

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 PETER M. BONUTTI

Appeal No. 2001-0628
Application No. 09/118,665

HEARD: July 17, 2003

Before COHEN, MCQUADE and NASE, Administrative Patent Judges.
MCQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Peter M. Bonutti appeals from the final rejection of claims 59 through 80 and 84 through 91, all of the claims pending in the application.

THE INVENTION

The invention relates to a "method for use in medical imaging" (specification, page 1). Representative claim 59 reads as follows:

59. A method of imaging a joint in a body of a patient, said method comprising the steps of providing an imaging unit having a chamber, positioning a joint in a patient's body in the chamber of the imaging unit with the patient in a seated orientation, gripping a portion of the patient's body adjacent to

Appeal No. 2001-0628
Application No. 09/118,665

THE REJECTIONS

Claims 59 through 68, 70, 71, 75 through 80 and 84 through 91 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a specification which fails to comply with the written description requirement of this section of the statute.

Claims 59 through 68, 70, 71, 75 through 80 and 84 through 91 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a specification which fails to comply with the enablement requirement of this section of the statute.

Claims 59 through 68, 70, 71 75, 77 through 80 and 88 through 91 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Knuttel in view of either Shellock or Captain Jack, and further in view of Cook.

Claims 69 and 72 through 74 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over either Shellock or Captain Jack in view of Cook.

Attention is directed to the brief (Paper No. 12) and answer (Paper No. 13) for the respective positions of the appellants and examiner regarding the merits of these rejections.

Appeal No. 2001-0628
Application No. 09/118,665

DISCUSSION

I. The 35 U.S.C. § 112, first paragraph, written description and enablement rejections of claims 59 through 68, 70, 71, 75 through 80 and 84 through 91

The written description and enablement requirements of 35 U.S.C. § 112, first paragraph, are separate and distinct. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). The test for compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventors 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. In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983). The content of the drawings may also be considered in determining compliance with the written description requirement. Id. Insofar as the enablement requirement is concerned, the dispositive issue is whether the appellants' disclosure, considering the level of ordinary skill in the art as of the date of the application, would have enabled a person of such skill to make and use the claimed invention without undue experimentation. In re Strahilevitz, 668 F.2d 1229, 1232, 212 USPQ 561, 563-64

Appeal No. 2001-0628
Application No. 09/118,665

(CCPA 1982). In calling into question the enablement of the appellant's disclosure, the examiner has the initial burden of advancing acceptable reasoning inconsistent with enablement. Id.

The examiner has advanced related rationales for the written description and enablement rejections, and the appellants, in turn, have argued the two rejections as one (see pages 10 through 13 in the brief). Hence, we too shall treat the rejections together.

The subject matter recited in the claims so rejected is specific to the vertically extending MRI primary coil 368 schematically illustrated in Figure 43 and briefly described in the specification on pages 37 and 38. Of particular interest is the passage on page 37, lines 21 through 25, which states that

[a] patient may be placed in a standing or seated position on a support 370 for imaging in the coil 368. A ram 372 is operable to move the patient into and out of the coil 368. Positioning fixtures, etc. are mounted to a support member 374.

The examiner views the appellants' specification as failing to comply with the written description requirement with respect to the claimed subject matter at issue because

[t]he specification fails to disclose a method of imaging a joint in an imaging chamber while the patient is seated or standing while gripping a portion of the patient's body with a cuff. Pages 37-38 and original claim 58 provide the only disclosure of the embodiment which images either a seated or standing patient. The

Appeal No. 2001-0628
Application No. 09/118,665

specification refers to "positioning fixtures" which are mounted to the support member but fails to disclose what those fixtures would be [answer, page 3].

In a similar vein, the examiner considers the appellants' specification as failing to comply with the enablement requirement with respect to the claimed subject matter at issue because

[g]iven the structure shown in figure 43 and appellant's [sic] comments regarding the lack of operability of the prior art devices in the disclosed vertical chamber, it is unclear as to which positioning fixtures would be used and mounted to enable them to operate in a vertical chamber. If appellant's [sic] previously disclosed positioning devices are used, appellant [sic] fails to show how the structure of such would be modified so as to enable its use in a vertical chamber [answer, page 4].

The appellants note that "[p]ages 8 through 36 of the specification, taken in conjunction with Figs. 1 through 42 of the application drawings, disclose various positioning fixtures which grip a portion of a patient's body adjacent to a joint with a cuff" (brief, page 11). According to the appellants, "any one of the positioning fixtures could be utilized with the upright imaging unit illustrated in Fig. 43" (brief, page 12). The appellants go on to explain that

[t]he positioning fixtures of Figs. 1 through 42 of the application have been described, prior to page 37 of the application, in conjunction with a horizontal imaging unit 12 (Fig. 1A). At page 47 [sic, page 37], lines 21 through 25 of the specification, it is

disclosed that the positioning fixtures of Figs. 1 through 42 could be utilized with an imaging unit having a vertically extending primary coil 368 (Fig. 43) rather than a horizontally extending imaging coil.

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...[i]t would be apparent to a person skilled in the imaging art that the positioning fixtures illustrated in Figs. 1 through 42 of the application drawings could be utilized with the upright imaging unit of Fig. 43 rather than a horizontal imaging unit.

The Examiner has not explained why the positioning fixtures of Figs. 1-42 can not be utilized with the vertical imaging unit of Fig. 43 rather than the horizontal imaging unit [brief, pages 12 and 13].

Contrary to the appellants' assertion, the description of the vertically extending MRI primary coil 368 on specification pages 37 and 38 does not expressly indicate that the earlier described "positioning fixtures" which grip a portion of a patient's body adjacent to a joint with a cuff could be utilized with the vertically extending MRI primary coil. The description of the MRI primary coil 368, however, cannot be read in a vacuum. When the reference on page 37 to the "positioning fixtures" is read within the context of the specification as a whole, it becomes clear that the appellants intended it to be inclusive of the previously described cuffs for gripping a portion of the patient's body adjacent to the joint. Thus, the disclosure of the application as originally filed would reasonably convey to the artisan that the appellants' had possession at that time of

Appeal No. 2001-0628
Application No. 09/118,665

the subject matter now recited in claims 59 through 68, 70, 71, 75 through 80 and 84 through 91.

Furthermore, the examiner has failed to advance acceptable reasoning for the proposition that the appellants' disclosure, considering the level of ordinary skill in the art as of the date of the application, would not have enabled a person of such skill to effect without undue experimentation a method as recited in claims 59 through 68, 70, 71, 75 through 80 and 84 through 91 including the step of gripping a portion of the patient's body adjacent to the joint with a cuff. In this regard, adapting the gripping cuff structure disclosed by the appellants to the vertically extending MRI primary coil 368 would appear to be a relatively simple and straightforward enterprise.

In light of the foregoing, we shall not sustain either of the 35 U.S.C. § 112, first paragraph, rejections of claims 59 through 68, 70, 71, 75 through 80 and 84 through 91.

II. The 35 U.S.C. § 103(a) rejection of claims 59 through 68, 70, 71, 75, 77 through 80 and 88 through 91 as being unpatentable over Knuttel in view of either Shellock or Captain Jack, and further in view of Cook

Appeal No. 2001-0628
Application No. 09/118,665

Knuttel, the examiner's primary reference in this rejection, discloses "an electromagnet for generating the static magnetic field needed for NMR tomography [i.e., NMR imaging], with a coil arrangement that generates an approximately homogenous magnetic field in the internal space defined by said coil arrangement and in which the body to be examined is located" (translation, page 3). Figure 3 illustrates a horizontally disposed electromagnet 21 wherein a patient lies on a table 23 designed for movement into and out of the electromagnet, and Figures 4 and 5 depict vertically disposed electromagnets 31 and 45 adapted to be lowered over the upper body of a standing patient (Figure 4) or a sitting patient (Figure 5).

Claims 59 through 68, 70, 71, 75, 77 through 80 and 88 through 91 recite methods wherein the patient is in either a seated or a standing orientation, or wherein the imaging unit has a chamber with an upright central axis. To meet these limitations, the examiner relies on the electromagnet embodiments shown in Figures 4 and 5 of the Knuttel reference. As implicitly conceded by the examiner (see pages 4 through 7 in the answer), however, these portions of the Knuttel disclosure do not respond to the limitations in independent claim 59, or the corresponding limitations in independent claims 64, 69 (from which claims 70

Appeal No. 2001-0628
Application No. 09/118,665

and 71 depend), 75 and 88, relating to the gripping and bending steps, to the limitations in claim 69 relating to the step of simulating joint loading by applying a tractive force, or to the limitations in claim 88 relating to the step of positioning a joint in a chamber of the imaging unit by maintaining the imaging unit stationary and moving the patient along the upright central axis of the unit. The examiner's reliance on Shellock, Captain Plastic and/or Cook to cure these shortcomings in Knuttel is not well founded.

Shellock discloses the practice of using kinematic MRI techniques on patients in prone or supine positions to analyze knee joints flexed through a specific range of motion.

The Captain Jack flyers broadly, and somewhat ambiguously, disclose positioning devices for use in kinematic MRI studies of wrists, ankles and knees. The letter to which the brochures are appended suggests that these positioning devices would be used on patients lying in prone or supine positions.

Cook discloses a method of assessing the physiological state of body joint by moving the joint against resistance through a range of motion and measuring electrical activity in the muscles controlling the joint. As shown in Figures 1 and 2, an exemplary embodiment of this method involves a cradle 1 into which the

Appeal No. 2001-0628
Application No. 09/118,665

forearm 2 of a subject is rigidly affixed via a strap 3, electrical detectors 4 applied to the forearm, and a hand grip 7 mounted for rotation about an axis 6 against a selected level of resistance.

In proposing to combine Knuttel, Shellock or Captain Jack, and Cook to reject claims 59 through 68, 70, 71, 75, 77 through 80 and 88 through 91, the examiner concludes that it would have been obvious in view of either Shellock or Captain Jack "to have modified Knuttel et al such that the vertical imaging system is combined with means for analyzing a joint" (answer, page 4), and in view of Cook "to have further modified Knuttel et al such that a cuff is used to grip a portion of the patient's body adjacent the body portion [sic, joint]" (answer, page 5) and "to have applied a force to the joint such that it can be analyzed under stress . . . to provide a complete analysis of the joint under normal use conditions" (answer, page 5).

Rejections based on § 103(a) must rest on a factual basis. In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177-78 (CCPA 1967). In making such a rejection, the examiner has the initial duty of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to

Appeal No. 2001-0628
Application No. 09/118,665

speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. Id.

In the present case, the disclosures by Shellock or Captain Jack of kinematic MRI techniques for analyzing knee, wrist and/or ankle joints would not have suggested modifying the methods respectively depicted by Figures 4 and 5 of Knuttel to include such kinematic techniques so as to account for the above noted bending limitations in the claims. To begin with, and as shown in Figures 4 and 5, Knuttel's vertically disposed electromagnets 31 and 45, in their operative positions, do not encompass a patient's knee, wrist and/or ankle joints. Furthermore, these vertically disposed electromagnets would not on their face appear to be amenable to the sorts of fixtures or mechanisms necessary to implement kinematic techniques for analyzing these or other joints. Cook's disclosure of a method of measuring electrical activity in the muscles controlling a joint using a forearm cradle, strap and resistance-adjustable hand grip does not cure this basic flaw in the proposed combination of Knuttel and either Shellock or Captain Jack, and would not have suggested further modifying Knuttel's MRI process to account for the above noted gripping and tractive force limitations in the claims. The applied references also fail to account for the recitation in

Appeal No. 2001-0628
Application No. 09/118,665

claim 88 of the step of positioning a joint in a chamber of the imaging unit by maintaining the imaging unit stationary and moving the patient along the upright central axis of the unit.

Thus, the combined teachings of Knuttel, either Shellock or Captain Jack, and Cook do not justify the examiner's conclusion that the differences between the subject matter recited in independent claims 59, 64, 69, 75 and 88 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. Hence, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claims 59, 64, 75 and 88, and dependent claims 60 through 63, 65 through 68, 70, 71, 77 through 80 and 89 through 91, as being unpatentable over Knuttel in view of either Shellock or Captain Jack, and further in view of Cook.

III. The 35 U.S.C. § 103(a) of claims 69 and 72 through 74 as being unpatentable over either Shellock or Captain Jack in view of Cook

For the reasons discussed above, the combined teachings of Shellock or Captain Jack in view of Cook do not warrant a conclusion of obviousness with respect to the subject matter recited in independent claim 69. Accordingly, we shall not sustain the standing 35 U.S.C. § 103(a) of claim 69, and

Appeal No. 2001-0628
Application No. 09/118,665

dependent claims 72 through 74, as being unpatentable over either
Shellock or Captain Jack in view of Cook.

SUMMARY

The decision of the examiner to reject claims 59 through 80
and 84 through 91 is reversed.

REVERSED

Appeal No. 2001-0628
Application No. 09/118,665

IRWIN CHARLES COHEN)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
JOHN P. MCQUADE)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
)	
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Appeal No. 2001-0628
Application No. 09/118,665

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