

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MAKO SURGICAL CORP.,
Petitioner,

v.

BLUE BELT TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2015-00630
Patent 6,205,411 B1

Before SALLY C. MEDLEY, KEVIN F. TURNER, and
WILLIAM M. FINK, *Administrative Patent Judges*.

TURNER, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner, Mako Surgical Corporation, filed a Petition requesting an *inter partes* review of claims 1–17 of U.S. Patent No. 6,205,411 B1 (Ex. 1001, “the ’411 Patent”). Paper 2 (“Pet.”). Patent Owner, Blue Belt Technologies, Inc., did not file a Preliminary Response. We have

jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

For the reasons that follow, we institute an *inter partes* review of claims 1–17 of the ’411 Patent.

A. Related Proceeding

The ’411 Patent is involved in the following lawsuit: *Mako Surgical Corp. v. Blue Belt Technologies, Inc.*, No. 0:14-cv-61263-MGC (S.D. Fla.). Pet. 1; Paper 5, 2.

B. The ’411 Patent

The ’411 Patent relates to an apparatus for facilitating the implantation of an artificial component of a body joint. Ex. 1001, Abstract. The Specification of the ’411 patent describes a system that provides a medical practitioner with a tool to precisely determine an optimally size and position of the artificial components in a joint to provide the desired range of motion of the joint following surgery. *Id.* at 4:66–5:2. The apparatus includes geometric pre-operative planner 12, that is used to create geometric models of the joint and the components to be implanted based on geometric data received from a skeletal structure data source 13, and is interfaced with pre-operative kinematic biomechanical simulator 14, that simulates movement of the joint using the geometric models for use in determining

implant positions, including angular orientations, for the components. *Id.* at 5:63–6:5.

C. Illustrative Claim

Claims 1, 10, and 17 are independent claims. Claims 2–9 directly or indirectly depend from claim 1, and claims 11–16 directly depend from independent claim 10. Claim 1 is reproduced below.

1. An apparatus for facilitating the implantation of an artificial component in one of a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint, comprising:

a pre-operative geometric planner; and

a pre-operative kinematic biomechanical simulator in communication with said pre-operative geometric planner wherein said pre-operative geometric planner outputs at least one geometric model of the joint and the pre-operative kinematic biomechanical simulator outputs a position for implantation of the artificial component.

Ex. 1001, 13:16–27.

D. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–17 are unpatentable based on the following grounds¹:

¹ Petitioner alleges that claims 1-17 are obvious over DiGioia II and other references, Pet. 29; a review of the actual discussion of the grounds, Pet. 28–46, however, reveals that Petitioner is not alleging obviousness of claims 1, 2, and 4–8 over DiGioia II, only anticipation.

Reference(s)	Basis	Challenged Claim(s)
DiGioia I ²	§ 103(a)	1–15 and 17
DiGioia I and DiGioia II ³	§ 103(a)	16
DiGioia II	§ 102(b)	1, 2, and 4–8
DiGioia II and O’Toole ⁴	§ 103(a)	3, 10–12, 15, and 16
DiGioia II and Taylor ⁵	§ 103(a)	9
DiGioia II, O’Toole, and Taylor	§ 103(a)	13 and 14
DiGioia II, Chao ⁶ , and O’Toole	§ 103(a)	17

II. ANALYSIS

A. Claim Interpretation

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Techs., LLC*, No. 2014-1301, 2015 WL 4097949, *7-8 (Fed. Cir. July 8, 2015) (“Congress implicitly approved the broadest reasonable

² A.M. DiGioia et al., “HipNav: Pre-operative Planning and Intra-operative Navigational Guidance for Acetabular Implant Placement in Total Hip Replacement Surgery,” 2nd CAOS Symposium, 1996 (Ex. 1005) (“DiGioia I”).

³ A.M. DiGioia et al., “An Integrated Approach to Medical Robotics and Computer Assisted Surgery in Orthopaedics,” PROC. 1ST INT’L SYMPOSIUM ON MEDICAL ROBOTICS AND COMPUTER ASSISTED SURGERY, pp. 106–111, 1995 (Ex. 1006) (“DiGioia II”).

⁴ R.V. O’Toole et al., “Towards More Capable and Less Invasive Robotic Surgery in Orthopaedics,” COMPUTER VISION, VIRTUAL REALITY AND ROBOTICS IN MEDICINE LECTURE NOTES IN COMPUTER SCIENCE, Vol. 905, pp. 123–130, 1995 (Ex. 1008) (“O’Toole”).

⁵ Taylor, et al., “An Image-Directed Robotic System for Precise Orthopaedic Surgery,” IEEE TRANSACTIONS ON ROBOTICS AND AUTOMATION, Vol. 10, No. 3, June 1994 (Ex. 1009) (“Taylor”).

⁶ E.Y.S. Chao et al., “Simulation and Animation of Musculoskeletal Joint System,” TRANSACTIONS OF THE ASME, Vol. 115, pp. 562–568, Nov. 1993 (Ex. 1007) (“Chao”).

interpretation standard in enacting the AIA,” and “the standard was properly adopted by PTO regulation.”). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioner proposes no specific constructions for any claim terms. Therefore, for the purposes of this decision, and on this record, we determine that no claim term needs express interpretation. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only those terms which are in controversy need to be construed, and only to the extent necessary to resolve the controversy).

B. Principles of Law

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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.*, 550 U.S. 398, 406 (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; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In that regard, an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for

a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; *see Translogic*, 504 F.3d at 1259. A prima facie case of obviousness is established when the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. *In re Rinehart*, 531 F.2d 1048, 1051 (CCPA 1976).

The level of ordinary skill in the art is reflected by the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

C. Obviousness of Claims 1–15 and 17 over DiGioia I

Petitioner contends that claims 1–15 and 17 are obvious over DiGioia I. Pet. 10–28. To support its contentions, Petitioner provides detailed explanations as to how DiGioia I meets or renders obvious each claim limitation. *Id.* Petitioner also relies upon a Declaration of Robert D. Howe, who has been retained as an expert witness by Petitioner for the instant proceeding. Ex. 1004.

DiGioia I describes a system and methods to determine optimal implant placement during hip replacement surgery through the use of pre-operative planning, a range of motion simulator, and intra-operative navigational tracking and guidance. Ex. 1005, Abstract. The pre-operative planner allows the surgeon to manually specify the position of the acetabular component within the pelvis based upon pre-operative CT images. *Id.* at 2. Fig. 3 of DiGioia I, reproduced below, illustrates connections between the pre-operative planner and a range of motion simulator.

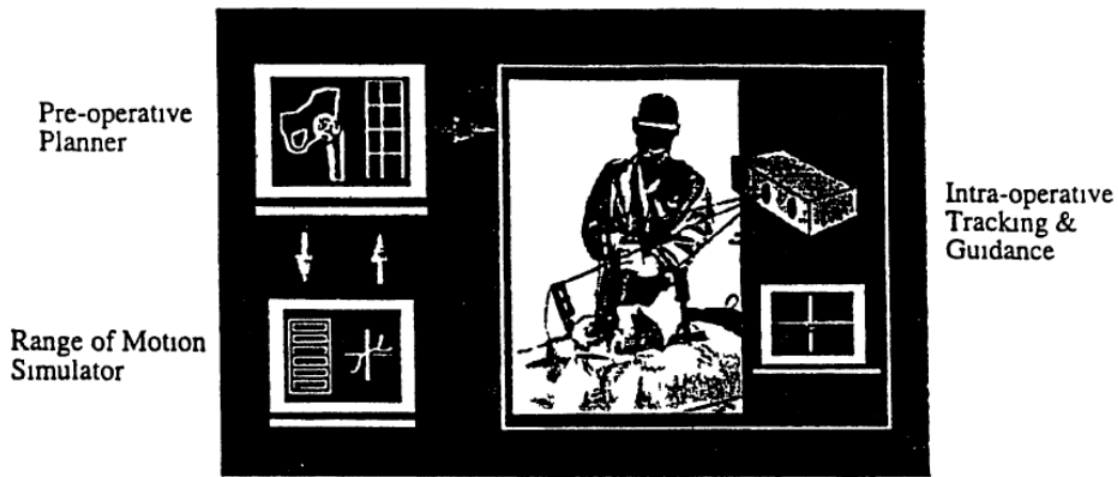


Figure 3 HipNav system overview

Fig. 3 of DiGioia I provides an system overview.

The pre-operative CT scan is used to determine the patient's specific bone geometry and different orthogonal views are presented to the surgeon. *Id.* at 3. The range of motion simulator performs a kinematic analysis which determines an "envelope" for the safe range of motions of the implant. *Id.* During the surgery, the system permits the surgeon to know the positions of the pelvis and acetabulum at all times, and optical tracking through a camera tracks the positions of special light emitting diodes, which may be attached to bones, tools, or other pieces of operating equipment. *Id.* at 4–5.

Petitioner acknowledges that specific elements of independent claims 1, 10, and 17 are not explicitly disclosed in DiGioia I. Pet. 14–15. Specifically, DiGioia I discloses that feedback from the simulator can aid the surgeon in determining optimal implant placement, and Petitioner alleges that it would have been obvious to utilize the feedback to modify the position of an implant, re-run the simulation to determine optimal position, and output that position to the pre-operative planner. *Id.* at 15, citing Ex.

1004 ¶ 38. At this juncture of the proceeding, we are persuaded by the Petition that such a modification would have been obvious.

Additionally, claim 17 requires the system to determine an implant position based on a predetermined range of motion and the calculated range of motion. Petitioner points out that DiGioia I discloses the calculation of a range of motion and states that the surgeon may choose to modify a selected position to achieve optimal implant positioning. Pet. 15. Petitioner alleges that it would have been obvious to consider the specific patient's functional needs and the range of motion needed to perform those functional needs, which could be predetermined, to help in determining optimal implant positioning. *Id.* at 15, citing Ex. 1004 ¶ 38. We are persuaded by the Petition such a modification would have been obvious. We are further persuaded, at this juncture of the proceeding, that Petitioner has established a reasonable likelihood that Petitioner would prevail in its challenge to independent claims 1, 10, and 17.

Petitioner also asserts that dependent claims 2–9 and 11–15 are also obvious over DiGioia I. Pet. 15–20. We have reviewed the Petition and the contentions made, and are persuaded, at this juncture of the proceeding, that Petitioner has established a reasonable likelihood that Petitioner would prevail in its challenge to dependent claims 2–9 and 11–15.

For example, claims 2 and 15 recite that the system also includes an intra-operative navigational module in communication with the pre-operative kinematic biomechanical simulator. The present record supports the contention that DiGioia I's disclosure of an "inter-operative guidance system," which uses "pre-operative information," to provide "navigational

feedback to the surgeon” as meeting these limitations. Pet. 15–16, Ex. 1005, 5–6.

As another example, claims 6 and 7 recite that the geometric planner outputs a geometric model of the component and/or an implant position based on that model. The present record supports the contention that DiGioia I discloses that “[t]he range of motion simulator estimates femoral range of motion based upon the implant placement parameters provided by the pre-operative planner,” and that it would have been obvious to a person of skill in the art to utilize the simulator feedback to modify the position of an implant, rerun the simulation to determine optimal position, and output that position to the pre-operative planner. Pet. 16–17, Ex. 1005, 2, Ex. 1004 ¶ 38.

Additionally, with respect to claims 11 and 12, those claims recite that the system also includes at least one display monitor or at least one controller, in communication with the system. The present record supports the contention that DiGioia I discloses that “the surgeon can position cross sections of the acetabular implant upon orthogonal views of the pelvis,” and it “allows the surgeon to manually specify the position of the acetabular component within the pelvis.” Pet. 19, Ex. 1005, 2–3. We concur that this would require the use of a display monitor and a controller.

For all of the above reasons, we are persuaded, at this juncture of the proceeding, that Petitioner has established a reasonable likelihood that Petitioner would prevail in its challenge to claims 1–15 and 17 as obvious over DiGioia I.

D. Obviousness of Claim 16 over DiGioia I and DiGioia II

Petitioner contends that claim 16 is unpatentable under 35 U.S.C. § 103(a) as obvious over DiGioia I and DiGioia II. Pet. 20, 26. To support its contentions, Petitioner provides detailed explanations as to how the prior art meets each claim limitation of claim 16. *Id.* Petitioner also relies upon the Declaration of Robert D. Howe for support. Ex. 1004.

Claim 16 depends directly from claim 10 and specifies that the system further comprises a robotic device in communication with the computer system and a surgical tool connected to the robotic device.

DiGioia II discloses an approach to improved surgical techniques incorporating pre-operative planning with biomechanical analysis and computer or robot-assisted surgery. Ex. 1006, 107–108. Fig. 1 of DiGioia II illustrates a robotic arm with a surgical tool. *Id.* Petitioner relies on these disclosures, and concludes that it would have been obvious to modify the system in DiGioia I to incorporate the robotic arm with the surgical tool of DiGioia II because they describe similar systems by the same authors, addressing the same problems, in the same approximate timeframe. Pet. 20.

We have reviewed the proposed ground of obviousness over DiGioia I and DiGioia II against claim 16, and we are persuaded, at this juncture of the proceeding, that Petitioner has established a reasonable likelihood that Petitioner would prevail in its challenge to claim 16 on this ground.

E. Remaining Grounds Challenging the Claims of the '411 Patent

Pursuant to 35 U.S.C. § 316(b), the rules for *inter partes* proceedings were promulgated to take into account the “regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and

the ability of the Office to timely complete proceedings.” The promulgated rules provide that they are to “be construed to secure the just, speedy, and inexpensive resolution of every proceeding.” 37 C.F.R. § 42.1(b). As a result, and in determining whether to institute an *inter partes* review of a patent, the Board, in its discretion, may “deny some or all grounds for unpatentability for some or all of the challenged claims.” 37 C.F.R. § 42.108(b).

We exercise our discretion and decline to institute review based on any of the other asserted grounds advanced by Petitioner that are not identified below as being part of the trial. 37 C.F.R. § 42.108(a).

III. CONCLUSION

For the foregoing reasons, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1–17 of the ’411 Patent are unpatentable. At this stage of the proceeding, the Board has not made a final determination with respect to the patentability of the challenged claims.

IV. ORDER

For the foregoing reasons, it is

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted for the following grounds of unpatentability:

Claim(s)	Basis	Reference(s)
1–15 and 17	§ 103(a)	DiGioia I
16	§ 103(a)	DiGioia I and DiGoioia II

FURTHER ORDERED that no other ground of unpatentability asserted in the Petition is authorized for this *inter partes* review; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; the trial will commence on the entry date of this decision.

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