BLO/ 070/96

PATENTS ACT 1977

Pat / Linda
3Y60

IN THE MATTER OF an application under section 72 by Söring Medizintechnik Gmbh for the revocation of Patent No 2188845 in the name of Birtcher Medical Systems Inc

FINAL DECISION

In an interim decision dated 30 April 1996, Dr Ferdinando found that many of the claims of this patent were invalid but that the allegation of invalidity against the remaining claims had not been substantiated. He ordered that the patent should be revoked unless the specification was amended to the satisfaction of the Comptroller within two months of the decision (a period which he later extended to fourteen weeks).

The proprietors have now submitted amendments to the claims. As laid down in Dr Ferdinando's decision, the applicants for revocation were given the opportunity to comment on the amendments, but they said they did not wish to do so. I have considered the amendments and am satisfied they meet the findings of Dr Ferdinando's decision in that they have the effect of deleting all the claims that he found invalid whilst retaining all the rest. I am also satisfied that they comply with section 76(3) because they do not result in the specification disclosing additional matter and they do not extend the protection conferred by the patent.

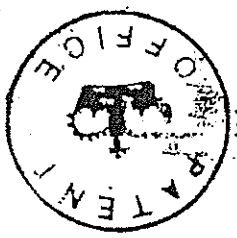
Under section 75(1) I can require the amendments to be advertised, but because they do no more than reflect Dr Ferdinando's decision, I do not feel this is necessary.

Accordingly, I allow the amendments, which are shown on the copy of the claims attached to this decision. On the basis of the specification so amended, I make no order for revocation.

There remains the question of costs. Although the patent is not being revoked, the scope of the claimed monopoly has been restricted significantly. Thus it was clearly in the public interest that this revocation was brought, and so I consider the applicants are entitled to a contribution towards their costs. I would normally assess that contribution by reference to the guidelines published in the Official Journal (Patents) for 1 June 1994. The present case, however, has been exceptional by normal Office standards. There was a large volume of evidence, there were demonstrations, cross examination of the applicants' witnesses lasted two days, and the hearing as a whole lasted eight days. In these circumstances, I have to be looking at figures somewhat higher than the maxima suggested by the guidelines for more-normal cases. Accordingly I direct that the patentees pay the applicants a sum of £3500.

Under the Rules of the Supreme Court, any appeal from this decision must be lodged within six weeks from today.

Dated this 30 day of September 1996



P HAYWARD
Superintending Examiner, acting for the Comptroller

THE PATENT OFFICE

393

Miss Durow
3Y60

PATENTS ACT 1977

IN THE MATTER OF an application under
Section 72 by Söring Medizintechnik GmbH
for the revocation of Patent No 2188845 in
the name of Birtcher Medical Systems Inc

SUPPLEMENTARY DECISION

On 30 April 1996 I issued an Interim Decision in which I found that certain claims of Patent No 2188845 were invalid but that allegations of invalidity against certain other claims had not been substantiated. I allowed the proprietors, Birtcher Medical Systems, a period of two months within which to file an amended specification in accordance with my findings, failing which I would revoke the patent. Following Order 104, rule 19(2)(b) of the Rules of the Supreme Court the period for appeal from the decision was set as six weeks, which period would expire on 11 June 1996.

On 3 June 1996 Lloyd Wise, Tregear & Co, patent agents for the applicants for revocation, Söring Medizintechnik GmbH, wrote to the Patent Office by facsimile letter requesting an extension of six weeks to the period within which to appeal against the Interim Decision. The reasons they cited were that the proceedings were particularly complex, and that they needed to consider the extent to which the claims which I had upheld in the Interim Decision were relevant to the applicants' activities and whether the interpretation I had given to these claims was consistent with their own and the applicants' original understanding. Thus, they stated, they were having to consider not only whether an appeal was advisable but also the grounds for appeal, taking account of my interpretation of the claims.

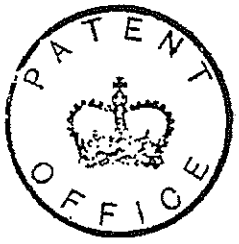
On the same day McNeight & Lawrence, patent agents for the proprietors, wrote to the Office by facsimile letter confirming their consent to the extension conditional upon the proprietors having a like extension and a further two weeks from the end of any extended term for

submission of amendments. On 5 June 1996 Lloyd Wise, Tregear & Co confirmed their agreement to this condition on behalf of the applicants for revocation.

Under Order 104, rule 19(8) the Comptroller has jurisdiction to allow extension of the time for appeal from one of his decisions, provided that the request for extension is made prior to the expiry of the initial appeal period. In the present case, both parties being in agreement and the case being of unusual legal and technical complexity and length, I am satisfied that the requested extension is justified, and I accordingly direct that any appeal by either party against my Interim Decision of 30 April 1996 should be lodged within twelve weeks after that date.

I also allow the requested extension in respect of filing amendments, and therefore order that any amendments to the specification of the patent in suit in accordance with the findings in my Interim Decision of 30 April 1996 should be submitted in the form set out in that decision within a period of fourteen weeks after the date of that decision. In the event that no amendments are submitted within that extended period I shall, subject to any appeal having been lodged by either party, issue a final decision revoking the patent.

Dated this 6 day of June 1996



Dr P FERDINANDO

Superintending Examiner, acting for the Comptroller

THE PATENT OFFICE

Miss Durow
3Y60
O / 70 /96

PATENTS ACT 1977

IN THE MATTER OF an application under section 72 by Söring Medizintechnik GmbH for the revocation of Patent No 2188845 in the name of Birtcher Medical Systems Inc

INTERIM DECISION

Patent Application No 8705485 was filed on 9 March 1987 in the name of C R Bard Inc, claiming a priority date of 8 April 1986 from corresponding US Application No 849950. The United Kingdom application is entitled "Electrosurgical conductive gas stream technique of achieving improved eschar for coagulation". The inventors were named as Francis T McGreevy, Carol Bertrand, and Karl W Hahn. In its broadest terms the invention has application to a branch of medicine in which electrosurgical equipment is used to perform a technique for causing coagulation of tissue by conducting radio frequency (RF) electrical energy through a conductive inert gas stream to tissue being treated.

The patent was granted on 29 November 1989 as Patent No 2188845. By deed of assignment dated the same date as grant the patent was assigned to the Birtcher Corporation, whose name was subsequently changed to that of the present proprietors, Birtcher Medical Systems Inc ("the proprietors").

On 18 January 1993 Söring Medizintechnik GmbH ("the applicants") lodged an application under section 72 for revocation of the patent. In their statement of case they sought revocation of the patent on two grounds, namely:

(a) the invention claimed is not a patentable invention;

(b) the specification of the patent does not disclose an invention clearly enough and completely enough for it to be performed by a person skilled in the art.

I will deal with the individual aspects of the applicants' statement when I consider the submissions made in respect of them. It is sufficient at this stage to state that the applicants have cited prior art which in their opinion destroys the novelty and/or the inventiveness of each and every claim in the patent. For the sake of completeness I will list all the documents which they have cited in their statement.

The first group of citations were those cited by the examiner in the United Kingdom Patent Office following the preliminary search and examination on the patent application in suit, namely:

GB 1014995 (Siemens-Reiniger); GB 671497 (Hanriot);
US 3903891 (Brayshaw); PCT Application No WO 82/02488 (Walker).

The second group of citations were those cited by the German examiner against the corresponding German Application No DE 3710489, namely:

US 2828747 (August); US 4040426 (Morrison); US 4057064 (Morrison);
US 4060088 (Morrison); US 4188927 (Harris); US 4271837 (Schuler);
US 4378801 (Oosten); US 4429694 (McGreevy - acknowledged in the patent);
US 4562838 (Walker - equiv to PCT appn WO/02488 cited by UK examiner);
German patent specification No 2504280 (Meinke).

Paragraph 6 of the statement particularly refers to claim 1 and alleges that properly construed it relates to a method of treatment of the human or animal body by surgery and is thus excluded from patentability by sections 4(2) and 1 of the 1977 Act. According to the statement, claims 2-8, 10-12, 14, 15, and 27-44 are similarly excluded. The applicants ask for the patent to be revoked and for an award of costs.

In support of their case the applicants filed evidence-in-chief on 9 December 1993 consisting of a statutory declaration by **Dr Bryan Philip Levitt**, Senior Lecturer in physical chemistry in the Department of Chemistry at the Imperial College of Science, Technology and Medicine, London University, appearing as expert witness on behalf of the applicants, supported by two exhibits, and one by **Esmond Antony Hitchcock**, a partner in the firm of Lloyd Wise Tregear & Co, representing the applicants, also accompanied by two exhibits.

It is convenient to mention here that the second of Dr Levitt's exhibits consists of a paper in the journal, "Digestive Diseases and Science", volume 24 No 11 (November 1979) which is entitled "Evaluation of electro fulguration in control of bleeding of experimental gastric ulcers". Its authors include M B Dennis and F E Silverstein and the paper has become known in these proceedings and in infringement proceedings in connection with the corresponding US Patent No 4781175 in the United States (the "Colorado litigation") as "the Dennis article".

The evidence-in-answer filed by the proprietors consists of affidavits filed on 9 May 1994 by eight deponents, namely **Francis Timothy McGreevy**, one of the inventors of the patent-in-suit, showing ten exhibits, **John R Ley**, the US patent attorney in the firm of Holland and Hart acting for the proprietors, with eight exhibits, **David Wells**, expert witness on behalf of the proprietors, with two exhibits, **Fred E Silverstein**, Professor of Medicine at the Department of Medicine of the University of Washington, Seattle, involved in the research team in the USA between 1974 and 1981 for evaluating various methods of coagulating bleeding ulcers, and expert witness in the "Colorado litigation", **Rory F McCloy**, Administrative Head of Department, Senior Lecturer and Honorary Consultant Surgeon at the Manchester University Department of Surgery, Manchester Royal Infirmary, with one exhibit, **William E Maya**, the proprietors' President and Chief Executive Officer, also with one exhibit, **John Gordon Lawrence**, the agent from McNeight and Lawrence dealing with the UK application leading to grant of the patent, and **Graeme Poston**, Consultant Surgeon at the Royal Liverpool University Hospital, with two exhibits.

Evidence-in-reply filed by the applicants on 14 November 1994 and 5 January 1995 consists primarily of an affidavit by **Holger Söring**, General Manager and owner of the applicants,

accompanied by nine exhibits and six US patents, an affidavit by **Alison Winifred Penfold**, a translator, who has exhibited extracts from textbooks written in German (with their sworn English translations), a second statutory declaration by **Bryan Levitt**, a statutory declaration by **Charles A Akle**, a Consultant General Surgeon in the private sector in the London Clinic, accompanied by two exhibits, and finally a statutory declaration by **Ashley R Dennison**, a Consultant Hepatobiliary Surgeon at Leicester General Hospital, accompanied by a single exhibit.

The hearing took place in two separate halves, the first on 20-23 June 1995 and the second, after a prolonged adjournment before a resumption date convenient to the parties could be found, and which I would much rather have avoided, on 20-23 November 1995. At the hearing Mr David Kitchin QC, instructed by Messrs Denton Hall, and Mr George Hamer, instructed by Lloyd Wise Tregear, appeared as counsel for the proprietors and for the applicants respectively. At the hearing cross-examination took place of Dr Levitt and Mr Söring for the applicants and Messrs Ley, McGreevy and Wells for the proprietors. The 8-day length of the hearing covering in all such an extended period of time is very unusual for a case before the Comptroller and, I must observe, is undesirable if the purpose of the Comptroller's jurisdiction is primarily to provide a relatively quick and inexpensive means of justice. It reflects several factors, including the length of the patent itself, with, in B-published form, 120 pages of text, 23 sheets of drawings and 56 claims, five of which are independent, the complex technical and legal issues which arose, and the multi-facetted nature of the attack mounted against the patent, with all claims challenged and almost all defended. These same factors have contributed greatly to a significantly longer period between the end of the hearing and the issue of this decision than is ideal, and than I would have preferred.

Unusually, on the second morning of the hearing, I convened the proceedings at the premises of Denton Hall for a demonstration of respective devices by both parties. A video record was made of the demonstrations but was not subsequently used in the proceedings by either side. However, previously filed video recordings exhibited by Mr McGreevy and Mr Ley were viewed during the hearing. A further video tape of experiments conducted in Germany was exhibited by Mr Hitchcock. I had the opportunity to view Mr Hitchcock's video tape in

advance of the hearing, but it was not subsequently referred to in the proceedings and, to a large extent, has been superseded by the demonstration.

There are some preliminary matters concerning admissibility of certain material, sought to be brought in formally as evidence, which have some bearing on the applicants' pleadings and the documents upon which they rely.

The first concerns some late-filed evidence. On 12 April 1995 the Patent Office received a second statutory declaration with five exhibits by Mr Hitchcock and a covering letter requesting that the declaration be formally admitted. These papers were also accompanied by a copy of a report of the "Proceedings of the 8th International Conference on Medical and Biological Engineering and the 22nd Annual Conference on Engineering in Medicine and Biology, 1969 Chicago, Illinois" ("the Chicago Conference") which had been referred to in paragraph 8 of Mr Ley's affidavit and had been cited by the Japanese Patent Office in connection with proceedings in respect of the corresponding Japanese Patent Application. Exhibits C to F to Mr Hitchcock's declaration were concerned with letters arranging for a preview of the demonstrations of various devices which both parties wished to present as part of the hearing, a video record of the preview which was held on 16 January 1995 at the applicants' premises, a written summary of the experiments carried out at the preview, nozzles of the type used in the experiments, and finally copies of US Patent Nos 4901720 (Bertrand) and 4901719 (Trenkosky), both assigned to C R Bard Inc, and which are said by Mr Hitchcock to disclose nozzles corresponding to those used in the preview.

The Office invited the proprietors to comment on the admissibility of the further evidence, failing which it was minded to allow the evidence. The proprietors replied that they were "not minded to question the admissibility of the further evidence", but sought time in which to consider whether they may wish to file further evidence specifically in reply to it.

In a letter dated 26 May 1995 the Office stated that the imminence of the hearing prevented the filing of any such reply evidence after 16 June 1995, and that the admissibility of the

applicants' further evidence and any such reply evidence filed by the proprietors would be considered as a preliminary matter at the hearing.

A further letter from the applicants, also dated 26 May 1995, accompanied another declaration by Mr Hitchcock formally exhibiting the Chicago Conference paper. The Office stated that at this late stage of the proceedings it was minded, subject to any comments received by the proprietors, not to admit the declaration as evidence. The proprietors replied, in a letter dated 8 June 1995, that their counsel wished to deal with this matter at the hearing.

Following argument at the hearing from both counsel, during the course of which the applicants sought to amend their statement of case and handed up a revised statement which *inter alia* incorporated the Chicago Conference paper as a further citation against claim 1, I decided to refuse amendment of the pleadings at such a late stage in the proceedings, but to admit the Chicago Conference paper as an item of evidence.

The admission or otherwise of the video record taken of the preview conducted at the premises of Söring in Germany was alluded to at the end of the fourth day of the hearing, and there was discussion as to its relevance. Mr Kitchin said that it had been overtaken by the demonstration that was carried out on the second day of the hearing. Mr Hamer agreed that it was not needed, and it played no further part in the proceedings.

Following a submission by Mr Kitchin that his side were in particular difficulty addressing the revocation action since, as he put it, the applicants' statement did not set out adequately the issues upon which they were attacking the patent, Mr Hamer offered to make his case clearer in readiness for the resumed second half of the hearing, and despite misgivings I decided to abide by that undertaking. However, the offer seems to have been interpreted as an opportunity for the applicants to rethink their case and to submit, on 23 October 1995, a "replacement statement of case" which, as compared with the original statement, added several new paragraphs and went into considerable detail as to how the applicants' case was to be framed, specifically introducing the Chicago paper into the list of documents already cited in the original statement. The proprietors objected that the revised statement raised new grounds

which did not fall within the scope of the original pleadings and attempted to introduce as a citation the Chicago paper, a course which I had "resisted and ultimately rejected". On the first day of the resumed hearing Mr Hamer acknowledged that he had overlooked the fact that I had expressly not allowed the Chicago paper to be admitted to the pleadings, and he handed up a revised version containing no reference to the Chicago paper. Mr Kitchin maintained his objections, and in the event Mr Hamer was content that the revised version of the statement should not be adopted as pleadings but should be used solely for the purposes of questioning. I was satisfied that the case could proceed on that basis, but made it clear that I would not at that very late stage, with the hearing already half-completed, have permitted pleadings to be formally amended.

In addition to the revised statement Mr Hamer referred to the fact that an affidavit by Mr Söring, together with three exhibits HS10, 11 and 12, had been lodged by hand at the front office of the Patent Office in London on 17 November 1995. These papers had not caught up with the rest of the papers by the time the hearing resumed on 20 November 1995. Although it is not necessary for me to go into detail as to the contents of those papers I will say merely that they concern German language brochures for argon gas coagulation apparatus marketed by Erbe (as re-badged Birtcher machines) and Valleylab (made under licence from Birtcher). The brochures are the same as documents which were handed up on Day 4 of the hearing and identified as X4 and X5. They were filed, so the affidavit states, as a result of statements made by Mr McGreevy and Mr Wells under cross-examination to the effect that the Birtcher ABC ("Argon Beam Coagulator" - the proprietors' commercial apparatus using the invention in suit) would not operate effectively at flow rates below four litres per minute whereas the brochures indicate that operation is possible at flow rates of 2 litres per minute in the case of the Erbe device and 0.5 litres per minute in the case of Valleylab.

Representations were made by Mr Kitchin as to why the affidavit should not be admitted and by Mr Hamer as to why it should. Mr Kitchin had already "put down markers" to the effect that he would object to any attempt by the applicants to adduce new evidence-in-chief into the proceedings, especially since cross-examination of his witnesses had been completed and Dr Levitt would probably be unavailable for the resumed hearing. The fact also that

Mr Söring had added comments of his own and that the submission of these documents had been justified on the basis that they "only arose at the hearing" was, Mr Kitchin argued, not tenable in revocation proceedings. Finally, the gas flow rates had always been an issue, the patent stating that the gas flow rate is from four litres upwards while some of the prior art disclosed lower flow rates as had been confirmed by Mr Wells in his declaration. To answer some of the questions now being raised by the applicants could well, Mr Kitchin contended, involve the proprietors bringing somebody from America.

Mr Hamer's primary position was based upon the fact that for the first time it was now said that the system would not work below 4 litres per minute. The applicants always knew that to be the case, but it had not previously been stated in evidence. Mr Hamer also said that it was not necessary for either Mr McGreevy or Mr Wells to be summoned to answer questions on how the Birtcher machine works; a simple telephone call to the USA, for example to Mr Ley, would have been easy enough to establish the truth. There had been plenty of time in which to do that.

As far as Mr Söring's affidavit and exhibits are concerned, I said that it did not seem to me that any fresh arguments were being put up either way compared to those made when the exhibited documents were brought in to questioning as items X4 and X5, except that their context was different, they now being exhibits to a fresh affidavit. While I was prepared to allow the documents to be used for questioning I was not prepared to allow them to enter formally as fresh evidence at that advanced stage of the hearing. Mr Hamer said that as regards the further evidence he would "have this as a ground for appeal in due course", with which observation, of course, I have no difficulty.

I come now to the hearing itself and to the substantive matters in issue.

The most prominent issues in the proceedings were (a) the construction of the claims of the patent-in-suit and (b) the teaching of the specification of the patent, in relation to sufficiency, and of certain of the most significant prior art. I must begin by construing the teaching of and monopoly claimed in the patent. It is necessary to deal with this in some detail.

The specification opens by explaining in broad terms that the invention is concerned with an electrosurgical technique for achieving coagulation or a haemostatic effect, by conducting RF electrical energy through a conductive inert gas stream to the tissue.

It continues with a summary of the background of the invention. Electrosurgery is the application of RF electrical energy to tissue. The energy is derived from an electrosurgical generator (ESG) whose characteristics may be controlled so as to determine the electrosurgical effect created, examples being pure cutting, combined cutting and haemostasis, fulguration and desiccation. The energy is applied either by a single electrode of small cross section cooperating with a large return electrode remote from the surgical site, or between a pair of electrodes adjacent the surgical site. Earlier ESGs, such as the "Bovie", have been the standard, but even more modern ESGs, such as in US 4429694 (McGreevy), still have disadvantages.

In conventional fulguration electrical arcing through the air from various locations on the electrode interacts with the tissue somewhat randomly. This leads to a collection of "arc holes" in the tissue distributed about larger holes where arcing has been concentrated. Thermal necrosis occurs in the tissue between the holes. The overall effect is the creation of an "eschar" (which in layman's language might be referred to as a "scab", although it was explained to me at the hearing that a scab could equally be dried blood on the surface of the tissue). The eschar has two distinct layers, one above the other. The first, a reticulum of tissue subject to necrosis, is created by the random pattern of arc holes, and is of uneven thickness. An underlying desiccation layer is also uneven in depth and location due to the randomness of the arcing. Thick areas of eschar tend to be fragile and crack when flexed, resulting in renewed bleeding. It is suspected that the most significant factor affecting the evenness or otherwise of the eschar is variation in impedance of the path taken by the arc between the electrode and the tissue. Effective fulguration of spongy vascular tissue such as the liver or spleen is difficult to achieve. Superficial coagulation often results, which can readily be damaged by fresh arcing, leading to renewed bleeding.

Other practical problems arise with conventional fulguration techniques. Accidental physical contact of the electrode with tissue or fluids leads to build-up on the electrode surface, requiring continual cleaning. Newly created eschars can be detached. Arcing can become even more random. The surgeon's view of the surgical site can be impeded. There is potential for cross contamination. Smoke resulting from the surgical site can produce a noxious odour and may be hazardous. Even optimising the operating characteristics of the ESG, such as in US 4429694, does not overcome all of these problems.

Thermal desiccation of tissue by use of a conventional ESG is effected by contacting the tissue with the electrode without arcing, the electrode being moved over the tissue. This technique runs the risk of the electrode becoming contaminated with the tissue and also leads to uneven desiccation. Only surface desiccation is possible by this technique, and it cannot be applied to thin fragile tissue.

The brief summary of the invention which follows outlines the technique as being one in which a predetermined ionisable gas is directed as a jet to the tissue at a predetermined flow rate sufficient to clear natural fluids from the tissue and to expose the underlying tissue whilst simultaneously conducting electrical RF energy in the gas jet through ionised conductive pathways. This is broadly in accordance with claim 1.

The resulting eschar is said to have an upper reticulum layer with a greater number of smaller arc holes than previously, together with greater wall thickness between the holes so as to provide a more flexible layer. The underlying desiccated layer is shallower in depth and more even. The overall result is a layer of tissue which has been subjected to thermal necrosis and desiccation to an extent such that the unaffected tissue beneath is substantially sealed. The gas jet should have sufficient flow rate to clear fluids from the tissue so that the eschar is formed in the stroma (supporting structure) of the tissue, as opposed to being formed on top of the fluid covering the tissue. The ESG should have a relatively broad internal impedance characteristic, resulting in the transfer of adequate power into fluids or fluid-perfused tissue at the low end of the impedance curve. At the high end of the impedance curve sufficient power should be transferred to ionise the gas flowing at the predetermined flow rate when the

jet is spaced from the tissue so as to avoid any effect on the tissue. Generally the high end of the impedance transfer characteristic of the ESG should be two or three times that of prior art solid state electrosurgical fulguration devices.

Following the brief outline of the drawings is a description of the preferred embodiment of electrosurgical unit (ESU) shown generally in figure 4. It has three main components, a so-called "pencil", gas delivery apparatus and an ESG. In use gas is supplied through channels (termed "lumens" in the specification) in a flexible cord to a nozzle where it is ionised by an electrode connected via a conductor passing through the cord to the ESG. A return channel is used for monitoring the effect of the device. A plate acts as the return electrode for current passing through the tissue. In the fulguration, or "macro", mode electrical energy is transferred to the tissue by a series of arcs. This creates in the tissue an upper arc hole reticulum layer on top of a desiccated layer, leaving the underlying tissue unaffected. There is a slight spreading of the jet above the surface of the tissue. In the desiccation, or "micro", mode electrical energy is transferred to the tissue in the form of a non-arcing conductive current. No arc holes are formed in the tissue and only a desiccation layer similar to the one obtained in the fulguration mode is formed on the surface of the tissue. The specification then describes each of the main elements in detail.

Pencil

The pencil consists of a handle into which the cord extends. The channels in the cord are coupled to a connector piece which communicates with the lower end of the pencil containing the electrode assembly itself connected through the central conductor to the ESG. A partitioning piece and gasket couple the gas channels through to the electrode portion. The gas nozzle has a tapered shape causing the gases to exit in a directed or laminar stream or jet. The electrode itself is supported by radial fins located within the nozzle. Attached to one of the ribs is a movable sector plate which, when the pencil is properly assembled, sealingly couples one of the gas channels with the return channel feeding back to the gas delivery apparatus where pressure and flow are monitored. The nozzle and electrode assembly is removable as a single unit from the pencil for cleaning or replacement of parts. Location of the conductor

in the centre of the cord reduces stray capacitance effects and thereby reduces leakage current which might otherwise be transmitted to the surgeon's hand.

Gas delivery apparatus

Depending upon whether macro or micro modes of operation are selected gas from one of the two sources is selected by a valve and passed through a pressure regulator to a gas delivery valve. After filtering the gas flow rate is controlled and passed into the channels of the cord. Pressure upstream and downstream of the flow controller is detected to ensure adequate flow and no obstructions. The selection valve, gas delivery valve and flow controller are all controlled by the surgeon. Return gas from the sensing channel of the cord is passed through a pressure transducer and a flow rate transducer to confirm that both the nozzle and the electrode support assembly of the pencil have been properly attached. Details of the connector coupling the gas supply and electrical power to the electrode are described with reference to figures 11A,B. These details are not in issue in the current proceedings and so will not be dealt with here, apart from mere mention of the fact that the coupling enables the cord and attached portions of the pencil to be separated readily for maintenance or sterilisation.

Electrosurgical generator (ESG)

There is considerable detail of the ESG, and it appears from the statement and counterstatement that the exact details of the ESG may be crucial to determining the issues involved in this case. However, it is convenient to give a general picture here of the ESG and to go into as much detail as necessary when particular matters arise.

Figure 12 shows the overall configuration of the ESG. A control switch enables power to the electrode to be switched on or off, allowing the surgeon to use the gas flow by itself to clear fluids from the tissue. A front panel contains controls enabling the surgeon to select the operative parameters, such as gas flow rate and choice of gas, as discussed in connection with the gas delivery apparatus. The heart of the ESG is the logic control. It prevents RF energy being supplied to the electrode until all operating parameters have been set by the surgeon and

all monitoring signals from the valves and gas return channel in the cord are satisfactory. The power supply control is then activated to energise the power supply which provides monitoring feedback to the supply control. An RF drive supplies excitation energy to a resonant output circuit at a frequency established by RF drive pulses. This circuit discharges at its resonant frequency to the pencil. Return current from the patient plate is also fed to the resonant circuit. An arc sense circuit monitors current from the resonant circuit to establish the proximity of the electrode to the tissue being treated and automatically adjusts the power level between minimum and maximum target levels and a predetermined active level. The result is that the power level is switched to "high" while the pencil is distant from the tissue and is reduced to minimum when the pencil moves into close proximity to the tissue.

When desiccation, a less aggressive procedure than fulguration, is to be performed a different gas is used and the energy applied to the electrode is at a constant lower active level. The arc sense circuit is disabled since switching between different levels is unnecessary. Under these conditions a corona discharge in the gas jet is created which can be aimed at the tissue undergoing treatment.

The control panel is represented schematically in figure 13. Switches enable the gas source and micro or macro modes to be selected, and potentiometers select variable gas flow rate and active power level, the latter being displayed on a digital display derived by a multiplexer. Various alarm conditions are indicated by lamps and an audible alarm may also be energised.

The logic control in figure 12 is schematically represented in figure 14. It is not necessary to deal with the detail of this circuit. It is sufficient merely to appreciate that the logic circuit achieves the various control situations already described with reference to the other integers of the electrosurgical unit. The only point of note is that the circuitry can produce so-called booster drive pulses of higher voltage or greater duration in order to initiate ionisation of the pathways within the gas jet. After the pathways have been established the drive pulses return to a condition sufficient to maintain them.

The power supply is represented in figure 15 and consists of a line transformer supplying a triac feeding a diode-rectifying bridge supplying high voltage to a filter. The power supply control of figure 10 is described with reference to figure 16. Again, it is not necessary to describe the detail of this circuit.

The RF drive and resonant output circuit, both of figure 10, are shown in figures 17 and 18 respectively and are said to be essentially the same as those in US 4429694 (McGreevy). The arc sense circuit, sensing adequate operation of the electrode assembly, is shown in figure 19. Among other things the circuit prevents fluttering of the power level occasioned by sporadic movement of the pencil over the tissue.

Gas characteristics

The specification explains the importance of having a sufficiently high flow rate of the gas so as to clear fluids, such as blood, from the surface of the tissue. This allows the electrical energy from the beam to enter the tissue stroma rather than having an effect only on the surface and thereby creating only a temporary coagulum which can easily be lost. An improved eschar is said to be obtained as a result.

Fulguration, or "macro" mode, requires a relatively high gas flow rate and the type of gas employed should be one that supports arcing. In thermal desiccation, or "micro" mode, a lower flow rate is adequate and the gas should be one which can be easily ionised so as to transfer electrical energy as a diffused current without arcing.

Argon is the preferred choice for fulguration as it readily creates an arc hole reticulum. It is denser than air and therefore clears the surgical site more readily. Typical flow rates of 4-13 standard litres per minute issuing from a nozzle of 0.1" diameter spaced 0.5 - 1.5 centimetres from the tissue have achieved satisfactory results. The greater number of arc pathways which results ensures more uniform distribution of electrical energy over the surgical site, and any argon absorbed in the bloodstream of the patient is cleared with the first pass through the lungs.

Helium is the preferred choice for thermal desiccation. Its low breakdown voltage enables low levels of energy to be transferred to the tissue without arcing. For the same pencil size and spacing as mentioned in connection with fulguration, flow rates from 0.08 - 1.6 standard litres per minute are all that is necessary for desiccation. The lower gas flow rate is not a handicap to clearing fluids from the surgical site since, where desiccation would be performed, there is unlikely to be much fluid. The gas flow rate is still sufficient to maintain an inert atmosphere at the surgical site. Fulguration can nevertheless still be achieved with helium if the electrical power delivered to the unit is increased to above 20 watts.

ESG impedance characteristics

The internal impedance characteristics of the ESG must be broad, as shown in figure 20, to achieve efficient energy transfer. The figure shows 100 watt and 50 watt curves as being relatively broad compared to corresponding curves from the ESG disclosed in US 4429694 (McGreevy) and curves from another, earlier, ESG.

The previous approach was to match output impedance of the ESG to typical tissue impedance, *ie* 300 - 600 ohms. US 4429694 (McGreevy) recognises that a superior haemostatic effect could be obtained by a higher output impedance in the ESG. Despite creating arcs of greater length and shorter duration, power delivery fell away above 1,500 ohms. The US patent recognised that there was a practical limit to the upper limit of impedance, above which directional control of the arc became ineffective.

By confining the electrical energy path within the gas jet, as in the present invention, the ESG impedance can be raised significantly. The broad impedance range is necessary at the lower end to deliver adequate power into tissues perfused with blood or other fluid which may have an impedance of only 10 ohms, and at the upper end to initiate ionisation in the gas jet, to sustain ionisation at high gas flow rates and to maintain ionisation when the pencil is distant from the tissue. A broad curve helps improve the capacity of the arcs and energy coupling pathways to respond to the instantaneous state of the system as a whole and to be less influenced by the many factors which influence the shape of the ESG load curve. The

specification acknowledges that the broader impedance curve was obtained by recognised techniques, such as "larger magnetics" in the output transformer, increase in the number of secondary terms, and higher limits in the limit circuits in the power supply control circuit shown in figure 16.

The body of the specification concludes with a comparison of results obtained using the invention and using comparable techniques performed with a unit as described in US 4429694 (McGreevy). Fulguration of 16 canine livers and spleens was performed. At seven days after surgery there was little difference but the invention gave significant improvements at 28 days following surgery. Equally significant improvements were obtained in comparative desiccation procedures.

The patent as granted contains 56 claims, of which claims 1, 45, 49, 54 and 55 are independent. They are all directed to an electrosurgical unit. Although I will need to consider all 56 claims in due course, I will confine my attention for the time being to claim 1, which reads:

> "1. An electrosurgical unit for creating an improved eschar in the stroma of tissue, comprising:
>
> means for conducting a predetermined gas in a jet to the tissue at a predetermined flow rate sufficient to clear natural fluids from fluid-perfused tissue and to substantially expose the tissue stroma; and
>
> means for transferring electrical energy at a predetermined radio frequency range in ionized conductive pathways at a predetermined power level within the gas jet in an electrical circuit which includes the tissue to create the eschar."

In terms of actual hardware the claim is straightforward enough. It is directed to an electrosurgical unit and it comprises only two means, namely means for conducting gas in a jet to the tissue and means for transferring electrical energy within the gas jet to have an effect

on the tissue. Furthermore, the two sides are in agreement as to the implications for the scope of the claim of the use of the word "for" in all three contexts in which it appears, namely "an electrosurgical unit **for** creating an improved eschar", "means **for** conducting a predetermined gas in a jet" and "means **for** transferring electrical energy". As Mr Kitchin agreed, the word means "suitable for" or "adapted for", and I accept that. However, there were several areas concerning the true construction of the claim over which the parties differed. I will deal with these contentious areas in turn.

The first concerns the requirement of an "improved eschar". Mr Hamer, on behalf of the applicants, posed the question "improved compared to what?". Mr Wells' affidavit is relevant in this regard. He is experienced in the field of research and development of medical instruments, including diathermy, and between 1970 and 1992 was first a Senior Engineer and then a Principal Engineer and physicist to the Department of Health Technical Branch. He was in charge of a group of physicists and engineers providing advice on the safety and design of medical surgical equipment, including diathermies. His affidavit describes how he was impressed with the results which he saw when he witnessed the Birtcher ABC machine being used in a liver resection surgical procedure at the Royal Liverpool Hospital in the presence of Mr Graeme Poston, who has made a separate deposition. Mr Wells' conclusions were that the eschar was particularly effective in stopping bleeding, required little surgical skill to create, was relatively thin and uniform in thickness, was very flexible compared to other eschars he had observed, and appeared to be very adherent to the tissue. He says specifically "there is no doubt in my mind that the eschar produced by the Birtcher ABC equipment is unique and is probably almost perfect". He goes on to say that the Birtcher ABC device achieved better eschar and coagulation characteristics than any of the units mentioned in the publication "Health Equipment Information" No 184, June 1988, ("HEI"), which is a report on an evaluation study carried out by the DHSS on various surgical diathermy units which were available at the time. Mr Wells was involved in the preparation and editing of this evaluation.

When Mr Wells was cross-examined by Mr Hamer on the nature of the eschar which he had witnessed being produced in Liverpool, he explained the particularly difficult conditions under which the procedure was carried out. The patient had "the most enormous tumour ... the liver

[was] highly perfused ... many of the blood vessels enlarged. The chap had other problems. He was probably on anti-coagulants, to some extent. The net result is that the possibility of bleeding was elevated." In answer to the question, "how can you tell that it had unique properties?" he confirmed that the eschar "was certainly thin because the surgeon was able to palpate the surface. You can see the outline of the tissue below it. This is quite unusual. If you form an eschar with a normal machine, there is so much carbonization and tissue damage on the surface that you cannot usually see things below". He went on to say that the surgeon made a cut to remove a piece of tissue and he could see "the surface was quite redder and much thinner than I would have expected".

Mr Wells' own experience on studying the effects of laser damage on tissue gave him insight into what he would expect as the normal depth of necrosis using lasers at different wavelengths and also in ordinary surgical diathermy over a period of some 20 years. Mr Wells was clear in his testimony as to the respects in which he regarded the eschar produced by the Birtcher ABC device to be "improved".

Not surprisingly Mr McGreevy, the inventor of the device, was absolutely clear that he too understood in what ways the eschar was improved. The patent itself describes the eschar created by the present invention on pages 12-13 as being:

> "characterised by an outer generally uniform depth reticulum of arc-created holes penetrating the tissue from a surface of the eschar; arc holes which are smaller in size, greater in number, more comparable or uniform in cross-sectional size, and substantially more uniformly spatially distributed over the surface of the eschar; and a greater wall thickness of tissue between adjacent arc holes which provides pliability without cracking. Below the arc hole reticulum there exists a generally uniform-depth thermally desiccated layer which separates the arc hole reticulum from the unaffected tissue. The thermal desiccation layer of the fulguration eschar available from the present invention is also shallower in depth compared to the thermal desiccation layer of an eschar created by prior fulguration techniques. In addition, the fulguration eschar

created by the present invention is further characterised by a substantial absence of charring and carbonization in the arc hole reticulum."

And on page 14 the specification states:

"compared to prior techniques of thermal desiccation coagulation, the thermally desiccated layer of the eschar obtained from the present invention is relatively thin and uniform in depth. It is characterised by an absence of perforations created by the electrical energy."

The specification clearly presents the "improved" eschar produced by the invention in comparison with prior eschars produced by prior equipment and technique.

Mr McGreevy's affidavit addresses the resulting eschar in some detail. Beginning at paragraph 38 he compares the eschar produced by his invention, as shown in figures 21, 22, 23A and 23B in the patent, with a prior art eschar shown in figures 1, 2, 3A and 3B. The prior art equipment used for comparison purposes was the System 5000 generator which, in his opinion, was the best available at the time. True colour photocopies of the colour micro photographs from which the figures in the patent were derived are exhibited at FTM2 in the case of the prior eschar and FTM3 in the case of the invention. Also at FTM4 are a series of similar colour photocopies of colour photomicrographs prepared for use in the Colorado litigation. Mr McGreevy explains in paragraphs 40-41 that he conducted experiments for the purposes of the Colorado litigation (which found that a device known as the Beamer One device was an infringement of the US counterpart of the patent-in-suit) as well as tests involving the Birtcher ABC and a model of the Dennis System. His analysis of the results in paragraph 41 indicates that all of the characteristic features of the eschar were to be found in the eschar created by the invention in suit. He says specifically:

"the eschar created by my invention ... was an outer generally uniform depth reticulum of arc-created holes penetrating the tissue from a surface of the eschar, with the arc holes having substantially comparable cross-sectional sizes, substantially uniform

spatial distribution over the surface of the eschar, and with the tissue of the reticulum between adjacent arc holes providing pliability without cracking. A generally uniform depth thermally desiccated layer of tissue separates the arc hole reticulum from the unaffected tissue below the uniform thermally desiccated layer. The arc hole reticulum is generally characterised by a shallower depth, by arc holes having generally smaller cross sectional sizes, by a larger number of arc holes distributed over a specific surface area of the eschar, more uniformity in the arc hole size, and by greater tissue wall thickness between adjacent arc holes, compared to the eschar created by prior art fulguration. Further still the thermal desiccation layer of the improved eschar is characterised by a shallower depth compared to the thermal desiccation layer of the prior art eschar created by prior art fulguration yet, further, the improved eschar is generally characterised by a substantial absence of charring and carbonization of the arc hole reticulum ..."

I should mention here that the devices with which the invention was compared in the experiments were those using standard electrosurgery without the use of gas. They include Valleylab Force 4, Valleylab Force 2, Birtcher 5000, Valleylab SSE3B, Aspen Excaliber, Birtcher 4400, Birtcher 3000, Valleylab SSE4, Valleylab SSE2L and Bovie CSV.

Mr McGreevy continues with a description of further comparative tests that he carried out during the course of the Colorado litigation which showed, according to his analysis, that his invention provided a greater uniformity of penetration and spread than was possible with the prior apparatus.

In cross-examination Mr McGreevy indicated that the effects he obtained at the inception of the invention showed a distinct improvement over what he had experienced previously. He noticed that there was an improved arc tunnel reticulum even when the apparatus he was using was no more than a crude set-up consisting of a straw into the side of which he had stuck a needle connected to a generator which he had to hand, and in which he simply blew through the straw towards a tissue sample held in front of the straw. It was that success which led him to look for ways to develop the idea into a prototype. He went on to say that he would have

looked at the walls inside the arc tunnels to see how red and dry they were and he would have made microscopic sections for examination under a microscope.

Mr McGreevy's evidence attests to his being able to judge the quality of an eschar produced by electrosurgical techniques and apparatus. His own CV confirms that he has not been trained as a surgeon and has no pretentions to be one. He is an engineer, with degrees in zoology and electrical engineering. In the period between 1965 and 1979 he was employed as an engineer of one kind or another, ranging from aircraft radar through electro-physiology to clinical engineering. His involvement between 1979 and 1989 continued on that track with research, development, evaluation and management of electromedical equipment. It is undoubtedly as a result of this close contact with the medical side of electrical engineering that he felt himself able to recognise an improvement in what had gone before in terms of quality of eschar. In his view it plainly did not require the skills of a surgeon to be able to make that judgment. For my part, however, since the quality of an eschar is essentially a surgical question, I would be more likely to be convinced by the direct judgements of surgeons than by those of engineers who, notwithstanding their long and distinguished involvement in the technology of electrosurgery, must presumably, in forming their own assessments of eschar quality, rely principally on the judgement of those whose professional reputation actually rests upon such matters as the effectiveness of sealing of surgical lesions, *viz* surgeons.

Three surgeons have made depositions in these proceedings about the eschar. Both Mr McCloy and Mr Poston have deposed to the effectiveness of the Birtcher ABC in various types of surgery. In particular, Mr McCloy, Administrative Head of Department, Senior Lecturer and Honorary Consultant Surgeon at the Manchester University Department of Surgery, Manchester Royal Infirmary, says of the ABC device that it is simple to use, can be rapidly set up and used to stop bleeding quickly where other devices would not have been successful, reduces the amount of surgical time, and has been particularly successful in sealing lymph nodes. However, he makes no reference to the nature of the eschar itself. Similarly, Mr Poston, Consultant Surgeon at the Royal Liverpool University Hospital specialising in liver surgery, is particularly impressed with the ability of the ABC device to save blood loss, reduce post-operative recovery, reduce surgical time, reduce abscess complications, *eg* from bile

leakage, and reduce the number of, or eliminate altogether, instances where it is necessary to re-open a patient to correct a problem arising from internal bleeding or bile leakage. Although he attributes these advantages to the coagulation properties of the ABC, he too does not describe the eschar itself, other than to say the Birtcher ABC has the ability "to create a good eschar".

Dr Silverstein is a Medical Doctor in the USA and Professor of Medicine at the Department of Medicine of the University of Washington, Seattle. His speciality is gastroenterology and his CV indicates that he has had a distinguished career in the field of medicine, particularly in gastroenterology endoscopy. In his affidavit he explains that he was the principal investigator of a research team which was assembled between 1974 and 1981 for the purpose of evaluating various methods of coagulating bleeding ulcers. The team was funded to the tune of $1 million from the US Government, and produced in November 1979 an article entitled "Evaluation of Electro fulguration in control of bleeding of experimental gastric ulcers", otherwise known as the "Dennis" article, which I have already mentioned. Despite extensive investigation of gas electrofulguration as reported in the Dennis article, the research team found that "tissue injury was unpredictable and deep" and that they "would not consider electrofulguration for clinical use unless the technique (could) be modified to reduce the depth of injury while preserving haemostatic effectiveness". The Dennis article itself sets out the strategy which the research team adopted in order to evaluate the effectiveness of their test procedures, which involved taking slices of treated tissue and examining them under a microscope. As far as Dr Silverstein's affidavit is concerned that is the full extent of his description of the eschar. However, he explains that he was a witness in the Colorado litigation, and his testimony in those proceedings is exhibited to his affidavit. But that testimony does not touch on the nature of the eschar. I conclude, therefore, that the evidence of the three surgeons does not assist me to construe the term "improved eschar" in claim 1.

The issue of whether an eschar produced by the invention can objectively be determined to be "improved" was also touched upon when Dr Levitt was questioned by Mr Kitchin on the colour photomicrographs of cross-sections through a prior art eschar (figure 3A) and through an eschar produced by the invention (figure 23A) corresponding to the monochrome figures

3A and 23A in the patent. The colour versions were the originals from which the monochrome copies were taken.

Dr Levitt is a Senior Lecturer in Physical Chemistry at Imperial College and he regards himself as "fully familiar with techniques of conducting electrical energy through gases". He has also conducted research into high temperature gas kinetics and energy transfer in gases. However, in his declaration he acknowledges that he is "not an expert in the practice of surgery", and in cross-examination he confirmed also that he was not "a medical man". Under Mr Kitchin's cross-examination he agreed that he was not qualified to comment on matters touching on the medical or surgical aspects of the issues involved in this case. In particular, he had not been involved in manufacture of electrosurgical equipment, nor the design or improvement of diathermy. Furthermore, he confirmed in court that the documents he had been asked to review in the case - namely the patent in suit, the statement of case, the counterstatement and all of the prior art documents cited in the statement on which the applicants base their attack on the patent - were sent to him by Lloyd Wise, Tregear & Co, the agents for the applicants for revocation. He was asked by them to "review the patent" and "to give an opinion on the extent to which the electrosurgical units described therein, and particularly those defined in the claims, differ from what is disclosed in those documents". He stated that he had not seen any of the documents, including the patent in suit, before the end of 1993. He willingly agreed that he was therefore having to "try and reconstruct the position of somebody skilled in the field" as of 1986 or 1987. He also accepted that he was "having to bring a measure of hindsight" into the question concerning the relevance of the Morrison and Brayshaw patents to the patent in suit in conjunction with other material brought forward in connection with this dispute, and he did not "claim a general knowledge of all the diathermy equipment that was available in the mid-1980s".

The situation as regards Dr Levitt, then, is that he has been called as an expert witness for the applicants but, by his own admission, his area of expertise is solely in the context of matters affecting the flow of electrical energy in a gas and **not** the surgical effect of electrosurgical apparatus in general and diathermy in particular, and he appears to have had no knowledge of the relevant art at the relevant time.

However, notwithstanding Dr Levitt's limited qualification to answer questions involving medical knowledge, he made what I regarded as a valid point concerning lines that had been drawn on the photomicrographs of the eschars produced by the prior art and by the invention. These lines allegedly showed the extent of the divisions between the arc reticulum and the desiccation layer on the one hand, and between the desiccation layer and the underlying, unaffected tissue on the other. Dr Levitt commented that he was unable to discern any particular significance in the choice of location of the line denoting the transition between the arc hole reticulum and the desiccation layer and he was therefore unable to form any meaningful opinion on the difference between the prior art eschar and the eschar created by the invention. While there was a *de facto* width difference between the eschars depicted in the figures, there was also an apparent difference in scale between the figures which tended to mask any differences, and there was no way of knowing the conditions under which the comparisons were made. I too was left unconvinced that the evidence of the colour photomicrographs, or their monochrome versions reproduced in the patent specification, would have enabled the skilled man to judge the relative qualities of the eschars.

Mr Hamer made the general point that the proprietors' counterstatement made no reference to "improved " having any effect at all in claim 1. Relative words are not usually approved in claims because of their lack of precision. Exceptions to this general rule can be accepted where the skilled man would know, or where evidence can demonstrate, that the word "improved" would import some significant meaning. In the present case, said Mr Hamer, we are not looking at exact quantities having precise boundaries as would arise, for example, where a feature is presented in terms of a numerical range or where the skilled man would understand the difference between, say, a "short spark", as in claim 8, and a "long spark". The situation is made even worse, in Mr Hamer's submission, because the claim is not dealing with a single factor, like "short" or "smooth", but a combination of factors which add up to make the "improved" eschar.

Even if one could answer the question "improved compared with what?", Mr Hamer submitted, there remained the question, "improved by how much?". The specification itself states on page 94 at lines 8 and 11 that the eschar in the liver was 93% as thick as that

produced by the prior art technique. Mr Hamer did not regard that as much of an improvement. He highlighted Mr McGreevy's testimony where, under cross-examination, he described the improvement he had obtained "simply by blowing down a straw", to use Mr Hamer's oversimplification, and Mr McGreevy's dismissal of Morrison's attempts which, according to page 1417 of Morrison's testimony in the Colorado litigation, in fact described an eschar of "only half the depth of ... eschar formed than was obtained with the other types of electrodes". Although Mr McGreevy did not regard that as an improvement over the prior art, Mr Hamer concluded that these apparently differing perceptions by Mr McGreevy illustrated the personal nature of relative terms. It may even, he suggested, mean that depth of eschar alone is not an indication of improvement.

Taking all of this into account, it seems to me that there are problems inherently associated with the way the eschar has been characterised as "improved" in claim 1. It appears from Mr McGreevy's testimony describing the eschar that examination of it carefully enough to judge whether indeed it is "improved" requires a section or sample of tissue to be taken and closely scrutinised to establish whether or not it has the required characteristics. As has been stated in the patent and by Mr McGreevy, the eschar not only has the surface finish that is said to characterise it but it also has very specific qualities under the surface. I refer in particular to the desiccated layer beneath the arc hole reticulum. In the patent the desiccation layer is said to be shallower and more uniform than in prior eschars. That description is matched by Mr McGreevy's own description of the desiccation layer in his affidavit.

That must surely pose a problem to a potential infringer. If he had devised his own equipment and used it under controlled conditions in the laboratory on animals or on *ex vivo* tissue it would be a comparatively straightforward task to take samples for testing, as Mr McGreevy himself acknowledges that he did in the Colorado litigation. However, under "live" conditions in theatre, not only might it be impracticable to take a sample from a patient after use of the equipment, but it might be life-threatening to do so, depending on the severity and/or location of the situation leading to that use. Under those circumstances the potential infringer would find it extremely difficult, if not impossible, to ascertain with any degree of confidence whether he had infringed the specific conditions set out in the patent claim. It might be

possible to concede that the surface effects on the treated tissue and in the arc hole reticulum, *viz* the pliability, thinness, evenness of arc holes, comparative thickness of tissue between arc holes, absence of carbonization etc, could be judged to be better or worse than the corresponding properties of the patent. But would the eschar created by this hypothetical potential infringer necessarily have to have all of these aspects on view for there to be a conclusive judgment that it was indeed "improved"? Although it was said for the proprietors that Dr Morrison did not obtain the improved eschar claimed for this invention and did not describe to any real extent such an eschar, his testimony in the Colorado litigation did put his impressions of the outward appearance of the eschar which his equipment had created in the following words, " ... very nicely dried and fused, gently brownish area of tissue ... as though you had painted it gently brown, rather than spattered it with brown and black." While there is no evidence before me to show either way whether the arc hole reticulum and the underlying desiccation layer in Dr Morrison's eschar had the characteristics claimed for the invention in suit, it does serve to illustrate the difficulties of assessing the qualities of an eschar purely from the surface when claims are made for improvements extending deeper into the tissue. On this basis I see no evidence to suggest that I should construe the reference to an "improved eschar" in such a way as to have a meaningful effect on the scope of claim 1, and I so conclude.

There was discussion of the significance for the construction of claim 1 of the several uses in the claim of the word "predetermined". The first occurrence, in relation to the "predetermined gas", gave the least cause for dispute. It is apparent from these proceedings that the gas has to be capable both of ionisation and of carrying an electrical discharge current to the tissue being treated. The choice of gas is dependent, to a significant extent, on the nature of the treatment being, or to be, effected. That was made evident from the specification itself. It is stated specifically in the passage beginning on page 80 at line 21 and ending on page 81 at line 15 that highly perfused bleeding tissue requires effective coagulation which is best achieved by the use (in "macro" mode) of a gas "which will readily conduct electrical energy in arcs", whereas thermal desiccation (or "micro" mode) requires a gas which is "easily ionized and which transfers electrical energy in the jet as a diffuse current without creating arcs". Pure argon is preferred for fulguration while helium is chosen for desiccation owing to its "lower breakdown voltage and lower impedance".

Mr McGreevy, under cross-examination, confirmed that "argon is the one most typically used in macro mode" and that, although helium could be used in macro mode, "it would not work terribly well", but he could not comment on whether argon could be used in the micro mode. The electro-physical properties of the gases, therefore, in terms of ionization, is at least one determining factor in the selection of gas for use in treatment on tissue. For all practical purposes the specification has narrowed the options down to argon and helium (see claim 14 for example), although the claims in general clearly comprehend other gases, and the description at page 83 line 25 to page 84 line 10 suggests that inert gases are the most suitable owing to their ability to clear oxygen from the treatment site and the predictability of their voltage breakdown characteristic. The range of inert gases is small, by definition, and to that extent the teaching of the patent specification as regards the "predetermined" nature of the gas is comparatively constrained. I am sure that the man skilled in the art of electromedical equipment would appreciate that for a gas to be suitable for gas electrofulguration, it must have the kind of characteristics which the specification has identified, and I am satisfied that claim 1 is clear and adequately definitive in this regard.

The meaning of "predetermined" when applied to the gas being conducted in a jet to the tissue "at a predetermined flow rate sufficient to clear natural fluids from fluid-perfused tissue and to substantially expose the tissue stroma" is not so clear cut, and is a matter of dispute. In this context the concept under consideration is one where the success or otherwise of the "predetermined" or selected flow rate is judged by the result. I note, in passing, that the proprietors' commercial product, the Birtcher ABC, has an automatic mode in which the gas flow rate is caused to "track" the electrical power applied to the device. I do not, in the context of these proceedings, have to address the question of whether such an automatic tracking arrangement is encompassed within the term "predetermined flow rate". The Birtcher ABC, it was explained by Mr McGreevy, produces a gas flow rate with a minimum of 4 litres per minute and a maximum of 10, although the specification comprehends a range from 4 to 13 litres per minute. In the manual mode the flow rate can be set independently of power but within safety limits designed to prevent an excessive flow rate being used in relation to the selected level of power so as to reduce the risk of carbonization.

In the demonstrations which were carried out on the second day of the hearing Mr Schueller-Iwesen for the applicants conducted comparative tests using different handpieces. In each case the gas flow rate was measured to be four litres per minute (the equipment being demonstrated not having a gauge) and was gradually reduced to show the transition from a fulgurating beam to a series of jumping sparks until eventually, with no gas, there was a return to normal spray coagulation. In Mr McGreevy's demonstrations he kept a constant power setting of 75 watts which, in the automatic mode employed, would have caused there to be a corresponding flow rate somewhere between four and ten litres per minute. The intention behind Mr McGreevy's demonstration was, among other things, to show the effectiveness of the Birtcher ABC at clearing fluids from the treatment site and of creating an improved eschar, and in this regard the question of whether the gas flow rate was "predetermined" is perhaps secondary.

Although the demonstrations were interesting in showing me the nature of the devices concerned, they were of little value *per se* in helping me resolve the issues before me. The conditions of use were not as controlled and regulated as they would have had to be for a proper scientific assessment, and of course the demonstrations were carried out on dead tissue, albeit taken from the same piece of "fresh", but undeniably deceased, liver. Also, although it was possible to observe (at a distance) the superficial effect of the various devices, no further physical tests or measurements of the eschars were carried out to demonstrate whether or not they had all of the properties which Mr McGreevy had testified to as regards the invention or those properties which I have already alluded to as being stated in the patent specification itself. It was also pointed out by Mr Söring that the ESG which Mr McGreevy was using in his demonstrations was the latest from Birtcher, namely the 6,400 which had been designed in 1991 and had a completely different gas flow characteristic in the hand-piece and an impedance two or three times that in the unit described in the patent, whereas that used on behalf of the applicants, namely the Bovie, was the closest they could get to what Mr McGreevy would have had at his disposal at the time the invention was conceived and under development.

In particular, even though Mr McGreevy attempted to demonstrate the effectiveness of the Birtcher ABC in clearing fluids, under the circumstances and conditions of the test I was not

able to judge whether or not it was any better or, for that matter, any worse, than any of the devices demonstrated by the applicants. Those devices, I should say, were reconstructions of prior art devices which the applicants were attempting to demonstrate were just as effective in their own right as the invention of the patent in suit. The weight that I feel able and justified to attach to these demonstrations is therefore minimal.

By the same token, the video recordings which were viewed in court were of interest as an introduction to the technology but, perhaps especially as regards the promotional video, caution must be exercised before reading much into them. No information was evident as to the conditions under which the recordings were made or, more importantly, whether the equipment that was seen in use, and equally the equipment, particularly the ESG, which was not seen, was in accordance with the equipment claimed in the patent.

However, it remains a feature of the claim that the means for conducting the predetermined gas must do so at a "predetermined flow rate" which is sufficient to achieve two effects, *viz* "to clear natural fluids from fluid-perfused tissue" and "to substantially expose the tissue stroma". Mr Kitchin emphasised this duality in his final address. He said:

> "First of all, the gas flow must push back and hold back the blood from the surface sufficiently far so that the arc energy stays in the column until it reaches the cleared stroma. This involves a consideration of the density of the gas, the diameter/size of the column and the flow rate and the pressure. What the machine must do is be such as to permit this to occur when it is delivered at fluid-perfused tissue. Of course, one could use it for any other purpose. One can direct it at the wall to dry paint, but that does not mean that the claim is insufficient or in any way unclear."

I need to establish what this requirement of "predetermined flow rate" would mean to the man skilled in the art. Mr Kitchin invited me to consider the evidence of Mr McGreevy. His explanation of the development of the invention, as set out in paragraphs 15 to 24 of his affidavit, includes recognition of the fact that profuse bleeding would overwhelm the ability of an electrosurgery generator to transfer adequate energy to the tissue to create coagulation.

The energy that was transferred was dispersed instead in the rapid blood flow and resulted in a floating or superficial eschar which inevitably loosened and allowed re-bleeding. He recognised that fluid needed to be cleared from the site while the energy was being applied. The need to clear fluids simultaneously with directing the energy into the tissue led him to the idea of directing the electrical energy to the tissue by a directed flow of ionized gas. That led him to try the straw and needle and showed him that there was promise in the idea.

Directing his attention then to specific aspects of the concept in order to maximize its potential, Mr McGreevy began experimenting with flow rates and evaluating the effect on fluid clearance. He became convinced that "reasonable" flow rates would achieve the objectives of clearing fluids "while still containing the ionized pathways and the electrical arc energy in the flow stream to transfer the electrical energy to the cleared area of the tissue." He attributed the success of the resulting apparatus to the synergistic relationship between fluid clearance and containment of the electrical energy within the ionized pathways in the gas stream. Under questioning, Mr McGreevy was adamant that the energy transfer was by current conduction (specifically I^2R losses), not by a field effect, and was more than a surface effect.

The question of actual flow rate and the effect on the tissue, or more significantly from a safety standpoint, the effect on the body of the patient undergoing treatment, was the subject of particular concern and debate in these proceedings. The figure for the flow rate of gas which led to much of this debate was four litres per minute. As far as Mr McGreevy was concerned that figure was the practical minimum flow rate for the invention to create the effects claimed. It was also the minimum value quoted for the fulguration (macro) mode in the patent specification, as I have already noted.

When Mr Hamer was questioning Mr McGreevy on the flow rate it appeared to me that he was attempting to establish what was the "real" flow rate that would be used under surgical conditions so that he could compare it with the prior art for novelty and inventive step arguments. However, the questions and answers are just as relevant for construction and sufficiency in this respect. Mr Hamer made the point that "large" flow rates would not seriously be considered for use in closed surgical procedures where the gases could not escape

from a body cavity, for example in laparoscopic procedures, gastric ulcers and knee joints. Mr McGreevy said he had not seen the list containing the current recommendations for conditions of use for at least six years and therefore could not say. He had left Birtcher before they commenced testing on endoscopic systems but he understood from the literature that the Argon Beam could be used safely and successfully in such procedures.

Mr Hamer came down specifically to four litres per minute for the next series of questions. Mr McGreevy was quite at ease with the possibility of extracting gas at the same rate as it was blown into a body cavity under controlled operating conditions without imposing any risks to the patient. The next series of questions were not, to my mind, dealt with entirely satisfactorily. In a confined space, Mr Hamer asked, would it be possible to use a smaller cross-section nozzle and reduce the flow rate correspondingly and yet still obtain the same effects? In response to Mr McGreevy's answer that you would need sufficient **mass** flow as opposed to **volume** flow, as had been demonstrated on the second day of the hearing, the discussion appeared to go down a blind alley. Mr McGreevy would only be drawn to say that "sufficient" gas flow was necessary to achieve the fulguration sought, whereas Mr Hamer seemed to be seeking a less equivocal answer. It was a question of momentum, said Mr McGreevy. It was not a case of reducing the nozzle size and still having a high velocity, since all that happened then was that the RF coupled into the side walls of, or the area surrounding, the depression in the fluid caused by the gas jet, and that diminished the energy available at the tissue itself. As an aid to understanding this phenomenon, I was handed a set of sketches illustrating the spread of the argon beam. That led the discussion further into whether or not the arcs contained within the beam took a helical path to the tissue. According to Mr McGreevy the length of the arcs is determined by the impedance of the generator and, come what may, "the length the arc wants to go is fixed". Mr Hamer did not accept that the arcs were helical. Colour photomicrographs of the arcs were handed up in an attempt to show that this was indeed so. While there do appear to be helices at the outermost boundary of the jet, it cannot be deduced with any certainty that the whole of the jet is made up of helices, and indeed it was suggested by Dr Levitt on behalf of the applicants that the helices were in fact nothing more significant than turbulence.

Mr McGreevy finally came to the point of acknowledging that the mass flow was the important parameter in achieving effective fulguration and that it was not possible to state what flow rate would be necessary for any particular size of nozzle as it was the spread of the arcs on the tissue that was material. When I interjected to ask Mr McGreevy whether or not the spread of the arcs on the tissue was "broadly independent of the diameter of the gas nozzle", he answered that it was not entirely so but "was very strongly affected by the electrical characteristics of the generator". If you used a smaller nozzle you would need to train the jet on the tissue for longer for it to spread sufficiently to create a fulgurated eschar, otherwise there would merely be a small spot of desiccated material. "I can tell you with absolute certainty that the spot size is not dependent on the diameter of the column", said Mr McGreevy. Eventually, he agreed that "to be practical ... in most situations ... in the macro mode" it would still be necessary to supply four litres per minute of argon with any nozzle of a useful size and later, "to ensure that the fluids are cleared, using argon arcing to tissue, the practical number that you need is four litres per minute". Mr Kitchin, in his closing address, made the point in this connection that the crucial question concerns at what levels of gas flow in relation to fluid-perfused tissue one gets the benefit of this invention. It was immaterial whether other devices operated with a lower gas flow rate, such as mentioned in page 18 of the Force GSU Unit operating manual exhibited to Mr Akle's affidavit and which specifies a range of 2 to 16 standard litres per minute. The crucial fact, according to Mr Kitchin, was that they have the capacity to operate at a level above that, such as four or more litres per minute.

Mr Hamer too, in his final address, took me to parts of the operating manual. The manual from which the exhibit was photocopied bore an "Effective Date: September 1991" and the parts of interest to Mr Hamer were the various cautions and warnings against using the Force GSU Unit under certain conditions. Thus, its safe and effective use was said at the top of page 4 of the manual to be, "to a large degree, solely under the control of the operator". In other words, the effectiveness of the device is not built into the equipment as was claimed for the Birtcher ABC by Mr Wells under cross-examination by Mr Hamer in the words "the eschar is not a function of the operator. It is a function of the equipment". To a certain extent that is contradicted by Mr McGreevy himself in the testimony to which I have just referred, namely

where he stated that it was necessary to train the jet on the tissue for it to spread sufficiently to obtain a fulgurated eschar if you were using a smaller nozzle. That clearly suggests that the apparatus is not inherently capable of automatically adjusting the parameters to obtain the characteristic eschar in dependence on the nozzle employed. Indeed Mr Wells was obliged to concede that the invention will not produce an improved eschar in all circumstances, whatever the surgical operations.

That strikes me as a significant distinction from *No-Fume v Pitchford* (1935) 52 RPC 231, where it was a simple matter to test whether or not an ash receptacle met the terms of the claim. Either the smoke came out or it did not. In the present case there are caveats that appear to be recognised by both sides to the effect that it will not always be possible for the invention to operated so as to produce the desired results. That, I would suggest, is a serious constraint in construing the invention as claimed in claim 1.

On page 5 of the manual there is a warning not to use the device in surgical procedures which would introduce argon gas into closed body cavities, such as laparoscopy or endoscopy, because of the risk of gas embolism. Although I take note of these points it must be recognised that they are made in connection with a manual which was published after the filing date of the patent, and which is not associated with the Birtcher device itself, being concerned with apparatus made under licence from Birtcher and there being no evidence that it is the same as a Birtcher device or, more significantly, as the device according to the patent. It may have undergone further development or refinement or the recommended conditions of use may have evolved since the ABC was conceived and developed, and certainly after Mr McGreevy's departure from Birtcher. That the manual also mentions gas flow rates as low as 2 and as high as 16 litres per minute tells me very little about either the state of the art or the teaching of the patent to the skilled man at the time the invention was conceived, filed, published or granted.

Mr Hamer then moved on to questions of embolism. He first suggested to Mr McGreevy that effective fulguration could be carried out with lower flow rates, as low as a quarter of a litre per minute. Mr McGreevy replied that he regarded this as "entirely impractical". In suggesting that the effective range of the device was wider than Mr McGreevy had envisaged

or than was described in the patent Mr Hamer appeared to be seeking to match the invention with prior art which had been (successfully or not) operating at this lower rate. Mr McGreevy was able to concede that there may be circumstances under which the invention would work at such low flow rates, but he prefaced any agreement to this with provisos as to those circumstances, for example the tissue having been wiped with a gauze immediately prior to application of the beam, or occluded by suture or clamp in the case of large arteries. Where there were arteries in excess of 3mm across it would be a case of weighing the risks of causing an embolism against the overall benefit to the patient by rapidly stemming the flow of blood. Mr McGreevy said he had done this himself many times in animal surgery.

It was a question of the surgeon using his ordinary skill to decide whether it was relatively safe to aim the jet towards a blood vessel of this size. It would be advisable not to do so where the vessel, specifically a vein of 2 to 3mm, was open and empty and under negative pressure. The surgeon would aim the jet at a shallow angle to the vessel and could see the surface of the blood in the vein and watch the eschar being formed. The exercise of commonsense was sufficient to reduce the risk of embolism, even though Mr McGreevy acknowledged that with any surgical procedure involving the blowing of gas there remained **some** risk of embolism. In the case of an artery of similar size still "pumping", as it was graphically put by Mr McGreevy, the surgeon would be more inclined to use the device as the surface of the blood could be seen and the development of the coagulation observed.

While Mr McGreevy's view of the proper construction of claim 1, as the inventor, is significant, I was invited by Mr Kitchin also to consider the evidence of Mr Wells. I have already considered Mr Wells' testimony in connection with his observations of a surgical procedure in Liverpool alongside Mr Poston. Mr Wells states in his affidavit that he believed there was a "remarkable synergism" between the gas jet and the radio frequency energy, and that "the patent calls for a device which produces a gas jet which must have high flow rates". The high flow rates would normally produce embolism, but this is not found to be problem because of the way in which the eschar is formed. Mr Wells referred specifically in cross-examination to flow rates of four litres per minute being necessary to achieve the synergistic effect. When questioned more closely by Mr Hamer on the basis for this conclusion, it

became apparent that Mr Wells was relying not on any of his own extensive experience in the electromedical equipment field, but on the teaching of the patent itself and on documents and evidence arising out of the current proceedings. He referred particularly to Morrison's testimony in the Colorado litigation, directing Mr Hamer's attention at one point to the fact that flow rates used by Morrison's team were held down and that consequently they did not achieve "a good result". Mr Hamer countered with the observation that Morrison did say that he got good coagulation but he did not describe the eschar. In consequence, Mr Wells could not possibly claim that because Morrison did not describe the eschar he got bad coagulation, nor could he say from his own knowledge whether or not Morrison was successful or unsuccessful in producing an eschar having the same or similar characteristics to the patent in suit. In fact, as I have already indicated, Dr Morrison did describe the eschar which he had produced, albeit superficially, in page 1417 of his testimony in the Colorado litigation.

Dr Levitt was also questioned by Mr Kitchin as regards the issue of fluid clearance. Following questioning about the desirability, if not the necessity, to clear fluids, particularly blood, from the treatment site and to keep the fluid back so that the electrical energy can couple into the tissue and not into the surface of the fluid where it would form an unstable eschar which could slough off and lead to renewed bleeding, Dr Levitt had to concede that, while his own intuition would lead him to believe that these would indeed be desirable objectives and that he would regard the flow rate and the size of the gas column to be significant parameters in the aim of achieving these objectives, he was not in a position to assist me as to the actual flow rates, size of column or diameter of column which would in practice be needed. I have already discussed the scope of Dr Levitt's expertise and the value of his evidence on essentially surgical matters.

On the subjects of ionization, arcing, maintenance of the beam once it has been initiated, and power, Dr Levitt was on more secure territory. He was able to agree with Mr Kitchin's interpretations that 40 to 200 watts was the sort of power used in other devices, too small a flow of gas would not support the arc, a narrower jet would restrict the amount of power that could be transferred to the tissue, as would a beam that was too diffuse, for example if the discharge started off too far away from the target, too narrow a beam would become unstable, too narrow a jet directed into fluid-perfused tissue would also tend to couple into the fluid

before the tissue, and a greater amount of fluid on the tissue would require a greater mass flow of gas.

As to the ESG itself, Dr Levitt was prepared to accept that the sort of voltage involved in initiating ionisation was 9,000 or 10,000 to 15,000, but he could not comment on the sort of voltages employed in earlier devices such as the Eschmann 311 and 411, Valleylab SSE3, Turner-Warwick SS2A and Downs Diadon 450, nor on the nature of the waveforms needed for initiation and maintenance of the discharge, even though sketches of high and low crest factor waveforms were handed up for the purpose. He could nevertheless find no reason to quarrel with Mr Kitchin's propositions, based on Mr McGreevy's testimony, that the long (helical) arcs were formed with a generator having a minimum impedance of 3,000 ohms, that the shape of the nozzle would be a contributory factor in achieving a stable beam able to produce the desired characteristics, and that there was a synergistic effect between the gas and the discharge, but he could not agree that the material of the nozzle would be likely to have any affect one way or the other.

In Mr Kitchin's summation, Dr Levitt agreed, as far as his expertise allowed him, that these aspects of the apparatus are those that lead to the generation of the conditions necessary to create the desired eschar. Although Mr Kitchin did not say so in words, the inference to be drawn from this agreement must surely be that it goes counter to what Dr Levitt said in the third paragraph of his second Statutory Declaration, *viz* that the effectiveness of the device "is as a consequence of its manner of use, and has little, if anything, to do with any novelty in the basic design of the device." In other words, the point I think Mr Kitchin would say he has made is that Dr Levitt's evidence on whether or not the **apparatus** is inherently capable of producing the desired eschar is inconsistent. That is the conclusion I would certainly draw from Mr Kitchin's questioning and Dr Levitt's answers.

Nothing that was said in the exchanges between Mr Söring and either Mr Kitchin (under cross-examination) or Mr Hamer (under re-examination) was to my mind of particular significance to the issues of claim construction (or sufficiency) and I do not feel the need at this stage to import to any significant extent or at all the contributions made in Mr Söring's testimony in

this regard. Perhaps the only exception to this concerns Mr Söring's affidavit where, at paragraph 8, he refers to the statement given in page 1417 of Morrison's testimony in the Colorado litigation, exhibited to Mr Ley's affidavit. There, Dr Morrison described the eschar which he had obtained as being a "very nicely dried and fused, gently brownish area of tissue" and "as though you had painted it gently brown, rather than spattered it with brown and black." While that is a description of the Morrison eschar, it is clearly not in the same terms as in the patent in suit nor is it in any way a statement of what the skilled man, in this case Dr Morrison, would necessarily have expected in terms of the qualities and appearance of an eschar at the relevant time in the history of the development of electrofulguration.

There is one further point in connection with flow rates that I would deal with specifically now. Mr Hamer said in his closing address that Mr McGreevy had alluded to situations where there would be very little fluid to clear and therefore it would be possible to use a lower flow rate. According to Mr Hamer, the device would still work. Mr Hamer's point was that, if that be so, what real limitation can be attached to the apparent limitation in claim 1 of the words "predetermined flow rate"? If there is more than one possible flow rate how are you to choose? The choice depends on the circumstances of use and not on the apparatus itself. If one tries to apply *No-Fume* to the claim there may be the situation just mentioned where you have little or no fluid and therefore it is not possible to say whether or not you are within the claim. In Mr Hamer's words, "what is the test?". In reply, Mr McGreevy wanted to know the conditions. Mr Hamer said that, in effect, Mr McGreevy had turned the question round. He referred in particular to the passage bridging pages 82 and 83 of the patent which state, at lines 2 to 3 of page 83, that "Flow rates from approximately 0.8 to 1.6 standard litres per minute" may be used. What he did not say, though, is that the rest of the sentence confines this range to "thermal desiccative effects". In fact the whole of the passage in question is concerned with desiccation in micro mode where "substantial fluid clearing problems will not be encountered. The relatively lower gas flow rate therefore poses no particular problem in clearing fluids."

It was permitted, Mr Hamer went on, from Peter Gibson LJ in *Glaverbel SA v British Coal Corp* [1995] RPC 255, to construe a claim "from a subordinate claim of narrower scope

appended to it", and I accept this. Applying that to the present circumstances, I note that claim 3, which is appended to claim 1 via claim 2, specifies that the RF energy is confined to arcs conducted in the ionized conductive pathways, *ie* macro mode. Likewise, claim 9, which is appended to claim 1 directly, specifies that the electrical energy is transferred as a non-arcing diffuse current in the ionized conductive pathways, ie micro mode. The logical deduction is that claim 1 inherently encompasses both micro and macro modes and therefore, by extension, encompasses all of the conditions and parameters which are associated with proper operation of the apparatus in both of those modes, insofar as they are consistent with the route by which the claims are appended to claim 1. That must mean, in my view, that claim 1 encompasses gas flow rates below and above the figure of four litres per minute to correspond with the micro and macro modes (desiccation and fulguration respectively) disclosed and described in the specification.

The conclusion I reach, therefore, as to the implications for the scope of claim 1 of the phrase "at a predetermined flow rate sufficient to clear natural fluids from fluid-perfused tissue and to substantially expose the tissue stroma" is that the word "predetermined" in this context has no greater significance than that the values concerned are chosen in advance (preselected), *ie* there is not necessarily an automatic relationship between the parameters which are qualified by the word predetermined.

As so construed, therefore, in its broadest aspect claim 1 relates to:

> "An electrosurgical unit for creating an eschar in the stroma of tissue, comprising:
>
> > means for conducting a predetermined (preselected) gas in a jet to the tissue at a predetermined (preselected) flow rate; and
> >
> > means for transferring electrical energy at a predetermined (preselected) radio frequency range in ionized conductive pathways at a predetermined (preselected) power level within the gas jet in an electrical circuit which includes the tissue to create the eschar."

With this construction of claim 1 in mind, I can now go on to consider the issue of sufficiency. Section 14(3) of the Patents Act 1977 requires that "the specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art".

The allegation of insufficiency is not elaborated in the applicants' statement, but at the hearing I was referred to what the proprietors considered to be the relevant authorities on sufficiency.

The Court of Appeal, in *Mentor Corporation and anr v Hollister Inc* [1993] RPC 7, dealt with sufficiency from the point of view that it is a "question of degree" and that "disclosure of an invention does not have to be complete in every detail, so that anyone, whether skilled or not, can perform it". The required degree cannot be laid down in any precise rule since it would require a precision which is not within the language which would have to be used to make the rule. That concept followed from *Edison & Swan Electric Light Co v Holland* (1889) 6 RPC 243. There was no reason to suppose even that such a hard and fast rule would be desirable as it would not, by its very nature, have the flexibility to cope with the different requirements of different inventions.

Lloyd LJ, delivering the *Mentor* judgment, went on to consider *No-Fume*, to which I was also referred. In both of these authorities the situation is that the addressee is taken to be a man skilled in the art who would be capable of correcting mistakes, repairing omissions and carrying out "routine" trials without the need to "exercise any inventive faculty". That form of words would rule out "unusually arduous or prolonged research".

In *International Business Machines Corporation's Application* [1970] RPC 533 at page 542 it was stated by Graham J that there was no greater requirement for sufficiency to be satisfied in respect of a "functional claim" than for any other form of claim. He said "sufficiency is a question of fact in each case and the requirement is the same whatever the form of claim". He specifically referred to claims of the *No-Fume* type as being those where the claim is limited by the result, *ie* they are "functional".

It was accepted by Mr Kitchin that certain aspects of the claims in suit were properly described as being of the *No-Fume* type, and that the proper construction was that set out by the *Mentor, IBM* and *No-Fume* authorities. In support, Mr Kitchin referred me to Mr McGreevy's evidence, in which he states, "the improved eschar was the only means available to me to describe the important interaction between the gas conducting means and the energy transfer means" and to Mr Mcgreevy's belief that the broad scope of the claims was "fair in the light of the significance and improvements" of his invention.

That is a *No-Fume* position. What Mr McGreevy appears to be saying is that as in the *No-Fume* case, he had to define the invention in terms of the result because there was really no other way. In the *No-Fume* case, the allowance by the Court of Appeal of claims which defined the invention by the result obtained was tempered by what appeared to be the necessary conditions, as set out in the headnote at the foot of page 231 of the RPC, that "proportions need not be exactly laid down, if there is a field in which the proportions may vary and yet within which success may be ensured, and if the dimensions are sufficiently described as to be ascertainable by tests not involving the exercise of any inventive faculty". That case was not decided merely on the allowability of claims defined by result; it provided conditions under which such allowance is tenable. It is a pre-requisite that there shall be sufficient description (of dimensions in the case of the *No-Fume* ash receptacle) for the dimensions to be ascertained without inventive ingenuity. I think that it would be perfectly acceptable to extend the Court of Appeal's conclusions as to "proportions" to parameters which otherwise satisfy the conditions which the Court laid down for them. That is effectively the proprietors' argument here. They say that their claims are allowable because there is sufficiency of description to justify the breadth of claim which they accept is of the *No-Fume* type, and according to the *No-Fume* judgment the patent satisfies the necessity for a sufficient description of the variables for the claim to be considered as adequately defining the monopoly.

Mr Kitchin contended that there had not been any challenge to the proprietors' view that the specification could be understood by the man skilled in the art sufficiently to produce equipment which would produce the required effect. He claimed that there was an attack creeping into the proceedings along the lines of insufficiency on the basis of a lack of clarity

of the claims. That was unacceptable in law as the statement of case had made out no such ground and Dr Levitt's evidence made no such allegation. Moreover, none of the evidence showed that those whom Mr Hamer called "the practical people working in this field" had any difficulty determining whether or not a device is within or without the claims. Not even Mr Söring had made a suggestion to counter this. Thus, said Mr Kitchin, there was no sustainable objection under this line of attack.

While I understand the point made by Mr Kitchin, I must nevertheless pay due regard to the fact that the section 72(1)(c) ground included in the statement of case inherently contains the aspect that "the patent does not disclose an invention clearly enough ... for it to be performed by a person skilled in the art." To an extent that meets Mr Hamer's argument, at least as regards the insufficiency-by-lack-of-clarity point, in the applicants' statement. I believe also that the objections raised by the applicants against claim 1 on the basis of the uncertain nature of the eschar and what is required of the eschar and the apparatus which produces it in order for it to qualify for the epithet "improved", would fall into the category of argument on clarity issues and at least some of those have been so argued with allegedly supporting evidence. I do not think that I can therefore dismiss this aspect of the attack as simply and completely as it seems Mr Kitchin would prefer.

Mr Kitchin handed me a copy of the Court of Appeal judgment in the case of *Chiron v. Murex Diagnostics* which was handed down on 2 November 1995. He said that it was the most recent case on the allowance of functional claims in the face of an attack on insufficiency. While I have not found it necessary to consider the whole of that judgment, nor was I invited to, it is relevant to these proceedings and of value to note that the Appeal Court found that *Biogen Inc v. Medeva plc [1995] RPC 25* was binding on them, and that the question of sufficiency has to be approached "on the basis of the principles of law as found in Biogen and to make the findings of fact necessary to enable those principles to be applied".

Mr Hamer relied on an interpretation of sufficiency which he presented as being implicit in *Biogen.* In that case Hobhouse LJ contrasted the revocation provisions under section 32(1) of the old law with those available under section 72(1) of the new. Section 72(1)(c) was one of

those quoted among the grounds for revocation available to an opponent under the 1977 Act, *ie* " the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art". Mr Hamer then said, "the first thing that one has to think about is what is the invention, and where does one want to look if one wants to see the invention?". He went on to take that as an invitation to look at the **disclosure** of the claims and to ask the question "does claim 1 disclose the invention clearly enough and completely enough to be performed by a person skilled in the art?". It was a necessary condition that the claim had to be comprehensible, otherwise there is not a sufficient description of the invention. He postulated that there was an overlap between clarity of claim and insufficiency because "in order to see whether the man skilled in the art is given enough information to be able to understand what the invention is and how he can perform it, he has to be able to see what it is. But there is an overlap between the two." He invited me to read the *Biogen* headnote at 9 and 10 and proposed that one cannot use the "classical" approach of looking to see whether the claim is supported by the description, rather one had to look at sufficiency in itself and say, "can you understand the claim enough to see if there is a disclosure in the body of the specification which covers the whole of the width of the claim?".

In summary, and in accordance with the headnote to the report of *Eastman Kodak's Co.'s Application* [1970] RPC 548 quoted in the *Biogen* case, Mr Hamer contended that, "an application could be rejected on the basis of insufficiency where claims were broad and indeterminate and of a speculative character". He submitted that the sufficiency requirement is not met if there is clarity of claim but the body of the specification does not provide sufficient information and, conversely, if the body of the specification provides a perfectly clear set of directions but the actual invention cannot be determined from the claims.

Looking at the actual words used in the judgment, however, I see that the question of sufficiency was being considered on the basis of the extent to which the description needs to provide enough information for the invention to be performed **across its full width**. That is clear in headnote 10. The body of that part of the judgment concentrating on sufficiency, *ie* pages 95 to 99, reviews the previous authorities and concludes that the sufficiency of a

disclosure is not decided on the basis of there being a disclosure of each and every embodiment, nor of a single embodiment, where a claim whose sufficiency is dependent on it is drafted so as to include a number of possible alternatives. Hobhouse LJ said, at page 96:

> "Wherever the claim is made in wide or loosely defined terms, a problem is liable to arise whether the description in the specification is sufficiently clear and full to enable someone to perform such an invention. It is a problem which arises from the width of the claim; it is not a matter of form nor is it the same as the relatively formal requirement that the specification include an example of an embodiment of the claim. It is an error to think that the sufficiency of the disclosure required can in any case be determined without having regard to the width and character of the invention claimed."

Considering the European Patent Office decisions in *Genentech I* (T292/85) [1989] OJEPO 275 (and [1989] 1 EPOR 1) at 282 (and 7) it was concluded, at page 97, that:

> "while the case illustrates that all possible applications of the patent need not be described, it confirms that the relevant test of sufficiency is certainly not whether a single application has been described."

Another relevant authority, *Biogen/Recombinant DNA* (T301/87), [1990] OJEPO 335, [1990] EPOR 190 at 201 held that "there is no need to provide instructions in advance how each and every member of the class would have to be prepared." Finally, it was said at page 98, in agreement with the Board in *Exxon/Fuel oils* (T/409/91), [1994] EPOR 149:

> "The disclosure must be sufficient to enable the whole width of the claimed invention to be performed. What will suffice to satisfy this criterion will vary depending on the nature of the claim that has been made. It is essential to apply the test having regard to the extent of the claim. It is not the law that the disclosure of a single embodiment will always satisfy the requirement regardless of the width of the claim."

As to the width if the claim, Mr Hamer, turning to the facts of the present case, contended that claim 1, and perhaps by implication also the other independent claims, was not comprehensible in itself by the man skilled in the art, even allowing for the interpretation of particular terms from the specification or from other evidence. In the present case, there was no such guidance to be had and there was no evidence to show that the skilled man would know what was meant. Applying the construction which he had deduced from *Glaverbel*, Mr Hamer reasoned that, since claims 31 and 40 specify laminar flow, claim 1 would be broad enough to include non-laminar flow. In the same way, the claim could cover the situation where there is a significant amount of oxygen entrained in the gas jet (claim 28 specifies no substantial amount); claim 1 covers more than the use of an inert gas (claim 15 expressly specifies one); the path lengths of the arcs do not necessarily have to be the same (via claim 42); macro and micro modes are both covered in claim 1 (via claims 3 and 9); the depth of the eschar is not necessarily diminished (via claim 6). In addition, Mr Hamer contended that the attempts to impose method limitations on the apparatus claim were such as to "render the claims, effectively, either method claims or they may be ineffective." In essence the claim was so unclear as to be insufficiently described.

I have already indicated my acceptance of Mr Hamer's argument on construction of the scope of a superior claim by reference to a narrower, subordinate claim. However, I am less persuaded to Mr Hamer's position on the possibility of treating the claims as providing **disclosure** against which to judge sufficiency. I recognise the authority of *Biogen* but, having viewed that judgement in its entirety, I can see nothing that requires me to adopt Mr Hamer's position. In my understanding, the judgement says nothing about the disclosure of a claim. Rather, in agreeing with the Board in the *Exxon* decision as to the meaning of sufficiency within the context of Article 83 of the European Patent Convention, which mirrors the wording of sections 14(3) and 72(1)(c) of the 1977 Act and which, under the provisions of section 130(7), are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions as the EPC, the Court of Appeal has come down quite firmly in support of the basis of sufficiency lying in the body of the specification. I have already quoted from page 96 of the *Biogen* case which, in my view, distinguishes quite specifically between the width of a claim and the sufficiency of "the description in the

specification". Again, as I have already quoted from the same page of the RPC, the headnote in *Eastman Kodak* refers to "the description of the invention" as a separate entity from the nature of the claims. Looking also to the primary legislation itself, section 14(1) of the 1977 Act sets out the requirements of a patent application, and at subsection (2) differentiates between the description of the invention on the one hand and the presence of a claim or claims on the other. Subsection (5) likewise, in defining the requirements for a claim, draws a clear distinction between the function of the claim, in terms of defining the monopoly sought (subsection (5)(a)), and support for the claim by the description (subsection (5)(c)). I am satisfied that the authorities, in discussing the disclosure of an invention in the context of sufficiency, would have regarded the "description" or the "disclosure" in the same way and I therefore reject this aspect of Mr Hamer's submission.

Turning to what may be called the question of classical insufficiency, it appears clear to me that the description, as I summarised it in the early part of this decision, details at some length all of the physical integers necessary to put together a device which, as far as hardware is concerned, would meet the terms of claim 1, even as I have decided it should be construed. I have no doubt that the skilled reader would find there plainly adequate instruction to put together the requisite hardware. There is description of each of the three main components, namely the pencil, gas delivery apparatus and electrosurgical generator (ESG). That is followed by disclosure relating to the gas characteristics and finally the ESG impedance characteristics. Each, in my long experience of reading patent specifications, is about as full a description as the skilled man is likely to get in any specification but, as I prefaced this discussion, only so far as the hardware is concerned.

It has been the applicants' position all along that the specification is deficient in that part of the description which is relevant to achieving the effects claimed. I have already identified from claim 1 the individual components, *ie* the means for conducting the gas jet to the tissue and the means for transferring electrical energy in the jet to the tissue. In respect of each of these the description has dealt adequately. The former has been covered in the section concerned with gas characteristics. The nature of the gas required for particular surgical procedures was discussed there, as was the need for the jet to clear the site of fluids and for

the electrical energy to enter the stroma as opposed to the fluid or the surface. Typical flow rates are disclosed along with nozzle sizes and maximum power ratings. The following section, on the ESG characteristics, provides information on the structure of the generator, augmented by circuit diagrams and performance curves in figures 12 to 20, and discusses the philosophy behind the departure of the impedance curve from prior art apparatus.

The next step of deciding whether or not that description is sufficient to enable the whole width of the invention to be performed, using the words of the authorities which I have quoted above, may indeed require certain knowledge available to the man skilled in the art, *ie* the electrosurgical equipment manufacturer. There is no doubt in my mind that the description gives as full a set of instructions as the skilled man could expect or would need to put together the hardware according to the description. To do the same in respect of the equipment defined in claim 1 would involve some value judgments as to whether the required eschar can be achieved. However, I have decided that claim 1, in its proper construction, is not limited by the qualities of eschar which the words of the claim ostensibly encompass. Nevertheless, I believe I must test the description to satisfy myself that it would, if required to do so, provide adequate information for the skilled man to achieve the desired eschar, at least under certain conditions of use.

The hardware includes a gas-selection valve, a pressure regulator to limit the gas pressure to a preset level, a gas-delivery valve which opens or closes to control the passage of gas and a flow controller which effects control of the flow rate according to the level selected by the surgeon. The electrosurgical generator is described in circuit diagram form in figure 12 and in progressively more detail in figures 13 to 19 as regards the front panel control, logic control, power supply, power supply control, RF drive, resonant output circuit and arc sense circuit, respectively. A full description is given of the functional relationships between the circuit blocks and their logical operation from initiating arcing to fully functioning fulguration or desiccation. Certain options are also catered for, such as that the gas selection switch and the mode selection switch automatically operate together so that selection of one of the gases always sets a specific mode of operation. The discussion of gas characteristics leading to the choice of gases in general and the choice for micro- and macro-modes, their flow rates, the

nozzle sizes and the fluid clearing and drying advantages, together with indications as to the corresponding ESG power requirements would, in my view, be quite adequate for the equipment to be operated by a skilled person.

Achievement of the eschar sought after would then be a matter for the operator. He could try different settings until he achieved the desired results. He may be expected to perform a number of "dry runs" in order to set the parameters to his satisfaction so as consistently and repeatably to obtain the desired eschar. The authorities that I have considered above certainly permit such trial and error approach and expect that it will be necessary and appropriate depending on the circumstances. They do not expect that every "i" shall be dotted and every "t" crossed in the specification.

On that basis I am satisfied that the description sufficiently describes the hardware necessary for the skilled man to construct the equipment which is the subject of claim 1, and I further believe that there are enough specific instructions as to how the equipment should be operated or, in the alternative, sufficient indications as to the crucial parameters which may need to be adjusted (after a reasonable, but not arduous, series of trials if need be) for the invention to be made to operate successfully, and even to achieve the eschar which has been particularly described in the specification. I therefore find that the applicants' charge of insufficiency fails.

I turn next to the questions of novelty and obviousness, dealing first with the charge of lack of novelty. It was put to me by Mr Kitchin that the proper test for novelty is that set out in *PLG Research Ltd v Ardon International* [1993] FSR 197 and *The General Tire & Rubber Company v The Firestone Tyre and Rubber Company Ltd and ors* [1972] RPC 457. In effect, there must be "clear and unmistakable directions" to do what the patentee claims to have invented and the disclosure must be "enabling". Mr Hamer did not dissent from that submission, and I am satisfied that this is the proper approach. I would merely add that the House of Lords in *Asahi's Application* [1991] RPC 485 has confirmed the doctrine of enabling disclosure as the means to establishing that the prior disclosure has been made available to the public.

It also emerged through the period of the hearing that the prior documents that the applicants would be relying on most heavily were Morrison (principally US Patent No 4,060,088 - "Morrison '088" - but also US 4,057,064 and 4,040,426 - "Morrison '064 & '426") and Brayshaw (US Patent No 3,903,891 - "Brayshaw '891"). I was also reminded by Mr Kitchin that Dr Morrison's testimony in the Colorado litigation has not been allowed in as evidence but was used in cross-examination for the purposes of questioning witnesses. I have sought to take full account of the evidence and testimony of witnesses in reaching my own conclusions as to what these documents taught the man skilled in the art at the relevant dates.

Considering first Morrison '088, I note that the patent was issued on 29 November 1977, *ie* over eight years before the priority date of the patent in suit. The abstract sums up the invention as "An electrosurgical method and apparatus for coagulation by fulguration where the electrical discharge is established through a formation of flowing inert gas where the formation may be either a diffuse blanket of the flowing gas or a well defined column thereof". The "Background of the Invention" indicates that the prior fulguration devices suffered from the same sort of unsatisfactory performance as is described in the patent in suit. The "Detailed Description of the Preferred Embodiments of the Invention" discloses with reference to figure 1 the use of a known source (*eg* that in US Patent No 3,699,967 to Anderson) of periodic bursts of high frequency electrical energy in the region of 200 kHz or higher and with a high crest factor (5 - 10) waveform. The source is coupled to an electrosurgical instrument comprising a handle supporting an electrode, directly or via an intermediate member in the form of a tube. The source is coupled to the electrode and there is a return path from the tissue to the source. A source of inert gas, typically nitrogen, the noble gases or mixtures thereof or helium, is connected to the instrument "to support an electrical discharge". Variations of electrode structures are described with reference to figures 2, 3 and 4. In figure 2 the gas flows along an annular space around a tungsten or stainless steel electrode and emerges near the tip of the electrode through an orifice which may be tapered to produce a focused, highly directed gas formation. The arrangement is said to permit a very long electrical discharge to pass "straight down the gas column". The discharge is described as being such that "it can be directed to the bottom of a fissure or crevice without deflecting to the sides".

In figure 3 the electrode is a hollow tube through which the gas flows to the tissue. The electrode has a truncated end to create a sharp point which, however, tends to burn away. In figure 4 the structures of both figures 2 and 3 are combined so that the gas flows around and through the electrode. The outer stream flows slower than the inner stream so as to protect the electrode from oxidation while the inner stream provides directionality. Argon may flow in the centre stream and nitrogen in the outer. Alternatively, argon may flow in the outer stream and helium in the inner.

In each of the arrangements in figures 2 and 3 the description states that the dimensions quoted for the nozzle diameters and the spacing between the electrodes and the support tubes are "not critical to the desired formation of the column of gas". Likewise, in all of these embodiments the gas flow rate typically established in the tubes is 0.02 standard cubic feet per minute (which converts to 0.5 litres per minute) while gas pressure is 0.25 psi, but these values too are said not to be critical.

The benefits of the arrangements thus far described are that a discharge length of 0.125 to 0.75 inches is obtained, discharge is controlled, easily directed and not readily deflected to the side, the electrode tip is cooler, there is less risk of the tip touching tissue since the discharge is longer, the discharge covers a well-defined area and can be swept across tissue to provide rapid coverage of wide areas, smoke and fumes are reduced by an order of magnitude, and "fulguration is excellent".

In figure 5, the apparatus is designed specifically to produce a diffuse blanket of inert gas between the electrode and the tissue. The instrument is described as being of similar configuration to a typical thermal-inert-gas (TIG) welder and includes a body/holder portion with a comparatively "blunt" end which cause the gas to exit in a diffuse, rather than directed, fashion. It is described nevertheless as having useful applications in electrosurgery. It is supplied with continuous or periodical high frequency energy from a source, as in the figure 2 embodiment.

In the embodiments according to figures 2, 3 and 5 discharge is initiated by the user placing his finger on the "intermediate member" or tube, and thereby establishing an auxiliary discharge between the interior of the tube and the electrode which, it is believed, is then swept by the flowing gas to the electrode tip.

It appears plain to me, on a straightforward reading of Morrison '088, that all of the integers of claim 1 of the patent in suit, as I have construed it, are disclosed. In particular, since I have decided that the detail of the "improved" eschar is not limiting, the disclosure in Morrison '088, which admittedly lacks a full description of the eschar, provides an enabling disclosure with clear and unmistakable directions to do what the writer of the patent in suit claims to have done. However, in case I have interpreted that disclosure in any way which is inconsistent with what the skilled man would have regarded as the teaching of the prior patent, I will consider what was said in that connection in evidence and submission.

Mr Kitchin, in his opening address and final submissions, claimed that Morrison '088 simply does not disclose the nature of the eschar (a point I have already disposed of), does not conduct gas at a flow rate sufficient to clear fluid and expose the stroma of the tissue (another point I have already disposed of), does not clearly disclose the transfer of energy within the gas jet and does not disclose the characteristics of the generator which are necessary to achieve the results which are achieved by the invention in suit. Mr Kitchin referred to Mr McGreevy's evidence in these respects.

In his affidavit Mr McGreevy challenged what he regarded as Morrison's application of welding techniques to electrosurgery. In particular he expressed concern at the aggressive nature of the discharge in welding compared to the more gentle approach necessary to deal with body tissue. Welding required intense heat at the surface of the metal, while electrosurgery required quite the reverse. On that basis the sort of discharge that Morrison's apparatus would be likely to provide would be unsuited to the electrosurgical environment. Morrison '088 had not addressed the problem of fluid clearance, probably because there was no such need in welding. If he had obtained such a good eschar why had he not described it? Morrison had said that the gas flow rate was not critical, whereas Mr McGreevy's experiments

had indicated that it was important for staunching bleeding and clearing fluid. Morrison was apparently teaching that the jet did not spread near the surface of the tissue. While that may be true for welding metal, where there is a uniform impedance, the situation is more unpredictable in body tissue as a result of variable impedance characteristics which Mr McGreevy's earlier research on eschars had shown to be a significant factor in arcing directionality.

He moved on to criticise Morrison's results as depicted by Morrison himself in the Colorado litigation, pointing to that testimony and to Morrison's own laboratory notebook. He said that Morrison just did not achieve the results which were attainable with Mr McGreevy's invention and that Morrison had failed to appreciate the important factors involved in achieving that end. Mr McGreevy dismissed all of the Morrison patents with the comment that they were of no assistance to him in making his invention. He stated that Morrison '088 talks only of "sparking" and that nothing in Morrison's testimony in the Colorado litigation or in his notebook would lead him to think that "Mr Morrison had discovered the non-arcing diffuse current 'micro' mode of electrosurgical coagulation" which he had invented.

I would digress a little here to note that while I agree with Mr McGreevy's summary as to Morrison's evidence not pointing to the micro mode of operation, that is only a "sub-field" of claim 1 which, as I have already mentioned, is cast in broad terms so as inherently to encompass both this and the macro mode. Therefore Morrison's "failure" to disclose the diffuse current discharge is not sufficient by itself to dispose of Morrison '088 in its entirety, as I believe Mr McGreevy acknowledges in paragraph 50 of his affidavit.

Mr McGreevy's summary of the Morrison patents is that his invention is distinguished over them *inter alia* on the grounds that they do not describe the fluid-clearing and stroma-exposing features (which of course I have held not to be limiting) and do not describe the interaction between the gas conducting means and the energy transferring means to achieve the improved eschar. Again, the improved eschar is a feature of claim 1 which I have held not to be limiting, and I am not aware of anything in claim 1 which specifically calls for any particular "interaction".

Mr McGreevy's answers to the questions put to him on Morrison by Mr Hamer in cross-examination were to the effect that Morrison was a welder who was attempting to transport welding technology into the radically different world of electrosurgery, that while Morrison may well have achieved satisfactory results with his design of apparatus on metal, where conditions were predictable, and even on *ex vivo* tissue, when it came to using the apparatus on living tissue the results were "a disaster, that the surgeon did not like it, he could not stop the bleeding and he could not understand what went wrong." In Mr McGreevy's view, Morrison was judging the effectiveness of his invention as much by the appearance of the beam as by tests on tissue.

Mr McGreevy was also of the opinion that, if Morrison really had achieved an eschar which was a major advance over prior attempts, he was under some sort of obligation to describe it. The mere absence of any such description seems to have been interpreted by Mr McGreevy as an admission that the eschar was not as good as he had obtained with the patent in suit, even though Morrison may have described it in the Morrison '088 as good or excellent. Mr Hamer reminded Mr McGreevy that Morrison had given a description in page 1417 of his testimony in the Colorado litigation which I have previously quoted which seemed consistent with an improved eschar, but Mr McGreevy did not accept that that description could be read as "improved" in the sense of what he had achieved in the invention in suit, and he suspected that the description was based on an eschar obtained, once more, on *ex vivo* tissue.

On the question of the risk of embolism, Mr McGreevy said that at the time he conceived the invention and was working to develop it he had spoken to a number of people skilled in the art, and they had said it was "absolute madness" to blow gas at rates sufficient to clear fluid. This followed an exchange between Mr Hamer and Mr McGreevy during which the latter acknowledged that, under certain conditions of use of the invention or indeed other electrosurgical ("IGE") devices, there may be so little fluid present that the surgeon might simply wipe it away before using the equipment. Also, under conditions where there was a considerable quantity of fluid the surgeon would want to wipe away the excess immediately prior to electrofulguration. It was during the process of electrofulguration that the benefits of the fluid-clearing performance of the invention were called into play. Mr McGreevy conceded

that, in a general fulguration procedure, someone doing so with a flow rate less than four litres per minute (figures as low as one or even one quarter of a litre per minute were specifically suggested by Mr Hamer) would not be using his invention. I take that to mean that, from Mr McGreevy's point of view, such a prior disclosure would not enable a person skilled in the art to put Mr McGreevy's invention, as claimed in claim 1, into effect. In other words, it would not be an enabling disclosure. Conversely, Mr McGreevy was adamant that in recognition of an upper, maximum flow rate that would be "safe" in terms of not causing embolism the design engineer, and not the surgeon, would build into the equipment an upper operating limit. Even though it might be possible to use the equipment in situations where high flow rates would, or might, not be dangerous the designer would have to build in an upper "safety" limit which would prevent the risk of embolism so as to allow the equipment to be used in a variety of situations. Mr McGreevy went so far as to say that Morrison had in fact suggested a pneumatic fuse "to ensure that his flow rate does not go up to the point where it can clear fluids." On the other hand, if the man skilled in the art were working on dead meat he could "crank it all the way, to 50 or 100 litres per minute."

I note at this point that Mr McGreevy's answer openly suggests that there would be no bar or prejudice to the skilled man operating an electrofulguration device on dead tissue in a range of gas flow rates where embolism in living tissue might, or almost certainly would, occur, as if that was some sort of distinction which his invention has over the prior art, but there is nothing in claim 1 that leads me to believe that the claim is restricted to living tissue.

Indeed, Mr Hamer followed a similar line of questioning with Mr McGreevy where the conclusion was reached that while the researcher may experiment with flow rates above an upper limit and below a lower limit that the designer of equipment may have either inherently imposed in the design of the machine or recommended (*eg* in an instruction manual), he was unlikely to waste his time researching outside what was regarded as a safe range. Referring to the statutory declaration of Mr Dennison, Consultant Hepatobiliary Surgeon at Leicester General Hospital, which is dismissive of the claims made for the effectiveness of the Birtcher ABC device and more effusive about other developments in the surgical field as regards liver and biliary surgery and techniques for stemming blood loss, Mr Hamer pointed to paragraph

20 where Mr Dennison acknowledges that limits are indicated on equipment by the Medical Physics Department at Leicester General Hospital. While he generally complies with those indications and operates within the advised range, he has occasionally exceeded them "to achieve a specific result, for example, to vaporize malignant oesophageal lesions". While I cannot say that such use would necessarily produce the kind of eschar that Mr McGreevy describes, it does indicate that it is not beyond the wit of the skilled man to "test the water" by going outside the range, or an upper "limit", which may have been previously advised.

Finally, on Morrison '088, Mr McGreevy agreed that it disclosed an electrosurgical unit for creating eschars in which an inert gas is conducted in a jet to the tissue, RF electrical energy is transferred in ionised pathways in the jet in a circuit including the tissue and the gas delivery speed and voltage and power are such that it is suitable for fulguration. As I have already construed claim 1 as relating precisely to that set of integers, operating together in the same way, it is clear to me that even Mr McGreevy in those terms in effect recognises that Morrison '088 actually teaches to the skilled man how to do what the patent in suit describes. Mr McGreevy in effect acknowledges that Morrison teaches the combination of hardware which is implicit in claim 1 of the patent in suit but without the "restrictions" in the words of that claim to the "improved" eschar which, as is now clear, I have held not to be limiting.

Mr Wells, in his testimony, was not so forthcoming. His assessment of Morrison was that the flow rates disclosed in Morrison '088 would not have got a sustained gas column, that the gas jet would not have been as directional as Morrison '088 shows, that there was not the relationship, *ie* the synergy, between the gas flow rate and the electrical energy transfer that there is in the patent in suit, and that there is no description of the eschar so there must be something missing from Morrison which Mr McGreevy had found, otherwise the eschars would be the same.

Mr Wells' own experience in testing and appraising diathermy equipment and observations on "several hundred" surgical procedures involving diathermy must, in fairness, be qualified by his own definition of "diathermy", which he gives in his affidavit as not necessarily involving gas jets. That is not to say that Mr Wells is unqualified to speak as an expert in the field of

gas electrosurgery or diathermy, but I may need to temper his contributions to this dispute. In particular there were certain areas of questioning where it emerged that his evidence was based on the material which had come under discussion in the course of the proceedings and not necessarily from his own, personal, professional experience as a technical expert in diathermy. For example, although he said that the eschar produced by the Birtcher device was superior to anything he had previously experienced, he was only able to judge the quality of the eschar by its outward appearance, and he acknowledged that, as far as he could determine, the results "compared favourably with the description of the improved eschar contained in the patent", although there is nothing before me that suggests that Mr Wells made any actual study of the eschar, apart from having seen a piece of fulgurated tissue removed from the patient by Mr Poston.

Mr Wells was also unable to give a committed answer to Mr Hamer's questions on what differences were there between Morrison '088 and the patent which enabled the patent, but not Morrison '088, to obtain the improved eschar. After a fairly lengthy exploration of gas jets, synergistic effects, directionality of the gas jet, its ability to support the arcs and whether or not the gas actually constituted a medium for transferring the electrical energy or whether it was merely a curtain, Mr Wells finally answered unequivocally that the only reason that Morrison did not produce the eschar of the patent in suit was that he had too low a flow rate. This low flow rate was to be compared to the patent which, according to Mr Wells' affidavit, "calls for a device which produces a gas jet which must have high flow rates" (which later he interpreted as not less than four litres per minute), as opposed to Morrison which was specifically limited to half a litre per minute and taught that there was no point in going any higher because of the risk of embolism. The figure of half a litre per minute was not found in Morrison '088, Mr Wells explained, but was something "subsequent". It was not a case of the skilled man reading Morrison and wanting to try increased flow rates but being deterred because of the risk of embolism; it was simply a case of Morrison teaching that there was no point in going higher.

As for whether Morrison taught that the gas flow rate was not critical, in the sense that anything would do, as had been suggested by Mr McGreevy as well as Mr Wells, Mr Hamer

referred Mr Wells to Morrison's testimony in the Colorado litigation at page 1423, where it was clearly stated that Morrison's team had experimented initially with flow rates that were well beyond the range he was allowed to work in, up to twenty times and down to one fifth the value that they were permitted to work in. That flow rate is given in Morrison'088 at the top of column 4 as 0.02 cubic feet per minute (or one half of a litre per minute). The point that Morrison was making was that he was attempting to produce a device which would be non-critical in the sense that "the surgeon did not have to be concerned about the adjustment of the gas flow particularly". That was Morrison's own view of the meaning of Morrison '088.

I am satisfied that none of what the witnesses have testified to has in any way moved me from the position I had reached as to the relevance of Morrison '088 against the novelty of claim 1 simply on a reading of the Morrison patent itself.

While Morrison '088 is sufficient by itself to dispose of claim 1, I will consider the other prior art cited by the applicants and argued before me. As far as claim 1 is concerned there is no additional disclosure in any of the other Morrison patents, *viz* '426 and '064, which although disclosing substantially the same matter as Morrison '088 in terms of the electrosurgical apparatus and its operation, are primarily concerned with initiation of the discharge by means of additional devices integrated within the handpiece.

Brayshaw '891 is entitled "Method and Apparatus for Generating Plasma", and its very title encapsulates one of the causes for argument as to its relevance against the novelty of the patent, namely the nature of the discharge.

In Brayshaw '891 an RF induction coil surrounds a tube through which is passed an argon (or helium, hydrogen and nitrogen) stream so as to strike up a gas plasma which emerges from a nozzle which is described as a "burner or torch tip designed and constructed for a specific application, such as cutting, heating or spraying". The plasma is described as "metastable". Significantly, lines 43 to 66 of column 4 specifically refer to the exceptional efficiency with which energy **in the form of heat** is transferred to a workpiece. In the case of application to

surgery a "plasma of metastable noble gas ... is attenuated to a cross-section which permits a narrow region of contact between the plasma and the tissue to be cut". Not surprisingly, Brayshaw '891 has been described in these proceedings as relating to a "plasma scalpel".

In Example I at columns 9 and 10 the device constructed according to Figure 5 was supplied with RF energy from a source of resonant frequency 90 MHz. Power at a level of 110 watts and 100 volts was delivered to the induction coil with a frequency tunable between 80 and 100 MHz. The gas flow rate was 1 cubic foot per hour. After striking the plasma at 90 MHz and producing a plasma issuing one inch from the nozzle the frequency was tuned to 92 MHz, whereupon the plasma was reduced to half its length. Dielectric materials in its path remained unaffected but electrically conductive materials received energy which heated or destroyed them in the region which the plasma contacted. On contact with animal or human tissue it "vaporized in a thin line to produce a substantially haemorrhage-free incision characterized by a complete absence of charred tissue".

Mr McGreevy's view of what Brayshaw '891 actually discloses was given in cross-examination. He said it was difficult to say with any certainty which type of plasma Brayshaw meant in his patent. There were various types, generated in different ways. He repeated the words of the patent that it was metastable, and contrasted the heating effect on the surgeon's hand in Brayshaw '891 compared to the absence of heat in his own patent. He added that the energy in Brayshaw '891 is transferred as molecular, kinetic energy and not by the transfer of electrical energy in ionized pathways as in the invention in suit. In fact there is no current as such in Brayshaw '891, according to Mr McGreevy. He attempted to explain the difference in terms of the effect on a haemostat, with the caveat that plasmas are difficult to comprehend and involve complex physics. The net effect was to try and get over the point that in the invention there is a current path which does not exist in Brayshaw '891. It was also said by Mr Kitchin that there is no electrical circuit through the patient, and even Mr Hamer agreed that Brayshaw '891 does not expressly say that there is one. Mr Hamer had explored the nature of the discharge also with Mr Wells, and had put to him the proposition that the description of the figure 5 embodiment in columns 8 to 9 of Brayshaw '891 disclosed a device in which a stream of gas passes a monopolar electrode where it is ionized and flows to the

surface of the tissue. Mr Wells was in agreement that there was a flow of ions but could not accept that there was any transfer of electrical energy in arcs between the handpiece and the tissue. As to the return current path, Mr Hamer in his final address tried to persuade me that it was inherent in electrosurgery that the patient will be connected to earth, and that it did not matter that the return electrode was not at zero potential. Referring to Mr Wells' testimony, he said that it was accepted that for decades there had only been monopolar and bipolar modes available in RF electrosurgery and that it was possible to switch easily between them. It was a workshop variant. The inference to be drawn is therefore that it is inevitable that there will be occasions where the Brayshaw '891 device is in use (or maybe is intended to be used) in situations where the patient is connected to zero potential through a patient plate and *ipso facto* the current path is complete. Dr Levitt, however, was of the opposite view. He pointed to there being a return path from the device to the generator, therefore not through the patient tissue, but it was possible that there might nevertheless be direct coupling of the RF energy through the gas into the tissue.

Attractive as Mr Hamer's argument sounds, I cannot accept that in the teaching in Brayshaw '891 there is either the transfer of electrical energy in ionized pathways in a gas jet or necessarily an electrical circuit including the tissue, both of which features are critical to the scope of claim 1 as I have interpreted it. In short, I find that there is no enabling disclosure in Brayshaw '891 which would teach the skilled man, *ie* that would give him clear and unmistakeable directions, that the invention of the patent in suit is to be found in Brayshaw '891.

Mr Kitchin referred also to the article entitled "Evaluation of Electrofulguration in Control of Bleeding of Experimental Gastric Ulcers" exhibited by Dr Levitt. Its authors include Dennis and Silverstein. While it is not in the pleadings, as Mr Kitchin reminded me, it was brought up to show that although it disclosed the use of a CO_2 gas jet coaxial with the electrical discharge electrode to clear away blood from experimental ulcers created in test animals, it did not produce the desired or even a satisfactory eschar. Further trials with various levels of argon in substitution for some or all of the CO_2 equally did not provide a satisfactory eschar. The fact that Dennis did involve the kind of ionized pathway type of discharge claimed in the

patent can be confirmed readily by the statement in the first two columns on page 845 that "The fulguration spark results from the ionization of the air between the electrode and the tissue. The use of a gas more easily ionizable than air allows the generation of a longer spark or generation of a spark using less power". The final conclusion was that the technique required modification before it could be considered for clinical use because of the depth of tissue injury.

While I agree with Mr Kitchin's assessment of the teaching of Dennis I have to mention again that I have already found the specific characteristics of the eschar detailed in claim 1 to be non-limiting. With that in mind, I would have to say that the apparatus disclosed in Dennis, including the patient plate indicated in Fig 1 as "ground", would seem to possess all of the features required of claim 1 and to that extent claim 1 is not novel relative to this publication, whose publication date, I should mention, appears at the foot of each page as November 1979.

Before turning to the other claims, it is convenient to consider the obviousness attack on claim 1, not least because I may be wrong in that finding, but also because I will need to consider obviousness in relation not only to the claims subordinate to claim 1 but also to the other independent claims and their subordinates.

Mr Kitchin addressed me as to the proper basis for considering obviousness. He referred me to the four-fold test set out in *Windsurfing International Inc v. Tabur Marine (Great Britain) Ltd* [1985] RPC 59 and subsequently approved in *Mölnlycke AB and another v. Procter & Gamble Limited and others* [1994] RPC 49, where it was said by the Vice-Chancellor that the criteria are objective, qualitative and not quantitative. Quoting from page 113:

> "The Act requires the court to make a finding of fact as to what was, at the priority date, included in the state of the art and then to find again as a fact whether, having regard to that state of the art, the alleged inventive step would be obvious to a person skilled in the art."

Moreover, at lines 7 to 15 it is set out that:

"In applying the statutory criterion and making these findings the court will almost invariably require the assistance of expert evidence. The primary evidence will be that of properly qualified expert witnesses who will say whether or not in their opinions the relevant step would have been obvious to a skilled man having regard to the state of the art. All other evidence is secondary to that primary evidence. In the past, evidential criteria may have been useful to help to elucidate the approach of the common law to the question of inventiveness. Now that there is a statutory definition, evidential criteria do not form part of the formulation of the question to be decided."

The Vice-Chancellor continued with a warning that the court's task would invariably be made more difficult by the fact that, in the nature of things, the expert witnesses would be considering the question of obviousness in the light of hindsight. Getting caught up in an investigation as to what specified individuals thought was obvious gives rise to complications, since their state of knowledge, though skilled, may not correspond to the statutory definition. It was particularly mentioned that questions of commercial success fall into the category of secondary evidence the weight of which would vary from case to case, and which would have to be kept firmly in its place so as not to obscure the fact that it is there "as an aid in assessing the primary evidence".

Mr Hamer was unable to contribute to this submission (other than to give his agreement that *Windsurfing* was the relevant authority for obviousness) since, as he put it, the limitations of claim 1 were so uncertain that he was unable to determine the step between what was disclosed in the prior art and what was claimed. His main position on claim 1 was that it was anticipated. As a default position he said that he would have to ask me to decide whether any lack of anticipation which may exist amounted to an inventive step. It would not be until he got to the later claims which deal with the electrical circuits that he "would be able to run obviousness sensibly".

The first *Windsurfing* test requires me to consider the state of the art at the priority date. That must include the prior art upon which the applicants base their attack on the patent and, at least as far as the Morrison and Brayshaw patents and the "Evaluation of Electrofulguration" paper

exhibited to Dr Levitt's affidavit are concerned, I have already considered their disclosure and any interpretation as to their teaching by the expert witnesses from both sides in the context of novelty and sufficiency. Mr Hamer did not go into any great detail on this, while Mr Kitchin presented me with a resume along the lines that the patent itself indicated. In order merely to put this into perspective without going into unnecessary depth it is sufficient to say that at the priority date of the patent attempts had been made, with varying degrees of success, to improve upon the somewhat crude methods in which a hot plate (cautery) or a metal wire is brought into direct contact with the tissue literally to seal or cut by burning. Electrosurgery, involving the application of high frequency current, dates from the end of the nineteenth century. A survey of electrosurgical devices, specifically diathermy units, was carried out by the Health Equipment Information Service of the NHS Procurement Directorate, and Mr Wells exhibited their published evaluations. The equipment covered eight models produced by Valleylab, Bard, Concept, Downs Diadon, Eschmann and GU Turner Warwick, with a promise of Erbe, Martin and Olympus to come. In all of these devices arcs pass through the air from various locations on the surface of an electrode and contact the tissue in random fashion. They suffer from the same deficiencies which the patent describes and which I have already covered, and the eschars they produce have the same sort of unsatisfactory qualities that likewise are covered in the patent. Mr McGreevy and Mr Wells, who can both properly be regarded as expert in their respective fields, have given their views on the qualities of prior art eschars and those created by the invention in their affidavits in confirmation that this overview of the state of the art is correct. In brief, prior eschars had poor flexibility and adherence, they were thicker, more likely to be carbonized, the electrode would tend to stick to the eschar and tear parts away, also leading to power loss, there were problems of visibility through smoke generation and there were suspicions of cross-contamination and the added risk of igniting gases produced in the body or the anaesthetic itself. Despite these disadvantages the methods continued to be used in surgery. The Electrosurgical Devices Evaluation that I mentioned above was not published until June 1988, about two years later than the priority date of the patent in suit. It cannot by itself therefore be regarded as definitive as to the state of the art at or before the priority date. However, none of the witnesses dissented from the view that this was a "working" assessment of the state of the art at least as regards diathermy.

What I have not yet included in this assessment is gas-assisted electrosurgery. I think it is fair to say that objectively both Mr Hamer and Mr Kitchin recognize the importance of the Morrison and Brayshaw patents, but there the similarity ends. They have each argued cogently as to what the teaching is in those documents and how it bears on the novelty of the patent in suit. It may be that they are not so far apart in terms of assessing inventiveness, depending on what I hold to be the step, assuming there is one, which separates the patent from the prior art.

Mr Kitchin summarised what he described as the failed attempts of the prior art to overcome the problems which I have just outlined. He referred me to some of the other documents which have been cited in these proceedings. They form themselves into distinct groupings. There are those that are concerned with providing a "blanket" of inert gas around the electrical spark or discharge as in Hanriot (GB 671497 - published 1952), Siemens-Reiniger (GB 1014995 - published 1965) and August (US2828747 - published 1958 and assigned to the Birtcher Corporation), as well as the "Crawford" system mentioned in Hanriot. There is no suggestion in any of these patents of arcing or any other form of electrical discharge; they are all of the type where the tip of the instrument contacts the tissue to cut it. The next category is epitomised by one patent to Walker (PCT/US82/00084 - published 5 August 1982; equivalent to US 4562838 - published in the USA 7 January 1986). Here the electrosurgical implement is augmented (i) by fluid ducts connected to a source of air under pressure or to a vacuum so as to disperse or remove smoke from the surgical site, and (ii) a light source adjacent to the tip of the instrument to illuminate the surgical site. The third category comprises devices having special control systems. In Meinke (US 4271837 - published 9 June 1981) an undesirable effect involving rectification of the RF current at the electrode tip to produce DC pulses which irritate the motor nerves of the patient is turned to advantage by using the DC as a means of detecting the temperature of the cutting electrode and using that to control the RF voltage and hence RF current to control the cutting temperature. Meinke (German language patent No DE 2504280 - published 5 August 1976 and with equivalent US 4209018 - published 24 June 1980) discloses a system in which the current applied to a high-frequency current tissue-coagulating electrode is monitored and held below the level at which arcing occurs which would otherwise vaporise tissue and produce harmful amounts of

albumen. That system deliberately inhibits arcing. A further document exhibited by Mr Söring as HS3, the English language translation of the German language HS2, is concerned with another inert gas blanketing device (as in Siemens-Reiniger '995) incorporating an arrangement in which the HF generator is switched on automatically by a gas sensor when the gas flow (repurified nitrogen at 1 to 7 litres per minute) is sufficient to blanket the HF discharge. The document itself does not carry the date of its publication but it is said in Mr Söring's affidavit that it is an extract from the "Kompendium Elektromedizin" which was published in 1978.

Mr Hamer urged me also to consider the position that was reached by Dennis and his team, including Dr Silverstein. His affidavit and the transcript of his testimony in Colorado describe how he was the principal investigator of a research team between 1974 and 1981 investigating methods of controlling bleeding of ulcers. He was particularly interested in endoscopic treatments. The research was funded to the tune of $1 Million from the US National Institute of Health, but in all they spent double that. His team included co-authors of the Dennis article. The scale of the operation was considerable,covering a variety of techniques from heater probe, monopolar and bipolar coagulation, the bicap probe, spray-on glue to two types of laser, but their results were described as disappointing. Their most notable success was in devising a method of creating ulcers with repeatable qualities, which was reported in the "Dennis article" published in "Gastroenterology" in 1981. Dr Silverstein states in his Colorado testimony that they tried a CO_2 gas jet around the needle tip electrode to clear blood off the area in the knowledge that it would be quickly absorbed and blown out of the lungs. Because that was not terribly successful they tried introducing argon gas into the CO_2 in various proportions up to 100% argon. Above 50% argon the device simply did not work in stopping bleeding, whereas every other technique they had been working with did. Following a four-month trial involving intense and minute examination of ulcers when treated by the device, the team decided there was no point in pressing ahead with fulguration techniques since they were not as safe as other techniques and had no other advantages to offer.

It seems clear that the art had developed over the years leading up to the priority date of the patent from the tissue-contacting electrode type to the high frequency, electrical discharge,

non-contact making type and, shortly before 1986, the gas-assisted, RF electrical discharge type epitomised in the Morrison and Brayshaw patents, as well as in the experiments, however unsuccessful, carried out by Silverstein and his team. I should make it plain that by "gas-assisted" I do not mean the gas blanket type of equipment described in Hanriot, for example, but the devices in which the electrical discharge takes place within the gas and is transferred within the gas to the tissue.

Following the *Windsurfing* formula, I now need to identify the inventive concept embodied in the patent. I have to share Mr Hamer's difficulties here. Since I have already construed claim 1 in the sense that it is **not** characterised by the nature of the eschar, Mr Kitchin's submissions on the nature of the eschar do not assist his case on obviousness any more than they did on novelty, and I would be forced to the inevitable conclusion that there is, in fact, no concept which takes the skilled man from the prior art into the alleged invention defined in claim 1 as I have construed it.

I should perhaps nevertheless go down the path of considering whether there would have been any significant divergence from this position if I had held that claim 1 was to be construed more narrowly. However, I do not feel able to place any reliance at all on the word "improved" to construe claim 1 differently from the way I have done so far. As regards the qualifications concerning the objective of clearing fluid I would have to say that the notion of using an inert gas for this very purpose was known from Silverstein's research. It is worthy of particular note that Dr Silverstein, in his Colorado testimony, states almost casually that they put a gas jet around the electrode to clear the blood off the area. There was no hint that this was anything other than a natural choice. There was no suggestion that it would have been sufficient simply to swab, sponge or otherwise physically and manually remove the blood, and there was apparently no perceived problem with using CO_2 as it was readily absorbed and disposed of by the body. Indeed, it is apparent from what has been said concerning the gas blanket approach in the prior art that the idea of blowing gas onto and/or around the surgical site had been around for a considerable time. It must be taken to be part of the common general knowledge to workers in the field of electrosurgery.

Mr Hamer's presentation of Mr McGreevy's conception and development of the invention included consideration of various aspects of the overall package. He mentioned in particular how Mr McGreevy had taken steps away from the conventional wisdom in a number of key areas. Instead of matching the generator impedance to that of the tissue he experimented with higher impedances and found a distinct improvement. He found that a high crest factor was detrimental and was in contrast to was disclosed in Morrison '088. He had come to the conclusion that it was necessary to clear the blood and other fluids away from the surgical site, and that to do that required an adequate gas flow rate. It would have been off-putting for Mr McGreevy to have read Dennis in advance of his research since Dennis' conclusions were against continuing with this technique as a satisfactory way of staunching bleeding and achieving a good eschar in the process.

While that may well be the case, and I do not question that the way Mr McGreevy reached the invention was as he described it in his affidavit, I have to return to the fact that I have found that the features which I have just listed, and which Mr Kitchin has tried to persuade me are relevant to this aspect of assessing the inventiveness of the invention, are either not included or not effective in claim 1, and I cannot take them into account as being features which in any way contribute to any inventive step over the prior art. Likewise I cannot take into account arguments which were put concerning questions of synergy between the gas flow rate and the entrainment of the electrical discharge within the gas jet. They too are features which I cannot draw from the claim. I am also of the view that the skilled man would have been in the same position at the priority date of the invention. As far as the knotty question of gas flow rates and embolism risk in particular is concerned Mr McGreevy was questioned by Mr Hamer on this and he acknowledged that any gas flow onto a fluid surface will have some effect and that the harder one blew the greater the effect. Mr McGreevy actually said that not only did Dennis achieve fluid clearance, he himself also did so when he reconstructed Dennis, but he did not get the combined fluid-clearing and energy transfer effect that he obtained with his own invention. The real question is whether it would have been open to anyone working in the field to use higher flow rates than were considered safe at the time.

Mr Kitchin's position was that the general wisdom, and indeed the advice and/or instructions from the major manufacturers of the day, was that it was unsafe to go above the level where there was a risk of embolism. From the totality of the evidence on the proprietors' behalf the level where the enhanced effects claimed for the quality of the eschar in the patent are obtained is at four litres per minute. That was said at the time to be "madness" but it has to be put in context. Researchers would not normally have been restricted to any particular figure when conducting trials on *ex vivo* tissue samples or *in vivo* on test animals. The exception may be where the terms of reference of a particular line of research were such that a particular outcome was being aimed for and that outcome must be workable within the normal guidelines of the time. Mr Kitchin's further submissions on the need to push back and hold back the fluid and as to the crucial nature of the density of the gas, the diameter/size of the column and gas pressure, as well of course as the gas flow rate, are all subject to the same difficulties inasmuch as they are not features brought out expressly in claim 1 and not capable of being automatically and inherently comprehended by the words of the claim. To take one point that Mr Kitchin raised by way of illustration, he said that it was important for the flow rate and the diameter of the column to be such as to confine and sustain the arcs. Too low a flow rate and the discharge will revert to sparking; too narrow or too diffuse a gas column and the arcs will not be properly confined. While there may well be critical parameters that will be inherent in the operation of the equipment and/or the settings placed upon the equipment by the surgeon, depending on the procedure to be undertaken, these features are not inherent in claim 1, whether qualified by the need to create the improved eschar as in the words of the claim, or whether more broadly interpreted as I have concluded is correct.

I do not find it possible therefore to identify the inventive concept embodied in the patent in order to take the next step required of me in following the four-stage process required in *Windsurfing*. To put it another way, the invention has fallen at the first hurdle. Had I considered that claim 1 does in fact have an inventive concept that I can identify in the face of the evidence put before me, I could then have gone on to consider the next step of assessing what the skilled but unimaginative addressee would have understood to be the common general knowledge in the art at the priority date. Had that been so I would have found that the common general knowledge was the same as the state of the art that I expressed above, since

it appears to me that in an art such as this where there were comparatively few companies involved in active research it is likely that any publication touching on the subject would have been disseminated or at least available to the key workers in the field. The common general knowledge would have included all of the prior art that I have reviewed so far and the "Evaluation of Electrofulguration" article which, although not enthusiastic about the effectiveness of the electrofulguration equipment used in the trials, did nevertheless contain a disclosure (especially of blood clearance by a jet of gas) which would have contributed to the understanding of the techniques and equipment in use and on paper at the time.

Any differences would have to lie with the nature of the eschar which, as before, I have disregarded in claim 1. In summary, therefore, I have come to the conclusion that claim 1 is not novel and lacks inventive step.

Since the applicants for revocation have attacked every claim of the patent and the proprietors have defended virtually all of them I will need to consider the patentability of each claim. Before doing that, however, it would be convenient here to address the question of whether the claims are excluded from patentability as being directed to a method of treatment of the human or animal body, as has been alleged by the applicants.

The applicants' statement raises this primarily against claim 1, and also against claims 2 to 8, 10 to 12, 14, 15, and 27 to 44. In each case the argument is that if the claim in question is to be construed in the sense that features concerning the gas flow rate and the nature of the energy transfer (which are features of its manner of use) are essential to the scope of the claim, regardless of whether those features impart novelty to the claim, then the claim must be directed to the use of the unit and not the unit itself. Therefore the claims must be deemed to be a method of treatment of the human or animal body by surgery and therefore excluded from patentability under section 1 of the Act as being incapable of industrial application according to section 4(2).

Mr Kitchin's response was that it was plain that the claims were to a new device and he particularly referred me to the way in which the Patent Encyclopaedia dealt with this matter

in para 5-232. The old test for a "vendible product" was still useful. Examples of patents which had been granted included one for a hearing aid involving a dental operation and another for a surgical dressing made by polymerising an elastomer precursor in situ. It was also said that a device was not excluded because it was used in connection with a therapeutic treatment if it did not play a part in the treatment. Drugs and appliances were patentable under previous Acts and still are. And of course, the current UK legislation, which is reflected in Article 52(4) of the EPC, is intended to have the same effect under the provisions of section 130(7). The EPO Guidelines unequivocally state in paragraph 4.2 that "Patents may, however, be obtained for surgical, therapeutic or diagnostic instruments or apparatus for use in such methods."

Secondly, Mr Kitchin observed that the applicants themselves, in the ASCO-T coagulator which they produce and which is presented in the extract exhibited to Mr Ley's affidavit, is a device in its own right even though it is described in terms of what it can do.

I do not find Mr Kitchin's second argument particularly persuasive, especially since the exhibit is not a patent with claims which could be compared in a direct way with those of the patent. His first argument, however, seems to me to be more cogent and more in accordance with the facts of the situation. The claims are undoubtedly couched in terms of apparatus. They are similar to the claims to the ash receptacle in *No-Fume* to the extent that the ash receptacle was defined in part by structural features and for the remainder in terms appropriate to its function. That is the essence of the claims before me, consisting as they do of items of hardware coupled with features of the effect obtained by operation of the hardware in a specific manner.

I tried to develop that position at the hearing by enquiring of both Mr Hamer and Mr Kitchin how they viewed the situation where the result of a claim of *No-Fume* type is defined in terms having a relationship with a new treatment of the type which is excluded from patentability. Both were agreed that they were unaware of any authorities that might cast some light on the question. I too know of none. Mr Hamer's response reaffirmed his basic objection that the result would effectively define a method which was excluded. Mr Kitchin took the view that a *No-Fume* type of claim reflects the nature of the apparatus and that a functional limitation

does not turn it into a method claim. The only matter of concern was whether or not the claim fell within the legislation's objective of "truly striking down methods of treatment and nothing else." That was in contrast to what he characterised as the legislative contortions of "Swiss type claims" to preserve the sanctity of claims to pharmaceutical compositions *per se*.

I find that the claims in question cannot reasonably be said to relate to methods of treatment, and neither can those parts of the claims which are characterised by the features concerning gas flow rate and energy transfer, whether or not these features have any limiting effect on the scope of the claims, be so said. Claims have been, and continue to be, allowed to apparatus characterised by result, as in the *No-Fume* case, and it would seem to me that it is perfectly proper that such a claim may, or perhaps must, include the means by which the result is to be achieved, even though the means may be specified in very general terms. Likewise, I do not believe that there is any difference in this respect between an invention in the medical field or one outside it. If it were otherwise, it would mean that any claim to surgical apparatus which contained a feature relating that feature to the surgical effect that it creates could be contested in the way that Mr Hamer has suggested. The fact that this is not the case is, I believe, a significant pointer to the intentions of the legislators that medical or surgical apparatus *per se* should be patentable and that the exclusion should apply solely to claims which are "truly", as Mr Kitchin put it, methods of treatment.

I therefore find that no claims of the patent should be revoked on the grounds that they are directed to a method of treatment has not been made out to my satisfaction.

Moving now to the remaining claims, I would have to observe that I have been presented with much less argument against them than against claim 1, even in respect of the other independent claims 45, 49, 54 and 55, and even though the pleadings and the statement of case appeared to treat all of the claims equally. The only concession that emerged at the hearing was that Mr Kitchin indicated that the proprietors claim no independent existence for claim 28, which merely claims that in the electrosurgical unit as defined in claim 27 "the gas jet is substantially absent of oxygen", a feature which, from the evidence, is clearly necessary to reduce the

effects of carbonization on the treated tissue. A question of possible concession by the proprietors also arose in relation to claim 44, but I shall deal with this in due order.

I will deal first with the remaining independent claims.

Claim 45 is as follows:

> "An electrosurgical unit for creating an electrosurgical effect on tissue, comprising:
>
> means for conducting a predetermined gas at a predetermined flow rate in a jet to the tissue;
>
> electrode means positioned within the gas jet and operative for transferring electrical energy to the tissue in ionized conductive pathways in the gas jet to achieve an electrosurgical effect;
>
> generator means for generating a first predetermined power level of electrical energy in a predetermined radio frequency range to create the electrosurgical effect and for generating a second predetermined power level of electrical energy at the predetermined radio frequency range, the second power level being substantially less than the first power level and substantially insufficient to create the electrosurgical effect;
>
> means for supplying the electrical power generated to the electrode means; and
>
> sensing means including means for operatively sensing a predetermined characteristic related to the distance between the electrode means and the tissue and for controlling the generator means to deliver the first power level when the electrode means is separated from the tissue by less than a predetermined distance and for controlling the generator means to deliver the second power level when the electrode means is separated from the tissue by greater than the predetermined distance."

In essence the claim is to electrosurgical apparatus in which the higher of two power levels is applied to an electrode within a gas jet when a characteristic relating to the distance between the electrode and the tissue is sensed to be less than a predetermined distance, so as to transfer RF energy in ionized pathways within the jet to create an electrosurgical effect on the tissue. The lower power level is applied when the characteristic is sensed to be greater than the predetermined distance, so that the electrosurgical effect is not then created.

Mr Hamer noted that this claim was a significant departure from the presentation of the invention as a whole in that it does not require the fluid clearing effect of the high flow rates, a feature which Mr Hamer described as the lynchpin of the case in the (unsuccessful) attempt to distinguish the invention from Morrison. Referring to Morrison '426 at column 4, lines 20 to 34, there is description of an arrangement in which sparking initiates once the electrode has been brought nearer to the tissue than a critical distance, after which the electrode can be drawn back to increase the arc length, and the power level that is required to initiate and maintain arcing increases. That was a system in which the power level changed from a lower to a higher level by itself, according to Mr Hamer, dependent on the distance from the tissue. Claim 45, however, needed a sensor, and that could be found in Meinke, where there is a sensor for the onset of arcing, and Harris, where there is a spark detection circuit to control the arc-only mode (column 4, line 23) and the non-arcing mode (column 2, lines 60 to 63), with manual switching between them. Spark detection would be a relevant sensor since, by reason of its being specified in claim 47, which is subordinate to claim 45 (via claim 46), claim 45 must comprehend the sensor being embodied in a spark detector. The argument against claim 45 was therefore that it was a mere collocation of the known Morrison system augmented with the standard features that come with generators.

Mr Kitchin argued that claim 45 was directed to a proper combination in which the parts interact. Neither the Morrison patents nor Brayshaw '891 disclosed a sensor related to the distance between tissue and electrode, and there was no basis for combining them with Meinke or Harris. There is a relationship between the sensing means and the generator because information from the sensor is used to control the generator.

As to mosaicing, a topic which would come into the discussion on several of the claims dependent upon claim 1, Mr Hamer's position was that the art consists of two quite distinct facets, namely the gas-assisted equipment and the generator. It would be possible and reasonable for the skilled man to use equipment and generator "off the shelf" and to test it to see what results he got. It was not relevant that no-one had described what effects he got from combining any particular type of electrofulguration equipment with any particular type of generator. It was relevant though that the proprietors had bought up Valleylab, the generator people, and the hand-held instrument people. Despite talk of synergy nothing special happens when argon is combined with radio frequency energy. This was confirmed, according to Mr Hamer, by the extract from a leaflet about the Beamer One Argon Beam Coagulation Cart which was handed up and which acknowledges that any one out of a list of generators would be suitable with the Beamer One Argon Beam Coagulator System. There was no suggestion that applying a generator known in cautery to argon-assisted electrosurgical apparatus would have any additional effect which could properly be regarded as synergy.

In my judgement neither Meinke nor Harris teach to the skilled man the concept of sensing a characteristic (even the presence of a single arc, as Mr Hamer had argued) in some way related to the distance between the electrode and the tissue and using it in the manner specified in claim 45 to control the power levels in the sense required to create or not create the electrosurgical effect. It follows that I do not see any justification for mosaicing either of these with Morrison or Brayshaw '891 and I therefore find that the challenge against claim 45 fails.

I do not need to concern myself in detail with the novelty or inventiveness of claims 46 to 48, which are dependent on claim 45, and therefore also survive the revocation challenge.

The next independent claim, claim 49, is as follows:

> "An electrosurgical unit for creating an eschar on tissue, comprising:
>
> means for creating a jet of a predetermined ionizable gas flowing at a predetermined flow rate;

electrode means positioned within the gas jet for transferring electrical energy to the gas jet in an electrical circuit which includes the tissue; and

electrosurgical generator means connected to the electrode means and operative for generating electrical energy at a predetermined radio frequency range and at a plurality of different predetermined power levels and operative to deliver the electrical energy generated to the electrode means to create ionized conductive pathways within the gas jet by which electrical energy is conducted to the tissue within the gas jet, said electrosurgical generator means comprising:

resonant circuit means having a natural resonant frequency within the predetermined radio frequency range and operative when energized by drive pulses to supply the electrical energy at the predetermined frequency range to said electrode means;

drive pulse generator means for supplying drive pulses of predetermined energy content to said resonant circuit means;

control means connected to the drive pulse generator means for controlling the drive pulse generator means to supply a plurality of predetermined different types of drive pulses, each predetermined different type of drive pulse having a different energy content;

sensing means connected to the resonant circuit means and to the control means and operative for sensing a predetermined electrical signal characteristic in the resonant circuit means which relates to a predetermined electrical condition in the ionized conductive pathways between the electrode means and the tissue, said sensing means supplying an active level signal to said control means upon sensing the predetermined electrical signal characteristic and supplying a target level signal to said control means when the predetermined electrical characteristic is not sensed;

said control means responding to the target level signal to control said drive pulse generator means to supply a target drive pulse of predetermined energy content sufficient to ionize the gas jet in a non-arcing state; and

said control means responding to the active level signal to control said drive pulse generator means to supply an active drive pulse of predetermined energy content sufficient to ionize the gas jet in arcs."

Mr Hamer likened this claim to claim 45 in that it too is not limited by reference to fluid clearance but instead concerns switching between two different levels which, in this case, happen to be chosen as the micro and macro modes. Mr Kitchin stuck rather closer to the words used in the claim to contend that it is concerned with establishing a target level in dependence on the sensed distance between tissue and electrode.

From the evidence that I have read and have been taken through, and by analogy with my reasoning in relation to claim 45, it is not evident to me that there is any disclosure in any of the cited specifications which would lead the skilled man to produce an electrosurgical apparatus incorporating the features of claim 49, and I therefore find that the challenge to the validity of claim 49 fails. Claims 50 to 53, being dependent upon claim 49, also survive the challenge to their validity.

Claim 54 is as follows:

"An electrosurgical unit for conducting electrical energy at a predetermined radio frequency range in an ionizable gas jet to tissue in an electrical circuit which includes the tissue to create an eschar in the tissue, comprising:

electrode means by which to transfer electrical energy to the gas jet; and

an electrosurgical generator means connected to the electrode means, said generator means having a sufficiently high end internal impedance to transfer sufficient electrical

energy in ionized conductive pathways in the gas jet while the gas jet is flowing at a predetermined sufficiently high flow rate to clear fluids from the surface of the stroma of a tissue perfused with natural fluids, and to sustain ionization when the gas jet is spaced sufficiently distant from the tissue to avoid any electrosurgical effect on the tissue; and wherein

the high end internal impedance of the electrosurgical generator means extends in excess of a value within the range of three to six thousand ohms; and

the predetermined gas flow rate is greater than four standard litres per minute."

Mr Hamer noted that this claim contains the sort of specific detail, especially concerning the numerical value attached to the gas flow rate, which he said should be attached to claim 1. It was also directed specifically to a monopolar system by reason of the direct reference to an electrical circuit including the tissue, and it was not hampered by reference to an "improved" eschar, but simply an eschar. However, he submitted, the claim had problems of clarity which had been highlighted in paragraph 22 of the statement of case, namely the reference to the high end internal impedance of the electrosurgical generator extending "in excess of a value within the range of three to six thousand ohms". Mr Hamer made the point that as far as he could tell the claim meant that the value was in excess of three thousand but within the range of three thousand to six thousand, and that it did not mean in excess of six thousand. Mr Kitchin did not address me on the construction of claim 54.

I am satisfied that Mr Hamer's construction of claim 54 is correct. The patent specifies values within the range three to six thousand, and none above six thousand. Under the heading "ESG Impedance Characteristics", pages 85 to 90 of the patent discuss the historical development of ESG impedances and indicate by reference to figure 20 how the effectiveness of ESGs has risen over the years. Upper and lower sets of curves relate to power delivery levels of 100 and 50 watts respectively. An early prior art ESG managed to provide power only up to about 1 kohms (curves 708 and 710). The ESG according to US4429694 (McGreevy) doubled the range up to about 2 kohms (curves 704 and 706), while the invention in suit is shown to

deliver power up to 5 kohms. The abscissa of figure 20 does not extend beyond five thousand ohms.

Mr Hamer suggested that the value of 2789 ohms specifically mentioned in the McGreevy patent US '694, although a little below the three thousand mark, was teaching that high impedances were desirable. Mr Wells would not be drawn into agreeing that the philosophy in 1986, when the invention was conceived, was to design impedance values to be several times the tissue impedance with the inevitable result that values up to six thousand ohms would be obvious, though he did concede that depending on which tissue you were interested in you might want to match in to tissue at three thousand ohms. That, of course, is the lower threshold level for the claimed range.

I do not find Mr Hamer's argument convincing to persuade me that the skilled man in 1986 would have found it obvious to have increased impedance to the range prescribed in claim 54. Since, furthermore, I am not persuaded on the evidence that the skilled man would, on the strength of the cited prior art and common general knowledge at the time, have found it obvious to use a gas flow rate in excess of four litres per minute, which, Mr Hamer noted, was the very sort of detail missing from claim 1, I find that the charge of lack in inventive step in claim 54 is unsubstantiated.

Claim 55 is as follows:

> "An electrosurgical unit for conducting electrical energy at a predetermined radio frequency range in a gas jet to tissue in an electrical circuit which includes the tissue, comprising:
>
> a pencil-like device adapted to be manipulated by the surgeon during the surgical procedure and comprising nozzle means for creating the gas jet and means for transferring the electrical energy in the gas jet to the tissue;

electrosurgical generator means for generating electrical energy at the predetermined radio frequency range;

gas supplying means for supplying gas by which to create the gas jet;

cord means operatively connecting the pencil-like device with the electrosurgical generator means and the gas supplying means, said cord means including an electrical conductor extending therealong and electrically connecting the electrosurgical generator means with the electrical energy transferring means to conduct electrical energy therebetween, said cord means also including a plurality of gas conducting lumens extending generally parallel to the electrical conductor and generally surrounding the electrical conductor;

means responsive to one of a predetermined gas pressure or gas flow condition within the pencil-like device and operative for preventing the electrosurgical generator means from delivering electrical energy upon detecting a failure to establish the predetermined one of the gas flow or gas pressure conditions;

said pencil-like device further comprises:

a handle connected to said cord means;

a nozzle and electrode support assembly having the nozzle means for creating the gas jet from gas supplied through the gas conducting lumens of said cord means and also comprising electrode means, the means for transferring the electrical energy from the electrical conductor of said cord means to the gas jet including the electrode means; and

coupler means connected to the handle and operative for removably connecting the nozzle and electrode support assembly to the pencil-like device;

said coupler means further comprises conduit means for operatively extending each lumen of said cord means through said coupler means; and

said nozzle and electrode support assembly comprises means operative when said nozzle and electrode assembly is properly connected in the pencil-like device for channelling gas supplied in one supply lumen in said cord means back to another sensing lumen in said cord means by which to sense the predetermined one of the gas flow or gas pressure conditions in said pencil-like device."

Mr Hamer's objection to this claim, as indicated in paragraph 23 of the statement, is that it concerns no more than a collocation of parts. Although he conceded that they were many in number that alone did not, he submitted, make the claim an invention. Mr Kitchin's simple response was to point out the various component part and to re-iterate that they co-operate as a whole to produce a device which is neither prior-published nor suggested in any of the prior art. In particular he claimed that the multiple lumen cord had not been previously disclosed at all and referred me to Dr Levitt's affidavit at paragraph 19 where he ventured the opinion that "the use of separate multiple tubes, or 'lumens' in the cord for the delivery and withdrawal of gas does appears to be new" on the basis of the documents he had reviewed.

Bearing in mind what I have said about Dr Levitt's qualifications to speak as a man skilled in the art, I nevertheless consider his analysis of the prior art to be generally fair and accurate, and in respect of this particular issue I am in agreement with him. I am also not persuaded that, in a claim of this complexity, Mr Hamer's simple collocation argument is effective, and I therefore find that the component parts of claim 55 interrelate in a way which would not necessarily have been expected, and that the validity attack on this claim fails.

I do not need to consider the validity of the refinement claimed in claim 56 which is appended to claim 55, and which therefore also survives.

I turn finally to the claims dependent upon claim 1, recalling that Mr Kitchin made no claim for the independent validity of claim 28 and that a related question arises concerning claim 44.

Claim 2 is directed to the RF power level, the gas flow rate and the gas being "selected to create the eschar in fresh blood-perfused tissue and to initiate the ionized conductive pathways in the gas jet when the gas jet is spaced a sufficient distance from the tissue to have no substantial fluid clearing effect on the tissue." Mr Kitchin took no point on the "fresh" fluid perfused tissue. Mr Hamer, on the other hand, considering the dual aspect of clearing fluid and creating the eschar, simply invited me to look at Mr McGreevy's testimony on the second day of the hearing, where he acknowledged that fresh fluid-perfused tissue has a lower impedance and therefore it would be easier to create an eschar using a "decent generator". His own System 5000 generator was the last major change in generator design before 1986, the priority date of the patent. So, Mr Hamer's argument was that if claim 2 means anything more, it lies in the selection of the parameters to effect initiation at a distance from the tissue.

He submitted first that all three Morrison patents, which he also suggested could be read together, disclose such an arrangement. In Morrison '064 there is discussion of the need in prior art systems to bring the electrode into contact with the tissue to initiate the discharge, whereas in Morrison '064 itself there are means to provide an auxiliary initiating discharge. The means may consist of a radio-active source or there may be an auxiliary gap across which an arc is struck to produce a long discharge from the electrode tip, after which the auxiliary arc is quenched to reduce the power consumption of the main discharge. Similar disclosure could be found in Morrison '426. Mr Hamer contended that this taught the need either to bring down the electrode to the tissue to initiate the discharge as in Morrison '088 or to use one of the auxiliary devices of '064 or '426.

Mr Kitchin submitted that the importance of the feature of discharge at a distance was to ensure that the corona is established before the jet is brought near enough to the tissue for there to be any risk of embolism. The Morrison patents, on the other hand, are concerned with providing separate means to establish the ionization and the arcing and there is no distinction drawn between establishing the corona and initiating the power level that will start the arcing. He likened the situation to "arming the weapon".

Looking at column 3 line 58 to column 4 line 2 of '064, for example, there is a clear description of the auxiliary means (which in the embodiment under consideration here is a filament) producing a corona discharge which becomes "heavy and luminous" as the active electrode is brought nearer to the tissue. The discharge is said to be effective for fulguration when the electrode is within about 0.5 inches from the tissue. In all of the other embodiments there is some form of auxiliary measure to initiate arcing. Plainly it is neither the selection of the gas, nor of the flow rate or the power level, which is responsible for initiating the corona. The situation in Morrison '426 is somewhat different. In the figure 2 embodiment, as described in column 3 line 40 to column 4 line 54, auxiliary tips in the path of the gas stream cause ionisation which is believed to be swept along by the gas flow to the main electrode. It is expressly stated at lines 57 to 66 that this effect is achieved assuming there is an appropriate electrical potential on the main electrode and that there is a return electrode, *ie* a patient plate. The heavy luminous discharge does not jump across to the tissue until the electrode-tissue spacing is less than a critical value, after which the electrode can be pulled back.

I do not find that either of these patents teaches the notion of initiating the discharge while the electrode is at a greater distance from the tissue than in normal use, as is the effect of the wording of claim 2. Morrison '426 discloses quite the reverse. No point was made concerning the main Morrison patent '088, and I am satisfied that it does not teach what is characterised in claim 2.

As a second submission in relation to claim 2, Mr Hamer said quite simply that all that was necessary to effect self-initiation was to increase the power and voltage as Mr Wells had agreed under cross-examination. Mr McGreevy likewise agreed that his System 5,000 would self-initiate without necessarily having to touch the tissue, but not reliably or predictably. It depended on many factors, including the history of the electrode, and on the waveform as well as the level of the voltage.

While I have some sympathy with Mr Hamer's viewpoint in this second argument and I accept both Mr Wells' expert opinion concerning the relationship between voltage and initiation and

Mr McGreevy's testimony that his device would self-initiate, albeit sporadically, that does not in my judgement go quite far enough to dispose of claim 2. That claim requires the discharge to be produced at a sufficient distance from the tissue so as not to have any substantial fluid clearing effect. The evidence I have on this aspect only tells me how self initiation can be enhanced; it does not state the circumstances under which this may or will be done. As far as the Morrison patents are concerned it is evident that the electrode still needs to be brought down towards the tissue despite auxiliary means to initiate arcing.

Despite my concerns about purported restrictions attaching (or not) to the nature of the eschar, I am not persuaded either that claim 2 is rendered obvious by any of the prior art cited in support of this objection, or by the allegation that because anyone would know how to get initiation it would automatically follow that the terms of claim 2 are met. I therefore find that the charge of invalidity against claim 2 is not substantiated.

Because of this conclusion I do not need to consider claim 3 (directed effectively to operation in the macro mode), since it is dependent upon claim 2 and therefore survives. Mr Kitchin acknowledged that this claim had no chance of survival if I had found that claim 1 was bad in the macro mode. I have not made a distinction between macro and micro modes in my findings on claim 1, so I do not need to call on Mr Kitchin's concession.

Turning to claims 4 to 7, these claims are directed to further qualifications as to the qualities of the eschar, particularly the nature of the arc hole reticulum and the underlying desiccation layer. I have already reviewed in detail the arguments relating to the significance of the quality of the eschar to the scope of claim 1, and conclude that since I have not found expressions concerning the nature of the eschar to be limiting in claim 1, the same reasoning applies to these claims, and I find that they too are invalid.

Claim 8 is appended to claim 4 and is directed to the arcs in the ionized pathways being "generally shorter in length and in time duration on the average compared to the arcs in a prior art electrosurgical unit operating in a fulguration mode and using a conventional active electrode in an atmospheric environment." The apparent contradiction between the

requirement of this claim that the arcs be shorter than in the prior art and the general tenor of the patent and these proceedings that the arcs are longer than in the prior art was answered by Mr Kitchin in terms that the claim had been inelegantly drafted and that what the proprietors were interested in was the shorter duration. It leads to a more effective arc hole reticulum which, the description in page 82 of the specification states, is a result of a smaller quantum of energy being transferred with each arc. Mr Kitchin supposed that the word were meant to refer to the length of time duration being shorter.

Mr Hamer contested that supposed "limitation" of claim 8 by referring me to the disclosure in Morrison of arcs whose lengths in one case were shorter and in another longer than those referred to in the patent and discussed with Mr McGreevy. Moreover, the length of the arc must be related to how close the electrode is held to the tissue. My understanding of that point was that it is not a function of the apparatus itself but of its manner of operation. Mr Hamer did not take up the point on arc duration to any extent, and Mr Kitchin's comments as to the proprietors' interest in this aspect and their willingness to defend the construction of claim 8 in this regard in a notional future infringement action leave me in some difficulty since I do not believe this issue has been fully argued.

If I turn to the patent itself, it is conjectured in page 92 at lines 20 to 21 that "the small arc holes and more even distribution of the arc energy are **probably** [emphasis added] related to the arc pathway lifetimes". The description then goes on to talk about some arcs taking longer paths while others take shorter paths. That seems to sum up the difficulty of the way in which this claim attempts to define a difference over the prior art in terms of arc duration. That must surely also be a feature of where the electrode is held relative to the tissue. In addition, the passage I have just quoted does not actually state that the arc duration is **shorter**; it merely says that they **may** contribute towards the improved effects. Further, the comparison made in the claim to "a" prior art electrosurgical unit without qualification gives the skilled man absolutely no reference by which to judge whether or not a potentially infringing device actually infringes. I find that claim 8 has no validity in its own right.

Claim 9, appended directly to claim 1, is concerned with the energy transfer being as a "non-arcing diffuse current in the ionized conductive pathways". The claim effectively relates to the "micro mode" part of claim 1. The applicants' statement alleges that this mode of operation is known from the prior art, particularly US 4188927 (Harris). However, in argument Mr Hamer relied on Meinke. There was some confusion in the bundles over which Meinke he was intending to use. In the event I was taken to the English translation of German patent No DT 2504280 which, it was agreed, was not the same document as US 4209018, although certain of the figures in these documents appear similar. Mr Hamer's point was that Meinke discloses a control system which detects the spark, once activated, and keeps the apparatus working in either the sparking or the non-sparking mode, whichever is selected. It provides disclosure of the selective transition between micro and macro modes which is absent from Morrison. Therefore, if there is any merit in the micro mode it has already been disclosed. It was also self-evident that if the power were turned down the apparatus would "get into the micro mode".

Mr Kitchin contested the argument based on Meinke on the grounds that it was not pleaded and could not be brought in at so late a stage in the proceedings. Also, inasmuch as the objection appeared to rely on mosaicing Morrison and Meinke, there was no foundation for combining these particular documents. What was more, Dr Levitt had been supplied with the documents by the applicants' patent agents, so there was no way of knowing how they had come to anyone's attention.

The arguments put up against this claim in connection with spark detection and the resulting selection of mode can be seen to be supported by the US patent No 4188927 (Harris) cited in the statement. It is concerned with an electrosurgical generator but mentions this feature even in the abstract. I feel safe to include it in connection with the objections to claim 9 by way of the statement even though it was not relied on in argument. No particular part of Morrison '088 was highlighted by Mr Hamer or in Dr Levitt's evidence, but I note that the abstract mentions "a diffuse blanket of [the] flowing gas" and this is reflected in the figure 5 embodiment at column 4 lines 41 to 56 where a diffuse blanket is again said to be created. While clearly the word "diffuse" appears in Morrison '088, it is in connection with the nature

of the gas jet and not of the discharge. I do not accept that Morrison '088 discloses the technical content of claim 9, nor does it suggest it.

For mosaicing of Meinke with Morrison to be successful, it seems to me that there must either be a reason for the skilled man to consider uniting the teachings of the two patents, or the technical content of at least one of them must be regarded as common general knowledge at the time. I have already said that the disclosure of Morrison would have been regarded as generally available to workers in the field at the priority date of the invention, and I believe that the diligent researcher would have been aware of Meinke. The fact that Meinke does indeed disclose control of the discharge to cause arcing or not leads me to the conclusion that the skilled worker at the time would have had sufficient information at his disposal to consider the application of discharge control as in Meinke to the Morrison system. On that basis I find claim 9 not inventive.

Claims 10, 11 and 12 are all characterised by the nature of the eschar created by the apparatus previously claimed in claim 9. They fall into the same category as other claims characterised in this way, and I find them invalid for the same reasons as for those other claims.

Claim 13 is appended directly to claim 1 and is concerned with the provision of means for selectively switching between the "micro" and "macro" modes. Mr Hamer referred to Mr McGreevy's evidence where he agreed that "it was well known to switch between two modes, cutting and fulguration or fulguration and desiccation." Moreover, other prior systems had a variety of modes such as in Ooster (US 4378801), Walker (US 4562838) and Harris (US 4188927). Mr Kitchin's response was simply that the applicants had not made out a case on the basis of the evidence for mosaicing these particular documents.

It appears to me that Harris discloses in column 2 lines 38 to 65 that electrosurgery usually commences in the desiccation mode and progresses to cutting or fulguration as the resistance rises and sparking begins. It is said to be desirable to have a desiccate-only mode for neurosurgery. Claim 1 is directed to the provision of two sources in an electrosurgical generator which respectively operate in desiccation and fulguration modes. Ooster is

specifically concerned with providing mode control switching, particularly for "pure cut, blend, fulgurate or desiccate" modes as listed for example in column 2 at lines 5 to 12. Likewise, Walker discloses in column 5 at lines 1 to 8 the provision of a switch 141 to control cut or coagulate modes. There is sufficient indication in the prior art in general terms for me to conclude that the provision of means to switch modes imparts no inventiveness to claim 13. Moreover, in my judgement the notion of mode switching in a wide range of technologies where more than one mode is possible would be plainly obvious to the relevant skilled man. I therefore find claim 13 invalid. I would also note that the passage from Harris that I quoted above is further evidence in support of my conclusion that there is no inventiveness in the feature of claim 9 relating to the operational mode where there is no sparking, ie the "micro" or desiccation mode.

Claims 14 and 15 can be dealt with together. They are contested in the statement only on the one ground of relating to an excluded method of treatment. I can immediately dismiss this objection for the same reasons as I rejected it in respect of claim 1. It cannot be the case that specifying the type of gas to be used in the electrosurgical apparatus transforms that claim into a method claim, let alone one excluded under section 4(2). However, Mr Hamer argued that both Mr McGreevy and Dr Levitt said that helium would be the normal choice for micro mode because of its lower ionization potential, and that argon would be the normal choice for macro mode for the converse reason. Mr McGreevy stated specifically that helium would not work terribly well in macro mode, but he could not say what would happen if you tried to use argon in the micro mode where there is less power available for ionization. The Birtcher 6400 generator which was used in the demonstrations does not have that mode available since it does not go down low enough in selectable power rating for the diffuse discharge required for desiccation. In addition Mr Hamer pointed to Morrison, which discloses the use of both argon and helium. For example, in columns 3 to 4 there is described an arrangement using helium and argon in concentric flows. In the face of the confirmation that Mr McGreevy gave as to the preferred choices depending on relative ease of ionization, it would seem that the inevitable choice would be helium for desiccation and argon for fulguration. As for the requirement in claim 15 for an inert gas as either of the gases in the micro or macro modes of claim 13, Mr Kitchin was not concerned to save it and Mr Hamer paid it relatively little attention. I am

satisfied that, without going to any particular document, the mere fact that a whole branch of electrosurgery known as Inert Gas Electrofulguration ("IGE") exists leaves me in no doubt that the skilled man would consider inert gases as a matter of course. I therefore find that claims 14 and 15 are not inventive and are thus invalid.

Claim 16, appended directly to claim 1, relates to the nozzle and the electrode being formed as a unit removable from the pencil-like hand-piece. The applicants' objection is that the claim is obvious in the face of Walker (WO 82/02488) which discloses the electrosurgical instrument with an auxiliary light and smoke removal features. The paragraph bridging pages 8 and 9 in Walker clearly discloses the nozzle and the electrode being in one piece which is interchangeable with others. A corresponding disclosure occurs in Walker (US 4562838) at column 4, lines 62 to 68. Mr Hamer also referred to Brayshaw '891 (not specifically pleaded in this respect in paragraph 10 of the statement), where a similar disclosure is found in column 8 at lines 45 to 57, and again in Siemens (UK 1014995) at line 14 of page 4 and in figure 3. In my judgment, the concept of replaceable or interchangeable nozzle/electrode combinations was on the evidence sufficiently well known at the priority date of the patent for it to have been an obvious design feature to incorporate in suitable electrosurgical equipment. I am not persuaded that there is any real limitation attaching to the requirement in the claim that the nozzle is "for creating a generally laminar jet". Claim 16 is thus invalid.

Claim 17, appended to claim 16 really adds nothing to claim 16, as Mr Hamer suggested, but if it does so it says no more than that the interchangeable nose piece is coupled to the gas and electrical supply. That goes without saying, otherwise the assembly would not operate. I find no separate validity for this claim.

Claim 18, appended to claim 17, is a safety feature preventing supply of electrical energy to the electrode until the nozzle/electrode assembly is properly connected. Mr Hamer's objection was based on good practice. Such safety devices are "a common feature in human life". They are found in coffee grinders and bayonet fittings for electric light bulbs. In Harris, Hanriot and Siemens there are sophisticated electrical safety devices preventing gas explosions and cutting off supply if the gas does not flow. I would also observe that the exhibited extract of

the "Kompendium Elektromedizin" discloses an arrangement in which the electrical discharge cannot proceed until there is enough gas flowing to form an effective blanket. I was not referred to any particular passages but I note that none of the arrangements in the prior art cited in these proceedings and touched on superficially by Mr Hamer is concerned with sensing proper coupling of the parts. Nevertheless, I agree that, as a concept, it has general application and would be found in many arts, such as those mentioned by Mr Hamer. Moreover, it seems to me to be inherent in Walker at least that there is no electrical connection to the electrode unless the nozzle/electrode is plugged in sufficiently that the electrode makes electrical connection with the conductor within the hand-piece. I am satisfied that there is no inventive ingenuity in applying such conventional measures to this equipment, and therefore that claim 18 is invalid.

Claims 19 and 20 concern the construction of the cord in the shape of a central electrical conductor surrounded by gas conductors (claim 19), which take the form of individual "lumens" (claim 20). Although Dr Levitt thought it was new, as I have previously mentioned in connection with claim 55, Mr Hamer said it was in Brayshaw '891 (figure 1, 2 and 5; column 9 lines 26 to 28 and 63), August (US 2828747) in figures 1 and 2 and column 2 line 32, and Siemens, figure 3. I find those disclosures equate with the requirements of claims 19 and 20 and that there would have been no obvious bar to the teaching of these documents being applied to the patent. Claims 19 and 20 are therefore invalid.

Claim 21 is appended to claim 1 and claims 22 to 25 are appended successively to claim 21. They were addressed as a block and that is how I will deal with them here. Mr Kitchin regarded them as important to the proprietors. They are concerned with automatic switching between a first power level at which arcing occurs and the eschar is created and a lower, target level where no arcing occurs, when a predetermined electrical condition is sensed in the ionized pathways. Mr Hamer's line of attack was that, first, the subject matter of claim 21 is within the generator, and, second, the prior art contains selective switching of power levels (as in McGreevy and Ooster, previously discussed) for different purposes and there is nothing inventive in the provision of automatic switching. Mr Kitchin's position was that there was an essential pre-requisite built in to claim 21 which required a condition within the ionized

pathways to be sensed in order to switch power levels automatically (instead of the operator needing to operate a foot pedal or the like) as the electrode approaches the patient for the purpose of preventing embolisation.

Following the same line of reasoning as I adopted for claim 45, I must come to the conclusion that there is no basis for combining the teaching in McGreevy, Meinke or Harris, notwithstanding that in claim 45 the feature of sensing a characteristic in the ionized conductive pathways was specifically related to the electrode/tissue separation. I do not accept Mr Hamer's argument that the provision of the automatic switching in claim 21 is a natural consequence of the manual (or pedal) switching performed in the prior art but for purposes which are not precisely the same as in claim 21. I therefore find that the charge of invalidity against claim 21, and consequently also against claims 22 to 25, fails.

Claim 26, appendant directly to claim 1, is very much in the same mould as claims 21 and 45 in that it is concerned with switching of power levels for particular purposes, in this claim that purpose being "to establish an operative separation of the pencil-like device form the tissue". In this respect it is more like the requirement of claim 45 to sense a characteristic related to the distance in question. Mr Hamer also took issue with the clarity of the claim. He said it was not clear what was meant by the "predetermined radio frequency range" and that there was nothing to connect the first frequency in the first mentioned predetermined range with the second frequency in the second mentioned range. They could be the same or different frequencies and a single frequency in each range does not define the range. The potential infringer would not know where he was. I share Mr Hamer's concerns. However, that was not an argument in the statement, and I am moreover satisfied that it would not in fact put the potential infringer in any significantly different position if the claim were drafted in clearer terms. Indeed, the claim should probably be construed as though the reference to "range" were omitted and the claim read as though only a single frequency value were specified, though it is not necessary for me to make a finding to that effect. I do not find it necessary to re-visit the arguments already considered in relation to claims 45 and 21 as regards switching and, accordingly, I find that the charge of invalidity against claim 26 fails.

Claim 27 is concerned with features of the eschar which I have already decided impart no novelty or inventiveness to the claims in which those features appear. I find this claim invalid.

Claim 28 has already been conceded on behalf of the proprietors, and I find it invalid.

Claim 29, appended to claim 27, is concerned with the provision of a limiter to restrict the gas flow rate to the level where arcs are supported without extinguishing the ionized pathways. Mr Hamer, while questioning the meaning of the claim (why have a limiter if the predetermined flow rate is at a maximum anyway?), contended that it would be the sort of thing that someone might do to prevent excessive flow being used. In addition, he pointed to Mr Wells' answer to the question put to him as to whether the skilled man would have thought of doing it, when he said, "I think it is unique in the context of this particular patent but you might well fit a limiter, yes. Mr Morrison did in his equipment". Mr Kitchin confined his defence of the claim simply to the need, from a safety angle, to provide a limiter. It was not a manner of operation as was generally swept up in paragraph 7 of the statement. I am satisfied that the provision of a limiter would be just the kind of overall safety measure that the skilled man would build into equipment of this kind, as confirmed by Mr Wells. Claim 29 therefore lacks inventiveness and is invalid.

Claim 30, also appended to claim 27, says merely that the RF range "includes those frequencies that result in conduction of the electrical energy substantially only through the ionized pathways of the gas jet". Mr Hamer postulated that it was either inherent in claim 1 or, if not, "it does not fulfil claim 1". Nothing has been said on behalf of the proprietors that persuades me to reach a different conclusion from Mr Hamer, and I therefore find that claim 30 has no separate validity.

Claim 31, also appended to claim 27, requires laminar flow for the gas jet. Mr Wells confirmed that laminar flow would be the objective in a system according to the invention, although he could not go so far as to say it would be obvious to do so. Mr Hamer thought it would be so and equated this claim with claim 28 since, without laminar flow, oxygen was more likely to be entrained. I agree, and find that claim 31 is invalid.

Claim 32, again appended to claim 27, requires each arc to be of substantially the same length. Mr Hamer compared this with Morrison, which says that the arcs go straight down from the tip of the electrode to the tissue. It is inevitable that the arcs will be of substantially the same length. Morrison '088, in column 3, lines 25 to 30, states "the discharge is straight down the gas column", and later "it can be directed to the bottom of a fissure or crevice without deflecting to the sides thereof". Mr Hamer regarded this as as good a disclosure of equal arc lengths as one was likely to find. There had been some exploration with Mr McGreevy as to the nature of the discharge, and he had suggested that individual arcs followed a helical path, handing up a colour photograph to confirm his understanding. This was not accepted by Dr Levitt on behalf of the applicants, who considered the apparently helical traces at the outermost surface of the column of gas to be turbulence. Whatever the reality of the nature of the discharge it appears to me that Morrison does indeed provide an enabling disclosure of equal path length sufficient to destroy the validity of this claim, and I therefore find that claim 32 is invalid.

Claim 33, appended to claim 27, is a claim to eschar features and I have held such features to be non-limiting. In the absence of any other subject matter in this claim I find it invalid.

Claim 34, appendant to claim 27, requires the generator to have an internal impedance such that initiation of ionization occurs at a sufficient distance from the tissue as to have no electrosurgical effect. It goes with claim 35, which requires the ionized pathways to be sufficiently long so as not to obscure visibly the formation of the eschar. Claim 34 is comparable to the latter part of claim 2, which I have found is not rendered invalid by the cited prior art, and by the same token I find the attack on claim 34 to fail.

Claim 35 was said by Mr Hamer to be disclosed in the statement in Morrison '088 at column 4 line 28 and column 3 lines 22 and 29, where the arcs produced by Morrison are four to six times longer than the prior art. Morrison was of course a cold plasma but its teaching of a longer jet remains relevant to the discharge in the patent in suit as regards this feature. It is also to be found in Brayshaw '891 where arc lengths of three-eighths and three-quarters of an inch are mentioned. There is also the difficulty of appreciating quite what the scope of the

claim is, since the nature of the electrosurgical procedure concerned may impose stricter limitations on viewing the surgical site than can reasonably be accommodated by a longer arc length. I find that there is no patentable subject matter in claim 35.

Claims 36, 37 and 38 are all directed at the micro or desiccation mode and are each characterized by the nature of the eschar. They are the equivalents to claims 9, 11 and 12 respectively, and are subject to the same criticisms. I therefore find these three claims invalid for the same reasoning as I have previously set out.

Claims 39 (conduction through ionized pathways), 40 (laminar flow), 41 (limiting electrical energy applied to the gas jet), 42 (equality of path lengths) and 43 (path lengths long enough to prevent visually obscuring the site) correspond in desiccation mode to the requirements in fulguration mode of claims 30, 31, 29, 32 and 35 respectively. For the reasons that applied to the earlier corresponding claims, I also find claims 39 to 43 invalid.

I believe that there may have been some confusion at the hearing in relation to claim 44, the last remaining claim which I must consider, and I am not convinced that I heard both sides unambiguously addressing this claim. At the end of the penultimate day of the hearing Mr Hamer described this claim as corresponding to claim 34, and, notwithstanding that this occurred during a part of Mr Hamer's submission which he characterised as "galloping", and which was therefore inevitably vulnerable to error in such a complex case, I believe that he was right in that claim 44 requires the internal impedance of the electrical generator means to be such that ionization ot the gas jet is initiated so far from the tissue as to achieve no electrosurgical effect. I note that I have found that the attack on claim 34 has not succeeded. However, during Mr Kitchin's equally hurried reply on the final day, Mr Hamer intervened to say that Mr Kitchin had abandoned claim 44, and Mr Kitchin appeared to agree that the applicants did not maintain independent validity for this claim. He did not otherwise address me on this claim. I am therefore in something of a quandary since, by analogy with claim 34, I am not inclined to find claim 44 invalid. In these rather unsatisfactory circumstances I consider that I have no alternative, notwithstanding Mr Kitchin's apparent concession, but to find that the charge of invalidity against claim 44 is **not** substantiated.

To summarise, then, I have found that the following claims are invalid:

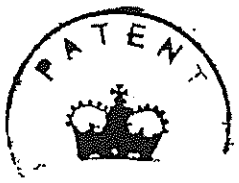
1; 4-20; 27-33; 35-43.

In respect of the following claims, however, I have found that the allegation of invalidity is not substantiated: 2,3; 21-26; 34; 44-56.

In these circumstances the appropriate order is, as provided under section 72(4), that Patent No 2188845 should be revoked unless within a period of two months from the date of this decision the specification is amended under section 75 to the satisfaction of the Comptroller. To that end the proprietors may, within the two month period, submit to the Patent Office proposed amendments in accordance with my findings in this decision. Such amendments should be shown in red ink on a copy of the B specification and a copy sent to the applicants for revocation, who will then have a period of one month to submit any comments thereon to the Patent Office, copied to the proprietors. I will then determine how matters should proceed. In the event that no amendments are submitted within the specified period I will issue a final decision revoking the patent.

I will defer the consideration of costs in the action to date until the final decision. Any appeal against this decision must be lodged within six weeks of the date of this decision.

Dated this 30 day of APRIL 1996



Dr P FERDINANDO

Superintending Examiner, acting for the Comptroller

THE PATENT OFFICE