

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

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BOARD OF PATENT APPEALS
AND INTERFERENCES

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

ROBERT F. LEVEEN
Junior Party,¹

v.

STUART D. EDWARDS,
RONALD G. LAX and HUGH SHARKEY,
Senior Party.²

Patent Interference No. 104,290

FINAL HEARING: May 15, 2002

Before PATE, SCHAFFER and LEE, *Administrative Patent Judges*.

PATE, *Administrative Patent Judge*.

¹ Application Serial No. 08/559,072, filed November 16, 1995. Accorded the benefit of U.S. Application Serial No. 08/410,344, filed March 24, 1995, now U.S. Patent No. 5,868,740, issued February 9, 1999.

² U.S. Patent No. 5,536,267, issued July 16, 1996, based on Application Serial No. 08/290,031, filed August 12, 1994. Accorded the benefit of Application Serial No. 08/148,439, filed November 8, 1993, now U.S. Patent No. 5,458,597, issued October 17, 1995.

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FINAL DECISION UNDER 37 CFR § 1.658

This is the second part of a bifurcated final decision in Interference No. 104,290. The first part was rendered by a trial section merits panel on April 23, 2002, and May 17, 2002 (Paper Nos. 348 and 351). We also herein make final a motions panel's decision granting LeVeen's preliminary motion 1, dated February 23, 2001, and contained in Paper No. 246. Accordingly, the decision on LeVeen's preliminary motion 1 is now merged with the two-part final decision.

The junior party inventor is Robert F. LeVeen. The junior party application is assigned to the University of Nebraska Medical Center, which has exclusively licensed the Radio Therapeutics Corporation. Radio Therapeutics Corporation is a subsidiary of Boston Scientific Corporation. The senior party inventors are Stuart D. Edwards, Ronald G. Lax, and Hugh Sharkey.³ The senior party patent is assigned to Rita Medical System, Inc.

The invention is directed to a radio frequency (rf) electric current probe for hyperthermic treatment of tumors in an

³ The senior party will henceforth be referred to in the singular, i.e., Edwards.

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organ by ablation of the tumor. EX-5004.⁴ Inside the probe are undeployed rf electrodes which may be deployed to penetrate an organ and surround a selected mass of tissue. To practice the treatment regime, the probe is advanced through an organ to the vicinity of a tumor. The electrodes are extended from the probe into a three-dimensional deployed position to surround the selected mass which includes the tumor. The deployed electrodes act as conductors for the rf electric current.

The count reads as follows:

A probe system comprising:

an elongate member with a distal end and a proximal end;

a handle at the proximal end of the elongate member; and

an electrode deployment device positioned at least partially in the elongate member and including a plurality of retractable electrodes that are inserted into tissue, penetrate tissue and surround a selected mass, each electrode having a nondeployed state when positioned in the elongate member and a distended deployed state when advanced from the elongate member defining an ablation volume between deployed electrodes, each deployed electrode having at least one radii of curvature; and

wherein the electrodes are advanceable in and out of the elongate member.

⁴ The following abbreviations are used throughout. The LeVeen Record, exhibits and briefs are abbreviated LR, LX-, and LB, respectively. Likewise, the Edwards Record, exhibits and briefs are abbreviated ER, EX-, and EB.

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The claims of the parties that correspond to the count are:

LeVeen: Claims 43 and 44

Edwards: Claim 32

Background

The interference was declared on July 16, 1999. During the interlocutory phase, a veritable plethora of motions were filed, in what might be termed interference by inundation. One significant preliminary motion with a bearing on this final hearing was Edwards' preliminary motion 2, a portion of which requested judgment on the ground that LeVeen's claims 43 and 44 are anticipated by Edwards' Patent No. 5,458,597 (the '597 patent) based on its filing date of November 8, 1993. In a decision⁵ by a panel of the trial section, this portion of the motion was deferred to this final hearing on priority.

In Paper No. 246, the panel granted a preliminary motion by LeVeen that Edwards' claim 32, the only Edwards claim designated as corresponding to the count, was unpatentable to

⁵ Paper No. 241.

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Edwards based on lack of descriptive support under 35 U.S.C. § 112, first paragraph. Since Edwards' only claim in the interference had been determined to be unpatentable to Edwards, the panel first ruled that junior party LeVeen need not put on a priority case.

The panel subsequently modified its ruling and required junior party to prove priority, because, notwithstanding the lack of written description for Edwards' claim, the Edwards specification still appears to be a constructive reduction to practice of at least one embodiment falling within the scope of the count. In this new order,⁶ Edwards was permitted to argue abandonment, suppression, or concealment at final hearing, to attack LeVeen's evidence of conception, reduction to practice, and diligence, and to introduce rebuttal evidence.

Issues

The following issues are raised by the parties in their briefs:

a) has junior party LeVeen established an actual reduction to practice before the effective filing date of the

⁶ Paper No. 270.

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involved Edwards patent, i.e., priority of LeVeen's subject matter corresponding to the count,

b) a motion (15) by junior party LeVeen to suppress the testimony of Daniel,

c) a motion (16) by junior party LeVeen to suppress the testimony of Hansen,

d) has junior party LeVeen abandoned, suppressed, or concealed the invention,

e) has junior party LeVeen established an invention date that would antedate the effective filing date of the senior party's involved patent under 37 CFR § 1.131, i.e., patentability of LeVeen's claims.

LeVeen Motion 15 to Suppress Testimony of Daniel

LeVeen moves to suppress the testimony of Edwards' witness Daniel. As noted in our discussion of the background of the interference, it was originally determined that LeVeen would proceed under 37 CFR § 1.131 to antedate the Edwards patent.⁷ At the time of that determination by a merits panel of the trial

⁷ Paper No. 246, February 23, 2001.

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section, no testimony on the part of Edwards was contemplated and Edwards was not given a time period for introducing any evidence. However, when the panel determined a limited priority testimony period was necessary, Edwards was given a time period for entry of rebuttal evidence. It was during this period that Edwards provided notice under 37 CFR § 1.671(e) that he intended to rely on the Daniel declaration during his duly authorized testimony period. It is clear that the Administrative Patent Judge (APJ) in charge of the interference afforded LeVeen the opportunity to cross-examine Edwards' witnesses in the order issued August 22, 2001. Accordingly, the Daniel declaration meets the requirements of 37 CFR §§ 1.671 and 1.672. Furthermore, inasmuch as LeVeen was afforded a period to request cross-examination of the witness, we can see no reason why the Daniel declaration should be suppressed. LeVeen, the moving party, has not satisfied his burden, and LeVeen Motion 15 to suppress the declaration of Daniel is DENIED.

LeVeen Motion 16 to Suppress Testimony of Hansen

LeVeen also moves (LeVeen Motion 16) to suppress the testimony of Edwards' witness Hansen. LeVeen argues that the

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testimony of Hansen should be suppressed because Dr. Hansen, by his own admission, was not one of ordinary skill in the art at the time the invention was allegedly reduced to practice by Fox and LeVeen in 1993. We acknowledge that Dr. Hansen has so testified at EX5170 at 47. However, this objection by LeVeen misses the mark. The level of ordinary skill in the art is an objective standard.⁸ It is the level of knowledge of a hypothetical person. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454, 227 USPQ 293, 297-98 (Fed. Cir. 1985). The subjective knowledge of any actual living person, such as Dr. Hansen, at any given time is simply beside the point. Either Dr. Hansen is an expert qualified to give an opinion about the level of skill in the art in 1993 or he is not. Based on his qualifications and his *curriculum vitae*, we are of the view that Hansen is such an expert.

⁸ Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696-97, 218 USPQ 865, 868-69 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

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Secondly, LeVeen argues that Hansen's testimony is irrelevant as based on a faulty legal conclusion that for a reduction to practice of the subject matter of the count, a successful test simulating or using the device in a living subject must be shown. LeVeen's argument is based on the premise that the count does not require the deployment or use of the device in living tissue. However, the case cited by LeVeen does not support LeVeen's argument. LeVeen cites **Koval v. Bodenschatz**, 463 F.2d 442, 447, 174 USPQ 451, 455 (CCPA 1972). While the case states that requirements derived from the objectives of one of the parties that are not reflected in limitations embodied in the count ordinarily cannot be imposed on an asserted actual reduction to practice,⁹ **Koval** affirmatively requires a relationship between the test conditions and the intended functional setting of the invention. *Id.* (citing **Knowles v. Tibbets**, 347 F.2d 591, 594, 146 USPQ 59, 61 (1965); **Voisinet v.**

⁹ In this instance, it appears that use in the organs of a living subject is an objective of **both** parties. See, for example, LX-1002 at 8, lines 19 and 20: "treatment region may be located anywhere in the body" or "will comprise a solid tumor within an organ of the body" and EX-5004, col. 4, line 43-44, "the delivery catheter is advanced percutaneously to an internal body organ or site."

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Coglianesse, 455 F.2d 1064, 1068, 173 USPQ 16, 19 (1972)). See also *Powell v. Poupitch*, 167 F.2d 514, 77 USPQ 379 (CCPA 1948) (aircraft rivet not specifically stated for aircraft in the count, not reduced to practice without flight testing). It is our finding that the intended functional setting of the subject matter of the count is to ablate targeted tissue such as tumors in an organ of a living subject. The functional setting of the subject matter of the count is not for ablating or cooking small portions of explanted organs with an electrosurgical unit. Such a functional setting would appear to have little utility. Accordingly, Hansen's testimony is not irrelevant on the ground alleged by LeVeen, and it will not be suppressed on this basis. Furthermore, Hansen has not required that the subject matter of the count be of commercial refinement in his opinion testimony as alleged by LeVeen. We do not find such a requirement in Hansen's declaration or deposition.

For the above discussed reasons, the LeVeen Motion 16 to suppress the Hansen testimony is DENIED.

The LeVeen Case for Priority of Invention

For victory in the priority phase of this final hearing, LeVeen is relying on an alleged actual reduction to practice

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before the filing date of the senior party benefit application which was November 8, 1993. As the junior party in an interference between cases which were at one time co-pending, junior party LeVeen bears the burden of proving priority, in this case an actual reduction to practice, by a preponderance of the evidence. *See Cooper v. Goldfarb*, 154 F.3d 1321, 1326, 47 USPQ2d 1896, 1900 (Fed. Cir. 1998) (*quoting Scott v. Finney*, 34 F.3d 1058, 1061, 32 USPQ2d 1115, 1117 (Fed. Cir. 1994)). Priority, conception, and reduction to practice are questions of law which are based on subsidiary factual findings. *Cooper*, 154 F.3d at 1327, 47 USPQ2d at 1901. In order to establish an actual reduction to practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the interference count; and (2) the invention worked for its intended purpose. *Id.*

It is our determination based on the following findings of fact that LeVeen has not established an actual reduction to practice before the critical November 8, 1993, date for the following reasons:

First, all limitations of the count were not reduced to practice. We have construed the count limitation of "selected

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mass" to mean a preselected mass. There is no evidence that any area in the explanted livers was first targeted, the apparatus used, and the target area inspected to compare the actual ablation accomplished to that ablation desired in the targeted area.

Next, there is no convincing evidence that the experiments were successful. Discounting conclusory statements from Fox, LeVeen and Kilzer made years after the experiments were undertaken, no standards for success were ever established and no contemporaneous recognition of success can be found in the records. Indeed, a grant proposal indicates the results were preliminary, and testimony and the grant proposal indicates the experiments were merely exploratory in nature.

Thirdly, the invention was not tested in its intended functional setting, so the inventors did not determine that it would work for its intended purpose. The interference subject matter was tested in an explanted liver in repose on an electrode plate. Credible testimony establishes that such experimental conditions do not simulate the impedance of the body of a patient, the movement of the organs in a patient under surgical conditions, or the heat-sink/cooling effect of blood flow of a living organism. Our findings of fact and conclusion of law follow.

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As an initial matter, we note that an argument of Edwards raises an issue of count construction. See EB10-11. The proper interpretation of a count is a question of law. **Credle v. Bond**, 25 F.3d 1566, 1571, 30 USPQ2d 1911, 1915 (Fed. Cir. 1994) (*citing Davis v. Loesch*, 998 F.2d 963, 967, 27 USPQ2d 1440, 1444 (Fed. Cir. 1993)). The established standard of count interpretation is that interference counts are to be given the broadest interpretation which they will reasonably support. **Mead v. McKirnan**, 585 F.2d 504, 507, 199 USPQ 513, 515-16 (CCPA 1978). Resort to a specification from which a claim on which the count is based or resort to extrinsic evidence is only appropriate or necessary when an ambiguity exists in the count. If an ambiguity is found, resort may be had to the specification of the patent from which the claims originate to resolve the ambiguity. **See In re Spina**, 975 F.2d 854, 856, 24 USPQ2d 1142, 1144 (Fed. Cir. 1992). Determination of the existence of an ambiguity requires consideration of both the language of the count and the reasonableness of the arguments indicating the count has different meanings. **Kroekel v. Shah**, 558 F.2d 29, 31-32, 194 USPQ 544, 546 (CCPA 1977). The mere fact that the parties ascribe different

meanings to a count or that the count is readable on more than one embodiment does not render the count ambiguous. *See id.* at 32, 194 USPQ at 547.

The specific language of the count at issue is the recitation wherein electrodes are "inserted into tissue and surround a selected mass" While this portion of the count is recited in functional language, it is our conclusion of law that the plain meaning of "selected mass" in the count means a preselected mass, i.e., the ability to position and deploy the claimed electrodes around a "treatment region" as LeVeen defines a tumor in his specification. LX-1002 at pages 4, 8, 9 and 17. The electrodes are thin, flexible wires, and we regard the ability of the wires to actually surround the tissue intended to be ablated to be an important feature of the claimed subject matter.

The following are our findings of fact with respect to LeVeen's priority case-in-chief. In 1992 and 1993, Dr. Robert LeVeen, the junior party inventor, was employed as a radiologist at the V.A. Medical Center in Omaha, Nebraska and at the University of Nebraska Medical Center. LX-1172, ¶1.

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Robert LeVeen states that he conceived the invention on April 6, 1992. LX-1172, ¶2. On that date he attended a lecture by Dr. John McGahan who described using a single needle electrode to ablate tissue in living animals and humans. *Id.* LeVeen further states that when leaving the lecture he conceived the idea of using curved electrodes to surround a selected portion of tissue and by applying radio frequency current to the electrodes "desiccate tissue surrounded by the curved electrodes." *Id.* This testimony by inventor LeVeen is uncorroborated.

LeVeen states that during the fall of 1992 and on Christmas Day 1992 he discussed his invention with his father and brother. LX-1172, ¶¶3, 4. These persons did not appear as witnesses, and this testimony by LeVeen is uncorroborated. LeVeen additionally states that he disclosed his invention to Dr. Philip D. Schneider sometime during the spring of 1993. LX-1172, ¶5. Schneider was not called as a witness.

In the spring of 1993, LeVeen assigned one of his assistants, Randy Fox, to work on building a prototype of the tissue ablation apparatus. LX-1172, ¶6; LX-1173, ¶3. Fox states that he was shown a Tiffany drink stirrer. *Id.* The ablation apparatus Dr. LeVeen had in mind would resemble the stirrer,

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although the ablation apparatus would be physically smaller.

Id. Fox describes the ablation apparatus in paragraph 4 of Exhibit 1173. Fox states that the "curved wire electrodes . . . would be deployed through a cannula by holding the cannula" In use, the cannula shaft can be held by a forceps or the operator's fingers. LR31, 47. Notwithstanding Edwards' argument that the cannula is not a handle, we construe the count term "handle" broadly, and note that the cannula can be held with a portion of the operator's hand.

LeVeen gave Fox a Dormier basket with which Fox was to fashion a prototype of the invention. LX-1173, ¶5. A Dormier basket is a surgical instrument used to retrieve concretions such as kidney stones or gallstones. LR91. LX-1127 is a photograph of a Dormier basket. The distal end of the Dormier basket was cut off, and the stainless steel spring wires were everted. LeVeen sketched this shape of the wires in EX-5144. The sketch shows that the four stainless steel wires were bent generally in the shape of one-half of a hyperboloid with the open end of the hyperboloid positioned distally. The everted wires of the basket become the deployable electrodes when the probe is inserted in a cannula. The cannula used on the prototype was 16 gauge.

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LX-1173, ¶7. The prototype was completed approximately one week prior to June 23, 1993. *Id.*

The proximal end of the modified Dormier basket was fastened to a jumper wire which was plugged into a Bovie® X-10 electro-surgical unit. LX-1173, ¶7. Thus, the spring wires become radio frequency current conductors when the electro-surgical unit is energized. *Id.*

Based on the above recited facts, and reconciling the spring 1993 date of paragraph 3 of LX-1173, with the one week prior to June 23 date of paragraph 7 of LX-1173, we credit LeVeen with a corroborated conception of the subject matter of the count on June 16, 1993.

Pursuant to instructions from Dr. LeVeen, Fox performed the first test of the tissue ablation apparatus. The tests were conducted in Rooms 5005-5007 of the Joint Cardiovascular Research Laboratories at the University of Nebraska Medical Center.

LX-1173, ¶6. The first tissue ablation test was an *in vitro* test on a freshly explanted pig's liver. The date of the first test was June 23, 1993. LX-1173, ¶9. The manager of the lab, Karen Kilzer, was present at the first test. LX-1173, ¶10; LX-1177, ¶¶5,6. The test was reported to Dr. LeVeen after it

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was conducted. LX-1173, ¶9. To perform the test, Fox placed the liver on a stainless steel ground plate¹⁰ and connected the ground plate to the "Patient Plate" terminal of the electro-surgical unit. LX-1173, ¶10. The four wire modified Dormier basket electrodes were loaded into the cannula. The cannula was inserted into the pig's liver. *Id.* While holding the proximal end of the cannula with one hand, Fox advanced the proximal end of the modified Dormier basket with the other hand. The wire electrodes were advanced through the cannula and out into the pig's liver where they distended and assumed their deployed configuration. *Id.* Fox then energized the electrosurgery unit to supply rf current to the electrodes to ablate the tissue between the electrodes. *Id.*

LX-1129 is a copy of Fox's lab notebook for June 23, 1993. LX-1173, ¶11. Fox placed a temperature probe in the center of the four electrodes to measure temperature under initial conditions and at the conclusion of the tests. *Id.* Fox recorded several tests with the electrosurgical instrument operated at ever-increasing power. In all tests, the

¹⁰ The plate is elsewhere described as aluminum.

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electrosurgical instrument was energized for 30 seconds. *Id.* The test results, i.e., the changes in temperature after 30 seconds of rf heating, are indicated in a table in LX-1129.

After the probe had been removed from the liver for the last time, the liver was dissected and photographed. LX-1173, ¶12. The tissue between the electrodes appeared browned and charred, i.e., ablated. *Id.*

Both Fox and LeVeen stated that they regarded the June 23, 1993 tests to have been successful tests, amounting to a reduction to practice of the subject matter of the count. LX-1173, ¶13; LX-1172, ¶12.

During the summer of 1993, Fox constructed several other embodiments of the probe. These embodiments utilized between eight to twelve electrodes fashioned of .0008 inch diameter stainless steel wire. A photograph of an eight electrode probe is entered into evidence as LX-1130. This electrode was used to conduct demonstrations on September 28, 1993. The demonstrations were conducted *in vitro* on beef liver. LX-1173, ¶17. LX-1131 is Fox's laboratory notebook that describes the demonstrations. *Id.* The separate demonstrations are labeled Nos. 1-5. The demonstrations were videotaped under fluoroscopy.

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The tape has been lost. Temperature measurements were taken at various distances from the electrodes. Kilzer witnessed these demonstrations, also. LX-1173, ¶19.

The results of the tests of September 28, 1993 were communicated to LeVeen at a later time. LeVeen watched the videotape, and inspected cut up beef liver samples that showed ablation and/or charring by the electrodes. LX-1173, ¶22.¹¹ Fox describes LX-1132-34 as photographs of the charring that resulted from the test. LX-1173, ¶22.

Between September 28, 1993 and October 18, 1993, Fox was occupied building electrodes for additional probes. LR228. Additional tests or demonstrations were undertaken on October 18 and October 20, 1993. LX-1173 ¶¶24-27. These tests were also described in Fox's lab book.

In summary, LeVeen is relying for reduction to practice on a series of *in vitro* experiments on harvested animal livers conducted from June 23 through October 20, 1983. The livers

¹¹ It is noted that Fox's declaration states that the probe tested on September 28, 1993 was a probe with eight electrodes. LX-1173, ¶15-17. However, in paragraph 21 Fox states that the liver had been charred "by the four electrodes" Cross-examination on this point reveals that undesirable charring was experienced around four of the eight electrodes. LR227.

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were placed on a conductive plate on a lab bench and a probe was inserted into the livers. Electrodes were deployed manually into the livers and rf electric current from the electrosurgical unit was used to ablate the liver tissue around the deployed electrodes.

In contradistinction to LeVeen's testimony that the successful tests establish a reduction to practice of the subject matter of the count, Edwards adduces testimony from an expert witness to the effect that demonstrations between June and October, inclusive, were not successful experiments in the required functional setting leading to a legal determination of reduction to practice. The Edward witnesses are Hansen and Siperstein.¹²

The following are our findings with respect to this testimony. According to Hansen, the experiments did not demonstrate the ability to accurately position the apparatus in an

¹² Much of the cross examination of Hansen consists of questions designed to show that Hansen is not an expert according to Hansen's own definition or showing that Hansen was not an expert or one of ordinary skill in the relevant art in 1993. It is our finding that Hansen is an expert in rf ablation of liver tumors based on education and experience, and we find his entire testimony to be relevant and credible.

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in vitro static sample of explanted tissue, let alone a dynamic organ. EX-5153, ¶10. Since the invention has been described as merely an improvement in a single needle ablation device, it would seem to be incumbent on the part of the experimenters to show that multiple electrodes could be accurately and repeatably deployed at a predesignated location in the target organ. Furthermore, Hansen states that the ability to deploy the electrodes at a designated target is made even more uncertain in that the tissue in a living patient undergoes movement due to respiration, arterial pulsation and peristaltic motion of adjacent organs. *Id.* Hence, the simple forcing of the distal end of the catheter to a random position in the explanted liver, as was apparently the experimental protocol used here,¹³ does not appear

¹³ Apparently, the experiments were undertaken with only a verbal protocol. LeVeen and Fox agree on this point. LR92; LR192. Kilzer is of the opinion that some written protocols existed. LR289-91. Notwithstanding the conclusory statements of Fox and LeVeen that the experiments were successful, it is difficult for the junior party to prove the success of any experiment without evidence of some sort of protocol or criteria for defining success. Note the following exchange at LR128:

Q Did that [oral] protocol define what was considered a successful ablation?

A In general--in a general sense, as before, large size and homogeneity was probably a parenthetical desired outcome, but it was not a criteria. ***There were no specific criteria.*** Criteria
(continued...)

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to satisfy the count limitations of localizing a selected tissue region and then surrounding the selected region with the electrodes.¹⁴ We fully credit the testimony of Hansen on this issue.

Hansen also declares that the bench conditions employed for the tests did not simulate real-life, physiological conditions. EX-5153, ¶11. It is our finding that the *in vitro* bench tests completely ignored the impedance characteristics of a living organism, and furthermore ignored heat-sink/blood flow cooling effects that would be experienced in a live test animal or human.

As noted above in our factual findings, the tests relied upon by LeVeen were conducted by placing an explanted animal liver on a ground plate that was connected to the ground

¹³(...continued)
are set when you're testing a hypothesis. **We were exploring-- these were still exploratory** [emphasis supplied].

¹⁴ The Fox declaration is silent with respect to test conditions of predesignating a selected mass in the liver, maneuvering the distal end of the cannula nearby and deploying the electrodes so that the selected mass is ablated.

Additionally, the fact that one round of experiments was performed under fluoroscopy is not necessarily indicative of guiding the cannula and deploying the electrodes to surround a mass that was selected before the experiment. It may be indicative simply of a desire to observe the operation and deployment of the electrodes.

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terminal of a Bovie® electrosurgical unit. We are in agreement with Hansen that the current flow path from the electrodes to the ground was directly from the liver tissue to the ground connection across the surface of the tissue in contact with the ground plate. EX-5153, ¶12. We are further in agreement that the impedance drop in the system was merely across the tissue of the explanted liver. *Id.*

It is our finding that in actual use with a live patient, the rf circuit established by the electrosurgical apparatus includes the targeted tissue in which the electrodes are placed along with the mass (composed of organs, tissue, and blood) between the targeted tissue and the ground pads or electrodes placed on the exterior of the body of the patient. EX-5153, ¶13. Thus, both the targeted tissue and the body mass contribute to the total impedance of the rf circuit, with the body mass typically contributing the major share. *Id.* Since the body mass typically dissipates the majority of the power, to disregard this mass in the tests seriously underestimates the amount of power needed to ablate tissue. *Id.* It is Hansen's expert opinion that in the 1993 time frame one of ordinary skill would not have known, absent *in vivo* testing or suitable modeling

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thereof, that simply increasing power would have generated an ablation volume between the electrodes without adverse consequence to surrounding tissue. EX-5153, ¶13.

We further note that at the time of the alleged reductions to practice, the prior art found it difficult to properly heat tumors sufficiently, and that tumors tended to become thermoresistant if they survived early treatment. LX-1146 at 20. This is another reason that testing *in vivo* to insure a correctly elevated temperature would appear necessary to establish a reduction to practice.

LeVeen also recognized that single needle ablation had exhibited problems with charring and gas formation. LX-1146 at 21. LeVeen states in the grant proposal¹⁵ that an array of needles would ablate a nearly spherical area of tissue and avoid charring, carbonization and gas formation. *Id.* Thus, LeVeen admits that the subject matter of the interference is intended to be qualitatively different from the prior art. The multiple needle array is not just an extrapolation of the single needle

¹⁵ LeVeen filed a grant proposal to request additional funding to continue tests on the invention. The proposal is LX-1146.

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device. It is this qualitative difference that would demand an **in vivo** test.

Hansen also stated, and we find credible, that **in vitro** testing can be useful for comparing performance of a prior art device, whose ablation characteristics are known, to a new device whose ablation characteristics are not known, before clinical testing. However such an **in vitro** test must approximate the impedance characteristics of a living organism. EX-5153, ¶14. Hansen testified that one medically acceptable manner of testing that approximates impedance is to place the organ of choice on an insulated plate and immerse the plate in an electrolyte solution buffered to the approximate impedance of a human body. **Id.**

Hansen also testified that the **in vitro** tests of a static explanted liver neglected to account for the heat-sink/blood circulation cooling effects of an organ in a living organism. This effect results from the fact that blood flowing through the heated tissue carries away the rf generated heat, much as an automobile's coolant carries heat from the engine block to the radiator. Hansen mentioned that this effect was recognized in the prior art including the McGahan publication.

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It is our additional finding that LeVeen recognized the heat-sink problem in his grant request proposal. LX-1146 at 24. LeVeen stated in the proposal:

All of the tests to date have been **ex-vivo**, and needless to say **in-vivo** testing must be performed. We recognize the significant heat sink afforded by flowing blood will alter the **in-vivo** results somewhat, but we are optimistic that this system has potential of ablating a large enough volume of tissue to be clinically useful in a large number of patients.

Thus, it can be seen that LeVeen recognized possible shortcomings in the tests as previously performed. LeVeen goes on to state in the potential pitfalls section of the proposal that dramatic heat-sink effects may result in insufficient heating **in vivo**. LX-1146 at 28.

Lastly, as recognized in our discussion of the lack of any formal protocol for the demonstrations, explorations, or experiments conducted in June through October of 1993, the only evidence that the experiments were regarded as successful are the non-contemporaneous conclusory statements of success found in the declarations. The declarations do not establish success by comparison to any formal oral or written protocol. LeVeen

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testified there were no criteria for success formally established. In this instance, we give the contemporaneous grant proposal substantially more credence. The experiments performed in June through October, inclusive were preliminary in nature, and *in vivo* tests were needed for a *de jure* reduction to practice.

Proof of actual reduction to practice requires demonstration that the embodiment relied upon as evidence of priority actually worked for its intended purpose. *Newkirk v. Lulejian*, 825 F.2d 1581, 1582, 3 USPQ2d 1793, 1794 (Fed. Cir. 1987). As was stated in *Paine v. Inoue*, 195 USPQ 598, 604 (Bd. Pat. Int. 1976):

The nature of testing required to establish a reduction to practice depends on the particular facts of each case; a common-sense approach is required to determine if the testing is sufficient. What is required is that it be reasonably certain the invention will perform its intended function in actual use. The tests must be sufficient to establish utility beyond probability of failure, and must be sufficient to give assurance the device will operate under normal working conditions for a reasonable length of time [citations omitted].

In *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1119 (Fed. Cir. 1994), the interfering subject matter concerned a hydraulic, inflatable penile implant. In considering what scope

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of testing of such a device would establish an actual reduction to practice, the court considered the in-an-out implantation and actuation of the device in a human subject's penis sufficient to establish a reduction to practice. Clearly, mere bench testing did not suffice. In **Manning v. Paradis**, 2002 U.S. App. LEXIS 14026, the subject matter concerned treating a patient in cardiac arrest by perfusing the aortic arch with an oxygen-rich solution. A well instrumented test in a living dog was held not to be a successful experiment establishing a reduction to practice of the claimed invention. Clearly bench testing would not have sufficed to establish that the invention actually worked for its intended purpose.

We have previously made factual findings, in relation to the motion to suppress Hansen's testimony, concerning the functional setting of the interfering subject matter. Our finding was that the functional setting for the interference subject matter was to ablate targeted tissue such as tumors in an organ of a living subject. In this record, we find unrebutted evidence from Hansen that bench or **in vitro** testing does not put into play important factors bearing on the invention's operability for its intended purpose. Based on this unrebutted

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evidence from Hansen, it is our determination that the tests or demonstrations performed by LeVeen and Fox in summer and fall of 1993, were not tests that satisfied the requirement of the count with respect to "selected mass," and were not tests that proved the invention would work for its intended purpose, inasmuch as the invention was not tested in its intended functional setting as required by the jurisprudence.

This determination is supported by evidence from LeVeen's grant proposal. An inventor (or anyone working in his behalf) cannot be given any greater credit for the success of a test than he himself claims. *Halbleib v. Bendix*, 50 App. D.C. 247, 270 F. 683 (1921); *Smith v. Nevin*, 73 F.2d 940, 944, 23 USPQ 353, 357 (CCPA 1934) ("If the inventor, at the time of his conception and test did not consider the test successful, the court cannot be called upon, at a later date, to give this test a status which the inventor did not attribute to it at the time."). *Cf. Wu v. Davis*, 167 USPQ 467, 472 (Bd. Pat. Int. 1968) (*in vitro* test, at best, was a screening test the mere passing of which fell far short of an actual successful reduction to practice of the count for a specific utility).

Finally, we find telling the testimony of LeVeen when he termed the demonstrations or experiments were "exploratory" in

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his testimony. LR128, line 24. We are in full agreement that the experiments were of an exploratory nature and were not intended or designed to be a reduction to practice of the subject matter of the interference.

In summary, it is our determination that the series of experiments from June through October 1993 were not a reduction to practice of the subject matter of the count.

Abandonment, Suppression or Concealment

Edwards raises the issue of abandonment, suppression, or concealment on the part of LeVeen. As noted above, we have determined that LeVeen failed to reduce the invention to practice by successful testing of the subject matter of the count in the June through October time frame. Accordingly, we do not reach the issue of the alleged abandonment, suppression, or concealment. "[W]ithout an actual reduction to practice there is no invention in existence which can be abandoned, suppressed, or concealed." *Peeler v. Miller*, 535 F.2d 647, 651, 190 USPQ 117, 120 (CCPA 1976).

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Levee Showing under 37 CFR § 1.131

With regard to the patentability of the LeVeen claims, the interlocutory merits panel gave LeVeen the opportunity of overcoming the filing date of Edwards by recourse to the provisions of 37 CFR § 1.131. The purpose of filing a § 131 affidavit is not to demonstrate prior invention *per se*, but merely to antedate the effective date of the reference. *In re Eickmeyer*, 602 F.2d 974, 978, 202 USPQ 655, 660 (CCPA 1979) citing *In re Moore*, 444 F.2d 572, 170 USPQ 260 (1971). Although the test for sufficiency of an affidavit under Rule 131(b) parallels that for determining priority of invention in an interference under 35 U.S.C. 102(g), it does not follow that Rule 131 practice is controlled by interference law. To the contrary, "[t]he parallel to interference practice found in Rule 131(b) should be recognized as one of convenience rather than of necessity." *Moore* at 580, 170 USPQ at 267. Thus, "the 'conception' and 'reduction to practice' which must be established under the rule need not be the same as what is required in the 'interference' sense of those terms." *Id.* Accordingly, LaVeen must show by a preponderance of the evidence a mere reduction to practice of his

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basic invention, which showing will also suffice as to claims differing therefrom only in details which are obvious to one of ordinary skill in the art. *In re Spiller*, 500 F.2d 1170, 1178, 182 USPQ 614, 620 (CCPA 1974). Furthermore, LeVeen does not have to show corroboration for the acts relied on with respect to a showing under 37 CFR § 1.131. *Ex parte Hook*, 102 USPQ 130 (Bd. App. 1953).

However, it is unnecessary for us to make new detailed findings with regard to the case under 37 CFR § 1.131, inasmuch as it is clear that the record does not support a conclusion that the invention of LeVeen claims 43 and 44 was reduced to practice before the critical date. Inasmuch as the Edwards specification taken as prior art discloses an intended purpose and functional setting for the invention, it was incumbent upon LeVeen to show a reduction to practice of the subject matter of his claims for their intended purpose.

As established by our factual findings, above, not all limitations of the claim were reduced to practice. We have construed the claim limitation of "selected mass" to mean a preselected mass, exactly as we have construed this limitation in the count. There is no evidence that any area in the explanted

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livers was first targeted, the apparatus used and the target area inspected to compare the actual ablation accomplished to that ablation desired in the targeted area.

Next, there is no convincing evidence that the experiments were considered successful. Discounting conclusory statements from Fox, LeVeen and Kilzer made years after the experiments were undertaken, no standards for success were ever established and no contemporaneous recognition of success can be found in the records. Indeed, the grant proposal indicates the results were preliminary, and testimony and the grant proposal indicates the experiments were merely exploratory in nature.

Thirdly, the invention was not tested in its intended functional setting, so the inventors did not determine that it would work for its intended purpose. The claimed subject matter was tested in an explanted liver in repose on an electrode plate. Credible testimony establishes that such experimental conditions do not simulate the impedance of the body of a patient, the movement of the organs in a patient under surgical conditions, or the heat-sink/cooling effect of blood flow of a living organism.

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Judgment

Judgment in Interference No. 104,290 is hereby entered against Junior party, Robert F. LeVeen on the ground of priority of invention and unpatentability. Robert F. LeVeen is not entitled to a patent containing claims 43 and 44, which claims correspond to the count in interference. Judgment on the ground of unpatentability is entered against senior party, Stuart D. Edwards, Ronald G. Lax, and Hugh Sharkey. Stuart D. Edwards, Ronald G. Lax, and Hugh Sharkey are not entitled to their claim 32, which claim corresponds to the count in interference.

It is FURTHER ORDERED that the motions panel decision granting LeVeen's preliminary motion 1, dated February 23, 2001, and contained in Paper No. 246, is herein made final for purposes of judicial review.



WILLIAM F. PATE, III)
Administrative Patent Judge)



RICHARD E. SCHAFER)
Administrative Patent Judge)



JAMESON LEE)
Administrative Patent Judge)

BOARD OF PATENT)
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INTERFERENCES)

WFP:psb

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