

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

Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PETER M. BONUTTI and JAMES S. HAWKINS

Appeal No. 1998-2637
Application No. 08/470,142

HEARD: MAY 15, 2001

Before ABRAMS, McQUADE, and BAHR, Administrative Patent Judges.
ABRAMS, Administrative Patent Judge.

DECISION ON APPEAL

The following claims are before us on appeal: 57-60, 62, 67, 70-78, 80-85, 127-129, 147 and 155.¹

We REVERSE.

¹Two amendments after the final rejection were entered. The status of the other claims of record in this application can be found on pages 1 and 2 of the Examiner's Answer.

BACKGROUND

The appellants' invention relates to a method for establishing communication with the interior of a vessel in a human body. An understanding of the invention can be derived from a reading of exemplary claim 57, which appears in the appendix to the appellants' Brief.

The prior art references of record relied upon by the examiner are:

Everett	2,830, 587	Apr. 15, 1958
Taricco	3,833,003	Sep. 3, 1974
Grayzel	4,921,479	May 1, 1990
Dubrul et al. (Dubrul)	5,183,464	Feb. 2, 1993
Lee et al. (Lee)	5,226,899	Jul. 13, 1993
Horzewski et al. (Horzewski)	5,318,588	Jun. 7, 1994
Melker et al. (Melker)	5,328,480	Jul. 12, 1994

The following rejections are before us.

Under 35 U.S.C. § 102(b):

(1) Claim 70 on the basis of Lee.

Under 35 U.S.C. § 103:

(2) Claims 57-60, 67 and 147 on the basis of Melker and Lee.²

(3) Claims 62 and 73-75 on the basis of Taricco and Lee.

(4) Claims 70-72, 76-78 and 80 on the basis of Grayzel and Lee.

(5) Claims 81 and 83-85 on the basis of Horzewski.

²Claim 147 appears inadvertently to have been omitted from the statement of this rejection in the Answer. The appellants have argued this rejection on page 47 of the Brief.

(6) Claim 82 on the basis of Horzewski and Grayzel

(7) Claims 127 and 128 on the basis of Everett.

(8) Claim 129 on the basis of Grayzel and Everett.

(9) Claim 155 on the basis of Dubrul and Everett.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the Answer (Paper No. 17) for the examiner's complete reasoning in support of the rejections, and to the Brief (Paper No. 13)³ and Reply Brief (Paper No. 25) for the appellants' arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

The appellants' invention is directed to a method of establishing communication with the interior of a vessel in a human body, such as a sac, organ, tube, duct or canal. As disclosed, the basic method utilizes a cannula comprising an elastic sheath which

³Although the examiner stated in Paper No. 14 that the Appeal Brief filed on June 9, 1997 (Paper No. 13) was defective, and required that a new Brief be filed, the Answer indicates that it is in response to Paper No. 13. The appellants subsequently requested that the substitute Brief (Paper No. 18) be ignored by the Board, which we have done.

encloses a plurality of longitudinally extending wires and is provided with a longitudinally extending central passage. The leading end portion of the cannula is constructed to pierce human body tissue, such as by having its sheath comprise a tapered leading end and a plurality of stiffening wires (see Figure 21, for example). The cannula is inserted through tissue in a radially unexpanded condition and can be expanded radially outwardly against the inner walls of the vessel in which it is installed.

The Rejection Under Section 102

Anticipation is established only when a single prior art reference discloses, either expressly or under the principles of inherency, each and every element of the claimed invention. See, for example, In re Paulsen, 30 F.3d 1475, 1480-1481, 31 USPQ2d 1671, 1675 (Fed. Cir. 1994) and In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

(1)

Claim 70 stands rejected as being anticipated by Lee. The method recited in claim 70 includes the steps of providing a cannula having a sheath which at least partially encloses a plurality of wires, piercing a side wall of the blood vessel with a leading end portion of the cannula, moving the sheath and the wires of the cannula through the opening formed by the piercing step, and advancing the sheath and the wires of the cannula along an inner side surface of a blood vessel.

Lee is directed to catheter (cannula) tubing, and discloses a catheter 10 comprising a polymer tube 22 which encloses a plurality of polymer stiffening elements 22. A “conventional catheter insertion device” in the form of a hollow needle 11 is provided on the end of the tubing “for penetration of a patient’s skin and placement of the catheter into the patient’s blood stream” (column 3, lines 11-15). It is clear from the Lee disclosure that needle 10, and not the catheter itself, pierces the skin and it is equally clear that the needle is not considered to be part of the catheter, for the reference states that “[c]atheter insertion devices are conventional in the art and do not form a part of this invention” (column 3, lines 15 and 16). The examiner nevertheless apparently considers needle 11 to be a part of the catheter in reaching the conclusion that Lee anticipates the method of claim 70. We do not agree with this interpretation. Moreover, there are no wires in needle 11.

It is our view that Lee fails to disclose or teach the claimed step of providing a cannula having a sheath which at least partially encloses a plurality of wires, and the step of “piercing a side wall of the blood vessel with a leading end portion of the cannula” (emphasis added). This being the case, Lee does not anticipate the subject matter recited in claim 70, and we will not sustain this rejection.

The Rejections Under Section 103

The test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. See, for example, In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In establishing a prima facie case of obviousness, it is incumbent upon the examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. See Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellants' disclosure. See, for example, Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988).

(2)

The first of the rejections under Section 103 is that independent claim 57 and dependent claims 58-60 and 67 are unpatentable over Melker in view of Lee. Claim 57 recites a method comprising a first step of providing a cannula with a sheath at least partially enclosing a plurality of wires "having leading end portions at a leading end portion of the sheath," engaging a surface area of the side wall of a vessel "with at least a portion of the leading end portion of at least one of the wires and at least a portion of the leading

end portion of the sheath,” “initiating formation of an opening in the surface area of the side wall of the vessel by pressing the leading end portion of at least the one wire and the leading end portion of the sheath against the surface area on the side wall of the vessel,” and thereafter moving the leading end portions of the wire and the sheath through the opening.

Melker discloses a “wire introducer” comprising a sheath 11 and a piercing wire 16 that has an end which extends beyond the end of the sheath, and therefore Melker fails to disclose the structure required by the first step of claim 57, that is, wires having a leading end portion at the leading end portion of the sheath. In addition, it is quite clear from the drawings and the explanation of the operation of the device that initiation of the opening in the skin is accomplished solely by means of the end of the wire and not by the wire and the sheath, and Melker thus also fails to disclose or teach the second and third steps of claim 57. Merely adding reinforcing wires to the Melker sheath, as proposed by the examiner based upon Lee, would not overcome these shortcomings in the basic structure and operation of Melker.

The combined teachings of Melker and Lee fail to establish a prima facie case of obviousness with regard to the method recited in claim 57, and we will not sustain the rejection of claim 57 or, it follows, of claims 58-60 and 67, which depend therefrom.

Claim 147 also has been rejected on the basis of Melker and Lee. This claim contains the steps of initiating formation of an opening by pressing a leading end of at least one of the wires and at least a portion of the leading end surface of the sheath adjacent to the one wire against the body tissue, moving the said leading end surfaces through the opening so formed, and then moving a leading end surface of a second wire through the opening. This rejection suffers from the same defects as were discussed immediately above with regard to claim 57, and we will not sustain it.

(3)

Claim 62, which depends from independent claim 57, and claims 73-75, which depend from independent claim 70, stand rejected as being unpatentable over Taricco in view of Lee. These claims add to the claims from which they depend the step of expanding the leading end portion of the sheath while it is disposed in the vessel by applying fluid pressure against an inner side surface of the sheath.

Lee has been discussed above with regard to the Section 102 rejection of claim 70, and the structure and method disclosed by Lee is equally as unresponsive against claim 57, which also requires that the end of the cannula, along with the wires, initiate formation of an opening in the vessel. Taricco discloses a cannula in which initial piecing of the vessel is accomplished by the cutting edge 25 of the tip of a trocar 22, which protrudes beyond the end of the cannula. Of course, claim 62 incorporates all of the

subject matter of claim 57, from which it depends, and with regard to claim 57, Taricco suffers from the same inadequacy as Lee, in that the piercing is accomplished solely by the wire (trocar). While Taricco does disclose an expandable portion in the sheath, the teachings of the two references nevertheless fail to meet the terms of claim 62, and the rejection will not be sustained.

The same situation exists with claims 73-75, and we will not sustain the rejection with regard to them, either.

(4)

Independent claim 70 and dependent claims 71, 72, 76-78 and 80 have been rejected as being unpatentable over Grayzel in view of Lee. The examiner is of the view that Grayzel discloses all of the subject matter recited in claim 70 except for the wires, but that it would have been obvious to add reinforcing wires to the Grayzel device in view of the teachings of Lee.

Grayzel discloses a removable and expandable sheath fabricated from a semi-stiff plastic which is used to pierce the side wall of a vessel to establish access for a cannula (column 2, lines 28-41). Grayzel does not disclose or teach that the cannula, or the sheath, for that matter, encloses a plurality of wires, as is required by the first step of claim 70. Grayzel also does not disclose or teach piercing the side wall of a blood vessel with a leading end portion of the cannula and, during performance of that step, moving the sheath

and the wires through the opening formed in the side wall of the vessel, which are the second and third steps of the claimed method. Lee discloses reinforcing wires enclosed in the walls of a cannula, but does not teach using such wires in the needle, which in the reference is the element that accomplishes the piercing of the wall of the vessel.

Therefore, Lee also fails to disclose or teach moving the sheath and the wires through an opening in the side wall of the vessel during the piercing step. The mere fact that the prior art structure could be modified does not make such a modification obvious unless the prior art suggests the desirability of doing so. See In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Clearly, neither of these references suggests the desirability of adding reinforcing wires to that portion of the catheter or sheath which pierces the side wall of the blood vessel, and that is what is necessary in order to perform the subsequent step of moving the wires and the sheath through the opening during the piercing step.

For the reasons expressed above, it is our conclusion that the combined teachings of Grayzel and Lee fail to establish a prima facie case of obviousness with regard to the subject matter recited in claim 70, and we will not sustain this rejection of the claim. It follows that we also will not sustain the like rejection of claims 71, 72, 76-78 and 80, which depend from claim 70.

Independent claim 81 and dependent claims 83-85 stand rejected as being unpatentable over Horzewski.

Claim 81 recites the steps of inserting a tubular sheath having a leading end portion with a continuous outer side surface into a blood vessel while the leading end portion has a first cross sectional size, increasing the cross sectional size by stretching the sheath with a tubular portion while the leading edge portion is in the blood vessel, increasing the cross sectional size of the blood vessel by pressing the continuous outer side surface of the leading end portion of the sheath against an inner side surface of the blood vessel, and then conducting a flow of fluid through the tubular member from a location outside of the body while the continuous outer side surface of the leading end portion of the sheath is pressing against the inner side surface of the blood vessel.

Horzewski discloses a cannula having a radially expandable outer sheath, the purpose of which is to allow the cannula to have a smaller cross section during insertion to the point of use than the cross section of the diagnostic device that will be introduced therethrough. Even if one were to assume, arguendo, that the Horzewski device is capable of performing the steps recited in claim 81, there is nothing in the disclosure that suggests, explicitly or implicitly, that the outer surface of the cannula be placed into contact with the inner surface of the blood vessel and then expanded to cause the cross section of the blood vessel also to be expanded. To the extent that the examiner's position is that

this would be the inherent result of operating the Horzewski device, we find no support in the reference for such a theory, and thus it stands merely as speculation on the part of the examiner.

A prima facie case of obviousness having not been established by Horzewski, we will not sustain the rejection of independent claim 81 or dependent claims 83-85.

(6)

Claim 82 has been rejected on the basis of Horzewski and Grayzel. It adds to the method of claim 81 the step of piercing the blood vessel with the leading end portion of the sheath. Horzewski and Grayzel have been explained above with regard to other rejections. It is our view that the shortcomings of Horzewski with regard to the method set forth in independent claim 81, from which claim 82 depends, are not alleviated by consideration of Grayzel.

The rejection of claim 82 is not sustained.

(7)

The examiner has rejected independent claim 127 and dependent claim 128 as being unpatentable over Everett. Claim 127 recites a method of establishing communication with the interior of a vessel with a cannula having an oval cross sectional configuration in a plane extending perpendicular to the longitudinal axis of the cannula, which comprises the steps of aligning the cannula with the blood vessel with the major axis of the oval cross section extending along a longitudinal axis of the vessel, piercing a side wall of the vessel with a leading end of the cannula while in said alignment to form an elongated opening in the side wall of the vessel, and moving the cannula through the elongated opening with the major axis of the oval cross section of the cannula aligned with a longitudinal axis of the opening in the side wall of the vessel.

Everett discloses a hypodermic needle having an oval cross sectional opening in a plane perpendicular to its longitudinal axis. The examiner has taken the position that it would have been obvious to align the major axis of the Everett needle with the longitudinal axis of the vessel "so that the extreme tip of the needle first contacts the blood vessel wall" (Answer, page 5). The appellants argue that no evidence has been provided in support of this position, and we must agree that such is the case. While the Everett needle might be capable of performing the claimed method, it also is capable of piercing the wall of the vessel and being inserted into the blood vessel while in other orientations with respect to the longitudinal axis of the vessel. Therefore, the examiner's position appears to be grounded in the hindsight afforded one who first viewed the appellants' disclosure.

The examiner therefore has not established that a prima facie case of obviousness is presented by Everett, and we will not sustain the rejection of claims 127 and 128.

(8)

We reach the same conclusion with regard to claim 129, which adds to claim 127 the step of expanding the cannula while its outer surface is in contact with the inner surface of the blood vessel, for Grayzel does not overcome the shortcoming of Everett explained with regard to the rejection of parent claim 127.

The rejection of claim 129 is not sustained.

(9)

Finally, independent claim 155 stands rejected as being unpatentable over Dubrul in view of Everett. This claim is directed to a method of establishing a flow of liquid between an interior of a vessel in a human body and a location outside of the human body. The method calls for a cannula having an oval cross sectional configuration as viewed in a plane perpendicular to a longitudinal axis of the sheath. It is the examiner's position that it would have been obvious to modify Dubrul's cannula by changing the round configuration to an oval one in view of the teachings of Everett "to resist bending in a plane" (Answer, page 5). We agree with the appellants that one of ordinary skill in the art would not have been motivated to make such a change to the Dubrul cannula for the reason given in view of the fact that Dubrul's cannula is made of an elastic and deformable material which is not intended to resist bending, and its operation might well be destroyed by doing so.

In view of the foregoing, the references fail to establish a prima facie case of obviousness and we will not sustain the rejection of claim 155.

SUMMARY

None of the rejections are sustained.

The decision of the examiner is reversed.

REVERSED

NEAL E. ABRAMS
Administrative Patent Judge

JOHN P. McQUADE
Administrative Patent Judge

JENNIFER D. BAHR
Administrative Patent Judge

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