

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. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TODD ALLEN BERG and CHRISTOPHER M. PRIGGE

Appeal No. 2000-2047
Application No. 09/014,759

ON BRIEF

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

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-26, which are all of the claims pending in this application.

We REVERSE.

BACKGROUND

The appellants' invention relates to an apparatus and method for creating an aperture at an access site in a patient's existing tubular body organ structure. An understanding of the invention can be derived from a reading of exemplary claims 1, 13, 23 and 24, which appear in the appendix to the Brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Kim	5,676,670	Oct. 14, 1997
Makower	5,830,222	Nov. 3, 1998
		(filed Oct. 11, 1996)

Claims 1-12, 23 and 25 stand rejected under 35 U.S.C. § 103 as being unpatentable over Makower.

Claims 13-22, 24 and 26 stand rejected under 35 U.S.C. § 103 as being unpatentable over Makower in view of Kim, each in view of the other.

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. 16) for the examiner's complete reasoning in support of the rejections, and to the Brief (Paper No. 15) and Reply Brief (Paper No. 17) 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.

Independent claim 1 is directed to an apparatus for creating an aperture in a tubular body organ. It comprises a delivery sheath insertable axially along the interior portion of the tubular body organ, a centering wire insertable axially along the interior of the sheath and adapted for piercing through the tubular body organ at an access site from the inside to the outside, and a cutting catheter insertable over the centering wire

including a distal end adapted for advancing through said patient's existing tubular body organ structure at said access site by rotation of said cutting catheter to produce an annular cut . . . from inside . . . to outside said tubular body organ structure to form said aperture by removal of tissue bounded by said annular cut (emphasis added).

It is the examiner's position that all of the subject matter recited in this claim is taught by the embodiment shown in Figure 2 of Makower, except for a cutting catheter for cutting an annular aperture. For this, the examiner looks to Makower's Figure 17, concluding it would have been obvious to use the annular knife disclosed therein with the Figure 2 embodiment to provide a larger aperture. As for the requirement in the claim that the cutting device be adapted to produce the annular cut by rotation, it is the examiner's view

that it “is so well known in the surgical instrument art to rotate an annular blade as it is advanced through tissue in order to provide a good cutting action” as to make it obvious to one of ordinary skill in the art (Answer, pages 3 and 4). The appellants reply by setting forth a number of reasons why there would have been no suggestion to combine selected features of the two embodiments in the manner proposed by the examiner, and that even if combined they would not yield the claimed invention (Brief, pages 7-15).

We find ourselves in agreement with the appellants that the teachings of Makower do not render obvious the subject matter recited in claim 1. Our reasoning follows.

In the embodiment of the Makower invention shown in Figure 2, a catheter is advanced through a tubular body organ over a guide wire. Extendable outwardly at an angle to the axis of the catheter and the guide wire is a sheath 26 on the end of which is a sharp-tipped probe 27. In operation, probe 27 is pushed through the wall of the tubular organ alone or along with sheath 26, and it pierces the wall of the tubular body organ from inside to outside and then proceeds through the adjacent tissue to pierce the wall of another tubular body organ from outside to inside. See column 4, line 41 et seq. There is no explicit teaching that the probe and the sheath make an annular cut, create an annular aperture by removing tissue bounded by an annular cut, or advance through the tubular body organ structure by rotation, all of which are required by the claim. Nor, in our view, is

there any reason to conclude that this inherently would occur, or that the probe and/or the sheath are even capable of being rotated.

In the embodiment shown in Makower's Figure 17, a guide wire 51 is advanced through the wall of the tubular body organ, followed by a generally cone-shaped dilating tip 170 that has a rearward-oriented annular blade on its proximal end. No details are provided as to how the wall initially is pierced. Once through the tissue, the dilating tip is pulled back to cut the tissue between the knife and a tissue cutting cannula assembly that still resides in the inside of the tubular body organ. See column 9, line 14 et seq. There is no explicit statement that the dilating tip is rotated during the cutting operation, nor does it appear that it inherently does so or even is capable of being rotated. Moreover, the cutting edge is not "advanced" through the tissue in the sense that it clearly is not the first element to pierce the tissue.

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 appellant's 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).

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).

We fail to perceive any teaching, suggestion or incentive which would have led one of ordinary skill in the art to modify the Figure 2 embodiment of Makower by replacing the piercing tip of the probe with the dilating tip and rearward-facing blade of Figure 17. In particular, we do not agree with the examiner that one of ordinary skill in the art would have done so in order to provide a larger opening through the tubular body organ structure; from our perspective, the artisan would have been motivated by the teachings of Makower's Figure 2 embodiment to simply use a larger piercing tip on the end of the guide wire. Moreover, even if it were considered, arguendo, that suggestion to make the modification proposed by the examiner exists, the resulting structure would not be adapted to advance through the tubular body by rotation of the cutter, which is required by the claim. In this regard, the examiner's position that it is "well known" to rotate a tissue cutting blade "to provide good cutting action" not only is merely an opinion unsupported by evidence, but

also begs the question of why the cutting action of Makower's Figure 17 nonrotating cutting blade would be improved by causing it to rotate. The examiner also fails to confront the problem of how the blade would be caused to rotate, inasmuch as structure capable of doing so appears not to be disclosed by Makower with regard to either of the embodiments.

It is our conclusion that the teachings of Makower fail to establish a prima facie case of obviousness with regard to the subject matter recited in claim 1. We therefore will not sustain the rejection of claim 1 or of claims 2-12, which depend therefrom.

Independent method claims 23 and 25 also contain the requirement that the advancing cutting catheter rotate to produce an annular cut through the tubular body organ structure. On the basis of the same reasoning applied to claim 1, the rejection of these two claims is not sustained.

Independent claim 13 stands rejected as being unpatentable over Makower in view of Kim or, in the alternative, Kim in view of Makower. This claim contains essentially the same elements as claim 1, except that it lacks the feature of rotating the cutting catheter. However, in addition to the guide wire being adapted to pierce through the patient's existing tubular body organ structure, this claim requires that the cutting catheter include on its distal end a plurality of distally directed cutting edges that extend radially out from the centering wire spaced from one another, each having a cutting edge inclined distally back

from its end which is closest to the centering wire, for cutting through the tubular body organ structure. In the first of the alternative rejections, it is the examiner's view that since Makower discloses a number of different "cutting member" shapes, such as are shown in Figures 2, 17 and 29, it would have been obvious to one of ordinary skill in the art to replace those with the star-shaped one shown in Kim "in order to form an effective cut in the blood vessel," since this is "apparently" what Kim teaches to be "desirable" (Answer, page 4). The examiner's theory is defective on several grounds. First of all, Makower actually shows only one piercing tip configuration, and that is the "sharp-tipped" probe pictured in Figures 2, 18 and 20. No means for piercing the tissue is shown in Figures 17 and 29, which show the guide wires already in place through the tissue, with no indication given as to how they got there. In our view, the conclusion to be drawn from this is that all of the piercing is done by the sharp-tipped probe, and therefore Makower does not teach using several different configurations, and the examiner's reasoning is defective on this point. Second, Figure 17 demonstrates that when a larger opening is required, Makower makes it by pushing dilating tip 170 through the small opening initially made by the guide wire, and then enlarging the opening by making an annular cut with rearward-facing blade 171. Thus, there is no teaching in Makower of making a larger initial opening by the use of a larger piercing device. As far as Kim is concerned, the examiner has not directed us to an explicit teaching of why the star-shaped perforating tip "effectively" cuts the tissue and

therefore is “desirable,” and we find no such assertion on our own. This being the case, it is our opinion that the only suggestion for selecting the particular tip disclosed in Kim’s Figure 10 over any other configuration is found in the hindsight afforded one who first viewed the appellants’ disclosure. This, of course, is not a proper basis for a rejection under Section 103. In re Fritch, 972 F.2d 1260, 1264, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

It therefore is our conclusion that the teachings of Makower in view of Kim do not establish a prima facie case of obviousness with regard to the subject matter recited in independent claim 13 and dependent claims 14-22, and we will not sustain this rejection. We reach the same conclusion, for the same reasons, with regard to independent method claims 24 and 26.

Considering Kim in view of Makower leads us to the same result. Here, it is the examiner’s position that it would have been obvious to add a guide wire to the Kim arrangement “to effectively guide” the device within the vessel, in view of Makower’s use of the same. Since an “essential feature” of the Kim puncturing headpiece is to be expandable and contractible (column 14, line 30 et seq.), we agree with the appellants that one of ordinary skill in the art would not have been motivated to install a guide wire in the center in view of the presence of mechanical (Figure 14) and fluid (Figure 15) means for causing expansion and contraction located along the centerline, for that would appear to

have, at the very least, a deleterious effect upon the operation of Kim's "essential" feature. In addition, as was the case in the alternative rejection, the examiner has not directed us to explicit teachings in Makower which support the conclusion that the addition of a guide wire to the Kim device would be advantageous. Again, the mere fact that a prior art structure could be modified does not make such a modification obvious in the absence of suggestion to do so. In re Gordon, supra.

The rejection of claims 13-22, 24 and 26 as being unpatentable over Kim in view of Makower is not sustained.

SUMMARY

Neither rejection is sustained.

The decision of the examiner is reversed.

REVERSED

IRWIN CHARLES COHEN
Administrative Patent Judge

NEAL E. ABRAMS
Administrative Patent Judge

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APPLICATION NO. 09/014,759

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DECISION: REVERSED

Prepared By:

DRAFT TYPED: 14 Aug 02

FINAL TYPED: