

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MAKO SURGICAL CORP.,
Petitioner,

v.

BLUE BELT TECHNOLOGIES, INC. and
CARNEGIE MELLON UNIVERSITY
Exclusive Licensee and 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*.

FINAL WRITTEN DECISION
Inter Partes Review
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

We have jurisdiction to decide this *inter partes* review under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons discussed herein, Petitioner has shown by a preponderance of the evidence that claims 1–17 of U.S. Patent No. 6,205,411 B1 (Ex. 1001, “the ’411 Patent”) are unpatentable. Additionally, Patent Owner has not shown by a preponderance of the evidence the patentability of its proposed substitute claims.

A. Procedural History

Petitioner, Mako Surgical Corporation, filed a Petition requesting an *inter partes* review of claims 1–17 of the ’411 Patent. Paper 2 (“Pet.”). No Preliminary Response was filed. Upon consideration of the Petition, on August 4, 2015, we instituted an *inter partes* review of claims 1–17, pursuant to 35 U.S.C. § 314. Paper 6 (“Dec.”).

Blue Belt Technologies, Inc., the named Patent Owner, sought authorization to file a motion to terminate because the Petition failed to name the true patent owner as a real party in interest, where the true patent owner was argued to be Carnegie Mellon University. We provided no authorization to file the motion to terminate because we found no requirement for Petitioner to name a patent owner’s real parties-in-interest. Paper 13, 2. We further determined that that the filing of mandatory notice (Paper 5), indicating that Blue Belt Technologies, Inc. is the exclusive licensee of the ’411 Patent and that Carnegie Mellon University is the owner of that patent, was sufficient to clarify the record in this proceeding. Paper 13, 2–3. We determined that Carnegie Mellon University was named as the

patent owner in this proceeding and is a party to the proceeding such that it would be bound by any judgment adverse to Blue Belt Technologies, Inc. *Id.* at 4. Therefore, herein, we collectively refer to the Patent Owner and the Exclusive Licensee as “Patent Owner.”

After institution, Blue Belt Technologies, Inc., filed a Patent Owner Response (“PO Resp.”), indicating that it was being filed on behalf of the party named as Patent Owner. Paper 11. Petitioner filed a Reply to the Patent Owner Response. Paper 23 (“Reply”). Patent Owner also filed a contingent Motion to Amend (Paper 12, “Mot.”), to which Petitioner filed an Opposition to Patent Owner’s Motion to Amend (Paper 25, “Opp. Mot.”), and Patent Owner filed a Reply to Petitioner’s Opposition (Paper 30, “Reply Mot.”). An oral hearing was held on April 7, 2016, with the transcript of the hearing included in the record. Paper 41 (“Tr.”).

Patent Owner filed a Motion to Exclude (Paper 33; “PO Mot. to Exclude”) certain portions of Exhibit 2006. Petitioner filed an Opposition to the Motion to Exclude (Paper 34; “Pet. Exclude Opp.”), and Patent Owner filed a Reply (Paper 38; “PO Exclude Reply”).

B. Related Proceedings

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.

C. 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 optimal 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, which is used to create geometric models of the joint and the components to be implanted based on geometric data received from skeletal structure data source 13. The geometric pre-operative planner 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.

D. 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.

E. Grounds of Unpatentability

We instituted an *inter partes* review of claims 1–17 on the following grounds (Dec. 11):

Claim(s)	Basis	Reference(s)
1–15 and 17	§ 103(a)	DiGioia I ¹
16	§ 103(a)	DiGioia I and DiGoioia II ²

II. ANALYSIS

A. 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

¹ 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”).

² 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 106–111 (1995) (Ex. 1006) (“DiGioia II”).

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 In re Translogic, Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). 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).

B. Claim Interpretation

In an *inter partes* review, we construe claim terms in an unexpired patent according to 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*, 793 F.3d 1268, 1277–78 (Fed. Cir. 2015) (“We conclude that Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA.”), *aff’d sub nom. Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Consistent with the broadest reasonable interpretation, claim terms are presumed to have their ordinary and customary meaning as understood by a person of ordinary skill in the art in the context of the entire patent disclosure. *Translogic*, 504 F.3d at 1257. Also, we must be careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) (“[L]imitations are not to be read into the claims from the specification.”). However, an inventor may

provide a meaning for a term that is different from its ordinary meaning by defining the term in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposed no specific constructions for any claim terms. Therefore, for the purposes of the institution decision, we determined 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).

Neither Patent Owner nor Petitioner asserts any specific claim constructions in their responsive papers. *See* PO Resp.; Reply. As such, no terms in this proceeding will receive express interpretation.

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.

i. DiGioia I, Petitioner's Contentions

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.

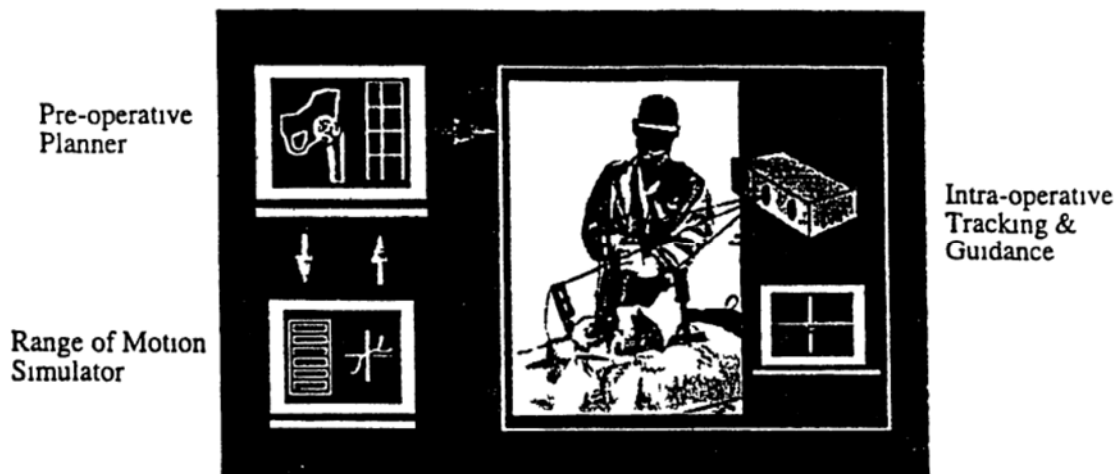


Figure 3 HipNav system overview

Fig. 3 of DiGioia I provides a 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, but are minor, obvious variations. 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).

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).

Petitioner also asserts that dependent claims 2–9 and 11–15 are also obvious over DiGioia I. Pet. 15–20. Claims 2 and 15 recite that the system also includes an intra-operative navigational module in communication with the pre-operative kinematic biomechanical simulator. Petitioner urges 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.

Additionally, 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. Petitioner urges 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 (quoting Ex. 1005, 2); Ex. 1004 ¶ 38.

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. Petitioner urges 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 (quoting Ex. 1005, 2–3).

ii. Patent Owner’s Contentions

a) Prior Art Status of DiGioia I

Patent Owner argues that DiGioia I is not prior art to the ’411 claims under 35 U.S.C. § 102(a). PO Resp. 18–27. First, Patent Owner contends that DiGioia I is not a publication “by others,” despite differences in named authorship and inventorship. *Id.* at 19–27 (citing *In re Katz*, 687 F.2d 450, 455 (Fed. Cir. 1982)). Relying on testimony of Dr. Branislav Jaramaz (Ex. 2002), listed both as an inventor on the ’411 Patent and as an author on DiGioia I, Patent Owner argues that the authorship of DiGioia I listed “everyone who had been recently involved in the day-to-day operations developing the HipNav system,” but the contributions of the authors not listed as inventors are not reflected in claims 1–17 of the ’411 Patent. *Id.* at 19–20 (citing Ex. 2002 ¶¶ 11, 13–17). Additionally, Patent Owner argues that there is an inventor not listed as an author because “by the time DiGioia I was published, Dr. Kanade had assumed an advisory role,” but that his original contributions supported the claims of the instant patent. *Id.* at 20–21 (citing Ex. 2002 ¶ 15; Ex. 2006, 52:10–53:19, 86:7–10).

In response, Petitioner contends that Dr. Jaramaz's declaration lacks foundation and is not reliable. Reply 11–17. Petitioner points out that Dr. Jaramaz does not know who decided to omit Dr. Kanade as an author of DiGioia I and “in describing Mr. Kischell's role in the article, Dr. Jaramaz was simply providing his opinion about what might have happened, rather than what did in fact happen.” *Id.* at 11–13 (citing Ex. 1011, 25:14–26:5, 26:6–29:18, 27:14–18, 47:9–19). Petitioner also provides a declaration of Mr. Kischell (Ex. 1013) and argues that the testimony evidences that Mr. Kischell's contributions were important to the project's success and were not insubstantial. *Id.* at 13–14. As such, Petitioner contends that the inventive entities are different, such that DiGioia I is prior art to the '411 claims under 35 U.S.C. § 102(a).

We must review the totality of circumstances in determining if a sufficient showing has been made that DiGioia I is not the work of the inventors of the '411 Patent. *See Katz*, 687 F.2d at 455–56. Although we acknowledge the points raised by Dr. Jaramaz, we are persuaded that his testimony provides more opinion than facts. The testimony of Mr. Kischell makes clear that he provided substantial and important portions to the overall disclosure of DiGioia I. However, it is not our role to determine whether Mr. Kischell should have been named as an inventor of the invention claimed in the '411 Patent; we assume that the inventorship listed on the '411 Patent is correct. As such, we are not persuaded that the inventive entity of the '411 Patent is the same as the authorship of DiGioia I, or that DiGioia I represents only the work of the inventors of the '411 Patent. Accordingly, we determine that DiGioia I qualifies as prior art under

35 U.S.C. § 102(a). In any event, we also consider whether DiGioia I is prior art under 35 U.S.C. § 102(b) as Petitioner asserts.

Patent Owner argues that the claims of the '411 Patent are entitled to the benefit of the filing date of U.S. Patent No. 5,880,976 (“the '976 Patent”), thus negating the application of DiGioia I under 35 U.S.C. § 102(b). PO Resp. 21–22. Patent Owner continues that the filing date of the '976 Patent was February 21, 1997, and the first public disclosure of DiGioia I was February 22, 1996, where the application that matured into the '411 Patent was a continuation-in-part of the application that matured into the '976 Patent. *Id.* Patent Owner also argues that to support the instant claims, there is no need of a verbatim list of joints, such as those found in the preambles of the independent claims, and that the joint disclosed in the '976 Patent is “representative of a class of surgeries.” *Id.* at 22–25 (citing Ex. 2003 ¶¶ 32–38). Petitioner contends that there is no support for other joints in '976 disclosure and that a general disclosure of a genus cannot provide written description support for the species. Reply 4–8. We agree with Petitioner that Patent Owner is not entitled to the benefit of the '976 Patent because the '976 Patent does not provide written description support for the claimed subject matter in the '411 Patent.

“To satisfy the written description requirement, the applicant must 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, and demonstrate that by disclosure in the specification of the patent.” *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011) (internal quotations and citations omitted). Additionally, the disclosure of a broad genus does not necessarily provide written description support for a

particular subgenus or species claimed. *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1344 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 1501 (2014).

In the instant case, we agree with Petitioner that the disclosure of the '976 Patent does not explicitly recite the myriad of joints recited in the claims of the '411 Patent, which are only found in the disclosure of the '411 Patent; Patent Owner does not argue otherwise. PO Resp. 22–23; Reply 5. Even if the total hip replacement surgery, disclosed in the '976 Patent, is representative of a class of surgeries, that would not necessarily provide written description support for specific surgeries in that class. Even assuming “one of ordinary skill in the art would have been able to apply the techniques described in the '976 Patent to surgeries involving a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, or a foot and ankle joint without undue experimentation” (PO Resp. 25 (citing Ex. 2004 ¶ 37)), such an observation goes to the obviousness of those other surgeries and not their disclosures.

In any event, even considering the arguments on the merits and that Petitioner has the burden of persuasion, Patent Owner has not provided sufficient evidence that the hip replacement surgery is representative as to the claimed joints that are claimed in the '411 patent. Dr. Cleary's testimony is conclusory because he does not explain sufficiently why all of the joints being claimed in the '411 patent would have been predictable from the example of hip surgery disclosed in the '976 Patent. Even Dr. Cleary recognizes that each joint has a different geometry. Ex. 2003 ¶ 27. Based on the record presented, we do not give substantial weight to Dr. Cleary's testimony that one of ordinary skill in the art would have recognized that

Patent Owner had possession of the genus claimed in the '411 patent from the species of the hip joint described in the '976 Patent.

Patent Owner also alleges that the Examiner disagreed with the proposition that there was no support for new claims in the continuation. PO Resp. 26–27. Patent Owner points to the Examiner's language in the April 5, 2000, Office Action stating that “[a]n 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,” as recited in claim 1 of the '411 Patent, was “fully disclosed in patent no[.] 5,880,976.” PO Resp. 26 (quoting Ex. 1002, 265). However, as Petitioner points out, the presence of the obviousness-type double patenting rejection does not demonstrate support for the recited joints. Nothing in this rejection shows that the specific joints claimed were adequately disclosed in the earlier specification for written description purposes. As such, we remain persuaded that DiGioia I is prior art to the '411 Patent claims under 35 U.S.C. § 102(a) or (b).

b) Obviousness of claims 1-15 and 17 over DiGioia I

Patent Owner also argues that Petitioner has not demonstrated that DiGioia I, or DiGioia I in view of DiGioia II, renders claims 1–17 obvious. PO Resp. 28. Patent Owner argues that DiGioia I does not disclose outputting a position for implantation, as provided in claims 1 and 10, because no rationale underpinning is provided by Petitioner. *Id.* at 28–31. Patent Owner continues that the first part of Petitioner's rationale to modify DiGioia I is conclusory, and Petitioner does not provide any reason why such a modification, i.e., to utilize feedback to re-run the simulation and output that position, would have been obvious. *Id.* at 29–30. Additionally,

Patent Owner argues that the second part of Petitioner's rationale to modify DiGioia I, based on the arrows illustrated in Fig. 3 of DiGioia I, is faulty because the arrows signify participation by the surgeon, and not bidirectional communication independent of the surgeon. *Id.* at 29–33.

In responding to Patent Owner, Petitioner points to portions of the Petition where DiGioia I discloses that “feedback from the simulator can aid the surgeon in determining optimal implant placement.” Reply 17 (citing Pet. 14–15; Ex. 1005, 2). We agree with Petitioner that portions of DiGioia I suggest this feedback process, as well as the system allowing for the system to “accurately place the implant in the predetermined optimal position.” Ex. 1005, 2. Although DiGioia I does not explicitly detail re-running the simulation, we are persuaded that such a repetition would have been understood as an obvious part of optimizing the placement.

Petitioner also notes that a modification can be made in a semiautonomous system that allows for surgeon input, i.e., that the output of a position for implantation does not negate surgeon involvement in placement. Reply 19–20. We agree that Petitioner's modification of DiGioia I does not require the formation of an autonomous system, without surgeon control. The independent claims merely require the outputting of a position for implantation, not a singular position that disallows surgical input.

With respect to the interpretation of DiGioia I's Fig. 3, Petitioner notes that Patent Owner's own declarants acknowledged that the units disclosed in DiGioia I pass information back and forth. *Id.* at 18–19 (citing Ex. 1010, 31:6–32:7; Ex. 1011 at 37:10–24, 41:1–4.). As well, Petitioner points to testimony of Dr. Jaramaz that, without his personal knowledge of

the system of DiGioia I, a person reading the article would not believe that the communication between the pre-operative planner and the range of motion simulator was narrowly limited. Reply 19 (citing Ex. 1011, 43:24–44:17). We agree and we are persuaded that one of ordinary skill in the art would have interpreted Fig. 3 as Petitioner suggests. See Pet. 15.

Additionally, although Patent Owner argues that Fig. 3 need not connote bidirectional communication independent of the surgeon, such specificity is not necessary. Claim 10, for example, merely details that the simulator is “in communication with” the planner, and any independence from the surgeon, as discussed above, is a matter of supposition by Patent Owner.

Patent Owner also argues that Petitioner’s declarant contradicts himself such that he professes that computers are superior to humans in processing quantitative data, but has also explained that a strength of humans is that they exercise good judgment and a weakness of computers is that they have poor judgment. PO Resp. 33–34 (citing Ex. 2006, 66:9–13; Ex. 2001, 212–213). We do not agree. Rather, we agree with Petitioner that the article (Ex. 2001) authored by Petitioner’s declarant, Dr. Howe, also addresses semiautonomous capabilities and is not necessarily contradictory of Dr. Howe’s declaration. Reply 21 (citing Ex. 2006 at 66:14–72:4).

Patent Owner also argues that Petitioner has failed to provide evidence that one of ordinary skill in the art would have had a reasonable expectation that the system of DiGioia I could be modified to utilize feedback to determine and output an optimal position. PO Resp. 34–35. To that point, Patent Owner notes that DiGioia I provides no algorithm or mathematical formula that would allow one of ordinary skill in the art to relate the 3-D implant location to the estimated femoral range of motion. *Id.*

However, we are not persuaded that Petitioner need provide an algorithm or mathematical formula to show obviousness. As discussed above, we are persuaded that Petitioner has sufficiently demonstrated how the system of DiGioia I could be modified to supply the claimed position for implantation.

Patent Owner also argues that DiGioia I's pre-operative planner doesn't necessarily output the geometric model and that there are other ways of receiving that model. *Id.* at 35–37 (citing Ex. 2003 ¶¶ 50–51). Petitioner asserts that Patent Owner's characterization amounts to an obvious variation, and does not distinguish the claims from the disclosure of DiGioia I. Reply 23. We agree with Petitioner that Patent Owner has acknowledged that the geometric model was an input to both the preoperative planner and the range of motion simulator (PO Resp. 36 (citing Ex. 2002 ¶ 10)), such that receiving the at least one geometric model of the joint from the pre-operative geometric planner would have been an obvious variation.

Patent Owner also argues that Petitioner has provided no teaching or suggestion that a person of ordinary skill in the art would have sought to use a 3D model, per claim 17, instead of 2D cross sections, as disclosed in DiGioia I. PO Resp. 37–38. Petitioner responds that the three orthogonal views, provided in DiGioia I, would have been understood to represent a 3D model. Reply 23–25. We agree with Petitioner that a 3D model can be represented by two-dimensional views of that model, and that one of ordinary skill in the art viewing Fig. 4 of DiGioia I would have interpreted the positioning of the implant across three orthogonal views of the pelvis as representing a three dimensional model.

For all of the above reasons, and based on the record before us, Petitioner has shown sufficiently, by a preponderance of the evidence, that DiGioia I renders the subject matter of claims 1–15 and 17 obvious.

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. Patent Owner disputes this ground on the same basis as Patent Owner disputes the ground over DiGioia I above.

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.

Patent Owner does not separately contest this ground against claim 16, relying on the arguments discussed above with respect to the first obviousness ground. As we do not find those arguments persuasive, we are persuaded that one of ordinary skill in the art would have combined

DiGioia I and DiGioia II as described with respect to 16, and we determine that Petitioner has shown, by a preponderance of the evidence, that claim 16 is obvious over DiGioia I and DiGioia II.

E. Patent Owner's Motion to Exclude

Patent Owner moves to exclude certain portions of Dr. Howe's redirect testimony (Exhibit 2006), alleging that this redirect testimony seeks to introduce concepts that could have been in the Petition or his original declaration. PO Mot. to Exclude, 1. Although not specified by page and line numbers in the Motion, we presume that Patent Owner seeks to exclude the specific questions asked on redirect and the answers to those questions (Ex. 2006, 86:21–91:3). *Id.* at 4.

In rendering the Final Written Decision, we do not rely on those portions of Howe's testimony that Patent Owner seeks to exclude. Accordingly, we *dismiss* Patent Owner's Motion to Exclude as moot.

III. MOTION TO AMEND

Patent Owner requests, should we find claims 1–17 to be unpatentable, cancellation of claims 1–17, and entry of substitute claims 18–34. Mot. 1–17 (citing, e.g., Exs. 1001, 2002, 2003, 2004, 2007, 2008). Petitioner opposes the request (Opp. Mot. 1–24), and Patent Owner replies (Reply Mot. 1–11).

A. Procedural Burdens

Patent Owner has the burden of proving patentability of a proposed substitute claim. *See Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1334 (Fed. Cir. 2015) (“the Board permissibly interpreted [37 C.F.R. § 42.20(c)] as imposing the burden of proving patentability of a proposed substitute claim

on the movant: the patent owner.”). Accordingly, at a minimum, Patent Owner has the burden of showing that (1) the substitute claims overcome all the grounds under which independent claims 1–17 were determined to be unpatentable, namely, 35 U.S.C. § 103 and (2) its request meets all the procedural requirements concerning motions to amend set forth, for example, in our rules, *Idle Free Systems, Inc. v Bergstrom, Inc.*, Case IPR2012-00027 (PTAB June 11, 2013) (Paper 26) (informative), and *MasterImage 3D, Inc. v. RealD Inc.*, Case IPR2015-00040 (PTAB July 15, 2015) (Paper 42) (precedential).

B. Nature of Substitute Claims

Patent Owner asserts substitute claims 18–34 in its Motion to Amend, with substitute claims 18, 27, and 34 being independent, and the other substitute claims being dependent on those claims. Mot. 18–23, Claim App’x. Claim 18 is considered representative of the substitute claims and is reproduced below:

18. (proposed substitute for claim 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, executing within a computer system, to:
generate a three dimensional geometric model of the hip joint based on skeletal geometric data; and
generate a three dimensional component model of the artificial implant; and
a pre-operative kinematic biomechanical simulator in communication with said pre-operative geometric planner and executing on the computer system to:
simulate movement of the hip joint with the artificial component in a test position using the geometric model of the hip joint and the component model;

calculate a range of motion of the artificial component and the hip joint for the test position based on the simulated movement; and

determine a position for implantation for the artificial component based at least in part on the calculated range of motion;

wherein said pre-operative geometric planner outputs at least one geometric model of the joint and the pre-operative kinematic biomechanical simulator outputs [[a]] the position for implantation of the artificial component in reference to the geometric model of the hip joint.

Id.

The changes to independent claim 10, namely substitute claim 27, are similar to the changes discussed above for claim 1. *Id.* Patent Owner's substitute claim 34, intended to replace claim 17, removes most of the enumerated joints listed in the preamble, leaving claim 34 directed to "implantation of an artificial implant in a hip joint." *Id.* Substitute claims 19–26 and 28–33 recite the same subject matter as the original claims, namely claims 2–9 and 11–16, which they seek to replace.

Patent Owner characterizes the substitute claims as being "clearly supported by the '976 Patent," that the amendments further limit the "pre-operative geometric planner" and the "'pre-operative biomechanical simulator' relative to the recitation of those elements in corresponding original independent claims 1 and 10, respectively," and that the substitute claims are further distinguished from the art of record. Mot. 2–3. Patent Owner also points to the original Specifications of the '976 and '411 Patents as fully supporting the substitute claims. *Id.* at 3–5.

Petitioner does not assert that the substitute claims fail to meet the procedural requirements concerning motions to amend set forth in the above

cited cases. *See* Opp. Mot. Rather, Petitioner asserts that DiGioia I is still prior art against the substitute claims under 35 U.S.C. § 102(a) and that Patent Owner has not established that the substitute claims are patentable over DiGioia I, DiGioia II, and other prior art of record. Mot. 2–23.

*C. Whether Substitute Claims are Patentable
Under 35 U.S.C. § 103(a)*

According to Patent Owner, the proposed substitute claims are patentable over the known prior art. *See id.* at 6–16. In particular, Patent Owner contends DiGioia I cannot serve as a basis for obviousness under 35 U.S.C. § 103(a) because it does not qualify as prior art under at least one subsection of 35 U.S.C. § 102. *Id.* at 7. The arguments raised with respect to the substitute claims are similar to those made against the subject claims of this proceeding. *Compare* Mot. 7–11, with PO Resp. 18–27. We have addressed those arguments above in Section II.C.ii.a, and we find them to be lacking for the same reasons, as discussed below.

With respect to the excising of other joints except for the hip joint from the preambles of the substitute claims, we agree that the claims may be entitled to the filing date of the '976 Patent, such that DiGioia I cannot be applied against the substitute claims under 35 U.S.C. § 102(b). However, our analysis of the inventorship of the instant '411 Patent and the authorship of DiGioia I remains unchanged, and we continue to find DiGioia I applicable against the substitute claims under 35 U.S.C. § 102(a).

Patent Owner also contends that the substitute claims are patentable over the art of record. Mot. 12–16. Patent Owner identifies the most

relevant prior art references of the references cited by Petitioner as Taylor³ and DiGioia II, and cites to Dr. Cleary that the substitute claims are patentable over those cited prior art references. *Id.* at 14–16 (citing Ex. 2003 ¶¶ 53–54, 56–59). Patent Owner argues that specific elements of independent, substitute claims 18, 27, and 34 are not taught by Taylor and DiGioia II, and the same references do not render substitute claims 18–34 obvious. *Id.*

In opposing Patent Owner’s Motion, Petitioner contends that Patent Owner has not established that the substitute claims would have been patentable over the prior art of record. Opp. Mot. 9–24. Petitioner argues that Patent Owner fails to distinguish the substitute claims from Chao⁴ and O’Toole⁵, which were cited in the Petition. *Id.* at 10–17. Petitioner also provides claim charts with respect to the proposed substitute claims, arguing that those claims are obvious over the proffered combination of DiGioia II, O’Toole, and Chao. *Id.* at 18–24.

With respect to DiGioia II, O’Toole, and Chao, Petitioner argues that a person of ordinary skill would have been motivated to combine DiGioia II with O’Toole, as O’Toole also describes a system for planning a hip

³ Taylor, et al., “An Image-Directed Robotic System for Precise Orthopaedic Surgery,” 10(3) IEEE TRANSACTIONS ON ROBOTICS AND AUTOMATION 261–275 (June 1994) (Ex. 1009) (“Taylor”).

⁴ E.Y.S. Chao et al., “Simulation and Animation of Musculoskeletal Joint System,” 115 TRANSACTIONS OF THE ASME 562–568 (Nov. 1993) (Ex. 1007) (“Chao”).

⁵ R.V. O’Toole et al., “Towards More Capable and Less Invasive Robotic Surgery in Orthopaedics,” 905 COMPUTER VISION, VIRTUAL REALITY AND ROBOTICS IN MEDICINE LECTURE NOTES IN COMPUTER SCIENCE 123–130 (1995) (Ex. 1008) (“O’Toole”).

surgery involving a femoral implant and a femur, and to combine DiGioia II with Chao, because Chao addresses the same subject matter, the simulation and animation of joints, and a desire to allow a user to simulate joint pressure distribution in order to improve joint replacement, including hip replacements. *Id.* at 11–13.

Petitioner also argues that newly added limitation “a pre-operative kinematic biomechanical simulator . . . executing on the computer system” is taught by DiGioia II and Chao. *Id.* at 13. Petitioner also argues that with respect to the “simulate movement of the hip joint with the artificial component” limitation and equivalents in the independent substitute claims, DiGioia II teaches these limitations. *Id.* at 14–16. Substitute claims 18 and 27 also include the limitation of “calculate a range of motion of the artificial component and the hip joint for the test position based on the simulated movement,” with an equivalent limitation in substitute claim 34, and Petitioner argues that Chao specifically addresses simulation and animation of joints. *Id.* at 16–17.

After review of Petitioner’s contentions and claim charts, we are persuaded that the substitute claims would have been obvious over a combination of DiGioia II, O’Toole, and Chao. Although Patent Owner has the burden of proving the patentability of the proposed substitute claims, the efficacy of Petitioner’s new obviousness ground can effectively demonstrate the failure of Patent Owner in meeting that burden. We address Patent Owner’s specific arguments against obviousness below.

Patent Owner argues that the statement in DiGioia II that the researchers were “working toward developing of an automatized procedure that will include biomechanical simulation as a component of a

preoperative surgical planner” means that the “simulate movement” limitations are not disclosed by DiGioia II. Mot. 16; Ex. 1006 at 110. However, as Petitioner responds, further development to make the system more autonomous is not necessary to satisfy the subject limitation of the claims. Additionally, a reference is prior art for all that it teaches and not simply for the invention it is trying to protect. *EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985). As such, DiGioia II may reasonably suggest to one of ordinary skill in the art the benefits of the automatized procedure, even if not fully realized. Thus, we do not find Patent Owner’s argument to be persuasive.

In addition, Patent Owner argues that Petitioner’s arguments, in its opposition to the Motion to Amend, do not account for the 3D geometric model and the 3D component model of artificial implant recited in the substitute claims. Reply Mot. 5–10. More specifically, with respect to the simulating limitations of the substitute claims, Patent Owner argues that DiGioia II cannot disclose these limitations because the authors had not yet developed the requisite “three dimensional models” of the hip joint or the acetabular cup and, thus, could not have simulated movement of the hip joint with the artificial component in a test position “using the geometric model of the hip joint.” *Id.* at 6–7. Patent Owner also argues that Petitioner’s reliance on DiGioia II’s axisymmetric model is faulty because substitute claims 18, 27, and 34 require the “three dimensional geometric model of the hip joint” to be generated based on “skeletal data,” not on ideal, symmetric characteristics of a hip joint. *Id.* at 7–8.

In addition, with respect to the calculating and determining limitations of the substitute claims, Patent Owner argues that the portion of

Chao cited in Petitioner's Opposition (Opp. Mot. 16 (citing Ex. 1007, 5)) only relates to simulation of joint pressure and motion and does not teach one of ordinary skill in the art how to calculate "a range of motion" based on simulation using a "three dimensional geometric model of the hip joint" and a "three dimensional component model of the artificial implant." We do not agree.

We consider the combination of DiGioia II, O'Toole, and Chao in determining the obviousness of the substitute claims, and not the references individually. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413 (CCPA 1981). O'Toole provides for both modeling and simulation based on 3D surface geometries. See Ex. 1008, 2–4. O'Toole considers geometric and physical model creation and suggests that multiple levels of complexity or realism are possible, with the addition of computed tomography (CT) or magnetic resonance imaging (MRI) data, and the use of idealized or full 3D geometry. *Id.* at 3–4.

Taking O'Toole, along with DiGioia II and Chao, we are persuaded that one of ordinary skill in the art would have determined a range of motion ("to simulate the mechanical consequences of a proposed surgery," Ex. 1008, 1), based on 3D models, as recited in the substitute claims. Thus, we do not find Patent Owner's argument to be persuasive.

In view of the foregoing, Patent Owner has not met its burden of showing substitute claims 18–34 to be patentable over the prior art of record, specifically the combination of DiGioia II, O'Toole, and Chao.

IV. CONCLUSION

For the foregoing reasons, we determine the following:

- a. Petitioner has shown by a preponderance of the evidence that claims 1–17 of the '411 Patent are unpatentable over DiGioia I or the combination of DiGioia I and DiGioia II; and
- b. Patent Owner has not shown that its proposed substitute claims 18–34 are patentable over the prior art.

V. ORDER

In consideration of the foregoing, it is
ORDERED that claims 1–17 of the '411 Patent are held unpatentable;
FURTHER ORDERED that Patent Owner's Motion to Amend is
denied;

FURTHER ORDERED that the Patent Owner's motion to exclude
evidence is *dismissed*; and

FURTHER ORDERED that, because this is a Final Written Decision,
parties to the proceeding seeking judicial review of the decision must
comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2015-00630
Patent 6,205,411 B1

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