

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SAMUEL F. LIPRIE

Appeal No. 94-1946
Application 07/589,079¹

ON BRIEF

MAILED

JUL 31 1995

PAT.&T.M.OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Before JOHN D. SMITH, TURNER and PAK, Administrative Patent Judges.

TURNER, Administrative Patent Judge.

DECISION ON APPEAL

¹ Application for patent filed September 27, 1990. According to appellant, the application is a continuation of Application 07/228,400, filed August 4, 1988.

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This is an appeal from the Examiner's decision finally rejecting claims 14, 16-18, 20-22, 25, 26 and 28-41 which are all of the claims remaining in the application. A copy of illustrative claims 14, 32 and 37 are appended to this decision.

The references of record relied upon by the Examiner are:

Hedger	4,190,461	Feb. 26, 1980
Liprie	5,084,002	Jan. 28, 1992

"MicroSelectron-HDR Iridium Source", published by Nucletron Corporation.

Claims 14, 16-18, 20-22, 25, 26, and 28-41 stand rejected under 35 U.S.C. § 112, first paragraph, on the ground that the specification does not provide enabling support for the invention. Claims 14, 16-18, 20-22, 26, 30, 31, and 40 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 14, 39 and 40 stand rejected under 35 U.S.C. § 102(a) as anticipated by the Nucletron Brochure. Claims 16-18, 20, 22, and 41 stand rejected under 35 U.S.C. § 103 as unpatentable over the

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Nucletron Brochure. Claim 21 stands rejected under 35 U.S.C. § 103 as unpatentable over the Nucletron Brochure in view of Hedger.

The subject matter on appeal is directed to a reusable radioactive source wire assembly for delivery into the body of a patient to treat cancerous tissue within the body comprising a delivery wire and an activated iridium core encapsulated within the tip of the delivery wire. A more detailed description can be gleaned from a reading of claims 14, 32, and 39. The invention also embraces a method of fabricating a radioactive source wire for in situ treatment of malignancies in patients. A more detailed description can be found in claim 37.

According to Appellant and the Examiner, the claims are to be grouped as follows:

- Claims 14 and 32 and claims dependent therefrom
(claims 14, 16-18, 20-22, 25, 26, and 32-36);
- Claims 28-31, 37 and 38; and
- Claims 39-41.

OPINION

We have carefully reviewed the record before us, including each of the arguments and comments advanced by

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Appellant and the Examiner in support of their respective positions. This review leads us to conclude that the Examiner's position is not well founded with respect to the rejection under 35 U.S.C. § 112, first paragraph, and the rejection of claims 14, 16-18, 20-22, 26, 31 and 40 under 35 U.S.C. § 112, second paragraph, and will not sustain the rejections. We agree with the rejection of claim 30 under 35 U.S.C. § 112, second paragraph, and the Examiner's conclusion regarding anticipation and obviousness under 35 U.S.C. § 102 and § 103 and will sustain the rejections. Our reasons follow.

REJECTION OF CLAIMS 14, 16-18, 20-22, 25, 26, AND 28-41
UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

We will not sustain this rejection. The linchpin in the Examiner's rejection is that the claims set forth a "drawing process" but fails to explain what type of machinery may be employed for such a process, from what size the platinum wire is drawn, what rate the wire is drawn at, whether the wire is heated for such a process, how the pure iridium core is "inserted" or "disposed" in a larger diameter platinum wire, how the pure iridium core is prevented from being pushed out of the

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undisclosed hole during the drawing process, or how two distinct elements become "substantially unitary" as set forth in claim 14. The Examiner further indicates that the specification fails to teach how the drawing process is implemented for the "extremely small diameter" and "difficulty in working with pure iridium" invention. It is said that there is no support for the "hole" and "aperture" limitations of independent claims 14, 32, 37, and 39. Finally, the Examiner states that there is no basis for any "before drawdown" dimension. In sum, the Examiner is not convinced that there is enabling support for the invention as claimed. We find ourselves in agreement with the comments of Appellant at pages 10-15 of the Brief. It is axiomatic that the specification is directed to one of ordinary skill in the art. As Appellant has stated at page 10, the process of drawing a wire down is conventional and well known by long-standing prior art. The Examiner questions how the elements become substantially unitary as is set forth in claim 14. The Examiner has offered no reasoning as to why the two elements would not act as a unit. The specification at page 10, lines 30+ provide a sufficient description of what is intended by "substantially unitary". To the extent that the rejection is predicated on lack of enablement, the Examiner has not established that a person having

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ordinary skill in the art would not be able to practice the claimed invention in view of the supporting disclosure in the specification. In re Marzocchi, 439 F.2d 220, 169 USPQ 367 (CCPA 1971); In re Strahilevitz, 668 F.2d 1229, 212 USPQ 561 (CCPA 1982). Accordingly, we will not sustain the rejection.

REJECTION OF CLAIMS 14, 16-18, 20-22, 26, 30, 31 AND 40
UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

We will not sustain this rejection as it applies to claims 14, 16-18, 20-22, 26, 31, and 40. The Examiner is of the opinion that the use of the term "unitary" to claim a device made of two separate and distinct elements held together by mere friction is inconsistent with the usage of the term in the parent application. On the basis of the record before us, we have no difficulty in understanding Appellant's use of the term "substantially unitary" and do not find its use to render the claims indefinite. The scope of the term "unitary" (as indicated by the Examiner at the bottom of page 6 of the Answer) is not the basis of the rejection. As indicated in the discussion above, Appellant describes at pages 10 and 11 the meaning of an integral or unitary delivery wire.

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Claims 17, 26, and 40 are said to be unclear how each of the claims place an objectively ascertainable structural limitation on the claimed device by claiming the structure of elements before they are formed into the device. These claims set forth limitations which further define the source prior to drawdown. Since the iridium core is inside of the delivery wire, its diameter before drawdown is not expected to change much, if at all. Thus, these parameters of diameter are revealing as to the size of the iridium core or source wire. For these reasons, we will not sustain the rejection. Insofar as claim 30 is concerned, we summarily affirm the rejection. Appellant acknowledges the indefiniteness at pages 17 and 18 of the Brief.

REJECTION OF CLAIMS 14, 39 AND 40 UNDER 35 U.S.C. § 102(a)
OVER THE NUCLETRON BROCHURE

We shall affirm this rejection primarily for the reasons advanced by the Examiner in the Answer. We offer, however, the following comments. We point out that the claims are directed to a source wire assembly for delivery into the body of a patient to treat cancerous tissue comprising

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-a flexible elongate metal delivery wire of a small diameter, and

-an iridium core encapsulated within the end of the delivery wire without welding of the core to the delivery wire. The Nucletron Brochure describes or depicts a source wire assembly for delivery into the body of a patient to treat cancerous tissue comprising

-a flexible elongate metal delivery wire of a small diameter, and

-an iridium core encapsulated within the end of the delivery wire without welding of the core to the delivery wire. The claims are directed to the product, i.e., the source wire assembly. The product of the Nucletron Brochure and the claimed product have not been shown to be different. Despite the process parameters set forth in claim 14, the wire assembly is being claimed and we find that the flexible elongate metal delivery wire and iridium core (encapsulated within the end of the wire) of the Nucletron Brochure to constitute a prima facie case of anticipation.

Appellant argues that the Nucletron Brochure describes a cable diameter which renders it unsuitable for various applications. We fail to see the relevance of the comment in the

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context of the rejection, particularly when the claims do not describe a cable diameter. We simply disagree with the statements of Appellant that the Nucletron Brochure source wire does not include a core encapsulated within the tip of a delivery wire without being welded to the tip. The Nucletron Brochure depicts, in our view, a core (the Ir-192) encapsulated within the tip or uppermost portion of the wire or cable.

Accordingly, we affirm the rejection.

REJECTION OF CLAIMS 16-18, 20, 22, AND 41
UNDER 35 U.S.C. § 103 OVER THE NUCLETRON BROCHURE

We shall affirm this rejection. We agree with the Examiner and affirm primarily for the reasons given by the Examiner. There is little in dispute here. Appellant argues simply that the Nucletron Brochure or Nucletron has been unable to reduce the dimensions of its wire and states that it is because of the nature of the configuration. However, Appellant has presented no objective evidence to support this argument.

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We agree with the examiner that it would have been obvious to vary or change the size of the wire and/or the size and activity of the core depending upon its ultimate use.

Accordingly, we affirm the rejection.

REJECTION OF CLAIM 21 UNDER 35 U.S.C. § 103
OVER THE NUCLETRON BROCHURE IN VIEW OF HEDGER

We shall affirm this rejection. The Nucletron Brochure has been discussed above. Hedger teaches at column 2, lines 39-44 the equivalence of stainless steel (as used in the Nucletron Brochure) and platinum (as in claim 21) as a covering for radioactive material to be used in treating tumors. The Examiner concludes, and we agree, that it would have been obvious to replace the stainless steel of the Nucletron Brochure with the platinum of Hedger particularly in view of their known equivalence as taught by Hedger. Appellant's only argument or comment is that Hedger adds nothing to cure the deficiencies in

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the primary reference. Since we disagree with Appellant's position regarding the primary reference, we summarily affirm the rejection over the Nucletron Brochure in view of Hedger.

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection.

Claims 32-35 are rejected under 35 U.S.C. § 102 as anticipated by or alternatively, under 35 U.S.C. § 103, as obvious over the Nucletron Brochure. By Appellant's omission to challenge the date of the Nucletron Brochure as a reference, its date, for purposes of rejection, is presumed to be sufficient. The Nucletron Brochure describes a radioactive assembly comprising an elongated unitary guide wire of small diameter and an encapsulated iridium core or source disposed within the guide wire. We find little or no difference between the assembly of the Nucletron Brochure and the claims which are directed to a radioactive assembly comprising an elongated unitary guide wire of small diameter and an encapsulated iridium core or source disposed within the guide wire. The process parameters do not distinguish the claims which are drawn to the assembly and not the process for its preparation. Irradiating the source material

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and the extent to which the source is to be irradiated is taught by the Nucletron Brochure and is a matter well within the skill of the art. Thus, we find the claims to be anticipated by, or at least obvious, over the Nucletron Brochure.

Claims 25, 26 and 36 are rejected under 35 U.S.C. § 103 as unpatentable over the Nucletron Brochure in view of Hedger. The Nucletron Brochure discloses and teaches an assembly comprising a guide wire and a core encapsulated therein. The guide wire is composed of stainless steel (Material A151-316). Hedger teaches the equivalence of platinum and stainless steel as sheathing or covering for radioactive materials. Thus, to substitute the platinum of Hedger for the stainless steel of the Nucletron Brochure would have been prima facie obvious to one of ordinary skill in the art. The Nucletron Brochure, as acknowledged by Appellant, employs the iridium source for the purpose of treating tumors. Hedger also employs the sheathing materials, i.e., stainless steel and platinum, in the same or similar environment. Thus, we find the substitution to be prima facie obvious and on this record, Appellant has not advanced or relied upon any evidence of unobvious or unexpected results.

Any request for reconsideration or modification of this decision by the Board of Patent Appeals and Interferences based

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Donald R. Greene
O'CONNOR, CAVANAGH, ANDERSON,
WESTOVER, KILLINGSWORTH & BESHEARS
One East Camelback Road
Suite 1100
Phoenix, AZ 85012-1656

APPENDIX

14. A reusable radioactive source wire assembly for delivery into the body of a patient via a guide duct by a remote afterloader located external to the body, to treat cancerous tissue within the body, comprising:

a flexible elongate substantially uniform metal delivery wire sufficiently long for delivery of the distal end thereof by the afterloader from a storage area therein to the vicinity of the site of the cancerous tissue in the patient's body suitable for the treatment thereof via the guide duct, and of sufficiently small diameter to traverse the guide duct during delivery and withdrawal without substantial binding therein, and sufficiently flexible for routing through tight curves in the guide duct, and

an activated iridium core encapsulated within the tip of the distal end of the delivery wire, without welding of the core to the delivery wire, for irradiating the cancerous tissue when the distal end is delivered to said vicinity,

wherein said iridium core is tightly encapsulated within the tip of the delivery wire and the wire is formed with said sufficiently small diameter by inserting the core into a hole in the tip of an oversize delivery wire and drawing the assembly of the wire and the core down to the desired diameter to become a substantially unitary source wire assembly.

32. A radioactive source wire for insertion into a patient's body for localized treatment of malignant tumors therein by irradiation and shrinkage of the tumor, comprising:

an elongate unitary guide wire of sufficiently small diameter and sufficient flexibility to traverse tight curves in the path to the malignant tumor to be treated,

a substantially cylindrical source, composed of material capable of activation to a sufficiently high radioactivity level for said treatment, tightly confined within and unwelded to the tip of the distal end of said guide wire,

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said source wire having been fabricated in part by assembling the source axially into a hole in the tip of a guide wire of larger diameter than said sufficiently small diameter and drawing the assembly down to the desired diameter and for tight confinement of the source therein.

37. The method of fabricating a radioactive source wire for in situ treatment of malignancies in patients, comprising:

assembling a source composed of material capable of activation to a radioactivity level sufficient for said treatment with a flexible elongate delivery wire of substantially uniform diameter to become a substantially integral unit, by introducing the source into a hole formed in the tip of a delivery wire larger than the desired diameter of the source wire to be used for the treatment and drawing and the assembly down to the desired diameter.