

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LARRY S. NICHTER

Appeal No. 96-2866
Application No. 08/185,221¹

HEARD: April 7, 1999

Before McCANDLISH, *Senior Administrative Patent Judge*, COHEN,
and MEISTER, *Administrative Patent Judges*.

MEISTER, *Administrative Patent Judge*.

DECISION ON APPEAL

Larry S. Nichter (the appellant) appeals from the final rejection of claims 20-26, the only claims remaining in the application.

¹ Application for patent filed January 24, 1994.

We REVERSE and, pursuant to our authority under the provisions of 37 CFR § 1.196(b), we will enter new rejections of the appealed claims.

The appellant's invention pertains to a method for fixating a bone by utilizing a wire having a cutting means disposed on one end thereof. Independent claim 20 is further illustrative of the appealed subject matter and a copy thereof may be found in the appendix to the brief.

The prior art relied on by the examiner is:

Longfellow	2,143,922	Jan. 17, 1939
Leuenberger	4,111,208	Sep. 5, 1978
Bray 1986	4,596,243	Jun. 24,

Additional prior art relied on by this merits panel of the Board is:

The prior art depicted in Fig. 5 of the drawings and described on pages 1 and 8 of the specification (the admitted prior art).

Claims 20, 22, 24 and 26 stand rejected under 35 U.S.C. § 103 as being unpatentable over Longfellow in view of Leuenberger.

Claims 21, 23 and 25 stand rejected as being unpatentable over Longfellow in view Leuenberger as applied to claims 20 and 24 above, and further in view of Bray.

Both of the above-noted rejections are bottomed on the examiner's view that:

Longfellow discloses a wire having a cutting edge that is placed in a bone as a fixation element (see Longfellow's figure 1 and appellant's specification pages 5 and 6 for a further discussion of these wires).² Longfellow discloses that the wires are inserted into and through the bone by drilling the wires into the bones in the normal manner (see appellant's specification, for a discussion on the normal ways of inserting these wires). However, Longfellow does not disclose that the wire is oscillated during its insertion. [Answer, page 4; footnote added.]

Thereafter, the examiner concludes that it would have been obvious to modify the insertion method of Longfellow by oscillating the fixation wires in view of the teachings of Leuenberger.

In our view, the examiner's position is based on speculation and unfounded assumptions. There is absolutely

² According to appellant's specification "K-wires" (i.e., Kirschner wires) are fixation wires which typically have two to four cutting edges on one end thereof (see page 6, lines 7 and 8) and are traditionally inserted or drilled into bone tissue by means of a rotary drill (see page 1, lines 8-26).

nothing in Longfellow which either teaches or fairly suggests that the wires 33 and 34 are Kirscher-type wires and "are inserted into and through the bone by drilling the wires into the bones in the normal matter" as the examiner asserts. Longfellow makes no mention of Kirscher wires and merely broadly states that "wires" are "inserted" through the bone fragments (see column 1, lines 39 and 40; column 2; lines 26 and 27). It does not follow that just because it is known in the art to drill Kirscher wires into bones by utilizing a rotary drill, that the "wires" 33 and 34 of Longfellow are likewise drilled into bones. Insofar as the broad statements in Longfellow that the wires 33 and 34 are "inserted" through the bone fragments are concerned, holes may have been first drilled through the bone fragments by a drill bit and the wires thereafter inserted through the holes. Moreover, it is not apparent that the wires of Longfellow even have the capability of being drilled into bones by means of a rotary drill. That is, there is no indication that the wires 33 and 34 have cutting edges or similar elements which would provide such capability. Obviousness under § 103 is a legal conclusion based on **factual evidence** (*In re Fine*, 837 F.2d 1071, 1073, 5

USPQ2d 1596, 1598 (Fed. Cir. 1988)) and the examiner may not resort to speculation or unfounded assumptions to supply deficiencies in establishing a factual basis (***see In re Warner***, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967)).

While both Leuenberger and Bray teach the drilling of holes in bones by the means of oscillating drill bits, there is nothing in either of these references which overcomes the deficiencies of Longfellow that we have noted above. This being the case, we will not sustain the rejections under 35 U.S.C. § 103 of claims 20, 22, 24 and 26 under 35 U.S.C. § 103 based on the combined teachings of Longfellow and Leuenberger and claims 21, 23 and 25 based on the combined teachings of Longfellow, Leuenberger and Bray.

Under the provisions of 37 C.F.R. § 1.196(b) we make the following new rejections:

Claims 20-26 are rejected under 35 U.S.C. § 112, first paragraph, as being based upon an original disclosure which fails to provide descriptive support for the subject matter now being claimed. We initially observe that the description requirement found in the first paragraph of 35 U.S.C. § 112 is separate from the enablement requirement of that provision.

See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560-64, 19 USPQ2d 1111, 1114-17 (Fed. Cir. 1991) and **In re Barker**, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977), **cert. denied**, 434 U.S. 1238 (1978). With respect to the description requirement, the court in **Vas-Cath, Inc. v. Mahurkar** at 935 F.2d 1563-64, 19 USPQ2d 1117 stated:

35 U.S.C. § 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession **of the invention**. The invention is, for purposes of the "written description" inquiry, **whatever is now claimed**.

. . . drawings alone **may** be sufficient to provide the "written description of the invention" required by § 112, first paragraph.

It is also well settled that the question of whether a modification is an obvious variant of that which is originally disclosed is irrelevant insofar as the written description requirement is concerned. **See, e.g., Lockwood v. American Airlines Inc.**, 107 F.3d 1565, 1571-72, 41 USPQ2d 1961, 1966

(Fed. Cir. 1997) and *In re Wohnsiedler*, 315 F.2d 934, 937, 137 USPQ 336, 339 (CCPA 1963). See also *In re Barker*, 559 F.2d at 593, 194 USPQ at 474, wherein the court, in quoting with approval from *In re Winkhaus*, 527 F.2d 637, 640, 188 USPQ 129, 131 (CCPA 1975) set forth: "That a person skilled in the art might realize from reading the disclosure that such a step is **possible** is not a sufficient indication to that person that the step is part of appellants' invention."

With these authorities in mind, we have carefully reviewed the original disclosure and fail to find descriptive support for the recitation in independent claim 20 of the step of

selecting said selected oscillating frequency and said selected force to minimize temperature elevation and thermal necrosis³ of said bone and its surrounding tissue. [Footnote added.]

It is stated on page 7 of the specification that

less force is required utilizing the method of the present invention as is necessary for the advancement of the wire when the wire is rotated in accordance with the prior art, at a speed equal to the oscillation frequency of the wire 16. The

³ *The American Heritage Dictionary*, Second College Edition, 1982, Houghton Mifflin Company, Boston, MA, defines "necrosis" as -- The pathologic death of living tissue in a plant or animal --.

oscillation frequency may be varied and is dependent upon many factors. However, it has been found that when the wire is oscillated at about 1200 oscillations per minute during advancement into the bone tissue, successful fixation may be obtained.

Page 8 of the specification also states

that the method in accordance with the present invention, utilizing an oscillating drill, generates less temperature elevation and less thermal damage. The apparatus and method of the present invention also may enable the insertion of K-wires at the same insertional force but lower rotational speeds, or vice versa, in order to reduce temperature elevation during drilling. This may have the beneficial result of causing less complications from thermal damage and a stronger wire holding strength over time.

It does not follow, however, that just because the specification states that (1) less force is required when the Kirscher wires are oscillated rather than rotated, (2) the oscillation frequency may be varied, (3) utilizing an oscillating drill generates less temperature elevation and less thermal damage and (4) the same force but lower rotational speeds, or vice versa, may reduce temperature elevation, that the appellant was in possession at the time of the filing of the application of the step of selecting the oscillating

frequency **and** force **to minimize** temperature elevation and thermal necrosis as claimed.

There is further no descriptive support for the recitation in independent claim 24 that the "fixation wire" (which as broadly recited includes all such wires) requires "comparatively more force" for removal from the bone than would be required for such a wire that was inserted by rotation. Fig. 8 of the drawing is directed to a bar chart that provides a comparative showing of the mean peak pull out force for each of three wires of different diameter.⁴ This comparative showing reveals that the mean peak pull out force for the Kirscher wires installed by a rotary drill are in some cases

⁴ According to pages 10-12 of the specification three different-sized trocar-tipped Kirscher or K-wires (0.028, 0.045 and 0.062 inches in diameter) were evaluated for drilling force and pull-out force on the tibias of two rabbits. With respect to this evaluation the specification states that:

Five new K-wires for each size were tested on three tibias using either the rotary or oscillating drill. Each tibia had ten drilled holes, 4mm apart, equally spaced along the mid-diaphysis. The SAS t-test was used to evaluate the differences in mean peak axial loads and mean peak pull-out forces for thirty point configurations for the two drills.
[Pages 10 and 11.]

greater than those installed by an oscillating drill. Thus, there is no descriptive support that the "fixation wire" (which as broadly recited includes all fixation wires) requires "comparatively more force for removal" as independent claim 24 sets forth. In this regard, it should be noted that there is a lack of descriptive support for claims which set forth essential elements of the invention in terms which are broader than the supporting disclosure. **See Gentry Gallery, Inc. v. Berkline Corp.**, 134 F.3d 1473, 1480, 45 USPQ2d 1498, 1503 (Fed. Cir. 1998).

Claims 24-26 are rejected under 35 U.S.C. § 112, first paragraph, as being based on a non-enabling disclosure. We initially observe that the test regarding enablement is whether the disclosure, as filed, is sufficiently complete to enable one of ordinary skill in the art to make and use the claimed invention without undue experimentation. **In re Scarbrough**, 500 F.2d 560, 566, 182 USPQ 298, 302 (CCPA 1974) and **In re Wands**, 858 F.2d 731, 737 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The experimentation required, in addition to not being undue, must not require ingenuity beyond that expected of one of ordinary

skill in the art. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976). Moreover, the specification must teach those of skill in the art how to make and use the invention as broadly as it is claimed. *See In re Goodman*, 11 F.3d 1046, 1050, 29 USPQ2d 2010, 2013 (Fed. Cir. 1993).

Here, as we have noted above in the rejection of these claims based on a lack of descriptive support, independent claim 24 sets forth that the "fixation wire" (which as broadly recited includes all such wires) requires "comparatively more force" for removal from the bone than would be required for a fixation wire that was inserted by rotation. The appellant's disclosure provides no adequate teaching of how **all** fixation wires may installed or inserted in such a manner so as to require "comparatively more force for removal" from the bone than would be required for a fixation wire installed by rotation. According to the comparative showing in Fig. 8, the appellant's disclosed method, at the most, will result in only **some** the fixation wires (dependent upon the particular diameter and particular location on the tibia) requiring comparatively more force for removal.

Claims 20 and 21 are rejected under 35 U.S.C. § 103 as being unpatentable over the admitted prior art in view of Leuenberger. The admitted prior art teaches a method of fixating bone by means of a wire having a cutting means at one end thereof comprising the steps of (1) unidirectionally rotating the wire, (2) pressing one end of the wire with a force that causes the wire to penetrate the bone and (3) fixating the bone with the wire, wherein the wire remains in the bone for a period of time sufficient for the bone to heal. Leuenberger, however, teaches that, when drilling bone with a unidirectional rotatable movement of a boring or drilling implement, damage of surrounding soft portions of the body may occur (see column 1, lines 14-22). In order to overcome this problem, Leuenberger teaches that the drilling implement (albeit a drill, miller or broaching tool; see column 1, line 32) should be advanced through the bone utilizing an alternating or oscillating movement (rather than unidirectional rotary movement). Leuenberger in lines 25-42 of column 1 reveals that, not only does such oscillating movement prevent damage of the soft tissue due to the motion of the tool or implement, but that it also diminishes heating to a large

degree (thus diminishing the risk of modification of the cellular structure, notably bone). In light of Leuenberger's teachings, one of ordinary skill in this art would have found it obvious to oscillate the fixation wire of the admitted prior art in order to achieve Leuenberger's expressly stated advantages of (1) avoiding damage to surrounding soft tissue caused by unidirectional rotation of the drilling implement and (2) diminishing the amount of heat generated to a large degree (thus diminishing the risk of modification of the cellular structure of the bone).

As to the step of selecting the oscillating frequency and the force so as to "minimize" temperature elevation and thermal necrosis of the bone, the selection of an optimum value is ordinarily an obvious matter which is within the skill of the art. Note *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990), *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980), *In re Fields*, 304 F.2d 691, 695-96, 134 USPQ 242, 245 (CCPA 1962), *In re Troiel*, 274 F.2d 944, 949, 124 USPQ 502, 505 (CCPA 1960) and *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

As to the particular frequency of "about 1200 oscillations per minute" as set forth in claim 25, the specification sets forth this parameter as "a specific example" (page 3) and further states that the "oscillation frequency may be varied and is dependent upon many factors" (page 7). Since the provision of an oscillation frequency of about 1200 oscillations per minute appears to solve no stated problem insofar as the record is concerned, we conclude that such a provision obvious is a matter engineering design choice. **See *In re Kuhle***, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975).

As evidence of nonobviousness the appellant has relied on declarations by Ashworth, Body and Talesisnik. Each of these declarations state essentially the same thing. Paragraphs 4 and 5 of each declaration states that the declarant is familiar with the references to Longfellow, Leuenberger and Bray which were relied on by the examiner and concludes that it would not have been obvious to insert an oscillating K-wire into bone in view of these teachings. Here, however, we have relied on the combined teachings of the admitted prior art and Leuenberger, rather than the specific reference combination relied on by the

examiner. Additionally, the statement regarding an oscillating K-wire is not commensurate with the scope of the claimed subject matter inasmuch as the claims on appeal more broadly recite "a wire."⁵ Moreover, while it is proper to give some weight to a persuasively supported statement of one skilled in the art on what was not obvious to him, obviousness is a question of law which we must decide (*see In re Weber*, 341 F.2d 143, 145, 144 USPQ 495, 497 (CCPA 1965) and *In re Vamco Machine and Tool, Inc.*, 752 F.2d 1564, 1574-75, 224 USPQ 617, 623 (Fed. Cir. 1985)), and an expert's opinion on the legal conclusion of obviousness is neither necessary nor controlling (*see Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1564, 7 USPQ2d 1548, 1554 (Fed. Cir. 1988)).

Paragraph 6 of each declaration states that it is "surprising" that less force is required to insert a wire by oscillation than by rotation and it is "even more unexpected"

⁵ It is well established that evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support. *See In re McLaughlin*, 443 F.2d 1392, 1396, 170 USPQ 209, 213 (CCPA 1971), *In re Tiffin*, 448 F.2d 791, 792, 171 USPQ 294 (CCPA 1971), and *In re Thompson*, 545 F.2d 1290, 1295, 192 USPQ 275, 277 (CCPA 1976).

that a wire which was oscillated would have comparatively greater holding strength than one inserted by rotation. These statements, are once again not commensurate in scope with the claimed subject matter. That is, there is no requirement in claims 20 and 21 that the wire be advanced with a force that is less than that required by a rotary drill or that the fixation wire requires comparatively more force for removal than a fixation wire inserted by rotation. Moreover, these statements are merely conclusory in nature and it is unclear what the declarant's conclusions are based on. Affidavits and declarations fail in their purpose when they recite conclusions with few facts to buttress the conclusions. ***See In re Brandstadter***, 484 F.2d 1395, 1406, 179 USPQ 286, 294 (CCPA 1973), ***In re Thompson, supra***, and ***In re DeBlauwe***, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). We also observe that, if the "even more unexpected" result of the oscillating wire having comparatively greater holding strength is based on the comparative showing in Fig. 8 of the drawings, then a comparatively greater holding strength is achieved only with respect to certain size wires at certain locations, rather than

"wires" in general as claimed. Moreover, the specification states that this value "does not appear to be statistically significant" (page 11, lines 12 and 13).

In summary:

The examiner's rejections of claims 20-26 under 35 U.S.C. § 103 are reversed.

New rejections of claims 20-26 under 35 U.S.C. § 112, first paragraph, and claims 20 and 21 under 35 U.S.C. § 103 have been made.

This decision contains new grounds of rejection pursuant to 37 C.F.R. § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 C.F.R. § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 C.F.R. § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new

grounds of rejection to avoid termination of proceedings
(§ 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

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

REVERSED
37 C.F.R. § 1.196(b)

HARRISON E. McCANDLISH)	
Senior Administrative Patent Judge)	
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)	
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)	BOARD OF PATENT
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