

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PETER J. WILK

Appeal No. 97-0939
Application 08/127,319¹

ON BRIEF

Before STAAB, MARTIN, and GONZALES, Administrative Patent Judges.

STAAB, Administrative Patent Judge.

DECISION ON APPEAL

¹ Application for patent filed September 27, 1993. According to the appellant, the application is a continuation of Application 07/913,601, filed July 14, 1992, now U.S. Patent 5,269,753, issued December 14, 1993.

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This is a decision on an appeal from the final rejection of claims 1-7 and 20-29, all the claims currently pending in the application. Two amendments have been filed subsequent to the final rejection. The first, submitted on July 17, 1995 (designated amendment "E" in the file) has been entered. The second, submitted July 31, 1997 (designated amendment "F" in the file) has been refused entry by the examiner.

Appellant's invention pertains to a method for use in laparoscopic hernia repair, and includes inter alia the steps of inserting a balloon between the abdominal muscles and the parietal peritoneum, and inflating the balloon to shift connective tissue between the abdominal muscles and the parietal peritoneum to form a space for performing the laparoscopic hernia repair operation on the herniated tissues. Independent claim 1, a copy of which is found in the appendix to appellant's second substitute brief (hereinafter, brief) filed March 19, 1996, is illustrative of the appealed subject matter.

The references of record relied upon by the examiner in support of rejections under 35 U.S.C. § 103 and 35 U.S.C. § 102(e) are:

Bonutti	5,163,949	Nov. 17, 1992 (Filing date Jul. 17, 1991)
Pena	5,178,133	Jan. 12, 1993 (Filing date Mar. 26, 1991)
Moll et al (Moll)	5,309,896	May 10, 1994 (Filing date Nov. 19, 1991)
Kieturakis et al (Kieturakis)	5,496,345	Mar. 5, 1996 (Effective filing date June 2, 1992)

The following rejections are before us for review:²

(a) claims 1-7 and 20-29 under 35 U.S.C. § 112, first paragraph, as being based on a specification, as originally filed, that “does not provide support for the invention as is now claimed” (answer, page 11);

(b) claim 25 under 35 U.S.C. § 112, second paragraph, “as being indefinite for failing to particularly point out and distinctly claim the subject matter which [appellant] regards as the invention” (answer, page 12);

(c) claims 1-7 and 20-29, “provisionally rejected under the judicially created doctrine of double patenting over claims 1-20 of U.S. Patent Application No. 08/602,913” (answer, pages 12-13); and,

(d) claims 20 and 27, “provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 18 of copending application Serial No. 602913” (answer, page 14).

(e) claims 1-3, 6, 7, 20, 21 and 24-29 under 35 U.S.C. § 103 as being unpatentable over Bonutti in view of Moll;

(f) claims 4, 5, 22 and 23 under 35 U.S.C. § 103 as being unpatentable over Bonutti in view of Moll and further in view of Pena;

(g) claims 20, 21, 24, 25, 27 and 28 under 35 U.S.C. § 102(e) as being anticipated by

²Rejections (b)-(d) and (g) are new rejections made for the first time in the examiner’s answer.

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Kieturakis;

The rejections are explained in the final rejection (Paper No. 11, mailed June 5, 1995), the examiner's answer (Paper No. 21, mailed August 22, 1996), the advisory letter (Paper No. 27, mailed November 12, 1997) in response to appellant's reply brief, and the supplemental examiner's answer (Paper No. 30, mailed December 30, 1997).

The opposing viewpoints of appellant are set forth in the brief (Paper No. 20, filed March 19, 1996), and the reply brief (Paper No. 24, filed July 31, 1997). In addition, a declaration under 37 CFR § 1.131 by inventor Peter J. Wilk (Paper No. 26) has been submitted with the reply brief for the purpose of "swearing behind" the Kieturakis patent that forms the basis for the newly entered § 102(e) rejection.

Rejection (a)

The 35 U.S.C. § 112, First Paragraph, Rejection

Looking first at the rejection of claims 1-7 and 20-29 under 35 U.S.C. § 112, first paragraph, we understand this rejection to be based upon the written description requirement of the first paragraph of § 112. In general, the test for determining compliance with the written description requirement of § 112 is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language under consideration. Further, it is

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also well settled that the content of the drawings may be considered in determining compliance with the written description requirement. *See Wang Lab., Inc. v. Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ 1767, 1774 (Fed. Cir. 1993); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1564, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). *See also In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

It is the examiner's view, as expressed on pages 2-3 of the final rejection, that the original disclosure does not provide descriptive support for the steps of claims 1, 20 and 27 of (1) removing the elongate instrument from the pre-peritoneal space, thereby permitting herniated tissue to project into said pre-peritoneal space, (2) after removal of the instrument from the pre-peritoneal space, performing a laparoscopic hernia repair operation on the herniated tissues, and (3) inflating the balloon any time after disposition rather than upon disposition thereof into the pre-peritoneal space. In addition, the examiner considers that the step of claims 2, 21 and 28 of (4) infusing a gaseous composition into the space to expand and maintain the same in an expanded state during the operation is not described in the original disclosure.

After reviewing appellant's disclosure as originally filed, it is our determination that the specification and drawings thereof, although somewhat incomplete, are sufficient to provide "written description" support within the meaning of the first paragraph of 35 U.S.C. § 112 for the steps called into question by the examiner. Support for step (1) is found, in our view, in a comparison of Figures 1

and 4 when considered in light of page 5, lines 4-7 and 22-23, of the specification, and from an understanding of the intended end result of the invention as a whole. Support for step (2) is found, in our view, in the first and third objects of the invention found on page 2 of the specification, and the summarized description of appellant's method as found on page 3, lines 14-18, when these portions of the specification are read in conjunction with Figures

1, 2 and 4. Figure 4 is especially pertinent in this respect in that it shows the herniated tissue HT projecting into the pre-peritoneal space PS formed by the balloon, the laparoscope 12 positioned through trocar sleeve 14 into the space PS, and the absence of the elongated instrument used to create the space PS. Support for step (3) is found in the specification at page 2, lines 23-24, and page 4, last two lines. In this regard, when read in context, an artisan would understand the word "upon" as used in the specification³ and claims as indicating that the balloon is disposed between the abdominal tissue AM and the peritoneum PP and then inflated. Finally, support for (4) is found in the specification at page 3, lines 4-7, and page 5, lines 14-17, especially in that these passages indicate that carbon dioxide gas is used to "maintain" the space PS in a desired state of expansion.

In reaching these conclusions, we reiterate that the test for compliance with the written

³See page 2, line 23, and page 4, penultimate line, of the specification.

description requirement of § 112 is not whether appellant's original disclosure exactly describes the subject matter claimed, but rather whether persons of ordinary skill in the art would have recognized that appellant invented what is now claimed. In that we believe an artisan would recognize from a review of the original disclosure as a whole that appellant invented what is now claimed, we will not sustain the examiner's rejection of the appealed claims under 35 U.S.C. § 112, first paragraph.

Rejection (b)

The 35 U.S.C. § 112, Second Paragraph, Rejection

The examiner has concluded that claim 25 is indefinite because of the double inclusion of the word "said" in describing one of the steps (i.e., "said said step of inserting said distal tip of said instrument including . . ." (claim 25, lines 3-4)).⁴ Appellant has failed to point out any error in the examiner's position and instead has submitted a proposed amendment (Paper No. 25) filed with the reply brief to overcome the rejection. The examiner, however, has refused to enter this proposed amendment. Advisory letter (Paper No. 27, mailed November 12, 1997).

The rejection under the second paragraph of § 112 is therefore still before us, and claim 25 has not been amended as set forth in the unentered proposed amendment. Under these circumstances, we will sustain the examiner's newly entered rejection of claim 25 under 35 U.S.C. § 112, second

⁴Although not rejected by the examiner on this ground, claim 27, line 21, contains a similar double inclusion of the word "said."

paragraph, since appellant has failed to point out any error in this rejection.

Rejections (c) & (d)

The Provisional Double Patenting Rejections

Each of the examiner's provisional double patenting rejections is based on appellant's application Serial No. 08/602,913. With respect to provisional rejection (f), appellant states that "[he] is prepared to submit a terminal disclaimer in accordance with current practice upon an indication that any of the claims of the instant application or Application 08/602,913 are allowable" (reply brief, page 5). No separate response is made with respect to rejection (g).⁵

It has always been the policy of this Board to summarily affirm rejections that are not argued by appellant. However, a review of the Patent Office records reveals that Serial No. 08/602,913 is now abandoned. Therefore, the basis for the standing provisional double patenting rejections no longer exists. Accordingly, we will not sustain these newly entered provisional double patenting rejections, notwithstanding appellant's failure to traverse them in the reply brief.

In the event Serial No. 08/602,913 is revived, the examiner should consider whether a new provisional double patenting rejection based thereon would be appropriate.

⁵Appellant is apparently of the view that the filing of a terminal disclaimer would overcome rejection (g) as well. However, in that provisional rejection (g) is based on 35 U.S.C. § 101, a terminal disclaimer would not be effective to overcome this rejection in the event the application upon which it is based were to issue as a patent.

Rejections (e) & (f)

The 35 U.S.C. § 103 Rejections

We appreciate that Bonutti discloses a method of using a balloon retractor to create a space in the body for a surgical procedure by first positioning the deflated balloon in the body at a desired location, then inflating the balloon with fluid, and thereafter manipulating the balloon to separate body tissue (column 7, lines 23-42). Bonutti also teaches that, depending on the application, the balloon can be left in place during the operation, or deflated and removed and

another instrument put into the space created (column 3, lines 50-52; column 4, lines 53-58). We also appreciate that Moll discloses the use of an inflated retractor to create a working space for a laparoscopic hernia repair operation (Figures 20A, 20B, 21 and the portions of the specification describing same). Our difficulty with the examiner's rejection, however, stems from its implied position that the combined teachings of these references would have suggested to one of ordinary skill in the art a method of using the balloon retractor of Bonutti in a hernia repair operation that includes the step of removing the balloon retractor instrument prior to performing the hernia repair operation on the herniated tissue, as now required by each of the independent claims on appeal. Clearly, Moll teaches that the retractor should in all instances remain in place during the operation. As to Bonutti, while the balloon can be deflated and removed, and another instrument put into the space created (column 3,

lines 50-52), whether or not this is done “depend[s] on the application” (column 4, line 53), and in particular notes that “[s]ome tissues will stay in place to allow this latter function, after the space has been created with the retractor” (column 4, lines 56-58). Missing from the combined teachings of the references, in our view, is any teaching that in a hernia repair operation, the tissues in question will stay in place so as to allow for removal of the retractor, or that, as a practical matter, the balloon of Bonutti could be removed even if the tissues will not stay in place. In light of these deficiencies in the disclosures of Bonutti and Moll, we will not sustain the standing § 103 rejection of claims 1-3, 6, 7, 20, 21 and 24-29 based on their combined teachings.

The Pena reference additionally applied in the § 103 rejection of claims 4, 5, 22 and 23 does not render obvious what we have found to be lacking in Bonutti and/or Moll. Accordingly, the standing § 103 rejection of these claims also will not be sustained.

Rejection (g)

The 35 U.S.C. § 102(e) Rejection

Appellant does not appear to challenge the examiner’s position that the disclosure of Kieturakis anticipates the subject matter of claims 20, 21, 24, 25, 27 and 28. Instead, appellant has submitted a declaration under 37 CFR § 1.131 by inventor Peter J. Wilk for the purpose of “swearing behind” the

effective filing date⁶ of the Kieturakis patent. Therefore, the dispositive issue with respect to this rejection is whether the Wilk declaration is effective to remove Kieturakis as a reference.

37 CFR § 1.131(b), in pertinent part, reads as follows:

[o

The showing of facts [required to overcome a reference cited against a claim] shall be such . . . as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application.

In the present instance, appellant contends that the Wilk declaration and supporting exhibits “establish a date of conception prior to the earliest effective filing date of Kieturakis et al., i.e., prior to June 2, 1992 . . . [and] diligence from the conception date to a subsequent (constructive) reduction to practice” (reply brief, page 2).

We have closely reviewed the Wilk declaration and supporting exhibits and have concluded, based on exhibits A-D, that appellant has established conception of the invention prior to June 2, 1992, the earliest effective date of the Kieturakis reference. However, we do not agree that appellant has established diligence from just prior to Kieturakis’ entry into the field on June 2, 1992 to appellant’s

⁶The effective filing date of Kieturakis is June 2, 1992, which is the filing date of the grandparent SN 07/893,988 application thereof. See item [60] on the cover sheet of the Kieturakis patent, as well as column 1, lines 5-7, of the specification.

constructive reduction to practice on July 14, 1992. The activities referred to in exhibits A-D, while pertinent to conception of the invention, do not show diligence in constructively reducing the presently claimed invention to practice because they are not directly related to the filing of a patent application directed to the presently claimed subject matter.

Turning to the remaining exhibits, exhibit E is a photocopy of the same sheet of appellant's notes and drawings as exhibit D, except that a portion of the sheet is obscured by what declarant Wilk characterizes as a "self-adhered note sheet"⁷. The writing within the bounds of the "note sheet" includes the initials "N.S.," the date "6/17/92," and several additional lines of text. Declarant Wilk states:

I wrote the note on a self-adhering note sheet and attached the note to the drawing of Exhibit D. The note has the initial "N.S." of my patent attorney Neil Sudol, indicating that I made the note during a meeting with my attorney on June 17, 1992. The note says that the invention had been "discussed previously" - with my attorney - and carries the words "same balloon as intussusception device" and "file separately" and "method claims only." [Declaration, paragraph 8.]

Exhibit F comprises photocopies of certain pages of an invoice from attorney Sudol dated July 1, 1992. The exhibit supports declarant Wilk's statements regarding the note sheet of exhibit E in the sense that it refers to a meeting between declarant Wilk and attorney Sudol on June 17, 1992 "re new

⁷The "self-adhered note" in question actually appears to be a hand drawn sketch intended to simulate a self-adhered note.

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inventions for May and June,” which new inventions include inter alia a “peritoneal balloon.”

Exhibit G comprises photocopies of certain pages of an invoice from attorney Sudol dated August 2, 1992. Under the heading “WO7-135 Peritoneal Clearance W/Balloon” are three entries pertaining to the preparation of a patent application that was apparently filed on July 14, 1992.

The critical period for diligence under 37 CFR § 1.131(b) begins just prior to the effective date of the reference (i.e., June 2, 1992) and ends with the date of constructive reduction to practice (i.e., July 14, 1992, the filing of application SN 07/913,601, the parent of the instant application). Appellant must account for the entire period during which diligence is required. *Gould v. Schawlow*, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966).

A period lacking activity of as little as two days has been held to be fatal. *In re Mulder*, 716 F.2d 1542, 1545, 219 USPQ 189, 193 (Fed. Cir. 1983) (37 CFR § 1.131 issue).

On the record before us, the earliest indication that appellant thought to file a patent application directed to the claimed method, and thus constructively reduce it to practice, is, at best, inventor Wilk’s alleged discussion with attorney Sudol at some unspecified date prior to June 17, 1992 (Wilk declaration, paragraphs 8 and 9; exhibits E and F). The record does not specify when the alleged

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discussion took place, or precisely what was discussed. Accordingly, even when viewed in a light most favorable to appellant, appellant's showing has not adequately accounted for the time from just prior to Kieturakis' entry into the field on June 2, 1992 up to the alleged discussion with attorney Sudol some time prior to June 17, 1992, a period of time that could have been up to two weeks. This unaccounted for period of time in appellant's attempt to show diligence coupling his conception to the effective filing date of the present application leaves a hiatus that is fatal to appellant's showing. *In re Mulder*, 716 F.2d at 1545, 219 USPQ at 193. We therefore conclude that appellant's evidence does not show diligence in constructively reducing the presently claimed invention to practice for the critical period *beginning just prior to* the effective filing date of Kieturakis to the filing date of the parent of the instant application, as required by 37 CFR § 1.131(b). It follows that we simply do not agree with appellant that "the short time between Appellant's conception and the filing of parent application No. 07/913,601 on

July 14, 1996 [sic, 1992] itself is evidence of Appellant's diligence in [constructively] reducing the invention to practice" (reply brief, page 3).

Thus, on the record before us, Kieturakis is still applicable as prior art. In that appellant has not specifically disputed the examiner's position that the Kieturakis disclosure anticipates the subject matter

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of claims 20, 21, 24, 25, 27 and 28, the standing § 102(e) rejection will be sustained.

Summary

Rejection (a) of claims 1-7 and 20-29 under 35 U.S.C. § 112, first paragraph, is reversed.

Rejection (b) of claim 25 under 35 U.S.C. § 112, second paragraph, is affirmed.

Provisional double patenting rejections (c) and (d) of claims 1-7 and 20-29 are reversed.

Rejections (e) and (f) of claims 1-7 and 20-29 under 35 U.S.C. § 103 are reversed.

Rejection (g) of claims 20, 21, 24, 25, 27 and 28 under 35 U.S.C. § 102(e) as being anticipated by Kieturakis is affirmed.

The decision of the examiner is affirmed-in-part.

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

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AFFIRMED-IN-PART

LAWRENCES J. STAAB)
Administrative Patent Judge)
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) BOARD OF PATENT
JOHN C. MARTIN)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
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