Neutral Citation Number: [2017] EWHC 712 (Pat)

Case No: HP-2015-000046

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Rolls Building
Fetter Lane
London, EC4A 1NL

Date: 06/04/2017

Before :

THE HON. MR JUSTICE BIRSS

- -

Between :

VARIAN MEDICAL SYSTEMS INTERNATIONAL AG	**Claimant**
- and -	
(1) ELEKTA LIMITED	
(2) ELEKTA HOLDINGS LIMITED	**Defendants**

- -
- -

Mr Iain Purvis QC and Mr Brian Nicholson (instructed by **Bristows LLP**) for the **Claimant**
Mr James Abrahams QC and Mr James Whyte (instructed by **Powell Gilbert LLP**) for the **Defendants**

Hearing dates: 27, 28 February 2017, 1, 2, 7, 8 March 2017

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Judgment Approved

Mr Justice Birss :

Introduction

1. This case concerns patent EP (UK) 0 963 218, entitled "Radiotherapy machine including magnetic resonance imaging system" granted on 8th June 2005. The patent was filed on 21st December 1998 claiming priority from a US filing on 19th December 1997. The inventor is Michael Green and the patent is referred to as the Green patent. The Green patent relates to a combination of a magnetic resonance imaging (MRI) system with a radiotherapy system. The sort of radiotherapy system which is typically used consists of a linear accelerator (Linac) to generate the high energy X-rays used for treatment.

2. The Claimant, Varian Medical Systems International AG, is the patentee and is a developer of radiation oncology tools. The Defendants, Elekta Limited and Elekta Holdings Limited, provide radiation therapy and radiosurgery equipment. This action is now one of a total of 34 actions before various courts around the world including the United States, Germany and the UK.

3. Radiotherapy involves the application of a beam of radiation onto a cancerous tumour from various angles. The aim is for only cancerous tissue to suffer a high cumulative dose of radiation, while the surrounding healthy tissue receives as low a dose as possible.

4. Ideally, the beam must be precisely directed at the tumour for the entirety of the treatment period. In practice, however, this is not achievable. Although the direction of the beam can be fixed, the location of the tumour cannot be. Patients do not remain entirely motionless during treatment and tumours can move within a patient's body either gradually over time or regularly. For example, a lung cancer tumour may move as a patient breathes. It is not possible to see the beam interacting with the tumour and surrounding tissues. As a result, radiotherapy has to be delivered on the basis of earlier acquired anatomical images – such as those obtained with an MRI system - to locate the cancer. It also means that, to account for movement of the tumour, the targeted volume for the radiation has to be increased to ensure that the whole of the tumour is hit. The result is that a substantial amount of healthy tissue may also receive a high dose of radiation, which can have devastating consequences for the patient's quality of life.

5. In a consortium which includes the Dutch company Philips as Elekta's technical partner and the University of Utrecht, Elekta has been developing a clinical system comprising a Linac and an MRI machine that can operate simultaneously, called the MR-Linac. Currently the MR-Linac is not approved for clinical use, so references to tumours in the context of the MR-Linac's functionality in what follows are references to intended clinical functionality. Using the system, MRI images can be obtained while the patient is lying on the treatment couch and the Linac can be used to deliver the appropriate X-rays to treat the tumour. The MRI system can image the tumour in such a way that the movement of, for example, a lung cancer tumour due to breathing can be tracked. The system has an automatic function whereby the X-ray beam is turned off if the tumour moves more than a certain distance from the target zone of the beam. Turning the beam on and off is called gating. This automatic gating function allows the X-ray beam to be irradiating the patient only when the tumour is

directly in the line of fire. This concentrates the beam energy on the tumour. Without this gating the beam would be on all the time with the result that more healthy tissue was irradiated.

6. Varian alleges that the MR-Linac machine infringes the Green patent because it is able to carry out this gating function. Elekta denies any such infringement and counterclaims for invalidity.

Procedural history

7. During the course of proceedings, on 13 October 2016 an inspection of Elekta's MR-Linac machines in Crawley was ordered. The inspected machine is referred to as the Crawley MRL-1. Also in that period Elekta were ordered to provide further disclosure but on 1 December 2016, I found that Elekta were in breach of the disclosure order and an unless order followed.

8. At the pre-trial review on 13 January 2017, Arnold J held that Elekta had breached the unless order because they served a large quantity of electronic documents on Varian purportedly pursuant to the unless order without having reviewed them to remove irrelevant or privileged material. Arnold J granted Elekta relief from sanctions on the basis that the cases regarding the Green patent's validity and infringement relating to the Crawley MRL-1 proceed to trial, but that the infringement case relating to offers of MR-Linac machines with functionality beyond the Crawley MRL-1 be adjourned to be heard in May 2017.

9. This judgment concerns the first part of these now bifurcated proceedings - i.e. the questions of the validity of the Green patent and infringement regarding the Crawley MRL-1. The gating function described above is what the Crawley MRL-1 can do. In this judgment I am not concerned with what wider functions of their MR-Linac Elekta may (or may not) have been offering.

The issues

10. The issues before me in this trial are:

    i) *Construction*. Varian's case is that claims 1, 4, 5, 7, 9 and 11 of the Green patent are independently valid and infringed. There are points on claim 1 and claim 4. No issues of construction arise on claims 5, 7, 9 or 11.

    ii) *Infringement*. Varian assert that the Crawley MRL-1's automated gating function makes it a system as claimed in claim 1 and the coil spacing arrangement makes it a system within claim 4. Elekta deny infringement.

    iii) *Insufficiency*. Elekta contend the patent is insufficient in that the invention cannot be made to work at all or without undue burden.

    iv) *Obviousness* in light of:

        a) United States patent US 5,537,452 (Shepherd); and

        b) International application WO 9722015 A1 (Van Vaals).

v) *Added matter*. Elekta contend that claim 1 involves added matter relating to the inputs to the control of the radiation beam and the nature of the control.

Technical background

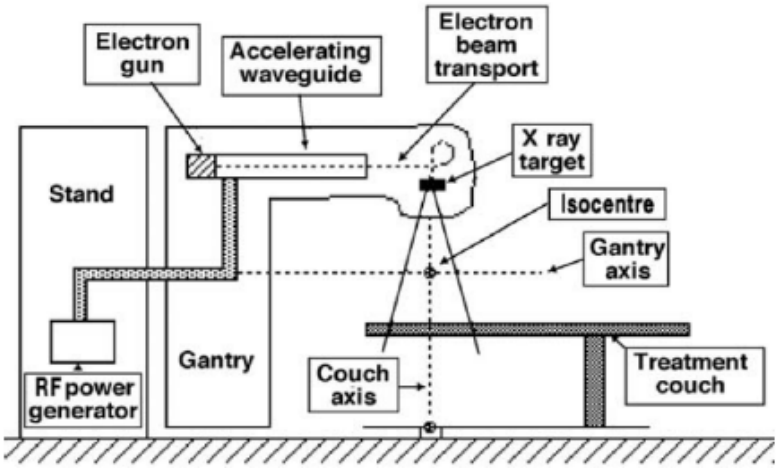
11. I am grateful to both parties for providing me with a detailed and helpful agreed Primer setting out the technical background to both MRI and radiotherapy. In order to provide some context to this judgment, I set out below a summary of the key background information.

Radiotherapy

12. Radiotherapy is the use of ionising radiation from X-rays, gamma rays, neutrons, protons and other sources to kill cancer cells, to shrink tumours, and for other medical uses. Ionising radiation is radiation that has a high enough level of energy to free electrons from atoms. The ionisation damages the DNA of cancerous cells, which in turn can prevent them from replicating and result in cell death. The effects are not specific to cancerous cells: ionising radiation damages DNA in healthy cells as well, although healthy cells are better able to repair DNA damage and so will be relatively less affected by – or at least better able to recover from – the radiation. The aim of radiotherapy is to target the cancerous cells and avoid damaging healthy cells as much as possible. It is this principle that underlies 'fractionation', a method of radiotherapy whereby the treatment is delivered through a number of discrete applications referred to as 'fractions', often given daily over several weeks.

13. There were various different types of radiotherapy in use at the priority date, which broadly fit into one of two groups: internal source or external source. Internal source radiotherapy can involve placing a small piece of radioactive material temporarily inside the body near the cancerous cells (brachytherapy). External source radiotherapy (which is the subject of this case) involves using radioactive radiation sources (such as Cobalt-60 which produces gamma rays) or electrically powered radiation sources (such as a Linac) outside the body to focus high-energy radiation beams onto the area requiring treatment.

14. Linacs use high-frequency electromagnetic fields to accelerate electrons to high energies through a linear tube. Most commonly, Linacs are used to deliver X-ray beam therapy. The agreed Primer contained a helpful schematic diagram at figure 6 showing the components of a Linac used to deliver X-ray beam therapy:



15. The electrons are produced in the first place by heating a metallic filament. They travel through a waveguide containing specially designed metallic chambers spaced at intervals along the waveguide in which the electrons are accelerated by being exposed to pulsing radiofrequency (RF) fields. The pulsed RF fields are produced using microwaves generated by a klystron or magnetron. The RF cavities in the accelerator are shaped to facilitate resonance of microwaves at specific frequencies. Energy is transferred from the microwaves to the electrons as they pass through the chamber, propelling them forwards. When the electrons leave the waveguide they collide with a heavy metal (e.g. tungsten) plate, producing high energy X-rays. The Linac also has a series of magnetic steering coils which direct the electrons on the right path in the waveguide and on to the target plate.

16. By colliding with the target plate the electron energy is thus converted into a spectrum of X-ray energies with the maximum energy equal to the incident electron energy. The X-rays are therefore a form of *bremsstrahlung* or braking radiation. Traditionally the electromagnetic spectrum would show X-rays as having lower frequency and therefore lower energy than gamma rays produced from a radioisotope like Cobalt-60. However today the Linac can accelerate the electrons so much that the electromagnetic radiation they produce can be more energetic than such gamma rays and the distinction between X-rays and gamma rays only really relates to the manner in which they are produced.

17. An important component which is not shown in the diagram is the collimator: a device which directs and shapes the radiation beam as it is emitted from the source head.

18. Electron beam therapy is another form of external beam radiotherapy where the electrons themselves are directed to a tumour site. As in X-ray beam therapy, electrons are accelerated in the waveguide by the pulsing RF fields. However instead of directing the electrons to a target, they pass to a scattering foil which directs the electrons themselves onto the target tumour. Many Linacs have a selectable arrangement which allows them to deliver either X-ray beam therapy or electron beam therapy.

Clinical use of radiotherapy

19. Before radiotherapy treatment begins, the patient will undergo a treatment planning process. Planning images are acquired of the patient in the treatment position to identify the position, shape and volume of the tumour. From these images, the treatment team can identify precisely the area of the body that will receive the radiation. In order for the images to be as helpful as possible, they must be obtained under conditions similar to those of the actual treatment position. Patient positioning is, therefore, crucial as it has a large influence on whether the treatment beam is directed accurately to the target area. The treatment team determines the coordinates of the isocentre (explained below) using simple geometry and positions the patient in the correct place using the images acquired. They will also mark the patient's skin with tattoos to act as a reference to ensure that the same basic positioning can be duplicated later for each treatment session.

20. To assist in the planning process the following volumes are generally defined:

    i) Gross Tumour Volume (GTV): the known extent of the tumour (to the extent visible in the images used for treatment planning).

    ii) Clinical Target Volume (CTV): a volume surrounding the GTV which allows for microscopic tumour spread or subclinical malignant tissue to be irradiated. The CTV must be treated with an adequate dose to fully sterilise the cells within it.

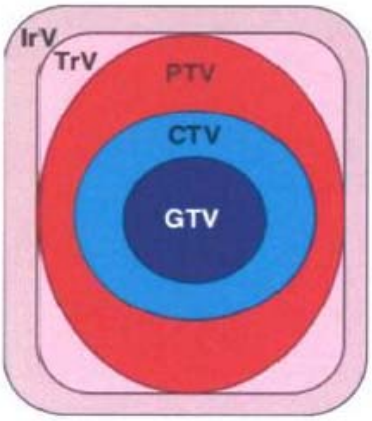
    iii) Planning Target Volume (PTV): a region surrounding the CTV which is to be treated with the prescribed dose. It is calculated by expanding the CTV to accommodate uncertainties in treatment delivery, for example tumour movement, to ensure that all of the CTV is irradiated with the required dose.

    iv) Treated Volume (TV or TrV): the tissue volume which, according to the approved treatment plan, is planned to receive a dose selected by the radiation oncologist as appropriate to achieve the purposes of the treatment.

    v) Irradiated Volume (IV or IrV): the tissue volume which receives a dose that is considered significant in relation to normal tissue tolerance.

    vi) Organs at risk (OAR): normal tissue sensitive to radiation which may significantly influence treatment planning.

21. The successively larger volumes are shown, in schematic cross-section, in Dr Fenwick's figure 5:



22. The images taken of the patient enable the GTV, CTV, PTV and OAR to be identified/defined. The dose to be delivered is then specified by a clinical oncologist. This information is used to develop a treatment plan specifying the manner in which doses are to be delivered through each fraction over the course of the whole treatment – i.e. the size, shape, angle and entry points etc of the treatment beams.

23. At the priority date, the main imaging techniques used in radiotherapy treatment planning were CT scanning and MRI.

24. CT scanning uses X-rays and is therefore unable to generate the soft tissue contrast obtainable by MRI. Despite this drawback, it remained the primary imaging method used at the priority date. This was in part due to the fact that CT imaging provides information on the electron density of the imaged tissue, which is necessary for treatment planning.

25. However, better soft tissue contrast could be obtained through use of MRI. MRI was particularly useful in dense areas of soft tissue (e.g. the prostate) where X-ray images could deliver very little contrast.

26. Imaging would generally be performed some considerable period (days or weeks) before the start of treatment delivery, which contributed to the uncertainty in tumour location and the need to define a PTV considerably larger than the CTV to allow for this uncertainty. There were some approaches in use or development at the priority date which allowed for a degree of on-the-day or in-treatment imaging, such as portal imaging which used X-rays from the treatment beam to obtain an X-ray image of the patient on the treatment couch. The images produced had low tissue contrast due to the use of high-energy treatment X-rays rather than diagnostic X-rays; however, they could assist in identifying the position of the patient's bony anatomy. Tomotherapy devices, which combined a Linac with a low resolution CT scanner had also been demonstrated experimentally, but had yet to be implemented in the clinic.

Rotational and conformal radiotherapy

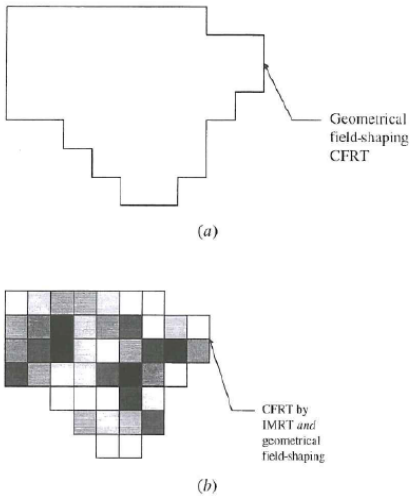
27. Methods of directing the radiotherapy beam more accurately on the tumour rather than healthy tissue are an important way of minimising side effects on the patient. In some cases a patient would be asked to hold their breath so that the tumour, for example on a lung, did not move while the beam was on. At the priority date, two particular targeting methods were rotational therapy and conformal therapy.

28. In rotational therapy, the radiation beam is emitted from a portion of the treatment machine which is mounted on a gantry that can be rotated (in the vertical plane) around the patient about a horizontal gantry axis. As the gantry rotates, the collimator axis (coincident with the central axis of the beam) moves in a vertical plane. The point of intersection of the collimator axis, the gantry axis, and the couch axis is known as the isocentre (shown in figure 6 from the Primer above). Using the rotating gantry to deliver the radiation beam means that the target area can be exposed to a high level of radiation, whilst reducing the amount of radiation the healthy tissue receives. This is because the radiation path through the body to the tumour changes as the gantry angle changes, with the tumour constantly being irradiated while healthy tissue is only exposed momentarily.

29. Conformal therapy is a technique whereby the radiotherapy beam is shaped to conform as closely as possible to the shape of the tumour being treated, typically from a number of beam angles. At the priority date, this could be achieved by using (i) customised-shaped blocks placed in the path of the beam; or (ii) a multi-leaf collimator (MLC) that is incorporated into the head of the machine. An MLC is a device made up of radiation-impermeable individual 'leaves' of a high atomic numbered material which can be moved in and out of the path of the beam to create an aperture of almost any shape, thereby shaping the beam itself. At the priority date these 'leaves' were usually made of tungsten or a tungsten alloy. Each leaf can be moved individually and together they create a field shape to match the shape of the tumour. With this method, it is possible to use more intense levels of radiation which are more effective in shrinking and killing tumours.

30. Intensity Modulated Radiotherapy (IMRT) is a development of conformal radiotherapy in which the conformed field is varied over time. In this way, the amount of radiation received by different parts of the target area over the course of a treatment fraction can be varied. IMRT was a hot topic at the priority date. At that time two promising methods for delivering IMRT were (a) using multiple static MLC shaped fields or (b) using dynamic MLC techniques. The former was known as "step and shoot". In that case the MLC leaves change position and the gantry rotates while the beam is off. With the latter dynamic approach the MLC leaves move position while the beam is on.

31. The difference between the effect of conformal therapy and IMRT can be illustrated with the following figure taken from Dr Williams' first report:



32. The overall shapes are the same and represent in effect the tumour and suspected cancerous tissue. Diagram (a) illustrates the geometric field shaping available with conformal therapy. Diagram (b) illustrates IMRT and the different cumulative intensities of radiation delivered to different areas. The darker areas show a higher cumulative intensity and could represent a thicker region of tumour.

Other relevant features of Linacs

33. At the priority date, a standard feature of Linacs was a pause button allowing treatment to be temporarily halted if, for example, the patient moved or suffered a sudden fit of coughing. As stated above, the ability to interrupt and re-start the delivery of the beam in this way is called "gating".

34. Many of the components of a Linac machine are highly susceptible to magnetic interference. For example, the path of moving electrons will curve in the presence of a magnetic field. As a result, a stray magnetic field will cause the path of the accelerated high energy electrons through the waveguide in a Linac to be deflected, interfering with or even stopping the beam altogether. At the priority date, the only type of magnetic interference Linacs were generally designed to correct for was that deriving from the Earth's magnetic field (approximately 0.05 millitesla or 0.5 gauss). Magnetic fields are measured in tesla or gauss and 1 G is 0.1mT. So in general gauss are used to refer to modest fields of the strength of the Earth's magnetic field and tesla are used to refer to very strong fields such as those generated by the magnets used in MRI.

35. Furthermore, Linacs also contain sources of RF interference, including the magnetron or klystron which generates the microwaves used in the electron accelerator.

MRI

Principles

36. MRI is a tomographic imaging technique i.e. a method of producing either 2D or 3D images of the internal structure of a solid object. MRI uses externally measured nuclear magnetic resonance (NMR) signals to produce images of internal physical and chemical characteristics of an object.

37. MRI is a highly valuable diagnostic tool. Its particular benefit compared to other imaging techniques, such as the X-rays used in CT scans, is its ability to distinguish between different types of soft tissue. This affords advantages in, for example, identifying a tumour in a soft tissue region such as the abdomen. In addition, MRI does not involve the use of ionising radiation and therefore does not have the potential harmful effects associated with other imaging methods, such as X-ray imaging.

38. An MRI image of the human body is essentially recording the collective response of approximately 3×10^{30} hydrogen nuclei (protons) in the body to the exposure of a magnetic field. The detail of the underlying science is beyond the scope of what is required for the purposes of this judgment, but in essence, powerful magnets are used to generate a strong magnetic field around the imaged object (the B_0 field). Within the B_0 field, the nuclear spin directions of the protons of the imaged object become aligned with the field axis, resulting in an overall magnetic component (the "bulk magnetization"). If a second magnetic field is introduced (the B_1 field) the spins will be perturbed and move out of alignment. If the B_1 field varies at the correct resonant frequency, it can induce precession of the spins around the direction of B_1. The spins will precess at a frequency called the Larmor Frequency. When the B_1 field is turned off, the protons' spins will gradually recover and fall back into alignment with the B_0 field. In this process, electromagnetic energy is emitted from the atoms and the varying magnetic field is picked up by an RF antenna capable of receiving signals at such frequencies.

39. This short, pulsed application of the transverse B_1 field is known as the "RF pulse". MRI works by measuring the time taken for the nuclear spins to re-align following perturbation (known as the "relaxation time"). There are two relaxation processes that govern the return of the protons to their original alignment with the B_0 field: longitudinal relaxation (T_1) and transverse relaxation (T_2). The significance of T_1 and T_2 is that they provide the tissue specific contrast in the MRI image, as different types of tissue with different T_1 and/or T_2 values show up with different signal intensity in the reconstructed image.

40. Relaxation times are affected by variations in the B_0 field, which can cause loss of phase coherence. For this reason, the B_0 field needs as far as possible to be uniform within the region being imaged. This uniformity is also referred to as "homogeneity". A lack of field homogeneity within the imaging region can significantly affect the quality of the images produced.

An MRI system

41. In addition to a unit which displays the generated images, an MRI system comprises the following main components: main field magnet, gradient coil system, RF transmitter, RF receiver, and pulse controller and central processor unit.

42. The main field magnet generates the initial B_0 field with which the spins of the hydrogen atom nuclei in the human body will align. The key requirements for the main field magnet are (i) the generation of a magnetic field of sufficient strength to enable a good signal to noise ratio (SNR) and (ii) good field homogeneity.

43. In general, higher strength magnetic fields generate a stronger signal, and can therefore give improved SNR. Systems with a field strength up to 0.5T can be made

using permanent magnets or electromagnets made of resistive material. These are still very strong magnetic fields but in the context of MRI are regarded as low field systems. So called "high field" systems, that is those with a field strength greater than 0.5T, require superconducting magnets. In a superconducting magnet the coils must be cooled using liquid helium, which boils at about 4 kelvin. The whole magnet has to be encased in a bulky cooling apparatus known as a cryostat.

44. Good field homogeneity aims to produce as near as possible uniform strength across the entire field of view. The larger the field of view, the more challenging it is to achieve sufficient homogeneity across it. In order to generate more uniform fields, the main field magnets are separated into discrete coil sections. In general, a greater number of sections results in greater field uniformity over a larger volume: at the priority date the best commercially available MRI magnets typically consisted of 6 sections. Another strategy to improve uniformity was "shimming", where small sections of iron, or alternatively small additional current coils, are placed in the interior of the magnet. Finally, in order to maintain uniformity, the main field magnet must be shielded from external magnetic interference.

45. At the priority date the majority of MRI magnets were closed cylinders. However, open magnets, with different sections of the magnet spaced apart, were also known. The advantage of such systems is that they can allow access to the patient by clinicians during imaging. An open magnet system that would have been known to the skilled person at the priority date was the GE Interventional MR Imaging suite. The GE system consisted of two separate cylindrical magnet sections, each surrounded by a cryostat (referred to as a "double donut" configuration). The treatment couch extended through the bore of both magnet sections, allowing the patient to be treated in the space between the donuts while being imaged by MRI. Care obviously had to be taken to ensure only non-magnetic equipment was used in the delivery of any such treatment. Mr Collins and Prof Morris included identical images of the GE double donut in their first reports:

46. While open configurations such as the GE "double donut" system offer advantages in allowing better access to the patient, they also present design challenges, including that of achieving sufficient homogeneity in the imaging region due to (i) the spacing between the magnet sections and (ii) the fact that placement of shimming coils is restricted in such a configuration.

47. MRI systems also incorporate three additional magnetic coils ("gradient coils") placed inside the main MRI magnet which act to create a gradient in the B_0 field along an x, y, or z axis, allowing 3D localisation of signals from within the region imaged. This is known as spatial localization and allows the attribution of a particular signal to a particular point or plane in the body. From this, the characteristics of the tissue at that point can be determined, thereby building up the image. In order to do this, it is necessary to make the resonance frequencies of the spins located in different positions differ. Since the spin resonance frequency is dependent on the magnitude of the B field experienced by the individual protons, it is possible to make the resonance frequency position dependent by spatially varying the magnetic field. This can be done by augmenting the B_0 field with a linear gradient field during the RF excitation period using the gradient coils.

48. The RF transmitter unit is an RF antenna coil located inside the magnet which induces the B_1 field by transmitting RF pulses at selected frequencies in order to excite the spin system of protons in the human body.

49. The RF receiver is a coil or an array of coils which picks up the energy emitted by the protons after the excitation of the spins by the RF transmitter unit. The design of the receiver affects the quality of the image. In some cases, a single coil serves as both the RF transmitter and the RF receiver.

50. The MRI machine requires a succession of different operations such as pulse generation, gradient switching, and receiver and transmitter switching, some of which take place sequentially or are scheduled to a strict timing schedule. The pulse controller and central processor unit undertakes all of these tasks and acts as the brain of the MRI system.

Shielding requirements

51. All MRI systems generate significant stray magnetic fields ("fringe fields"), which are particularly severe when superconducting magnets are used. These fringe fields can interfere with other devices containing magnetic components, open the MRI up to interference, and present safety concerns. At the priority date, it was generally accepted that the fringe field measured at a location 2-3 metres from the machine should be kept at or below 0.5 mT. In addition, the MRI system itself needed to be protected from interference by magnetic objects or equipment, so as not to disturb the homogeneity of the main field. In both cases this was accomplished by the use of passive shielding (lining the magnet with ferromagnetic plating, usually steel) and/or active shielding (using "compensation coils" to generate magnetic fields which counteract the fringe field). Furthermore, shielding of the various components within the MRI system is also necessary, for example the gradient coils must be actively screened to prevent stray eddy currents which could cause image distortion.

52. A further design consideration is the need to protect the system from external RF interference, which can interfere with the signals recorded by the highly sensitive RF receiver. For this reason, at the priority date the whole room in which an MRI system was contained was generally surrounded by a Faraday cage.

The Elekta MR-Linac

53. The basic configuration of Elekta's MR-Linac can be seen in this computer generated picture (best seen in colour):

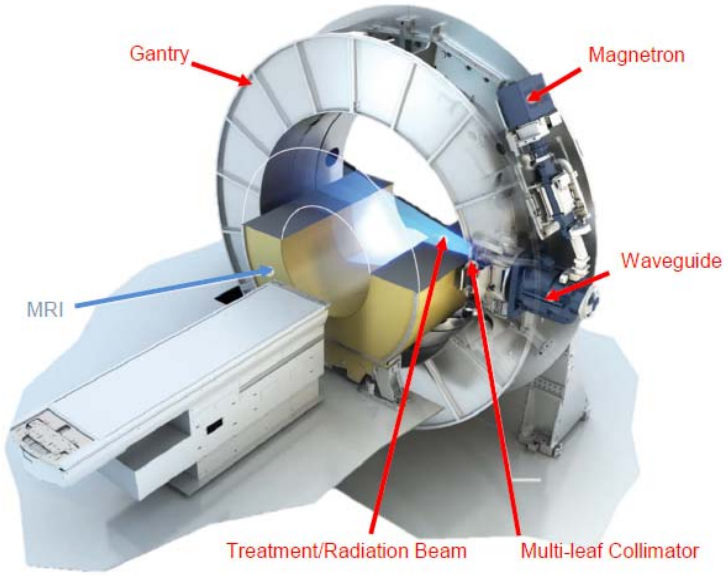


Figure 1 – 3D computer generated image of MRL

54. The MRI part is indicated by the blue arrow and cut away yellow and blue part. The Linac parts are indicated by the red arrows. The bed can move into the bore of the MRI machine. Around the MRI is a gantry and the Linac is mounted on the gantry. Some of the components of the Linac are mounted around the circumference of the gantry circle and the radiation beam is directed radially with respect to that circle.

55. A side view of the MR-Linac can be seen in this CAD image:

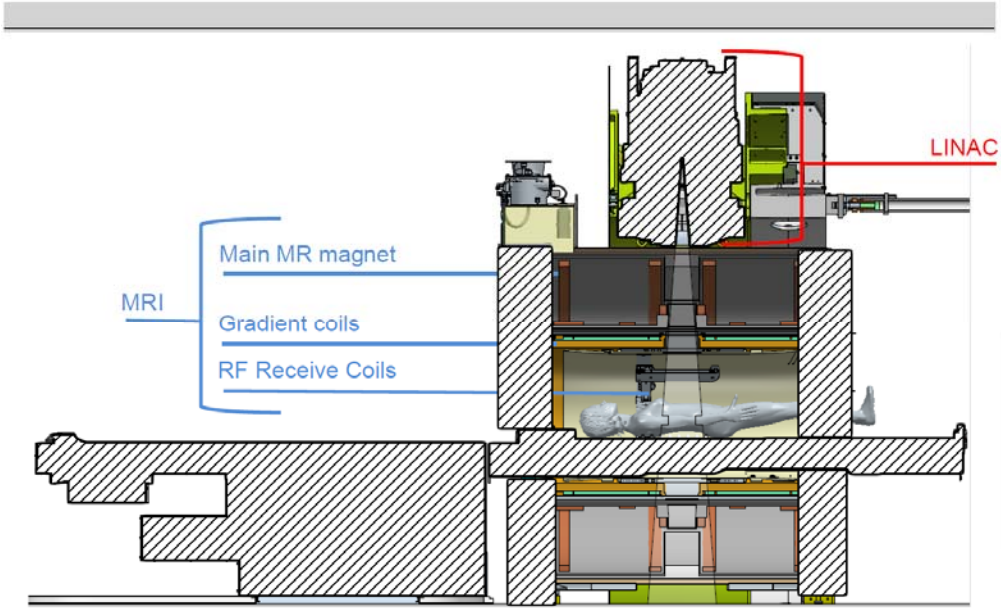


Figure 2 – CAD image of MRL side view section

56. This shows a patient in position inside the machine and the blue markings indicate parts of the MRI system, showing the main MR magnet, gradient coils and RF receive coils. The Linac is marked with red. Irrelevant trade secret details which are trade secrets are shaded out.

57. More detail of the MR system (with irrelevant trade secret details shaded out) can be seen in the following diagram:

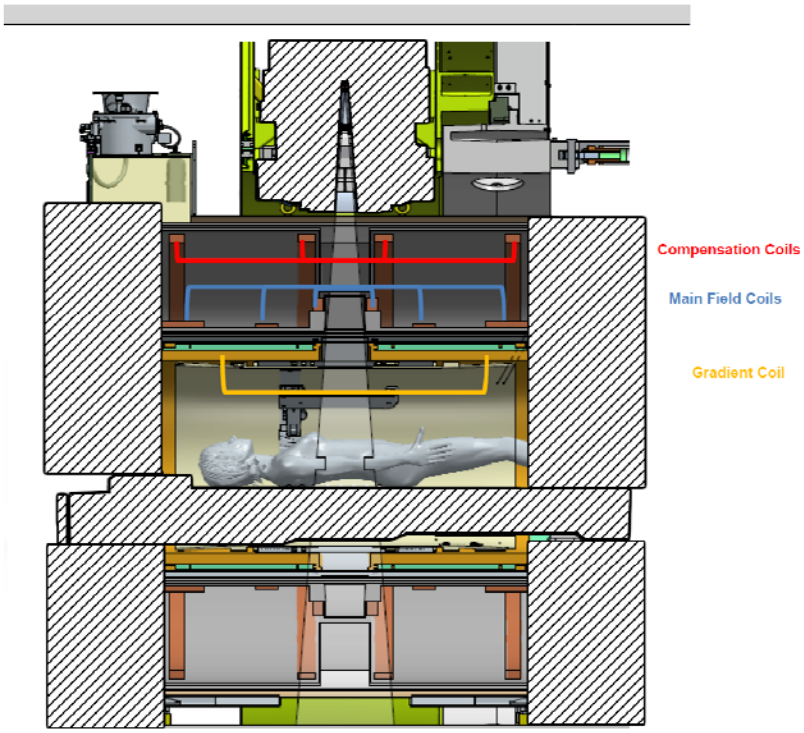


Figure 4 – Compensation Coils, Main Field Coils and Gradient Coils in the MRI Component

58. In this diagram the red, blue and yellow lines are not themselves the coils indicated, they are pointers to the coil components shown in the diagram. The coils indicated are the main field coils, compensation coils and gradient coils.

59. The system can apply a radiation beam to a patient and at the same time the MRI system can acquire MR images from the patient. The gating function of the system which is alleged to infringe is addressed in context below.

The witnesses

60. Each party called two expert witnesses – one each on MRI and one each on radiotherapy. Varian called Professor Peter Morris as their MRI expert and Dr John Fenwick on radiotherapy. Elekta called Mr David Collins on MRI and Dr Peter Williams regarding radiotherapy.

61. Prof Morris is Professor of Physics at the University of Nottingham and, from 1994 to August 2016, was Head and (from 2014) Director of the Sir Peter Mansfield Imaging Centre, a research facility for the development of novel magnetic resonance techniques and for their application in biomedical and other fields. He was an

important member of the group which effectively invented MRI, led by Sir Peter Mansfield, and co-authored the seminal textbook which established its fundamental principles. His contribution to MRI research has been recognised by the award of a CBE and other prestigious awards.

62. Elekta acknowledge Prof Morris as a premier leader in MRI research. They submit that in cross-examination he failed time and again to answer the questions put. In my judgment the tendency in his testimony which Elekta refer to was due to Prof Morris' wish to give precise and appropriate answers to the questions he was being asked. It does not undermine the weight to be attached to his evidence. In cross-examination Prof Morris was a good witness.

63. Elekta also submit that Prof Morris' written reports wholly failed to reflect his views on the scale of the task of implementing the Green patent. That is a fair criticism of his report. It was clear from his testimony in cross-examination that Prof Morris' opinion was that the patent was a sufficient disclosure albeit that making a combined MRI and Linac system was very difficult task. His written reports reflected the former but not the latter and lacked balance as a result. I will have that in mind when assessing his written evidence. It does not undermine his views expressed in cross-examination.

64. Dr Fenwick is a senior lecturer at the Institute of Translational Medicine of Liverpool University and a consultant in the Department of Physics at the Clatterbridge Cancer Centre. His background is in physics research relating to radiotherapy. He has particular expertise in computer modelling techniques of radiotherapy and in the development of quality control/quality assurance systems. His work has not involved the engineering or design aspects of Linacs, albeit his work in constructing quality control processes for tomotherapy machines has involved some consideration of relevant engineering aspects.

65. Rightly, Elekta did not criticise Dr Fenwick. He was an excellent witness.

66. Mr Collins is a Consultant Clinical Scientist and Team Leader in Functional Imaging at the ICR UK Cancer Imaging Centre, which is closely related with the Royal Marsden Hospital. His work is focused on the development of applications for MRI techniques in cancer research and treatment.

67. Varian criticise Mr Collins in various ways and submit that the nature of his expertise meant he was not able to give useful evidence on the design, manufacture and engineering of MRI machines. I will deal with that in context. I will also address in context Varian's submission that Mr Collins applied a double standard in his evidence when drawing an unfavourable comparison between what was disclosed in the Green patent with the contents of a later Philips patent.

68. Varian submit that Mr Collins made various mistakes which exposed his lack of relevant expertise. Mr Collins did make some errors but he corrected them. They were not very significant. One which stood out was a point regarding the cause of the banging noise made by MRI machines. Mr Collins appeared to have misunderstand what the cause of that noise was. That was surprising.

69. Finally, Varian drew attention to Mr Collins' involvement in the Elekta MR-Linac project. In cross-examination Mr Collins acknowledged this and agreed that he was not neutral. This acknowledgement was to his credit and I am sure Mr Collins was doing his best to help the court. That is reflected in his oral evidence on obviousness which is addressed in context.

70. Dr Williams was formerly a Principal Grade Physicist at The Christie Hospital in Manchester and the Director of the North Western Medical Physics Department based at The Christie. During his career at The Christie, he was responsible for providing scientific and engineering support for radiotherapy and ensuring adherence with the relevant quality standards. He was involved in the introduction of conformal radiotherapy into clinical practice in the UK in the late 1980s and early 1990s. He is now retired.

71. Varian submit that Dr Williams appeared to consider that it was his role to come up with imaginative ideas as to how the prior art (Van Vaals) could be adapted to radiotherapy. I will address that in context.

72. Varian also submit that Dr Williams was in no position to give opinions on the alleged difficulties in building or engineering a Linac which did not interfere with the MRI or was not interfered with by the MRI because he was not a Linac engineer. This is much too broad a point. Dr Williams did not work for a Linac manufacturer but was experienced in the engineering aspects of Linacs. Amongst other things he was the author of a 1997 textbook on medical Linacs.

73. Dr Williams was a good witness.

The skilled team and common general knowledge

74. It was common ground that in this case the person skilled in the art was a team and that the skilled team includes MRI skills and radiotherapy skills. It is convenient to reflect this by thinking of the skilled team as comprising an MRI skilled person and a radiotherapy skilled person (an RT skilled person). This is not a case like ***Schlumberger v EMGS*** [2010] EWCA Civ 819 in which the skilled team comprises different notional persons from the point of view of obviousness as it does for sufficiency. MRI imaging was being used for radiotherapy planning and many UK hospitals had interdisciplinary medical physics departments at the priority date.

75. Of course, the fact that the skilled team has the same composition for obviousness and sufficiency does not mean they are in the same position when considering the prior art for obviousness and when considering putting the invention into practice for sufficiency. Those two situations are different.

76. It was common ground between Mr Collins and Prof Morris that the MRI skilled person would have at least the following attributes:

    i) In-depth knowledge of the scientific principles underlying MRI technology;

    ii) Clinical experience using MRI technology and image acquisition sequences; and

iii) Experience designing and developing conventional MRI systems.

77. There was a debate about the MRI skilled person's knowledge of regulatory matters but the point is irrelevant. There was a small point about the extent of an MRI skilled person's knowledge of radiotherapy. As to that, I accept Prof Morris' evidence which was that the MRI skilled person would understand the scientific principles relating to how radiotherapy worked and that it was commonly used in oncology.

78. It was common ground between Dr Fenwick and Dr Williams, that the RT skilled person would:

i) Specialise in radiotherapy;

ii) Possesses in-depth knowledge of the scientific principles underlying radiotherapy;

iii) Have substantial experience working with conventional radiotherapy equipment and in particular linear accelerators in combination with multi-leaf collimators; and

iv) Have experience in designing and implementing treatment plans on conventional radiotherapy equipment.

79. There was a debate about the extent of the RT skilled person's awareness of the various imaging modalities used in medical imaging and an understanding of the scientific principles underlying them. On this, I find that the RT skilled person would understand the basic scientific principles underlying MRI. They may have actually used MRI images to assist with treatment planning but, if not, they would be well aware of the idea of doing this.

80. All of the matters addressed above as technical background would have been part of the common general knowledge of the skilled team except of course the discussion of the Elekta MR-Linac.

81. Two particular topics arose relating to common general knowledge: (a) accurate targeting and (b) magnet design and designers. They are both best dealt with in context.

The Green patent

82. Paragraph [0001] of the patent explains that the invention relates to systems for radiotherapy treatment in which the region to be treated is irradiated by the beam substantially simultaneously with an MRI system imaging the region. The system is arranged so that the beam is not incident on a coil assembly of the imaging system.

83. In a section from paragraph [0002] to [0015] the patent then addresses the background and sets out a number of objectives.

84. At paragraph [0002] the patent refers to an item of prior art called Norman (WO 90/14861) which has been used to define the preamble of claim 1. Norman is a combined CT imaging system and therapy X-ray source whereas the preamble in the

claim simply describes a radiotherapy machine with a radiotherapy beam along an axis through a treatment region, but nothing turns on that.

85. Paragraphs [0003] to [0006] describe how radiotherapy machines work, referring to the Varian machine called the CLINAC which would be familiar to the RT skilled person. The difficulties in positioning a patient so that the tumour is at the isocentre of the radiotherapy machine are described as is the problem that the similarity between surrounding soft tissue and the diseased tissue makes defining the boundaries difficult using current diagnostic and imaging techniques appropriate for radiotherapy machines. At paragraph [0007] the use of portal imaging is described. The drawback of using X-rays delivered by the Linac to image the target area is the lack of soft tissue contrast in this imaging method. What can be imaged are the bones and then the location of the tumour inferred but the inference is not precise because of the lack of rigidity of the soft tissue and the patient's unavoidable body movements. The use of tattoos as "fiducial markers" is mentioned. These concepts are all common general knowledge.

86. The effect of the inadequacies of the pre-priority date technologies are summarized by the patent in [0008] and [0009]. In [0008], the patent explains that:

> "Because the region desired to be treated is usually not located exactly as planned with respect to the isocenter of the radiotherapy system, insufficient quantities of radiotherapy beam energy are deposited in the region desired to be treated and excessive amounts of radiotherapy beam energy are deposited in healthy tissue in a volume abutting the region desired to be treated. Consequently, the tissue in the abutting volume is subjected to undesired and unnecessary damage so healthy organs adjacent the tumour site are damaged."

87. Obviously the primary aim of the treatment is to ensure destruction of the cancerous cells. Therefore, as the patent explains in paragraph [0009], the response to the difficulties referred to in paragraph [0008] has been to increase the size of the irradiated area and increase the radiotherapy dosage to ensure complete cell death. Whilst this compensates for the risk of missing the tumour, it causes yet more radiation to be absorbed by healthy tissue abutting the treatment region "in some cases resulting in devastating quality of life effects on the subject". The paragraph ends by identifying an object of the invention as to "provide a new and improved method of, and apparatus for enabling a radiotherapy beam to be accurately positioned on a desired region to be treated by the beam".

88. Further objects are set out in paragraphs [0010] to [0015]. They are respectively: ease of retrofitting a machine onto existing radiotherapy devices, ability to acquire 2D and 3D high contrast spatially resolved images of soft tissue within and around the area to be treated, avoiding the radiotherapy beam being incident on the excitation coil assembly, direct detection of the effect of the radiotherapy beam on irradiated tissue, a relatively low cost way of determining if the desired region is actually being treated, and a system in which secondary electron skin dosage is reduced by the magnetic field of the MRI system.

89. Next at paragraph [0016] the patent states that "these and other" objects of the present invention are achieved by the system of claim 1. The skilled reader would not think

that every system within the claims had to fulfil every single objective. Claim 1 (broken down into convenient integers) is in this form:

(i) A system comprising a radiotherapy machine for deriving a radiotherapy beam arranged to be propagated along a beam axis through a treatment region,

characterised in that

(ii) the system further comprises a magnetic resonance imaging system arranged to image the treatment region and volumes abutting the treatment region,

(iii) whereby the system comprises means for controlling the spatial distribution and intensity of the radiation applied to the treatment region in real time during treatment.

90. The issues on construction of the claim are addressed below. At this stage all one needs to note is that, consistent with the first object in paragraph [0009], the invention provides for an MRI system to image the treatment region and surrounding tissue and a means for controlling the radiation applied to the region in real time during treatment.

91. Embodiments of the invention are described from paragraphs [0017] to [0021]. At paragraph [0017] the beam is said not to be incident on the magnetic coil assembly of the MRI system. Paragraph [0018] refers to the coil assembly having "spaced segments" for producing the main DC magnetic field. "Spaced segments" arises as a point on construction of claim 4. Paragraph [0019] describes a geometric arrangement in which the coil assembly is mounted independently of movement of the beam axis and a patient couch fits within the central openings of the coil segments while at paragraph [0020] the idea of mounting the coil assembly so that it moves as the beam axis moves is mentioned. Further geometries are described in paragraph [0021].

92. Paragraph [0022] states that a feature of the invention is that the magnetic field is relatively low, sufficient to provide the minimum necessary spatial resolution and sensitivity for determining whether the radiotherapy beam is incident on the desired region to be treated. This means that conventional as opposed to superconducting coils may be used although superconducting system can be used if desired. Paragraph [0023] refers to the idea of using so called "high temperature" superconductors for parts of the system. The high temperature being 77 K, the temperature of boiling liquid nitrogen as opposed to 4.2 K for liquid helium. The idea of pulsing, in order to avoid interference between the MRI system and an electron beam therapy approach is referred to.

93. Paragraph [0024] describes the option of using superconducting RF pick up coils. This idea had been discussed at the priority date but has not found favour in the art. The paragraph also refers (from col 5 ln 17) to the idea of decoupling of the magnetic fields from the radiotherapy machine and the magnetic fields of the MRI machine using compensation coils. This is a form of shielding. It is "active" shielding because it is generated by electrically driven coils. The alternative "passive" shielding comes from plates made of materials like steel.

94. The issue of shielding arises in the insufficiency case. Varian emphasise the teaching about active shielding in the patent as an important part of the disclosure. The reader would not see paragraph [0024] as containing anything surprising or insightful. It is at the most conceptual level. It would be part of the common general knowledge of the skilled team that both a Linac and an MRI machine involved and were susceptible to magnetic fields and required shielding of some kind. The concepts of active and passive shielding were also both part of the common general knowledge. Given the idea of combining a Linac and an MRI system, the idea that they need to be shielded using either active or passive shielding or a combination of the two was entirely obvious.

95. Paragraph [0025] introduces as a feature of the invention the capability of the MRI system to detect the effects of the radiotherapy beam irradiating tissue. This occurs because the NMR spectral parameters of the image region will alter as a result of the radiation impinging on the tissue. This is the start of a section dealing with the idea of detecting the effect of irradiation which runs from paragraph [0025] to [0030].

96. Paragraphs [0026] and [0027] described the physics of NMR. Paragraph [0027] also mentions that the presence of free radicals can modify the spin relaxation times and resonant frequencies of nearby nuclei. Paragraph [0028] describes that the physics of NMR explains why one gets the improved soft tissue contrast of MRI images as opposed to an X-ray image of the same tissue. It makes the point that the position of the cancerous tumour can therefore be determined directly on the radiotherapy machine with much greater precision using MRI than X-ray techniques which can only determine position by inference from the bones. Paragraph [0029] states that "in addition" the spatial location and intensity of the irradiation effects of the therapy beam on tissues can be determined in real time because free radicals are one of the primary products of the irradiation of tissue and free radicals cause a large change in the NMR spectral parameters. Paragraph [0030] pulls together what has been discussed in this section and describes that the presence of the free radicals and ionisation products can be detected and imaged using the MRI system. The three dimensional information relating to the spatial distribution of the radiotherapy beam on the treated tissues (i.e. the effect of the irradiation) is correlated with previously gathered three dimensional data concerning the position of the tumour so that the radiotherapy beam can be confined to the tissue to be treated and controlled so as not to be incident on abutting tissue. This enables the total radiation dose to the patient to be reduced and collateral damage to healthy tissue to be minimised. An MR image in the absence of radiation will show cancerous tissue while with the beam on the MR image will show the extent of the tissue being irradiated.

97. This idea of using the MRI system to detect the effect of irradiation is not referred to in claim 1. I will address what if anything flows from that in the context of added matter.

98. The next important section is a brief description of the drawings in paragraph [0032] and then a description of the preferred embodiments from paragraph [0033] onwards. Figure 1 is a block diagram and then the remaining figures relate to three embodiments. Figures 2/3 are one, figures 4/5 are another and figures 6/7 are a third. These three embodiments differ in their geometry. Figures 8 to 12 all related to the figure 6/7 embodiment.

99. It is convenient to address the figure 2/3 embodiment. Figure 2 (below) shows the combined system in which the Linac radiotherapy head rotates outside the MRI coils and around an axis that is coincident with the axis of the MRI coils.

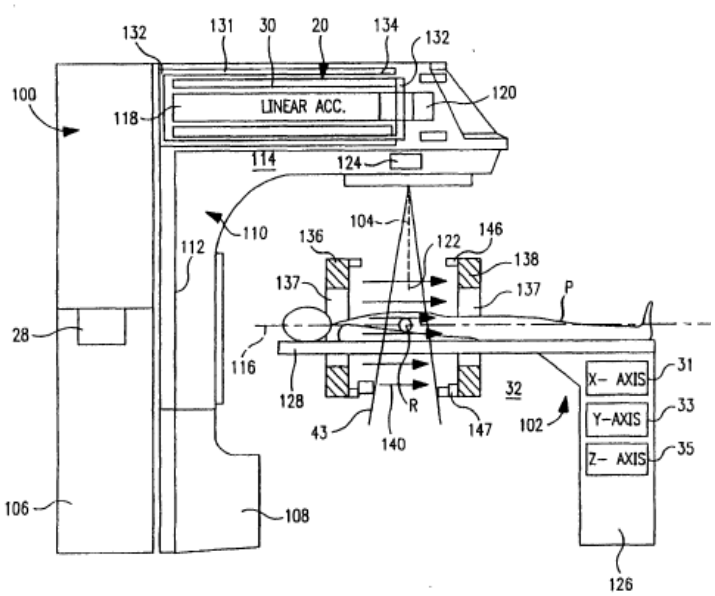


FIG. 2

100. This illustrates how the Linac (marked "Linear Acc") can be used with an MRI (represented by the assembly about the couch). The radiation beam is directed to a patient lying in the magnetic field of the MRI machine. The details of the construction of this and the other embodiments are not significant.

101. Detecting the effect of irradiation and then correlating this with the known position of the cancerous cells is the only method of controlling the irradiation during treatment which is described in this detailed section of the patent, from paragraph [0033] to [0066]. For example, paragraph [0039] describes moving the position of the patient, and therefore the tissue irradiated by the beam, in response to the correlation. This is done using motors which alter the position of the couch. A real time three-dimensional correlation is referred to at paragraph [0040].

102. This section of the patent also describes using a conventional radiotherapy machine (paragraph [0050]), and ensuring that the beam does not intersect any portion of the main coils, the gradient coils or the RF coils (e.g. paragraphs [0052] and [0060]).

103. Figure 10 is described in paragraph [0054]. It shows a compensation coil arrangement for active shielding in combination with the main coils in figure 6. In figure 10 the main coil windings are item 136 and the compensation coils are items 154 and 156. There seems to be an error in paragraph [0054] which describes figure 10 about the relative diameters, but nothing turns on it. The content of the teaching about active shielding was discussed above in relation to paragraph [0024]. This further material does not add anything of substance. The two figures are:

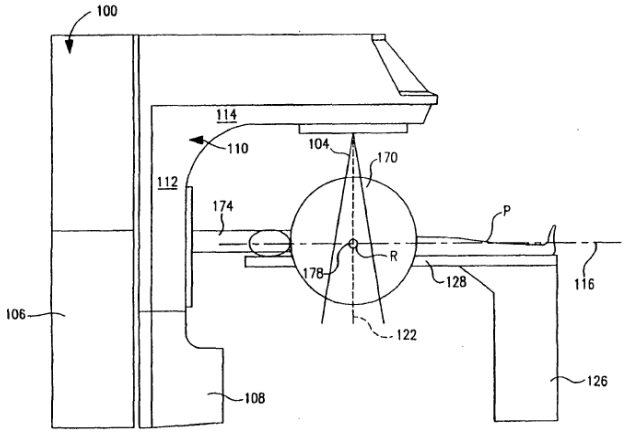


FIG. 6

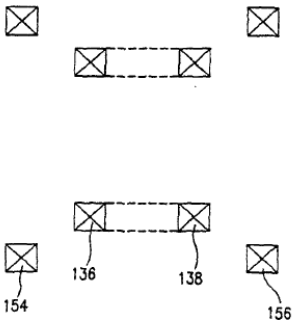


FIG. 10

104. An arrangement in which the couch is on rails and a number of couches can be shuttled back and forth to facilitate patient access and efficient use of the machine is shown in figures 11 and 12 and discussed in paragraphs [0064] – [0066].

Construction/infringement

105. This is a case in which it is convenient to consider the issues of claim construction and infringement at the same time since the points on construction all relate to infringement.

Claim 1

106. Claim 1 broken into three integers (i) to (iii) has been set out above. The claim describes a system with two physical components which I will refer to as a Linac and an MRI machine, recognising that the claim is not limited to a Linac but covers any radiotherapy machine. The Linac is referred to in integer (i), the MRI machine in integer (ii) and at integer (iii) the claim provides that the system has means for controlling the radiation applied in real time during treatment.

107. No issues of construction arise concerning integer (i). A point on integer (ii) is about what the treatment region is. This comes up again in relation to integer (iii) and is best dealt with there. The Crawley MRL-1 includes both a Linac and an MRI system, and there is no dispute that it satisfies integers (i) and (ii).

108. A number of points arise on integer (iii). They can be listed as follows:

(a) Control by reference to what?

(b) The treatment region.

(c) Real time during treatment.

(d) Spatial distribution and intensity.

109. I will take each point in turn.

(a) Control by reference to what?

110. Integer (iii) refers to means for controlling the irradiation in some way but none of integers (i) to (iii) spell out what that control is by reference to. Putting it another way - what are the inputs to the control system? Read purposively there is a clear answer - the purpose of the imaging system is to provide information to use in order to exercise the control. That is clear from the claim itself and it is clear when that claim is read in the context of the specification.

111. Elekta submit that the claim is to be construed more narrowly than this. They contend that the claim requires control by detecting the effect of irradiation, such as the production of free radicals. They rely on various parts of the specification for this but in particular paragraphs [0025] and [0030]. Since the MR-Linac does not work this way, on this basis Elekta contend there is no infringement.

112. Varian submit there is no basis for this in the language of the claim and contend that Elekta's construction amounts to the addition of a further requirement not mentioned in the claim at all. Varian point to Mr Collins' concession during cross-examination that a skilled reader would perfectly well understand that he had all the information he needed to implement claim 1 without being able to view the irradiated tissue. This accords with the views of Dr Fenwick, whose opinion was that the RT skilled person would not think it necessary to detect the radiation products in order to be able to position the X-ray beam since, combined with the knowledge of the precision of a Linac, the MRI images obtained will show the tumour and so are enough to control the beam to accurately target the tumour. Varian contend that the claim is satisfied as long as any MRI imaging information is used as a means for control, and that the detection of irradiation products such as free radicals is merely one that is "nice to have" out of a range of possible inputs.

113. I reject Elekta's case on this. The claim simply does not contain a limitation that control has to be based on detecting the effects of irradiation. The skilled reader would understand the claim in a much simpler way. They would see that the claim does not expressly refer to what the control means has to take into account but they would readily understand that they were being told to use whatever imaging was being undertaken by the MRI machine. The fact the claim does not mention information about irradiation products stands out to the skilled reader as something they do not have to use. A conventional form of imaging will be sufficient to control the radiation applied.

114. Accordingly the MR-Linac falls within this aspect of the claim.

(b) The treatment region

115. The issue here is whether "treatment region" refers in effect to the tumour (and surrounding potentially cancerous tissue) (i.e. effectively the CTV) or whether it includes the wider volumes of healthy tissue which would normally be irradiated in a conventional radiotherapy treatment (i.e. effectively the PTV).

116. The point arises from an issue of infringement and to explain the issue it is necessary to describe how the automatic gating function of the MR-Linac alleged to infringe works.

117. The MR-Linac enables images to be obtained while the treatment plan is being carried out i.e. during the fraction. They can be received while the radiation beam is on. It has two imaging modes: (i) non-volumetric images can be acquired and displayed to the operator during the fraction, or (ii) volumetric images can be acquired, but these are not displayed to the operator during treatment and are stored offline for analysis after the fraction. The volumetric images are irrelevant. In non-volumetric imaging mode, the machine has a motion tracking function which calculates and presents to the operator information about whether the tumour has moved during the fraction. If the tumour moves outside of the target area of the beam by more than a certain distance, the machine will either (i) generate a prompt to the operator to manually pause the beam or (ii) automatically pause the beam itself (i.e. without the operator having to press the pause button). When the tumour returns to the target area, the beam will restart, again either via the operator manually releasing the pause button or automatically. Gating the beam in either manner does not change the amount of radiation emitted by the machine during the fraction; it merely introduces a pause in delivery until the tumour returns to the target area of the beam.

118. Thus Elekta contend, correctly, that their automatic gating function does not change the amount of radiation applied to the patient. Therefore, if "treatment region" can be equated to the PTV, it is the case that the automatic gating function does not change the amount of radiation that would have been applied to that region without gating. On the other hand, as Varian point out, the automatic gating function does change the amount of radiation applied to the tumour. Automatic gating means the beam irradiates a smaller volume of healthy tissue and is concentrated on the tumour. The point turns on what the treatment region is. At this stage, I am using the term "amount of radiation applied" without addressing the argument about what intensity and spatial distribution mean.

119. In my judgment the treatment region means the region the physician wants to treat, i.e. the diseased or potentially diseased tissue, and not the healthy tissue which the physician would rather avoid irradiating. It is the natural reading of the claim by the skilled person but it is also supported by paragraphs [0004] to [0007] of the patent which refer to the treatment region "which is usually a cancerous tumour or lesion" (Col 1 ln39-40). In effect the term "treatment region" refers to the CTV rather than the PTV.

120. So integer (ii) requires the MRI system to image the treatment region as well as the volumes abutting the treatment region and integer (iii) requires means for controlling the radiation applied to the treatment region itself. The fact that the automatic gating function in the MR-Linac does not alter the amount of radiation applied to the patient, or applied to a volume like the PTV, does not avoid infringement because what matters is that relative to the tumour, the amount of applied radiation is controlled.

(c) Real time during treatment

121. There was some confusion about this at trial on both sides. Elekta's opening document used imprecise language and in closing Varian relied on it but then clarified their position in a different way. In the end I believe the position on "treatment" was actually common ground but given the lack of clarity in the parties' positions, I will decide it.

122. The question is about the period during which the control is applied, in other words what does the claim mean by referring to controlling the applied radiation "in real time during treatment"? The term "during treatment" is capable of referring to three broad possibilities. The three possibilities are (a) that treatment refers to the whole course of cancer radiotherapy of a patient over many months and with multiple fractions, (b) that it refers to the course of a single fraction whether the beam is on or off, or (c) that it refers to the time when the beam is actually on.

123. Although out of context it is natural to refer to the whole course of multiple fractions of cancer therapy as treatment, no-one suggests that is what the claim is referring to. No skilled reader would interpret the claim that way. Option (a) is wrong.

124. Option (c) was what the imprecise language in Elekta's opening referred to and what Varian in closing picked up on. This would mean that the period being referred to is the time when the beam is actually on, irradiating tissue; and that could be consistent with paragraph [0001] of the patent which refers to irradiation by the beam being substantially simultaneous with imaging the region. At some points in the argument there also seemed to be a suggestion that the time required for imaging in claim 1 was different from the time required by the claim for the control to operate.

125. In closing Varian suggested that their case was that the imaging had to occur while the beam was on but then confirmed that their case was as set out in paragraph 54 of their opening submissions. This states:

> "Read as a whole, this element of the claim [*in real time during treatment*] therefore requires that there is a real time means, responsive to the MRI images, to control the distribution of units of radiation received across the tumour and the abutting tissue, over a period of treatment."

126. Counsel for Varian then confirmed that in this paragraph the "period of treatment" referred to was the fraction. It did not mean just the time when the beam was on and consequently the claimed result is control of the amount of radiation applied over the fraction. In addition however the submission is that the control means has to be responsive in real time. Real time in this context would be understood as connoting a degree of immediacy (cf "substantially simultaneously" in para [0001]). I accept Varian's submission in paragraph 54 of their opening understood in the manner just described. It makes sense of the whole phrase "means for controlling … in real time during treatment" in the context of the document as a whole and it recognises that the claim language does not purport to distinguish between the time when the beam is on and the time when the beam is off. It is the logical construction of the phrase in claim 1. It means that "treatment" bears the meaning in option (b).

127. Further support for this comes from the fact that imaging is not what the claim language is referring to expressly with the words "during treatment". Those words refer to the means for controlling the amount of radiation applied. I can see that the skilled reader could understand that having means to control something within a certain time frame has implications for the timeframe in which the input information is gathered and responded to but with the claim written the way it is, there is no basis for interpreting those two timeframes differently.

(d) Spatial distribution and intensity

128. There was a significant difference between the parties in relation to how the terms "intensity" and "spatial distribution" should be interpreted.

129. Elekta's case addressed the control of "intensity" and "spatial distribution" separately whereas Varian read them together. For convenience, I will take them separately.

Intensity

130. The radiotherapy experts agreed that the standard scientific meaning of "intensity" is the rate of energy passing through an area, the amount per unit time. Imagining a light bulb, this is the brightness of the bulb. It is a quantity which can be measured and which can change from moment to moment. Another word for this is flux.

131. One needs to take care when using words like energy and brightness in the context of electromagnetic radiation because each photon has an energy related to its frequency by Planck's constant. When in this case there are references to the X-ray beam having an energy of 4 MeV, that is a reference to the energy of the photons rather than the number of photons being emitted. A photon of blue light has a higher energy than a photon of red light but that is different from saying that a blue lamp is brighter than a red lamp. A brighter lamp is emitting more photons than a dimmer lamp.

132. In the specific context of IMRT however, a usage has grown up of the word "intensity" to mean the total amount of radiation over a period (for a given area). That is the quantity which is modulated in IMRT. Mathematically, this is the time integral of the intensity in the usual scientific sense. Another word for this is "fluence". This sort of "intensity" can only be described by reference to a defined period: it does not change moment to moment.

133. From the evidence of Dr Fenwick and Dr Williams I find that the RT skilled person would (a) understand the difference between flux and fluence and, in particular, they would understand that in the context of IMRT, the word "intensity" is used to mean fluence not flux; and (b) also understand that on a Linac, one can control the intensity in both senses. By adjusting the pulse repetition frequency at any moment in time one can control the flux and by delivering more or less radiation over a defined period of time one can control the fluence. This is all common general knowledge.

134. Elekta point out that the Green patent does not mention IMRT or contain any suggestion it is an IMRT system. They submit that whenever the descriptive parts of the patent use the term "intensity", it is either used in an irrelevant sense to refer to the magnetic field or it is used in its normal scientific sense of flux and not in its IMRT sense of fluence. In cross-examination Dr Fenwick agreed as much. Elekta tied this to the idea of control in real time. If control has to be in real time then it must be talking about varying the beam intensity in real time, i.e. to flux. So Elekta contend that it follows that the RT skilled person would read claim 1 without any preconception as to which of the two senses of the word "intensity" was being used. They would consult the description of the invention to discover in which sense the patentee was using the term and they would conclude it meant flux.

135. This point is relevant for infringement because if, in the claim, intensity means flux then there is no infringement. The MR-Linac does not control the flux of the beam.

136. Varian's submission is that in the claim intensity refers to the actual dose of radiation received in the course of a fraction. This reference to dose confuses the issue a little because, as Dr Williams explained in cross-examination, the concept of a dose properly understood involves considering how the tissue has been affected by the radiation impinging on it. In other words, for a given fluence, the dose received by one tissue may well be different from the dose received by another. Although the word "dose" can be used loosely to refer to the radiation fired at a tumour over a period, the precise meaning in this art is what I have described.

137. Having heard the experts, I am sure the term intensity would not be understood by a skilled reader to refer to dose in its strict sense. It is either talking about flux or fluence. One may well be able to draw inferences about what the fluence or flux was from the dose received by certain tissue but that is another matter.

138. The gravamen of Varian's submission is that "intensity" in the claim would be understood in the same sense as it is used in IMRT. Therefore in the claim it refers to fluence over the treatment period (i.e. the fraction) not to flux. They support this by reference to paragraph [0008] of the patent which, while it does not use the word "intensity", does talk about the problem being addressed as the fact that without good targeting insufficient "quantities of radiotherapy beam energy" are deposited in the tumour and excessive "amounts of radiotherapy beam energy" are deposited in healthy tissue. Varian's submission about this paragraph is as much related to "spatial distribution" as it is to "intensity". The argument is that what matters is the total dose and the actual distribution over the fraction in which the dose was administered.

139. I agree that paragraph [0008] supports Varian's case because it makes the point that what is desired is to control the total energy received (i.e. the fluence) not just the rate at which it is being applied (i.e. the flux). The same applies to the distribution in space of that fluence.

140. As for the instances of the word "intensity" appearing in the description which Elekta rely on, Varian submit that they are not examples of the same usage in the claim and are therefore irrelevant.

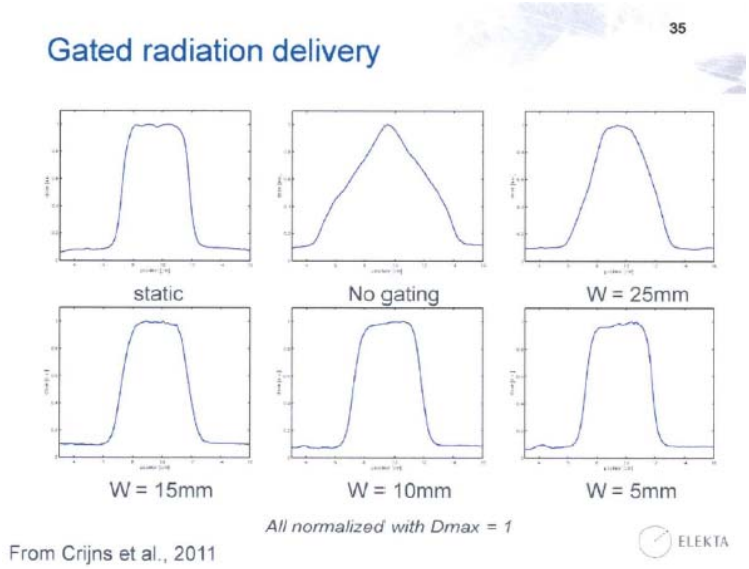
141. Standing back, it seems to me that although the control is intended to be responsive in real time, that does not mean that what has to be controlled is the flux of the beam. I prefer Varian's submission on this to Elekta's. The fact that IMRT is not mentioned in the patent does not mean it is irrelevant, it is part of the common general knowledge and the RT skilled person would have well in mind that in this art intensity bears two different meanings. Of course one could achieve the result required by the claim with a machine which varied the flux in real time but the claim is not so limited. The purpose of the invention described would be understood by the skilled reader to be able to control the fluence received by the treatment region over the whole period of the treatment.

Spatial distribution

142. As to controlling "spatial distribution", Elekta submit that this integer is about moving and/or reshaping the beam. The only such means that Varian can point to in the Crawley MRL-1 is the ability to gate the delivery of the beam. Elekta say that that is insufficient to infringe the Green patent, on the basis that (i) simply pausing the beam does not change the spatial distribution of the radiation, (ii) the words used in the claim, in the context of the description, would be understood as referring to a more sophisticated functionality - moving and/or reshaping the beam so that it hits the target.

143. Varian do not agree. The essentials of their case have been referred to already. Putting it in terms of the findings on construction so far, their argument is that what matters is the fluence received and the actual distribution of that fluence across the treatment region during the fraction. The claim does not require the beam itself to be moved or reshaped.

144. Again this is another argument best understood in the context of infringement. The gating function of the Crawley MRL-1 machine has been explained above. The effect of gating in general can be understood from the following figure – which is not from the Crawley machine but helps explain the issue. The data in the figure is extracted from a paper by *Crijns et al* 2011 Phys Med Biol 56 4815:



145. These six graphs can be understood as six different cases in which radiation is applied to a tumour. In each graph the x axis is one dimension in space and the y axis is the dose received by tissue. In the top row the first, left hand graph represents a tumour which is not moving and shows the dose received as a result of a beam applied directly at the tumour. One can take it that in that graph the extent of the tumour on the x axis is the same as the area with the high dose. The graph is shaped like a top hat.

146. In the next graph (top row, middle) the tumour and its surrounding tissue are moving from side to side along the x-axis, for example due to breathing. The beam does not move and is on continuously. So when the tumour is at the extreme left hand side of

its movement, some of the beam will be impinging on healthy tissue to the right of the tumour and only the right hand part of the tumour will be irradiated. As the tumour moves sideways in front of the beam the situation changes until the tumour has gone as far as it can in the other direction. In that case now the right hand side of the tumour has escaped from the beam. What is irradiated is the left hand side of the tumour and the healthy tissue to the left of the tumour. The resulting pattern of dose received by the tissue as a whole including the tumour is the triangular shaped graph. Only the centre of the tumour has received a full dose and healthy tissue to either side has also been irradiated indicated by the bottom of the triangle being wider than the top hat.

147. The next four graphs (top row, right hand side and all three on the bottom row) show the effect of gating while the tumour is moving. The radiation beam is only on when the tumour is directly in the path of the beam. The difference between the four gating graphs relates to the width of the gating window and does not matter. These graphs illustrate the point that by using gating when the tumour is moving, the targeting is improved. In his first report Dr Fenwick expressed the view that these graphs provide "a simple demonstration of how the spatial distribution and intensity of the beam can be controlled by gating".

148. For the purpose of considering these graphs the distinction between dose and fluence does not matter.

149. In my judgment Varian are right on construction. The graphs demonstrate that one can control the spatial distribution of the radiation applied by gating. With a moving tumour, gating the beam causes the applied radiation to be distributed in different locations in space and in different total amounts than it would otherwise have been. It allows the treatment to be targeted on the tumour even when it is moving. Elekta is wrong to say that simply pausing the beam does not change the spatial distribution of the radiation. It will do in a case in which the tumour is moving, e.g. in respiratory gating. The skilled reader would understand this and therefore there is no good reason why the claim would be understood as requiring any more sophisticated functionality such as physically moving and/or reshaping the beam.

150. Varian also submit that there was no evidence that reshaping the beam in real time was possible on the machines in existence in 1997. Whether the evidence goes that far is not significant. The point is that to a skilled reader at the priority date the idea of reshaping the beam in real time would be significant and they would expect a clear teaching if they were being told to undertake it. There is no such teaching in the patent.

151. At this point it is convenient to deal with a further infringement point taken by Elekta. This is that even if it can be said the gating function of the Crawley MRL-1 system satisfies the claimed requirement for control of spatial distribution, that is all it is doing. Switching the beam on and off cannot amount both to controlling spatial distribution and to controlling intensity. I disagree. Dr Fenwick's evidence about gating shows that spatial distribution and intensity are interrelated and that respiratory gating does indeed control both. I reject Elekta's submission.

152. Finally, Elekta argue that the Norman application WO90/14861 on which the preamble to claim 1 is based refers to automatic gating and so, since the reader is

deemed to know how patents are drafted, the reader would not think this gating was what the characterising features of claim 1 refer to. The features are supposed to be different from Norman. I reject that argument. The characterising features are different from Norman anyway. The first feature is MRI imaging whereas Norman uses CT. The second feature implicitly requires use of the information generated by MRI and that is not in Norman either. Moreover, even assuming the reader noticed that gating was in Norman (and the patent does not draw that to the reader's attention), that is not a strong enough reason to read the words of claim 1 in a different way.

Claim 1 conclusion

153. I have dealt with all the issues of construction relating to claim 1. At the same time I have dealt with infringement. The Crawley MRL-1 machine infringes claim 1.

Claim 4

154. Claim 4 is as follows:

> "A system as claimed in claim 1, 2 or 3, wherein the imaging system includes a magnetic excitation coil assembly, the magnetic excitation coil assembly including first and second spaced segments on opposite sides of the region so an axis of the beam is between the first and second segments, the beam axis being arranged to turn about another axis arranged to approximately extend through the region and approximately intersect the beam axis, the magnetic excitation coil assembly being mounted independently of movement of the beam axis."

155. This is concerned with the relative positioning of the coil assembly elements of the MRI and the radiation beam axes. It is most easily understood by reference to figure 2 of the Green patent, which shows the beam axis numbered 104 passing between the two segments of the magnet assembly numbered 136 and 138. Because the beam can rotate, its isocentre lies on another axis 116 that passes through the coils. This ensures that the beam never intersects with the MRI coils and further ensures that the isocentre of the beam is always in the homogeneous region of the MRI's main field.

156. The argument here relates to the words "spaced segments". Elekta contend, supported by Mr Collins, that this language in claim 4 would be understood to indicate that what is referred to is an open magnet system like the GE double donut machine. The point is that the Crawley MRL-1 does not have such an open configuration as can be seen from the images in the relevant section above.

157. Varian contend that the Green patent simply calls for the segments of the magnetic coils to be spaced apart so the beam can pass between them. The purpose of this is to ensure that the beam does not intersect any portion of the main coils and ensures that the beam's isocentre is always in the homogeneous region of the MRI's main field. Whether the segments are encased in a cylinder as in the Crawley MRL-1 is irrelevant. On this construction, the Crawley MRL-1 infringes because its beam passes between the main coil windings.

158. The terms "spaced" and "segment" are not terms of art and expert evidence does not assist on this issue.

159. The patent describes three embodiments, in figures 2/3, figures 4/5 and figures 6/7 respectively. Considering these embodiments and the patent as a whole reveals that two kinds of gap are discussed. One kind of gap exists to allow the beam to miss the main coils and the other is to allow access to the patient by a doctor in a similar way to the gap between the two magnet units in the GE double donut system. In effect Elekta argue that "spaced segments" refers to the latter patient access gap while Varian argue it refers to the former beam gap.

160. In paragraph [0032] the text describes figures 2, 4 and 6 and draws attention to both kinds of gap, using similar language for both. This does not advance the issue nor do the other passages in the specification, some of which refer to the patient access gap and some to the beam gap (e.g. paragraphs [0055], [0058] and [0060])

161. Returning to the claim, it seems to me that the answer is in the claim itself. The claim expressly identifies the purpose of the spaced segments as being "so an axis of the beam is between the first and second segments". This supports Varian's construction that the purpose of the spaced segments is to create the beam gap. It does not support Elekta's patient access gap argument and I conclude that Varian are right. Accordingly the Crawley MRL-1 infringes claim 4.

162. A different way of considering Elekta's argument is to focus on the casing. Really Elekta are seeking to read claim 4 as if it is limited to a system in which the two coil segments are in two distinct casings whereas the Crawley MRL-1 has only one casing (and one Faraday cage and one cryostat). However there just is no such language in the claim. Claim 4 is indifferent as to the configuration of things which are not mentioned in the claim such as the casing or Faraday cage or cryostat.

Insufficiency

163. Elekta's case on insufficiency is, in summary, that building a combined machine that falls within the claims of the Green patent would have required the skilled team to solve problems with which it had never previously had to grapple, and to engage in lengthy research projects with no guarantee of success. Its pleaded case on insufficiency focused on three elements:

    i) insufficient instructions to construct a machine whereby the radiotherapy beam and the MRI would operate without causing interference to each other;

    ii) no adequate instructions to enable imaging or detecting the position of the radiotherapy beam by the presence of free radicals and ionisation products in the manner described in paragraph [0030]; and

    iii) no adequate instructions to construct an MRI machine with a magnetic field of sufficient strength and/or homogeneity to capture an image with sufficient resolution to distinguish the tumour from abutting volumes in a time frame to enable real time control.

164. The pleaded case developed over the course of the proceedings and the course of the trial and gave rise to an argument about the pleadings. I decided one argument about the pleadings in the opening but another arose in the closing. I will address the detail of the remaining pleading points in context. At this stage I will observe that these pleading points all arose because Elekta's pleaded case is unspecific and, as the evidence developed, the case became focussed on particular issues. Both sides bear responsibility for this. I am quite sure that the issues ought to have been pleaded in more detail by Elekta but once they were addressed in Elekta's experts' evidence Varian's experts then addressed them in detail in reply statements. Having done that it is not sensible for Varian to wait until trial to complain about the lack of specificity of the pleadings on the issues they did address.

The law

165. A patent specification must disclose the invention clearly enough and completely enough for it to be performed by a skilled person (s72 1977 Act, Art 83 EPC). If it is not possible to carry out the invention at all or only with an undue burden, the disclosure is not sufficient. This is so called classic insufficiency (as opposed to Biogen insufficiency or ambiguity).

166. To answer the question one needs to know what sort of thing has to be produced and how much effort is too much. This has been addressed in ***Mentor v Hollister*** [1993] RPC 7 (and see also Aldous J at [1991] FSR 557), ***Halliburton v Smith*** [2006] EWCA Civ 1715 (and see Pumfrey J [2006] RPC 2), ***Regeneron v Bayer*** [2013] EWCA Civ 93 (and see Floyd J at [2012] EWHC 657 (Pat)) and ***Idenix v Gilead*** [2016] EWCA Civ 1089. It is impossible to discuss the principles without in effect putting a "gloss" on the statute but it is necessary nevertheless.

167. The standard of what has to be produced can best be described in general terms as a workable prototype (***Mentor v Hollister***). That is a useful expression because it conveys the idea that the thing certainly does have to work but it does not have to be of sufficiently high quality to be ready to be sold. As Floyd J put it in ***Regeneron*** at first instance (at 206):

> "A patent is not insufficient because it may take much work to develop the most elegant or refined embodiment of its inventive concept. If one were to carry on with the refinement, one would still be making use of the principle disclosed in the patent, working towards an improved embodiment of it."

On appeal the point was not challenged (para 165).

168. Applied in the context of this case, this principle means that what must be able to be built is not merely a machine which can fire some kind of radiation beam and can generate MR images of any quality no matter how low. The system has to be suitable for performing and controlling radiotherapy on a human patient. However, that suitability is concerned with the technical attributes of the system and not with regulatory issues which might need to be satisfied before being permitted to test it on a patient. As long as the machine is suitable for treating humans at a technical level, regulatory issues do not matter.

169. More difficult to summarise is the legal standard relating to how much effort is required. The skilled person (or team) will be a team seeking success. If success can be achieved using the "ordinary steps of trial and error which the skilled man would realise would be necessary and normal to produce a practical result" then the patent is sufficient (Aldous J in ***Mentor v Hollister***). On appeal Lloyd LJ agreed with Aldous J and also said that it was acceptable to expect the skilled team to carry out trials that were not "unusually arduous or prolonged". Varian drew attention to Pumfrey J's formulation in ***Halliburton*** at paragraph 131 (and approved by the Court of Appeal), that the test has to be viewed in the light of the technology in issue:

> "…one must be on one's guard against formulations that gloss the statutory requirement as there is always a risk that they will end up being substituted for it. This is a particular risk where the subject of the specification is very complex and its development would anyway be expected to accompanied by a great deal of work. What is 'prolonged' in this context? It is always necessary to keep a balance between the interests of the public and the interests of the patentee in the sense that it is necessary to guard against imposing too high a standard of disclosure merely because the subject matter is inherently complex."

170. In the same paragraph from Floyd J's judgment in ***Regeneron*** which I have quoted above, the learned judge said this about the nature of the work required and its relationship to the art in question:

> "… one has to bear in mind that the industry in question is one where careful experimentation with a degree of trial and error, sometimes extending over months and years, is entirely normal."

171. Recently, in ***Idenix*** at paragraph 171, Kitchin LJ said, to similar effect:

> "A patentee need not describe the ordinary steps which the skilled person would expect to have to take to implement the invention, and it is perfectly apt to describe these steps as "routine". If, on the other hand, the skilled person is required to carry out work which is far from routine then this may be a matter which suggests the disclosure is insufficient. All will depend upon the nature of the art in which the invention is made and the attributes of the skilled person."

172. There is no need for me to add to these statements. The law is clear albeit not easy to apply.

173. The industry in question here builds systems which involve linear particle accelerators and some of the strongest kinds of magnets ever built. They may use superconductivity and be submerged in a bath of liquid helium. The routine tasks undertaken are complex and difficult. That is not a licence to leave the skilled team with an undue burden in putting the invention into effect but it is against that background that sufficiency must be judged.

174. Elekta emphasise that the skilled team would see that the patent did not describe a machine which has actually been built and so when seeking to put the invention into practice they would not have the reassurance of seeing that the inventor had actually constructed a system as described. Similarly they submit that the specification proposed a series of blind alleys which make the work harder. In effect this is a submission about the motivation of the team trying to put the invention into practice.

175. Motivation of a skilled person is capable of being relevant to obviousness as one of many factors so why not insufficiency? Varian submit that the correct approach in law is that the skilled person is seeking success and that this sort of argument about motivation was not relevant. I do not agree. The weight to be given to factors like this will depend on the facts but in principle it seems to me that these factors are capable of being relevant. There is no requirement in law that the inventor must have built the machine before patenting it but neither should the inventor set traps for the skilled person. A skilled person seeking to successfully make their own machine, who can see that the proposal in a patent has been taken all the way to a demonstrably working system, may be likely to persevere to a greater degree after an initial failure than one who can see the proposal is merely conceptual and has followed a patent's teaching down a number of blind alleys, failed and had to back up again. The latter may well represent an undue burden and insufficiency.

General points

176. Before dealing with the detail there are quite a number of general topics to address.

Prima facie case and shifting onus

177. First, Elekta contend that they have raised a prima facie case of insufficiency and so while the legal burden of proof remains with Elekta, as the challengers to validity, an evidential onus has shifted to Varian (and Varian have failed to establish it).

178. Elekta argue that it has been established that the skilled person could not build any of the examples described in the patent and that the contrary is not seriously contended. Varian's case is that the skilled team would adopt the geometry shown schematically in figures 2 and 3 but Elekta say that Varian could not and do not submit that the skilled team could build what is actually shown in those figures. The reasons relied on are:

    i) In the figures the MRI is small, no 1997-era MRI was that small, and Elekta's evidence that an MRI could not be fitted under a conventional Linac of the sort depicted in the figure was not challenged.

    ii) The magnetic shielding suggested is wholly insufficient. Although there is a rudimentary iron sleeve 131 around the waveguide, the Linac shown has numerous other components that would require shielding. In any case, one cannot simply fit an iron sleeve or other shielding components into a Linac gantry in the way shown in Fig.2.

    iii) There is no RF shielding of the MRI and no obvious place for it to go.

179. Therefore Elekta submit it is incumbent on Varian to explain and identify what system they say the skilled team could build without undue burden. Elekta say this is important because the issues interrelate and cannot be considered in isolation.

180. There are a number of points together in these submissions. I will take the shifting onus argument first. Varian contend that the burden of proof rests with Elekta and has not been shifted. At the level of the fundamental question of whether the disclosure is insufficient or not, I accept Varian's submission. Both sides have called detailed evidence on sufficiency and criticize each other's case in detail. On points of detail it may be useful to analyse this case in terms of a shifting onus but I reject the submission that at an overarching level Elekta has established that the patent is prima facie insufficient such that Varian bear an evidential onus to establish sufficiency. That is because the reasons relied on do not go far enough.

181. The first reason relied on is about retrofitting. It is coupled with the point about which figures the skilled team would use. The patent describes the radiotherapy machine 20 (see e.g. figure 2) as conventional (paragraph [0050]) or relatively conventional (paragraph [0033]) and, consistent with that, the radiotherapy machine depicted in the figures looks recognisably like a conventional CLINAC at the priority date. Much of Elekta's evidence was directed to the impossibility of "retrofitting", in other words trying to fit an MRI system with a known Linac. I am satisfied that Elekta have proved that retrofitting cannot be done without undue effort. However retrofitting is not a requirement of the invention. The invention includes a machine made from scratch. So the fact that retrofitting cannot be done without undue effort does not mean the patent is insufficient. It may represent a blind alley and I will address that below but the fact that retrofitting cannot be done does not relieve Elekta of the onus of proving insufficiency from the point of view of a skilled person making a system from scratch.

182. It was common ground that the general arrangement in figure 2/3 would be the place the skilled team would start. They would not set out to try and build figures 4/5 or 6/7 first. It is also true that in the evidence there is no working machine which is in accordance with figures 2/3. Varian had a tendency in argument to equate the Elekta MR-Linac with figure 2/3 as if they are the same but they differ in a number of ways. The relationship between the beam axis and the axis of the main magnetic field is the same in both. However the way the Linac rotates around the MRI is different as between the MR-Linac and figure 2. The long axis of the linear accelerator is parallel to the long axis of the patient on figure 2 but in the MR-Linac those two axes are perpendicular. Also no cryostat is shown in figure 2.

183. Nevertheless the fact that there is no working system in evidence exactly as shown in the figures does not raise a prima facie case of insufficiency either. Just because those working in the field have chosen to make a system which differs from figure 2 is not probative of the proposition that a figure 2 device could not be built.

184. The second reason is about magnetic shielding. This was a major area of debate and both sides called evidence about it. Elekta say a number of detailed points arise and Varian make a detailed response. To analyse this in terms of a prima facie case and shifting onus is unnecessary and unhelpful.

185. The third reason is about RF shielding. Elekta are correct it is not mentioned in the patent but that does not establish prima facie insufficiency. The point will need to be considered with the benefit of the detailed evidence called by both sides.

186. The three points alone or together do not establish a prima facie case that the patent is insufficient. No overall evidential onus has shifted to Varian.

Identifying what system has to be built to be sufficient

187. Elekta's argument seeks to criticise Varian for not identifying what system they say the skilled team could build. That is not a good point. Varian's approach has been to meet the points raised by Elekta in evidence with evidence from their experts. In seeking to meet Elekta's case point by point Varian did not advance a positive case about what single system they say could or should have been built. Elekta could have sought to pin down their opponents at an earlier stage in the proceedings but they did not. I have already mentioned the unspecific nature of the pleadings on insufficiency.

188. Elekta are correct that the patent will be insufficient unless the skilled person can build a single machine to the relevant standard without undue burden but the patentees are entitled to answer the evidential case against them point by point if they wish.

189. In fact it is clear what a skilled team would set about building having read the patent. For the MRI they would use a system in the same style as the GE double donut and direct the beam in the space between the magnets. The MRI system would have the same performance as the GE double donut. Prof Morris' evidence was that this sort of performance would be adequate and Elekta accept that this would satisfy the requirements for soft tissue imaging in the patent's combined machine. The GE double donut used a 0.5T superconducting magnet. It could produce adequate images with an adequate albeit small field of view. The fact that the extremities of some patients did not fit in the field of view does not matter. The signal to noise ratio was also adequate. The fact that various properties of the GE double donut are only "adequate" is not very surprising because of the sacrifices in performance which were accepted at the time to allow for the GE double donut's feature of access to the patient. Adequacy is sufficiency.

190. Elekta point out, as they are entitled to, that the GE double donut had involved serious engineering challenges in the design, manufacture and cooling, brings with it a problem of increased size because of splitting the magnet into two halves, and had a large fringe field. These issues will be addressed in detail.

191. As for the Linac part of the combination, Varian's case accepted that one would have to build a Linac in which the length from the source to the isocentre was longer than the usual 100 cm distance. This length is called the SAD (source axis distance). It might have to be about 150cm. This has consequences but Varian contend they were all within the competence of the skilled team to address.

192. In terms of shielding (magnetic and RF), the shielding clearly has to be sufficient to allow the system to work. I will address that in detail below.

193. To be within the claims the system must have the right control means. It was common ground between the experts that the skilled team could not build a system in which the effects of irradiation could be imaged or the irradiation controlled by correlating the effects of irradiation in some way. The system which the experts thought a skilled team would set out to construct given the patent was one in which conventional MRI images are used to control the irradiation.

194. The theory given in the patent about detecting the effects of radiation is credible in the sense that free radicals are indeed produced by irradiation, and free radicals will in principle affect nuclear spin relaxation and resonance, and NMR does in principle pick up changes in spin relaxation and resonance. However the free radicals produced by irradiation are short lived and may well not persist long enough to create a measurable effect. There is no evidence that the effect is large enough to be detectable in practice at all, let alone detectable in a way which could be useful to put the invention into practice. I find it cannot be done. Accordingly if the claim did require the MRI system to image the effects of irradiation or required control by reference to the effects of irradiation in some way then it would be insufficient and invalid.

195. Finally on this topic, it bears pointing out that the skilled team therefore has to build a new MRI machine and a new Linac, both of which differ from the existing machines on sale at the time. To design, manufacture and build a new MRI individually or a new Linac system individually was within the capability of the relevant skilled person. Both machines are built by teams, not individuals. These are each very complex tasks and take a lot of work but manufacturers of such systems existed at the time. That does not prove that the team can build a combined machine because that raises special issues for the Linac and the MRI aspects, but it is relevant context.

What happened in practice

196. The third general topic is the evidence of what has and has not happened in practice. Elekta submitted in opening that Varian had tried and failed to make an MR-Linac. That point had not been properly foreshadowed and I ruled it out. What is true is that Varian do not have an MR-Linac product today and there is no evidence they ever built one. Whether that is because it was too difficult or because they chose to focus their financial resources elsewhere one cannot say. I also know that today Varian are looking at an MRI on rails system but, assuming a rails based system is outside the claim (see Shepherd below), the two kinds of arrangement will have their own advantages and disadvantages. Again this does not support the inference that Varian are doing it on rails because they cannot make the invention work. At an earlier stage in these proceedings, if Elekta had wanted to seek to build on inferences about what Varian have and have not done, they could have pleaded a case or sought disclosure. They did not.

197. Conversely Varian point out that Elekta self evidently have built a combined MR-Linac with their partners and so Elekta can call directly on the testimony of skilled people who have done it. Varian say that the fact that Elekta has not called a witness who has had to grapple with (for example) the shielding issues and found them impossible to solve without inventive insight, is telling. Elekta's approach is to rely on statements in scientific papers which describe the work at Utrecht which led to the MR-Linac and note the references in them to the work involving a "major

breakthrough" and the like. Similarly Elekta rely on papers from two other groups who appear to have built a working MRI-Linac combination (Prof Fallone and Viewray). Varian describe the extracts from the papers relied on by Elekta as "sound bites".

198. Elekta are entitled to rely on these papers as evidence of what happened in the real world and the experts have commented on them. Nevertheless this approach required the papers to be interpreted and is less direct than actually calling witnesses who did the work. Varian are entitled to make the point that Elekta could have called such witnesses.

Blind alleys

199. It is convenient to deal with Elekta's blind alleys point at this stage. Elekta say the patent makes the skilled team's job harder for eight reasons which, while some may be small on their own, together are significant.

200. The first and second points are both about retrofitting. Elekta are right that the patent does propose using a conventional Linac, says this is an object of the invention and says in paragraph [0010] that retrofitting is easy. It is clear on the evidence that retrofitting is not easy. In fact I believe the skilled team would not even try and retrofit an MRI system with an existing Linac. When thinking about the design they would readily see that this sort of retrofitting was likely to be difficult and not worth the effort. If they tried to retrofit they would fail but, as I have said, the skilled team would not even embark on it. What the team would do is set out to make a new Linac with a longer SAD. So the blind alley is not a very long one. However the team would not ignore the fact that the patent expressly teaches this and asserts it is easy. This is wrong and would reduce the team's faith in the teaching.

201. The third blind alley point is the suggestion to use superconducting RF coils. This was a topic of interest at the priority date as a way to improve the SNR at low field strengths, however it has never been realized in practice. In his report Prof Morris said it was viable but in cross-examination he agreed it was not a very sensible option. The skilled team would consider it but they would not think this was a necessary way to go. If they tried in my judgment they would fail, but this is not a significant blind alley.

202. The fourth and fifth issues are points of detail about RF and gradient coils. The patent at paragraph [0053] teaches to fixedly mount the RF coils to the inside of the gradient coils. Prof Morris agreed this was an odd way of using an RF coil. The skilled team would not follow the patent's advice about RF coil placement nor about gradient coil placement but I am not satisfied anything turns on it. Prof Morris thought the skilled team would come up with more sophisticated solutions. The arrangement of the gradient coils in figure 8 is strange and would be seen as such. The placement of the RF coil or gradient coils does not support a ground of insufficiency.

203. The sixth point is about detecting the effects of radiation. I have already addressed that. It cannot be done but it is not a requirement of the invention.

204. The seventh is "the implication that figures 2 and 3 show sufficient shielding when in fact they leave a number of relevant parts unshielded". I reject that argument. The

skilled reader would not draw an inference that figures 2 and 3 purported to show sufficient shielding. They do not show compensation coils at all.

205. The eighth point is that the patent does not mention RF shielding at all. Elekta say this fooled Prof Morris into thinking that this was not an issue, so he omitted it from his first report and the MRI skilled person would presumably make the same error. This is not a blind alley as such but an aspect of Elekta's case that the patent makes the skilled team's job harder.

206. The point is an argument that the Linac is a source of RF noise and the MRI needs to be shielded from it. The way to shield RF is with a Faraday cage. Conventional MRI machines at the priority date had a Faraday cage built into the walls of their room but that would not shield the MRI from a Linac situated in the same room since the Linac would be inside the conventional Faraday cage. In closing Varian suggest that Elekta have not established that RF shielding of the Linac was actually needed to make a working system. I disagree. Prof Morris' testimony is clear evidence that shielding the MRI from RF interference generated by the Linac required considerable effort and was necessary.

207. On the other hand, the MRI skilled person knew that RF noise was capable of being picked up by an MRI machine (hence the Faraday cage). The RT skilled person would know that Linacs are a source of RF noise given how they work and the skilled team would either realise this needed to be addressed or find out in the course of the project. The lack of teaching is another respect in which the patent is unhelpful but to elevate it further than that is exaggeration.

Motivation

208. I turn to consider the motivation of the skilled team.

209. The patent does not suggest a machine has been built, and all the indications are to the contrary. No actual results (e.g. tests from a working machine or from testing intermediate systems) are presented. It is a purely conceptual document.

210. The skilled team would see that aside from the basic idea of a combination of an MRI and Linac and the proposal to detect the effects of irradiation, both of which are new, the content of the document represents the application of the common general knowledge on top of those two ideas. That includes the geometry of figure 2 in directing the beam between the coils and it includes the idea of using active and passive shielding.

211. Taking the conceptual nature of the patent and considering Elekta's eight blind alley points together, there are respects in which the patent would not strongly motivate the skilled team. Nevertheless it does disclose the basic idea of a combined MRI and Linac system and at this point it is convenient to consider some evidence from Prof Morris which Elekta rely on. Upfront in their closing Elekta submit:

> First, it is incredibly difficult to make an MR-Linac ("MRL"), a task well beyond the skilled team at the priority date. So much so that Prof. Morris volunteered that the team that had that basic idea would not even attempt to progress it, and accepted

> that actually solving the problems necessary to achieve a working prototype would require the making of patentable inventions (even with the "benefit" of the Green patent).

212. Prof Morris' view about this issue is not adequately summarized in that submission. He did say in cross-examination that if the team had had the basic idea they would be put off by the challenges (T2/234-235) and at a different point in the cross-examination he also said that in implementing the basic idea you would come up with some particularly novel solutions that actually did a better job than your first idea (T2/218). However knitting these answers together in the way Elekta have does not reflect the totality of his evidence. Taking his evidence as a whole, the Professor's opinion was that building the MRI aspects of a combined MRI and Linac was difficult and the task of building a machine as good as the defendants' MR-Linac would be beyond the competence of the unimaginative skilled team (or the MRI member of it). He thought that given the basic idea the skilled team would see the task as very challenging but they would not think a workable system was beyond their ability. As he said in another passage of cross-examination, the MRI aspects "would not be a problem".

213. Overall, although the patent does not inspire confidence, the skilled team's view on reading it would be that to produce a machine would indeed be difficult but they would see no reason in principle why the combined system would not work or could not be made to work. They would embark on the task with that motivation.

Specific points on insufficiency

214. I now turn to the specific technical detail although it is inevitable that in doing this other wider evidence needs to be considered. That is particularly true for the magnetic shielding issue which cuts across the whole sufficiency case. Also part of Elekta's case is that regardless of whether these points could be dealt with, to do so is not routine work and either alone or with everything else, it all adds up to an undue burden. The specific technical topics are:

(a) Magnetic shielding.

(b) RF shielding.

(c) Increasing the SAD.

(d) The perturbative effects of the magnetic field on the irradiation.

215. Elekta also raise points about the RF coils – superconducting and positioning but I have addressed them already.

(a) Magnetic shielding

216. In their submissions the parties referred to "shielding the MRI from the Linac" and "shielding the Linac from the MRI" but it was not clear that they were using these expressions in the same sense as one another. It is not necessary to put it that way. The debates about magnetic shielding relate to three issues. The first is about fringe fields emanating from the MRI, the second, related to the first, is that the shielding

has to cope with the fact that the Linac will rotate, and the third point is about shielding inside the Linac.

217. On fringe fields the dispute was about whether the skilled team would be able to achieve the necessary homogeneity of the main magnetic field with the nearby presence of a Linac which can rotate. The Linac contains components which can interact with the fringe field thereby influencing the homogeneity of the main field. The solution to these problems is to use active and passive shielding including compensation coils and to have a shimming coil system to deal with distortions in the homogeneity of the magnetic field. The question is whether it can all be done without undue burden.

Mr Collins' evidence

218. Elekta's expert evidence on shielding and fringe fields was from Mr Collins. The opinions expressed by Mr Collins in his report did not withstand cross-examination, particularly when it came to issues of magnet design. A telling example was that in his reports Mr Collins had described the task of ensuring the stability of the superconducting state of the conductor as a one of the "major magnet engineering challenges" at the priority date and today. However the following occurred in cross-examination:

> Q. It is just that at the beginning of that paragraph you say, in entirely general terms, "As one of the major magnet engineering challenges in MRI design". It is clearly something that skilled MRI magnet makers are extremely competent in dealing with.
>
> A. I completely agree.
>
> [T/2/287]

219. So, as Varian submit, this shows that what Mr Collins described in his report as a major challenge is something which is within the skills of relevant skilled person. His report has to be read with that in mind.

220. I have considered whether this qualification to his evidence was really about magnet design or was concerned with building an MRI system in general. Taking magnet design first, there is no doubt that Mr Collins is not a magnet maker nor has he designed any form of MRI shielding. For example, he accepted that all he could say about the difficulty of ensuring that the shimming system could deal with rotation by the Linac was to point out that there is no example in the patent of that particular arrangement actually being put into practice. Someone with expertise in magnet design and shimming would be able to go further than that.

221. However, the limits to Mr Collins' expertise had more extensive implications than just magnet design. Mr Collins was knowledgeable about MRI in general and was able to help the court understand how MRI machines work. He also had specific experience in how to modify or adjust an existing MRI system but his expertise did not require him to design or build an MRI system and he had never done so. Adjusting an existing MRI machine is not the task of the skilled team in putting the patent into practice. Varian submit that Mr Collins accepted he did not have relevant expertise on the topic of building MRI systems. They rely on a passage in cross-

examination in which Mr Collins said he "had to admit" that he was not really in a position to make a judgment about how difficult it would be to build an MRI on the basis of the information provided in the patent [T2/306-307]. I accept Varian's submission.

222. In their written closing (paragraph 193) Elekta realistically accept that Mr Collins was not an expert in questions of MRI design/manufacture. Nevertheless in the closing speech Elekta's counsel submitted that the court regularly hears evidence from experts who know a lot about the subject but are not manufacturers. That is true in a very general sense but the matter cannot be dealt with at such a high level. The issue is whether a workable system could be built by a skilled team given the information in the patent. The opinions of someone at a distance from that process will usually carry less weight than those of someone with direct expertise of doing it. Elekta also submit that it was not open to Varian, when presented with a problem like how to deal with the rotating Linac near the MRI, to simply say that it is something which a magnet designer would deal with on the footing that Elekta had not called a magnet design witness to contradict Varian's assertion. I do not accept that submission. First I am sure the skills required in MRI magnet design would be part of the skills of the MRI skilled person. Second Prof Morris has experience participating in the design and building of MRIs. He was part of the team which built the first ever MRI machine. He is well able to comment on what different members of a team who would be called upon to build such a machine would do. He was able to speak about what a relevant magnet designer would and would not be capable of.

223. Mr Collins compared the disclosure of the Green patent to that in a patent application from Philips which was about a combined MRI and radiotherapy machine, such as a Linac. The Philips application was WO 2012/164527 A1 claiming priority from 2011. The Philips patent is directed to the design of a magnet with a zero crossing zone of low fringe field to enable the placement of a Linac. It is essentially concerned with the Utrecht toroidal field discussed below. Mr Collins put it forward as an exemplar of what the skilled person would expect in terms of compensation coils. However when the content of the document was put to Mr Collins in cross-examination, although by comparison to the Green patent there is much more text, more detailed diagrams and references to numbers such as dimensions and current density, in substance the Philips application is just as conceptual as the Green patent. It might motivate the skilled team a bit more but there is nothing concrete in the Philips application which a skilled person would not derive using the common general knowledge starting from Green, nor anything to relieve the burden of the work. In my judgment Mr Collins' opinion was influenced by the origin of the documents. The point on the Philips application does not matter in terms of technical detail because its date is so much later than the priority date.

224. Elekta submit that even without Mr Collins' evidence, the patent is insufficient, based on Prof Morris' oral evidence and on the secondary evidence (i.e. the published papers). I will deal with the papers first.

Slides and a review article

225. Elekta rely on a slide presentation given by a D. A. Jaffray in 2015. There are over 100 slides. The document indicates that Prof Jaffray is at the University of Toronto. There is a section on "Challenges for MR-guided RT". The page relied on (p46) is

headed "Challenge: Magnetic Field Interaction" and visually depicts the fringe field. In fact the pages 46-48 all have the same heading, show the fringe field and how the interaction between it and the Linac can affect MRI field homogeneity and can affect the Linac. It is not in dispute that these issues arise but this evidence is of no significant value in assessing how significant the "challenges" actually are.

226. In the draft judgment I drew the inference that Prof Jaffray has some involvement with the consortium. This seemed to me to be a natural inference from the references to Utrecht and Elekta in the document, which also refers to Varian as well. Elekta submitted that in fact Prof Jaffray does not have some involvement with the consortium and the inference should be deleted. Varian submitted the sentence should stand because I had formed my own view on the document. Looking at the document again in the light of these submissions I would draw the same inference, particularly given page 2 which indicates that Prof Jaffray has a financial interest in some of the technology reported and lists Philips, Elekta and Varian amongst the organisations with which he has a research collaboration. I infer the professor also has some contact with Varian.

227. Elekta also rely on a review article by Schmidt and Payne (Phys Med. Biol. 60 (2015) R232-361). The review is about radiotherapy planning using MRI in general. It refers to real time MRI guided radiotherapy as being now under development and states:

> "As with the MR-PET combination, it has been a huge challenge to combine the modalities together, so that both the imaging and the treatment behave as required, in particular to operate the accelerator close to the magnetic field, and to gain access for the beam into the centre of the magnet, and to avoid significant RF interference from the accelerator into the images. While not yet widely available, these developments hold great promise."

228. Prof Morris agreed in cross-examination that this was a fair summary of the position in 2015 and that it had been a huge challenge to get this far. That is relevant contextual evidence that the task is a significant challenge.

The Utrecht toroidal field

229. Elekta rely on a 2016 paper from the Utrecht group (Lagendijk, van Vulpen and Raaymakers) which refers to a "major breakthrough" in this connection. It describes using a modification of active shielding magnets to create a toroidal field outside the MRI system with a zero magnetic field region in a ring around the MRI. The sensitive Linac components are positioned to rotate in the ring of zero field. When the idea of a toroidal field was put to Prof Morris he referred to a known PET imaging system but he did not suggest that this sort of toroidal field was well known at the priority date. In my judgment this zero field toroidal fringe arrangement is a clever solution but it is specific to the configuration of the Elekta MR-Linac in a manner which differs from figure 2 of the patent.

230. Varian argue that the paper suggests that the workers regarded the idea of using active shielding itself as a major breakthrough. I do not interpret the paper that way. The

interpretation point turns on whether the word "adaption" in the sentence "The major breakthrough was the adaption of the concept of active shielding" should be read as "adoption" on the footing that the author is Dutch and made a mistake. I am not prepared to draw that inference. Read as a whole and given the common general knowledge I prefer to interpret the paper as a statement that what the authors regarded as a major breakthrough was adaption, i.e. modification, of active shielding. The following sentence in the paper also supports that interpretation. However the debate about this paper illustrates the difficulty in relying on inference from papers like this instead of hearing evidence from the people who built the machine.

231. However, Elekta's reliance on this paper is misplaced. It does not support an inference that a breakthrough, of the kind the skilled team are incapable of without an undue burden, would be needed to shield the Linac from the MRI magnets when putting the patent into practice. The skilled team would not be thinking about a system with the configuration of the Elekta MR-Linac.

The Utrecht experience

232. In addition to specific points, Elekta rely on the work of the Utrecht group overall (in collaboration with Elekta and Philips). The essential submission is that the group's idea for a combined machine was first presented at a conference in 2000 (ESTRO), with the first clinical grade prototype installed in June 2014 some 14 years later. Intervening work was reported in various papers (eight are referred to). Elekta say the work involved a number of innovations. Elekta submit it is impossible to suggest that the Utrecht work was routine or required no invention. This submission is all very well but as I have mentioned already what Elekta have not done is call witnesses directly from the Utrecht group to establish anything concrete. Prof Morris regarded the Elekta MR-Linac as a very high quality machine. There is insufficient evidence to infer from what I know of the Utrecht work that the 14 year timescale shows that the patent is insufficient.

Viewray

233. There is a third party organisation called Viewray. As best one can tell they have an MR-Linac product of their own. They have apparently filed a number of patent applications. There much less evidence about Viewray than there is about Utrecht and I will not place weight on Viewray. There is a point on RF shielding but that can be addressed in context.

The experience of Prof Fallone

234. Elekta rely on various papers concerning the work of a group led by Prof Fallone. They submit that his work consisted of a textbook illustration of insufficiency. Broadly, Elekta say one can see that the Fallone group built a phase one machine which could not be used to treat humans and then did further work, altering their design as they went.

235. One of the points is about fringe fields. Conventionally an MRI has a fringe field of 0.5mT about 2 – 3 m away. The Linac or large parts of it will have to be located closer to the MRI than that and the skilled team would expect they had to set up the

compensation coils of the MRI to produce a lower field than that and at a distance some centimetres from the MRI system rather than metres away.

236. From the paper in 2010 (Med. Phys. 37 (9) September 2010 St Aubin et al) it appears that when Prof Fallone's group made their first prototype they assumed that the fringe fields needed to be reduced down to 0.05mT, which is the same level as the Earth's magnetic field. Elekta rely on a statement in the paper that designs of fringe fields based on this strict 0.05 mT limit would be "extremely complicated or impossible". The paper then states that they did further work and concluded the fringe field did not need to be that low. The paper explains that once they realised they did not need a fringe field as low then the shielding was simple and effective.

237. Elekta rely on the quotation about "extremely complicated or impossible" but when the passage was put to Prof Morris he did not agree that the group had operated in a realistic way because you would start by working out what the fields needed to be. His view was that it was possible to get fields orders of magnitude lower than the main field strength using passive and active screening of a relatively simple nature and that this was general knowledge. I prefer to rely on Prof Morris' testimony than the paper.

238. Moreover given that Prof Morris did not agree with the way in which Prof Fallone's group worked, without hearing from a member of that group I am not prepared to place weight on the statements in these papers about how easy or difficult the tasks were nor am I prepared to place weight on how long the group took to produce their systems.

239. A distinct issue (not concerned with placing weight on the papers) is that the *St Aubin* 2010 paper from the group refers to the use of optimisation software. Elekta established that this software was not available in 1997 but Prof Morris did not accept that this mattered. He said that optimisation software was very widely used in the 1980s; his undergraduates used it; it was not true to say that optimisation methods were not available; and what was true was that they were not integrated into an easy to use package. I accept the Professor's evidence. The argument about optimisation software does not help.

Prof Morris' evidence

240. Prof Morris did not believe that arranging passive and active shielding to produce suitable fringe fields around the MRI to allow the Linac to operate was beyond the abilities of the skilled team. The particular issue I need to address is the fact that the Linac will be able to rotate. The Professor accepted that this made the shielding task more difficult, but did not consider this to be a difficult task for the skilled person. He thought a sensible solution was to reduce the field as much as possible using active screening of the magnet and have some passive shielding around the Linac.

241. Elekta criticise the Professor for then stating that the first thing you would do is try to remove as many ferrous components from the Linac. Their point is that a Linac has many ferrous components and this would not work. But the Professor had acknowledged he did not know if that was possible because he was not a radiotherapy person. This does not undermine his evidence.

242. The cross-examination continued relating to rotation and Prof Morris said you would have a ring around the centre. If this ring is the same as the toroidal field described by the Utrecht paper then I was not persuaded it is what a skilled person would do.

243. Next Prof Morris referred to the use of varying the currents in the shimming fields to ensure homogeneity. Elekta submit this was an extraordinary suggestion but the Professor gave clear evidence that it was common general knowledge and supported it with a full explanation about the history of shim coils, the use of gradient coils as shim coils, and a dynamic shimming proposal in 1997 (actually 1996) which attracted a lot of attention. He concluded that the skilled person would get there reasonably comfortably.

244. This testimony had all been prompted by counsel putting a 2014 paper by the Utrecht group (Crijns and Raaymakers, Phys Med Biol 59 (2014) 3241-3247) to the Professor. Elekta seek to rely on the paper to show that dynamic shimming was still on the drawing board 18 years after a proposal by a group led by Blamire which is referred to in the paper. I am prepared to accept that dynamic shimming has not been used in the intervening period but even if that is so it does not undermine the Professor's evidence. Prof Morris' opinion was that, if need be, the skilled person would use dynamic shimming to deal with rotation of the Linac by the application of their common general knowledge. Elekta simply have not proved otherwise and I accept the Professor's evidence.

245. The need to deal with rotation is Elekta's best point in this context but I reject it. I find that the fringe fields from the MRI, active and passive shielding and the need to deal with a rotating Linac do not present an undue burden to the notional member of the skilled team with the role of magnet design. That the team would have or have access to such a member cannot be disputed since the team's task involves building an MRI machine.

Shielding inside the Linac

246. There is no doubt that a Linac contains magnetic components (such as the electron beam, the magnetron/klystron and MLC motors). The real issue is the electron beam. Varian submit that the technology for Linacs to deal with varying magnetic fields was known, essentially the point was to use the steering coils in the Linac to ensure the electron beam was on track. Varian also submit that Dr Williams accepted this. So he did. Elekta contend that there is positive evidence that the unimaginative skilled person would not have thought of this for two reasons. One is based on Prof Fallone and I do not accept it. The other is that Dr Fenwick himself did not think of the solution when considering the point in his second report in response to Dr Williams' first report or in his oral evidence.

247. Elekta are right that Dr Fenwick did not mention steering coils in this context but that does not have the significance Elekta attribute to it. The sequence is as follows. Dr Williams in his first report made the point that the RT skilled person would be concerned about the effect of the MRI magnet on the electron beam in the Linac if the field was greater than the Earth's magnetic field (0.05mT). In his reply report Dr Fenwick said that he agreed that stray fields could interact with the Linac components (generally) and expressed the view that the RT skilled person would speak to the MRI skilled person who would then arrange appropriate shielding. The cross-examination

simply confirmed this. So Dr Fenwick's report was on the footing that the problem would be solved by MRI shielding. He did not consider what he would do if the level of stray fields produced with the MRI shielding was higher than the Earth's magnetic field and therefore the Linac would be encountering a new higher field. Dr Williams' evidence in cross-examination was that depending on the strength of the stray fields, the problem could be solved using steering coils. Steering coils can cope with fields larger than the Earth's magnetic field. Dr Williams was happy that existing steering coils could already deal with fields three times stronger but he thought twenty times stronger was another matter.

248. There is a relationship between this issue and the previous issue of fringe fields. A fringe field of 0.05mT more or less eliminates the Linac shielding problem because a Linac can already cope with that since it is the level of the Earth's magnetic field. A fringe field of ten times that (0.5mT) located about 2 – 3 m away from the MRI was conventional but of course the Linac will be much closer to the MRI than that. As Prof Morris said you would start by working out what the fields needed to be. The team would balance two factors. The RT skilled person would no doubt start with the idea of 0.05mT as the fringe field at the Linac but Dr Williams' evidence shows that from the RT skilled person's point of view there is a range of strengths above 0.05mT which can be handled and there is a limit. From the MRI skilled person's point of view lower levels of the fringe field require more effort in terms of active and passive shielding than higher fringe fields. The question is whether the team could come up with a fringe field level low enough to be something the steering coils can cope with but high enough to be achievable at the relevant distance from the MRI without undue difficulty.

249. Having listened to all the experts and doing my best with the evidence as a whole I am confident that without undue effort the MRI skilled person would be able to arrange MRI fringe fields lower than 1mT at the Linac in a combined system, whereas I doubt MRI fringe fields as low as 0.05mT could be achieved there without an undue burden. In other words I find that the MRI fringe fields below twenty times the Earth's magnetic field can be achieved without undue burden. The evidence does not allow me to say that the achievable field would be as low as three times the Earth's field (0.15mT) but it seems to me that the relevant point is that the achievable field would be below the level which Dr Williams said a Linac's steering coils could not handle.

250. Elekta has not established that a combination of shielding to reduce the fringe fields from the MRI plus passive shielding for some Linac components and use of the steering coils could not be made to provide adequate magnetic shielding for a working combined MRI and Linac system by the skilled team. More particularly Elekta have not established that the upper limit of the capacity of the Linac to handle the fields is lower than the lower limit of the capacity of MRI shielding. There is no shift of an evidential onus to Varian on this issue. I reject this as an insufficiency.

(b) RF shielding

251. The patent does not mention RF shielding. I have rejected Varian's suggestion that a need for RF shielding was not established. The Linac is a source of RF noise and the MRI will need to be shielded. Prof Morris did not know that this would be a problem but once the point was put to him he did not think it was a huge issue. There would

need to be a Faraday cage in between the source of RF noise (the Linac) and the MRI. Since the Faraday cage would be made of copper this was not a problem because copper is diamagnetic and so you can put as much as you like with the MRI without significantly affecting the MRI field. He said he was not suggesting that some considerable effort was not required to actually achieve it but the principles of how the skilled team would go about it have been clear for a very long time. Elekta suggested that their own solution of a Faraday cage which is integral with the magnet casing was innovative but Prof Morris did not agree.

252. Mr Collins accepted Faraday cages were well known and routinely used. He suggested it was a major problem but the cross-examination showed that his point was that it was not mentioned in the patent. He did not disagree with the proposition that there was no obvious issue with throwing a cage around the MRI where there is clearance between the MRI and the Linac. He also accepted that an RF shield was not mentioned in the Philips patent, which he regarded as sufficient.

253. Viewray dealt with this RF interference using a Faraday cage which had small gaps in it but found that the interference still leaked out so they lined the cage with carbon fibre sheets, which Prof Morris thought was a "nice solution".

254. Overall, Elekta submit the RF shielding point was a totally new and very difficult problem. I do not accept that characterisation. The skilled team would realise (or find out) that they needed to employ a Faraday cage to shield the MRI from Linac RF interference. They would have no undue difficulty doing so. It would need to be a cage with no gaps as they would realise or find out, therefore the X-ray beam would have to go through the Faraday cage. This would attenuate the beam somewhat but that is best addressed in relation to the SAD. RF interference does not support the case on insufficiency.

(c) Increasing the SAD

255. In order to make a Linac which could be fitted with an MRI machine the skilled team would need to increase the SAD of the Linac. The three issues with increasing the SAD are (1) that dose rate decreases; (2) the 'penumbra' increases; and (3) the projection of the leaves from an MLC means that for the same resolution, they need to be thinner. Other lesser important consequences were mentioned but if none of these three points get Elekta home, the others will not either.

256. To allow a Linac to fit, the skilled team need to increase the SAD from the conventional 100cm to 150cm. This would reduce the dose rate by a factor of 2.25 because the radiation is governed by the familiar inverse square law. There are two options, both readily apparent to the skilled team. Either you accept a lower dose rate and reconfigure the treatment planning software accordingly or you are going to need a bigger Linac. Dr Fenwick thought the first option was not "particularly practically problematic". He said it might mean you needed to increase the beam on time in a 15 minute fraction from 2 minutes to 4 minutes but that "would not be disastrous at all". As for the second option, from Dr Fenwick's answers in cross-examination I find a Linac could not be built in 1997 with a sufficient increase in the PRF (Pulse Repetition Frequency) to bring the dose rate back up by the whole 2.25 factor but the PRF could be increased without undue difficulty and, given the first option, some combination of both options is also available without real difficulty.

257. Before finishing this dose rate point there is a related issue that a thin copper Faraday cage to shield out RF interference would also attenuate the beam. Dr Fenwick agreed the effect would need to be considered but Mr Collins accepted that the Faraday cage would not be a significant barrier to X-rays. This point makes no difference.

258. I conclude that the dose rate reduction from increasing the SAD does not give rise to insufficiency.

259. In figure 2 of the patent the beam is shown as a triangle fanning out from the Linac. In practice as the beam fans out from the Linac the edges have a lower flux than the centre. This penumbra is caused by two things. First the source is not a single point and so what is depicted as a single triangle emanating from a point is in fact a collection of triangles from a row of points looking side on as in figure 2. So in the middle of the beam, rays from all the points are present but at the edge only rays from some of the points are present, hence a lower flux. The second cause of the penumbra is the collimator. Rays in the middle go through the hole of the collimator unimpeded while rays away from the hole hit the collimator full on and are stopped. However assuming the edges of the collimator are square, some rays near that edge will only pass through a thinner piece of collimator material and may not be fully attenuated. This creates a not fully attenuated penumbra in the beam. In practice the penumbra is a zone in which the dose rate falls from 80% to 20%.

260. By increasing the SAD the actual size of this penumbra when it reaches the patient will necessarily be larger. That would need to be taken into account. Dr Fenwick calculated that increasing the SAD from 100cm to 140cm increases the penumbra at the patient from 4mm to 6mm. Dr Fenwick said it would have to be investigated but it was not put to him that they were difficult or led to any problems. Dr Williams accepted Dr Fenwick's calculation was right and accepted that if the slight increase in penumbra was necessary to achieve the control promised by a combined Linac and MRI system, it was a sacrifice worth making. There is nothing in this penumbra point.

261. Finally, the geometric effect of increasing the SAD has an impact on MLC leaves. Recall the figure in the background section which illustrates conformal therapy and IMRT and shows a sort of blocky beam shape. The edges of the blocks are all the same length and that length is standardised so as to facilitate treatment planning. The leaves of the MLC are designed with a certain thickness such that when the beam is projected onto the patient the blocks have the right standardised length at the isocentre. Dr Fenwick agreed that one would want to maintain the block size at the patient in order to conform the shape of the beam to the tumour. To achieve this needs thinner MLC leaves. The leaves are made of tungsten which is a refractory metal and hard to work. Dr Fenwick agreed this would be a significant engineering challenge.

262. I accept Dr Fenwick's evidence but this is not a relevant insufficiency. No doubt the skilled team would like to do these things in order to make a good system but the invention does not require it. Even assuming changing the MLC leaf thickness is unduly burdensome, the claimed invention could be made to work fine.

(d) The perturbative effects of the magnetic field on the irradiation

263. Part of radiotherapy treatment planning in practice involves detailed modelling calculations of the effect of the beam on the tumour and the surrounding tissue. The desired effect of the X-rays involves the creation of secondary electrons which themselves act to kill cancer cells. As a matter of basic physics electrons are influenced by magnetic fields and so if the radiotherapy is to be applied to a patient inside an MRI magnet system, the effects of this magnetic field need to be taken into account in the modelling calculations. The field will have some kind of perturbative effect.

264. In their first report Dr Williams and Dr Fenwick both said this had to be done but the experts disagreed whether it could be. Dr Williams said that the algorithms in use in 1998 did not take magnetic fields into account. In their reply reports the experts responded and explained why they disagreed with one another. The issue turns on planning software and Monte Carlo simulations. The details of Monte Carlo simulation do not matter. The technique involves running many simulations side by side using a range of starting conditions chosen at random.

265. Dr Fenwick explained that the algorithms calculate the primary photon fluence throughout a patient and then convolve this with a "kernel" which describes the dose distribution resulting from the photon interactions at a point. In effect the kernel represents the effect of a single photon in one place and convolution applies that effect to all the photons across the region treated. A suitable algorithm had been described by Rock Mackie in 1985 in what was a standard reference work by 1997. The kernels used were derived from Monte Carlo simulations. Dr Fenwick explained that the effect of a magnetic field is to "tilt" the kernels. He thought the calculations could have been made at any time in the 1990s since magnetic fields can straightforwardly be included in the radiation transport calculations. He said it would be easy and quite accurate for doses in the tissue. The position was different at the interfaces (tissue-air and tissue-lung). For accurate calculations including the interface an approach published by Ma et al in July 1998 would achieve this. That is after the priority date. Dr Fenwick had a particular interest in the area of these Monte Carlo simulations and was able to give this evidence.

266. Dr Williams explained his view that while he accepted that Monte Carlo modelling was known to the skilled person, he did not believe it was being used in a clinical setting at the priority date. The calculations would also take a long time on the computers of that period.

267. Varian did not cross-examine Dr Williams on the point. Elekta's cross-examination did not take Dr Fenwick's evidence much further.

268. Dr Fenwick agreed that the RT skilled person would not create a treatment planning system on their own but he maintained it could be done, the point was simply that it was not something the ordinary radiotherapy physicists did. I find that since treatment planning software was available in 1997, it could be produced and so the RT skilled person would either do it themselves or approach someone who could.

269. It was put to Dr Fenwick that the "tilted" kernels were very clever. He did not agree and explained that they arose out of running the Monte Carlo simulation, which is what would be done. I accept that evidence.

270. What one is left with is that Dr Fenwick disagreed with Dr Williams and gave cogent reasons for his opinion which were not shifted in cross-examination. Dr Williams' evidence was not cross-examined to but the content of Dr Williams' opinion was contradicted by Dr Fenwick and the basis for that contradiction survived cross-examination.

271. In closing, Elekta emphasised that Dr Fenwick's evidence left open the point about interfaces because the papers relied on were after 1997. That is true but Dr Williams did not mention interfaces at all. His evidence was put in general terms and at that general level I prefer Dr Fenwick's evidence. It is true that there is an outstanding point on interfaces but there is no evidence about how significant this point would be. For example there is no evidence as to the degree of the inaccuracy in the dose calculation this would cause without using the post-published approach. I am not satisfied the interfaces issue gives rise to insufficiency.

Insufficiency overall

272. I have rejected all of Elekta's individual points but it is important to see Elekta's case as a whole. Elekta's submission is that to overcome these points is not routine work, and even if they are each solvable individually, as a whole it all adds up to placing an enormous burden on the skilled team. They submit the work is to be fairly called a "research project" and therefore requires too much of the skilled team.

273. To produce an MRI machine of a GE double donut style of sufficient quality involved challenges of a known kind. The magnetic fields of the MRI machine need to be sufficiently homogenous to provide useful images. To produce a Linac which can fire the beam between the magnets also involves challenges caused by a longer SAD and the consequential changes that gives rise to. Saving the point on tissue interfaces, these Linac challenges are also of a known kind. The two devices individually already have shielding of various sorts but to put them together the skilled team has to shield the one from one another. This involves magnetic shielding and RF shielding but what is needed is not new kinds of shielding but the application of existing techniques. Again the challenges are of a known kind. In terms of the character of the work to be carried out, all of it has the same character as the work a Linac maker or an MRI maker would have to undertake to design and build a new product. The combination creates extra constraints for the design but a design always has constraints. None of the detailed technical issues involve any members of the skilled team having to solve new problems or solve old problems in a new way. The only tenable exceptions are the tissue interfaces point and shielding a rotating Linac. The former is minor and its impact is unproven. The latter is, as I have said before, Elekta's best point. The MRI skilled person has not had to deal with a large rotating object which interacts with the MRI's magnetic fields before but it is ultimately just a shielding task. Setting up appropriate shielding is part of the common general knowledge.

274. Over and above the basic idea in the patent, the document does not inspire confidence but the team would expect a combined machine could be made. Bearing in mind how

complicated the two machines are anyway, I do not believe making a workable prototype of the combined system is really all that difficult. It requires an awful lot of essentially routine work by a substantial team over a lengthy period. In this field that is not an undue burden. I reject the insufficiency case.

Varian's pleading objection

275. In closing Varian objected to two of the points addressed above on the basis they were not pleaded. Varian took particular exception to these two points because they were not canvassed in Elekta's opening submissions. The two points were (i) the location of the RF coil and (ii) the perturbative effects of the magnetic fields.

276. It is quite true that the pleaded case does not refer to either point but the plea is pitched at such a high level of generality that on this approach most of the insufficiency case had not been pleaded. The time to take such an objection was well before trial. The perturbative effects point is an acute example. In their initial reports both sides' experts raised the same issue and then in their reply reports both sides' experts gave evidence in response to what the other side's expert had said. Varian were not taken by surprise by this issue in any way. Counsel for Varian did not object when questions were put on the topic in cross-examination. It is not open to a party to give positive evidence on a topic, give evidence in reply on the same topic, make no objection when the point is cross-examined to and then in closing object to the topic being considered on the ground the topic is not pleaded.

277. The point on RF coil placement is the same. RF coil placement was referred to Prof Morris in his second report in table 1 at (g) in reply to a point made by Mr Collins in his first report at paragraph 193(g). There was no objection to the cross-examination of Prof Morris on the point.

278. I reject Varian's pleading objection.

Obviousness

279. Elekta's obviousness case assumes Varian's construction and infringement cases succeed and assumes that the patent is a sufficient disclosure because the skilled team could build a combined MR-Linac.

280. Section 3 of the Patents Act 1977 (based on Art 56 EPC) provides:

> "An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which formed part of the state of the art…"

281. The structured approach set out by the Court of Appeal in ***Pozzoli SpA v BDMO SA*** [2007] EWCA Civ 588 is well established and so are the principles applicable. I will not rehearse them.

282. One point of principle arose about the degree of interest with which a skilled person would approach an item of prior art and there was reference to statements by Laddie J in ***Inhale v Quadrant*** [2002] RPC 21 at [47]. In my judgment the law is clear from ***Windsurfing*** [1985] RPC 59, ***Asahi v Macopharma*** [2002] EWCA Civ 466 and the

observations of Laddie J in ***Inhale***. As a matter of law, the skilled person is deemed to read any given prior art document with interest. That law exists to protect the public. However, the skilled person's reaction to an item of prior art will depend on the facts and circumstances, including their common general knowledge, what problems they may or may not be interested in, and what the document says. The fact a document is in a different field from their own is a relevant factor. It does not stop the skilled person from reading it with interest but it may mean they do so and then put it to one side. One legally appropriate outcome is for the skilled person to say: I have read it with interest but I am not interested.

283. The skilled team has been identified already as has the common general knowledge. Nevertheless, I should deal with a particular aspect of common general knowledge which Elekta emphasise in their obviousness case.

284. Elekta submit that at the priority date in 1997 the skilled team, and in particular the RT skilled person, knew that as a result of the necessity to "shoot" blind and due to movement of the tumour between planning and treatment, between fractions, and during a fraction, it followed that they had to irradiate a much larger tissue volume than just the volume believed to contain cancer. They also had a real concern about missing the tumour and/or hitting healthy tissue. Therefore, Elekta submit, the primary concern of the RT skilled person at the priority date was the accurate targeting of the radiation. I accept these submissions which were supported by the evidence of both Dr Williams and Dr Fenwick. Targeting was a major problem. However, Elekta go further and take two additional points.

285. First they submit that two further developments meant that accurate targeting was becoming even more important at the priority date. They were the advent of conformal therapy and beyond that the advent of IMRT. I accept that submission.

286. Second they submit that there was growing interest in respiratory gating. It was understood that this could potentially provide very significant benefits to patients; but it was being held back by inadequate means for determining the movement of the tumour during treatment. Counsel put to Dr Fenwick that the skilled person would have loved to do respiratory gating but the one thing that was holding them back was the absence of a system that could reliably image tumour movement during treatment. He agreed. I accept this second submission of Elekta too.

287. Turning to the cited prior art, Elekta has three obviousness cases ("Van Vaals", "Shepherd scenario 1" and "Shepherd scenario 2"). For each of them, Elekta's case is that the RT skilled person, when presented with the prior art, would think of the idea of combining an MRI system with a radiotherapy machine, and would approach the MRI skilled person for assistance. Consistently with this way of putting Elekta's case, they did not put to Prof Morris that the idea was obvious from the perspective of the MRI skilled person. They also submit that the evidence of Mr Collins in cross-examination, that the invention was not obvious to him, is not relevant.

Van Vaals

288. Van Vaals is a proposal for a combined MRI and ultrasound treatment system. It is entitled "Method and device for heating by means of ultrasound guided by magnetic resonance imaging." Dr Fenwick's description of it was as follows: Van Vaals

discloses a system which integrates MRI with an ultrasound treatment system. In this configuration, the ultrasound is used therapeutically to treat a target region (such as a cancerous tumour), not for imaging purposes. The ultrasound destroys tumour tissue by heating.

289. Notably, Van Vaals takes as a given the idea of using MRI to image a target region being irradiated by ultrasound (p1 ln 4-15). It was not clear to me to what extent all the relevant witnesses were aware of that technique, absent what Van Vaals states, but I do not believe either side suggested it was common general knowledge and so it does not matter.

290. Van Vaals then explains at p1 ln16-19 that a drawback of what he regards as a known method is that:

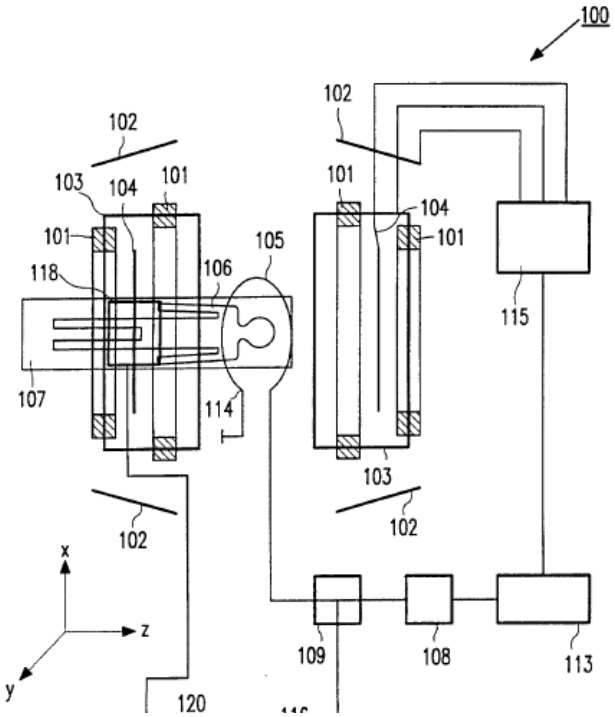
> "when the target region of the body moves, for example due to the patient's respiration, body tissue which does not belong to the target region is moved into the focal region, so that it is undesirably heated by the ultrasound."

291. Therefore what is proposed is to use MRI imaging to determine the movement or instantaneous position of the target region and then use that information to control the ultrasound source. Thus the ultrasound heating is concentrated substantially within the moving target region and the tissue outside the target is hardly heated (p1 ln20-28).

292. Van Vaals describes several ways in which positional information can be derived and used to control the ultrasound. The first method is simply to determine the instantaneous position within the target region to be treated, and to adjust the focus of the ultrasound to that position (tracking, page 4, lines 27-34), or to trigger the beam on only when the target volume lies in the region the ultrasound is focused on (gating, page 5 lines 1-6). Another method is to measure the speed of the movement of the target region and use this to control the ultrasound in either of the following ways:

> "postpone the ultrasound treatment when the speed of the movement of the treatment region exceeds a given threshold (page 3, lines 31 to 34);
>
> estimate the position of the target region and adjust the position of the ultrasound focus to follow the target region (page 4, lines 1 to 4)."

293. An extract from figure 1 of Van Vaals is as follows:



294. The main coils of the MRI machine are items 101 and 104. Note that rectangle 103 is not a piece of casing but it one set of the gradient coils of the MRI (along with 102 and 104). The RF coil is item 105. The patient is lying on the couch and the ultrasound transducer is item 118. It is built into the couch. As drawn the ultrasound would be directed to the patient's groin region, consistent with the known use of ultrasound heating to treat prostate cancer.

295. There was a suggestion that there was an error in this figure because the ultrasound transducer is shown to the left of the RF coil. Varian submit that Dr Williams did not deal with this technical error in the drawing. I do not believe there is any error. The point is that the couch can move sideways to slide the patient into position. There is no reason to reduce the weight to be placed on Dr Williams' evidence for this reason.

296. Elekta's submission is that the RT skilled person reading Van Vaals would immediately see and understand the benefit provided by the real-time MRI, and appreciate that the same benefit would be relevant to any form of cancer therapy which targeted the tumour within the patient's body. In other words, it would be obvious to such a person that the guidance provided by the MRI in Van Vaals would be equally valuable to Linac therapy, so it would require no invention for the RT skilled person to go to an MRI skilled person and ask them about the idea of a Linac version of Van Vaals. There is no doubt that the MRI skilled person's reaction to the idea of combining a radiotherapy machine and an MRI machine is that it would be challenging but Elekta contend that if, contrary to their case, the patent is a sufficient disclosure then that could only be because the concept alone, despite being recognised as challenging, was a sufficient teaching for the skilled team to build a combined MRI – Linac machine. This would be reflected in the response of the MRI skilled person to the approach from the RT skilled person. Elekta submit that their case on the RT skilled person was supported by both Dr Williams and Dr Fenwick. As regards the

MRI witnesses, again Elekta submit that if their evidence in the end leads to a conclusion of sufficiency, then the patent must be obvious.

297. Varian point out that what is disclosed in Van Vaals is an add-on to existing functionality and that nothing in the document suggests a general use outside that context. They submit that the idea of leaping from this to the idea of using a rotating Linac mounted outside the MR machine and transmitting its beam through the gap between the coils was way beyond what would occur to the unimaginative skilled person at the priority date. Varian also make the point that Van Vaals is a patent from the Philips company, who were engaged in radiotherapy as well as MRI and ultrasound at the relevant time and yet they appear not to have come up with the invention.

298. Varian submit that the cross-examination of both Dr Fenwick and Prof Morris was the kind of step by step approach which is not good evidence of obviousness and is infected with hindsight. The cross-examination did involve steps but in relation to Van Vaals I reject the criticism. The starting point with Dr Fenwick was respiratory gating. This was a problem of real interest to the RT skilled person at the priority date. It does not involve hindsight to start the cross-examination there. As for Prof Morris, Elekta's case involves a degree of choreography between the two members of the skilled team. In my judgment that is a legitimate way of analysing the circumstances as long as one remembers the holistic nature of the overall obviousness question. Indeed the alternative would be to put the RT skilled person and the MRI skilled person even closer together from the outset which would be unfair to the inventor.

299. As regards Elekta's witnesses, Varian contend that their evidence on obviousness is compromised by their method of instruction, which involved hindsight, for example because they saw the patent before being asked for their reaction to the prior art. I will bear in mind how the witnesses were instructed but it is not a factor on which I will place much weight. As in many cases, since they were truly experts in their fields, both witnesses knew or could readily work out that the case was about the MRI/Linac combination before being given any material and so an attempt to insulate them would have been wholly artificial.

300. Varian also rely on Mr Collins' cross-examination in which he accepted that Van Vaals worked on the basis of synergy between heating from ultrasound and MRI and also accepted that the idea of transforming Van Vaals by ditching ultrasound would not have occurred to him without invention.

301. Varian are correct that Van Vaals as a document does not refer to radiotherapy. It is also true that the skilled reader would see there is a synergy between the ultrasonic heating and the ability of MRI to detect that heating, and that the transducer (etc.) in Van Vaals can be combined with an MRI machine in a straightforward way. Nevertheless, I find that if the RT skilled person read Van Vaals it would immediately make them think of the idea of a combined machine which enabled MRI images to be produced during radiotherapy, for use in controlling the Linac. That is because Van Vaals offers the possibility of doing accurate respiratory gating, which the RT skilled person would undoubtedly want to have for radiotherapy. They would read it with interest and having done so they would be interested. These conclusions are supported by the evidence of Dr Fenwick. They are also supported by Dr Williams

although Varian contend that Dr Williams had been instructed to come up with imaginative ideas and suggested that a symptom of the point was his reference in cross-examination to brachytherapy as a possible way forward over Van Vaals. I do not believe Dr Williams thought his task was to make inventions given Van Vaals. He did make the suggestion of brachytherapy but he also considered using external radiotherapy as well. The existence of another obvious thing does not necessarily undermine obviousness.

302. In any case Dr Fenwick had no difficulty with the idea that an RT skilled person would see from Van Vaals that if they had a system which generated MR images during radiotherapy treatment those images could be used for accurate respiratory gating.

303. The RT skilled person would well understand that the kind of synergy between ultrasound and MRI (detecting heating) would not occur in a combined radiotherapy/MRI system and would also understand (without speaking to their MRI colleague) that combining a Linac with MRI was likely to be much more complicated to construct than Van Vaals' combination of ultrasound with MRI. The RT skilled person alone knows enough about MRI for that. However, neither of these points alone or together is enough to indicate that the RT skilled person would not have the idea nor think it was worthwhile.

304. Mr Collins' evidence does not affect this because his perspective is quite different from that of the RT skilled person.

305. The only issue which caused Dr Fenwick to pause was whether the RT skilled person would approach an MRI colleague to discuss taking the idea further. He was not sure they would but accepted it was more likely than not with the reservation that they may not get a positive answer. In my judgment, given that both kinds of skilled persons would be in the same department and would regularly share ideas, the unimaginative RT skilled person would raise this idea with the MRI skilled person because the possible advantages relating to respiratory gating are so obviously significant. The MRI person would listen with interest.

306. The reaction of the MRI skilled person would have three aspects. First they would explain that monitoring any heating processes would not be possible but MRI would be able to image a tumour and would be able to follow its movement. Second, as Prof Morris' evidence shows, they would note in figure 1 of Van Vaals a geometry of the MRI system which is similar to the well known GE double donut device with the main coils arranged in rings, with the patient lying in the bore of the rings, and a space in the middle of them. However, third, the MRI skilled person would think that combining a Linac and a MRI machine was a major challenge.

307. The third point about the challenging nature of the task requires further consideration but before doing so I will mention that I accept certain further aspects of Elekta's case. If a combined machine was obvious then it would have to have a gating button to pause the beam if necessary since that was common general knowledge, was a standard feature of every Linac, and gating is described expressly in Van Vaals. Furthermore, subject to the same premise, I do not accept Varian's submission that the idea of using a rotating Linac mounted outside the MR machine and transmitting its beam through the gap between the coils is inventive here. These aspects of

geometry are obvious over Van Vaals. The MRI skilled person would have the GE double donut configuration in mind anyway as a matter of common general knowledge and the idea would be reinforced by the figure in Van Vaals. It would be obvious to direct the radiation beam between the coils using a standard kind of rotating Linac design. Moreover the shielding requirements of claims 9 and 11 would be obvious too. Thus if the combined machine is obvious, it follows that all of claims 1, 4 to 7, 9 and 11 would be invalid.

308. Turning to the third point, as I have said already, Elekta submit that if the patent is sufficient despite the paucity of the disclosure in the patent, it must follow that the invention was obvious once the RT skilled person spoke to the MRI skilled person. Counsel for Varian submit that this is wrong in principle and refer generally to the ***Synthon v SKB*** paroxetine mesylate litigation which ended in the House of Lords at [2005] UKHL 59. The case was not in the authorities bundle but I do not need to turn to it in detail to reject Elekta's argument if it is put as a submission of principle. That is because the position of the skilled person is not the same in the two situations and so the conclusion that if it is sufficient it must be obvious does not follow. One needs to examine the circumstances. On the other hand, evidence directed to one situation may be relevant to the other and this is reflected in the way each side puts its case on obviousness. So far as I can see, Varian's written closing makes nothing of this third point in relation to obviousness, no doubt because they wish to emphasise the sufficiency of the disclosure. By the same token, Elekta's written closing on obviousness only addresses the argument as a squeeze.

309. It might also be said that the third point is irrelevant because having got this far the skilled team have effectively conceived of everything within the claims and so the patent must be invalid. I do not believe that would be a fair approach at least in a case like this. For one thing the skilled team will only go on and consider things like geometry of a possible machine if they think it is worthwhile to do so. So the third point is material to the issues I have to decide.

310. The question is just how much of a major challenge, at the priority date and without hindsight, would the MRI skilled person think the idea of a combined MRI and Linac machine would be. I have addressed Prof Morris' evidence about how difficult the task would be in the sufficiency section above. His opinion was that given the basic idea of a combined MRI and Linac, the skilled team would see the task as very challenging but they would not think a workable system was beyond their ability. I find that the skilled team's view would be that to produce a combined machine would be difficult but they would see no reason in principle why the combined system would not work or could not be made to work. Given the desirability of the goal, the challenges would not deter the skilled team. They would arrive at the invention.

311. Varian's point on Philips is the rhetorical question – if it is obvious over their own Van Vaals document why is there no evidence Philips thought of it at the time? As it happens, in around 1997 Elekta acquired the radiotherapy interests of Philips Medical Systems but there is no suggestion this is an answer.

312. One can take this Philips argument a little further because there is some evidence that the idea only started to be taken forward by the groups now involved in the consortium some years after 1997. The first evidence that any of those organisations were thinking of an MR-Linac dates from 2000. So I accept Varian have a point here

as a form of secondary evidence but it is just as speculative to work out what Philips may or may not have done with Van Vaals as it is to speculate about why Varian themselves have not produced an MR-Linac since claiming the invention 20 years ago. This secondary evidence is not strong enough to carry significant weight in the obviousness analysis.

313. Standing back, I will consider the question of inventive step overall. I find that the invention is obvious. A skilled team which involves an RT skilled person and an MRI skilled person interacting with each other does not involve hindsight. This is not a case like ***Schlumberger*** in which the invention brought two kinds of skilled people together. The two skilled people already interacted with each other. Accurate targeting in general and the problems of tumour movement were a major issue in the common general knowledge at the priority date. Van Vaals is addressed to this very problem and teaches the use of MRI imaging during treatment as a solution. It is not mentioned in Van Vaals but to an RT skilled person it would be obvious to think of applying this to external radiotherapy. The MRI skilled person would not dismiss the idea. They would think that it was a major challenge to combine the two machines but they would see the problems as matters which could be addressed using known techniques. The relevant claims are invalid.

Shepherd

314. Shepherd was published in 1996. Both parties used the figure below to describe it.

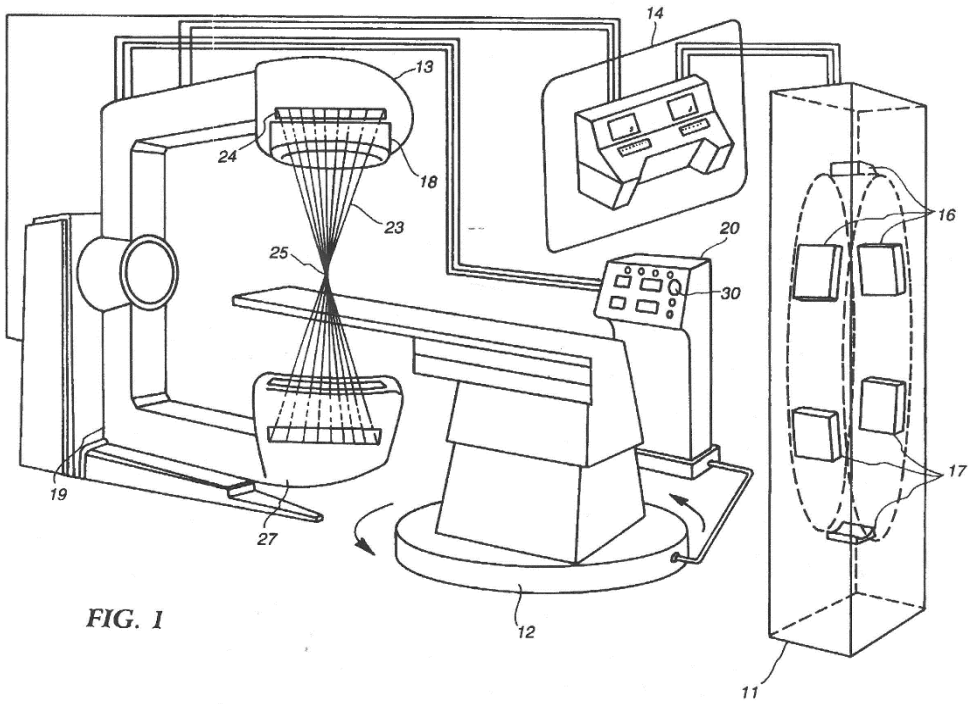


FIG. 1

315. Shepherd comprises a CT or MRI scanner (11), a bed (12), a control computer and a multi-beam Cobalt-60 radiotherapy machine (13). The course of events is, in summary: (i) the patient is positioned on rotatable bed 12; (ii) the bed is rotated into the CT or MRI unit (the figure actually shows a CT scanner (on the right) rather than an MRI unit); (iii) the patient is scanned by the CT or MRI, and the position of the

bed adapted so as to ensure that the co-ordinates of the target tumour are in the position used by the treatment planning software; (iv) the bed is then rotated into position within the radiotherapy unit; (v) the radiotherapy treatment plan is applied. As drawn in figure 1, it looks like the bed would crash into the CT scanner as it turns however Shepherd explains at col 4 ln 40-43 that the bed itself can slide horizontally on the rotating post. The overall idea of the system is to reduce the scope for positional errors as compared to the conventional approach to treatment planning. Conventional treatment planning requires re-positioning the patient on different machines and at quite different times. Using Shepherd's system the patient is positioned accurately on the treatment bed in the first place.

316. For Shepherd scenario 1, Elekta say that it would be obvious to make a Linac version of the machine shown in figure 1 of Shepherd and that such a machine without any further modification would fall within claim 1 of the Green patent. I have no doubt Elekta are right that it would indeed be obvious to make a version of Shepherd using a Linac instead of a Co-60 source. It is true that Shepherd itself is clearly interested in and claims the Co-60 source and describes a special source with seven collimated radiation beams which come to a focus at the patient and have a "beam catcher" underneath (all shown schematically in figure 1 above). It is also true that the document itself acknowledges the use of linear accelerators in radiotherapy (col 1 ln29 et seq) and describes their drawbacks, presenting the Co-60 arrangement as an advantage. But nevertheless to a skilled person the idea of using the rotating bed and scanner to improve targeting would obviously be useful for Linac based radiotherapy too. The experts did not disagree with Elekta's case on this aspect and I accept the first stage in Elekta's argument.

317. The question therefore is how does this obvious development over Shepherd stand in relation to claim 1? This is a system which looks more or less like figure 1 above but instead of the Co-60 source there is a conventional rotating Linac to apply the radiotherapy and the scanner is an MRI machine. I did not have my attention drawn to any evidence about shielding or interference between the two devices, presumably because one could deal with it simply by (for example) having some sort of shielded movable door between the MRI and the radiotherapy set up.

318. Taking the words of claim 1, the set up would be "A system comprising a radiotherapy machine for deriving a radiotherapy beam arranged to be propagated along a beam axis through a treatment region". It would "comprise a magnetic resonance imaging system arranged to image the treatment region and volumes abutting the treatment region". So integers (i) and (ii) of claim 1 are satisfied.

319. Counsel for Elekta proposed a scenario in which a patient had a coughing fit in the middle of the radiation treatment. It is not an unreal suggestion. If this occurred the beam would be switched off by the operator. Re-registration of the patient on the couch would be required and counsel's point is that this scenario 1 version of Shepherd would be useful in that case. The bed could be turned to allow the patient to be rescanned to relocate the tumour and accurately position the patient and the bed. Then the bed could be rotated back under the Linac and the fraction restarted. Since the claim is a product claim with functional limitations ("means for" etc.) the legally relevant issue is whether the Shepherd scenario 1 device would be suitable for performing those functions. The skilled person does not have to think of doing so. I agree with Elekta that this is a legitimate way to analyse the issue in law and I also

agree that the scenario 1 system would indeed be capable of doing what is described here.

320. Therefore as I have construed the term, scenario 1 would be a system "whereby the system comprises means for controlling the spatial distribution and intensity of the radiation applied to the treatment region" and this would happen "during treatment", in other words during a treatment fraction. The question is whether this amounts to control in "real time". Counsel for Varian submit that this sort of scenario does not show control in real time. Real time control does not mean simply any control within a fraction, it means something more immediate than that. I agree. Although one cannot draw a simple bright line and say real time control means control on a time scale of less than X seconds or Y minutes, wherever the boundary lies, I do not believe a skilled person would describe the scenario advanced by Elekta as control in real time. To the extent it is a matter of evidence, I have not had my attention drawn to any evidence that they would. I reject this obviousness case.

321. Elekta's alternative scenario 2 case is like their case over Van Vaals. The argument is that reading Shepherd the skilled RT skilled person would think of the possibility of a combined machine and would approach the MRI skilled person. After that the position is similar to the case over Van Vaals.

322. Elekta say that both Dr Williams and Dr Fenwick agreed that a combined MR-Linac, enabling imaging during radiotherapy treatment, was also obvious in light of Shepherd. That is not a fair reflection of the evidence. When pressed on the point about simultaneous imaging Dr Williams made reference to the knowledge that a "tomotherapy unit", in which the imaging and the treatment facility are combined, would have been in use in a local hospital but he later acknowledged that these systems were not on sale until after the priority date although the concept was known. I was not persuaded this was strong evidence of obviousness.

323. Varian submit that the cross-examination of Dr Fenwick got off to a bad start by commencing with a point of hindsight: putting as a matter of technical fact that "an even better solution to that suggested in Figure 1 [*of Shepherd*] would be co-locating the imaging system on the Linac gantry so that you could image during treatment". Dr Fenwick agreed. Varian's point is that while we know today that this is so, to start the questions on obviousness with this point is hindsight and begs the question. Counsel for Elekta submit this was simply telling the witness what the topic of the questioning was and that Elekta do not rely on the answer as evidence of obviousness. In my judgment this does reduce the weight to be given to Dr Fenwick's answers immediately afterwards even though those questions, in isolation, are legitimate. This is very different from the cross-examination relating to Van Vaals in which counsel oriented the witness by reference to the common general knowledge concerns about targeting tumours and respiratory gating.

324. I was not persuaded by scenario 2. Taking the document itself, it is very different from Van Vaals. Shepherd does not consider issues arising out of movement of the target during treatment and there is no suggestion of imaging the patient during treatment to deal with that problem. The RT skilled person at the priority date was aware of techniques such as portal imaging or cone beam X-ray scanning which in effect amount to forms of CT scanning operating during treatment. They had drawbacks because the X-rays did not have the soft tissue contrast which would

visualise the tumour but the position of the bones would be shown and the location of the tumour could then be inferred. To the RT skilled person armed with that common general knowledge, Shepherd is a deliberately different arrangement pointing in the opposite direction from a concept of imaging simultaneously with irradiation. I find they would not think of anything which would prompt them to go and talk to their MRI colleague about a possible combination of radiotherapy and MRI. Without that the obviousness case cannot get any further and I reject it.

Added matter

325. During the course of prosecution amendments were made to the claims of the application for the Green patent. The application as filed had 39 claims. The relevant ones are the widest method claim 1 and the widest product claim 9, as follows:

> 1. A method of treating a region of a subject with a radiotherapy beam derived from a radiotherapy machine which comprises imaging the region and volumes abutting the region with a magnetic resonance imaging system while irradiating the region with the beam.
>
> 9. In combination, a radiotherapy machine for deriving a radiotherapy beam for a region of a subject on a treatment couch, and a magnetic resonance imaging system the region and volumes abutting the region.

326. Granted claim 1 is set out above. It is a product claim and is narrower in scope than claim 9. It does not matter whether claim 1 as granted is to be treated as a set of amendments from claim 1, claim 9 or anything else but it is convenient to represent it starting from claim 9. Represented as underlined additions and struck through deletions, it is as follows:

> 1. ~~9. In combination, ~~A system comprising a radiotherapy machine (20) for deriving a radiotherapy beam arranged to be propagated along a beam axis through a treatment region, ~~for a region of a subject on a treatment couch, and~~
>
> **characterised in that**
>
> the system further comprises a magnetic resonance imaging system (22) arranged to image ~~for imaging~~ the treatment region and volumes abutting the treatment region,~~ substantially simultaneously with the region being irradiated by the beam~~
>
> whereby the system comprises means for controlling the spatial distribution and intensity of the radiation applied to the treatment region in real time during treatment.

327. No amendments were made to the description save to insert paragraph numbers, a new paragraph [0002] about the claim preamble and to adjust the consistory clause at paragraph [0016] to change it from wording which corresponded more or less to

application claim 1 into a reference to claim 1 as granted. There were also tiny amendments to paragraphs [0001] and [0017] but they do not matter.

328. Elekta say the amendments cause the patent to contain added matter and make the patent invalid under s72(1)(d) and s76 of the 1977 Act (Art 123(2) EPC). They rely on the law set out by Kitchin LJ in ***Nokia v IPCom*** [2012] EWCA Civ 567 at paragraphs 46-60. They say the following things in the patent are added matter:

i) The reference to control of spatial distribution and intensity.

ii) Real time imaging of soft tissue, which Elekta say Prof Morris understood to be an aspect of the invention, is not disclosed.

iii) Control by reference to soft tissue images is not disclosed.

329. Elekta also submit there has been an impermissible intermediate generalisation by adding the control feature into broad claim 9 without its essential counterpart that the control derives from imaging the effects of the radiation. This is another, perhaps clearer, way of putting the third kind of added matter relied on above.

330. Varian say the amendments are nothing more than the kind of broadening of coverage without any new teaching which is lawful following the line of cases from ***AC Edwards v Acme*** [1992] RPC 131 and including ***Texas Iron Works Inc's Patent*** [2000] RPC 207 and ***AP Racing Ltd v Alcon Components Ltd*** [2014] RPC 27.

331. Varian also rely on the recent judgment of the Court of Appeal in in ***IPCom v HTC*** [2017] EWCA Civ 90 at paragraphs 116-117 to the effect that if the claims are construed broadly because of the broad teaching which the skilled person would draw from the description, then there is unlikely to be added matter as a result of the broad claim, unless the description has changed.

332. This is another area of patent law which is familiar, not too difficult to state, but difficult to apply. I do not believe Varian meant this but at times their submissions could be understood as suggesting that if an amendment increased the scope covered then it was necessarily lawful and did not add matter. This would be wrong. The line of cases from ***AC Edwards*** onwards above shows that the fact that an amendment increases the scope of what is covered does not make that amendment add matter. But it does not mean that increases in coverage get a free pass. If an amendment which increases coverage also has the effect of the patent disclosing new matter then that amendment is unlawful. Putting it another way – if all the amendment achieves is an increase in scope relative to what went before then it does not add matter (***AC Edwards***) but the fact it increases scope does not mean it cannot also add matter. That latter question just depends on the particular circumstances.

333. Sometimes the ***AC Edwards*** point arises from a generalisation. So in ***AC Edwards*** itself the application disclosed a coil spring and had been generalised to spring means. The latter is of wider scope but while it would cover a different kind of spring from a coil, such as a leaf spring, it does not disclose the idea of a leaf spring and so the wider scope does not add matter. Similarly in ***AP Racing*** the application disclosed a J shaped unit and had been generalised to an asymmetric unit. Asymmetric has wider scope than J shaped and might cover (say) F shaped or P shaped. However

"asymmetric" does not disclose the idea of an F shaped or P shaped unit and so the wider coverage does not add matter. If one asked the question – what would the skilled person build given the patent after amendment, the skilled person would still use a coil spring in ***AC Edwards*** or a J shaped unit in ***AP Racing***. So there was no added matter.

334. I turn to the particular points made by Elekta. In order to address them it is convenient to refer to passages in the description using the paragraph numbers in the granted patent. This is a mild heresy since those numbers were not there in the application but it makes the points much clearer.

Control of spatial distribution and intensity

335. The argument on spatial distribution is that all that is described in the application is adjusting the position of the beam relative to the patient but "controlling the spatial distribution … of the radiation applied to the treatment region" not only covers a wider concept, those words positively disclose the idea of changing the beam shape. That idea is not in the application. I reject this point. All these words do is have wider coverage than the application. They cover more but do not disclosure more. On ***AC Edwards v Acme*** there is no added matter.

336. As for intensity or to be exact "intensity of the radiation applied to the treatment region" as I have construed the term, Elekta submit that the application does not disclose this at all and this is plain added matter. I do not agree. This is an example of the point made in ***HTC v IPCom*** relied on by Varian. I have reached the construction of the term based on reading the patent as a whole including the description. Since the description has not changed in this respect it is hard to see how there is any added matter. Putting the point more positively, I believe a skilled reader given the application as filed would understand that what was being controlled in the context of the disclosure of control in the application as filed included the "intensity of the radiation applied to the treatment region" as I have interpreted that term. There is no added matter here.

Real time imaging of soft tissue

337. I believe this is part of the next point (below) and I will address it as such.

Control by reference to soft tissue images / intermediate generalisation

338. This is the major issue. Elekta's submission is that the patent application only discloses the concept of controlling the radiation applied to the treatment region in the context of using the MRI to detect the effects of irradiation and correlating these effects with previously gathered soft tissue imaging data (see e.g. paragraph [0030]). So the only disclosure of the control feature is one in which the effects of irradiation are an essential input. In the granted claim this control feature has been taken out of context and separated from its essential input feature. On my findings on construction and infringement it is clear that the claim covers more than Elekta say is disclosed because the Elekta MR-Linac infringes even though it does not detect the effects of radiation. But Elekta say that the claim also means that the patent discloses more too. Elekta say the patent now discloses the idea of controlling the beam using soft tissue imaging rather than the effects of irradiation.

339. Here Varian again take the ***HTC v IPCom*** point and the ***AC Edwards*** point. They say that at worst all that has happened is a broadening of coverage but, furthermore, if the broad coverage is the right construction based on the specification then there is unlikely to be added matter.

340. As the structured approach to added matter in ***Bonzel v Intervention*** [1991] RPC 553 makes clear, the starting point must be to read the application through the eyes of the skilled reader to work out what is disclosed. That is where I will start.

341. Looking at the application itself on its own and doing my best to avoid hindsight knowledge of the granted patent, the idea of controlling the radiation applied to the treatment region is plainly disclosed but I can find no disclosure either expressly or by necessary implication of the idea of doing this control other than by using the MRI to detect the effects of irradiation.

342. Control using the detected effects of irradiation is the only way control is described for the specific embodiments from what is now paragraph [0033] onwards – see paragraphs [0039] and [0040]. In the more general section of the description before the figures that is how the control is described in paragraph [0030] too. Varian's best point is paragraph [0028], which does refer to the position of the tumour being determined directly on the radiotherapy machine using MRI, however when that is read in context it is part of the whole section from paragraph [0025] to paragraph [0030] and would not be understood as a teaching to control the radiation applied by using only this kind of soft tissue imaging to the exclusion of using the effects of radiation.

343. The claims of the application include wider claims than claim 1 as granted but they say nothing about control. The claims of the application which do mention control also refer expressly to irradiation products, that is claims 3 and 6 and see also claim 38. One exception is claim 39 of the application but the control referred to there is limited to moving the couch and neither side suggested it made any difference.

344. So the relevant disclosure is not in the application. Now ***AC Edwards*** means that the fact the claim covers the technique of controlling the beam using soft tissue imaging alone does not answer the question. That coverage does not make the claim add matter. The issue is what is disclosed by the patent. On this the point made in ***HTC v IPCom*** does not help.

345. Varian suggest that relevant evidence came from Mr Collins when he agreed in cross-examination that the skilled person would perfectly well understand that he had all the information he needed to implement claim 1 without the "nice to have feature of viewing the irradiated tissue". Similarly they refer to uncross-examined evidence in Dr Fenwick's report that

> "The skilled RT physicist would not think it necessary to detect the radiation products in order to be able to position the beam since, combined with the knowledge of the precision with which the Linac was constructed and maintained, the MR images obtained are enough to control the radiation beam to accurately target the tumour"

346. However neither Mr Collins nor Dr Fenwick were focussing on the application in giving this evidence. They were focussing on the patent. If anything that kind of evidence, to the extent it is relevant, is against Varian because it indicates that the patent does indeed disclose the idea of using the MR images themselves, rather than the detection of irradiation, to control the radiation beam.

347. In my judgment this case is unlike ***AC Edwards*** and the cases in that line because the patent not only covers more than was disclosed in the application, it actually does disclose more too. The claims are part of the disclosure and while that is true anyway, paragraph [0016] expressly refers to claim 1 in the description. The reference to a means for controlling the beam in claim 1 necessarily requires the skilled reader to think about what information is to be used to control the beam. The claim makes clear that the only information to be gathered is MR imaging. That is the information the reader would understand they are being told to use. That is why Dr Fenwick and Mr Collins had the view they had. It is because the patent, in a subtle but vital way, does teach more than the application.

348. I find that claim 1 is bad for added matter.

349. Before leaving this point, I will record that it occurred to me that there may be a relationship between the problems of added matter and sufficiency in this case. Given that the test for sufficiency is generally summarised as requiring an enabling disclosure (***Synthon***) perhaps the finding on sufficiency, based as it is on a combined system which does not use the detected effects of irradiation, is tantamount to a finding that such a system is disclosed, and not just covered, by the patent. The only means of control disclosed in the application does not work. I do not need to resolve that issue, which was not canvassed in argument.

Conclusion

350. The patent is invalid on the grounds of obviousness over Van Vaals and added matter. The claim is sufficient and would have been infringed if valid.

351. This decision is different from the judgment of the Landgericht Mannheim between the same parties in relation to the German designation of this EP patent (7 O 194/15). They interpreted the claim as being limited to control using the detected effects of irradiation. The judges in that court include very experienced patent judges and I would not differ from their view lightly. But I respectfully disagree with the construction of claim 1 they have reached. Overall the outcome in both courts is that Varian have lost but the reasons are distinct.

Postscript

352. After providing a copy of the draft judgment to the parties' representatives in accordance with CPR Part 40 Practice Direction 40E I was informed that the parties had settled and invited by both parties not to hand down this judgment. I heard the parties in private and decided to hand it down. In summary my reasons were these. Since the draft judgment had been provided to the parties the court has a discretion whether to hand down or not (***Prudential Assurance Co. v McBains Cooper*** [2000] EWCA Civ 172). A key factor is the public interest. The validity and proper scope of

a patent are matters which affect the public as well as the parties. This judgment finds the patent is invalid and so the public interest outweighs any private interest.