” (*i.e.*, a single image). Varian posits that Claim 20 is invalid in that it “sweeps too broadly, encompassing embodiments that *do* determine movement from only a single image in addition to those that may also use other information.” (emphasis added). Varian further contends that because Claim 20 is invalid for lack of enablement, the asserted “dependent” claims are also invalid. Thus, Varian argues that Claims 21-26, 28-32 and 36-38 of the '554 Patent all incorporate independent Claim 20 by reference, either directly or indirectly, and therefore, all dependent claims “fall” with the independent one. In other words, Varian contends that Pitt’s asserted patent claims are invalid for lack of enablement because they do not teach how to detect patient movement from a single frame of the video transmission generated by the camera of the claimed apparatus.

Pitt strongly disputes Varian’s contention, and notes that Varian concedes in its Brief, that the claims *do* teach how to detect patient movement from multiple frames of the video camera’s output. Doc. No. 399 at 46, citing Doc. No. 365 at 51.

The parties agree that an enablement inquiry begins with claim construction. Varian then asserts that for purposes of the '554 Patent, the word “image” should be construed to mean either a single frame or multiple frames from the video output of the camera used in the claim apparatus. Doc. No. 365 at 52-53. In other words, Varian asks this Court to construe the word “image” to refer to the medium in which an object is visually represented, rather than the subject matter that is being depicted. This Court finds this argument to be unconvincing.

The plain meaning of the word, “image,” is a visual representation of a physical object. *See e.g.* “Image,” Dictionary.com (accessed December 30, 2011) defining “image” as “a physical

likeness or representation of a person, animal, or thing, photographed, painted, sculptured, or otherwise made visible.” Pitt argues, and this Court agrees, that the word “image” connotes not the *medium* of representation (photograph, video, painting, etc.), but rather, the *content* that is depicted. Therefore, an “image” of a patient, is a visual representation of the patient, in whatever medium it is depicted. To wit: the “image” is the visual representation of the patient.

Varian argues that its proposed construction of the word “image” is “reinforced by the patent’s use of the word” - - an argument which this Court also finds to be unpersuasive. The ‘554 Patent claims an apparatus that is “responsive to movement of a patient.” The apparatus has a “camera means” that generates an “image” – that is, the camera generates a visual representation of a physical object. The ‘554 Patent also specifies the particular “image,” that is relevant to the claimed invention - - a patient. The “image” of the patient is, by the very nature of the claimed invention and the context of both claim language and the specification, a visual representation of the patient that shows the patient’s movement. The ‘554 Patent consistently uses the term “image” in exactly that way to refer not to specific frames of the video camera’s output, but rather to a visual representation of a patient who (obviously) will be moving. The ‘554 Patent, therefore, teaches how to detect movement from that image.

In addition to the arguments regarding the plain meaning of the word “image,” Varian contends that the asserted claims of the ‘554 Patent are not enabled because, by claiming an apparatus that can detect movement from “*an* image of a patient,” (emphasis added) they purportedly claim, but do not teach, that an apparatus can detect movement from a single video frame as well as from multiple video frames. Varian offers no applicable case law to support their contention that “a” and “an,” in patent parlance, can mean “one or more.” Rather, the cited case law seems to support Pitt’s counter-argument that the words “a” and “an” in patent claims

are to be construed in context and in a manner which is consistent with the claim language and specification. *See e.g. Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 365 F.3d 1299, 1305-06 (Fed. Cir. 2004) (construing “a” and “an” in context of claim language and specification); and *Elkay Mfg. Co. v. EBCO Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999) (“a” or “an” can mean “more than one” depending on the context in which the article is used).

The Court finds these arguments to be wholly unconvincing. First, as rehearsed, Varian’s construction of both the words “image” and the preceding word “an,” are not plausible. Furthermore, the context of the ‘554 Patent makes it obvious that the patent is directed to an apparatus that detects movement from a video image of a patient (not just a single snapshot from the video image, but rather, it would have to be construed to refer to multiple frames of a video transmission). It is the view of this Court, that these arguments do nothing to advance Varian’s burden of proving lack of enablement by “clear and convincing evidence.” Furthermore, as Pitt’s expert witness on the issue of invalidity (Dr. Siochi) points out, he considered and rejected this contention that the “single image” issue renders the ‘554 invalid for lack of enablement, and thus, his opinion by itself defeats Varian’s Motion for Summary Judgment on this issue. Doc. No. 400-17 at ¶ 10 (incorporating Validity Report at Doc. No. 320, ¶¶ 72-73). Accordingly, Varian’s Motion for Summary Judgment on the basis of invalidity for lack of enablement has been denied.

E. Varian’s Non-Treatment RPMs Infringe the ‘554 Patent Under the Doctrine of Equivalents.

The Court previously held, as set forth in fn. 2, hereinabove, that it would be unfair to rule upon Varian’s Motion for Summary Judgment regarding its belated defense of non-infringement on the basis of its new contentions regarding the “capabilities” of its Non-Treatment RPMs. Because of this ruling, the Court will not provide a lengthy analysis on this

issue, but does find, in any event, that Varian's Non-Treatment RPMs differ only insubstantially from Pitt's patent claims, and therefore, the doctrine of equivalents is applicable.

The doctrine of equivalents, which was established by the Supreme Court of the United States over 60 years ago in *Graver Tank & Mfg. Co., Inc. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950), provides a scope of protection to a patent claim that exceeds its literal meaning to "prevent an infringer from stealing the benefit of the invention." As more fully discussed in the Standard of Review (Section (IV)(A)(2)) above, the doctrine of equivalents is applicable, where, as here, the accused device does not fall within the literal scope of a claim element as construed by the Court, but instead includes a feature that differs insubstantially from the claim element. *Warner Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997).

The Court finds that the Non-Treatment RPMs meet all the elements of Claim 20: camera means that captures and digitizes images of the patient, processing means, and the means determining movement of the patient from the digital image signals, including movement associated with breathing.

Varian argues that its Non-Treatment RPMs do not satisfy the "gating means" element of Claim 20, even when operated in the prospective gating mode. Varian argues that "gating" in Claim 20 requires one signal that causes the beam generator to turn on a radiation beam, and a separate signal that causes the beam generator to turn the beam off, whereas the prospective gating of Varian's Non-Treatment RPMs generates a single signal that causes the beam generator (here a CT imager) to turn on and then turn off a radiation beam.

The claim construction of this Court, however, of "gating signals" does not distinguish between separate on/off signals, and a combined on/off signal. Furthermore, the Court finds that

any alleged difference between the two is insubstantial and therefore falls within the range of equivalents of the “gating means.”

F. Issues of Revenues (Damages) May Proceed To A Jury

Varian argues that the revenues from the linear accelerator must be excluded from the royalty base under the Entire Market Value Rule and that the revenues from sales of the RPM designed for use with PET and CT scanners must be excluded from the royalty base because that RPM device does not infringe any asserted claims of the ‘554 Patent. The Court finds that the first point should be argued before a jury, and the second point is really an attempt to re-argue liability (which liability rulings have already been made against Varian). The Court will re-visit this issue at the trial on damages during the motions in limine phase.

G. The “Proposed Modification” to the RPM System Literally (And Under the Doctrine of Equivalents) Infringes the ‘554 Patent

Varian next argues that a proposed modification to the RPM System warrants a summary determination that, as a matter of law, it would avoid infringement of the ‘554 Patent literally and/or under the doctrine of equivalents. Accepting as true all of Varian’s factual assertions regarding the nature and effect of the proposed modification, the Modified RPM System would still infringe the ‘554 Patent both literally, and under the doctrine of equivalents.

In June of 2010, Varian made its first attempt to design around the ‘554 Patent, by placing an optical filter on the lens of the RPM System’s video camera. Doc. No. 401 at 66 and 36-37. The alleged purpose of the optical filter is to limit any images of the patient to a very faint background. The focus, therefore, of the redesign was on Claim 20’s camera means, which “generate[es] digital image signals representative of an image of [the] patient.” The 2010 redesign project was abandoned, however, because Varian concluded that using an optical filter alone would not satisfactorily achieve its objective of preventing the RPM camera from

generating an image of the patient at the same time ensuring that the RPM System functions. Doc. No. 401, Statement of Additional Material Facts, at ¶ 9-11.

The latest “proposed modification,” that is the subject of the current motion, is the result of a development process that commenced in April 2011, and according to Pitt, was first disclosed over five (5) months *after* the close of fact discovery (on April 28, 2011). *Id.* at Statement of Additional Material Facts, at ¶ 12-13 (although Varian disputes that contention, the conclusions of this Court in this regard moot the issue of requests for further discovery).

Varian claims that the redesigned RPM System differs from the current version in two respects. Doc. No. 401 at ¶ 67. First, the “camera of the RPM system as redesigned is equipped with an optical glass filter that fits over the camera lens.” *Id.* at ¶ 68. As Pitt emphasizes, and this Court agrees, this alleged “fix” is very similar to the 2010 redesign listed above. Importantly, Varian admits that the filter does not prevent the RPM camera from capturing or generating a background image of the patient. *Id.* at ¶ 69.

Secondly, the RPM System modification includes “a circuit board containing an analog filter [that] is placed between the camera and the frame grabber, which digitizes the video signal from the camera.” *Id.* at ¶ 70. Varian contends that the analog filter is a circuit which “performs a thresholding procedure on the analog video signal from the RPM camera and thereby eliminates any remaining background image of the patient from the video signal, leaving only an image of the reflective markers on the RPM marker block.” *Id.* at ¶ 71.

It is the view of this Court that the second component of the proposed redesign, like the first component, does not fully achieve Varian’s goal because the circuit board does not necessarily prevent digitization of the background image of the patient. Rather, only if a component of the circuit board (known as the potentiometer, which is an adjustable device) is set

to a particular threshold level, would it prevent digitization of the background image of the patient. Also, there is no universally “correct” threshold setting, and the particular threshold setting that would prevent the RPM System from generating and processing digital images of the patient because of variables (including but not limited to conditions in the treatment room). Not only does Varian admit that if the potentiometer is set to threshold levels lower than the ideal setting the image of the patient may be digitized, but also it concedes that dialing the potentiometer to its lowest setting will prevent the circuit board from performing its intended function of preventing patient image digitization. *Id.*, Statement of Additional Material Facts, at ¶ 19. Varian’s own Rule 30(b)(6) witness testified that there may be circumstances under which no threshold setting will prevent digitization of the patient image. *Id.*, Statement of Additional Material Facts, at ¶ 20. It appears then that Varian’s primary defense to literal infringement is that the modifications to the RPM System would not literally infringe if operated in a particular way.

The asserted claims of the ‘554 Patent are apparatus claims rather than method claims. Accordingly, the test for infringement is whether the RPM System is *capable* of functioning in a way that would infringe the ‘554 Patent. It is well settled, and in fact, Varian noted its own briefs on claim construction that “Claim 20 is an apparatus claim . . . so the real issue is whether the claimed apparatus is *capable of* using natural fiducials.” *See Cyrix Corp. v. Intel Corp.*, 846 F.Supp. 522 536 (E.D. Tex. 1994), *aff’d*, 42 F.3d 1411 (Fed. Cir. 1994) (unpublished) (“To infringe an apparatus claim, it is not necessary for an accused device actually to be performing the functions specified by the claim. All that is required is that the device have the claimed structure, and that this structure in the device have the capability of functioning as described by the claim.”).

The Court denies Varian's Motion for Summary Judgment as to non-infringement of the proposed modification to the RPM System, because the proposed changes not only literally infringe the '554 Patent as a matter of law, but also, the modified RPM System infringes the '554 Patent under the doctrine of equivalents.

As rehearsed, infringement under the doctrine of equivalents occurs if the difference between the accused devices and the claim limitation are "insubstantial," meaning that "the element performs substantially the same function in substantially the same way to obtain substantially the same result as the claim limitation." *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1316-17 (Fed. Cir. 1999) (citing *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 608 (1950)).

No reasonable juror could find that the proposed modifications provide any functional or technical changes. First, the optical filter proposed by Varian does not block the image of the patient from being captured and generated by the RPM camera. Therefore, the modified system is really no different than the current one, because both allow a faint image of the patient to pass through the camera lens. Second, the analog circuit board is also purely cosmetic because the only function it performs (preventing the image of the patient from being digitized) is redundant and unnecessary to the operation of the RPM System. According to Varian, the software currently used in the RPM System eliminates the patient image. See Doc. No. 401-1 at 12 ("Varian's RPM Respiratory Gating System does not use an image of the patient to determine the patient's position; it only uses an image of retroreflective markers on a marker block. It uses a simple thresholding step to eliminate all objects within the camera's field of view other than the markers before any other processing of the image occurs"). Preventing digitization of the signals representing the image of the patient has no purpose if those signals will be eliminated

before further processing of the image regardless of whether they are digital or analog. The RPM System “as modified” performs substantially the same function in substantially the same way to achieve substantially the same result as the “camera means,” and “processing means.”

Furthermore, the “two major functional differences” set forth by Varian are actually irrelevant to infringement of Claim 20. First, Varian posits that the ‘554 Patent system can determine patient motion based on natural marks on the patient’s body, while the RPM [System] as redesigned cannot.” Doc. No. 365 at 40. However, the fact that the modified RPM System, would use only artificial fiducials (as opposed to natural fiducials) is irrelevant, because the RPM System has always relied exclusively on artificial fiducials. Either way, this Court (as set forth by the Special Master’s Report and Recommendation on Claim Construction and affirmed by this Court) has already ruled that the distinction between natural and artificial fiducials is irrelevant to infringement under Claim 20 (because this Court finds that Claim 20 covers the use of natural fiducials, artificial fiducials, or both). Doc. No. 283, at 14-15. Therefore, the fact that the modified (or redesigned) RPM System uses only natural fiducials does nothing to distinguish it from the current version of the system, which, as the Court has already held, literally infringes Claim 20. Second, Varian claims that unlike “the ‘554 system[. . . the RPM [System] as redesigned [cannot] . . . display an image of the patient on the same monitor as other information related to patient motion.” The Court finds this distinction to be extraneous to the issue of whether the RPM System infringes Claim 20. In contrast to dependent Claims 32, 36, and 37, Claim 20 does not even mention, let alone require, the use of a monitor. Accordingly, whether the RPM System displays an image of the patient on a single or multiple monitors, or no monitor at all, is immaterial to the infringement analysis.

Finally, Varian's argument on equitable estoppel grounds is also unconvincing. Varian argues that Pitt represented during the claim construction proceedings that Varian's proposed modification to the RPM System would not infringe the '554 Patent, and that Varian redesigned the RPM in reliance on that (mis)representation. According to Pitt, it acknowledged to the Special Master (concerning a Finnish patent and the Peltola prior art) that the PTO found that it did not invalidate the '554 Patent. Pitt distinguished the Peltola prior art from the patent-in-suit by showing that Peltola used an optical filter which was placed on the camera lens that prevented the camera from capturing an image of the patient, while the camera in the '554 Patent invention had no optical filter, and therefore does capture an image of the patient. Consistent therewith, Pitt acknowledged that if the RPM camera lens had an optical filter that prevented it from generating an image of the patient, the RPM would not *literally* infringe Claim 20. Of course, that does not address the separate question of whether it would still infringe under the doctrine of equivalents - - which the Court has found that it does. In any event, the modified or redesigned RPM System does not meet this criterion, because as Varian admits, the optical filter (unlike the Peltola filter) does not prevent the camera from generating an image of the patient, albeit allegedly a "very faint" one. Doc. No. 401 at 38, ¶ 69.

Accordingly, with regard to the modified RPM System, Pitt has established infringement under the doctrine of equivalents as a matter of law, and therefore, to the extent Pitt requests additional discovery related to the redesign, said Motion is denied as moot.

H. Issue of Willful Infringement May Proceed To A Jury

Varian now attempts to argue that Pitt's claim for willful infringement should not go to a jury. This Court disagrees. According to the applicable legal standard (as set forth in the Standard of Review Section (IV)(D)), willful infringement is established where the clear and

convincing evidence shows that: (1) “the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent,” and (2) “this objectively-defined risk was either known or so obvious that it should have been known to the accused infringer.” *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007). The Court must focus its inquiry on pre-litigation conduct. *Id.* at 1373.

The Court finds that the following evidence is sufficient to allow this issue to be put before a jury. First, Pitt shared its patent applications, and the concepts and technology underlying them, with Varian assuming that Varian was to be a trusted business partner. According to the deposition testimony of Dr. Greenberger, he stated: “I am a representative of the University of Pittsburgh, and I recall that I noticed Varian of the existence of these patents [prior to the filing of the lawsuit]. I recall two separate times since the patents were issued that Varian was looking at them.” Doc. No. 400-22 at p. 3-4. The deposition testimony of Dr. Greenberger also presents facts that Varian took that information, ended its partnership with Pitt, and eventually proceeded to develop the infringing products. Interestingly, Varian allegedly did not seek advice of counsel to confirm that its products would not infringe its former partner’s patents. Only after its products were launched, did Varian approach Pitt with what could be construed as a “casual offer of nuisance value” payment in hopes of avoiding litigation.

The Court has already found that Varian’s products employ the same technology and concepts that Pitt shared with Varian during their partnership. There are facts from which a fact finder could conclude that Varian knew of Pitt’s application to patent that technology and further knew that patents claiming that technology as Pitt’s inventions had issued. These facts, and those cited in the preceding paragraph establish an “objectively high likelihood” that Varian’s development and launch of products using the same technology would infringe Pitt’s patents.

The Court also finds Varian's arguments that because it has come forward with certain defenses (including non-infringement and invalidity), it should be absolved of even the potential for liability for willful infringement, to be unpersuasive. Varian cites a non-precedential opinion of the Federal Circuit for the proposition that its ability to come up with non-infringement and invalidity defenses in litigation shields it from its pre-litigation willful infringement. See Doc. No. 365 at 45 (citing *Black & Decker, Inc. v. Robert Bosch Tool Corp.*, 260 Fed. Appx. 284 (Fed. Cir. 2008)). However, a careful reading of that opinion (although not binding authority) reveals that it does not support Varian's position. Rather, the Federal Circuit simply declared the issue of willfulness moot on appeal, and stated that if willfulness were considered again on remand, the accused infringer's "legitimate defense to infringement claims and credible invalidity argument" would be probative of an "objectively high likelihood" that the defendant's activity would not infringe.

In *i4i Ltd P'ship v. Microsoft Corp.*, 670 F.Supp.2d 568, 581 (E.D. Tex. 2009), *aff'd on other grounds*, 589 F.3d 1246 (Fed. Cir. 2009), the United States District Court for the Eastern District of Texas rejected the same argument that Varian advances, that the presentation of valid defenses in litigation immunizes the infringer from a willfulness finding. The Court found that the defendant's argument in that regard was "premised on an overly broad reading of *Seagate*," and a misreading of *Black & Decker*. *Id.* at 580. The Court stated the following, which is equally applicable here, and bears repeating:

[T]he number of creative defenses that [defendant] is able to muster in an infringement action after years of litigation and substantial discovery is irrelevant to the objective prong of the *Seagate* analysis. Rather, the correct analysis focuses on whether, given the facts and circumstances prior to Microsoft's infringing actions, a reasonable person would have appreciated a high likelihood that acting would infringe a valid patentThe subject prong

then focuses on whether [defendant] knew or should have known of that likelihood.

Id. at 581-582.

Varian's argument that the jury should be prohibited from determining willfulness goes beyond even what defendant did in *i4i*. In *i4i*, the defendant moved for judgment as a matter of law after the jury heard the evidence of willfulness. Whereas, here Varian seeks the Court to usurp the function of the jury - - which this Court will not do.

Furthermore, despite Varian's argument that the PTO granted Varian's request for reexamination of the patents in suit, this does not insulate Varian from potential liability for its willful infringement. *See Krippelz v. Ford Motor Co.*, 636 F.Supp.2d 669, 671 (N.D. Ill. 2009) (the granting of a reexamination request "cannot be considered to have decreased the objective likelihood that [the defendant] was infringing a valid patent.") Indeed, the Federal Circuit has ruled that reexamination grants and interim PTO rejections are "not probative evidence on the question of patentability."

The Court, as a matter of law, rules on the existing record that Varian's reliance on its alleged non-infringement, and its reliance on the other non-liability issues and defenses raised by Varian were not reasonable, and was objectively reckless. Pitt has proven, as a matter of law, by clear and convincing evidence that the objective prong of *Seagate* is met as to the legal issues. *See Powell v. Home Depot*, ___ F.3d ___, 100 U.S.P.Q.2d 1742, 1751-1752, and fn. 1 2011 WL 5519820 (Fed. Cir. November 14, 2011).

Simply put, Pitt has put forth sufficient evidence of willfulness to avoid summary judgment, and this issue is best resolved by a jury. *See Sollami Co. v. Kennametal, Inc.*, 2007 WL 6137395 at *11 (W.D. Pa. December 28, 2007)(This Court found sufficient evidence of

willfulness to avoid summary judgment, without making ultimate determination as to whether non-movant had “adduced ‘clear and convincing’ evidence”). Therefore, defendant’s Motion for Summary Judgment as to willfulness has been denied. See Doc. No. 425.

VI. Conclusion

After careful consideration of this most voluminous record, the Court finds that the RPM System infringes Pitt’s ‘554 Patent as a matter of law, and therefore, has GRANTED Pitt’s partial Motion for Summary Judgment. The Court has also DENIED Varian’s Motion for Summary Judgment in its entirety. Finally, as set forth hereinabove, the Court will conduct a trial on the issue of willfulness only (as previously set forth by Order of December 21, 2011 – see doc. nos. 425 and 426).

An appropriate Order (issued on December 21, 2011 at doc. no. 425) has been filed.

SO ORDERED this 30th day of December, 2011.

s/Arthur J. Schwab
Arthur J. Schwab
United States District Judge

cc: All Registered ECF Counsel and Parties