

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

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RANDY WESTLUND, BRUCE TOCKMAN,
CHRISTINA REPASKY, LYLE A. BYE and
BRIAN D. SOLTIS

Appeal 2007-0811
Application 10/128,997
Technology Center 3700

Decided: September 27, 2007

Before WILLIAM F. PATE III, TERRY J. OWENS, and
LINDA E. HORNER, *Administrative Patent Judges*.

WILLIAM F. PATE III, *Administrative Patent Judge*.

DECISION ON APPEAL
STATEMENT OF THE CASE

This is an appeal from the rejection of claims 1-33. These are the only claims in the application. We have jurisdiction under 35 U.S.C. §§ 134 and 6.

The claimed invention is directed to a lead assembly for installation to the superior vena cava and the right atrium into the coronary sinus and the great coronary vein in the human heart.

Claim 1 reproduced below, is further illustrative of the claimed subject matter.

1. A lead assembly comprising:

a lead body adapted to carry signals, the lead body having a proximal end and a distal end, and an intermediate portion therebetween;

a connector located at the proximal end of the lead body;

at least one conductor disposed within the lead body;

the lead body having at least one preformed biased portion at an intermediate portion of the lead body;

an unbiased, flexible tapered portion disposed between the biased portion and the distal end of the lead body, the tapered portion distal to the biased portion is substantially more flexible than the biased portion, the distal portion of the lead having a tapered portion adapted to be implanted within a passage; and

at least one electrode coupled with at least one conductor.

The references of record relied upon by the Examiner as evidence of obviousness are:

Williams	US 4,932,407	Jun. 12, 1990
Ayers	US 5,476,498	Dec. 19, 1995
Stevens	US 5,916,193	Jun. 29, 1999
Warman	US 6,021,354	Feb. 01, 2000
Hine	US 6,070,104	May 30, 2000
Carson	US 6,377,856 B1	Apr. 23, 2002

Claims 1-7, 10-20, 22-27, 29-30, 32 and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Warman in view of Hine and/or in the alternative, in further view of Williams.

Claims 8, 28 and 31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Warman in view of Hine and/or in the alternative, with the additional teachings of Williams as applied, and further in view of Stevens.

Claim 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Warman in view of Hine and/or in the alternative, with the additional teachings of Williams as applied, and further in view of Ayers.

Claim 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Warman in view of Hine and in the alternative additionally in view of Williams as applied above, and further in view of Carson.

ISSUES

The sole issue for consideration is whether Appellants have established that the Examiner erred in rejecting claims 1-33 on the ground of obviousness.

FINDINGS OF FACT

Warman discloses a single path lead for insertion via the superior vena cava through the right atrium into the coronary sinus and thus into the great coronary vein. The lead body of Warman is adapted to carry a signal and has a proximal end and a distal end with an intermediate portion therebetween. Connectors 22, 24 are provided at the proximal end of the lead body. Conductors 46, 48, and 50 are disposed within the lead body. As disclosed, Warman has a preformed biased portion and an intermediate portion of the lead body. Warman calls this part of his lead curved section B, and curved section B has electrodes 16 and 18 provided on the preformed biased portion. Surrounding the preformed biased portion are curved sections A and C which are provided to allow stretching of the lead while the fixation portion or the preformed portion is secured in location in the vein. We note that Warman discloses that the portions not disposed in the vena cava may be made more pliable than the portions applied in the vena cava. Col. 2, ll. 28-30. We note further that Warman discloses a tip electrode 12 as a steroid eluting, porous, sintered electrode. Col. 4, ll. 49-50. The fixture portion or biased portion of Warman can take the shape of sigmoidal or sinusoidal curve or it can take the shape of a spiral or helix. See Figure 4 and col. 6, ll. 40-48. The cross section in Figure 2 shows lumens in the lead body 10 of Warman. Following the convention typical

for patent drawings, we take Figure 2 as typical of the cross section of the Warman device, and we concur with the Examiner in his finding that the lumens of Warman are isodiametric. With respect to Figure 8 in Warman, Warman appears to show a tapered distal end in this embodiment. We credit the Examiner's finding in this regard, inasmuch as the other embodiments seem to show a rounded or blunt tip. With an abundance of caution, the Examiner has cited Hine and Williams which disclose cardiac leads which have a tapered flexible tip.

Turning first to the disclosure of Hine, Hine discloses a molded nose 110 for the cardiac lead for improved maneuverability within the tortuous cardiac vein. See col. 4, ll. 26-32. Hine further discloses that the most distal portion of the lead 100 is the most flexible portion. That is, in Figure 2, section 200 is more flexible than section 201 which in turn is more flexible than section 202. See col. 4, l. 62-col. 5, l. 43. See also col. 3, ll. 4-31. The function of this gradient of flexibility is to aid in maneuverability and to cause the various electrodes to be brought into and remain in contact with the right atrial wall and the coronary sinus wall.

Williams discloses another cardiac lead in Figure 1 that has a tapered electrode head 24. The distal tip or head of the lead is to facilitate the passage of the lead into the coronary sinus and into the great vein. For this purpose, Williams discloses both a tapered or frustoconical tip 24 and a blunt or rounded tip 56.

Stevens discloses a catheter for use in supplying and withdrawing fluids from the heart. Turning to Figures 4A and 4B, we note that the catheter has a soft tip 614 at the distal end 606 of the shaft. The soft tip is to minimize trauma to tissue when the catheter is being introduced. See col. 11, ll. 20-32. The soft tip 614 is provided with radiopaque material to allow visualization by fluoroscopy as the catheter is introduced into the heart. See col. 11, ll. 58-60.

Ayers discloses another lead for implantation in the human heart wherein the electrode 44 forms the entire part of the preformed biased portion. From the electrode to the tip is a taper as seen in Figure 2.

Carson discloses another lead implanted into the heart using a guide catheter through which the lead is introduced while the lead is stiffened with the use of an internal stylet. See col. 4, ll. 35-56.

PRINCIPAL OF LAW

“Section 103 forbids issuance of a patent when ‘the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.’” *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734, 82 USPQ2d 1385, 1391 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, and (3) the level of skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). *See also*

KSR, 127 S.Ct. at 1734, 82 USPQ2d at 1391 (“While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.”) The Court in *Graham* further noted that evidence of secondary considerations “might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” 383 U.S. at 18, 148 USPQ at 467.

In *KSR*, the Supreme Court emphasized “the need for caution in granting a patent based on the combination of elements found in the prior art,” *id.* at 1739, 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious.

In particular, the Supreme Court emphasized that “the principles laid down in *Graham* reaffirmed the ‘functional approach’ of *Hotchkiss*, 11 How. 248.” *KSR*, 127 S.Ct. at 1739, 82 USPQ2d at 1395 (citing *Graham*, 383 U.S. at 12, 148 USPQ at 464 (emphasis added)), and reaffirmed principles based on its precedent that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* The Court explained:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

Id. at 1740, 82 USPQ2d at 1396. The operative question in this “functional approach” is thus “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.*

ANALYSIS

Our findings with regards to the scope and content of the prior art are outlined above. Warman differs from the claimed subject matter in possibly not showing a flexible tapered portion extending from the preformed biased portion to the distal end of the lead. Hine discloses such a flexible tapered portion. We agree with the Examiner that it would have been obvious at the time Appellants’ invention was made to taper and render flexible, the distal portion of Warman’s lead body if, indeed, Warman’s body is not tapered and flexible. Hine teaches one of ordinary skill to do so to improve the maneuverability in the cardiac vein. This is the simple substitution of one known element for another to obtain predictable results.

Appellants argue that the combination of Warman and Hine does not include every element of the claim and that there is no suggestion or motivation to combine these references. We certainly disagree. As we have outlined in our findings, each and every element of the claim is found in Warman with the possible exception of the tapered tip. Appellants further argue that Warman teaches away in that Warman discloses a thin lead body whereas Hine creates maneuverability by tapering only the end of the body. In our view, the teaching of Hine is clear. Whatever the diameter of the lead, when maneuvering in the tortuous cardiac vein, it is ideal to provide a molded, tapered nose to improve maneuverability and to prevent damage to

the narrow veins. We regard this as an express teaching or suggestion in the prior art for the use of the tapered flexible tip on the lead in Warman. We also regard the tip 24 disclosed by Williams as teaching a tapered tip for the same purpose.

Appellants argue that there is no teaching in Warman for the lumens to be isodiametric as claimed in claim 3. On the contrary, we believe that the diameter of the outside of the lead of Warman is shown as uniform and Figure 2 is a typical cross section of the lead. We believe that the Examiner is correct in concluding that there is no evidence to assume that the lumens are not isodiametric. We find that the Examiner has shown Warman discloses isodiametric lumens by a preponderance of the evidence.

With respect to the argued 120 degrees limitation of claims 7 and 20 the Examiner states that it would have been obvious to arrange the electrodes in various formations, including being 120 degrees apart, in order to insure proper and efficient contact. Answer, page 6. We agree. It is apparent to us that the exact angle between the contacts is based partly upon anatomy, which is well known, and partly upon the geometry of the biased portion of the lead. One of ordinary skill would have found the 120 degree separation to have been obvious, inasmuch as the prior art clearly recognizes the importance of contact, and not only contact, but contact at the correct location. The level of skill with respect to an implantation pacemaker is quite high, both with respect to training and education and consequences of failure of the device. Thus, the exact angle between the electrodes is well within the skill in this art.

With respect to radiopacity as found in claim 8, we agree with the Examiner that radiopacity is universally utilized on devices of this type so that fluoroscopy can be used to introduce these devices into their correct locations. Thus, it is our conclusion that it would have been obvious to provide radiopacity in the Warman device as taught by Stevens.

Turning to claim 11, Appellants argue that the steroid eluting contact shown in Warman does not meet the claim language. As we understand it, the disclosure of Warman is to a porous sintered electrode in which the eluting substance is combined with the powdered metal and sintered together. Thus, the eluting material comes from the pores in the sintered body and the pores are substantially surrounded with the metal of the electrode. Furthermore, Warman discloses the electrode as a substantially bulbous member on the distal end of the catheter. Therefore, Warman teaches a drug eluting member adjacent a conductor. Further, since the conductor is on the bulbous, rounded end of the lead of Warman, it would have been obvious to provide an eluting drug collar adjacent the tapered portion of Warman as modified by Hine.

With respect to independent claims 12 and 23 we refer Appellants to our Findings of Fact and our conclusions of obviousness made with respect to claim 1.

REMAND TO THE EXAMINER

It is noted that the Examiner has cited Carson as teaching a guidewire for implanting the lead of Warman. As we understand Carson, however, Carson uses a guiding catheter through which the lead is advanced along with a stiffening stylet to maneuver the lead in place. We do not regard the stylet as a guidewire, nor do we regard the guiding catheter as a guidewire. Consequently, we reverse the rejections of claims 21 and 30-33 as not showing a guidewire. However, we understand that guidewires are conventional in this art, and we remand the application to the Examiner for further consideration of whether it would have been obvious to include provisions for a guidewire when the instant invention was made.

This remand to the examiner pursuant to 37 CFR § 41.50(a)(1) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)) is made for further consideration of a rejection. Accordingly, 37 CFR § 41.50(a)(2) applies if a supplemental examiner's answer is written in response to this remand by the Board.

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CONCLUSION

The Examiner has not established the prima facie obviousness of claims 21 and 30-33 which call for a guidewire insertion. The case is remanded to the Examiner for further consideration of this issue.

The decision of the examiner rejecting claims 1-19 and 22-29 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a) (1) (iv).

AFFIRMED-IN-PART; REMANDED

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SCHWEGMAN, LUNDBERG,
WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS MN 55402