Patent Owner and Exclusive Licensee's Demonstrative Slides

IPR2015-00630 and IPR2015-00629

U.S. Patent Nos. 6,205,411 and 6,757,582

Patent Trial and Appeal Board
April 7, 2016

Blue Belt Technologies, Inc. and Carnegie Mellon University
Exhibit 2012
Blue Belt Technologies Inc. and Carnegie Mellon University v. Mako Surgical Corp.
IPR2015-00630

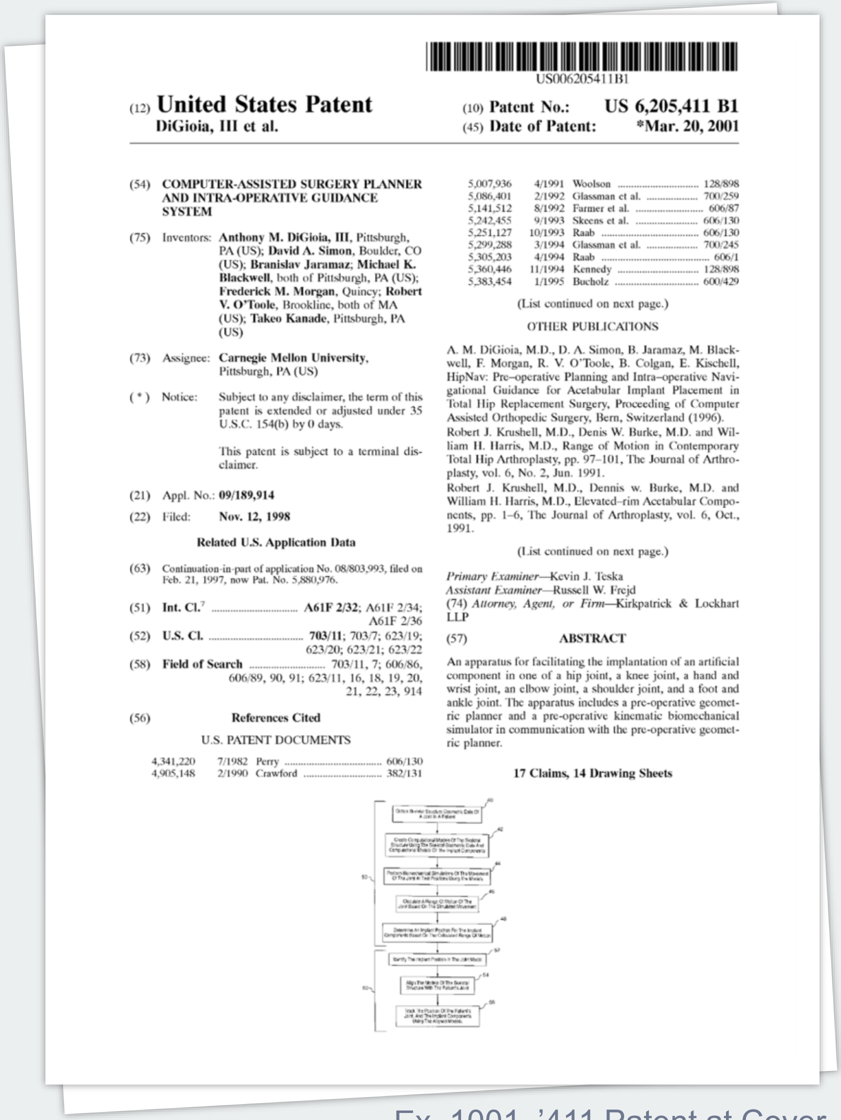
Order of Presentation – ’411 Patent

- **Introduction**

- **Topics in Dispute**

1. **DiGioia Is Not Prior Art**
2. **DiGioia Does Not Render Claims 1-15 and 17 Obvious and DiGioia in View of DiGioia II Does Not Render Claim 16 Obvious**
3. **Motion to Amend**
4. **Motion to Exclude**

Introduction – ’411 Patent



US006205411B1

(12) **United States Patent**
DiGioia, III et al.

(10) **Patent No.:** **US 6,205,411 B1**
(45) **Date of Patent:** ***Mar. 20, 2001**

(54) **COMPUTER-ASSISTED SURGERY PLANNER AND INTRA-OPERATIVE GUIDANCE SYSTEM**

(75) Inventors: **Anthony M. DiGioia, III**, Pittsburgh, PA (US); **David A. Simon**, Boulder, CO (US); **Branislav Jaramaz**; **Michael K. Blackwell**, both of Pittsburgh, PA (US); **Frederick M. Morgan**, Quincy; **Robert V. O’Toole**, Brookline, both of MA (US); **Takeo Kanade**, Pittsburgh, PA (US)

(73) Assignee: **Carnegie Mellon University**, Pittsburgh, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/189,914**

(22) Filed: **Nov. 12, 1998**

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/803,993, filed on Feb. 21, 1997, now Pat. No. 5,880,976.

(51) **Int. Cl.**^{7} **A61F 2/32**; A61F 2/34; A61F 2/36

(52) **U.S. Cl.** **703/11**; 703/7; 623/19; 623/20; 623/21; 623/22

(58) **Field of Search** 703/11, 7; 606/86, 606/89, 90, 91; 623/11, 16, 18, 19, 20, 21, 22, 23, 914

(56) **References Cited**

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5,007,936	4/1991	Woolson	128/898
5,086,401	2/1992	Glassman et al.	700/259
5,141,512	8/1992	Farmer et al.	606/87
5,242,455	9/1993	Skeens et al.	606/130
5,251,127	10/1993	Raab	606/130
5,299,288	3/1994	Glassman et al.	700/245
5,305,203	4/1994	Raab	606/1
5,360,446	11/1994	Kennedy	128/898
5,383,454	1/1995	Bucholz	600/429

(List continued on next page.)

OTHER PUBLICATIONS

A. M. DiGioia, M.D., D. A. Simon, B. Jaramaz, M. Blackwell, F. Morgan, R. V. O’Toole, B. Colgan, E. Kischell, HipNav: Pre–operative Planning and Intra–operative Navigational Guidance for Acetabular Implant Placement in Total Hip Replacement Surgery, Proceeding of Computer Assisted Orthopedic Surgery, Bern, Switzerland (1996).

Robert J. Krushell, M.D., Denis W. Burke, M.D. and William H. Harris, M.D., Range of Motion in Contemporary Total Hip Arthroplasty, pp. 97–101, The Journal of Arthroplasty, vol. 6, No. 2, Jun. 1991.

Robert J. Krushell, M.D., Dennis w. Burke, M.D. and William H. Harris, M.D., Elevated–rim Acetabular Components, pp. 1–6, The Journal of Arthroplasty, vol. 6, Oct., 1991.

(List continued on next page.)

Primary Examiner—Kevin J. Teska
Assistant Examiner—Russell W. Frejd
(74) *Attorney, Agent, or Firm*—Kirkpatrick & Lockhart LLP

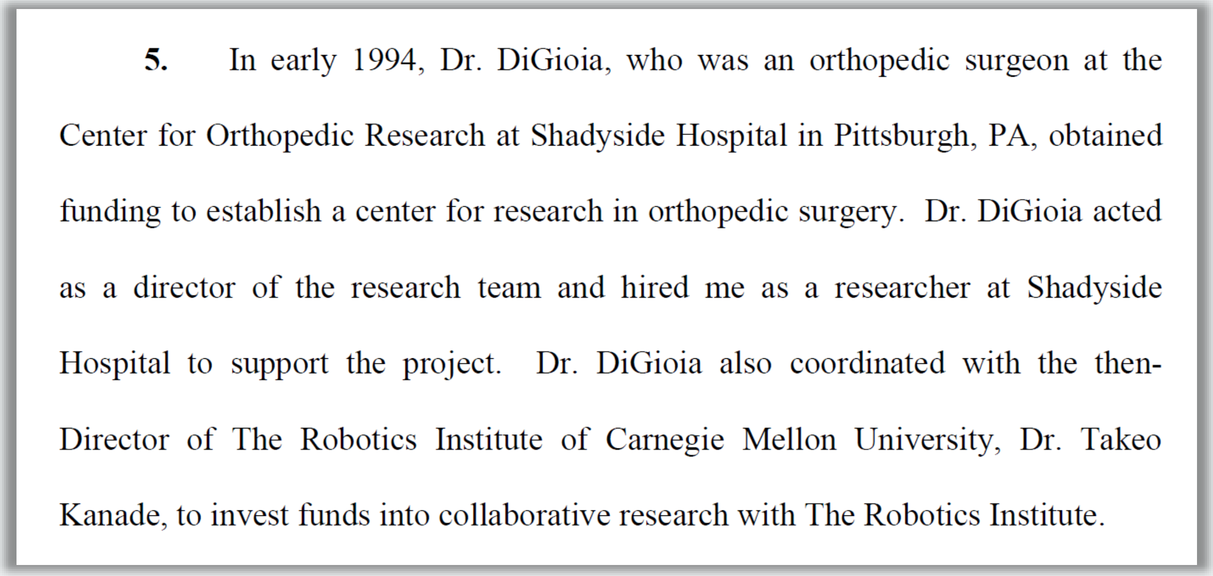
(57) **ABSTRACT**

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. The apparatus includes a pre-operative geometric planner and a pre-operative kinematic biomechanical simulator in communication with the pre-operative geometric planner.

17 Claims, 14 Drawing Sheets

Ex. 1001, ’411 Patent at Cover

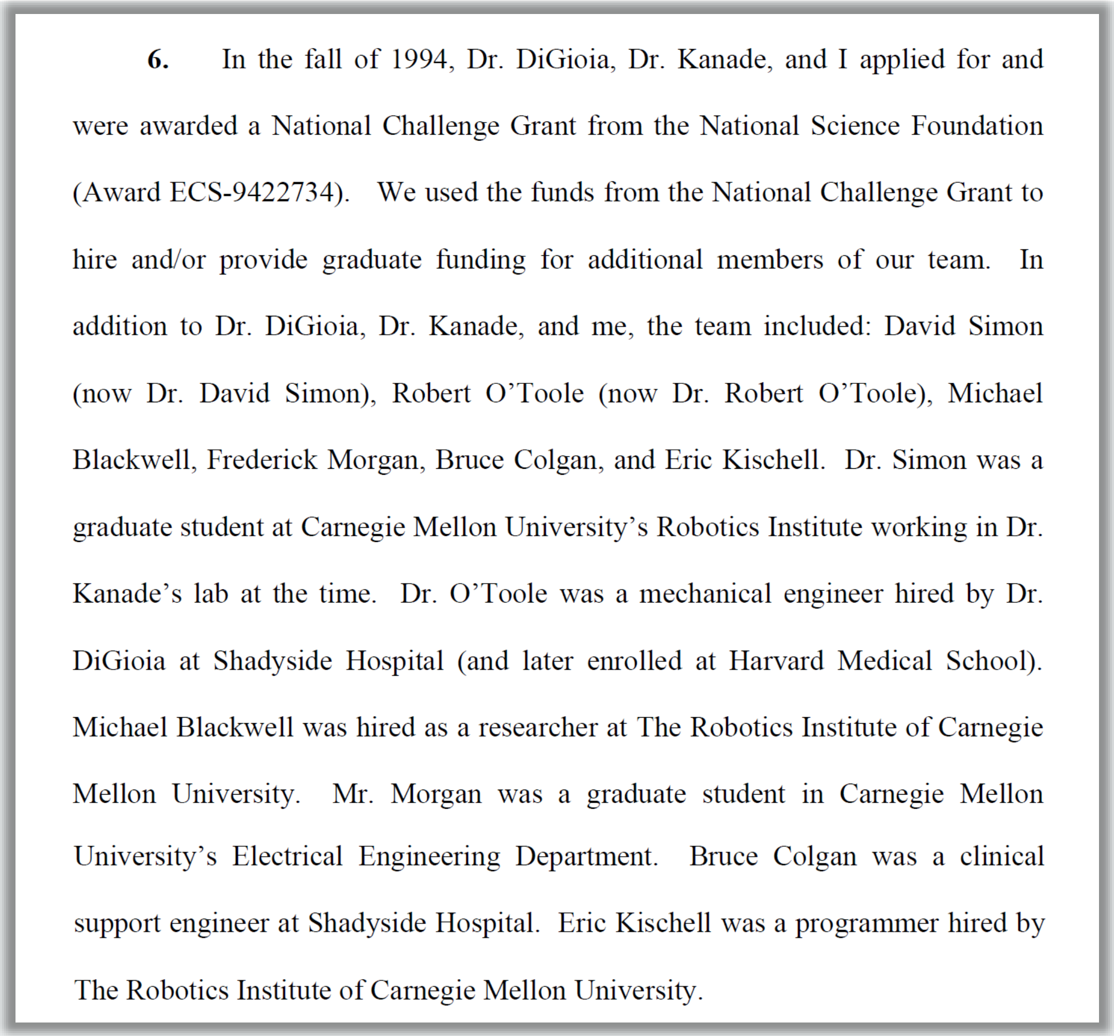
Introduction – Shadyside and CMU Joint Research



5. In early 1994, Dr. DiGioia, who was an orthopedic surgeon at the Center for Orthopedic Research at Shadyside Hospital in Pittsburgh, PA, obtained funding to establish a center for research in orthopedic surgery. Dr. DiGioia acted as a director of the research team and hired me as a researcher at Shadyside Hospital to support the project. Dr. DiGioia also coordinated with the then-Director of The Robotics Institute of Carnegie Mellon University, Dr. Takeo Kanade, to invest funds into collaborative research with The Robotics Institute.

Ex. 2002, Jaramaz Decl. at ¶ 5
Paper No. 11, Patent Owner Response at 6

Introduction – Shadyside and CMU Joint Research



6. In the fall of 1994, Dr. DiGioia, Dr. Kanade, and I applied for and were awarded a National Challenge Grant from the National Science Foundation (Award ECS-9422734). We used the funds from the National Challenge Grant to hire and/or provide graduate funding for additional members of our team. In addition to Dr. DiGioia, Dr. Kanade, and me, the team included: David Simon (now Dr. David Simon), Robert O'Toole (now Dr. Robert O'Toole), Michael Blackwell, Frederick Morgan, Bruce Colgan, and Eric Kischell. Dr. Simon was a graduate student at Carnegie Mellon University's Robotics Institute working in Dr. Kanade's lab at the time. Dr. O'Toole was a mechanical engineer hired by Dr. DiGioia at Shadyside Hospital (and later enrolled at Harvard Medical School). Michael Blackwell was hired as a researcher at The Robotics Institute of Carnegie Mellon University. Mr. Morgan was a graduate student in Carnegie Mellon University's Electrical Engineering Department. Bruce Colgan was a clinical support engineer at Shadyside Hospital. Eric Kischell was a programmer hired by The Robotics Institute of Carnegie Mellon University.

Ex. 2002, Jaramaz Decl. at ¶ 6
Paper No. 11, Patent Owner Response at 6

Order of Presentation – ’411 Patent

- Introduction

- Topics in Dispute

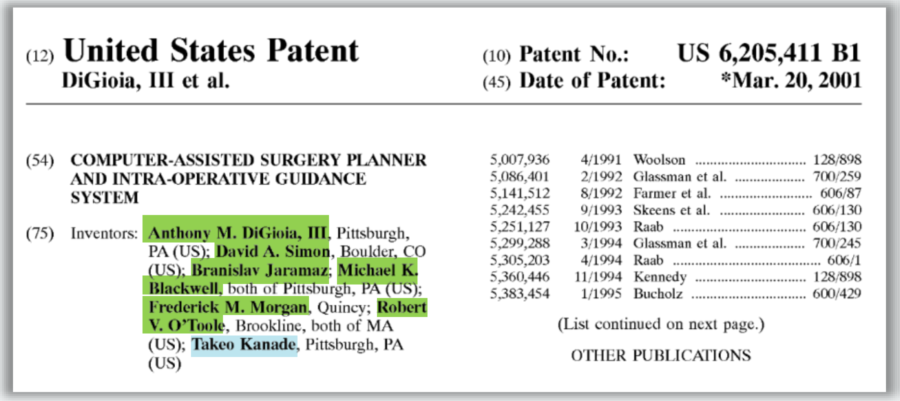
1. DiGioia Is Not Prior Art

2. DiGioia Does Not Render Claims 1-15 and 17 Obvious and DiGioia in View of DiGioia II Does Not Render Claim 16 Obvious

3. Motion to Amend

4. Motion to Exclude

DiGioia Is Not “By Another”



(12) **United States Patent**
DiGioia, III et al.

(10) **Patent No.: US 6,205,411 B1**
(45) **Date of Patent: *Mar. 20, 2001**

(54) **COMPUTER-ASSISTED SURGERY PLANNER AND INTRA-OPERATIVE GUIDANCE SYSTEM**

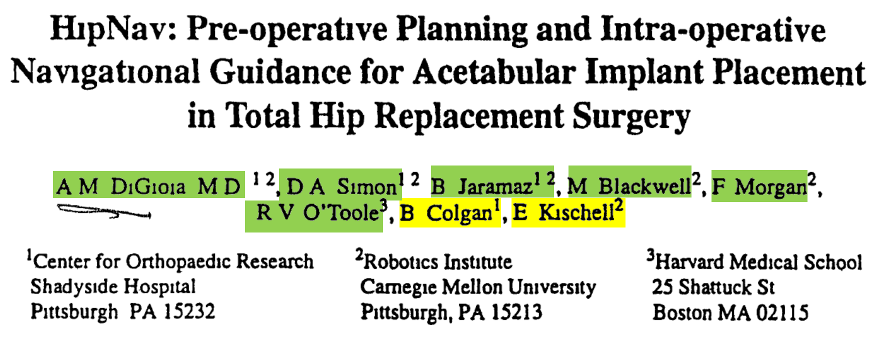
(75) Inventors: **Anthony M. DiGioia, III**, Pittsburgh, PA (US); **David A. Simon**, Boulder, CO (US); **Branislav Jaramaz**; **Michael K. Blackwell**, both of Pittsburgh, PA (US); **Frederick M. Morgan**, Quincy; **Robert V. O’Toole**, Brookline, both of MA (US); **Takeo Kanade**, Pittsburgh, PA (US)

5,007,936	4/1991	Woolson	128/898
5,086,401	2/1992	Glassman et al.	700/259
5,141,512	8/1992	Farmer et al.	606/87
5,242,455	9/1993	Skeens et al.	606/130
5,251,127	10/1993	Raab	606/130
5,299,288	3/1994	Glassman et al.	700/245
5,305,203	4/1994	Raab	606/1
5,360,446	11/1994	Kennedy	128/898
5,383,454	1/1995	Bucholz	600/429

(List continued on next page.)

OTHER PUBLICATIONS

Ex. 1001, ’411 Patent at 1
Paper No. 11, Patent Owner Response at 19



HipNav: Pre-operative Planning and Intra-operative Navigational Guidance for Acetabular Implant Placement in Total Hip Replacement Surgery

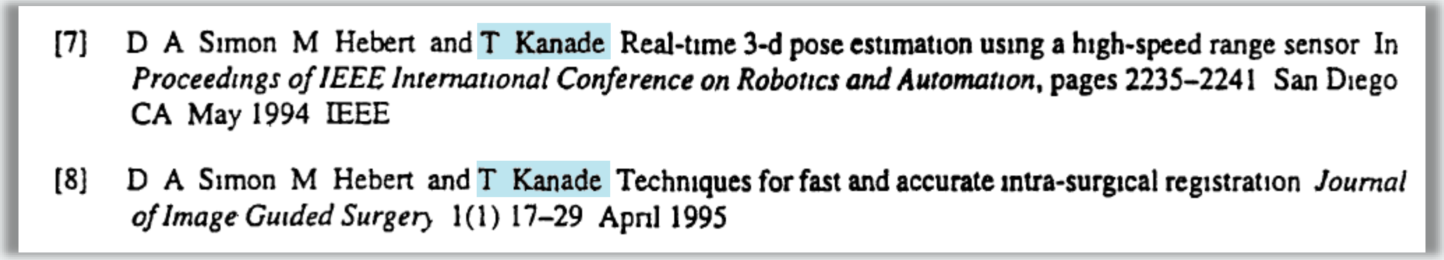
A M DiGioia M D [1 2], D A Simon[1 2], B Jaramaz[1 2], M Blackwell[2], F Morgan[2], R V O’Toole[3], B Colgan[1], E Kischell[2]

[1]Center for Orthopaedic Research
Shadyside Hospital
Pittsburgh PA 15232

[2]Robotics Institute
Carnegie Mellon University
Pittsburgh, PA 15213

[3]Harvard Medical School
25 Shattuck St
Boston MA 02115

Ex. 1005, DiGioia at 1
Paper No. 11, Patent Owner Response at 19

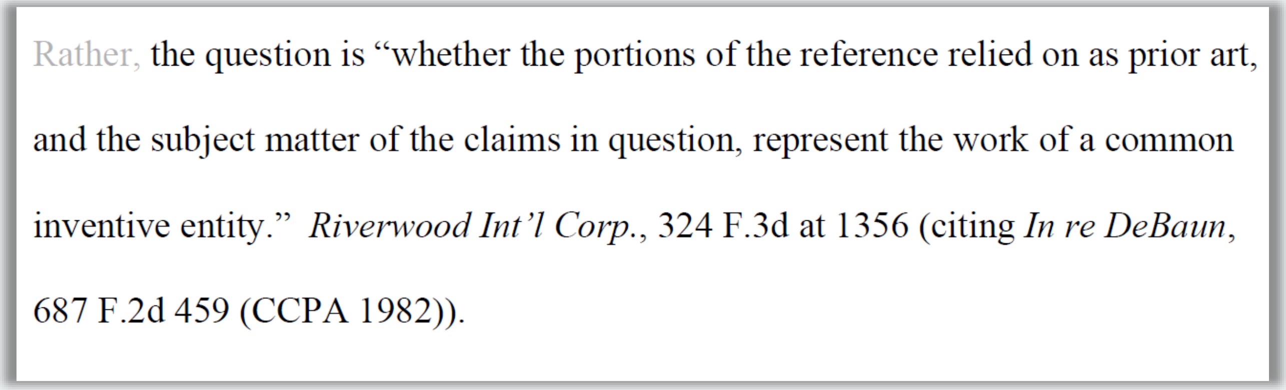


[7] D A Simon M Hebert and T Kanade Real-time 3-d pose estimation using a high-speed range sensor In *Proceedings of IEEE International Conference on Robotics and Automation*, pages 2235–2241 San Diego CA May 1994 IEEE

[8] D A Simon M Hebert and T Kanade Techniques for fast and accurate intra-surgical registration *Journal of Image Guided Surgery* 1(1) 17–29 April 1995

Ex. 1005, DiGioia at 8
Ex. 2002, Jaramaz Decl., at ¶ 15
Paper No. 11, Patent Owner Response at 20

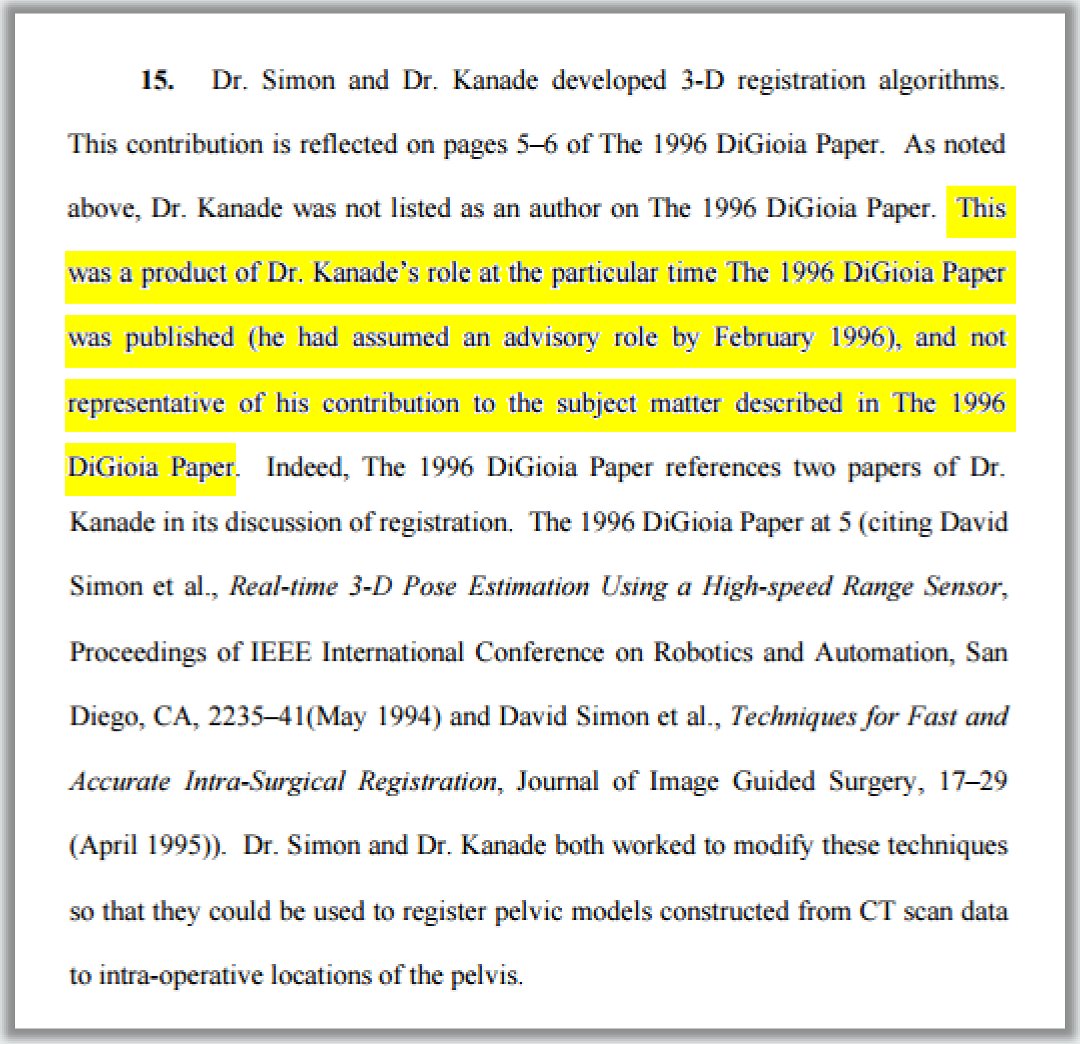
DiGioia Is Not "By Another"



Rather, the question is "whether the portions of the reference relied on as prior art, and the subject matter of the claims in question, represent the work of a common inventive entity." *Riverwood Int'l Corp.*, 324 F.3d at 1356 (citing *In re DeBaun*, 687 F.2d 459 (CCPA 1982)).

Paper No. 11, Patent Owner Response at 19

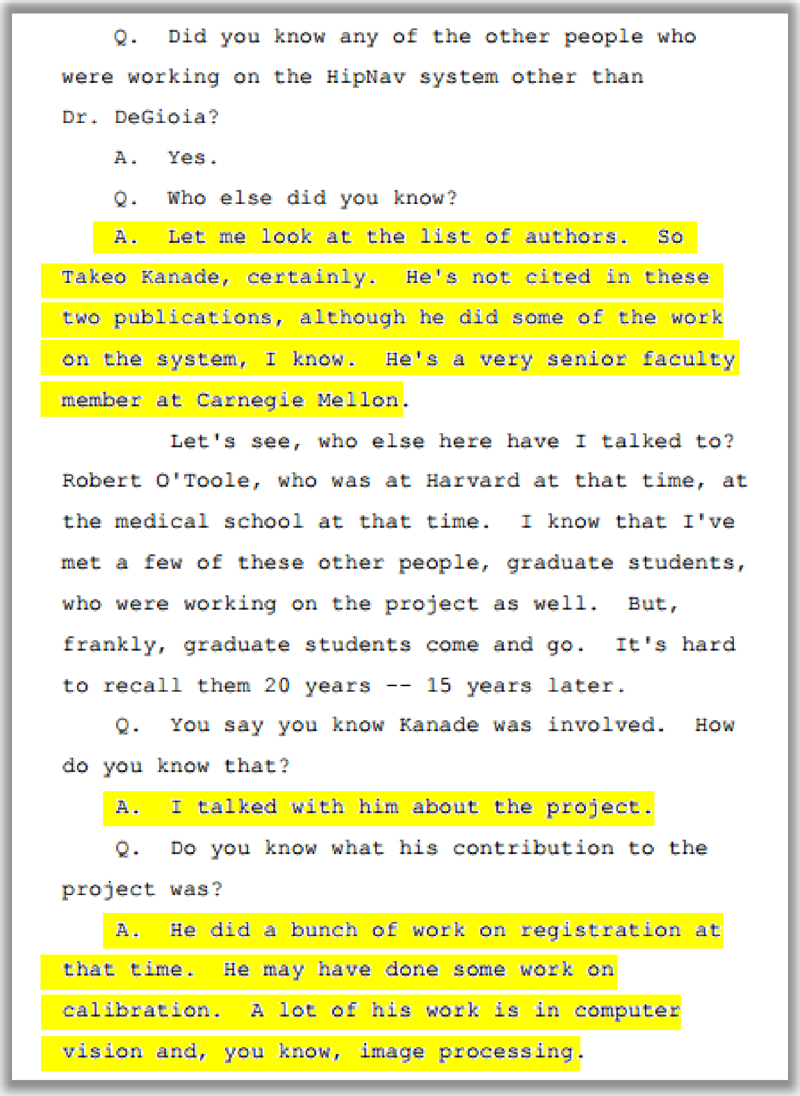
Dr. Takeo Kanade's Contributions



15. Dr. Simon and Dr. Kanade developed 3-D registration algorithms. This contribution is reflected on pages 5–6 of The 1996 DiGioia Paper. As noted above, Dr. Kanade was not listed as an author on The 1996 DiGioia Paper. This was a product of Dr. Kanade's role at the particular time The 1996 DiGioia Paper was published (he had assumed an advisory role by February 1996), and not representative of his contribution to the subject matter described in The 1996 DiGioia Paper. Indeed, The 1996 DiGioia Paper references two papers of Dr. Kanade in its discussion of registration. The 1996 DiGioia Paper at 5 (citing David Simon et al., *Real-time 3-D Pose Estimation Using a High-speed Range Sensor*, Proceedings of IEEE International Conference on Robotics and Automation, San Diego, CA, 2235–41(May 1994) and David Simon et al., *Techniques for Fast and Accurate Intra-Surgical Registration*, Journal of Image Guided Surgery, 17–29 (April 1995)). Dr. Simon and Dr. Kanade both worked to modify these techniques so that they could be used to register pelvic models constructed from CT scan data to intra-operative locations of the pelvis.

Ex. 2002, Jaramaz Decl. at ¶ 15
Paper No. 11, Patent Owner Response at 19

Petitioner’s Expert Confirmed That Dr. Kanade Contributed to HipNav



Q. Did you know any of the other people who were working on the HipNav system other than Dr. DeGioia?

A. Yes.

Q. Who else did you know?

A. Let me look at the list of authors. So Takeo Kanade, certainly. He's not cited in these two publications, although he did some of the work on the system, I know. He's a very senior faculty member at Carnegie Mellon.

Let's see, who else here have I talked to? Robert O'Toole, who was at Harvard at that time, at the medical school at that time. I know that I've met a few of these other people, graduate students, who were working on the project as well. But, frankly, graduate students come and go. It's hard to recall them 20 years -- 15 years later.

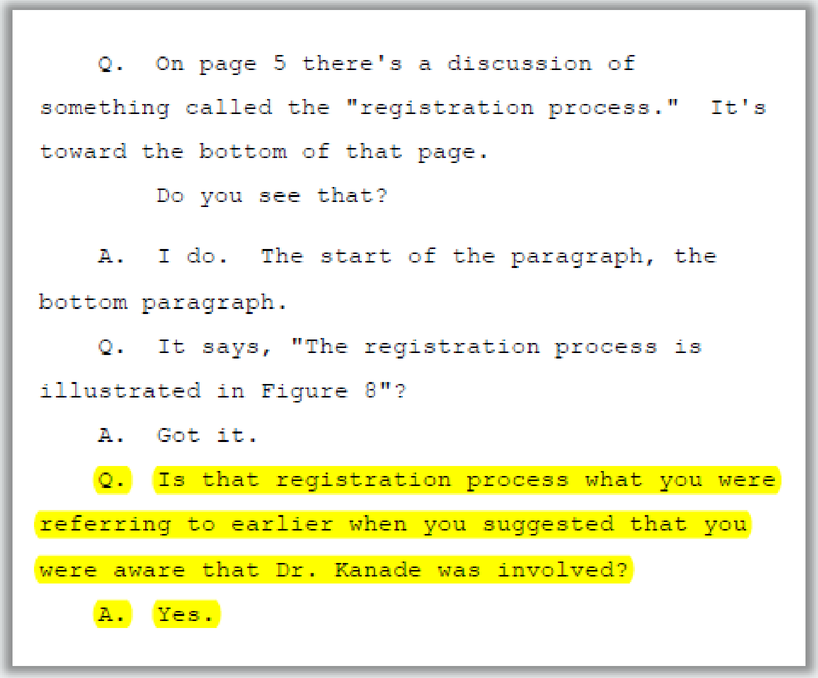
Q. You say you know Kanade was involved. How do you know that?

A. I talked with him about the project.

Q. Do you know what his contribution to the project was?

A. He did a bunch of work on registration at that time. He may have done some work on calibration. A lot of his work is in computer vision and, you know, image processing.

Ex. 2006, Howe Dep. at 52:18-53:19
Paper No. 11, Patent Owner Response at 21



Q. On page 5 there's a discussion of something called the "registration process." It's toward the bottom of that page.

Do you see that?

A. I do. The start of the paragraph, the bottom paragraph.

Q. It says, "The registration process is illustrated in Figure 8"?

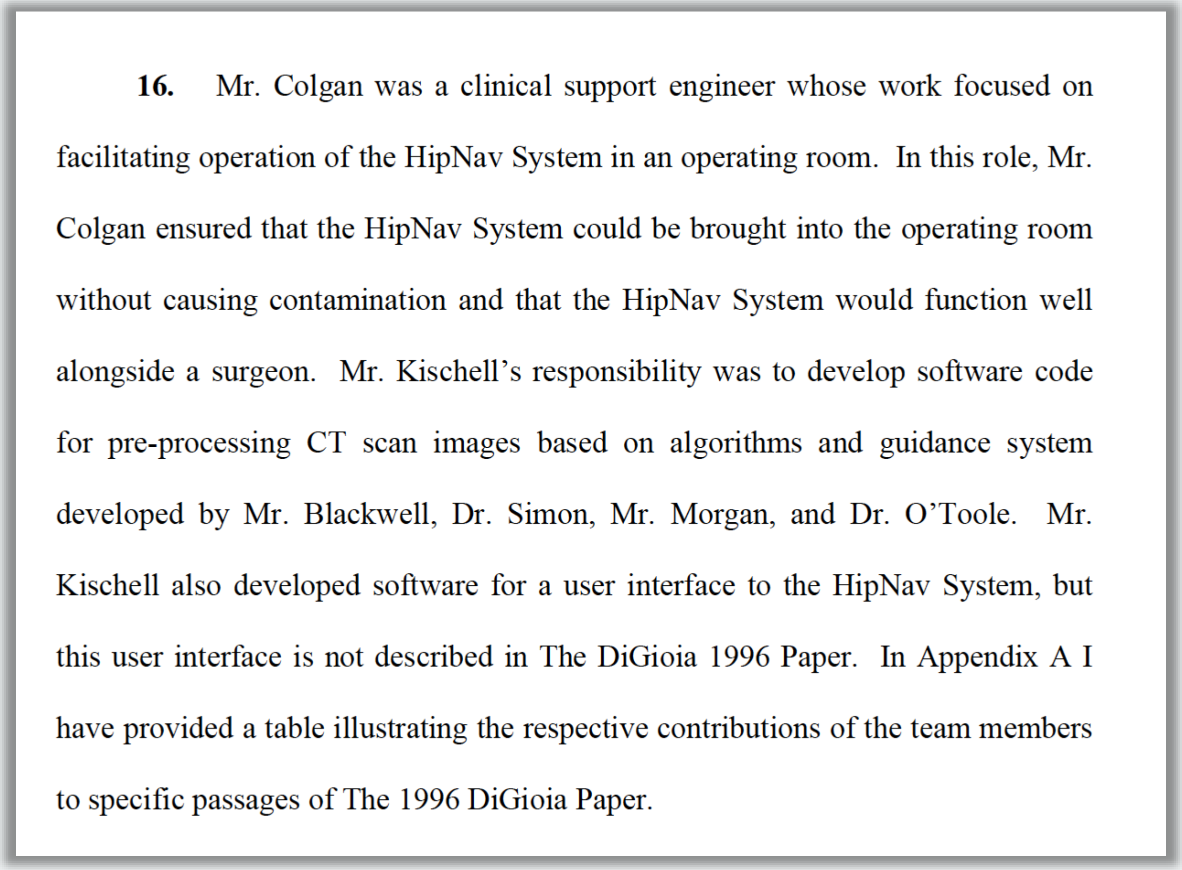
A. Got it.

Q. Is that registration process what you were referring to earlier when you suggested that you were aware that Dr. Kanade was involved?

A. Yes.

Ex. 2006, Howe Dep. at 85:22-86:10
Paper No. 11, Patent Owner Response at 21

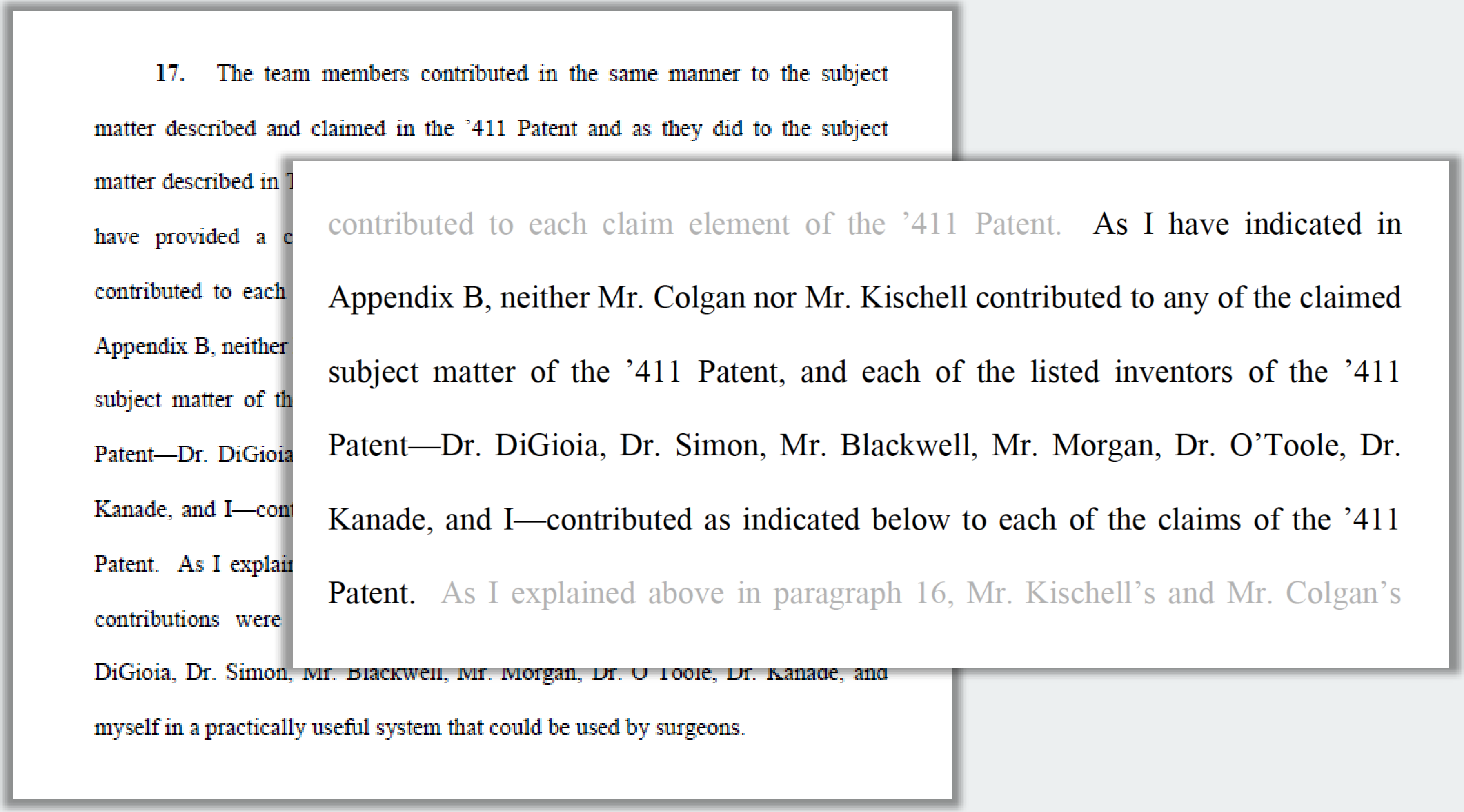
Mr. Kischell’s & Mr. Colgan’s Contributions Are Not Recited in the ’411 Claims and Not Reflected in the Relied-Upon Portions of DiGioia



16. Mr. Colgan was a clinical support engineer whose work focused on facilitating operation of the HipNav System in an operating room. In this role, Mr. Colgan ensured that the HipNav System could be brought into the operating room without causing contamination and that the HipNav System would function well alongside a surgeon. Mr. Kischell’s responsibility was to develop software code for pre-processing CT scan images based on algorithms and guidance system developed by Mr. Blackwell, Dr. Simon, Mr. Morgan, and Dr. O’Toole. Mr. Kischell also developed software for a user interface to the HipNav System, but this user interface is not described in The DiGioia 1996 Paper. In Appendix A I have provided a table illustrating the respective contributions of the team members to specific passages of The 1996 DiGioia Paper.

Ex. 2002, Jaramaz Decl. at ¶ 16
Paper No. 11, Patent Owner Response at 19

Mr. Kischell's & Mr. Colgan's Contributions Are Not Recited in the '411 Claims and Not Reflected in the Relied-Upon Portions of DiGioia

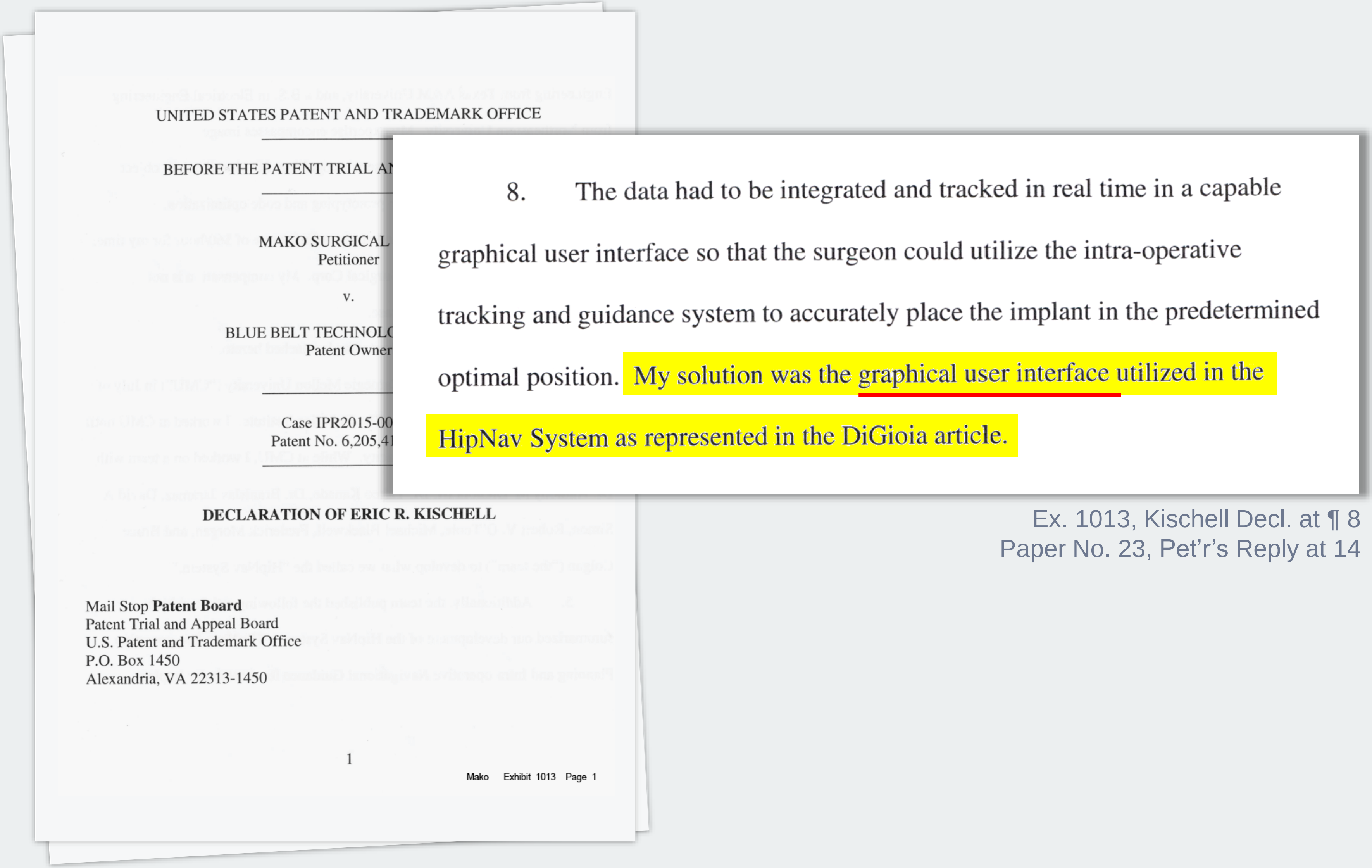


17. The team members contributed in the same manner to the subject
matter described and claimed in the '411 Patent and as they did to the subject
matter described in T
have provided a c
contributed to each
Appendix B, neither
subject matter of th
Patent—Dr. DiGioia
Kanade, and I—con
Patent. As I explai
contributions were
DiGioia, Dr. Simon, Mr. Blackwell, Mr. Morgan, Dr. O'Toole, Dr. Kanade, and
myself in a practically useful system that could be used by surgeons.

contributed to each claim element of the '411 Patent. As I have indicated in Appendix B, neither Mr. Colgan nor Mr. Kischell contributed to any of the claimed subject matter of the '411 Patent, and each of the listed inventors of the '411 Patent—Dr. DiGioia, Dr. Simon, Mr. Blackwell, Mr. Morgan, Dr. O'Toole, Dr. Kanade, and I—contributed as indicated below to each of the claims of the '411 Patent. As I explained above in paragraph 16, Mr. Kischell's and Mr. Colgan's

Ex. 2002, Jaramaz Decl. at ¶ 17
Paper No. 11, Patent Owner Response at 19

Mr. Kischell's Declaration Does Not Establish That He Contributed to the Cited Portions of DiGioia



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AN

MAKO SURGICAL
Petitioner

v.

BLUE BELT TECHNOLO
Patent Owner

Case IPR2015-00
Patent No. 6,205,41

DECLARATION OF ERIC R. KISCHELL

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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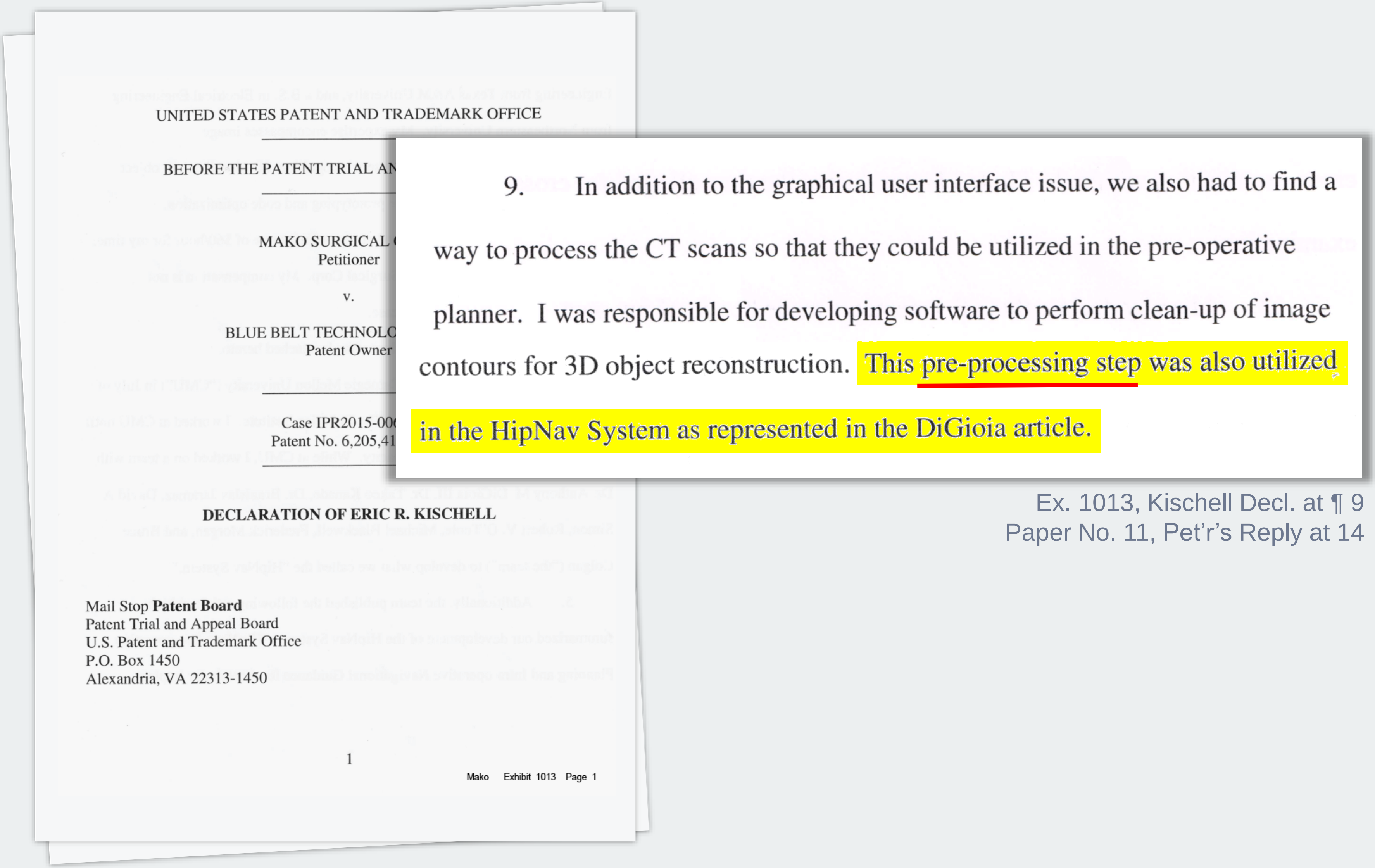
Mako Exhibit 1013 Page 1

8. The data had to be integrated and tracked in real time in a capable graphical user interface so that the surgeon could utilize the intra-operative tracking and guidance system to accurately place the implant in the predetermined optimal position. My solution was the graphical user interface utilized in the HipNav System as represented in the DiGioia article.

Ex. 1013, Kischell Decl. at ¶ 8
Paper No. 23, Pet'r's Reply at 14

Mr. Kischell's Declaration Does Not Establish That He Contributed to the Cited Portions of DiGioia



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AN

MAKO SURGICAL
Petitioner

v.

BLUE BELT TECHNOLO
Patent Owner

Case IPR2015-00
Patent No. 6,205,41

DECLARATION OF ERIC R. KISCHELL

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U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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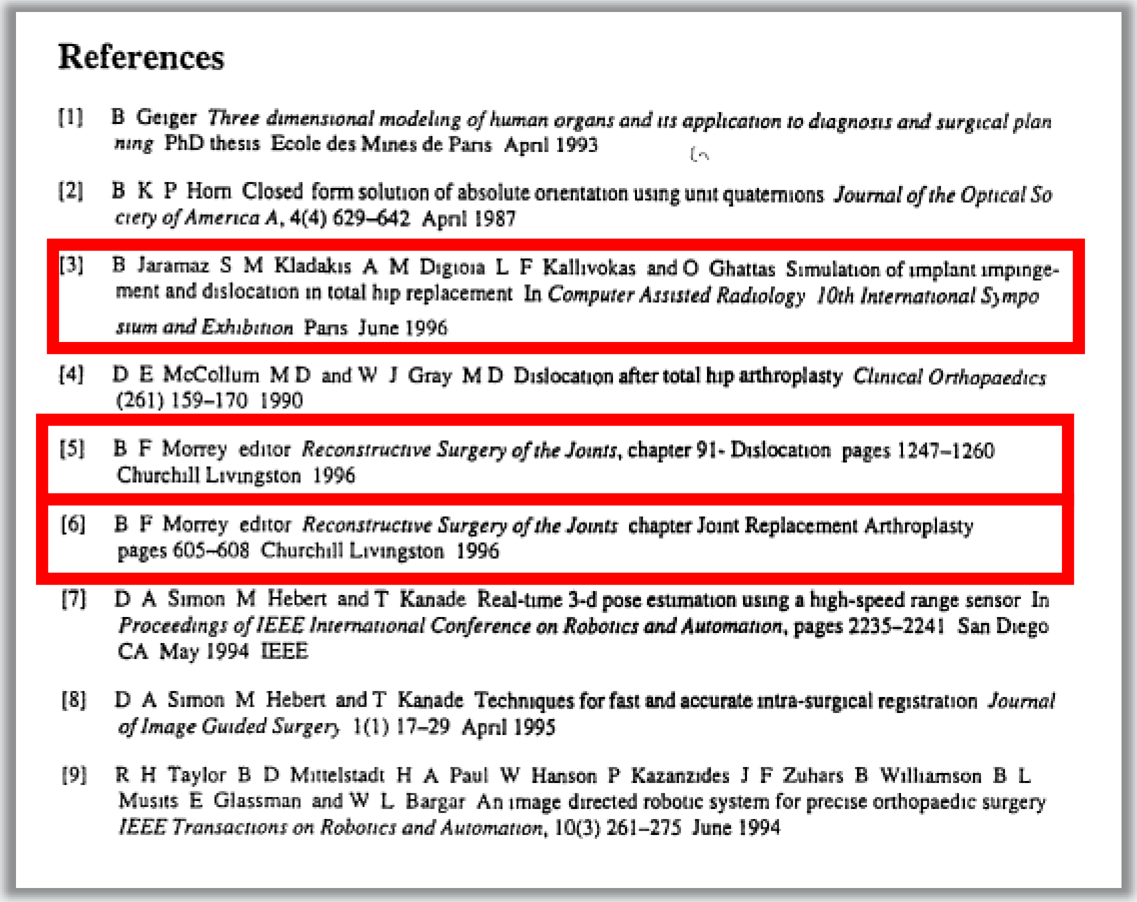
Mako Exhibit 1013 Page 1

9. In addition to the graphical user interface issue, we also had to find a way to process the CT scans so that they could be utilized in the pre-operative planner. I was responsible for developing software to perform clean-up of image contours for 3D object reconstruction. This pre-processing step was also utilized in the HipNav System as represented in the DiGioia article.

Ex. 1013, Kischell Decl. at ¶ 9
Paper No. 11, Pet'r's Reply at 14

DiGioia Was Published in November 1996



References

[1] B Geiger *Three dimensional modeling of human organs and its application to diagnosis and surgical planning* PhD thesis Ecole des Mines de Paris April 1993

[2] B K P Horn Closed form solution of absolute orientation using unit quaternions *Journal of the Optical Society of America A*, 4(4) 629–642 April 1987

[3] B Jaramaz S M Kladakis A M Digioia L F Kallivokas and O Ghattas Simulation of implant impingement and dislocation in total hip replacement In *Computer Assisted Radiology 10th International Symposium and Exhibition* Paris June 1996

[4] D E McCollum M D and W J Gray M D Dislocation after total hip arthroplasty *Clinical Orthopaedics* (261) 159–170 1990

[5] B F Morrey editor *Reconstructive Surgery of the Joints*, chapter 91- Dislocation pages 1247–1260 Churchill Livingston 1996

[6] B F Morrey editor *Reconstructive Surgery of the Joints* chapter Joint Replacement Arthroplasty pages 605–608 Churchill Livingston 1996

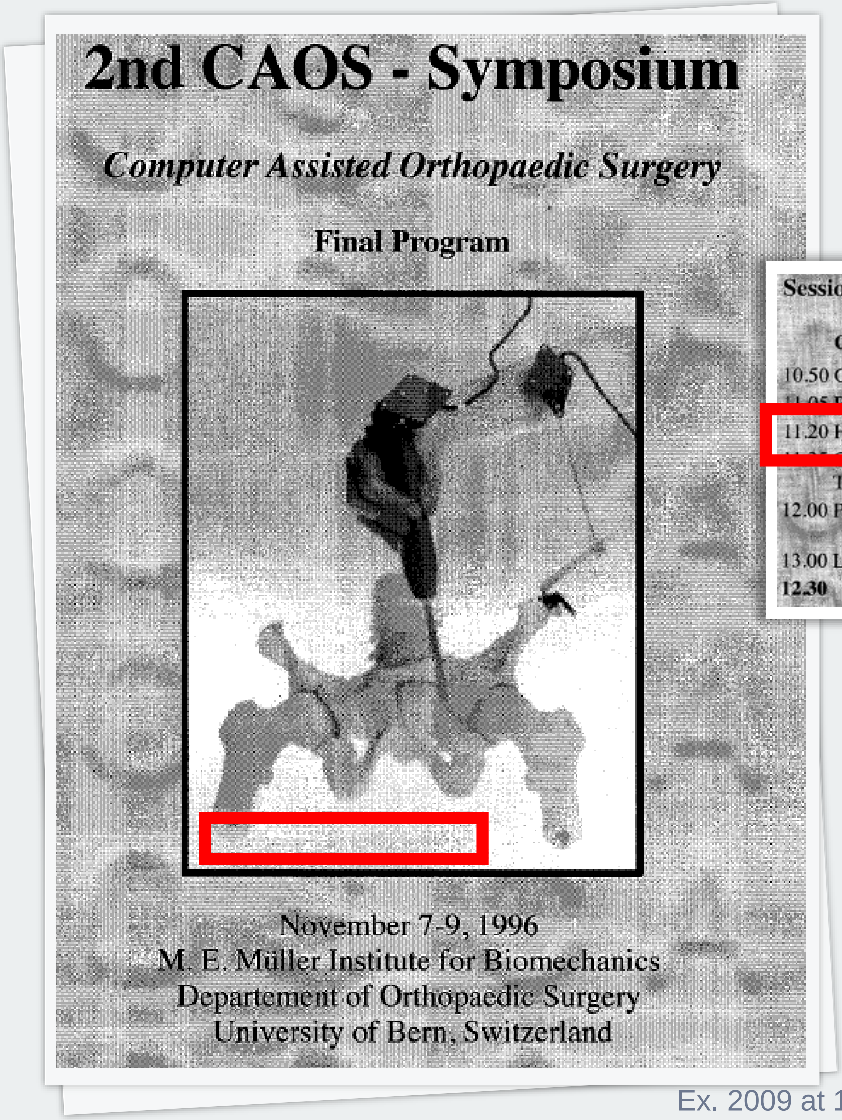
[7] D A Simon M Hebert and T Kanade Real-time 3-d pose estimation using a high-speed range sensor In *Proceedings of IEEE International Conference on Robotics and Automation*, pages 2235–2241 San Diego CA May 1994 IEEE

[8] D A Simon M Hebert and T Kanade Techniques for fast and accurate intra-surgical registration *Journal of Image Guided Surgery* 1(1) 17–29 April 1995

[9] R H Taylor B D Mittelstadt H A Paul W Hanson P Kazanzides J F Zuhars B Williamson B L Musits E Glassman and W L Bargar An image directed robotic system for precise orthopaedic surgery *IEEE Transactions on Robotics and Automation*, 10(3) 261–275 June 1994

Ex. 1005, DiGioia at 7-8
Paper No. 30, Reply to Opposition to Motion to Amend at 2-3

DiGioia Was Published in November 1996



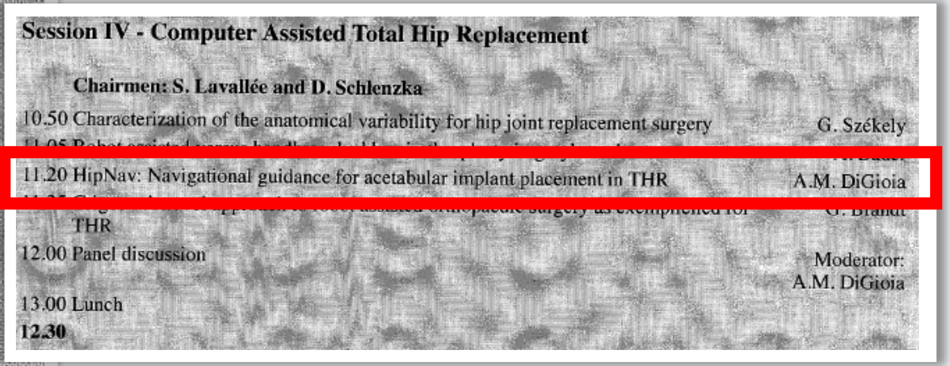
2nd CAOS - Symposium

Computer Assisted Orthopaedic Surgery

Final Program

November 7-9, 1996
M. E. Müller Institute for Biomechanics
Departement of Orthopaedic Surgery
University of Bern, Switzerland

Ex. 2009 at 1
Paper No. 30, Reply to Opposition to Motion to Amend at 3



Session IV - Computer Assisted Total Hip Replacement

Chairmen: S. Lavallée and D. Schlenzka

10.50 Characterization of the anatomical variability for hip joint replacement surgery — G. Székely

11.20 HipNav: Navigational guidance for acetabular implant placement in THR — A.M. DiGioia

THR

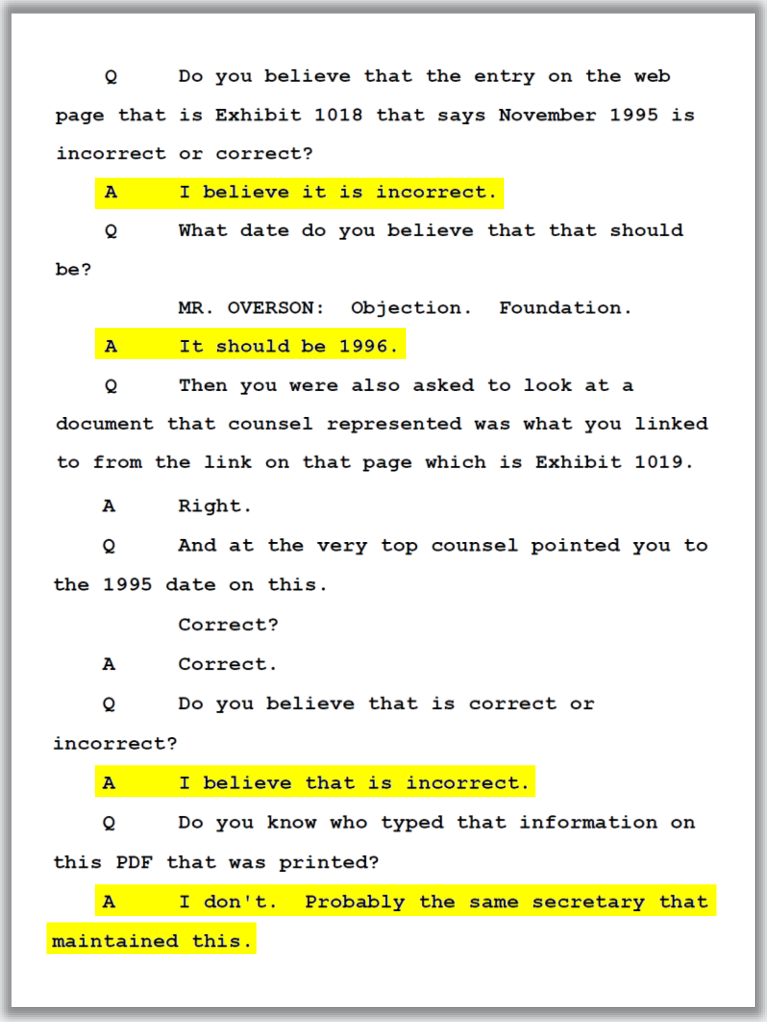
12.00 Panel discussion — Moderator: A.M. DiGioia

13.00 Lunch

12.30

Ex. 2009 at 6
Paper No. 30, Reply to Opposition to Motion to Amend at 3

DiGioia Was Published in November 1996



Q Do you believe that the entry on the web page that is Exhibit 1018 that says November 1995 is incorrect or correct?

A I believe it is incorrect.

Q What date do you believe that that should be?

MR. OVERSON: Objection. Foundation.

A It should be 1996.

Q Then you were also asked to look at a document that counsel represented was what you linked to from the link on that page which is Exhibit 1019.

A Right.

Q And at the very top counsel pointed you to the 1995 date on this.

Correct?

A Correct.

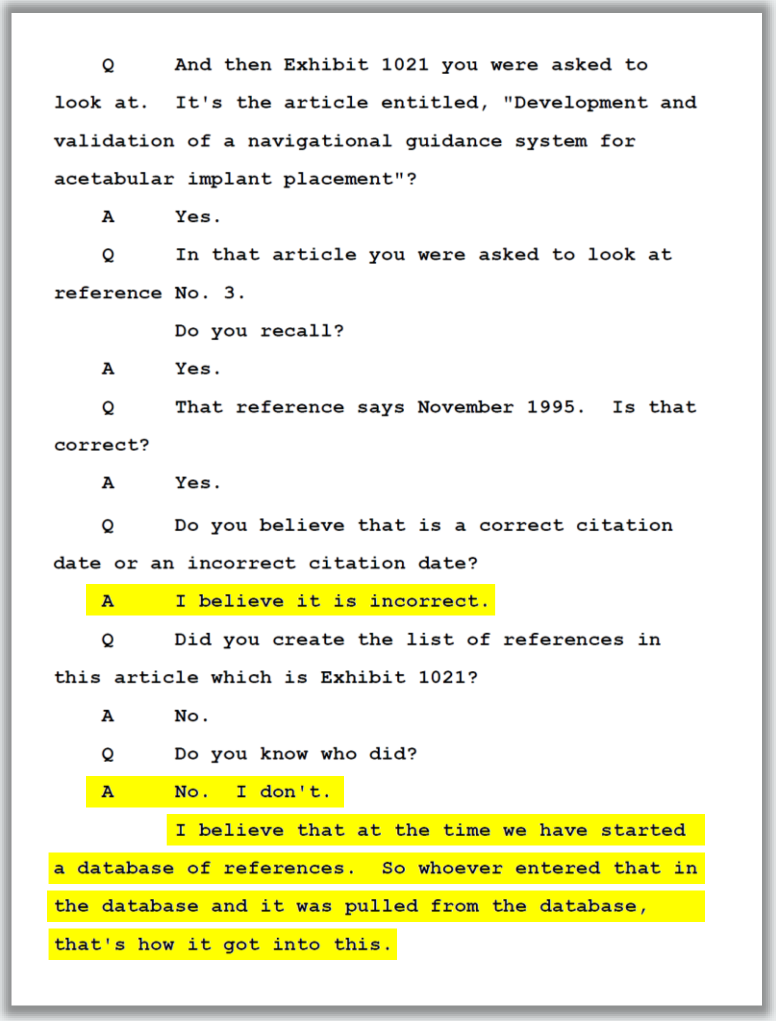
Q Do you believe that is correct or incorrect?

A I believe that is incorrect.

Q Do you know who typed that information on this PDF that was printed?

A I don't. Probably the same secretary that maintained this.

Ex. 1012, Jaramaz Dep. at 61:15-62:12
Paper No. 30, Reply to Opposition to Motion to Amend at 4



Q And then Exhibit 1021 you were asked to look at. It's the article entitled, "Development and validation of a navigational guidance system for acetabular implant placement"?

A Yes.

Q In that article you were asked to look at reference No. 3.

Do you recall?

A Yes.

Q That reference says November 1995. Is that correct?

A Yes.

Q Do you believe that is a correct citation date or an incorrect citation date?

A I believe it is incorrect.

Q Did you create the list of references in this article which is Exhibit 1021?

A No.

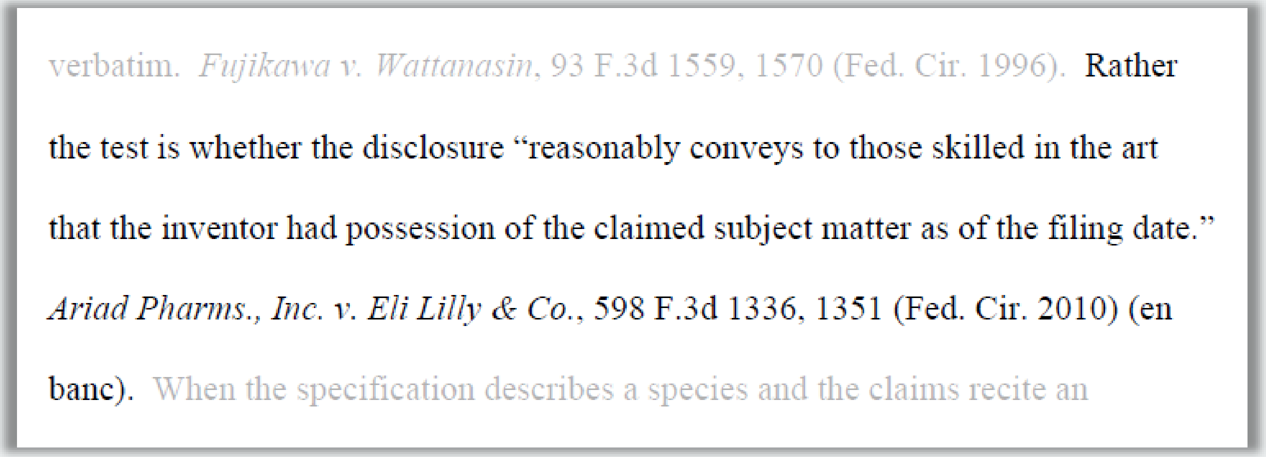
Q Do you know who did?

A No. I don't.

I believe that at the time we have started a database of references. So whoever entered that in the database and it was pulled from the database, that's how it got into this.

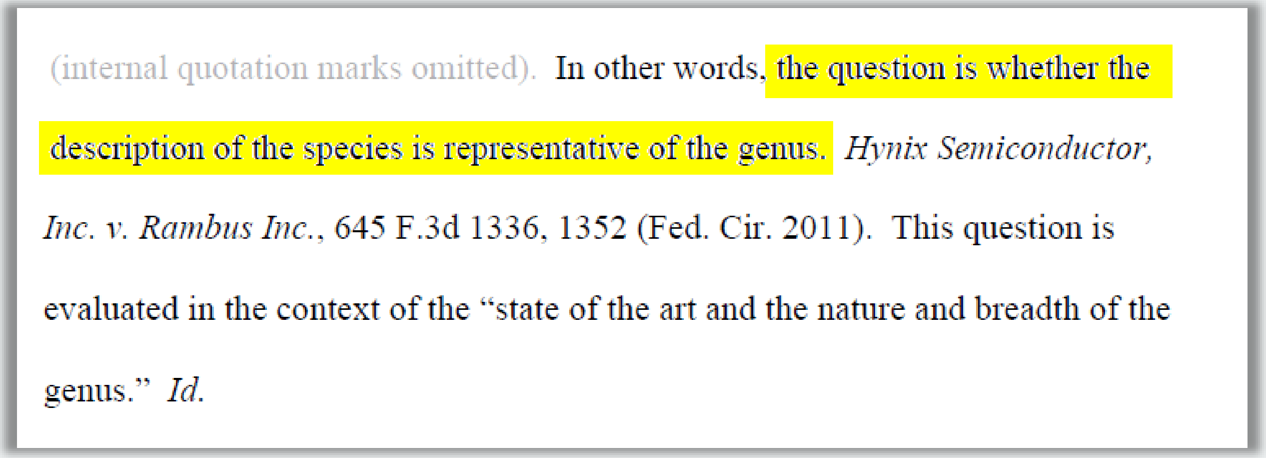
Ex. 1012, Jaramaz Dep. at 62:14-63:12
Paper No. 30, Reply to Opposition to Motion to Amend at 4

The ’411 Patent is Entitled to Claim the Benefit of the ’976 Patent’s Filing Date



verbatim. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). Rather the test is whether the disclosure “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). When the specification describes a species and the claims recite an

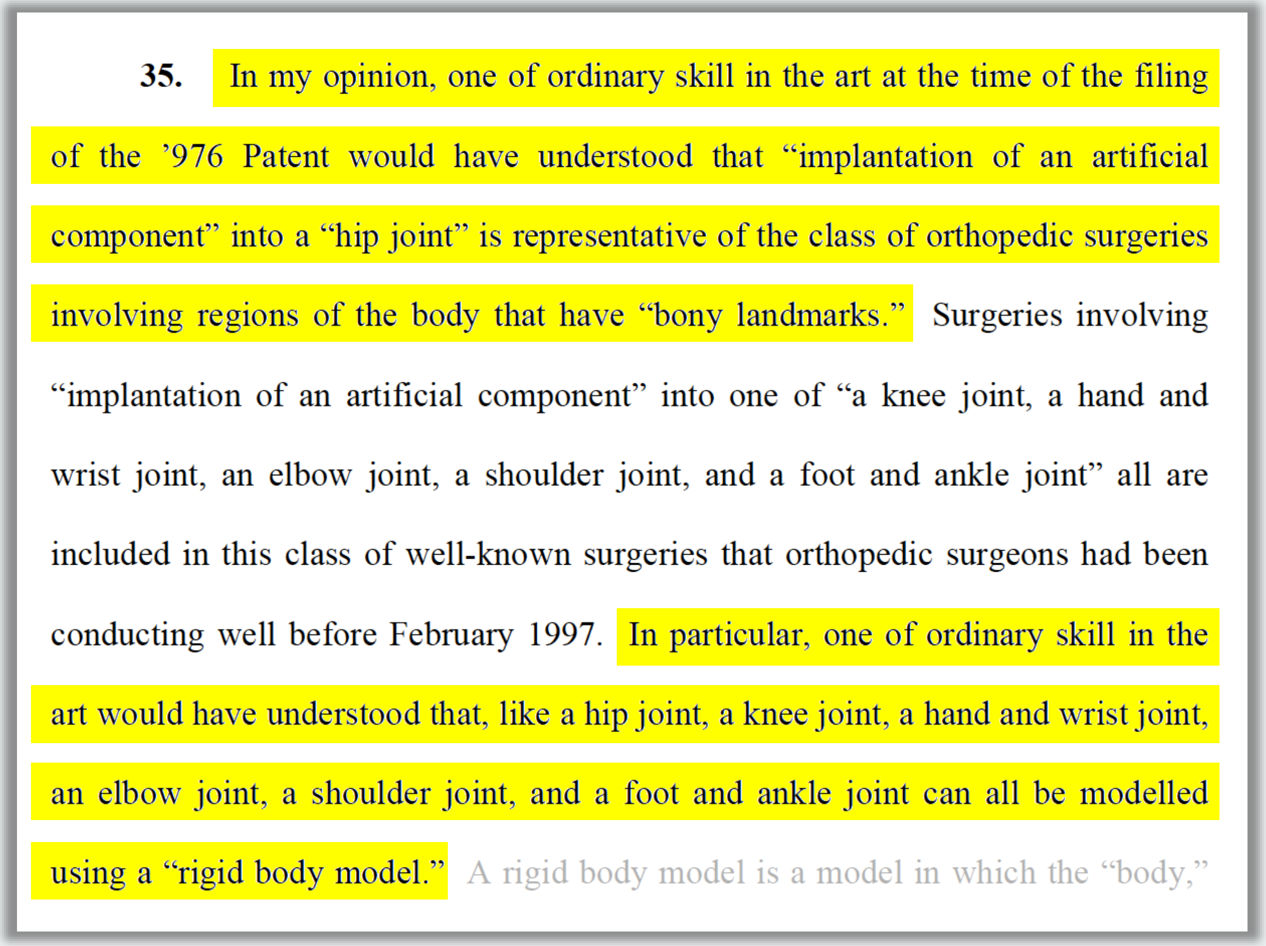
Paper No. 11, Patent Owner Response at 23



(internal quotation marks omitted). In other words, the question is whether the description of the species is representative of the genus. *Hynix Semiconductor, Inc. v. Rambus Inc.*, 645 F.3d 1336, 1352 (Fed. Cir. 2011). This question is evaluated in the context of the “state of the art and the nature and breadth of the genus.” *Id.*

Paper No. 11, Patent Owner Response at 23-24

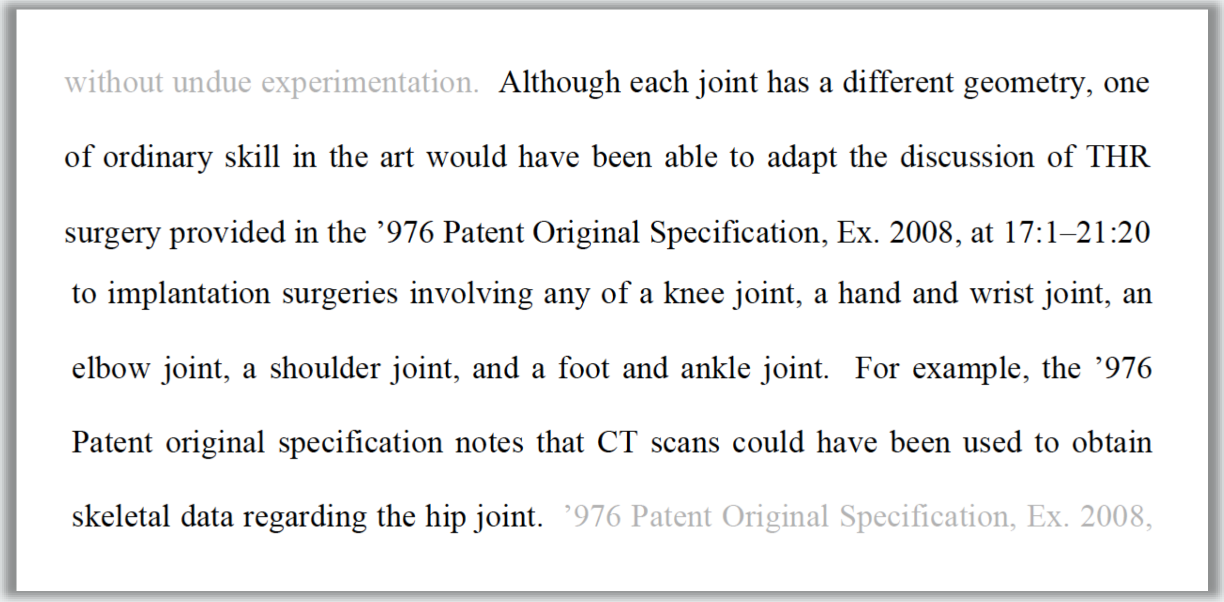
Hip Replacement Surgery is Representative of the Surgeries Recited in the ’411 Patent Claims



35. In my opinion, one of ordinary skill in the art at the time of the filing of the ’976 Patent would have understood that “implantation of an artificial component” into a “hip joint” is representative of the class of orthopedic surgeries involving regions of the body that have “bony landmarks.” Surgeries involving “implantation of an artificial component” into one of “a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint” all are included in this class of well-known surgeries that orthopedic surgeons had been conducting well before February 1997. In particular, one of ordinary skill in the art would have understood that, like a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint can all be modelled using a “rigid body model.” A rigid body model is a model in which the “body,”

Ex. 2004, Cleary Decl. ¶ 35
Paper No. 11, Patent Owner Response at 24

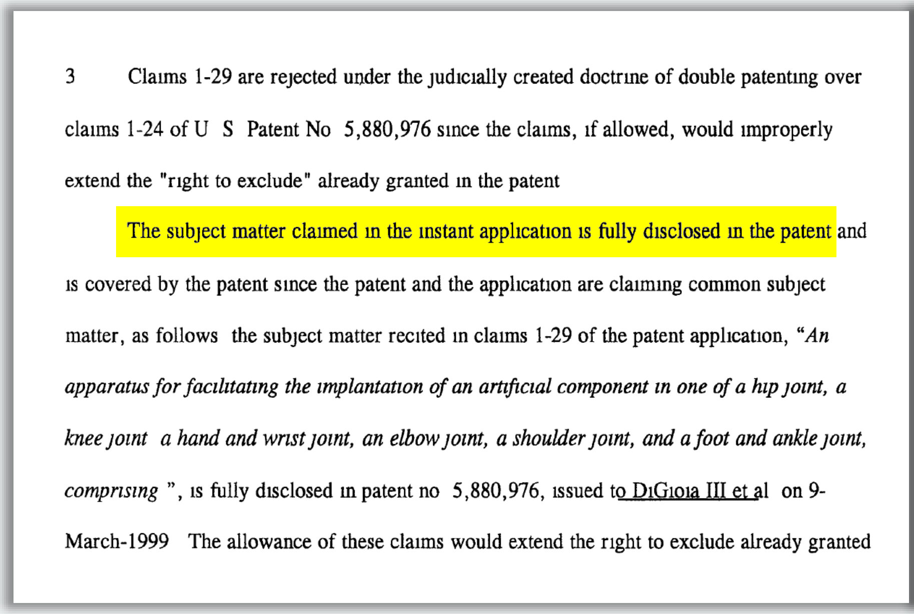
A POSA Would Have Been Able to Apply the Teachings of the ’976 Patent to the Surgeries Claimed in the ’411 Patent



without undue experimentation. Although each joint has a different geometry, one of ordinary skill in the art would have been able to adapt the discussion of THR surgery provided in the ’976 Patent Original Specification, Ex. 2008, at 17:1–21:20 to implantation surgeries involving any of a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint. For example, the ’976 Patent original specification notes that CT scans could have been used to obtain skeletal data regarding the hip joint. ’976 Patent Original Specification, Ex. 2008,

Ex. 2003, Cleary Decl. ¶ 37
Paper No. 11, Patent Owner Response at 25

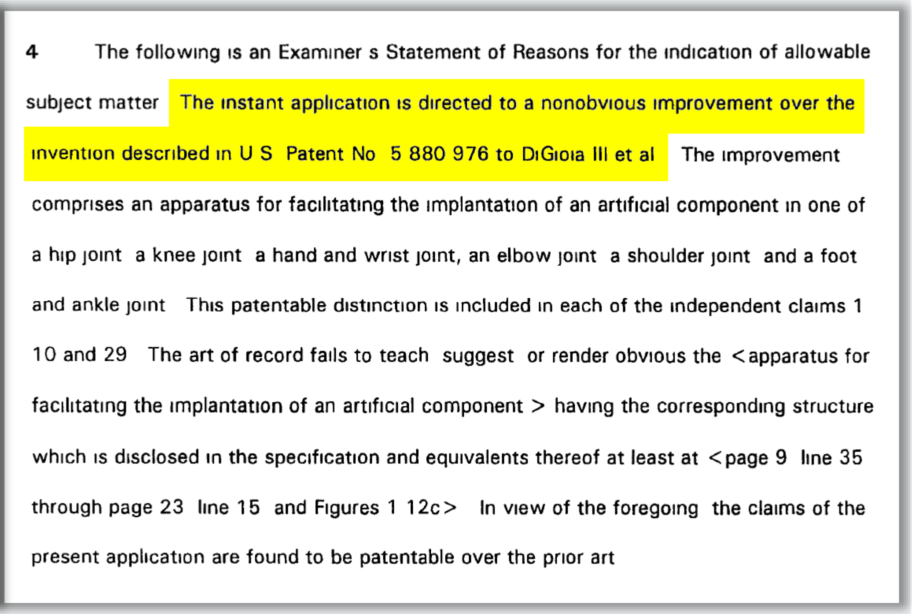
The Prosecution History of the ’411 Patent



3 Claims 1-29 are rejected under the judicially created doctrine of double patenting over claims 1-24 of U S Patent No 5,880,976 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows the subject matter recited in claims 1-29 of the patent application, “*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* ”, is fully disclosed in patent no 5,880,976, issued to DiGioia III et al on 9-March-1999 The allowance of these claims would extend the right to exclude already granted

Ex. 1002, ’411 Patent File History, p. 265
Paper No. 11, Patent Owner Response at 26



4 The following is an Examiner s Statement of Reasons for the indication of allowable subject matter The instant application is directed to a nonobvious improvement over the invention described in U S Patent No 5 880 976 to DiGioia III et al The improvement comprises 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 This patentable distinction is included in each of the independent claims 1 10 and 29 The art of record fails to teach suggest or render obvious the <apparatus for facilitating the implantation of an artificial component > having the corresponding structure which is disclosed in the specification and equivalents thereof at least at <page 9 line 35 through page 23 line 15 and Figures 1 12c> In view of the foregoing the claims of the present application are found to be patentable over the prior art

Ex. 1002, ’411 Patent File History, at 287-88
Paper No. 11, Patent Owner Response at 26

Order of Presentation – ’411 Patent

- Introduction

- Topics in Dispute

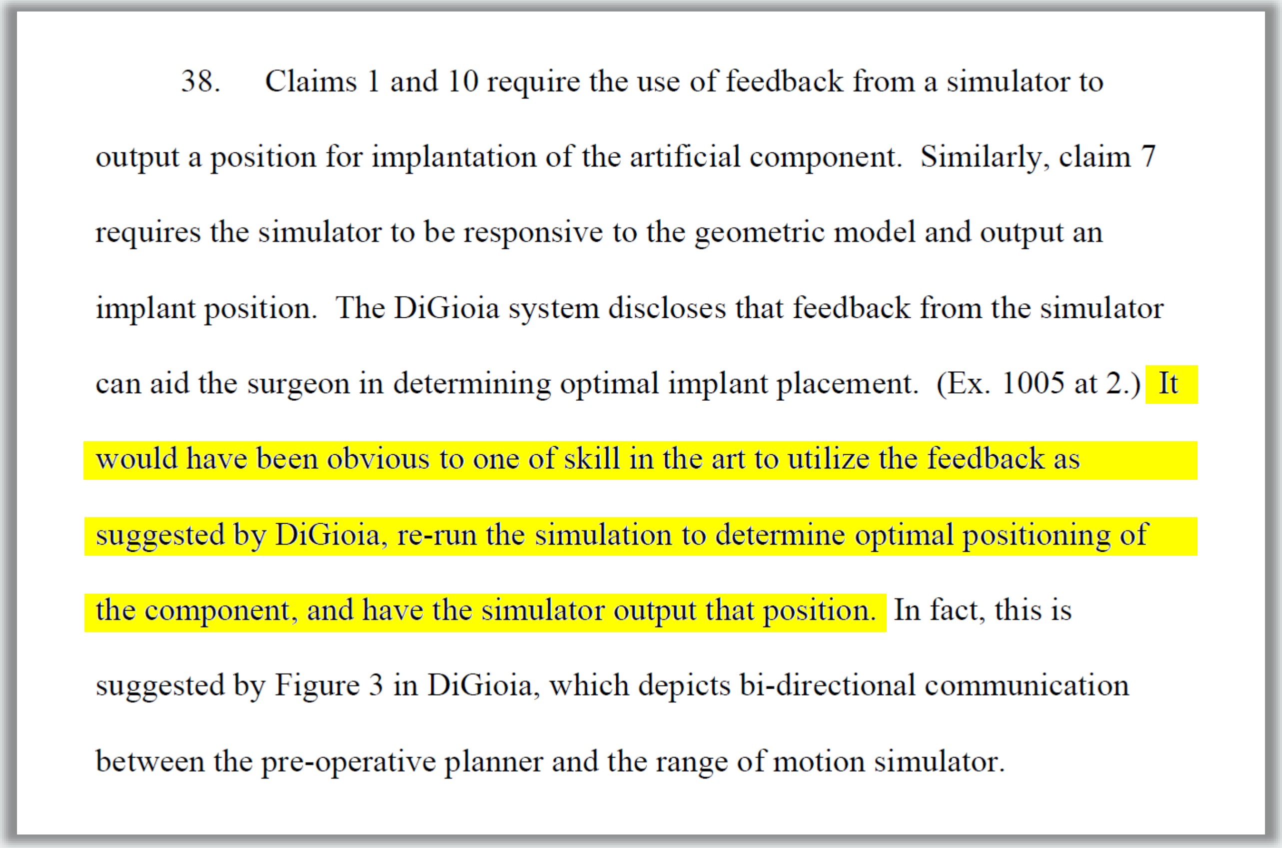
1. DiGioia Is Not Prior Art

2. **DiGioia Does Not Render Claims 1-15 and 17 Obvious and DiGioia in View of DiGioia II Does Not Render Claim 16 Obvious**

3. Motion to Amend

4. Motion to Exclude

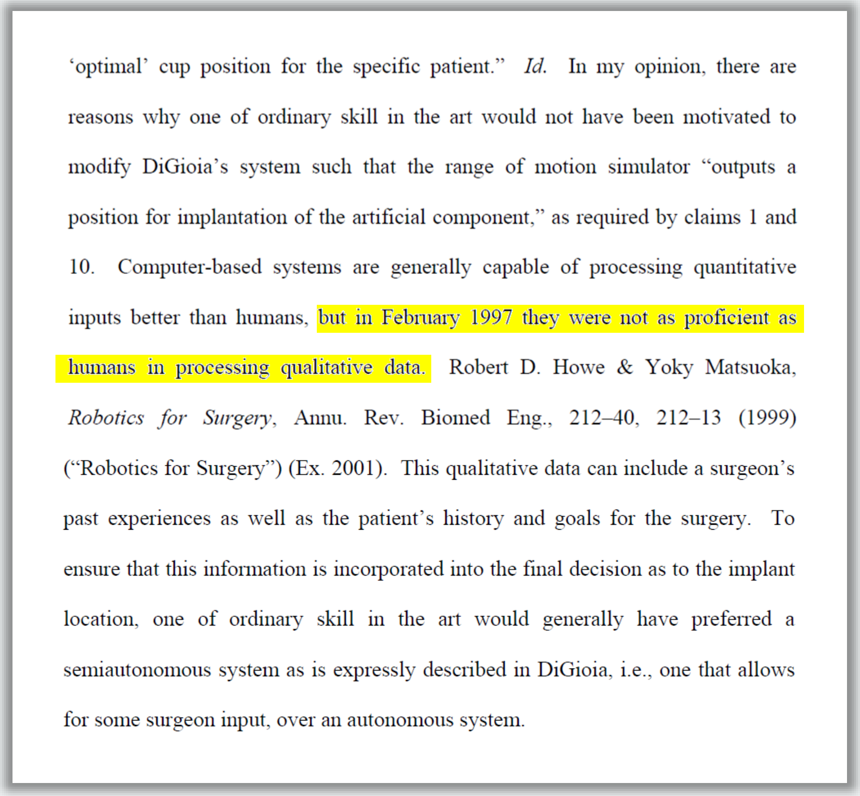
Petitioner's Expert's Conclusory Testimony Does Not Establish Obviousness



38. Claims 1 and 10 require the use of feedback from a simulator to output a position for implantation of the artificial component. Similarly, claim 7 requires the simulator to be responsive to the geometric model and output an implant position. The DiGioia system discloses that feedback from the simulator can aid the surgeon in determining optimal implant placement. (Ex. 1005 at 2.) It would have been obvious to one of skill in the art to utilize the feedback as suggested by DiGioia, re-run the simulation to determine optimal positioning of the component, and have the simulator output that position. In fact, this is suggested by Figure 3 in DiGioia, which depicts bi-directional communication between the pre-operative planner and the range of motion simulator.

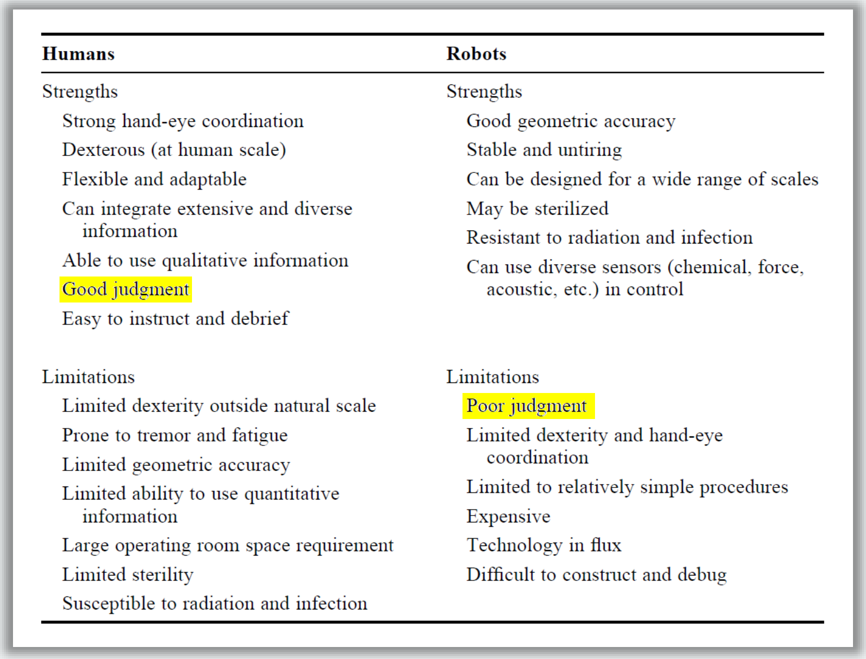
Ex. 1004, Howe Decl. at ¶ 38
Paper No. 11, Patent Owner Response at 29

A POSA Would Not Have Been Motivated to Modify DiGioia



'optimal' cup position for the specific patient." *Id.* In my opinion, there are reasons why one of ordinary skill in the art would not have been motivated to modify DiGioia's system such that the range of motion simulator "outputs a position for implantation of the artificial component," as required by claims 1 and 10. Computer-based systems are generally capable of processing quantitative inputs better than humans, but in February 1997 they were not as proficient as humans in processing qualitative data. Robert D. Howe & Yoky Matsuoka, *Robotics for Surgery*, Annu. Rev. Biomed Eng., 212–40, 212–13 (1999) ("Robotics for Surgery") (Ex. 2001). This qualitative data can include a surgeon's past experiences as well as the patient's history and goals for the surgery. To ensure that this information is incorporated into the final decision as to the implant location, one of ordinary skill in the art would generally have preferred a semiautonomous system as is expressly described in DiGioia, i.e., one that allows for some surgeon input, over an autonomous system.

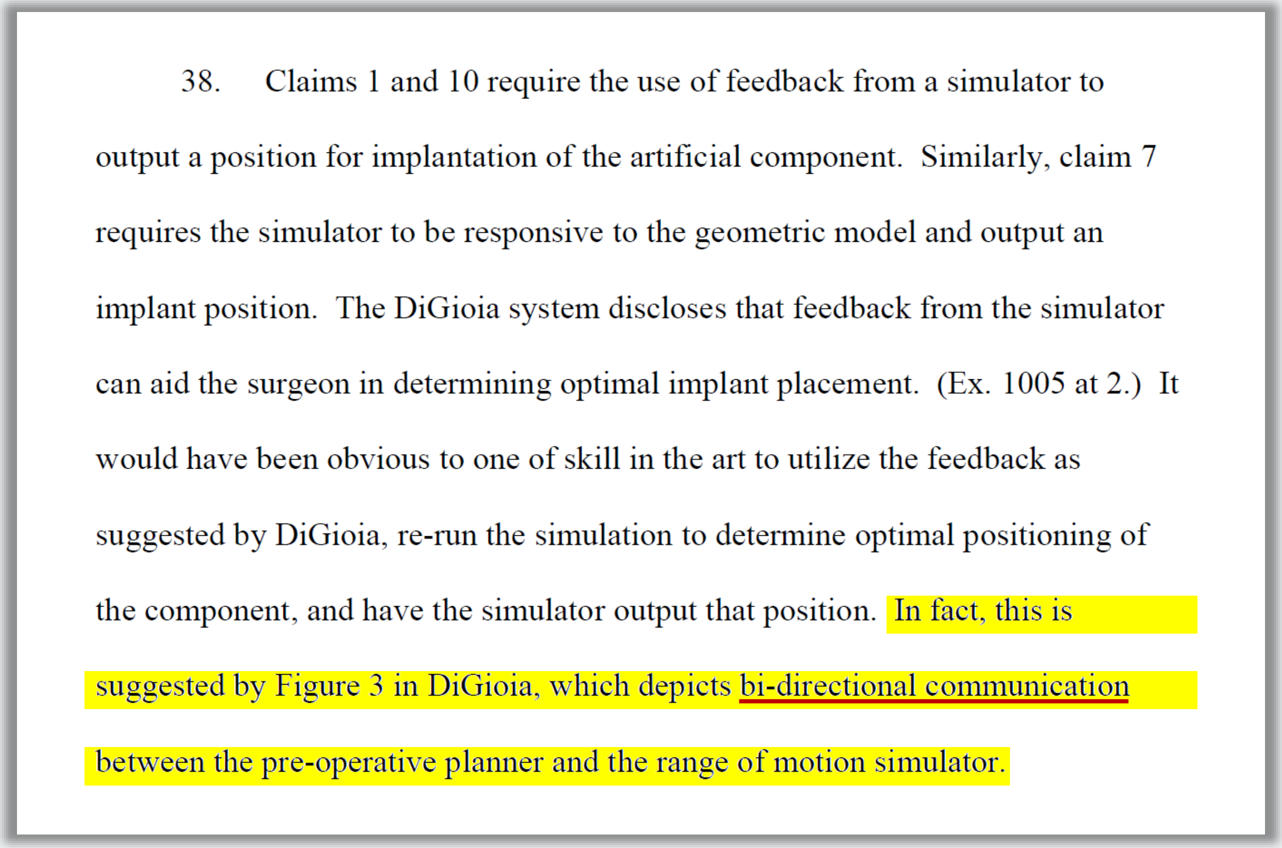
Ex. 2003, Cleary Decl. at ¶ 45
Paper No. 11, Patent Owner Response at 34



Humans	**Robots**
Strengths	Strengths
Strong hand-eye coordination	Good geometric accuracy
Dexterous (at human scale)	Stable and untiring
Flexible and adaptable	Can be designed for a wide range of scales
Can integrate extensive and diverse information	May be sterilized
Able to use qualitative information	Resistant to radiation and infection
Good judgment	Can use diverse sensors (chemical, force, acoustic, etc.) in control
Easy to instruct and debrief	
Limitations	Limitations
Limited dexterity outside natural scale	Poor judgment
Prone to tremor and fatigue	Limited dexterity and hand-eye coordination
Limited geometric accuracy	Limited to relatively simple procedures
Limited ability to use quantitative information	Expensive
Large operating room space requirement	Technology in flux
Limited sterility	Difficult to construct and debug
Susceptible to radiation and infection	

Ex. 2001, Robotics for Surgery at 213
Paper No. 11, Patent Owner Response at 33

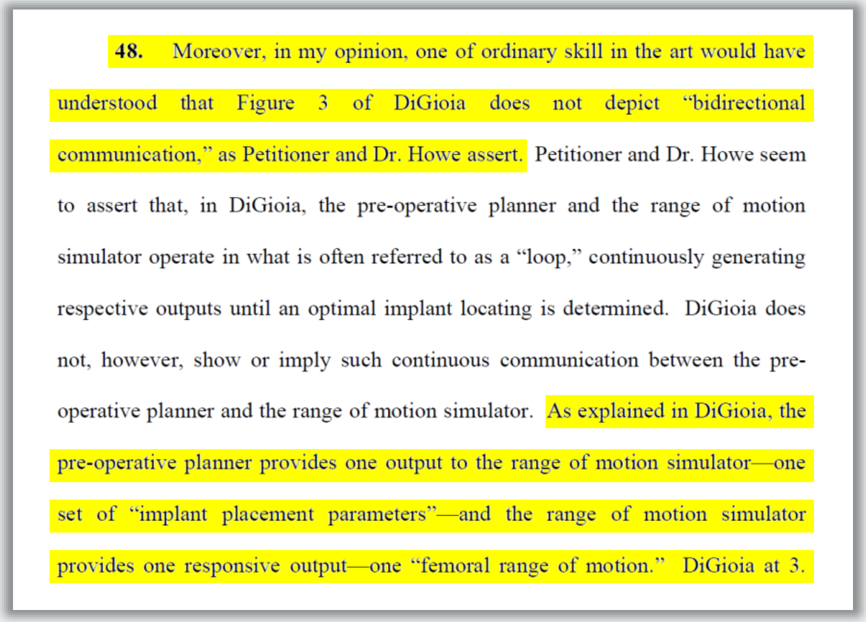
Petitioner's Expert's Conclusory Testimony Does Not Establish Obviousness



38. Claims 1 and 10 require the use of feedback from a simulator to output a position for implantation of the artificial component. Similarly, claim 7 requires the simulator to be responsive to the geometric model and output an implant position. The DiGioia system discloses that feedback from the simulator can aid the surgeon in determining optimal implant placement. (Ex. 1005 at 2.) It would have been obvious to one of skill in the art to utilize the feedback as suggested by DiGioia, re-run the simulation to determine optimal positioning of the component, and have the simulator output that position. In fact, this is suggested by Figure 3 in DiGioia, which depicts bi-directional communication between the pre-operative planner and the range of motion simulator.

Ex. 1004, Howe Decl. at ¶ 38
Paper No. 11, Patent Owner Response at 29

Figure 3 of DiGioia Does Not Show "Bi-Directional Communication"



48. Moreover, in my opinion, one of ordinary skill in the art would have understood that Figure 3 of DiGioia does not depict "bidirectional communication," as Petitioner and Dr. Howe assert. Petitioner and Dr. Howe seem to assert that, in DiGioia, the pre-operative planner and the range of motion simulator operate in what is often referred to as a "loop," continuously generating respective outputs until an optimal implant locating is determined. DiGioia does not, however, show or imply such continuous communication between the pre-operative planner and the range of motion simulator. As explained in DiGioia, the pre-operative planner provides one output to the range of motion simulator—one set of "implant placement parameters"—and the range of motion simulator provides one responsive output—one "femoral range of motion." DiGioia at 3.

Ex. 2003, Cleary Decl. at ¶ 48
Paper No. 11, Patent Owner Response at 32

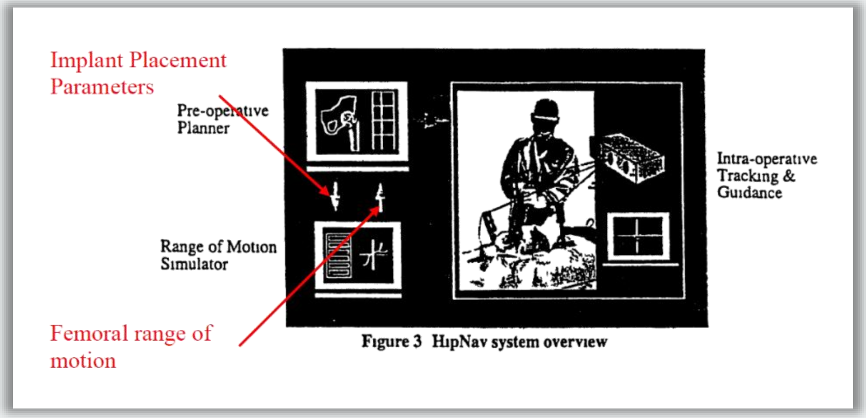
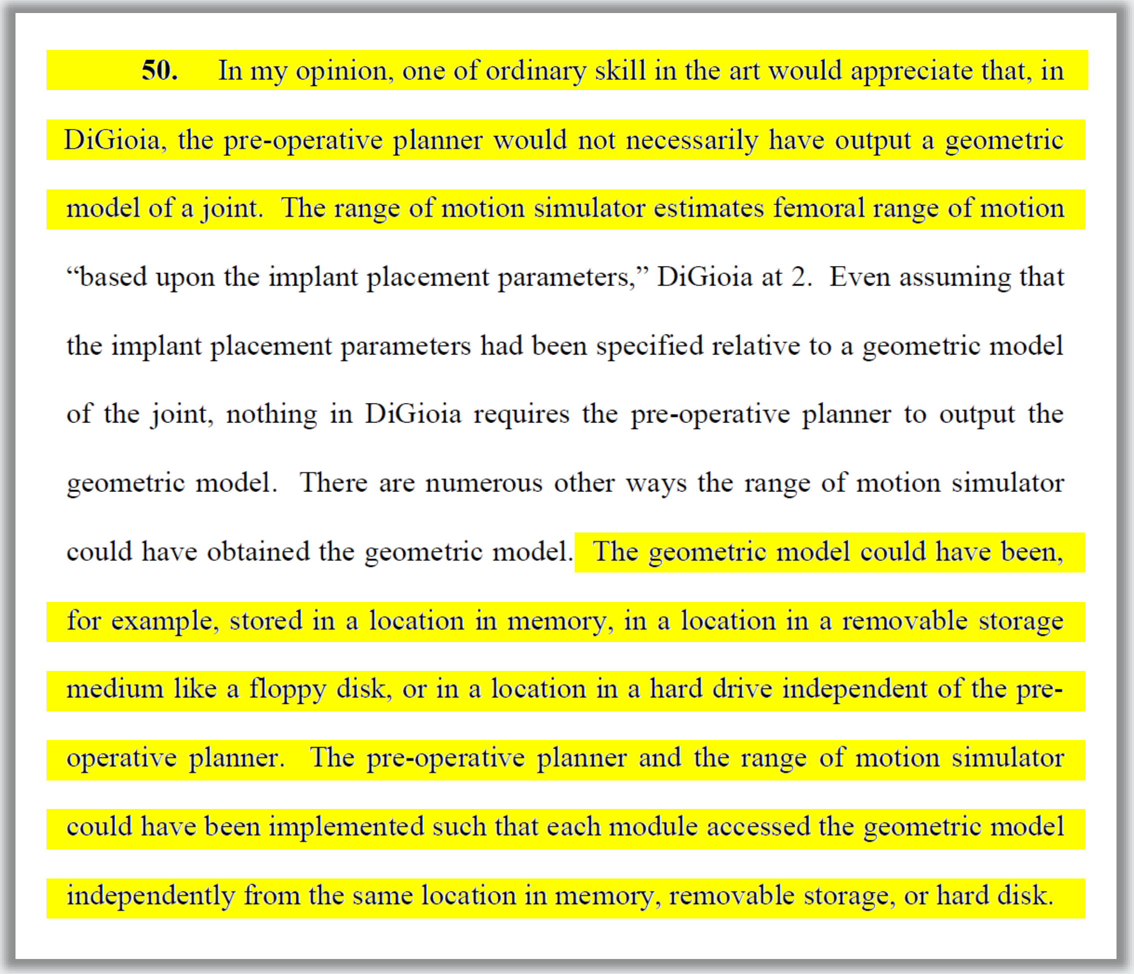


Figure 3 HipNav system overview

Ex. 2003, Cleary Decl. at ¶ 47
Paper No. 11, Patent Owner Response at 31

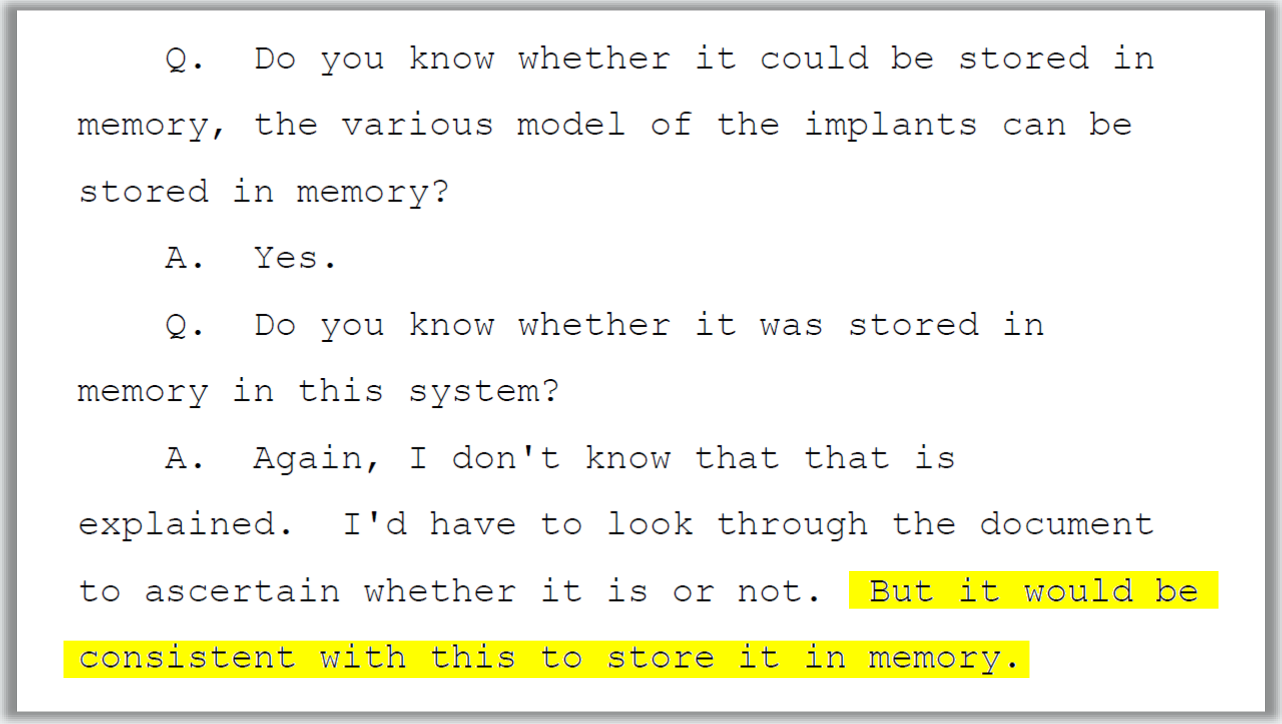
DiGioia Does Not Disclose "Pre-operative Planner" That "Outputs At Least One Geometric Model Of The Joint," As Recited In Claim 1



50. In my opinion, one of ordinary skill in the art would appreciate that, in DiGioia, the pre-operative planner would not necessarily have output a geometric model of a joint. The range of motion simulator estimates femoral range of motion "based upon the implant placement parameters," DiGioia at 2. Even assuming that the implant placement parameters had been specified relative to a geometric model of the joint, nothing in DiGioia requires the pre-operative planner to output the geometric model. There are numerous other ways the range of motion simulator could have obtained the geometric model. The geometric model could have been, for example, stored in a location in memory, in a location in a removable storage medium like a floppy disk, or in a location in a hard drive independent of the pre-operative planner. The pre-operative planner and the range of motion simulator could have been implemented such that each module accessed the geometric model independently from the same location in memory, removable storage, or hard disk.

Ex. 2003, Cleary Decl. at ¶ 50
Paper No. 11, Patent Owner Response at 36

Petitioner’s Expert Acknowledged That Storing the Geometric Model in Memory Would be “Consistent” With DiGioia



Q. Do you know whether it could be stored in memory, the various model of the implants can be stored in memory?

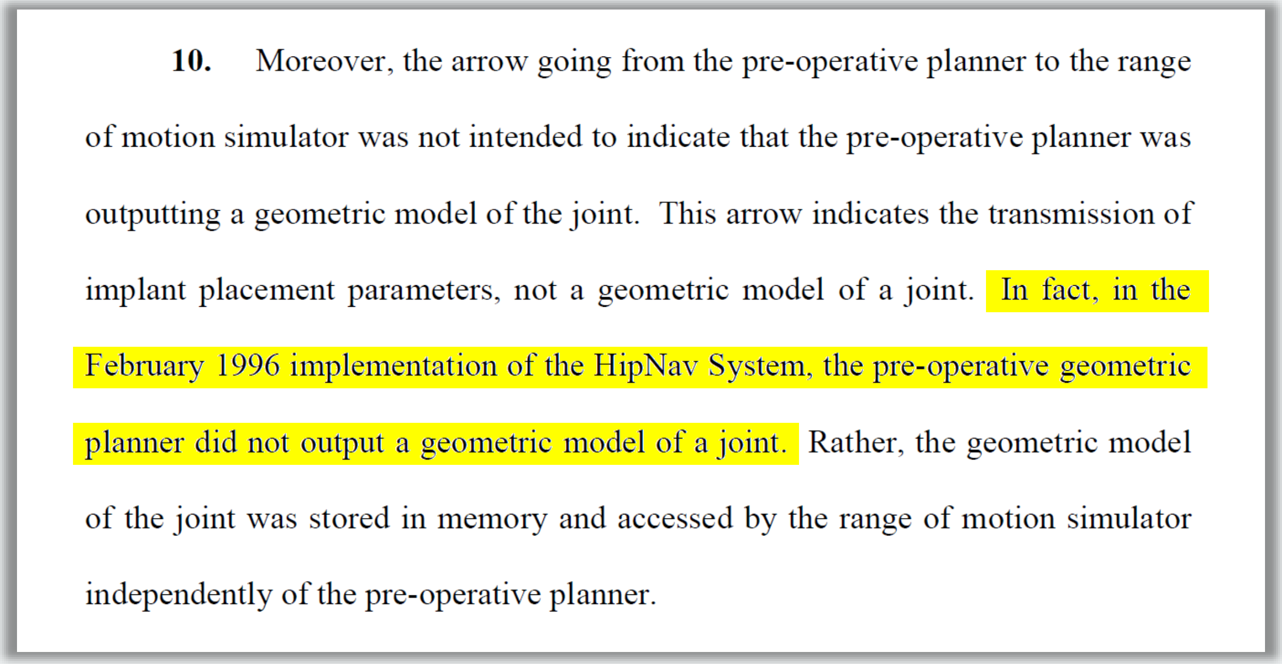
A. Yes.

Q. Do you know whether it was stored in memory in this system?

A. Again, I don't know that that is explained. I'd have to look through the document to ascertain whether it is or not. But it would be consistent with this to store it in memory.

Ex. 2006, Howe Dep. at 85:12-21
Paper No. 11, Patent Owner Response at 36

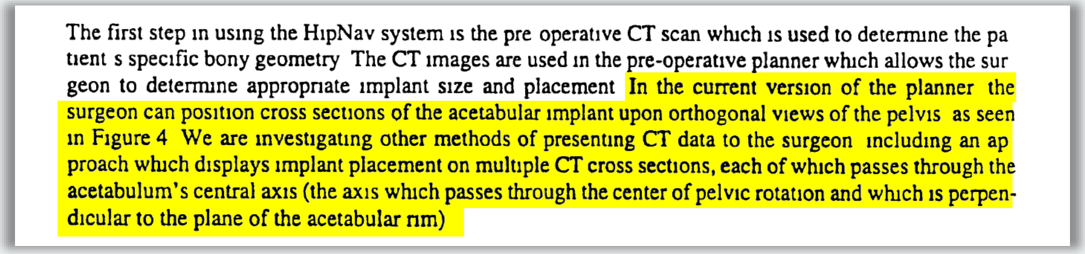
The Pre-Operative Planner Did Not Output a Geometric Model of a Joint in the February 1996 Implementation of HipNav



10. Moreover, the arrow going from the pre-operative planner to the range of motion simulator was not intended to indicate that the pre-operative planner was outputting a geometric model of the joint. This arrow indicates the transmission of implant placement parameters, not a geometric model of a joint. In fact, in the February 1996 implementation of the HipNav System, the pre-operative geometric planner did not output a geometric model of a joint. Rather, the geometric model of the joint was stored in memory and accessed by the range of motion simulator independently of the pre-operative planner.

Ex. 2002, Jaramaz Decl. at ¶ 10
Paper No. 11, Patent Owner Response at 36

DiGioia Does Not Disclose "Creating a Three Dimensional Component Model of the Artificial Implant," as Recited in Claim 17



The first step in using the HipNav system is the pre operative CT scan which is used to determine the patient s specific bony geometry The CT images are used in the pre-operative planner which allows the surgeon to determine appropriate implant size and placement In the current version of the planner the surgeon can position cross sections of the acetabular implant upon orthogonal views of the pelvis as seen in Figure 4 We are investigating other methods of presenting CT data to the surgeon including an approach which displays implant placement on multiple CT cross sections, each of which passes through the acetabulum's central axis (the axis which passes through the center of pelvic rotation and which is perpendicular to the plane of the acetabular rim)

Ex. 1005, DiGioia at 3
Paper No. 11, Patent Owner Response at 37

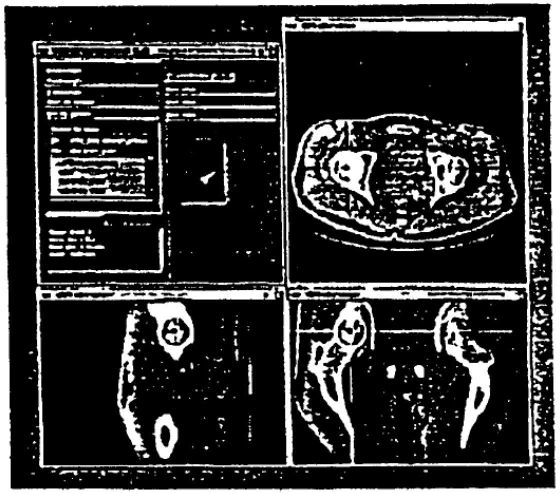
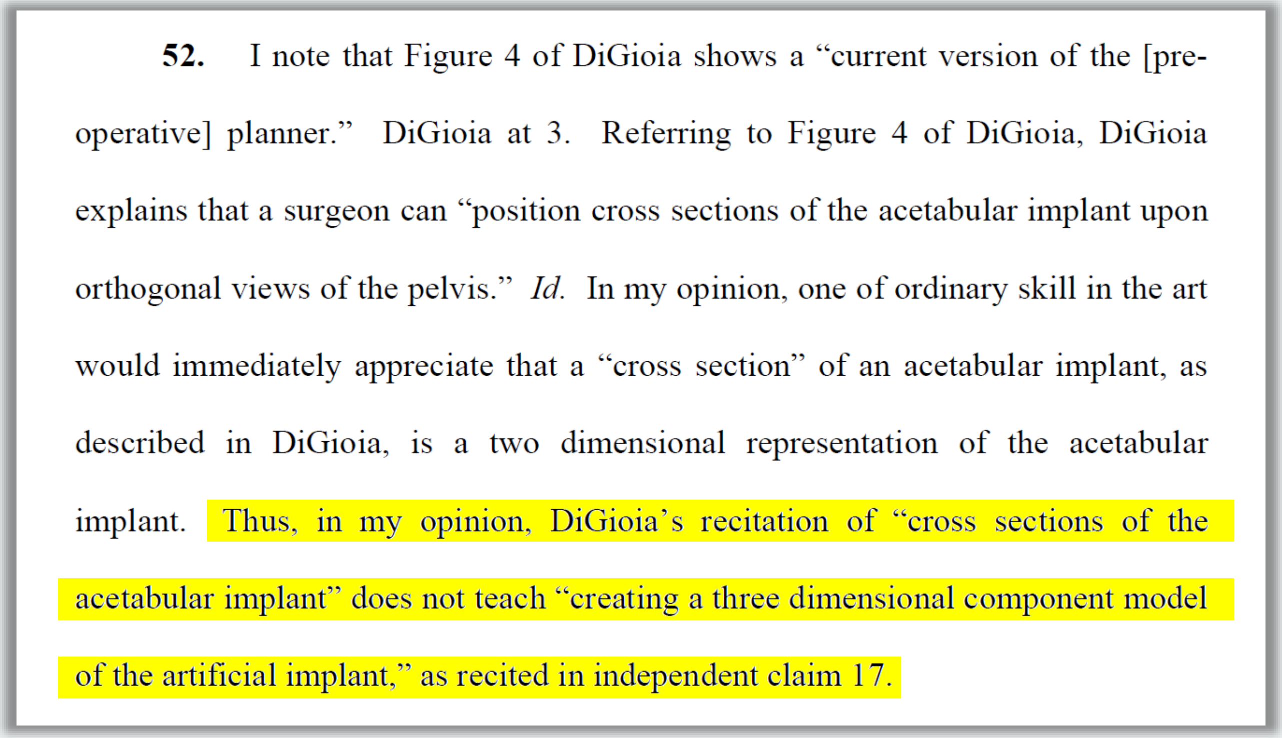


Figure 4 Pre-operative planner

Ex. 1005, DiGioia at Fig. 4
Paper No. 2, Petition at 26

DiGioia Does Not Disclose “Creating a Three Dimensional Component Model of the Artificial Implant,” as Recited in Claim 17



52. I note that Figure 4 of DiGioia shows a “current version of the [pre-operative] planner.” DiGioia at 3. Referring to Figure 4 of DiGioia, DiGioia explains that a surgeon can “position cross sections of the acetabular implant upon orthogonal views of the pelvis.” *Id.* In my opinion, one of ordinary skill in the art would immediately appreciate that a “cross section” of an acetabular implant, as described in DiGioia, is a two dimensional representation of the acetabular implant. Thus, in my opinion, DiGioia’s recitation of “cross sections of the acetabular implant” does not teach “creating a three dimensional component model of the artificial implant,” as recited in independent claim 17.

Ex. 2003, Cleary Decl. at ¶ 52
Paper No. 11, Patent Owner Response at 37

Order of Presentation – ’411 Patent

- Introduction

- Topics in Dispute

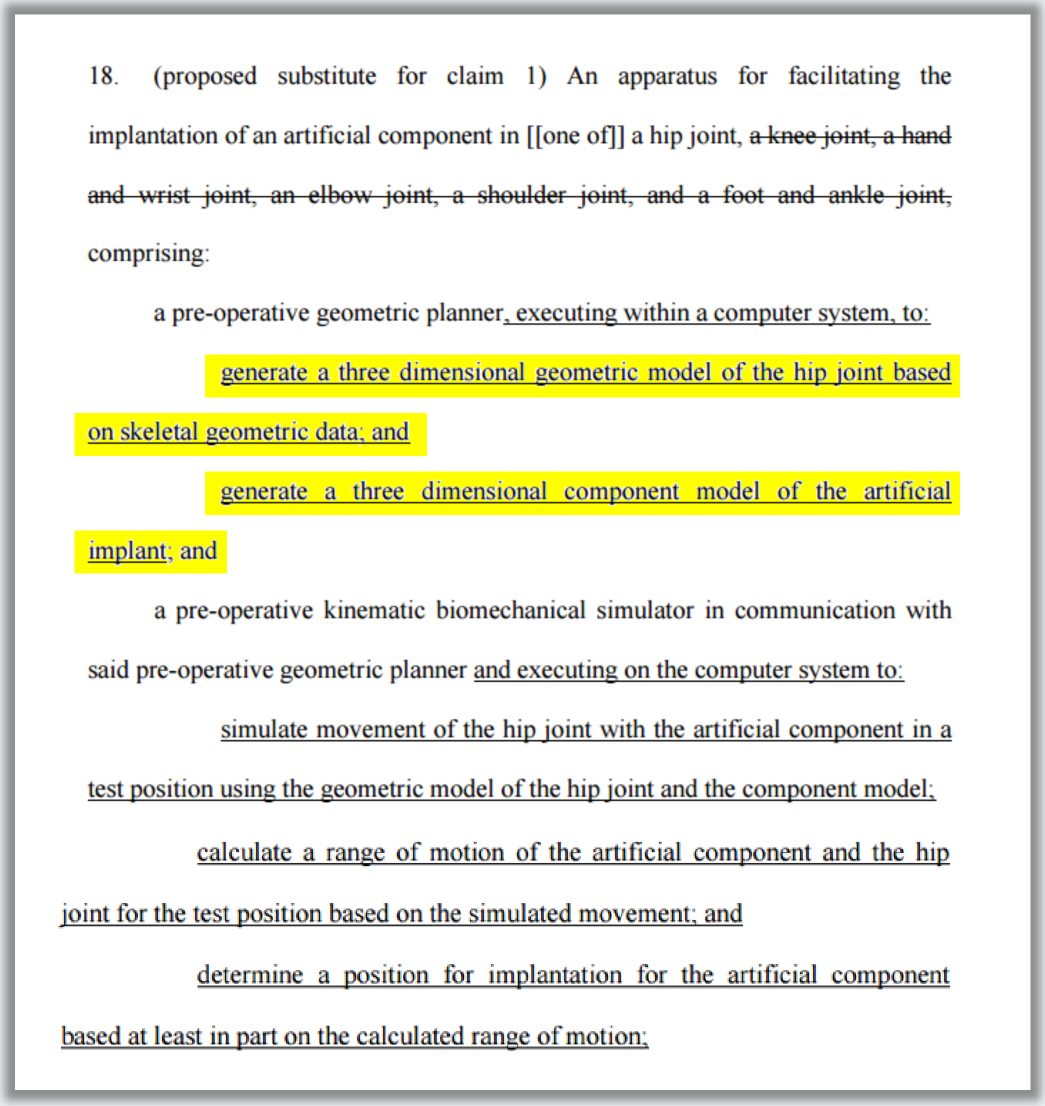
1. DiGioia Is Not Prior Art

2. DiGioia Does Not Render Claims 1-15 and 17 Obvious and DiGioia in View of DiGioia II Does Not Render Claim 16 Obvious

3. **Motion to Amend**

4. Motion to Exclude

Proposed Substitute Claim 18



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:

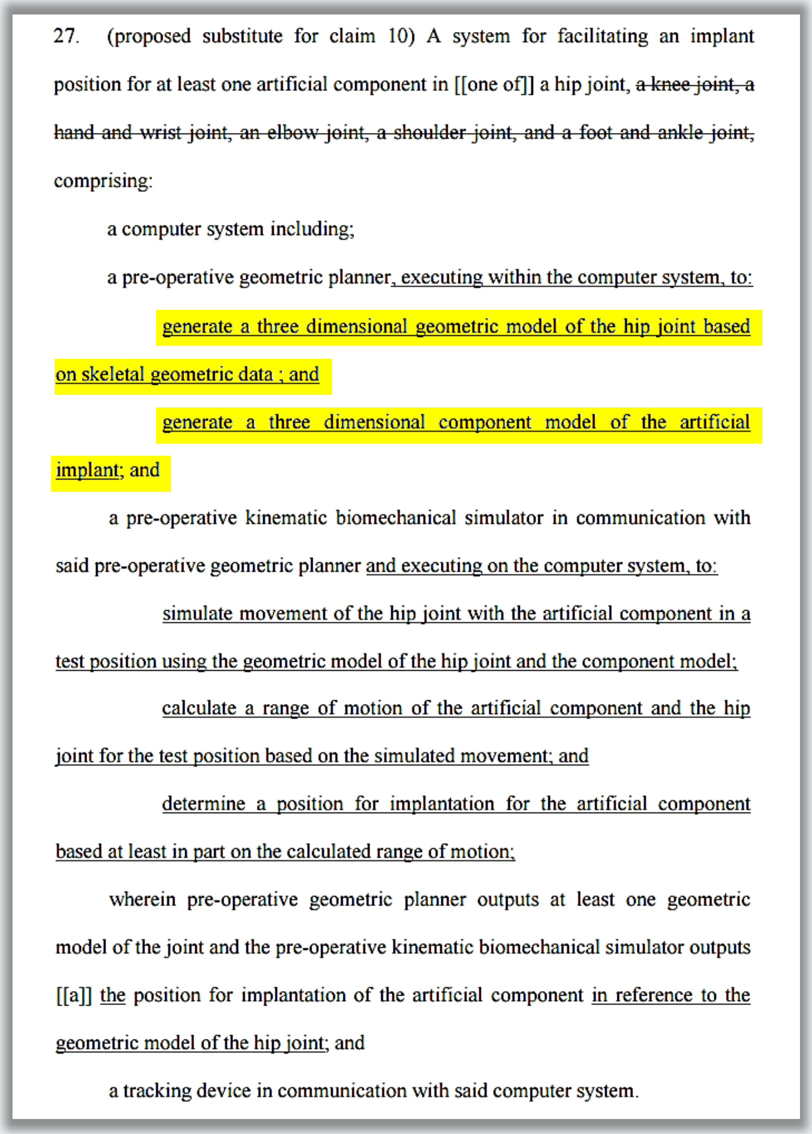
simulate movement of the hip joint with the artificial component in a test position using the geometric model of the hip joint and the component model;

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;

Paper No. 12, Motion to Amend at 18-19

Proposed Substitute Claim 27



27. (proposed substitute for claim 10) A system for facilitating an implant position for at least one 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 computer system including;

a pre-operative geometric planner, executing within the 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

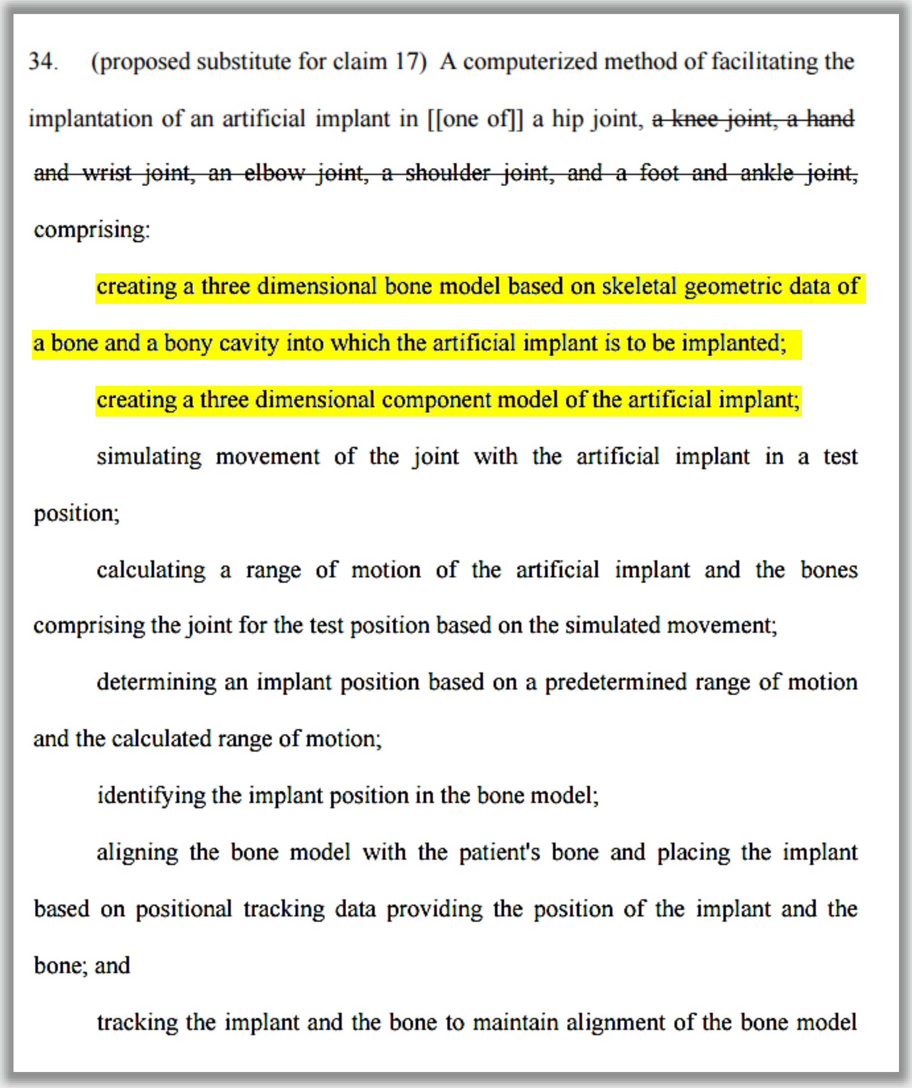
determine a position for implantation for the artificial component based at least in part on the calculated range of motion;

wherein 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; and

a tracking device in communication with said computer system.

Paper No. 12, Motion to Amend at 20-21

Proposed Substitute Claim 34



34. (proposed substitute for claim 17) A computerized method of facilitating the implantation of an artificial implant 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:

creating a three dimensional bone model based on skeletal geometric data of a bone and a bony cavity into which the artificial implant is to be implanted;

creating a three dimensional component model of the artificial implant;

simulating movement of the joint with the artificial implant in a test position;

calculating a range of motion of the artificial implant and the bones comprising the joint for the test position based on the simulated movement;

determining an implant position based on a predetermined range of motion and the calculated range of motion;

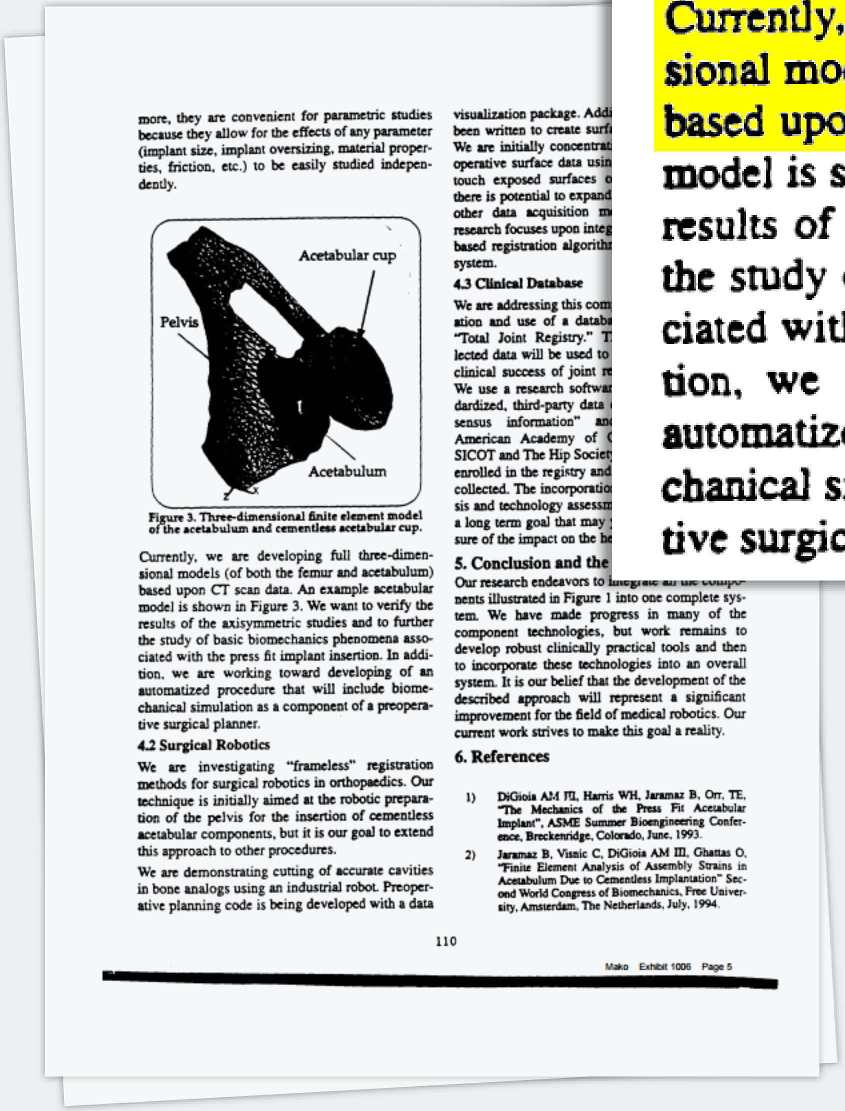
identifying the implant position in the bone model;

aligning the bone model with the patient's bone and placing the implant based on positional tracking data providing the position of the implant and the bone; and

tracking the implant and the bone to maintain alignment of the bone model

Paper No. 12, Motion to Amend at 22-23

DiGioia II Does Not Disclose a "Three-Dimensional Model of the Hip Joint" or a "Three-Dimensional Component Model of the Artificial Component"



more, they are convenient for parametric studies because they allow for the effects of any parameter (implant size, implant oversizing, material properties, friction, etc.) to be easily studied independently.

Figure 3. Three-dimensional finite element model of the acetabulum and cementless acetabular cup.

Currently, we are developing full three-dimensional models (of both the femur and acetabulum) based upon CT scan data. An example acetabular model is shown in Figure 3. We want to verify the results of the axisymmetric studies and to further the study of basic biomechanics phenomena associated with the press fit implant insertion. In addition, we are working toward developing of an automatized procedure that will include biomechanical simulation as a component of a preoperative surgical planner.

4.2 Surgical Robotics

We are investigating "frameless" registration methods for surgical robotics in orthopaedics. Our technique is initially aimed at the robotic preparation of the pelvis for the insertion of cementless acetabular components, but it is our goal to extend this approach to other procedures.

We are demonstrating cutting of accurate cavities in bone analogs using an industrial robot. Preoperative planning code is being developed with a data

visualization package. Addi
been written to create surf
We are initially concentrat
operative surface data usin
touch exposed surfaces o
there is potential to expand
other data acquisition m
research focuses upon integ
based registration algorith
system.

4.3 Clinical Database

We are addressing this com
ation and use of a databa
"Total Joint Registry." T
lected data will be used to
clinical success of joint re
We use a research softwa
dardized, third-party data
sensus information" an
American Academy of C
SICOT and The Hip Society
enrolled in the registry and
collected. The incorporatio
sis and technology assessm
a long term goal that may
sure of the impact on the he

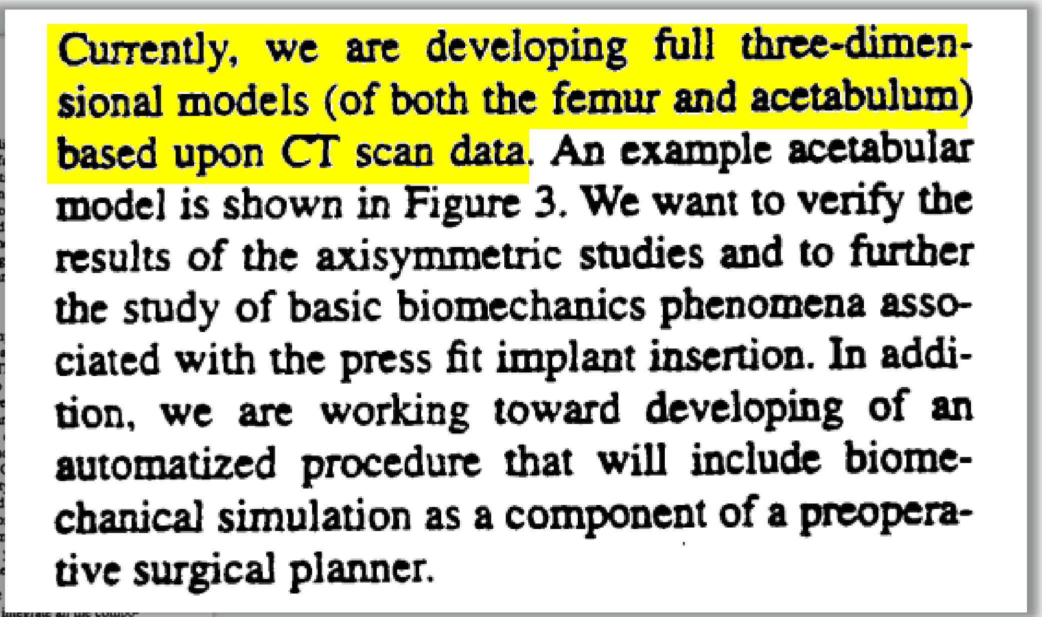
5. Conclusion and the

Our research endeavors to
nents illustrated in Figure 1 into one complete system. We have made progress in many of the component technologies, but work remains to develop robust clinically practical tools and then to incorporate these technologies into an overall system. It is our belief that the development of the described approach will represent a significant improvement for the field of medical robotics. Our current work strives to make this goal a reality.

6. References

1) DiGioia AM III, Harris WH, Jaramaz B, Orr, TE, "The Mechanics of the Press Fit Acetabular Implant", ASME Summer Bioengineering Conference, Breckenridge, Colorado, June, 1993.

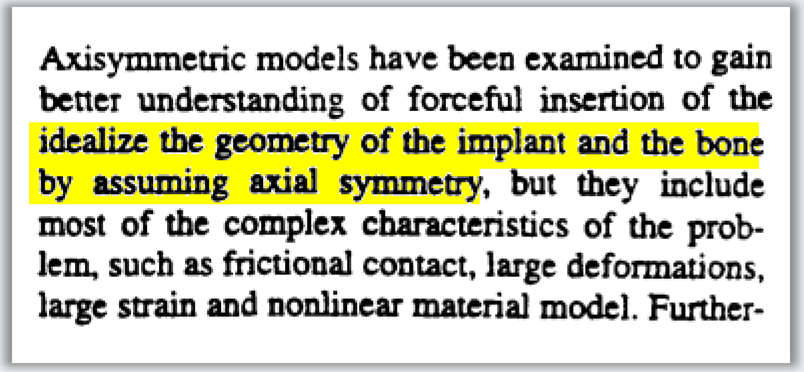
2) Jaramaz B, Visnic C, DiGioia AM III, Ghattas O, "Finite Element Analysis of Assembly Strains in Acetabulum Due to Cementless Implantation" Second World Congress of Biomechanics, Free University, Amsterdam, The Netherlands, July, 1994.



Currently, we are developing full three-dimensional models (of both the femur and acetabulum) based upon CT scan data. An example acetabular model is shown in Figure 3. We want to verify the results of the axisymmetric studies and to further the study of basic biomechanics phenomena associated with the press fit implant insertion. In addition, we are working toward developing of an automatized procedure that will include biomechanical simulation as a component of a preoperative surgical planner.

Ex. 1006, DiGioia II at 110
Paper No. 30, Reply to Opp. to Motion to Amend at 7

DiGioia II's "Axisymmetric Model" Is Not a "Three Dimensional Model of a Hip Joint" Generated Based On "Skeletal Data"



Axisymmetric models have been examined to gain better understanding of forceful insertion of the idealize the geometry of the implant and the bone by assuming axial symmetry, but they include most of the complex characteristics of the problem, such as frictional contact, large deformations, large strain and nonlinear material model. Further-

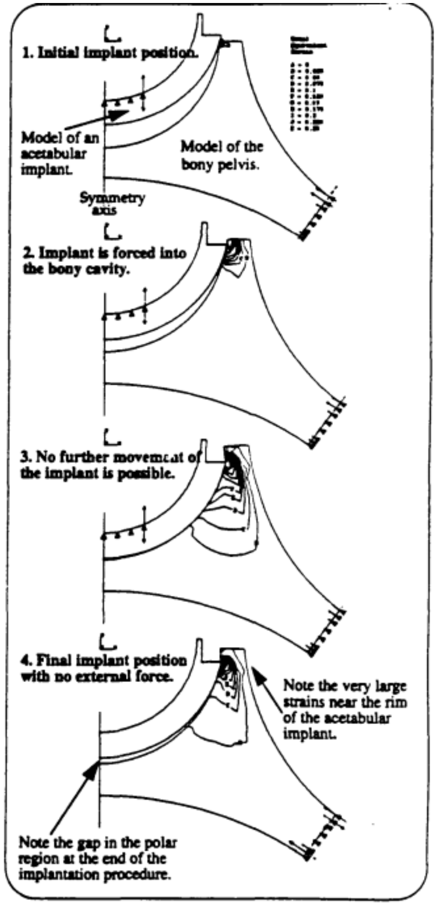
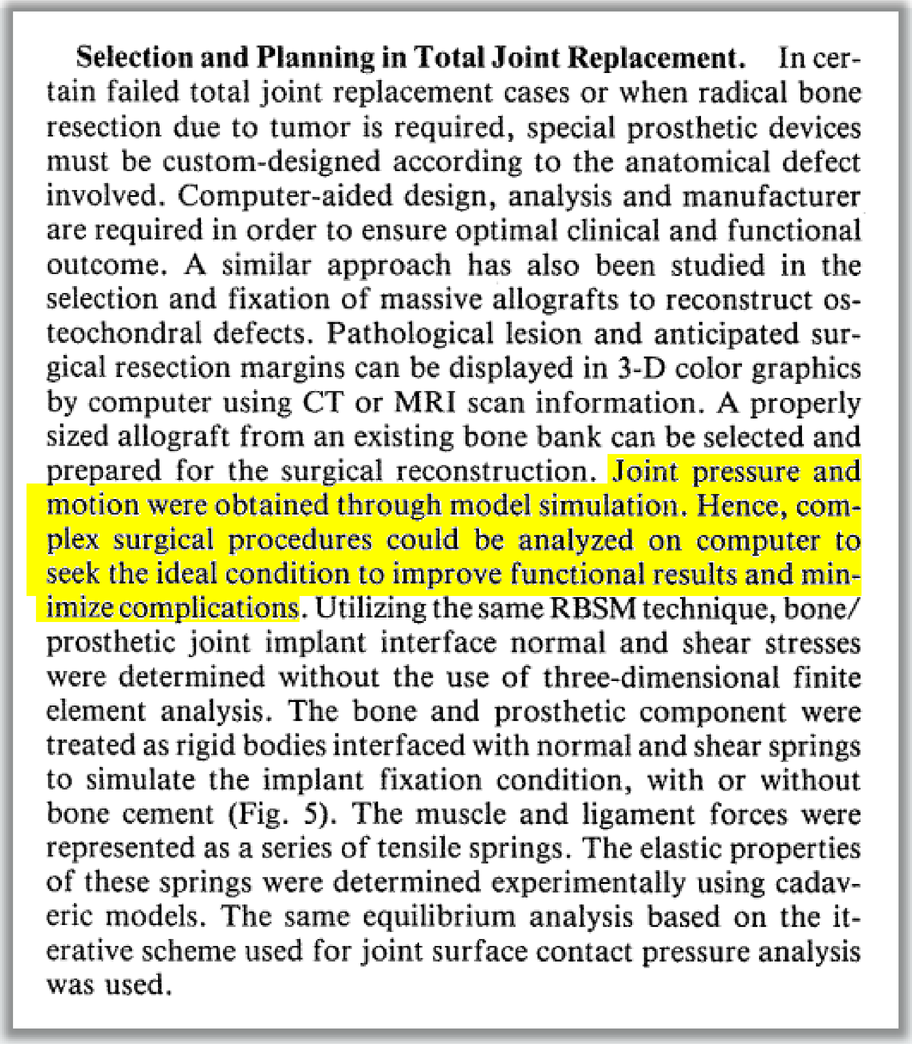


Figure 2. Axisymmetric model of the insertion of a cementless acetabular cup into a prepared acetabular cavity.

Ex. 1006, DiGioia II at 109
Paper No. 30, Reply to Opp. to Motion to Amend at 7-8

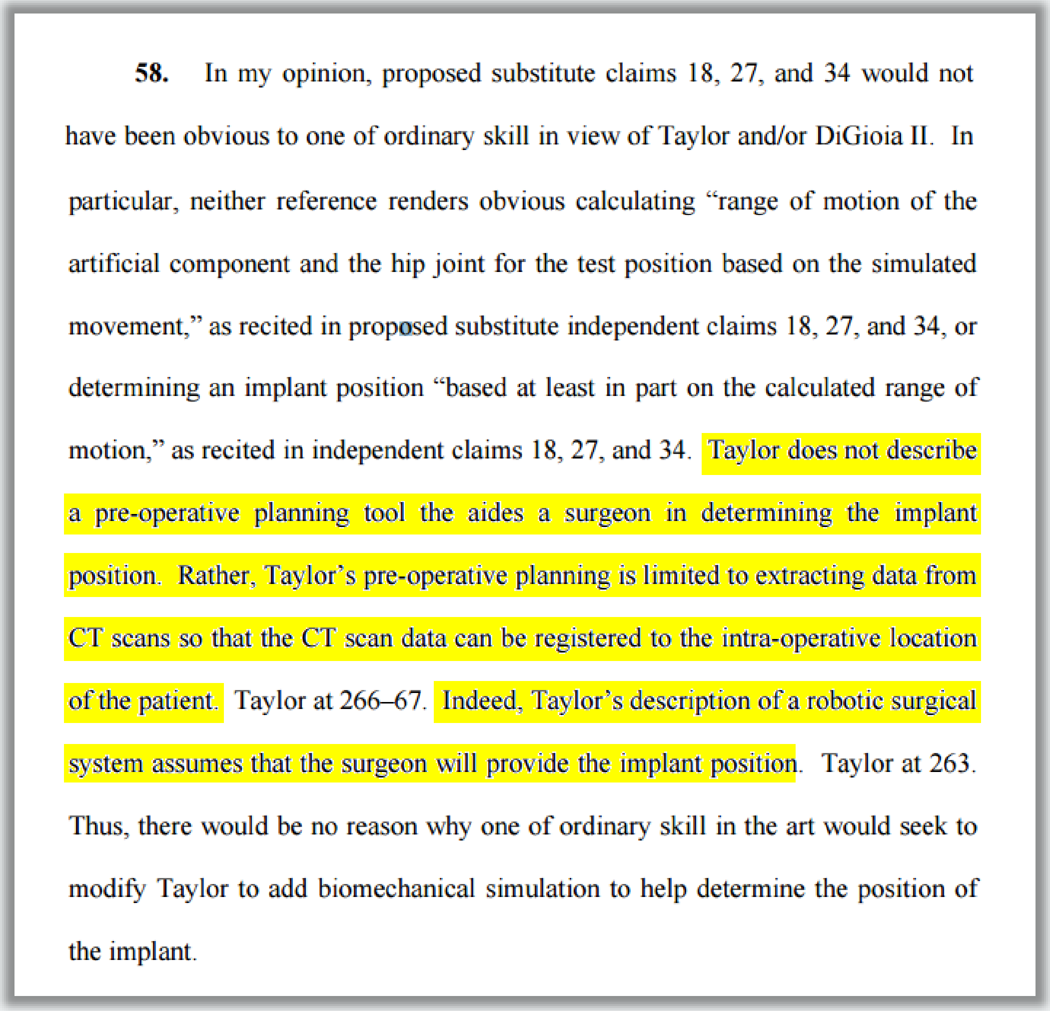
Chao Does Not Disclose a "Three-Dimensional Model of the Hip Joint" or a "Three-Dimensional Component Model of the Artificial Component"



Selection and Planning in Total Joint Replacement. In certain failed total joint replacement cases or when radical bone resection due to tumor is required, special prosthetic devices must be custom-designed according to the anatomical defect involved. Computer-aided design, analysis and manufacturer are required in order to ensure optimal clinical and functional outcome. A similar approach has also been studied in the selection and fixation of massive allografts to reconstruct osteochondral defects. Pathological lesion and anticipated surgical resection margins can be displayed in 3-D color graphics by computer using CT or MRI scan information. A properly sized allograft from an existing bone bank can be selected and prepared for the surgical reconstruction. Joint pressure and motion were obtained through model simulation. Hence, complex surgical procedures could be analyzed on computer to seek the ideal condition to improve functional results and minimize complications. Utilizing the same RBSM technique, bone/prosthetic joint implant interface normal and shear stresses were determined without the use of three-dimensional finite element analysis. The bone and prosthetic component were treated as rigid bodies interfaced with normal and shear springs to simulate the implant fixation condition, with or without bone cement (Fig. 5). The muscle and ligament forces were represented as a series of tensile springs. The elastic properties of these springs were determined experimentally using cadaveric models. The same equilibrium analysis based on the iterative scheme used for joint surface contact pressure analysis was used.

Ex. 1007, Chao at 5
Paper No. 30, Reply to Opp. to Motion to Amend at 9

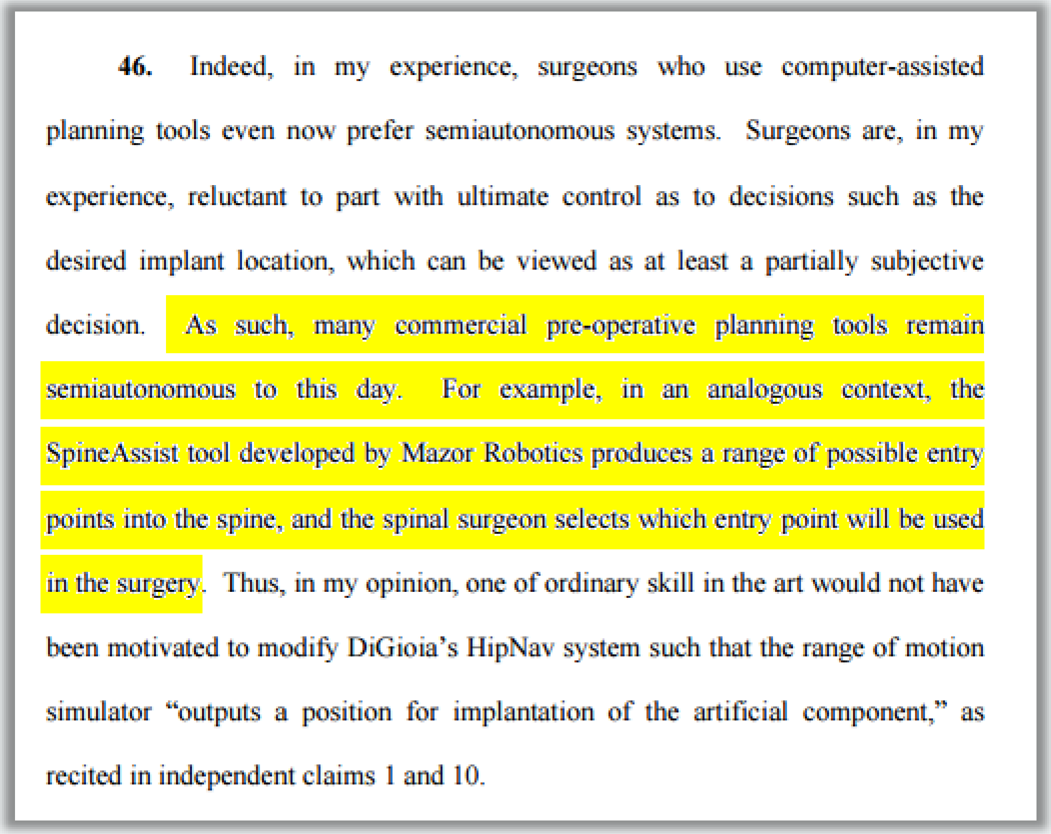
Taylor Does Not Render Proposed Claims 18, 27, and 34 Obvious



58. In my opinion, proposed substitute claims 18, 27, and 34 would not have been obvious to one of ordinary skill in view of Taylor and/or DiGioia II. In particular, neither reference renders obvious calculating “range of motion of the artificial component and the hip joint for the test position based on the simulated movement,” as recited in proposed substitute independent claims 18, 27, and 34, or determining an implant position “based at least in part on the calculated range of motion,” as recited in independent claims 18, 27, and 34. Taylor does not describe a pre-operative planning tool the aides a surgeon in determining the implant position. Rather, Taylor’s pre-operative planning is limited to extracting data from CT scans so that the CT scan data can be registered to the intra-operative location of the patient. Taylor at 266–67. Indeed, Taylor’s description of a robotic surgical system assumes that the surgeon will provide the implant position. Taylor at 263. Thus, there would be no reason why one of ordinary skill in the art would seek to modify Taylor to add biomechanical simulation to help determine the position of the implant.

Ex. 2003, Cleary Decl. at ¶ 58
Paper No. 12, Motion to Amend at 16

Dr. Cleary Did Not Admit SpineAssist Was Prior Art



46. Indeed, in my experience, surgeons who use computer-assisted planning tools even now prefer semiautonomous systems. Surgeons are, in my experience, reluctant to part with ultimate control as to decisions such as the desired implant location, which can be viewed as at least a partially subjective decision. As such, many commercial pre-operative planning tools remain semiautonomous to this day. For example, in an analogous context, the SpineAssist tool developed by Mazor Robotics produces a range of possible entry points into the spine, and the spinal surgeon selects which entry point will be used in the surgery. Thus, in my opinion, one of ordinary skill in the art would not have been motivated to modify DiGioia's HipNav system such that the range of motion simulator "outputs a position for implantation of the artificial component," as recited in independent claims 1 and 10.

Ex. 2003, Cleary Decl. at ¶ 46
Paper No. 22, Patent Owner Response at 34

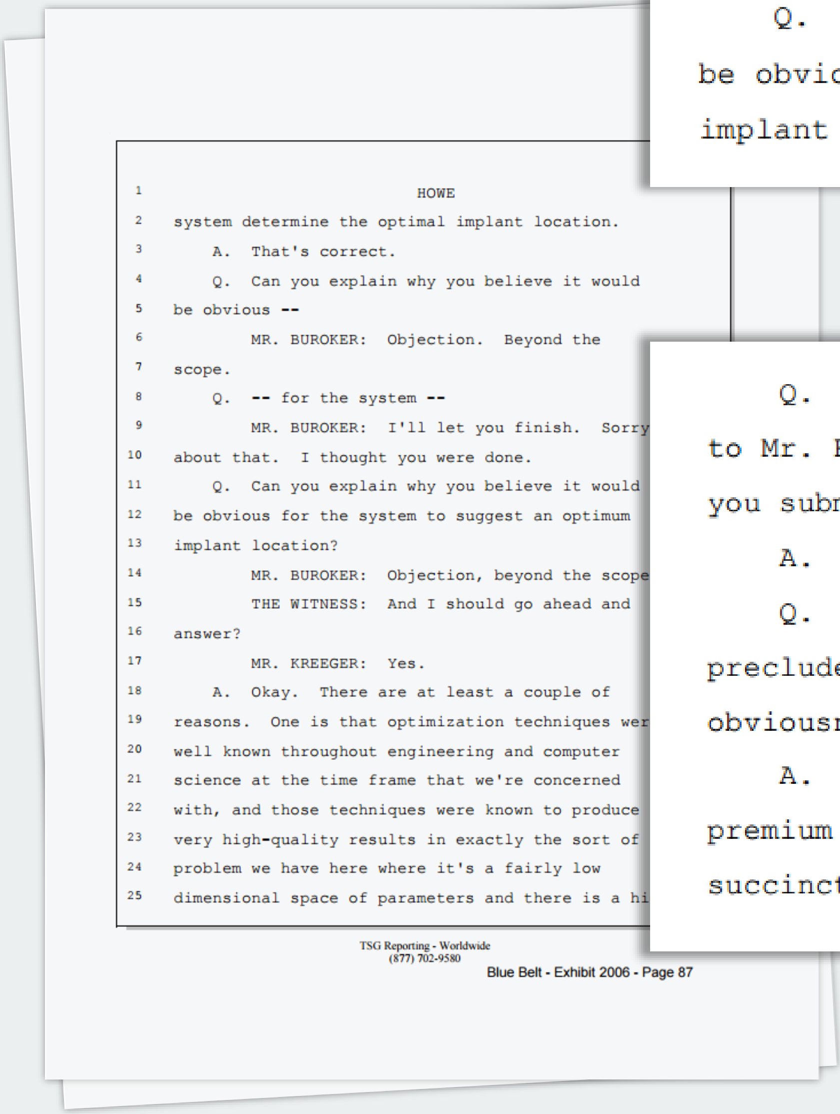
Order of Presentation – ’411 Patent

- Introduction

- Topics in Dispute

1. DiGioia Is Not Prior Art
2. DiGioia Does Not Render Claims 1-15 and 17 Obvious and DiGioia in View of DiGioia II Does Not Render Claim 16 Obvious
3. Motion to Amend
4. **Motion to Exclude**

Dr. Howe's Redirect Testimony Should Be Excluded



HOWE

system determine the optimal implant location.

A. That's correct.

Q. Can you explain why you believe it would be obvious --

MR. BUROKER: Objection. Beyond the scope.

Q. -- for the system --

MR. BUROKER: I'll let you finish. Sorry about that. I thought you were done.

Q. Can you explain why you believe it would be obvious for the system to suggest an optimum implant location?

MR. BUROKER: Objection, beyond the scope

THE WITNESS: And I should go ahead and answer?

MR. KREEGER: Yes.

A. Okay. There are at least a couple of reasons. One is that optimization techniques wer well known throughout engineering and computer science at the time frame that we're concerned with, and those techniques were known to produce very high-quality results in exactly the sort of problem we have here where it's a fairly low dimensional space of parameters and there is a hi

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Blue Belt - Exhibit 2006 - Page 87

Q. Can you explain why you believe it would be obvious for the system to suggest an optimum implant location?

Ex. 2006, Howe Dep. at 87:11-13
Paper No. 38, Reply to Opp. to Mot. to Exclude at 1

Q. Sir, that explanation you've just provided to Mr. Kreeger was not contained in the declaration you submitted in this IPR petition, right?

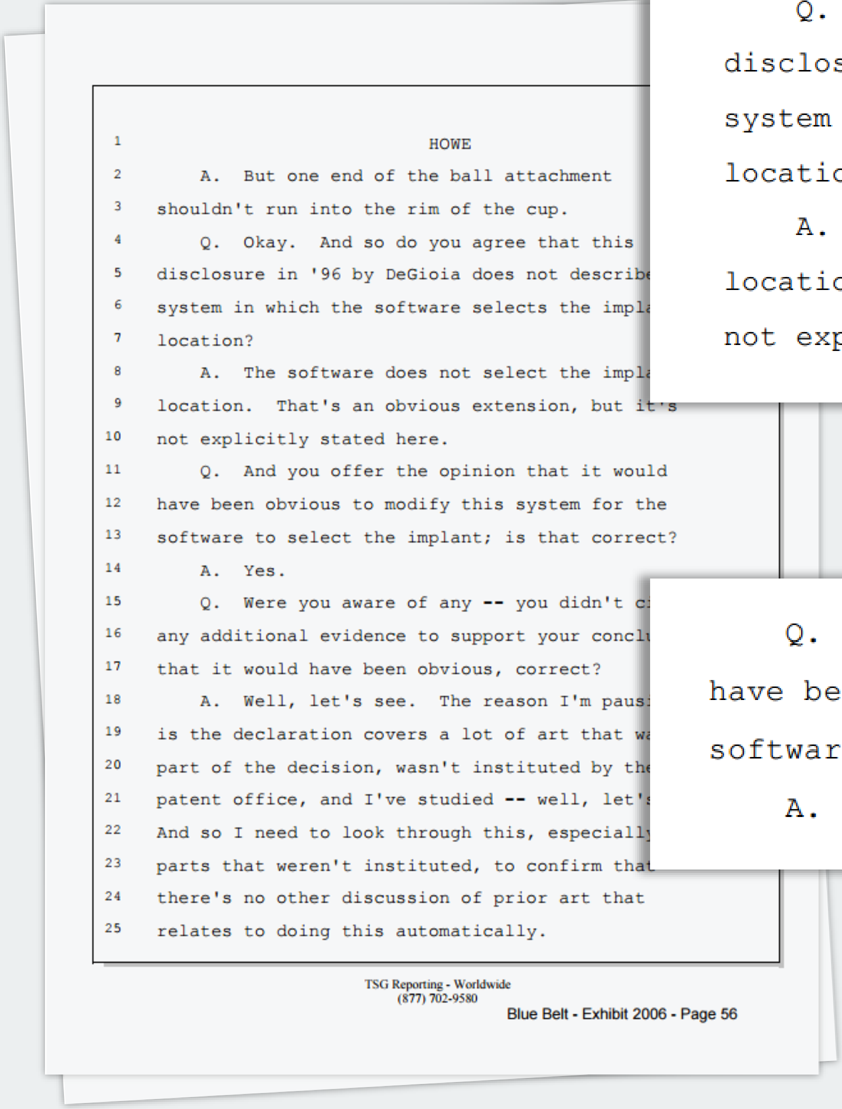
A. That's right.

Q. Was there any reason why you were precluded from providing a detailed opinion about obviousness?

A. Well, succinctness, you know, there's a premium on providing, you know, a clear and succinct document.

Ex. 2006, Howe Dep. at 91:6-15
Paper No. 38, Reply to Opp. to Mot. to Exclude at 7

PO's Cross Examination Did Not Open the Door for the Redirect



HOWE

A. But one end of the ball attachment shouldn't run into the rim of the cup.

Q. Okay. And so do you agree that this disclosure in '96 by DeGioia does not describ system in which the software selects the impla location?

A. The software does not select the impla location. That's an obvious extension, but it's not explicitly stated here.

Q. And you offer the opinion that it would have been obvious to modify this system for the software to select the implant; is that correct?

A. Yes.

Q. Were you aware of any -- you didn't c any additional evidence to support your conclu that it would have been obvious, correct?

A. Well, let's see. The reason I'm paus is the declaration covers a lot of art that wa part of the decision, wasn't instituted by the patent office, and I've studied -- well, let's And so I need to look through this, especiall parts that weren't instituted, to confirm that there's no other discussion of prior art that relates to doing this automatically.

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(877) 702-9580

Blue Belt - Exhibit 2006 - Page 56

Q. Okay. And so do you agree that this disclosure in '96 by DeGioia does not describe a system in which the software selects the implant location?

A. The software does not select the implant location. That's an obvious extension, but it's not explicitly stated here.

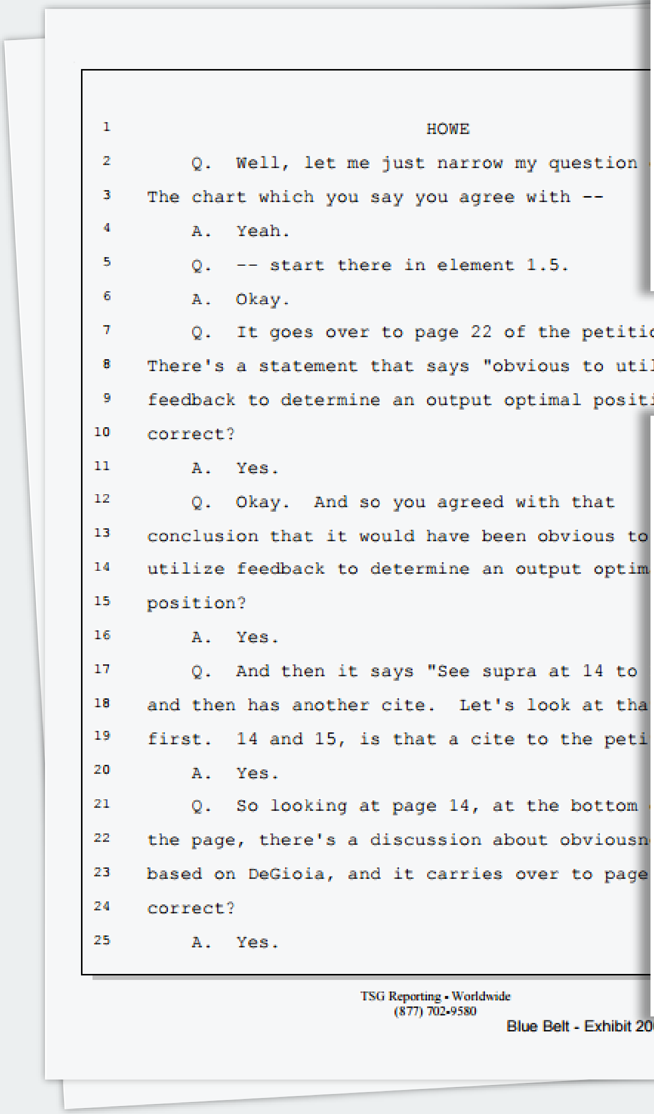
Ex. 2006, Howe Dep. at 56:4-10
Paper No. 34, Opp. to Mot. to Exclude at 2

Q. And you offer the opinion that it would have been obvious to modify this system for the software to select the implant; is that correct?

A. Yes.

Ex. 2006, Howe Dep. at 56:11-14
Paper No. 34, Opp. to Mot. to Exclude at 3

PO's Cross Examination Did Not Open the Door for the Redirect



HOWE

Q. Well, let me just narrow my question
The chart which you say you agree with --

A. Yeah.

Q. -- start there in element 1.5.

A. Okay.

Q. It goes over to page 22 of the petition.
There's a statement that says "obvious to utilize feedback to determine an output optimal position," correct?

A. Yes.

Q. Okay. And so you agreed with that conclusion that it would have been obvious to utilize feedback to determine an output optim
position?

A. Yes.

Q. And then it says "See supra at 14 to
and then has another cite. Let's look at tha
first. 14 and 15, is that a cite to the peti

A. Yes.

Q. So looking at page 14, at the bottom
the page, there's a discussion about obviousn
based on DeGioia, and it carries over to page
correct?

A. Yes.

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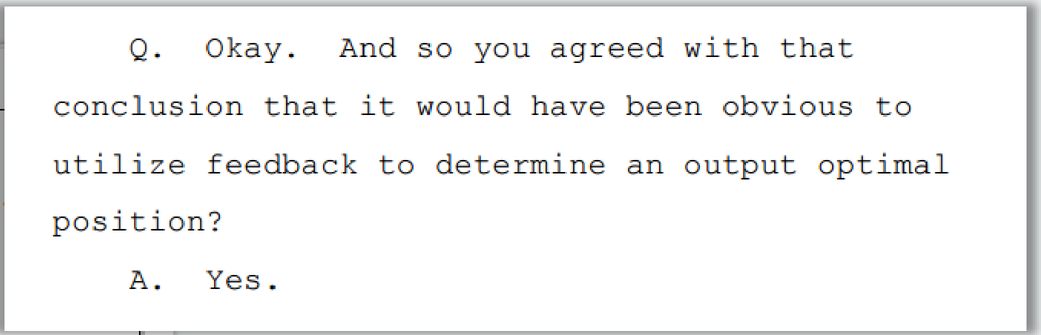
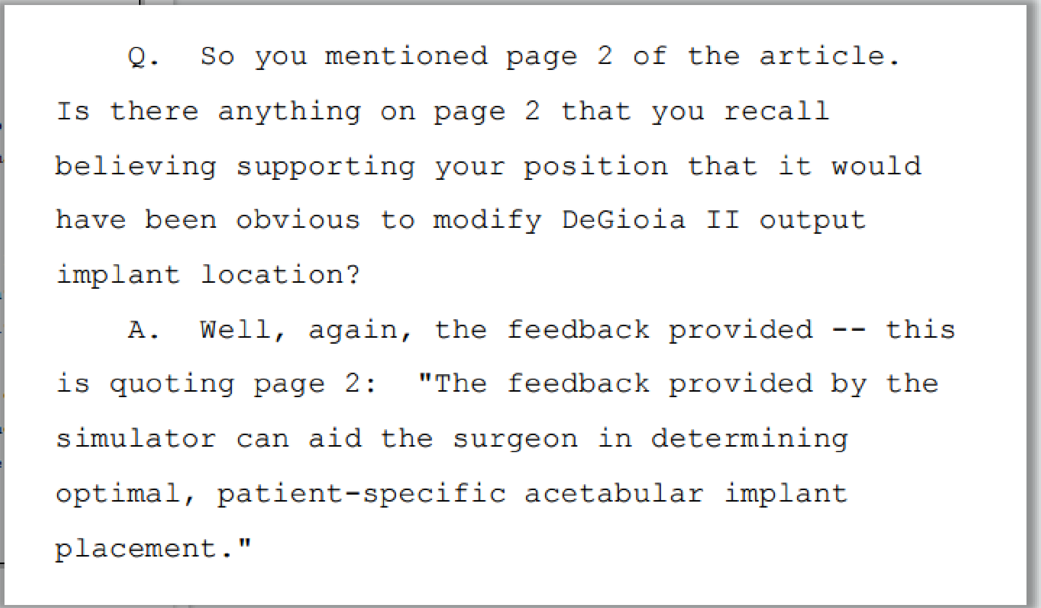
Blue Belt - Exhibit 2006 - Page 57



Q. Okay. And so you agreed with that conclusion that it would have been obvious to utilize feedback to determine an output optimal position?

A. Yes.

Ex. 2006, Howe Dep. at 57:12-16
Paper No. 34, Opp. to Mot. to Exclude at 3



Q. So you mentioned page 2 of the article. Is there anything on page 2 that you recall believing supporting your position that it would have been obvious to modify DeGioia II output implant location?

A. Well, again, the feedback provided -- this is quoting page 2: "The feedback provided by the simulator can aid the surgeon in determining optimal, patient-specific acetabular implant placement."

Ex. 2006, Howe Dep. at 59:5-14
Paper No. 34, Opp. to Mot. to Exclude at 3

Order of Presentation – ’582 Patent

- **Introduction**

- Topics in Dispute

1. Claim Construction

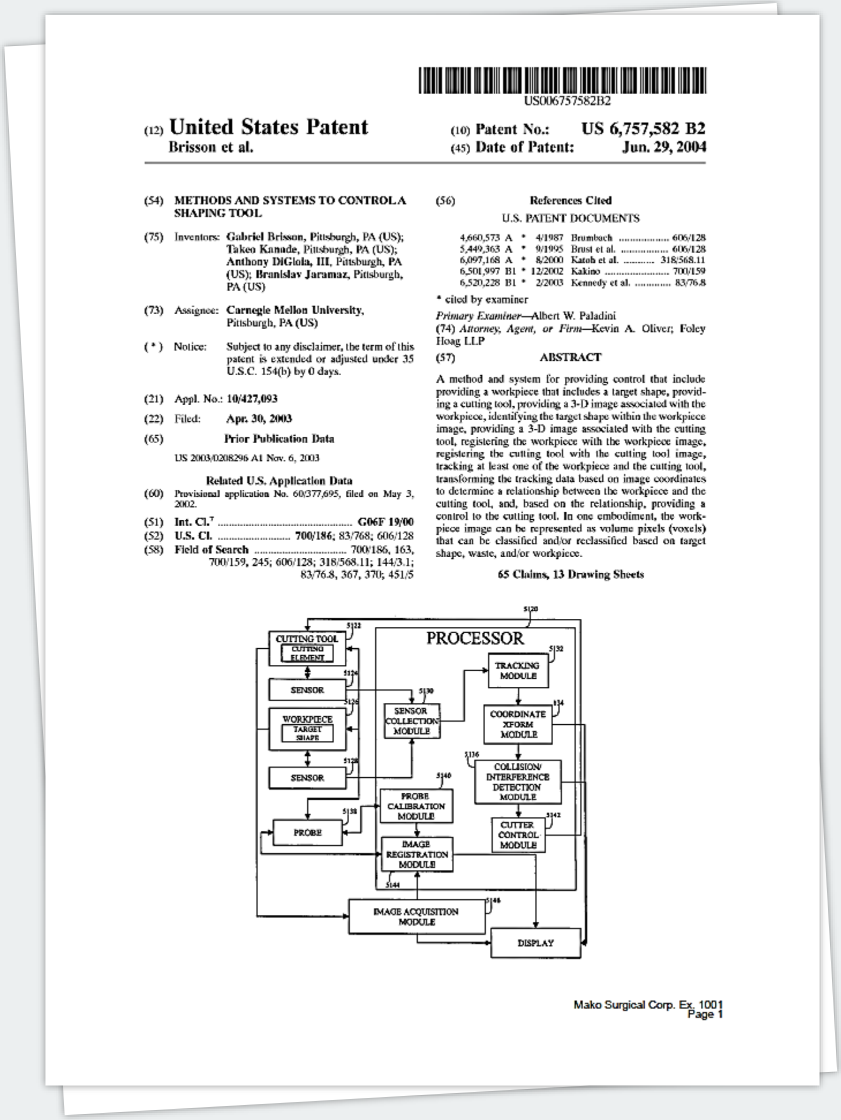
2. Taylor Does Not Anticipate Independent Claims 1, 17, and 24 and Their Dependent Claims

3. Taylor and DiGioia Do Not Render Claim 7 Obvious

4. Taylor and Delp Do Not Render Claims 48 and 49 Obvious

5. The Motion to Exclude Should be Granted

Introduction – ’582 Patent



US006757582B2

(12) **United States Patent**
Brisson et al.

(10) **Patent No.:** **US 6,757,582 B2**
(45) **Date of Patent:** **Jun. 29, 2004**

(54) **METHODS AND SYSTEMS TO CONTROL A SHAPING TOOL**

(75) Inventors: **Gabriel Brisson**, Pittsburgh, PA (US); **Takeo Kanade**, Pittsburgh, PA (US); **Anthony DiGioia, III**, Pittsburgh, PA (US); **Branislav Jaramaz**, Pittsburgh, PA (US)

(73) Assignee: **Carnegie Mellon University**, Pittsburgh, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/427,093**

(22) Filed: **Apr. 30, 2003**

(65) **Prior Publication Data**

US 2003/0208296 A1 Nov. 6, 2003

Related U.S. Application Data

(60) Provisional application No. 60/377,695, filed on May 3, 2002.

(51) **Int. Cl.**^{7} **G06F 19/00**
(52) **U.S. Cl.** **700/186**; 83/768; 606/128
(58) **Field of Search** 700/186, 163, 700/159, 245; 606/128; 318/568.11; 144/3.1; 83/76.8, 367, 370; 451/5

(56) **References Cited**

U.S. PATENT DOCUMENTS

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6,501,997	B1	*	12/2002	Kakino	700/159
6,520,228	B1	*	2/2003	Kennedy et al.	83/76.8

* cited by examiner

Primary Examiner—Albert W. Paladini
(74) *Attorney, Agent, or Firm*—Kevin A. Oliver; Foley Hoag LLP

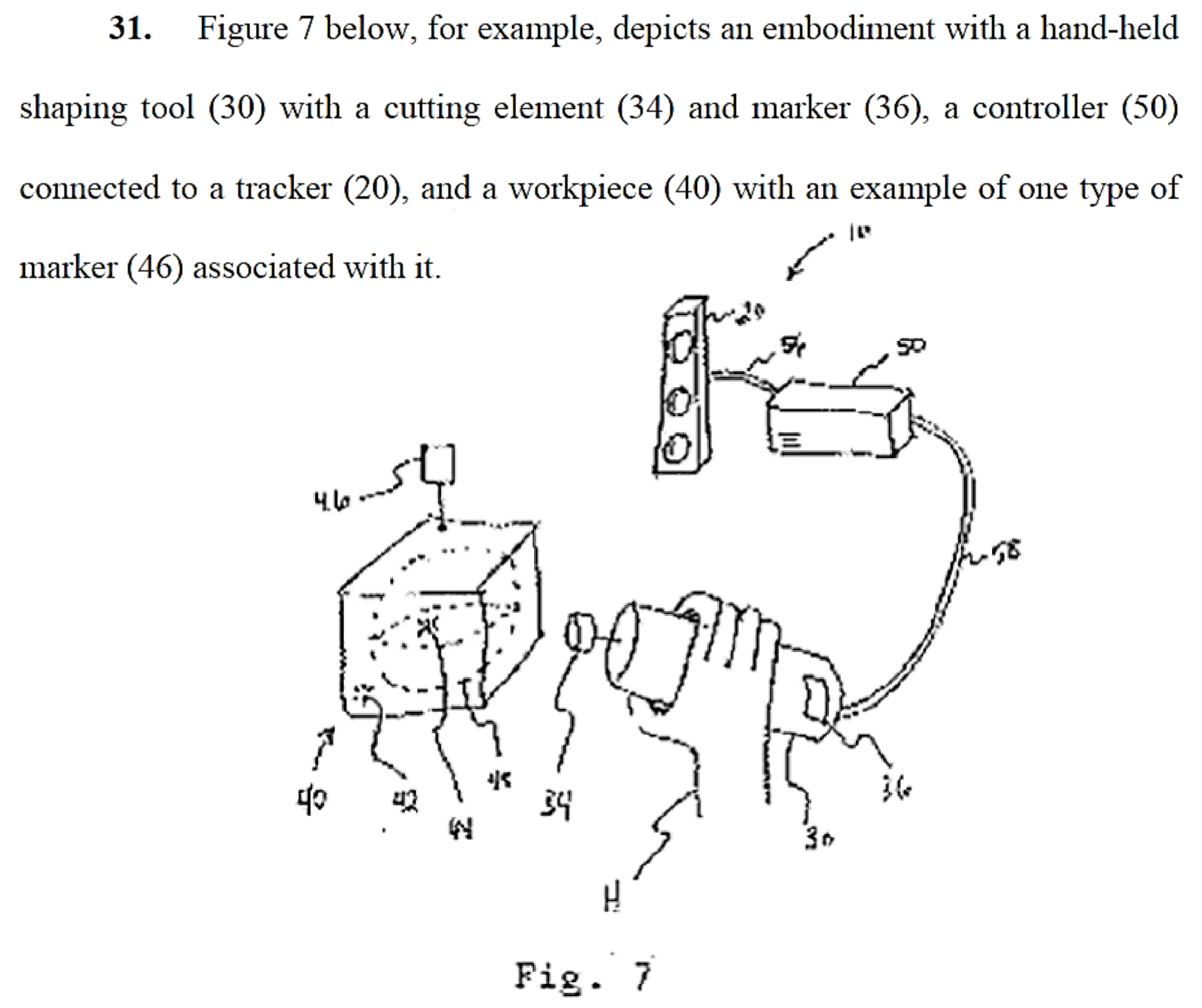
(57) **ABSTRACT**

A method and system for providing control that include providing a workpiece that includes a target shape, providing a cutting tool, providing a 3-D image associated with the workpiece, identifying the target shape within the workpiece image, providing a 3-D image associated with the cutting tool, registering the workpiece with the workpiece image, registering the cutting tool with the cutting tool image, tracking at least one of the workpiece and the cutting tool, transforming the tracking data based on image coordinates to determine a relationship between the workpiece and the cutting tool, and, based on the relationship, providing a control to the cutting tool. In one embodiment, the workpiece image can be represented as volume pixels (voxels) that can be classified and/or reclassified based on target shape, waste, and/or workpiece.

65 Claims, 13 Drawing Sheets

Mako Surgical Corp. Ex. 1001
Page 1

Introduction – ’582 Patent



31. Figure 7 below, for example, depicts an embodiment with a hand-held shaping tool (30) with a cutting element (34) and marker (36), a controller (50) connected to a tracker (20), and a workpiece (40) with an example of one type of marker (46) associated with it.

Fig. 7

Ex. 1001, ’582 Patent at Fig. 7
Ex. 2004, Cleary Decl. at ¶ 31

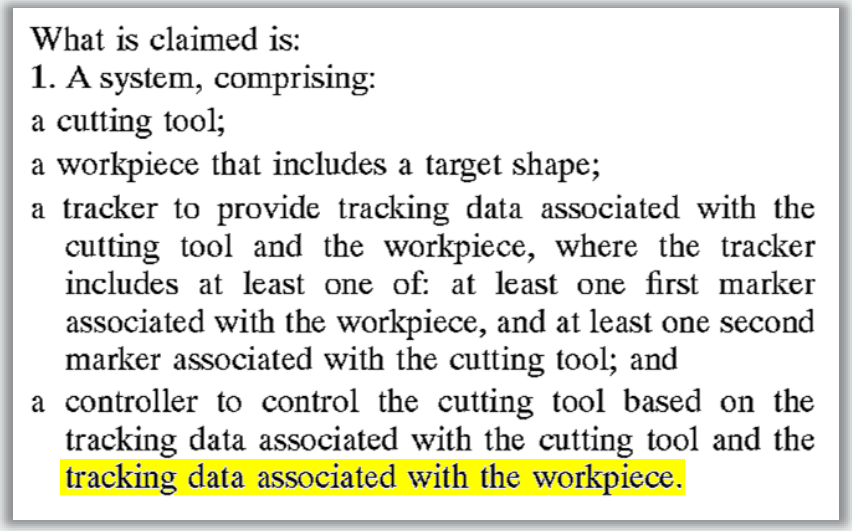
Order of Presentation – ’582 Patent

- Introduction

- Topics in Dispute

1. Claim Construction
2. Taylor Does Not Anticipate Independent Claims 1, 17, and 24 and Their Dependent Claims
3. Taylor and DiGioia Do Not Render Claim 7 Obvious
4. Taylor and Delp Do Not Render Claims 48 and 49 Obvious
5. The Motion to Exclude Should be Granted

Claim Construction – "Tracking Data"



What is claimed is:

1. A system, comprising:

a cutting tool;

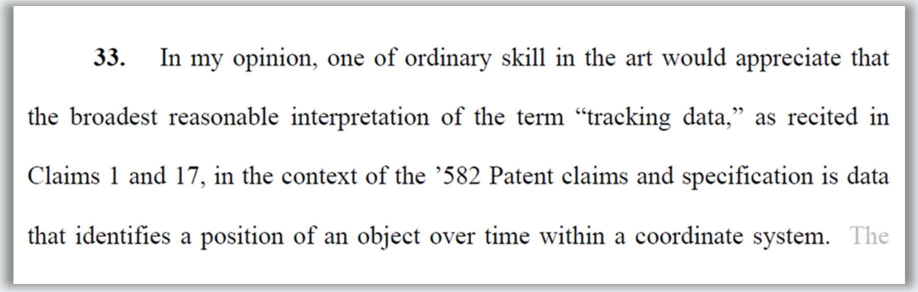
a workpiece that includes a target shape;

a tracker to provide tracking data associated with the cutting tool and the workpiece, where the tracker includes at least one of: at least one first marker associated with the workpiece, and at least one second marker associated with the cutting tool; and

a controller to control the cutting tool based on the tracking data associated with the cutting tool and the tracking data associated with the workpiece.

Ex. 1001, '582 Patent at 20:35-47

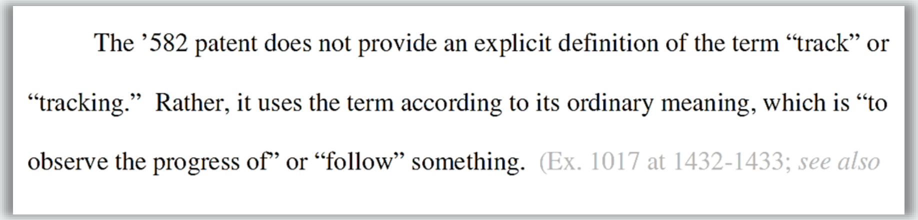
Patent Owner's Proposed Construction



33. In my opinion, one of ordinary skill in the art would appreciate that the broadest reasonable interpretation of the term "tracking data," as recited in Claims 1 and 17, in the context of the '582 Patent claims and specification is data that identifies a position of an object over time within a coordinate system. The

Ex. 2004, Cleary Decl. at ¶ 33
Paper No. 10, Patent Owner Response at 8

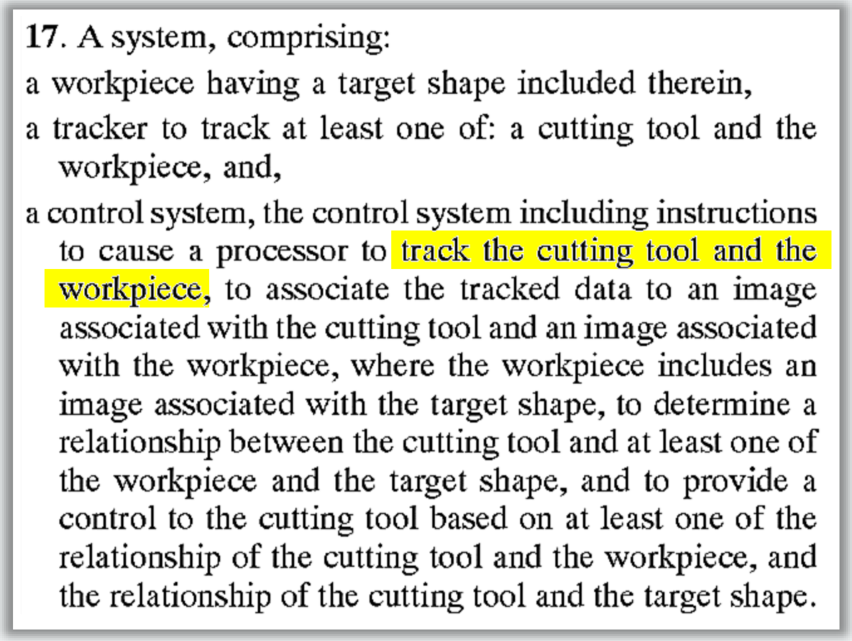
Petitioner's Proposed Construction



The '582 patent does not provide an explicit definition of the term "track" or "tracking." Rather, it uses the term according to its ordinary meaning, which is "to observe the progress of" or "follow" something. (Ex. 1017 at 1432-1433; *see also*

Paper No. 13, Pet'r's Reply at 2

Claim Construction – "Tracking Data"



17. A system, comprising:

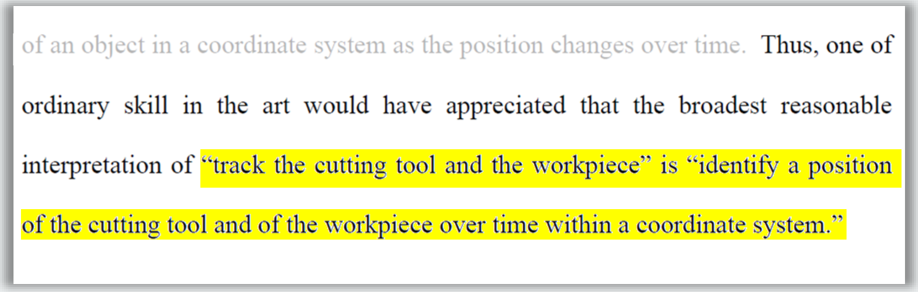
a workpiece having a target shape included therein,

a tracker to track at least one of: a cutting tool and the workpiece, and,

a control system, the control system including instructions to cause a processor to track the cutting tool and the workpiece, to associate the tracked data to an image associated with the cutting tool and an image associated with the workpiece, where the workpiece includes an image associated with the target shape, to determine a relationship between the cutting tool and at least one of the workpiece and the target shape, and to provide a control to the cutting tool based on at least one of the relationship of the cutting tool and the workpiece, and the relationship of the cutting tool and the target shape.

Ex. 1001, '582 Patent at 21:39-53

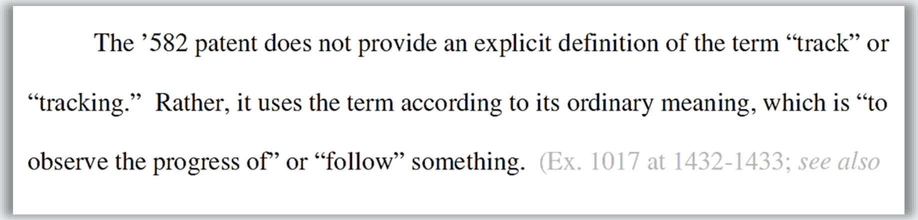
Patent Owner's Proposed Construction



of an object in a coordinate system as the position changes over time. Thus, one of ordinary skill in the art would have appreciated that the broadest reasonable interpretation of "track the cutting tool and the workpiece" is "identify a position of the cutting tool and of the workpiece over time within a coordinate system."

Ex. 2004, Cleary Decl. at ¶ 35
Paper No. 10, Patent Owner Response at 9

Petitioner's Proposed Construction



The '582 patent does not provide an explicit definition of the term "track" or "tracking." Rather, it uses the term according to its ordinary meaning, which is "to observe the progress of" or "follow" something. (Ex. 1017 at 1432-1433; *see also*

Paper No. 13, Pet'r's Reply at 2

Claim Construction – “Tracking Data”

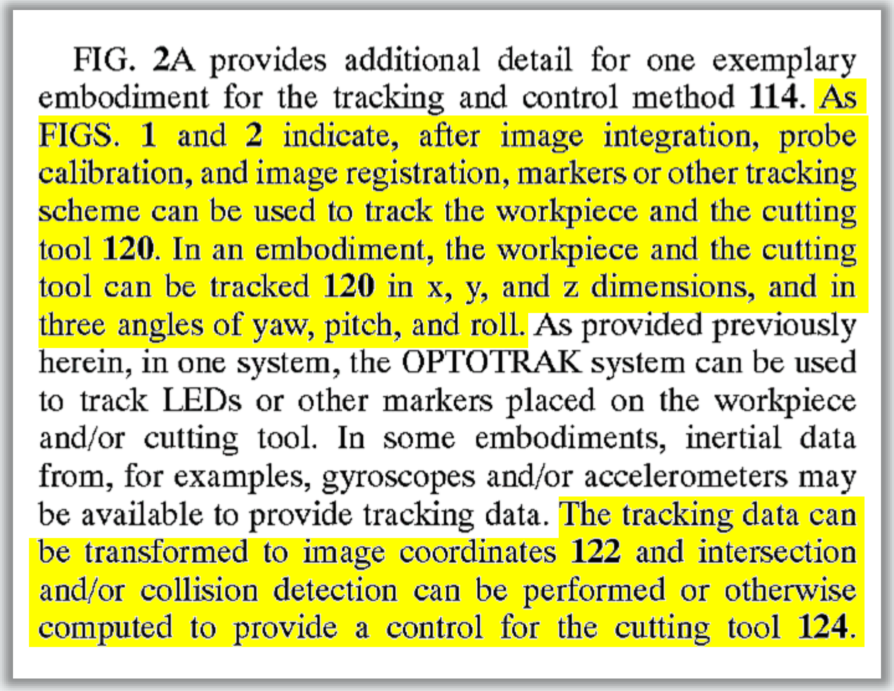
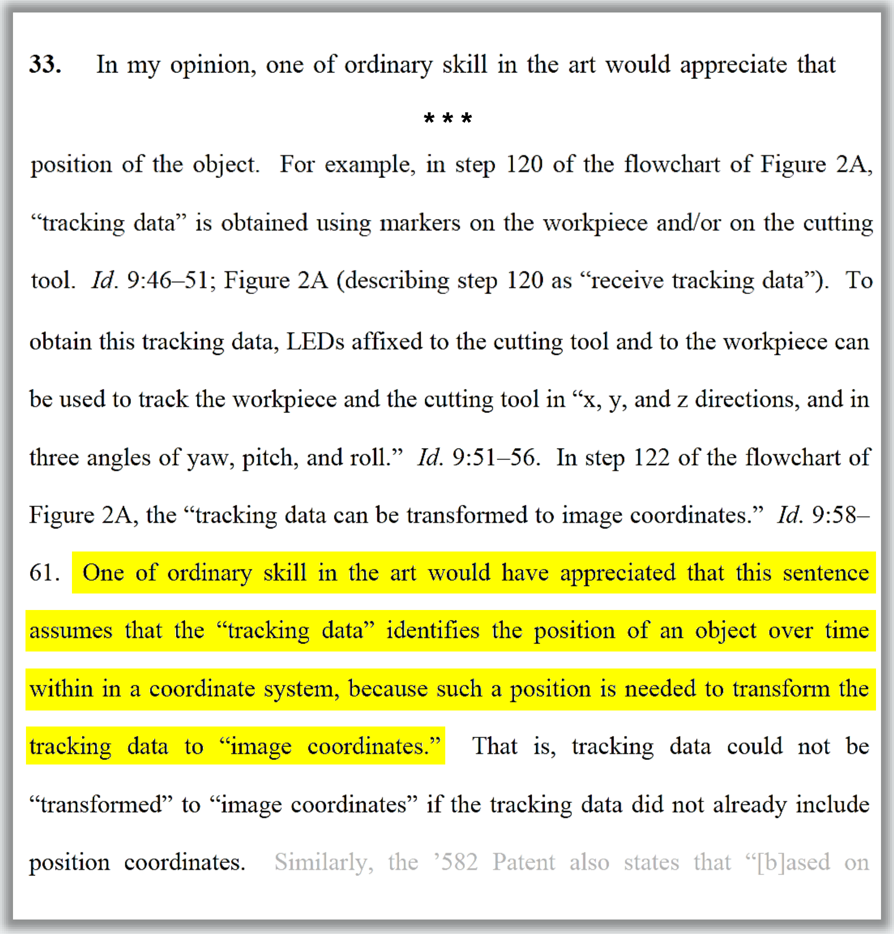


FIG. 2A provides additional detail for one exemplary embodiment for the tracking and control method **114**. As FIGS. 1 and 2 indicate, after image integration, probe calibration, and image registration, markers or other tracking scheme can be used to track the workpiece and the cutting tool **120**. In an embodiment, the workpiece and the cutting tool can be tracked **120** in x, y, and z dimensions, and in three angles of yaw, pitch, and roll. As provided previously herein, in one system, the OPTOTRAK system can be used to track LEDs or other markers placed on the workpiece and/or cutting tool. In some embodiments, inertial data from, for examples, gyroscopes and/or accelerometers may be available to provide tracking data. The tracking data can be transformed to image coordinates **122** and intersection and/or collision detection can be performed or otherwise computed to provide a control for the cutting tool **124**.

Ex. 1001, ’582 Patent at 9:46-60
Paper No. 10, Patent Owner Response at 8



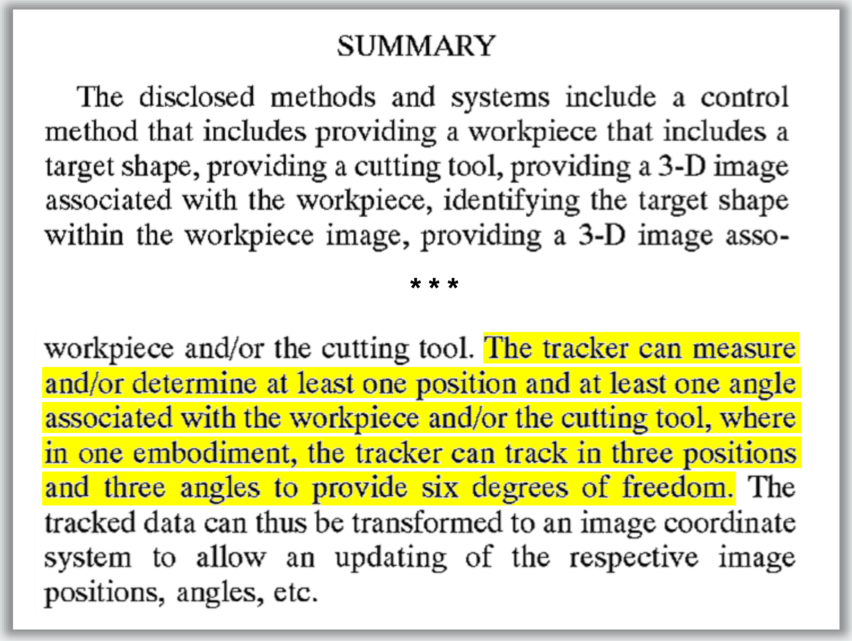
33. In my opinion, one of ordinary skill in the art would appreciate that

* * *

position of the object. For example, in step 120 of the flowchart of Figure 2A, “tracking data” is obtained using markers on the workpiece and/or on the cutting tool. *Id.* 9:46–51; Figure 2A (describing step 120 as “receive tracking data”). To obtain this tracking data, LEDs affixed to the cutting tool and to the workpiece can be used to track the workpiece and the cutting tool in “x, y, and z directions, and in three angles of yaw, pitch, and roll.” *Id.* 9:51–56. In step 122 of the flowchart of Figure 2A, the “tracking data can be transformed to image coordinates.” *Id.* 9:58–61. One of ordinary skill in the art would have appreciated that this sentence assumes that the “tracking data” identifies the position of an object over time within in a coordinate system, because such a position is needed to transform the tracking data to “image coordinates.” That is, tracking data could not be “transformed” to “image coordinates” if the tracking data did not already include position coordinates. Similarly, the ’582 Patent also states that “[b]ased on

Ex. 2004, Cleary Decl. at ¶ 33
Paper No. 10, Patent Owner Response at 8

Claim Construction – “Tracking Data”



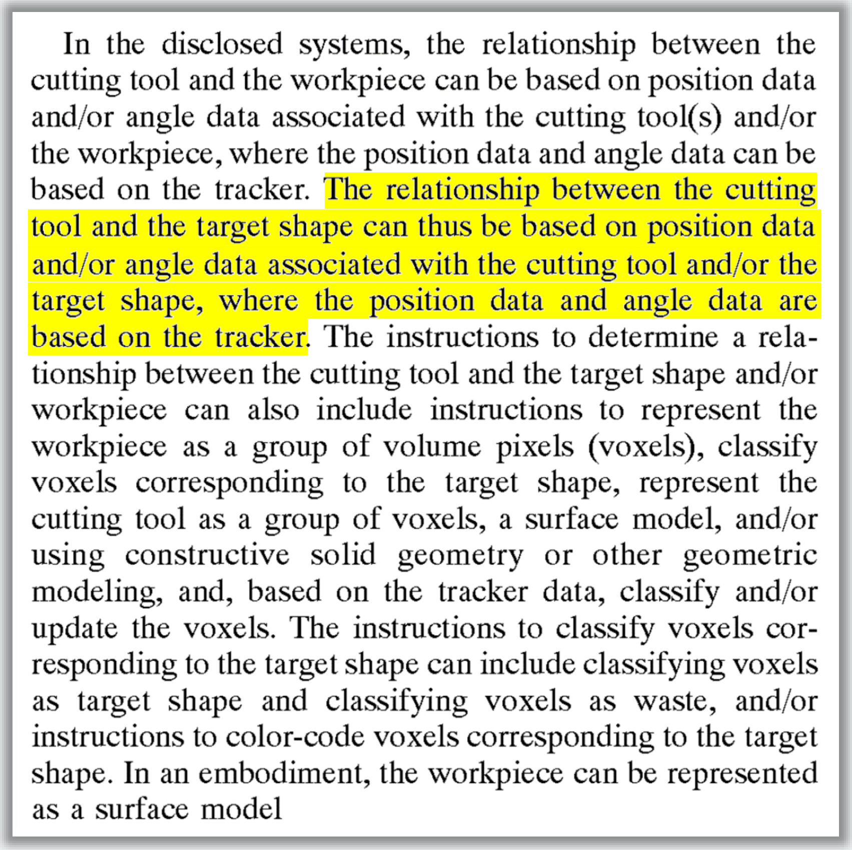
SUMMARY

The disclosed methods and systems include a control method that includes providing a workpiece that includes a target shape, providing a cutting tool, providing a 3-D image associated with the workpiece, identifying the target shape within the workpiece image, providing a 3-D image asso-

* * *

workpiece and/or the cutting tool. The tracker can measure and/or determine at least one position and at least one angle associated with the workpiece and/or the cutting tool, where in one embodiment, the tracker can track in three positions and three angles to provide six degrees of freedom. The tracked data can thus be transformed to an image coordinate system to allow an updating of the respective image positions, angles, etc.

Ex. 1001, ‘582 Patent at 1:53-2:52
Paper No. 10, Patent Owner Response at 8



In the disclosed systems, the relationship between the cutting tool and the workpiece can be based on position data and/or angle data associated with the cutting tool(s) and/or the workpiece, where the position data and angle data can be based on the tracker. The relationship between the cutting tool and the target shape can thus be based on position data and/or angle data associated with the cutting tool and/or the target shape, where the position data and angle data are based on the tracker. The instructions to determine a relationship between the cutting tool and the target shape and/or workpiece can also include instructions to represent the workpiece as a group of volume pixels (voxels), classify voxels corresponding to the target shape, represent the cutting tool as a group of voxels, a surface model, and/or using constructive solid geometry or other geometric modeling, and, based on the tracker data, classify and/or update the voxels. The instructions to classify voxels corresponding to the target shape can include classifying voxels as target shape and classifying voxels as waste, and/or instructions to color-code voxels corresponding to the target shape. In an embodiment, the workpiece can be represented as a surface model

Ex. 1001, ’582 Patent at 4:62-5:16
Paper No. 10, Patent Owner Response at 8

Claim Construction – "Tracking Data"

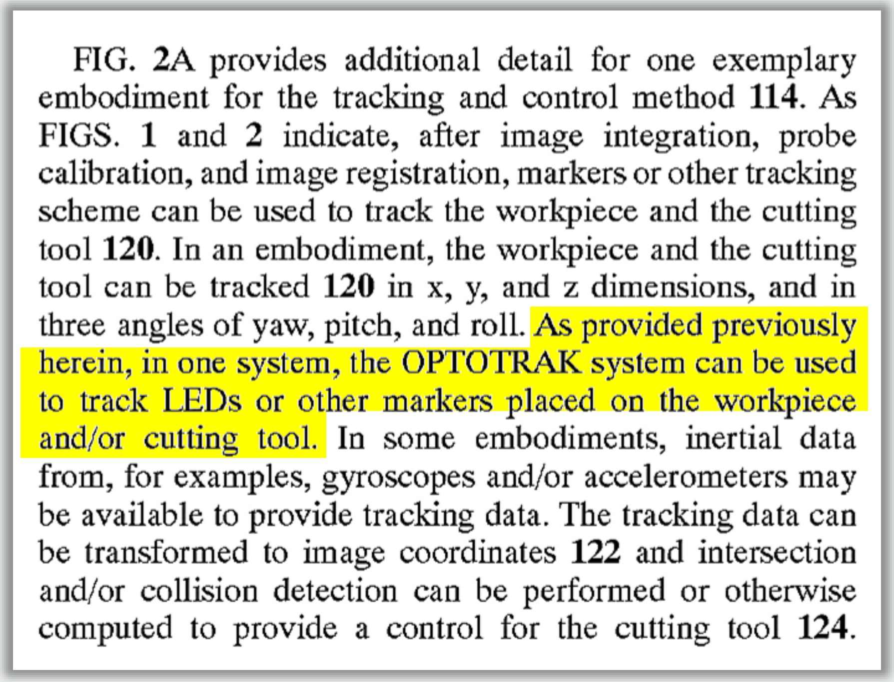
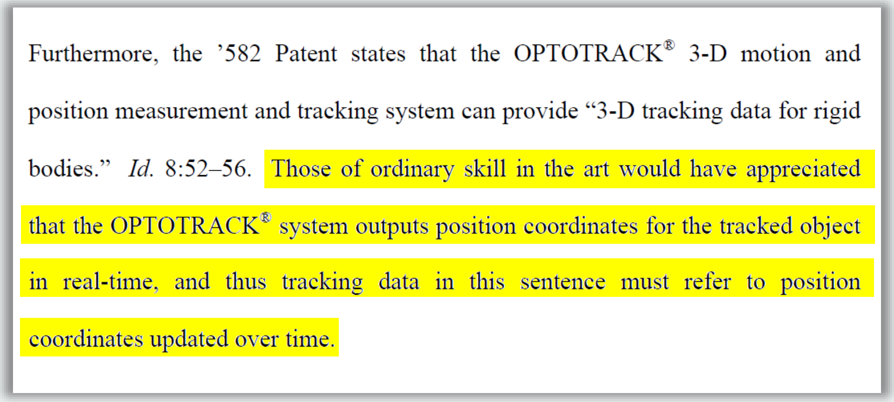


FIG. **2A** provides additional detail for one exemplary embodiment for the tracking and control method **114**. As FIGS. **1** and **2** indicate, after image integration, probe calibration, and image registration, markers or other tracking scheme can be used to track the workpiece and the cutting tool **120**. In an embodiment, the workpiece and the cutting tool can be tracked **120** in x, y, and z dimensions, and in three angles of yaw, pitch, and roll. As provided previously herein, in one system, the OPTOTRAK system can be used to track LEDs or other markers placed on the workpiece and/or cutting tool. In some embodiments, inertial data from, for examples, gyroscopes and/or accelerometers may be available to provide tracking data. The tracking data can be transformed to image coordinates **122** and intersection and/or collision detection can be performed or otherwise computed to provide a control for the cutting tool **124**.

Ex. 1001, '582 Patent at 9:46-60
Paper No. 10, Patent Owner Response at 8



Furthermore, the '582 Patent states that the OPTOTRACK® 3-D motion and position measurement and tracking system can provide "3-D tracking data for rigid bodies." *Id.* 8:52–56. Those of ordinary skill in the art would have appreciated that the OPTOTRACK® system outputs position coordinates for the tracked object in real-time, and thus tracking data in this sentence must refer to position coordinates updated over time.

Ex. 2004, Cleary Decl. at ¶ 33
Paper No. 10, Patent Owner Response at 8

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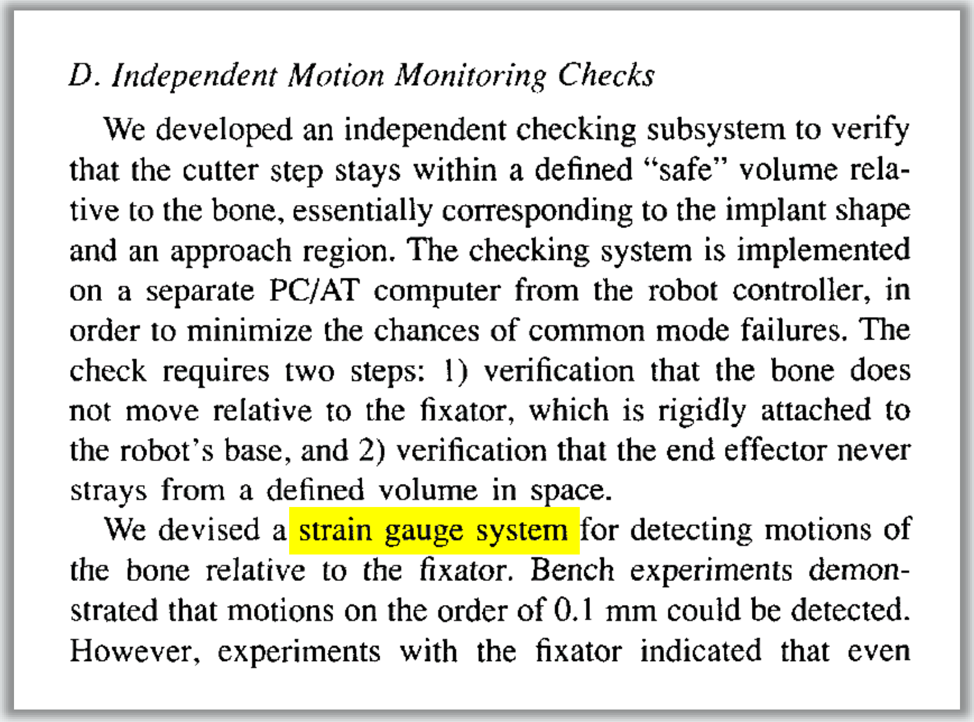
1. Claim Construction
2. **Taylor Does Not Anticipate Independent Claims 1, 17, and 24 and Their Dependent Claims**
3. Taylor and DiGioia Do Not Render Claim 7 Obvious
4. Taylor and Delp Do Not Render Claims 48 and 49 Obvious
5. The Motion to Exclude Should be Granted

Taylor Does Not Teach the "Tracking Data" Limitations of Claims 1 and 17



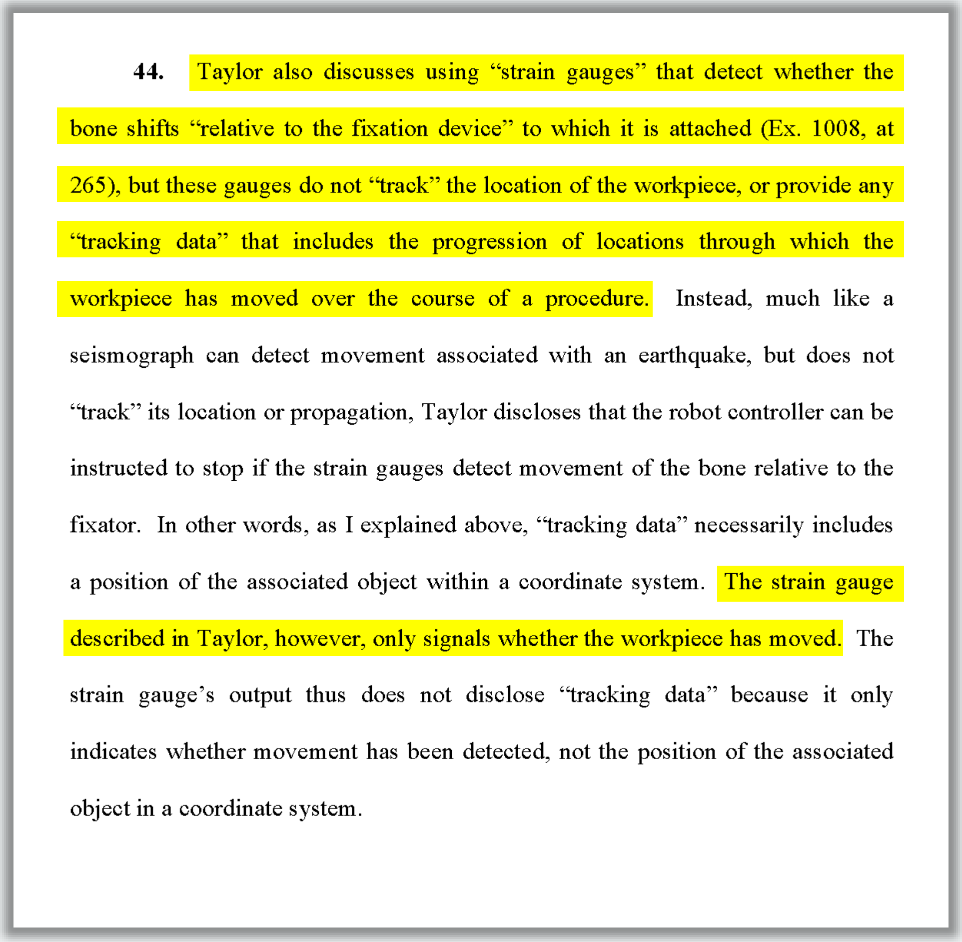
D. Independent Motion Monitoring Checks

We developed an independent checking subsystem to verify that the cutter step stays within a defined "safe" volume relative to the bone, essentially corresponding to the implant shape and an approach region. The checking system is implemented on a separate PC/AT computer from the robot controller, in order to minimize the chances of common mode failures. The check requires two steps: 1) verification that the bone does not move relative to the fixator, which is rigidly attached to the robot's base, and 2) verification that the end effector never strays from a defined volume in space.

We devised a strain gauge system for detecting motions of the bone relative to the fixator. Bench experiments demonstrated that motions on the order of 0.1 mm could be detected. However, experiments with the fixator indicated that even

Ex. 1009, Taylor at 270
Paper No. 1, Petition at 22

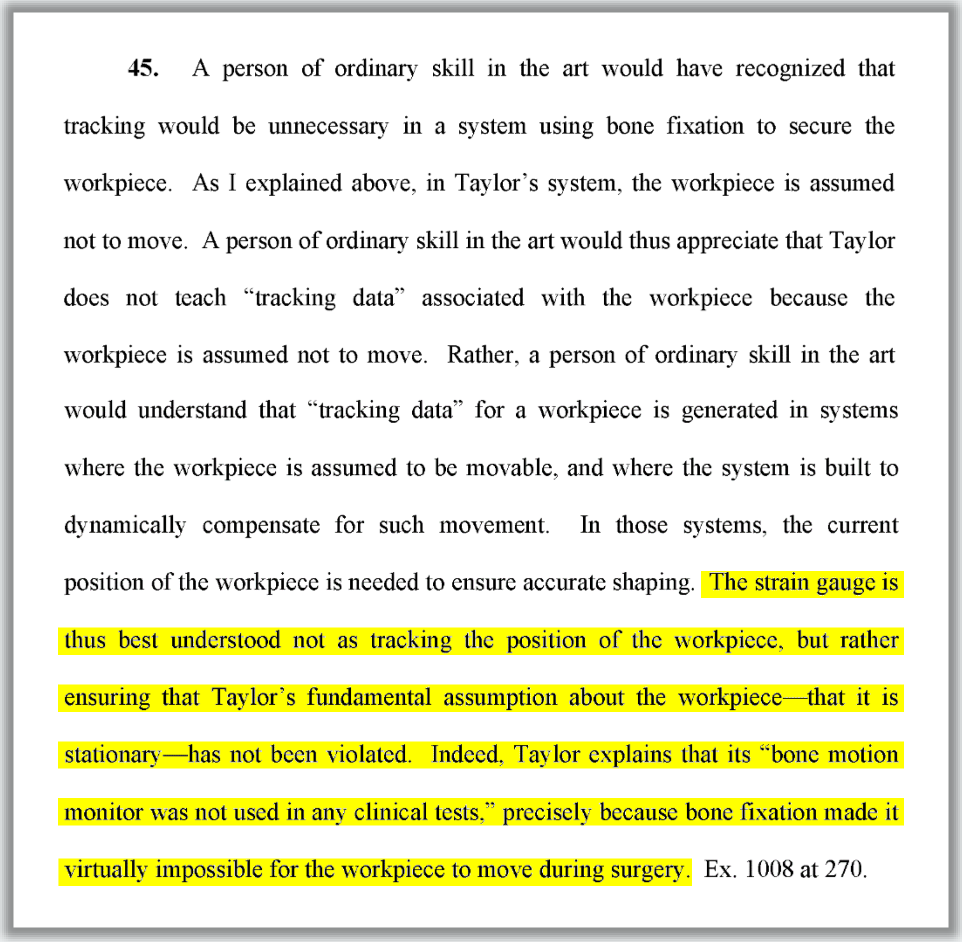
Taylor Does Not Teach the "Tracking Data" Limitations of Claims 1 and 17



44. Taylor also discusses using "strain gauges" that detect whether the bone shifts "relative to the fixation device" to which it is attached (Ex. 1008, at 265), but these gauges do not "track" the location of the workpiece, or provide any "tracking data" that includes the progression of locations through which the workpiece has moved over the course of a procedure. Instead, much like a seismograph can detect movement associated with an earthquake, but does not "track" its location or propagation, Taylor discloses that the robot controller can be instructed to stop if the strain gauges detect movement of the bone relative to the fixator. In other words, as I explained above, "tracking data" necessarily includes a position of the associated object within a coordinate system. The strain gauge described in Taylor, however, only signals whether the workpiece has moved. The strain gauge's output thus does not disclose "tracking data" because it only indicates whether movement has been detected, not the position of the associated object in a coordinate system.

Ex. 2004, Cleary Decl. at ¶ 44
Paper No. 10, Patent Owner Response at 17-18

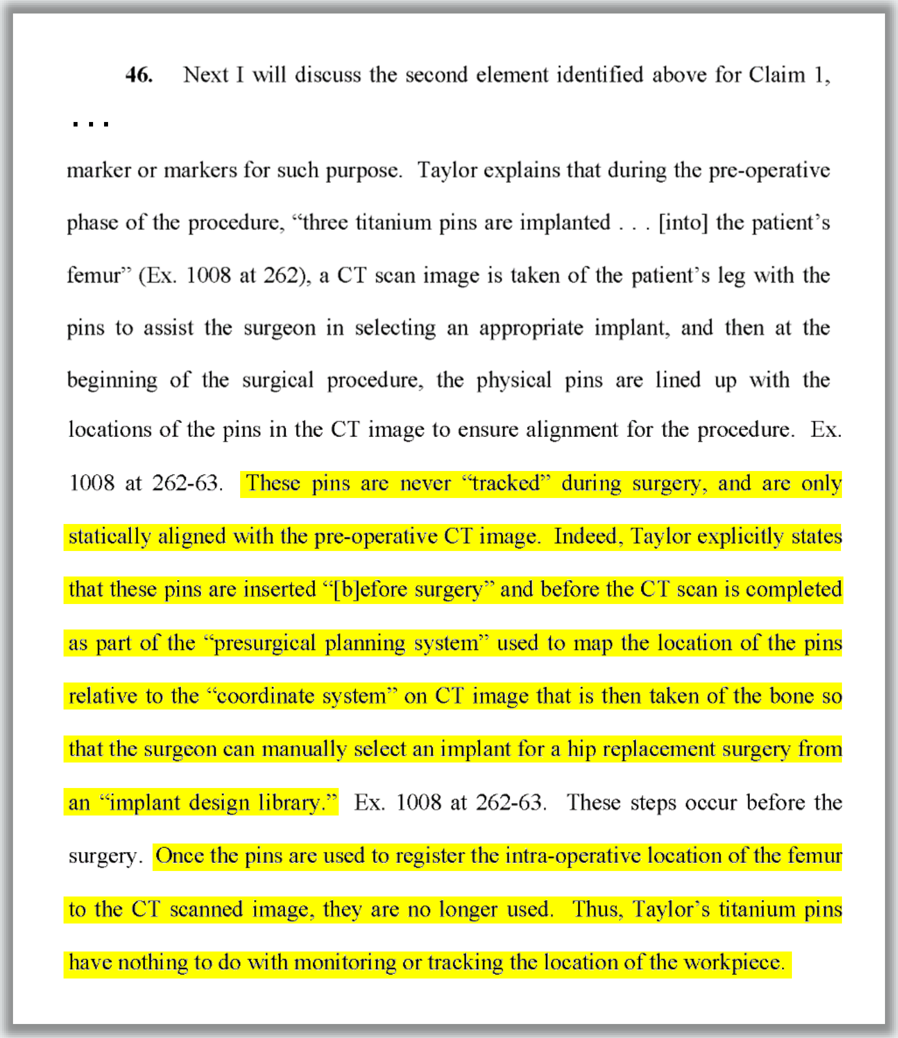
Taylor Does Not Teach the “Tracking Data” Limitations of Claims 1 and 17



45. A person of ordinary skill in the art would have recognized that tracking would be unnecessary in a system using bone fixation to secure the workpiece. As I explained above, in Taylor’s system, the workpiece is assumed not to move. A person of ordinary skill in the art would thus appreciate that Taylor does not teach “tracking data” associated with the workpiece because the workpiece is assumed not to move. Rather, a person of ordinary skill in the art would understand that “tracking data” for a workpiece is generated in systems where the workpiece is assumed to be movable, and where the system is built to dynamically compensate for such movement. In those systems, the current position of the workpiece is needed to ensure accurate shaping. The strain gauge is thus best understood not as tracking the position of the workpiece, but rather ensuring that Taylor’s fundamental assumption about the workpiece—that it is stationary—has not been violated. Indeed, Taylor explains that its “bone motion monitor was not used in any clinical tests,” precisely because bone fixation made it virtually impossible for the workpiece to move during surgery. Ex. 1008 at 270.

Ex. 2004, Cleary Decl. at ¶ 45
Paper No. 10, Patent Owner Response at 17-18

Taylor Does Not Teach the "Tracking Data" Limitations of Claims 1 and 17



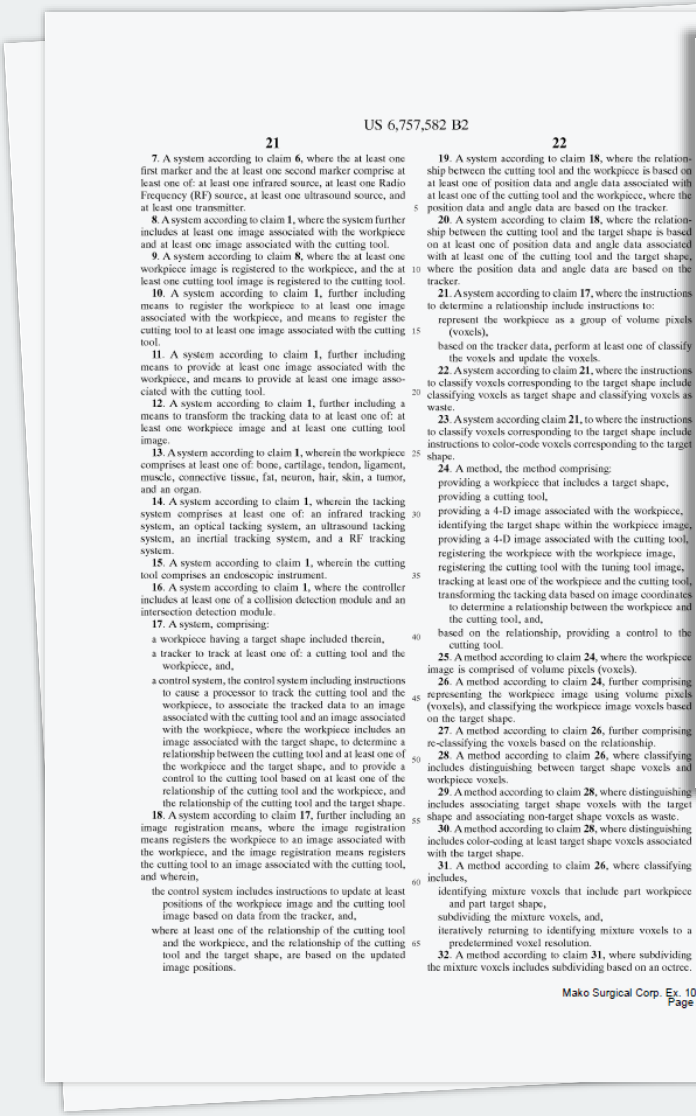
46. Next I will discuss the second element identified above for Claim 1,

. . .

marker or markers for such purpose. Taylor explains that during the pre-operative phase of the procedure, "three titanium pins are implanted . . . [into] the patient's femur" (Ex. 1008 at 262), a CT scan image is taken of the patient's leg with the pins to assist the surgeon in selecting an appropriate implant, and then at the beginning of the surgical procedure, the physical pins are lined up with the locations of the pins in the CT image to ensure alignment for the procedure. Ex. 1008 at 262-63. These pins are never "tracked" during surgery, and are only statically aligned with the pre-operative CT image. Indeed, Taylor explicitly states that these pins are inserted "[b]efore surgery" and before the CT scan is completed as part of the "presurgical planning system" used to map the location of the pins relative to the "coordinate system" on CT image that is then taken of the bone so that the surgeon can manually select an implant for a hip replacement surgery from an "implant design library." Ex. 1008 at 262-63. These steps occur before the surgery. Once the pins are used to register the intra-operative location of the femur to the CT scanned image, they are no longer used. Thus, Taylor's titanium pins have nothing to do with monitoring or tracking the location of the workpiece.

Ex. 2004, Cleary Decl. at ¶ 46
Paper No. 10, Patent Owner Response at 19-20

Taylor Does Not Teach a "4-D Image," as Recited in Claim 24



US 6,757,582 B2

21

7. A system according to claim **6**, where the at least one first marker and the at least one second marker comprise at least one of: at least one infrared source, at least one Radio Frequency (RF) source, at least one ultrasound source, and at least one transmitter.

8. A system according to claim **1**, where the system further includes at least one image associated with the workpiece and at least one image associated with the cutting tool.

9. A system according to claim **8**, where the at least one workpiece image is registered to the workpiece, and the at least one cutting tool image is registered to the cutting tool.

10. A system according to claim **1**, further including means to register the workpiece to at least one image associated with the workpiece, and means to register the cutting tool to at least one image associated with the cutting tool.

11. A system according to claim **1**, further including means to provide at least one image associated with the workpiece, and means to provide at least one image associated with the cutting tool.

12. A system according to claim **1**, further including a means to transform the tracking data to at least one of: at least one workpiece image and at least one cutting tool image.

13. A system according to claim **1**, wherein the workpiece comprises at least one of: bone, cartilage, tendon, ligament, muscle, connective tissue, fat, neuron, hair, skin, a tumor, and an organ.

14. A system according to claim **1**, wherein the tacking system comprises at least one of: an infrared tracking system, an optical tacking system, an ultrasound tacking system, an inertial tracking system, and a RF tracking system.

15. A system according to claim **1**, wherein the cutting tool comprises an endoscopic instrument.

16. A system according to claim **1**, where the controller includes at least one of a collision detection module and an intersection detection module.

17. A system, comprising:

a workpiece having a target shape included therein,

a tracker to track at least one of: a cutting tool and the workpiece, and,

a control system, the control system including instructions to cause a processor to track the cutting tool and the workpiece, to associate the tracked data to an image associated with the cutting tool and an image associated with the workpiece, where the workpiece includes an image associated with the target shape, to determine a relationship between the cutting tool and at least one of the workpiece and the target shape, and to provide a control to the cutting tool based on at least one of the relationship of the cutting tool and the workpiece, and the relationship of the cutting tool and the target shape.

18. A system according to claim **17**, further including an image registration means, where the image registration means registers the workpiece to an image associated with the workpiece, and the image registration means registers the cutting tool to an image associated with the cutting tool, and wherein,

the control system includes instructions to update at least positions of the workpiece image and the cutting tool image based on data from the tracker, and,

where at least one of the relationship of the cutting tool and the workpiece, and the relationship of the cutting tool and the target shape, are based on the updated image positions.

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19. A system according to claim **18**, where the relationship between the cutting tool and the workpiece is based on at least one of position data and angle data associated with at least one of the cutting tool and the workpiece, where the position data and angle data are based on the tracker.

20. A system according to claim **18**, where the relationship between the cutting tool and the target shape is based on at least one of position data and angle data associated with at least one of the cutting tool and the target shape, where the position data and angle data are based on the tracker.

21. A system according to claim **17**, where the instructions to determine a relationship include instructions to:

represent the workpiece as a group of volume pixels (voxels),

based on the tracker data, perform at least one of classify the voxels and update the voxels.

22. A system according to claim **21**, where the instructions to classify voxels corresponding to the target shape include classifying voxels as target shape and classifying voxels as waste.

23. A system according claim **21**, to where the instructions to classify voxels corresponding to the target shape include instructions to color-code voxels corresponding to the target shape.

24. A method, the method comprising:

providing a workpiece that includes a target shape,

providing a cutting tool,

providing a 4-D image associated with the workpiece,

identifying the target shape within the workpiece image,

providing a 4-D image associated with the cutting tool,

registering the workpiece with the workpiece image,

registering the cutting tool with the tuning tool image,

tracking at least one of the workpiece and the cutting tool,

transforming the tacking data based on image coordinates to determine a relationship between the workpiece and the cutting tool, and,

based on the relationship, providing a control to the cutting tool.

25. A method according to claim **24**, where the workpiece image is comprised of volume pixels (voxels).

26. A method according to claim **24**, further comprising representing the workpiece image using volume pixels (voxels), and classifying the workpiece image voxels based on the target shape.

27. A method according to claim **26**, further comprising re-classifying the voxels based on the relationship.

28. A method according to claim **26**, where classifying includes distinguishing between target shape voxels and workpiece voxels.

29. A method according to claim **28**, where distinguishing includes associating target shape voxels with the target shape and associating non-target shape voxels as waste.

30. A method according to claim **28**, where distinguishing includes color-coding at least target shape voxels associated with the target shape.

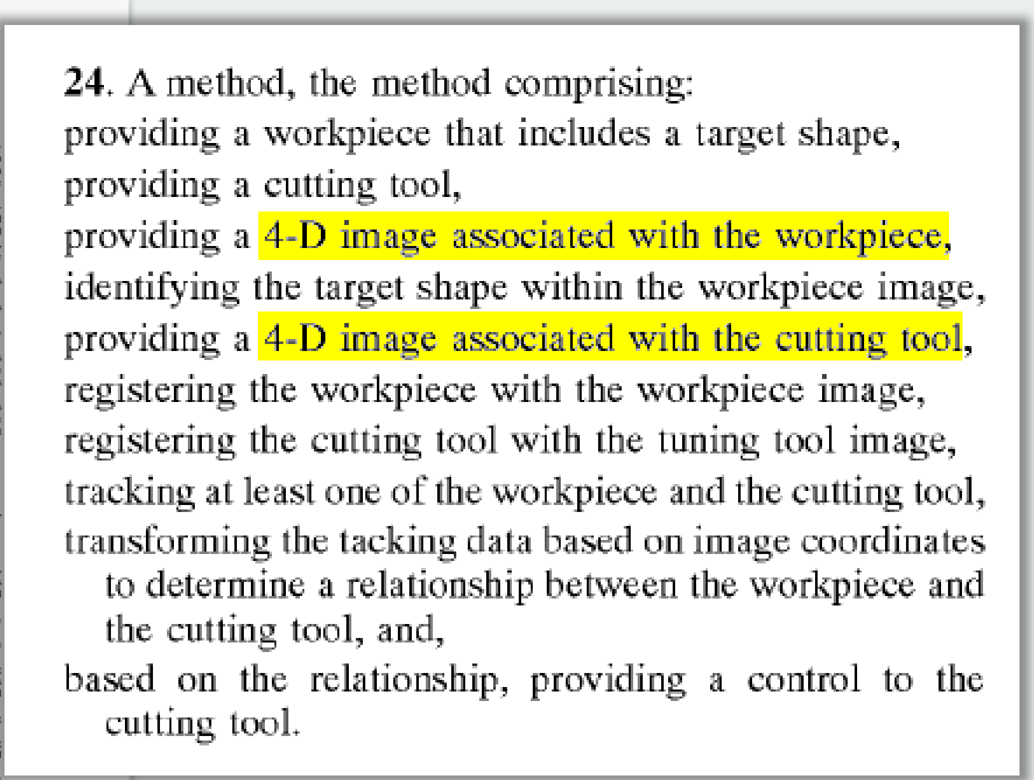
31. A method according to claim **26**, where classifying includes,

identifying mixture voxels that include part workpiece and part target shape,

subdividing the mixture voxels, and,

iteratively returning to identifying mixture voxels to a predetermined voxel resolution.

32. A method according to claim **31**, where subdividing the mixture voxels includes subdividing based on an octree.



24. A method, the method comprising:

providing a workpiece that includes a target shape,

providing a cutting tool,

providing a 4-D image associated with the workpiece,

identifying the target shape within the workpiece image,

providing a 4-D image associated with the cutting tool,

registering the workpiece with the workpiece image,

registering the cutting tool with the tuning tool image,

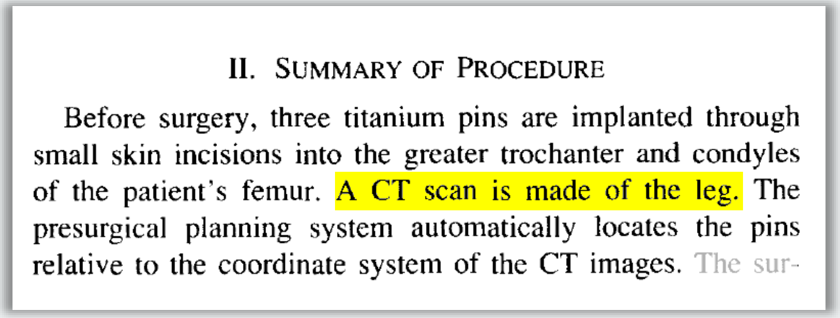
tracking at least one of the workpiece and the cutting tool,

transforming the tacking data based on image coordinates to determine a relationship between the workpiece and the cutting tool, and,

based on the relationship, providing a control to the cutting tool.

Ex. 1001, '582 Patent at 22:26-40

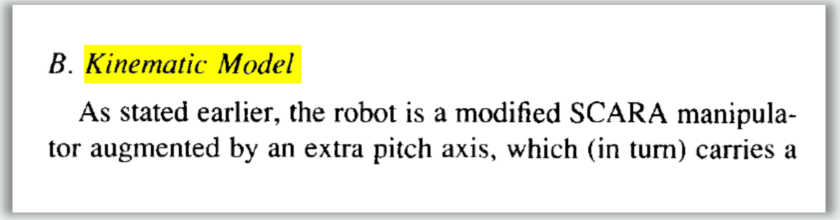
Taylor Does Not Teach a “4-D Image,” as Recited in Claim 24



II. SUMMARY OF PROCEDURE

Before surgery, three titanium pins are implanted through small skin incisions into the greater trochanter and condyles of the patient’s femur. A CT scan is made of the leg. The presurgical planning system automatically locates the pins relative to the coordinate system of the CT images. The sur-

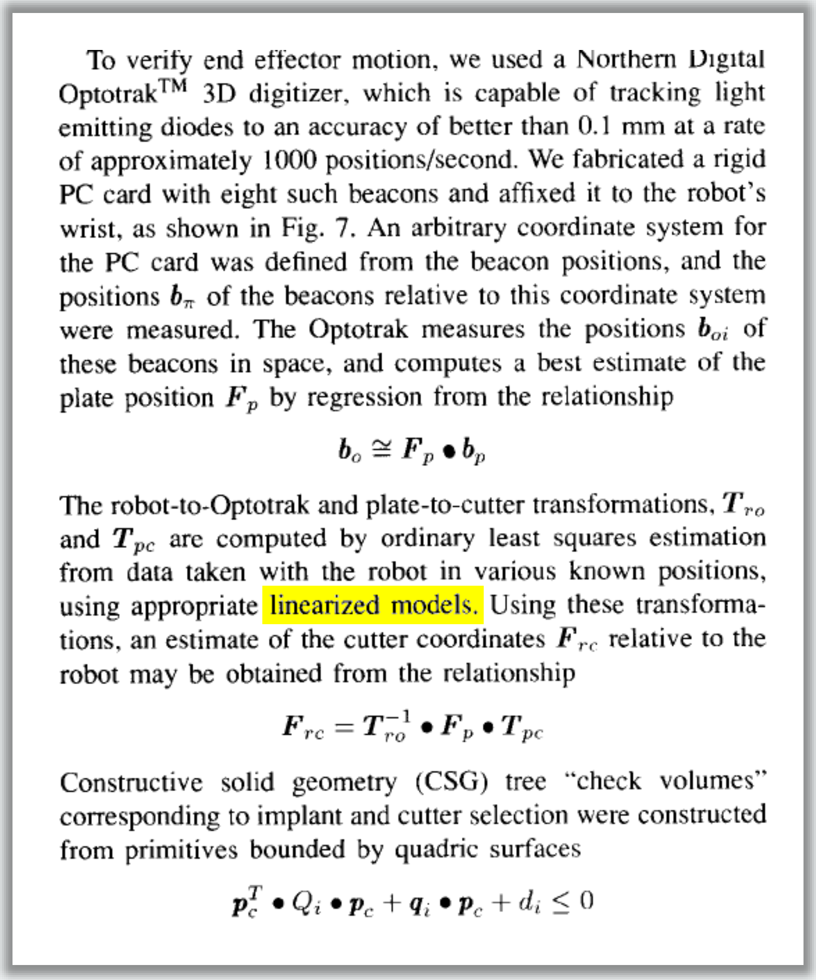
Ex. 1008, Taylor at 262
Petition at 24, 29



B. Kinematic Model

As stated earlier, the robot is a modified SCARA manipulator augmented by an extra pitch axis, which (in turn) carries a

Ex. 1008, Taylor at 268
Petition at 24, 29



To verify end effector motion, we used a Northern Digital Optotrak^{TM} 3D digitizer, which is capable of tracking light emitting diodes to an accuracy of better than 0.1 mm at a rate of approximately 1000 positions/second. We fabricated a rigid PC card with eight such beacons and affixed it to the robot’s wrist, as shown in Fig. 7. An arbitrary coordinate system for the PC card was defined from the beacon positions, and the positions $\boldsymbol{b}_\pi$ of the beacons relative to this coordinate system were measured. The Optotrak measures the positions $\boldsymbol{b}_{oi}$ of these beacons in space, and computes a best estimate of the plate position $\boldsymbol{F}_p$ by regression from the relationship

$$\boldsymbol{b}_o \cong \boldsymbol{F}_p \bullet \boldsymbol{b}_p$$

The robot-to-Optotrak and plate-to-cutter transformations, $\boldsymbol{T}_{ro}$ and $\boldsymbol{T}_{pc}$ are computed by ordinary least squares estimation from data taken with the robot in various known positions, using appropriate linearized models. Using these transformations, an estimate of the cutter coordinates $\boldsymbol{F}_{rc}$ relative to the robot may be obtained from the relationship

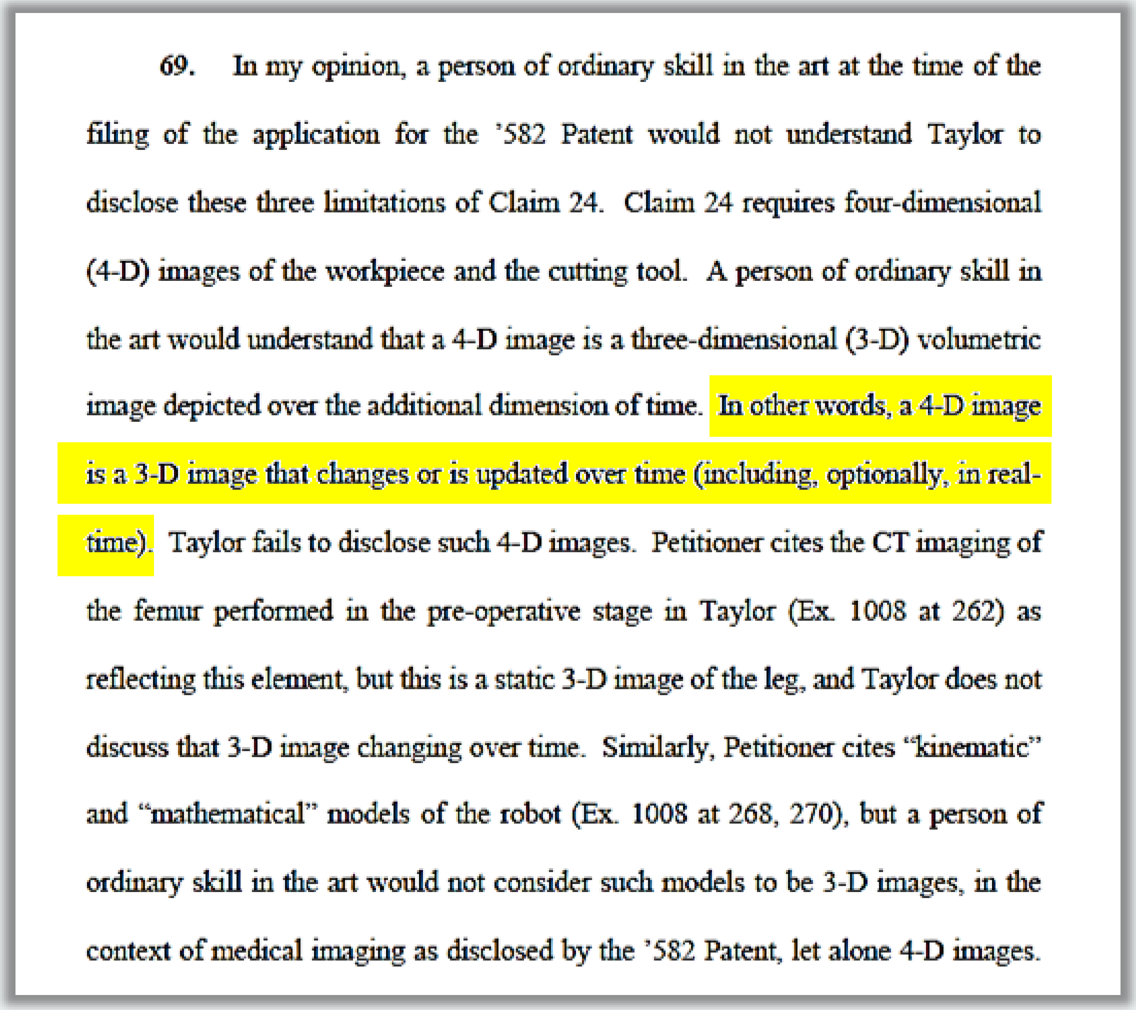
$$\boldsymbol{F}_{rc} = \boldsymbol{T}_{ro}^{-1} \bullet \boldsymbol{F}_p \bullet \boldsymbol{T}_{pc}$$

Constructive solid geometry (CSG) tree “check volumes” corresponding to implant and cutter selection were constructed from primitives bounded by quadric surfaces

$$\boldsymbol{p}_c^T \bullet Q_i \bullet \boldsymbol{p}_c + \boldsymbol{q}_i \bullet \boldsymbol{p}_c + d_i \leq 0$$

Ex. 1008, Taylor at 270
Paper No. 1, Petition at 24, 29

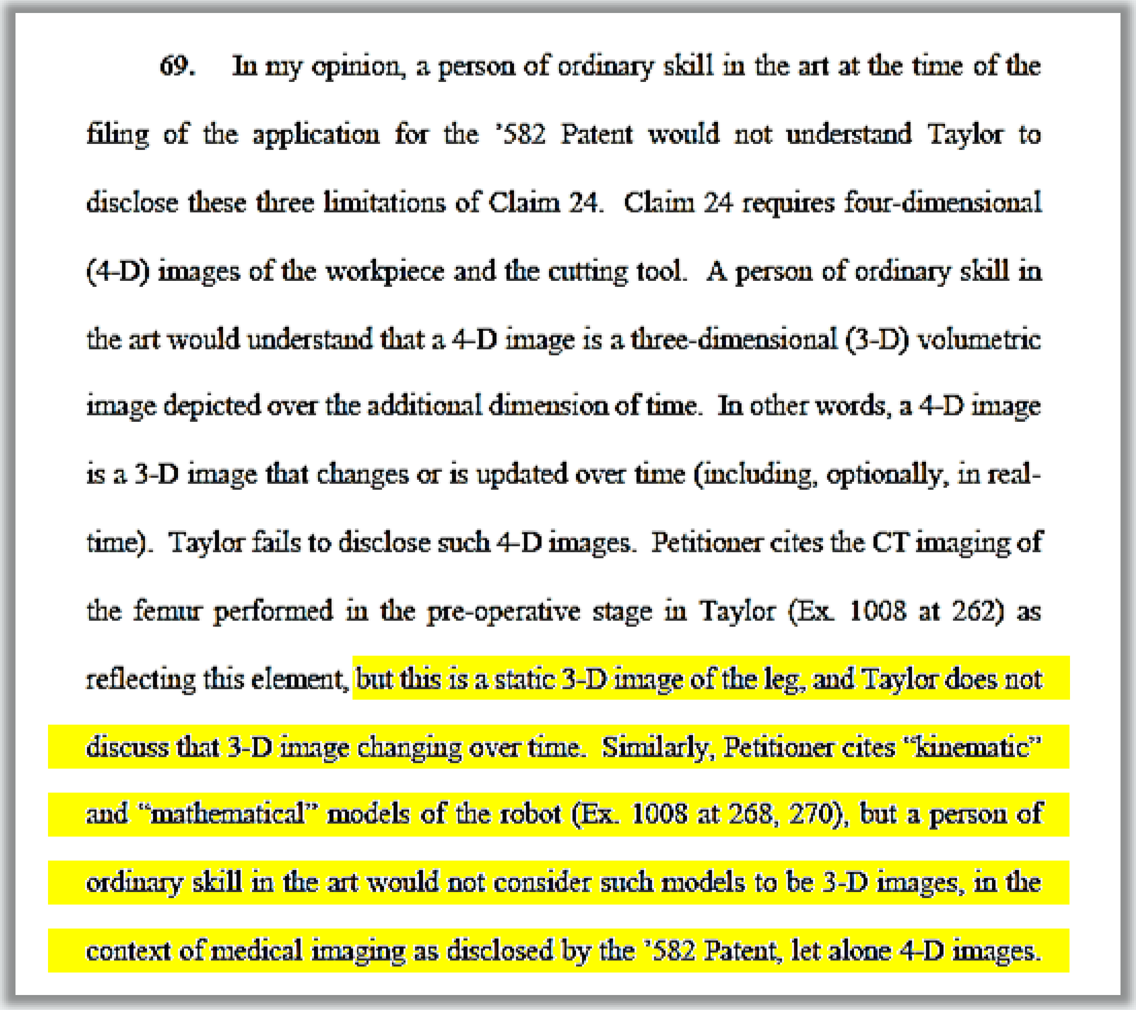
Taylor Does Not Teach a "4-D Image," as Recited in Claim 24



69. In my opinion, a person of ordinary skill in the art at the time of the filing of the application for the '582 Patent would not understand Taylor to disclose these three limitations of Claim 24. Claim 24 requires four-dimensional (4-D) images of the workpiece and the cutting tool. A person of ordinary skill in the art would understand that a 4-D image is a three-dimensional (3-D) volumetric image depicted over the additional dimension of time. In other words, a 4-D image is a 3-D image that changes or is updated over time (including, optionally, in real-time). Taylor fails to disclose such 4-D images. Petitioner cites the CT imaging of the femur performed in the pre-operative stage in Taylor (Ex. 1008 at 262) as reflecting this element, but this is a static 3-D image of the leg, and Taylor does not discuss that 3-D image changing over time. Similarly, Petitioner cites "kinematic" and "mathematical" models of the robot (Ex. 1008 at 268, 270), but a person of ordinary skill in the art would not consider such models to be 3-D images, in the context of medical imaging as disclosed by the '582 Patent, let alone 4-D images.

Ex. 2004, Cleary Decl. at ¶ 69
Paper No. 10, Patent Owner Response at 39

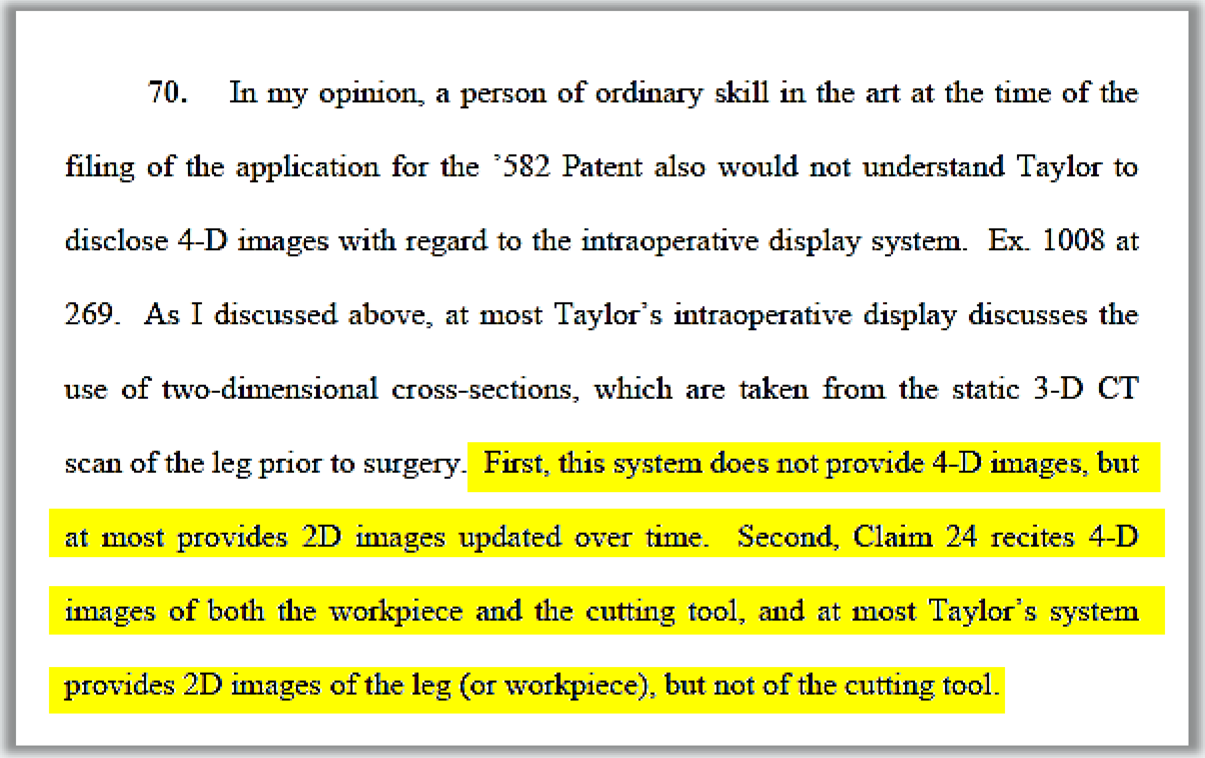
Taylor Does Not Teach a "4-D Image," as Recited in Claim 24



69. In my opinion, a person of ordinary skill in the art at the time of the filing of the application for the '582 Patent would not understand Taylor to disclose these three limitations of Claim 24. Claim 24 requires four-dimensional (4-D) images of the workpiece and the cutting tool. A person of ordinary skill in the art would understand that a 4-D image is a three-dimensional (3-D) volumetric image depicted over the additional dimension of time. In other words, a 4-D image is a 3-D image that changes or is updated over time (including, optionally, in real-time). Taylor fails to disclose such 4-D images. Petitioner cites the CT imaging of the femur performed in the pre-operative stage in Taylor (Ex. 1008 at 262) as reflecting this element, but this is a static 3-D image of the leg, and Taylor does not discuss that 3-D image changing over time. Similarly, Petitioner cites "kinematic" and "mathematical" models of the robot (Ex. 1008 at 268, 270), but a person of ordinary skill in the art would not consider such models to be 3-D images, in the context of medical imaging as disclosed by the '582 Patent, let alone 4-D images.

Ex. 2004, Cleary Decl. at ¶ 69
Paper No. 10, Patent Owner Response at 39

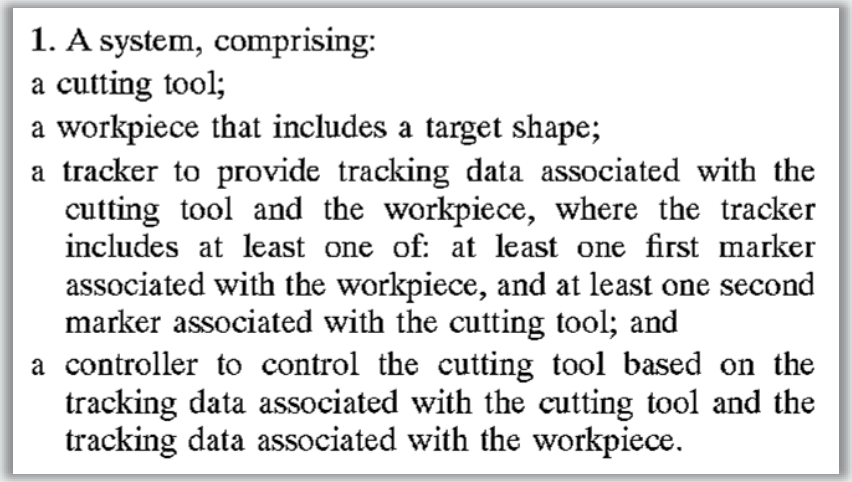
Taylor Does Not Teach a “4-D Image,” as Recited in Claim 24



70. In my opinion, a person of ordinary skill in the art at the time of the filing of the application for the ’582 Patent also would not understand Taylor to disclose 4-D images with regard to the intraoperative display system. Ex. 1008 at 269. As I discussed above, at most Taylor’s intraoperative display discusses the use of two-dimensional cross-sections, which are taken from the static 3-D CT scan of the leg prior to surgery. First, this system does not provide 4-D images, but at most provides 2D images updated over time. Second, Claim 24 recites 4-D images of both the workpiece and the cutting tool, and at most Taylor’s system provides 2D images of the leg (or workpiece), but not of the cutting tool.

Ex. 2004, Cleary Decl. at ¶ 70
Paper No. 10, Patent Owner Response at 39

Taylor Does Not Anticipate Claim 9



1. A system, comprising:

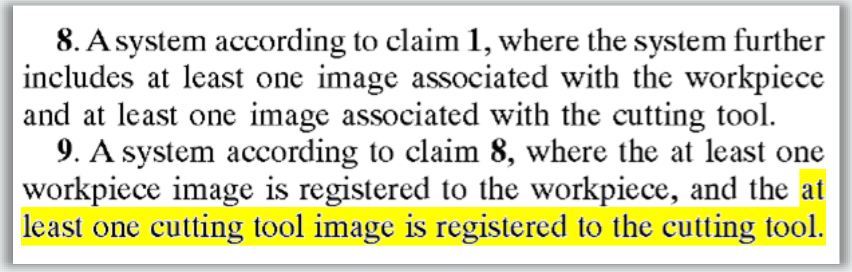
a cutting tool;

a workpiece that includes a target shape;

a tracker to provide tracking data associated with the cutting tool and the workpiece, where the tracker includes at least one of: at least one first marker associated with the workpiece, and at least one second marker associated with the cutting tool; and

a controller to control the cutting tool based on the tracking data associated with the cutting tool and the tracking data associated with the workpiece.

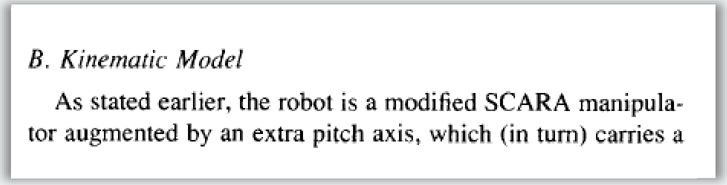
Ex. 1001, '582 Patent at 20:36-47



8. A system according to claim **1**, where the system further includes at least one image associated with the workpiece and at least one image associated with the cutting tool.

9. A system according to claim **8**, where the at least one workpiece image is registered to the workpiece, and the at least one cutting tool image is registered to the cutting tool.

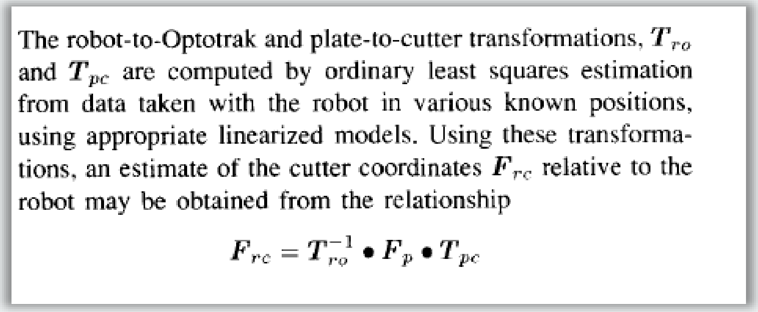
Ex. 1001, '582 Patent at 21:6-11



B. Kinematic Model

As stated earlier, the robot is a modified SCARA manipulator augmented by an extra pitch axis, which (in turn) carries a

Ex. 1008, Taylor at 268
Paper No. 1, Petition at 24

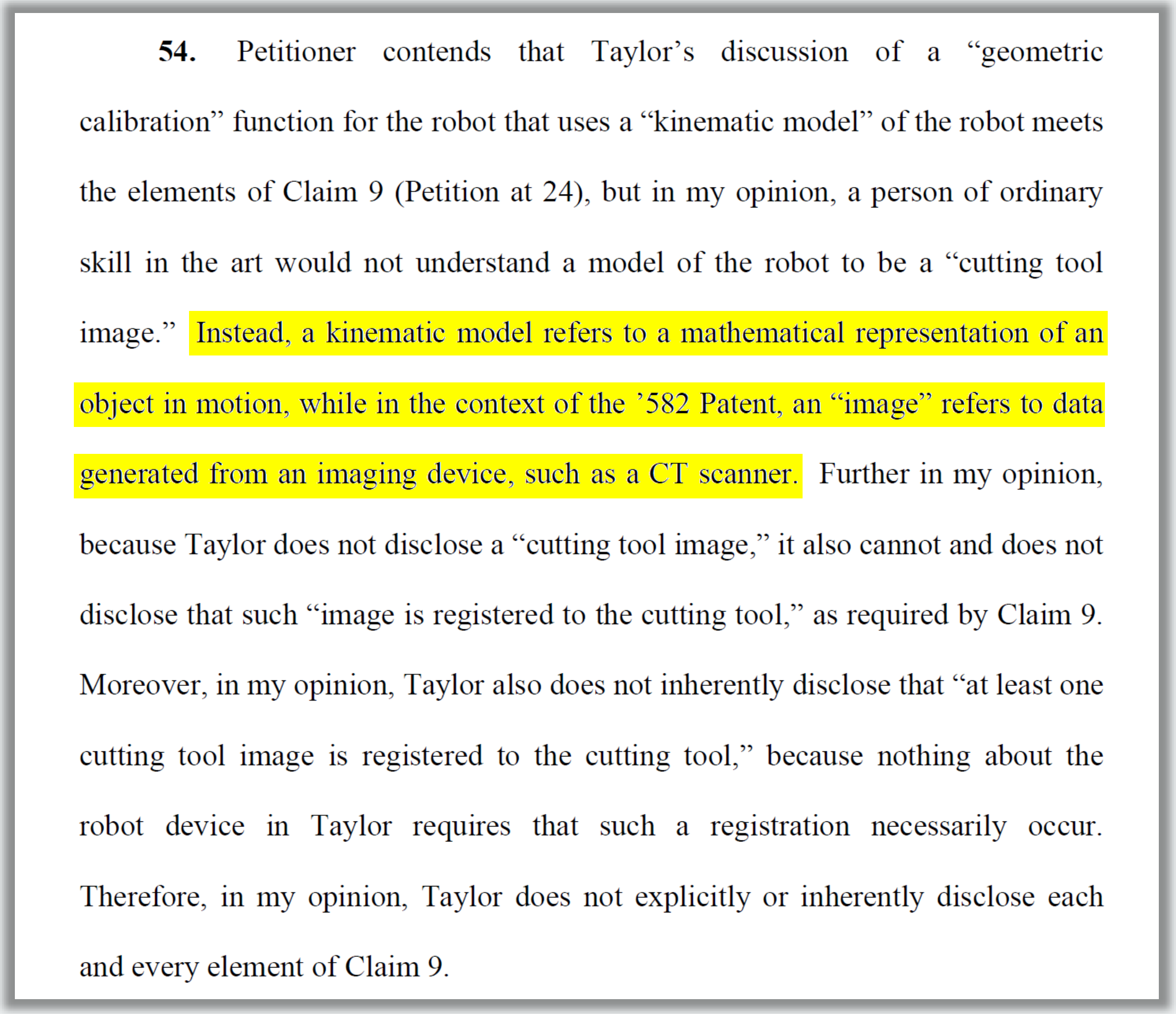


The robot-to-Optotrak and plate-to-cutter transformations, $\boldsymbol{T}_{ro}$ and $\boldsymbol{T}_{pc}$ are computed by ordinary least squares estimation from data taken with the robot in various known positions, using appropriate linearized models. Using these transformations, an estimate of the cutter coordinates $\boldsymbol{F}_{rc}$ relative to the robot may be obtained from the relationship

$$\boldsymbol{F}_{rc} = \boldsymbol{T}_{ro}^{-1} \bullet \boldsymbol{F}_{p} \bullet \boldsymbol{T}_{pc}$$

Ex. 1008, Taylor at 270
Paper No. 1, Petition at 24

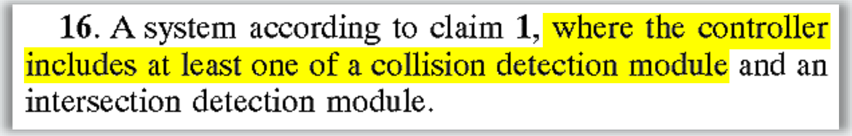
A Mathematical Representation Does Not Teach a “Cutting Tool Image”



54. Petitioner contends that Taylor’s discussion of a “geometric calibration” function for the robot that uses a “kinematic model” of the robot meets the elements of Claim 9 (Petition at 24), but in my opinion, a person of ordinary skill in the art would not understand a model of the robot to be a “cutting tool image.” Instead, a kinematic model refers to a mathematical representation of an object in motion, while in the context of the ’582 Patent, an “image” refers to data generated from an imaging device, such as a CT scanner. Further in my opinion, because Taylor does not disclose a “cutting tool image,” it also cannot and does not disclose that such “image is registered to the cutting tool,” as required by Claim 9. Moreover, in my opinion, Taylor also does not inherently disclose that “at least one cutting tool image is registered to the cutting tool,” because nothing about the robot device in Taylor requires that such a registration necessarily occur. Therefore, in my opinion, Taylor does not explicitly or inherently disclose each and every element of Claim 9.

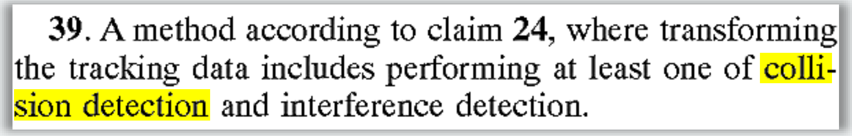
Ex. 2004, Cleary Decl. at ¶ 54
Paper No. 10, Patent Owner Response at 25

Taylor Does Not Anticipate Claims 16, 39, 54, 55, and 57



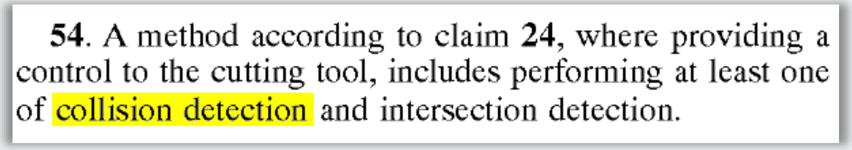
16. A system according to claim **1**, where the controller includes at least one of a collision detection module and an intersection detection module.

Ex. 1001, ’582 Patent at 21:36-38



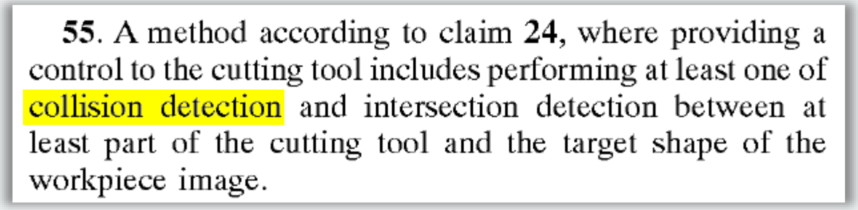
39. A method according to claim **24**, where transforming the tracking data includes performing at least one of collision detection and interference detection.

Ex. 1001, ’582 Patent at 23:21-23



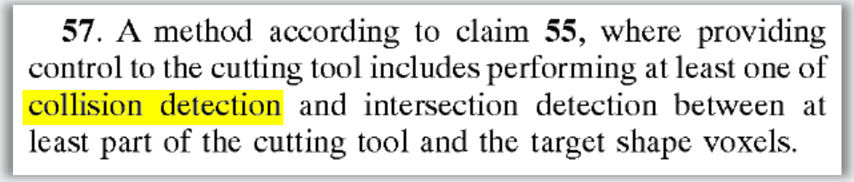
54. A method according to claim **24**, where providing a control to the cutting tool, includes performing at least one of collision detection and intersection detection.

Ex. 1001, ’582 Patent at 24:18-20



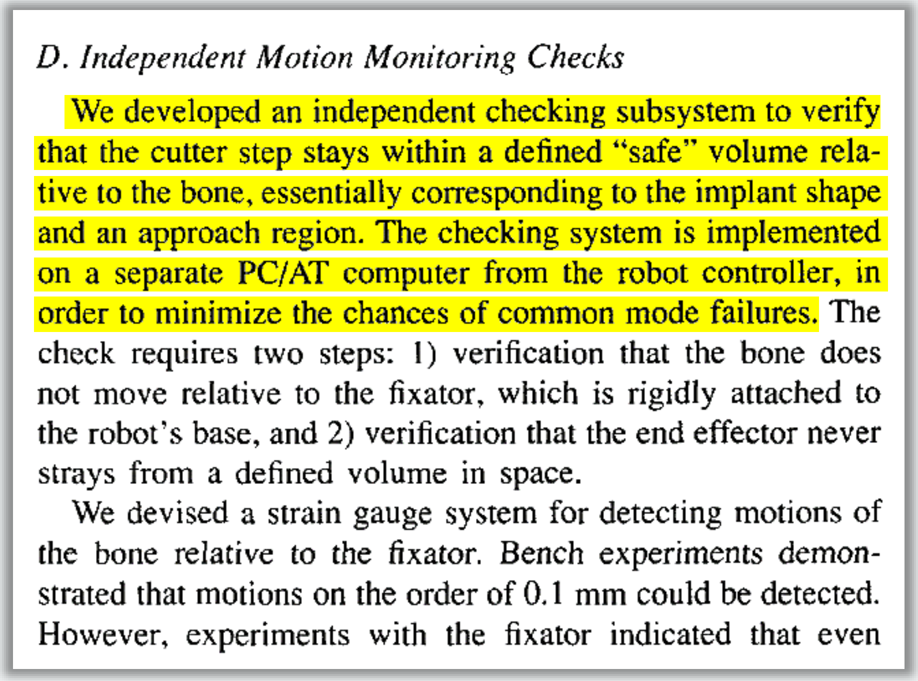
55. A method according to claim **24**, where providing a control to the cutting tool includes performing at least one of collision detection and intersection detection between at least part of the cutting tool and the target shape of the workpiece image.

Ex. 1001, ’582 Patent at 24:21-25



57. A method according to claim **55**, where providing control to the cutting tool includes performing at least one of collision detection and intersection detection between at least part of the cutting tool and the target shape voxels.

Ex. 1001, ’582 Patent at 24:30-33



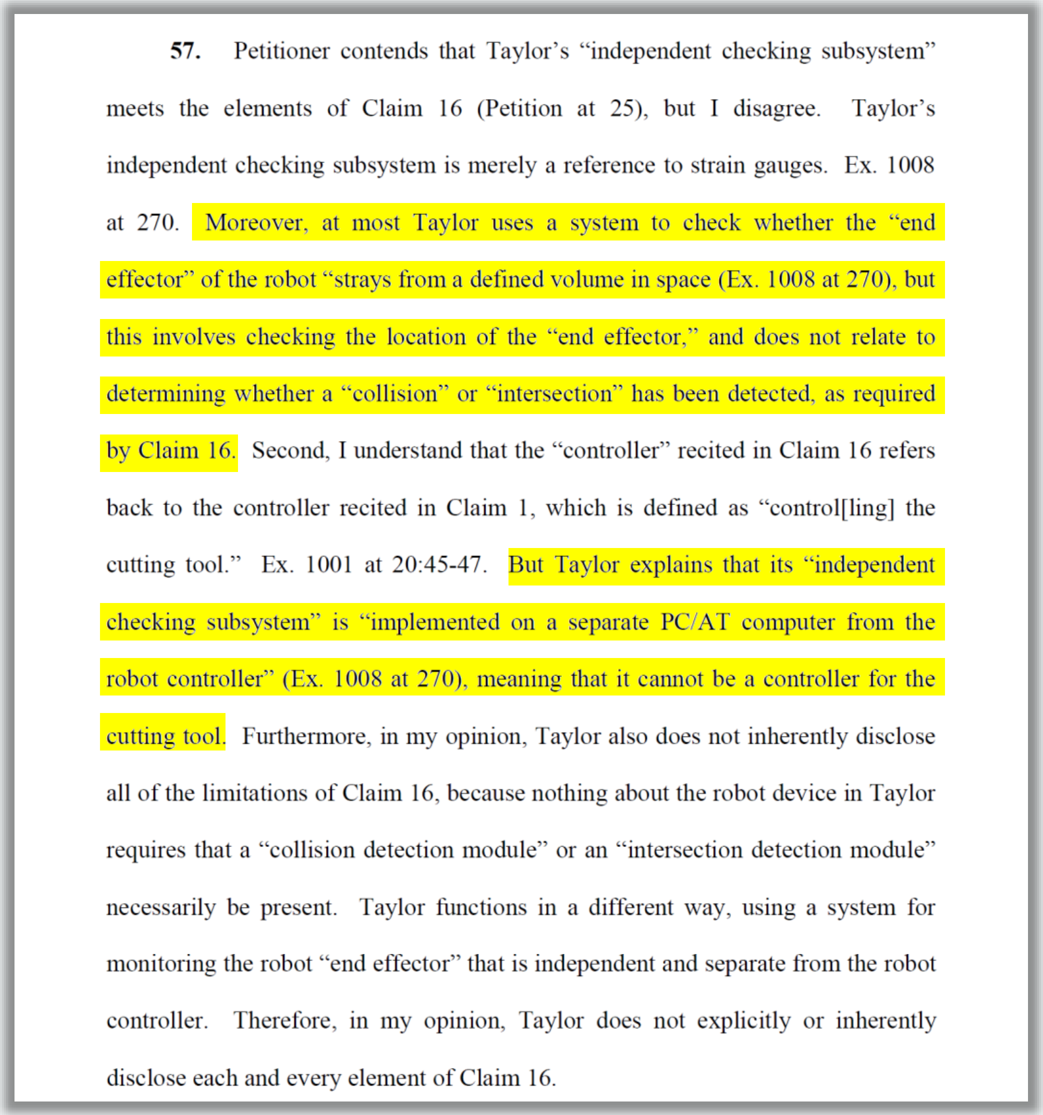
D. Independent Motion Monitoring Checks

We developed an independent checking subsystem to verify that the cutter step stays within a defined “safe” volume relative to the bone, essentially corresponding to the implant shape and an approach region. The checking system is implemented on a separate PC/AT computer from the robot controller, in order to minimize the chances of common mode failures. The check requires two steps: 1) verification that the bone does not move relative to the fixator, which is rigidly attached to the robot’s base, and 2) verification that the end effector never strays from a defined volume in space.

We devised a strain gauge system for detecting motions of the bone relative to the fixator. Bench experiments demonstrated that motions on the order of 0.1 mm could be detected. However, experiments with the fixator indicated that even

Ex. 1008, Taylor at 270
Paper No. 1, Petition at 25

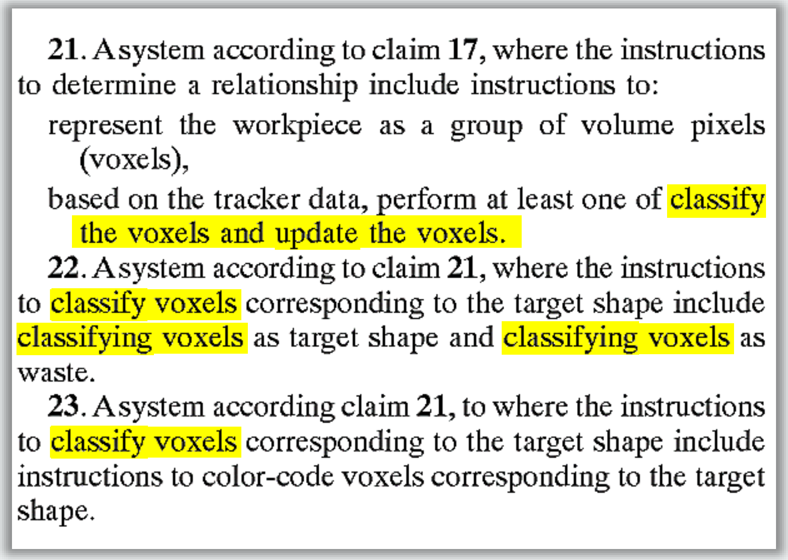
Taylor Does Teach “Collision Detection” by the “Controller”



57. Petitioner contends that Taylor’s “independent checking subsystem” meets the elements of Claim 16 (Petition at 25), but I disagree. Taylor’s independent checking subsystem is merely a reference to strain gauges. Ex. 1008 at 270. Moreover, at most Taylor uses a system to check whether the “end effector” of the robot “strays from a defined volume in space (Ex. 1008 at 270), but this involves checking the location of the “end effector,” and does not relate to determining whether a “collision” or “intersection” has been detected, as required by Claim 16. Second, I understand that the “controller” recited in Claim 16 refers back to the controller recited in Claim 1, which is defined as “control[ling] the cutting tool.” Ex. 1001 at 20:45-47. But Taylor explains that its “independent checking subsystem” is “implemented on a separate PC/AT computer from the robot controller” (Ex. 1008 at 270), meaning that it cannot be a controller for the cutting tool. Furthermore, in my opinion, Taylor also does not inherently disclose all of the limitations of Claim 16, because nothing about the robot device in Taylor requires that a “collision detection module” or an “intersection detection module” necessarily be present. Taylor functions in a different way, using a system for monitoring the robot “end effector” that is independent and separate from the robot controller. Therefore, in my opinion, Taylor does not explicitly or inherently disclose each and every element of Claim 16.

Ex. 2004, Cleary Decl. at ¶ 57
Paper No. 10, Patent Owner Response at 27

Taylor Does Not Teach "Classifying," "Updating," "Identifying" "Voxels" as Required by Claims 21-23, 26-30, 40-42, 50-52, and 56



21. A system according to claim **17**, where the instructions to determine a relationship include instructions to:

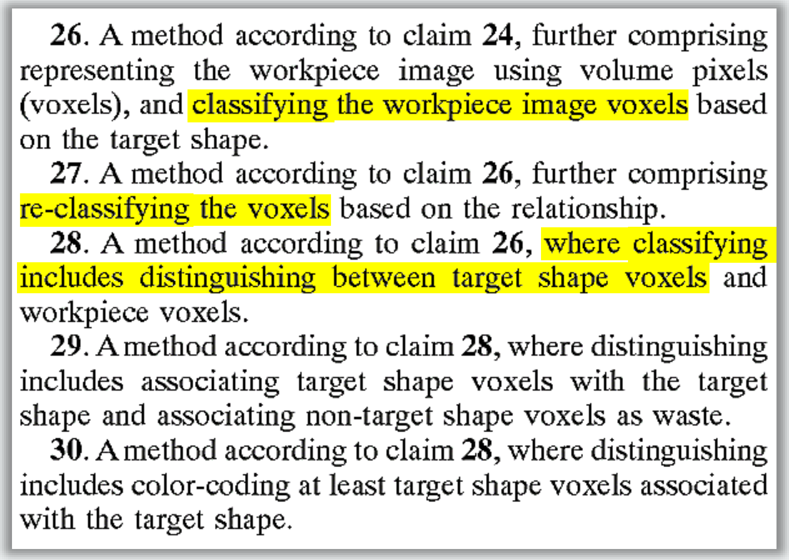
represent the workpiece as a group of volume pixels (voxels),

based on the tracker data, perform at least one of classify the voxels and update the voxels.

22. A system according to claim **21**, where the instructions to classify voxels corresponding to the target shape include classifying voxels as target shape and classifying voxels as waste.

23. A system according claim **21**, to where the instructions to classify voxels corresponding to the target shape include instructions to color-code voxels corresponding to the target shape.

Ex. 1001, '582 Patent at 22:12-25



26. A method according to claim **24**, further comprising representing the workpiece image using volume pixels (voxels), and classifying the workpiece image voxels based on the target shape.

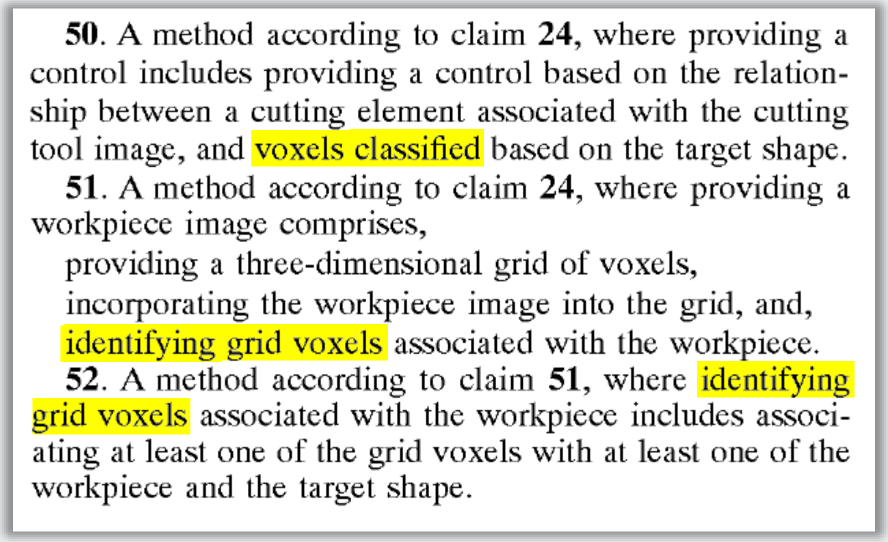
27. A method according to claim **26**, further comprising re-classifying the voxels based on the relationship.

28. A method according to claim **26**, where classifying includes distinguishing between target shape voxels and workpiece voxels.

29. A method according to claim **28**, where distinguishing includes associating target shape voxels with the target shape and associating non-target shape voxels as waste.

30. A method according to claim **28**, where distinguishing includes color-coding at least target shape voxels associated with the target shape.

Ex. 1001, '582 Patent at 22:43-57



50. A method according to claim **24**, where providing a control includes providing a control based on the relationship between a cutting element associated with the cutting tool image, and voxels classified based on the target shape.

51. A method according to claim **24**, where providing a workpiece image comprises,

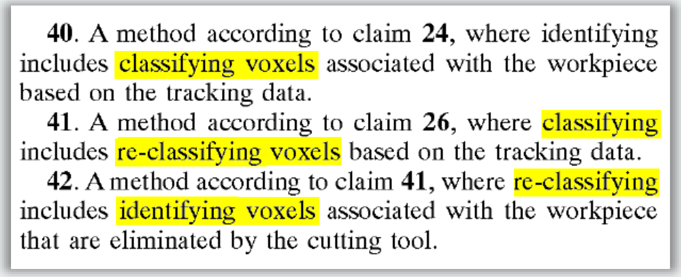
providing a three-dimensional grid of voxels,

incorporating the workpiece image into the grid, and,

identifying grid voxels associated with the workpiece.

52. A method according to claim **51**, where identifying grid voxels associated with the workpiece includes associating at least one of the grid voxels with at least one of the workpiece and the target shape.

Ex. 1001, '582 Patent at 23:56-24:9

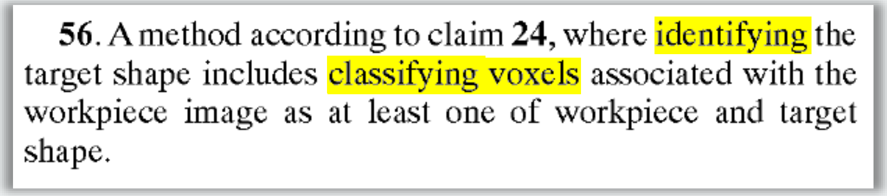


40. A method according to claim **24**, where identifying includes classifying voxels associated with the workpiece based on the tracking data.

41. A method according to claim **26**, where classifying includes re-classifying voxels based on the tracking data.

42. A method according to claim **41**, where re-classifying includes identifying voxels associated with the workpiece that are eliminated by the cutting tool.

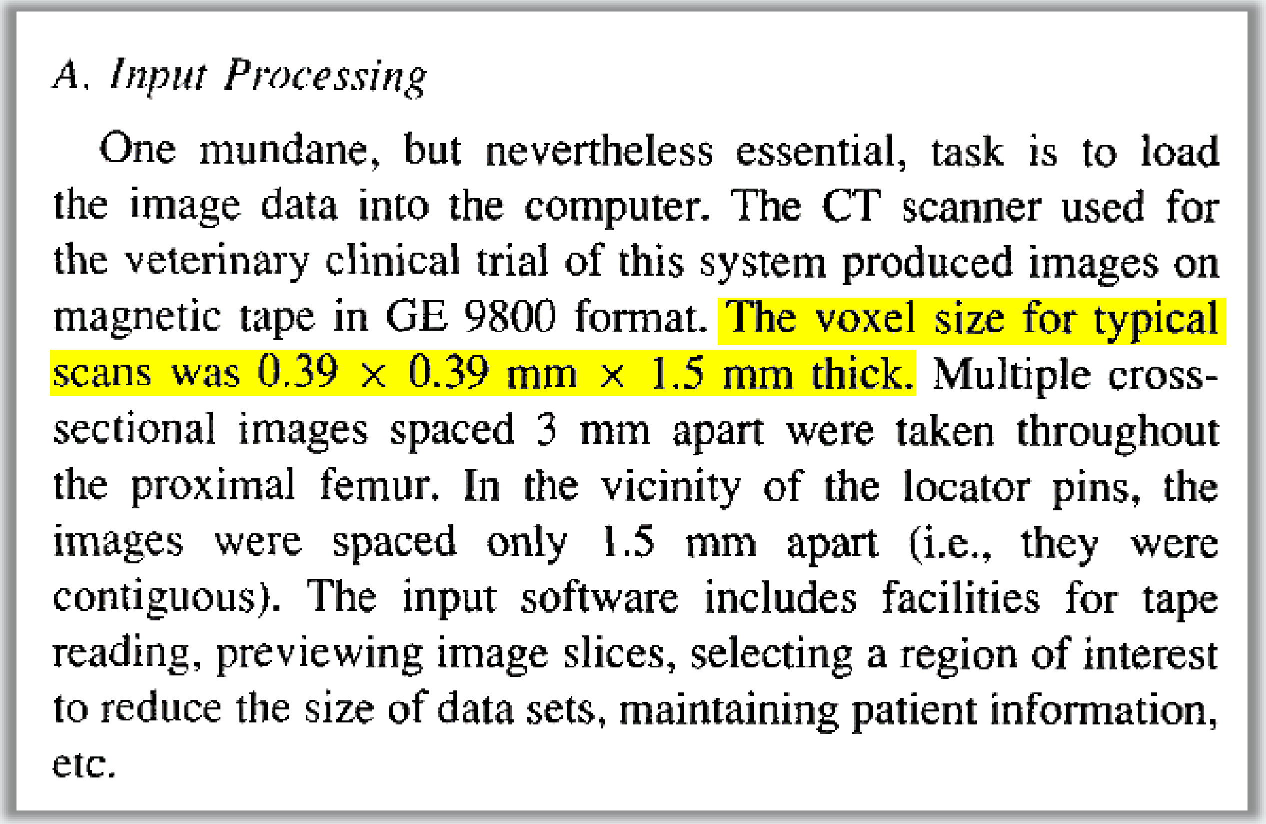
Ex. 1001, '582 Patent at 23:24-31



56. A method according to claim **24**, where identifying the target shape includes classifying voxels associated with the workpiece image as at least one of workpiece and target shape.

Ex. 1001, '582 Patent at 24:25-28

Taylor Does Not Teach "Classifying," "Updating," "Identifying" "Voxels" as Required by Claims 21-23, 26-30, 40-42, 50-52, and 56

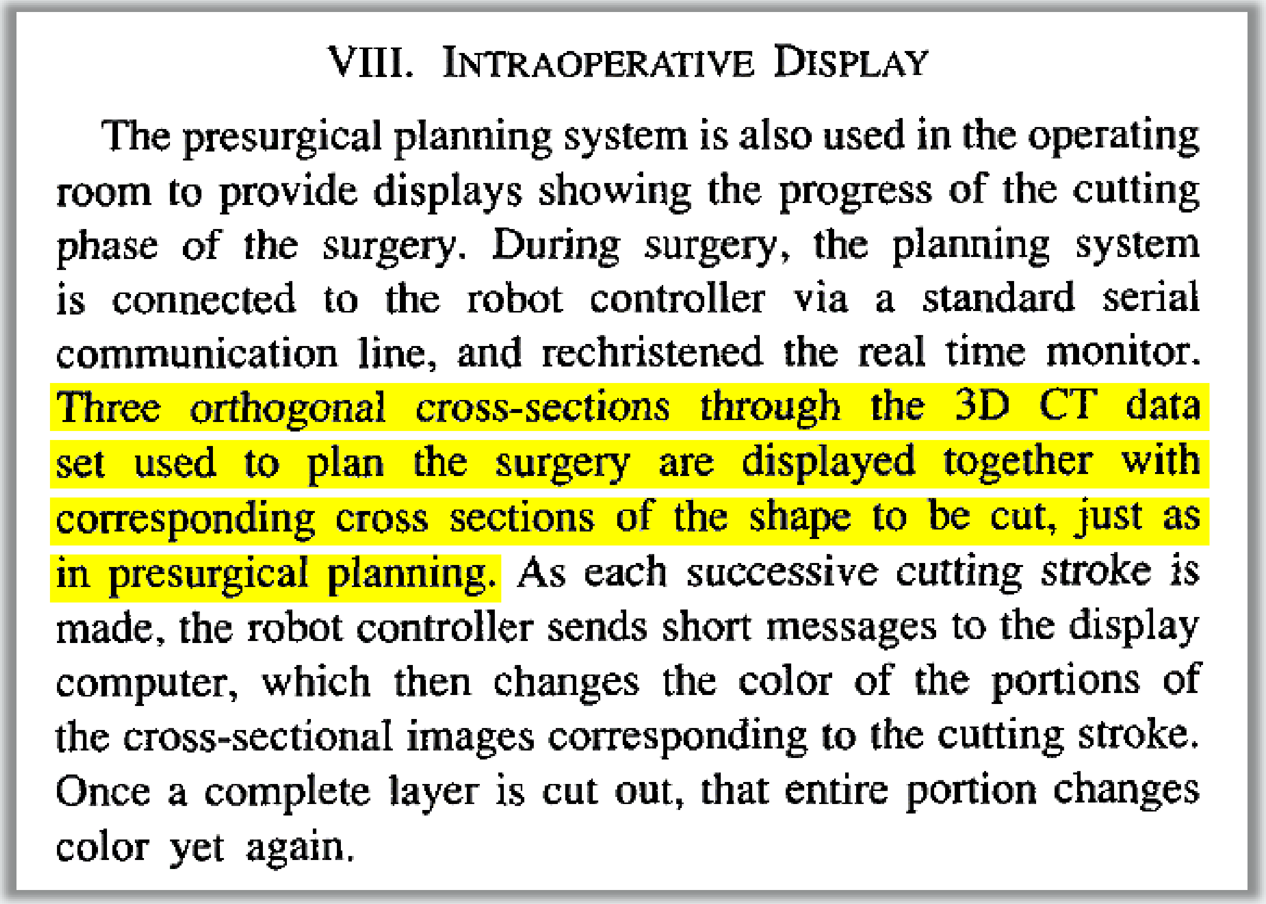


A. Input Processing

One mundane, but nevertheless essential, task is to load the image data into the computer. The CT scanner used for the veterinary clinical trial of this system produced images on magnetic tape in GE 9800 format. The voxel size for typical scans was 0.39 × 0.39 mm × 1.5 mm thick. Multiple cross-sectional images spaced 3 mm apart were taken throughout the proximal femur. In the vicinity of the locator pins, the images were spaced only 1.5 mm apart (i.e., they were contiguous). The input software includes facilities for tape reading, previewing image slices, selecting a region of interest to reduce the size of data sets, maintaining patient information, etc.

Ex. 1008, Taylor at 266
Paper No. 1, Petition at 28

Taylor Does Not Teach “Classifying,” “Updating,” “Identifying” “Voxels” as Required by Claims 21-23, 26-30, 40-42, 50-52, and 56

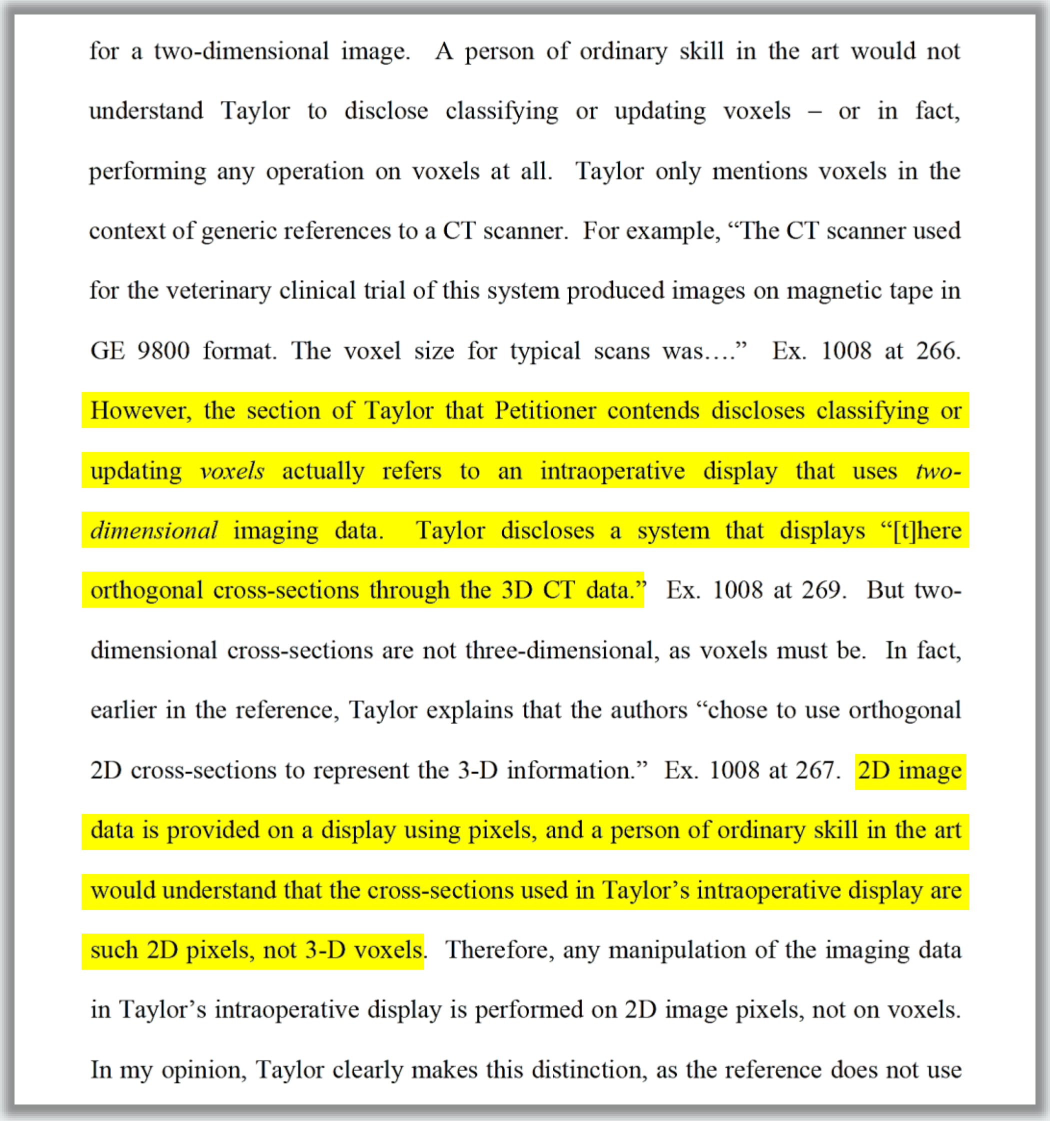


VIII. INTRAOPERATIVE DISPLAY

The presurgical planning system is also used in the operating room to provide displays showing the progress of the cutting phase of the surgery. During surgery, the planning system is connected to the robot controller via a standard serial communication line, and rechristened the real time monitor. Three orthogonal cross-sections through the 3D CT data set used to plan the surgery are displayed together with corresponding cross sections of the shape to be cut, just as in presurgical planning. As each successive cutting stroke is made, the robot controller sends short messages to the display computer, which then changes the color of the portions of the cross-sectional images corresponding to the cutting stroke. Once a complete layer is cut out, that entire portion changes color yet again.

Ex. 1008, Taylor at 269
Paper No. 1, Petition at 28

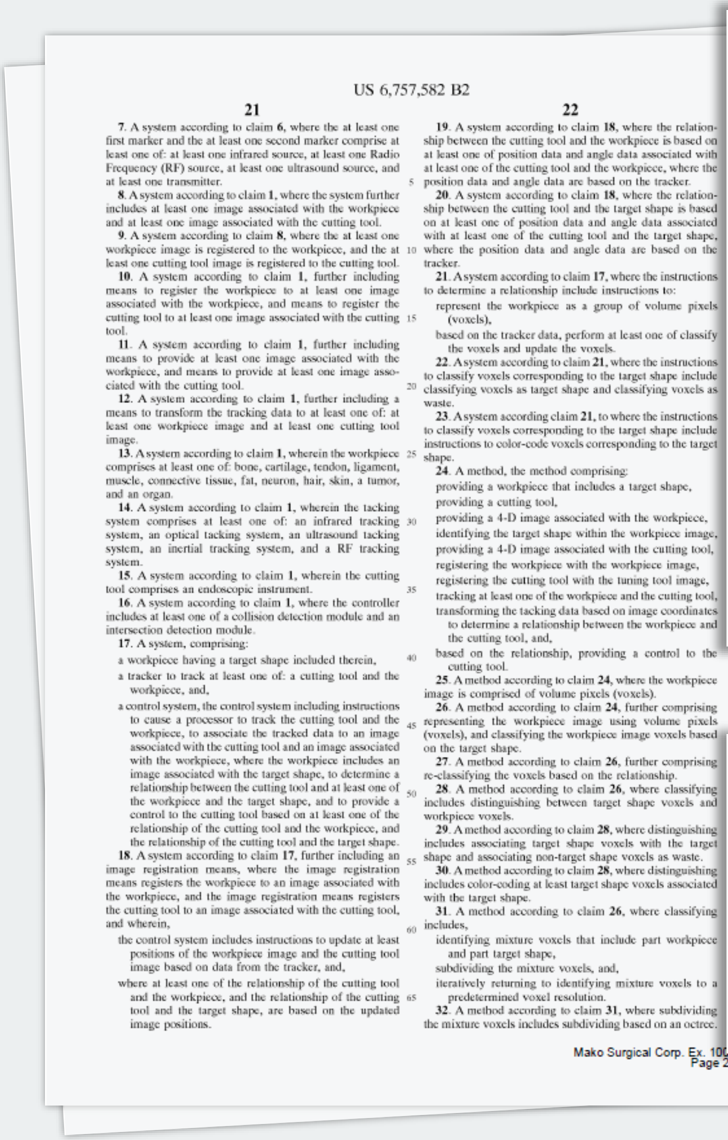
Taylor Does Not Teach “Classifying,” “Updating,” “Identifying” “Voxels” as Required by Claims 21-23, 26-30, 40-42, 50-52, and 56



for a two-dimensional image. A person of ordinary skill in the art would not understand Taylor to disclose classifying or updating voxels – or in fact, performing any operation on voxels at all. Taylor only mentions voxels in the context of generic references to a CT scanner. For example, “The CT scanner used for the veterinary clinical trial of this system produced images on magnetic tape in GE 9800 format. The voxel size for typical scans was….” Ex. 1008 at 266. However, the section of Taylor that Petitioner contends discloses classifying or updating *voxels* actually refers to an intraoperative display that uses *two-dimensional* imaging data. Taylor discloses a system that displays “[t]here orthogonal cross-sections through the 3D CT data.” Ex. 1008 at 269. But two-dimensional cross-sections are not three-dimensional, as voxels must be. In fact, earlier in the reference, Taylor explains that the authors “chose to use orthogonal 2D cross-sections to represent the 3-D information.” Ex. 1008 at 267. 2D image data is provided on a display using pixels, and a person of ordinary skill in the art would understand that the cross-sections used in Taylor’s intraoperative display are such 2D pixels, not 3-D voxels. Therefore, any manipulation of the imaging data in Taylor’s intraoperative display is performed on 2D image pixels, not on voxels. In my opinion, Taylor clearly makes this distinction, as the reference does not use

Ex. 2004, Cleary Decl. at ¶ 64
Paper No. 10, Patent Owner Response at 33

Taylor Does Not Anticipate Claims 35 and 36



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7. A system according to claim **6**, where the at least one first marker and the at least one second marker comprise at least one of: at least one infrared source, at least one Radio Frequency (RF) source, at least one ultrasound source, and at least one transmitter.

8. A system according to claim **1**, where the system further includes at least one image associated with the workpiece and at least one image associated with the cutting tool.

9. A system according to claim **8**, where the at least one workpiece image is registered to the workpiece, and the at least one cutting tool image is registered to the cutting tool.

10. A system according to claim **1**, further including means to register the workpiece to at least one image associated with the workpiece, and means to register the cutting tool to at least one image associated with the cutting tool.

11. A system according to claim **1**, further including means to provide at least one image associated with the workpiece, and means to provide at least one image associated with the cutting tool.

12. A system according to claim **1**, further including a means to transform the tracking data to at least one of: at least one workpiece image and at least one cutting tool image.

13. A system according to claim **1**, wherein the workpiece comprises at least one of: bone, cartilage, tendon, ligament, muscle, connective tissue, fat, neuron, hair, skin, a tumor, and an organ.

14. A system according to claim **1**, wherein the tacking system comprises at least one of: an infrared tracking system, an optical tacking system, an ultrasound tacking system, an inertial tracking system, and a RF tracking system.

15. A system according to claim **1**, wherein the cutting tool comprises an endoscopic instrument.

16. A system according to claim **1**, where the controller includes at least one of a collision detection module and an intersection detection module.

17. A system, comprising:

a workpiece having a target shape included therein,

a tracker to track at least one of: a cutting tool and the workpiece, and,

a control system, the control system including instructions to cause a processor to track the cutting tool and the workpiece, to associate the tracked data to an image associated with the cutting tool and an image associated with the workpiece, where the workpiece includes an image associated with the target shape, to determine a relationship between the cutting tool and at least one of the workpiece and the target shape, and to provide a control to the cutting tool based on at least one of the relationship of the cutting tool and the workpiece, and the relationship of the cutting tool and the target shape.

18. A system according to claim **17**, further including an image registration means, where the image registration means registers the workpiece to an image associated with the workpiece, and the image registration means registers the cutting tool to an image associated with the cutting tool, and wherein,

the control system includes instructions to update at least positions of the workpiece image and the cutting tool image based on data from the tracker, and,

where at least one of the relationship of the cutting tool and the workpiece, and the relationship of the cutting tool and the target shape, are based on the updated image positions.

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19. A system according to claim **18**, where the relationship between the cutting tool and the workpiece is based on at least one of position data and angle data associated with at least one of the cutting tool and the workpiece, where the position data and angle data are based on the tracker.

20. A system according to claim **18**, where the relationship between the cutting tool and the target shape is based on at least one of position data and angle data associated with at least one of the cutting tool and the target shape, where the position data and angle data are based on the tracker.

21. A system according to claim **17**, where the instructions to determine a relationship include instructions to:

represent the workpiece as a group of volume pixels (voxels),

based on the tracker data, perform at least one of classify the voxels and update the voxels.

22. A system according to claim **21**, where the instructions to classify voxels corresponding to the target shape include classifying voxels as target shape and classifying voxels as waste.

23. A system according claim **21**, to where the instructions to classify voxels corresponding to the target shape include instructions to color-code voxels corresponding to the target shape.

24. A method, the method comprising:

providing a workpiece that includes a target shape,

providing a cutting tool,

providing a 4-D image associated with the workpiece,

identifying the target shape within the workpiece image,

providing a 4-D image associated with the cutting tool,

registering the workpiece with the workpiece image,

registering the cutting tool with the tuning tool image,

tracking at least one of the workpiece and the cutting tool,

transforming the tacking data based on image coordinates to determine a relationship between the workpiece and the cutting tool, and,

based on the relationship, providing a control to the cutting tool.

25. A method according to claim **24**, where the workpiece image is comprised of volume pixels (voxels).

26. A method according to claim **24**, further comprising representing the workpiece image using volume pixels (voxels), and classifying the workpiece image voxels based on the target shape.

27. A method according to claim **26**, further comprising re-classifying the voxels based on the relationship.

28. A method according to claim **26**, where classifying includes distinguishing between target shape voxels and workpiece voxels.

29. A method according to claim **28**, where distinguishing includes associating target shape voxels with the target shape and associating non-target shape voxels as waste.

30. A method according to claim **28**, where distinguishing includes color-coding at least target shape voxels associated with the target shape.

31. A method according to claim **26**, where classifying includes,

identifying mixture voxels that include part workpiece and part target shape,

subdividing the mixture voxels, and,

iteratively returning to identifying mixture voxels to a predetermined voxel resolution.

32. A method according to claim **31**, where subdividing the mixture voxels includes subdividing based on an octree.

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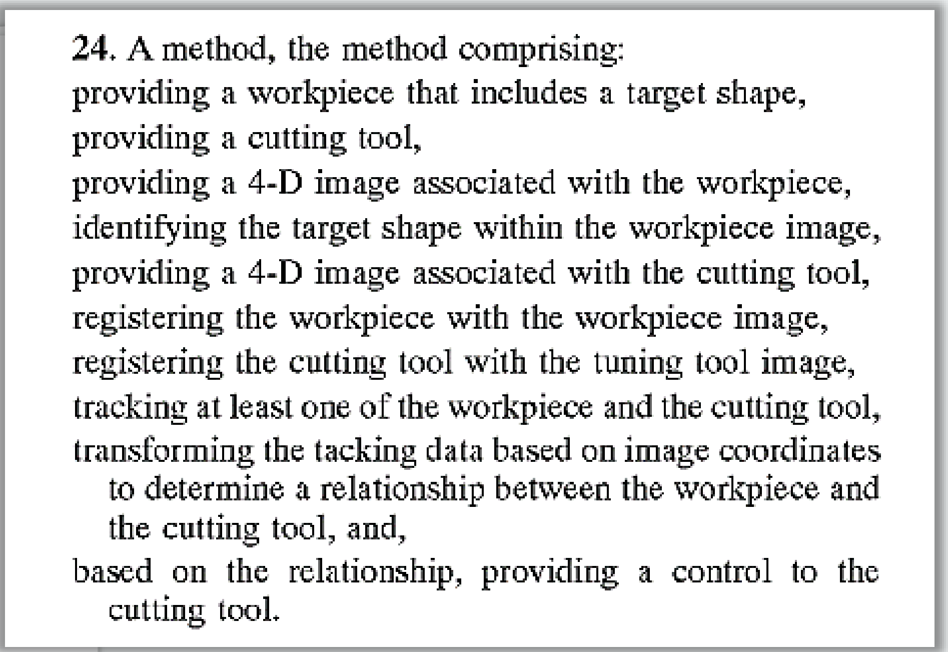


24. A method, the method comprising:

providing a workpiece that includes a target shape,

providing a cutting tool,

providing a 4-D image associated with the workpiece,

identifying the target shape within the workpiece image,

providing a 4-D image associated with the cutting tool,

registering the workpiece with the workpiece image,

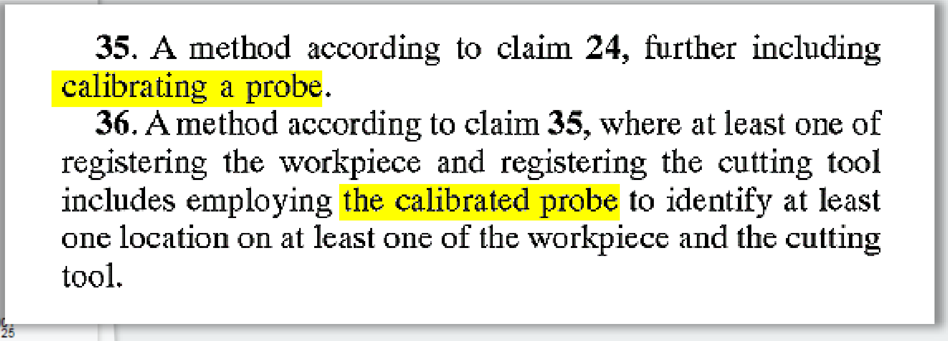
registering the cutting tool with the tuning tool image,

tracking at least one of the workpiece and the cutting tool,

transforming the tacking data based on image coordinates to determine a relationship between the workpiece and the cutting tool, and,

based on the relationship, providing a control to the cutting tool.

Ex. 1001, '582 Patent at 22:26-40

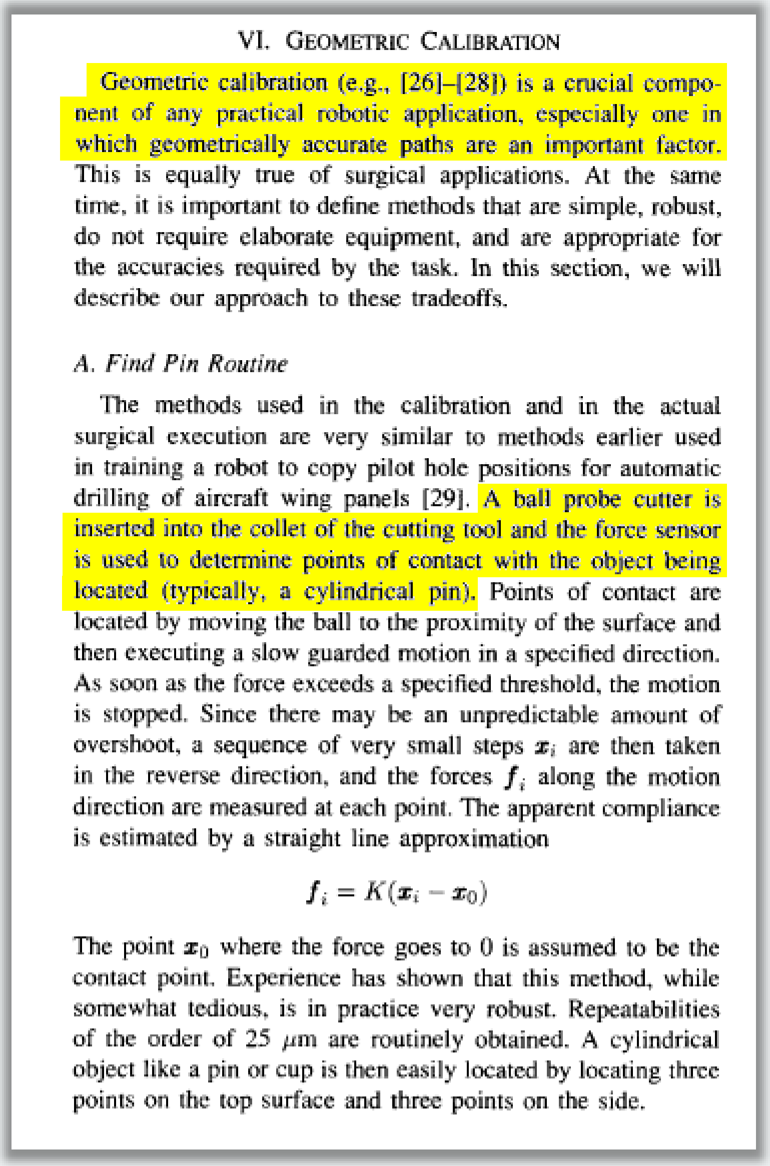


35. A method according to claim **24**, further including calibrating a probe.

36. A method according to claim **35**, where at least one of registering the workpiece and registering the cutting tool includes employing the calibrated probe to identify at least one location on at least one of the workpiece and the cutting tool.

Ex. 1001, '582 Patent at 23:7-13

Taylor Does Not Anticipate Claims 35 and 36



VI. GEOMETRIC CALIBRATION

Geometric calibration (e.g., [26]–[28]) is a crucial component of any practical robotic application, especially one in which geometrically accurate paths are an important factor. This is equally true of surgical applications. At the same time, it is important to define methods that are simple, robust, do not require elaborate equipment, and are appropriate for the accuracies required by the task. In this section, we will describe our approach to these tradeoffs.

A. *Find Pin Routine*

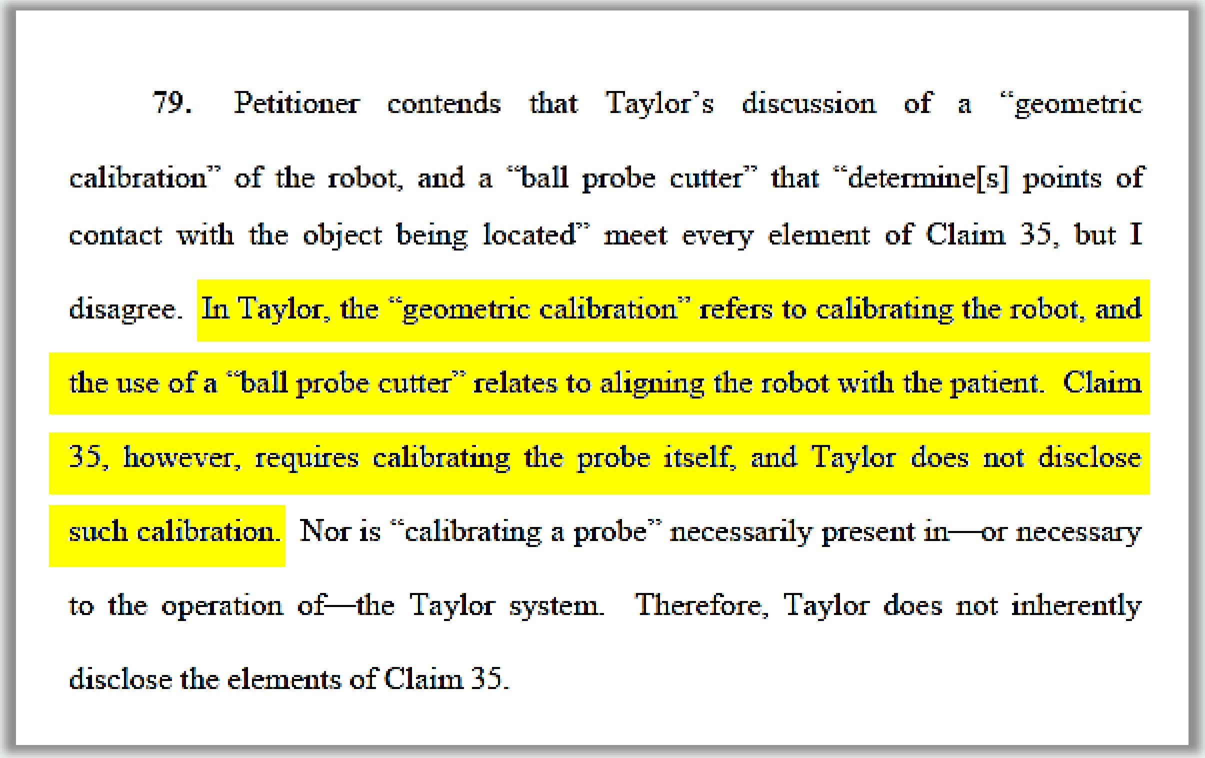
The methods used in the calibration and in the actual surgical execution are very similar to methods earlier used in training a robot to copy pilot hole positions for automatic drilling of aircraft wing panels [29]. A ball probe cutter is inserted into the collet of the cutting tool and the force sensor is used to determine points of contact with the object being located (typically, a cylindrical pin). Points of contact are located by moving the ball to the proximity of the surface and then executing a slow guarded motion in a specified direction. As soon as the force exceeds a specified threshold, the motion is stopped. Since there may be an unpredictable amount of overshoot, a sequence of very small steps $\boldsymbol{x}_i$ are then taken in the reverse direction, and the forces $\boldsymbol{f}_i$ along the motion direction are measured at each point. The apparent compliance is estimated by a straight line approximation

$$\boldsymbol{f}_i = K(\boldsymbol{x}_i - \boldsymbol{x}_0)$$

The point $\boldsymbol{x}_0$ where the force goes to 0 is assumed to be the contact point. Experience has shown that this method, while somewhat tedious, is in practice very robust. Repeatabilities of the order of 25 μm are routinely obtained. A cylindrical object like a pin or cup is then easily located by locating three points on the top surface and three points on the side.

Ex. 1008, Taylor at 268
Paper No.1, Petition at 31

Taylor Describes Geometric Calibration Using a Probe, Not Calibration of a Probe



79. Petitioner contends that Taylor's discussion of a "geometric calibration" of the robot, and a "ball probe cutter" that "determine[s] points of contact with the object being located" meet every element of Claim 35, but I disagree. In Taylor, the "geometric calibration" refers to calibrating the robot, and the use of a "ball probe cutter" relates to aligning the robot with the patient. Claim 35, however, requires calibrating the probe itself, and Taylor does not disclose such calibration. Nor is "calibrating a probe" necessarily present in—or necessary to the operation of—the Taylor system. Therefore, Taylor does not inherently disclose the elements of Claim 35.

Ex. 2004, Cleary Decl. at ¶ 79
Paper No. 10, Patent Owner Response at 43-44

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- Topics in Dispute

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2. Taylor Does Not Anticipate Independent Claims 1, 17, and 24 and Their Dependent Claims

3. **Taylor and DiGioia Do Not Render Claim 7 Obvious**

4. Taylor and Delp Do Not Render Claims 48 and 49 Obvious

5. The Motion to Exclude Should be Granted

Taylor and DiGioia Do Not Render Claim 7 Obvious

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deployment and use. The blade **504** may be extended or retracted with respect to an aperture **514**. The tool **30** may include a casing **308**. The casing may be formed of plastic or metal. The casing **308** may have a lubricious coating (not shown) to facilitate displacement of the tool **30** through a cannula. Examples of lubricious coatings include but are not limited to polyethylene, silicone, and hydrophilic substances.

FIG. **13** depicts a cross-section of the tool **30** shown in FIG. **12**. The blade **504** may advance or retract through an aperture **514** in the casing **308**. The position of the blade **504** may be controlled by an inner shaft **802** and an outer shaft **804**. The inner shaft **802** and the outer shaft **804** may be coaxial. The inner shaft **802** can couple to the blade **504** and cause the blade **504** to rotate when the inner shaft **802** rotates under drive power **803**. The inner shaft **802** can couple to the outer shaft **804** by a series of threads **806**. If the inner shaft **802** and the outer shaft **804** rotate at the same speed, then the blade **504** will neither advance nor retract. However, if different speeds are applied to the inner shaft **802** and the outer shaft **804** by a differential **808**, then the blade **504** can be repositioned. For example, if the inner shaft **802** is given a greater speed than outer shaft **804**, then the blade **502** can advance. Conversely, if the inner shaft **802** is given a lesser speed than outer shaft **804**, then the blade **502** can retract. The differential **808** may set speeds of the inner shaft **802** and the outer shaft **804** in response to a signal **54** from a controller (not shown), as described above.

Those or ordinary skill in the art will recognize that the methods and systems disclosed herein have wide applicability to surgical and non-surgical techniques. For example, the disclosed methods and systems can be applied to embodiments and/or applications that may employ stereo lithography, fused deposition machine (FDM), architecture, sculpting, and other areas.

The disclosed methods and systems thus include methods and systems to track a workpiece and a cutting tool, transform the tracked coordinates to the image coordinates, update the images accordingly based on the workpiece and/or cutting tool characteristics (i.e., cutting element size, dimensions, physical characteristics, etc.), and compute a control signal for transmission to the cutting tool.

The methods and systems described herein are not limited to a particular hardware or software configuration, and may find applicability in many computing or processing environments. The methods and systems can be implemented in hardware or software, or a combination of hardware and software. The methods and systems can be implemented in one or more computer programs, where a computer program can be understood to include one or more processor executable instructions. The computer program(s) can execute on one or more programmable processors, and can be stored on one or more storage medium readable by the processor (including volatile and non-volatile memory and/or storage elements), one or more input devices, and/or one or more output devices. The processor thus can access one or more input devices to obtain input data, and can access one or more output devices to communicate output data. The input and/or output devices can include one or more of the following: Random Access Memory (RAM), Redundant Array of Independent Disks (RAID), floppy drive, CD, DVD, magnetic disk, internal hard drive, external hard drive, memory stick, or other storage device capable of being accessed by a processor as provided herein, where such aforementioned examples are not exhaustive, and are for illustration and not limitation.

The computer program(s) is preferably implemented using one or more high level procedural or object-oriented

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programming languages to communicate wit
system; however, the program(s) can be im
assembly or machine language, if desired. The
be compiled or interpreted.

The processor(s) can thus be embedded in
devices that can be operated independently or
networked environment, where the network ca
example, a Local Area Network (LAN), wide
(WAN), and/or can include an intranet and/o
and/or another network. The network(s) can
wireless or a combination thereof and can use
communications protocols to facilitate com
between the different processors. The proce
configured for distributed processing and c
some embodiments, a client-server model
Accordingly, the methods and systems can ut
processors and/or processor devices, and t
instructions can be divided amongst such sing
processor/devices.

The device(s) or computer systems that integ
processor(s) can include, for example, a perso
(s), workstation (e.g., Sun, HP), personal dig
(PDA), handheld device such as cellular
another device capable of being integrated wit
(s) that can operate as provided herein. Acc
devices provided herein are not exhaustive and
for illustration and not limitation.

Many additional changes in the details, m
arrangement of parts, herein described and illus
made by those skilled in the art. According
understood that the following claims are not to
the embodiments disclosed herein, can inclu
otherwise than specifically described, and ar
preted as broadly as allowed under the law.

What is claimed is:

1. A system, comprising:

a cutting tool;

a workpiece that includes a target shape;

a tracker to provide tracking data associated with the cutting tool and the workpiece, where the tracker includes at least one of: at least one first marker associated with the workpiece, and at least one second marker associated with the cutting tool; and

a controller to control the cutting tool based on the
tracking data associated with the cutting
tracking data associated with the workpi

2. A system according to claim **1**, where th
is at least one of a hand-held and a free-hand

3. A system according to claim **1**, wherein th
includes at least one cutting element, and whe
element comprises at least one of: at least one
one rotatable blade, at least one retractable blad
water jet, at least one particulate jet, at least on
and at least one ultrasonic lithotriptor.

4. A system according to claim **1**, where
controls the cutting tool by providing a control
least one of: at least partially retract at leas
element, and at least partially reduce a rotati
least one cutting element.

5. A system according to claim **1**, where
transmits a control signal to the cutting too
control signal includes at least one of: an an
digital signal, and no signal.

6. A system according to claim **1**, where
includes tracking data based on at least three positions and at least three angles.

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What is claimed is:

1. A system, comprising:

a cutting tool;

a workpiece that includes a target shape;

a tracker to provide tracking data associated with the cutting tool and the workpiece, where the tracker includes at least one of: at least one first marker associated with the workpiece, and at least one second marker associated with the cutting tool; and

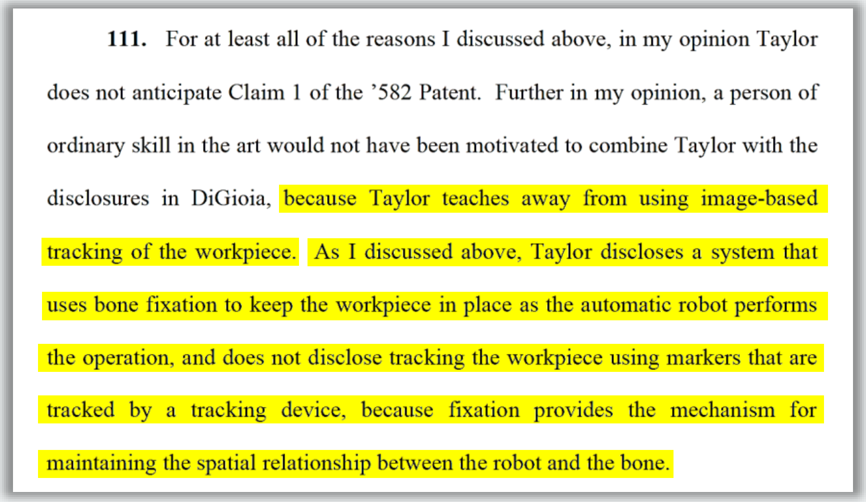
a controller to control the cutting tool based on the tracking data associated with the cutting tool and the tracking data associated with the workpiece.

Ex. 1001, ’582 Patent at 21:35-47

7. A system according to claim **6**, where the at least one first marker and the at least one second marker comprise at least one of: at least one infrared source, at least one Radio Frequency (RF) source, at least one ultrasound source, and at least one transmitter.

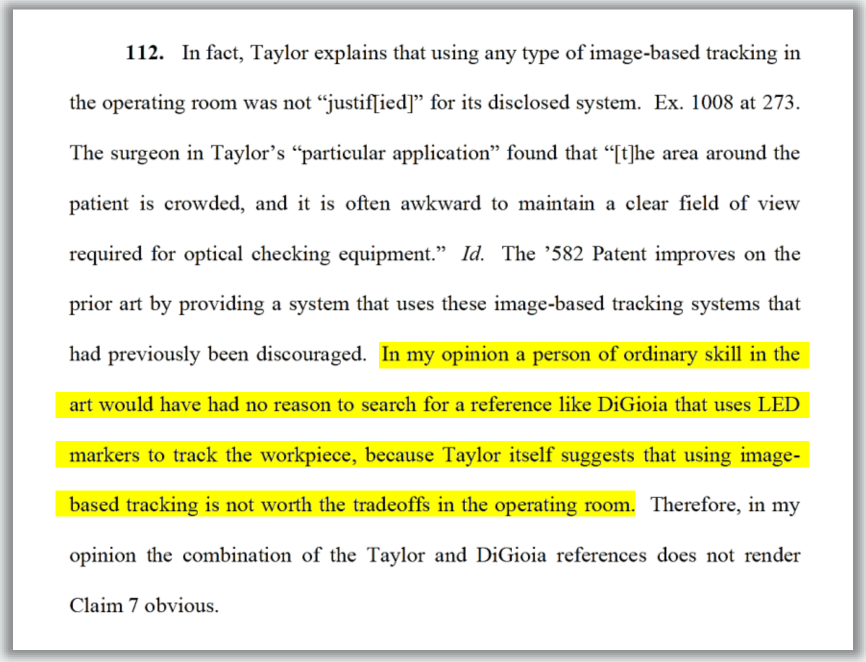
Ex. 1001, ’582 Patent at 22:1-5

Taylor and DiGioia Do Not Render Claim 7 Obvious



111. For at least all of the reasons I discussed above, in my opinion Taylor does not anticipate Claim 1 of the ’582 Patent. Further in my opinion, a person of ordinary skill in the art would not have been motivated to combine Taylor with the disclosures in DiGioia, because Taylor teaches away from using image-based tracking of the workpiece. As I discussed above, Taylor discloses a system that uses bone fixation to keep the workpiece in place as the automatic robot performs the operation, and does not disclose tracking the workpiece using markers that are tracked by a tracking device, because fixation provides the mechanism for maintaining the spatial relationship between the robot and the bone.

Ex. 2004, Cleary Decl. at ¶ 111
Paper No. 10, Patent Owner Response at 56



112. In fact, Taylor explains that using any type of image-based tracking in the operating room was not “justif[ied]” for its disclosed system. Ex. 1008 at 273. The surgeon in Taylor’s “particular application” found that “[t]he area around the patient is crowded, and it is often awkward to maintain a clear field of view required for optical checking equipment.” *Id.* The ’582 Patent improves on the prior art by providing a system that uses these image-based tracking systems that had previously been discouraged. In my opinion a person of ordinary skill in the art would have had no reason to search for a reference like DiGioia that uses LED markers to track the workpiece, because Taylor itself suggests that using image-based tracking is not worth the tradeoffs in the operating room. Therefore, in my opinion the combination of the Taylor and DiGioia references does not render Claim 7 obvious.

Ex. 2004, Cleary Decl. at ¶ 112
Paper No. 10, Patent Owner Response at 56

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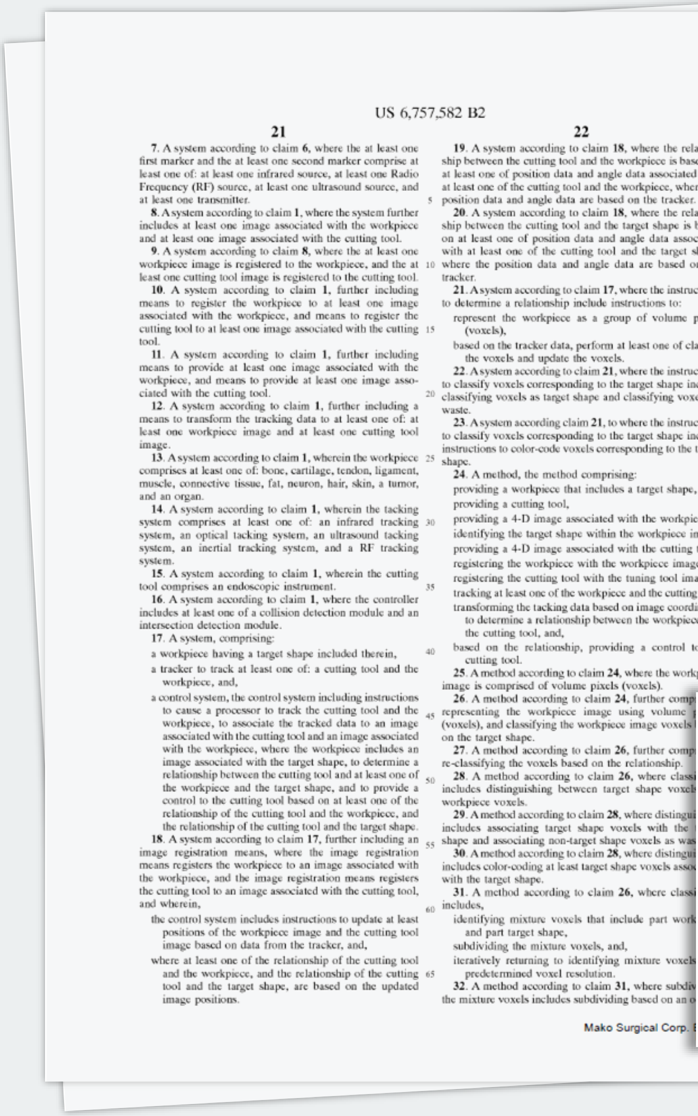
4. **Taylor and Delp Do Not Render Claims 48 and 49 Obvious**
5. The Motion to Exclude Should be Granted

Taylor and Delp Do Not Render Claims 48 and 49 Obvious



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7. A system according to claim **6**, where the at least one first marker and the at least one second marker comprise at least one of: at least one infrared source, at least one Radio Frequency (RF) source, at least one ultrasound source, and at least one transmitter.

8. A system according to claim **1**, where the system further includes at least one image associated with the workpiece and at least one image associated with the cutting tool.

9. A system according to claim **8**, where the at least one workpiece image is registered to the workpiece, and the at least one cutting tool image is registered to the cutting tool.

10. A system according to claim **1**, further including means to register the workpiece to at least one image associated with the workpiece, and means to register the cutting tool to at least one image associated with the cutting tool.

11. A system according to claim **1**, further including means to provide at least one image associated with the workpiece, and means to provide at least one image associated with the cutting tool.

12. A system according to claim **1**, further including a means to transform the tracking data to at least one of: at least one workpiece image and at least one cutting tool image.

13. A system according to claim **1**, wherein the workpiece comprises at least one of: bone, cartilage, tendon, ligament, muscle, connective tissue, fat, neuron, hair, skin, a tumor, and an organ.

14. A system according to claim **1**, wherein the tacking system comprises at least one of: an infrared tracking system, an optical tacking system, an ultrasound tacking system, an inertial tracking system, and a RF tracking system.

15. A system according to claim **1**, wherein the cutting tool comprises an endoscopic instrument.

16. A system according to claim **1**, where the controller includes at least one of a collision detection module and an intersection detection module.

17. A system, comprising:

a workpiece having a target shape included therein,

a tracker to track at least one of: a cutting tool and the workpiece, and,

a control system, the control system including instructions to cause a processor to track the cutting tool and the workpiece, to associate the tracked data to an image associated with the cutting tool and an image associated with the workpiece, where the workpiece includes an image associated with the target shape, to determine a relationship between the cutting tool and at least one of the workpiece and the target shape, and to provide a control to the cutting tool based on at least one of the relationship of the cutting tool and the workpiece, and the relationship of the cutting tool and the target shape.

18. A system according to claim **17**, further including an image registration means, where the image registration means registers the workpiece to an image associated with the workpiece, and the image registration means registers the cutting tool to an image associated with the cutting tool, and wherein,

the control system includes instructions to update at least positions of the workpiece image and the cutting tool image based on data from the tracker, and,

where at least one of the relationship of the cutting tool and the workpiece, and the relationship of the cutting tool and the target shape, are based on the updated image positions.

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19. A system according to claim **18**, where the relationship between the cutting tool and the workpiece is based on at least one of position data and angle data associated with at least one of the cutting tool and the workpiece, where the position data and angle data are based on the tracker.

20. A system according to claim **18**, where the relationship between the cutting tool and the target shape is based on at least one of position data and angle data associated with at least one of the cutting tool and the target shape, where the position data and angle data are based on the tracker.

21. A system according to claim **17**, where the instructions to determine a relationship include instructions to:

represent the workpiece as a group of volume pixels (voxels),

based on the tracker data, perform at least one of classify the voxels and update the voxels.

22. A system according to claim **21**, where the instructions to classify voxels corresponding to the target shape include classifying voxels as target shape and classifying voxels as waste.

23. A system according claim **21**, to where the instructions to classify voxels corresponding to the target shape include instructions to color-code voxels corresponding to the target shape.

24. A method, the method comprising:

providing a workpiece that includes a target shape,

providing a cutting tool,

providing a 4-D image associated with the workpiece,

identifying the target shape within the workpiece image,

providing a 4-D image associated with the cutting tool,

registering the workpiece with the workpiece image,

registering the cutting tool with the tuning tool image,

tracking at least one of the workpiece and the cutting tool,

transforming the tacking data based on image coordinates to determine a relationship between the workpiece and the cutting tool, and,

based on the relationship, providing a control to the cutting tool.

25. A method according to claim **24**, where the workpiece image is comprised of volume pixels (voxels).

26. A method according to claim **24**, further comp representing the workpiece image using volume (voxels), and classifying the workpiece image voxels on the target shape.

27. A method according to claim **26**, further comp re-classifying the voxels based on the relationship.

28. A method according to claim **26**, where classi includes distinguishing between target shape voxel workpiece voxels.

29. A method according to claim **28**, where distingui includes associating target shape voxels with the shape and associating non-target shape voxels as was

30. A method according to claim **28**, where distingui includes color-coding at least target shape voxels asso with the target shape.

31. A method according to claim **26**, where classi includes,

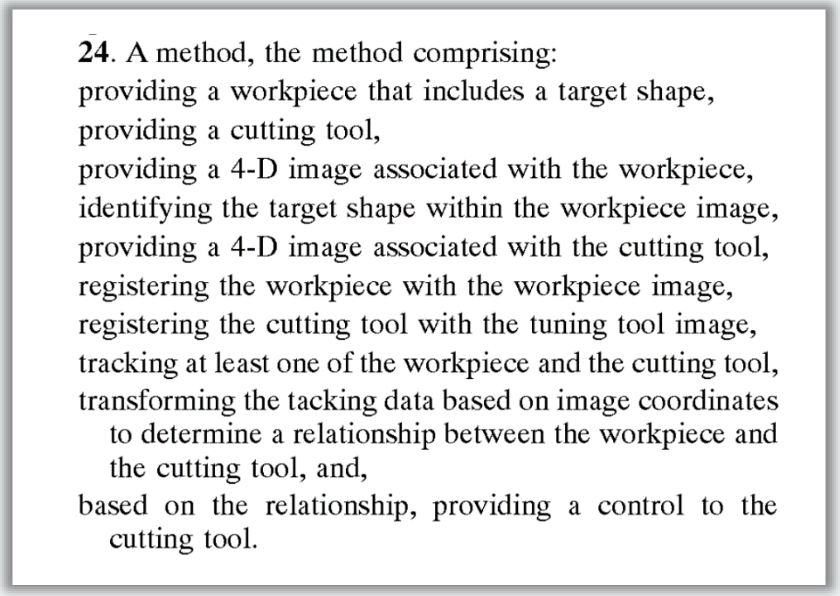
identifying mixture voxels that include part work and part target shape,

subdividing the mixture voxels, and,

iteratively returning to identifying mixture voxels predetermined voxel resolution.

32. A method according to claim **31**, where subdiv the mixture voxels includes subdividing based on an o

Mako Surgical Corp.



24. A method, the method comprising:

providing a workpiece that includes a target shape,

providing a cutting tool,

providing a 4-D image associated with the workpiece,

identifying the target shape within the workpiece image,

providing a 4-D image associated with the cutting tool,

registering the workpiece with the workpiece image,

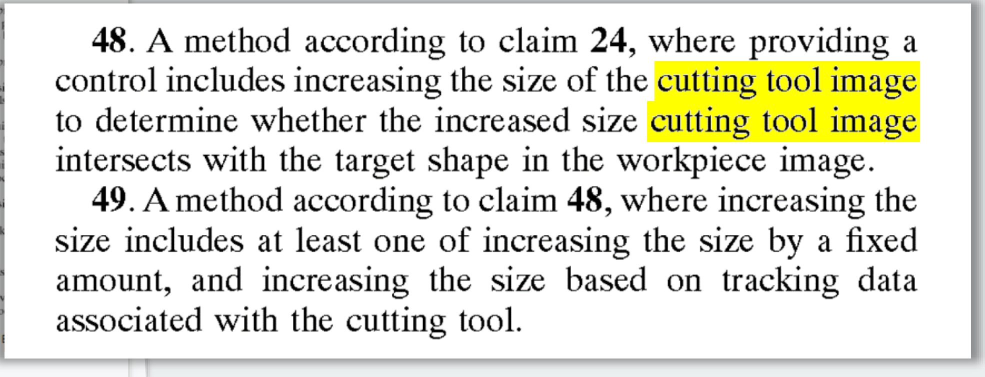
registering the cutting tool with the tuning tool image,

tracking at least one of the workpiece and the cutting tool,

transforming the tacking data based on image coordinates to determine a relationship between the workpiece and the cutting tool, and,

based on the relationship, providing a control to the cutting tool.

Ex. 1001, ’582 Patent at 25:26-42

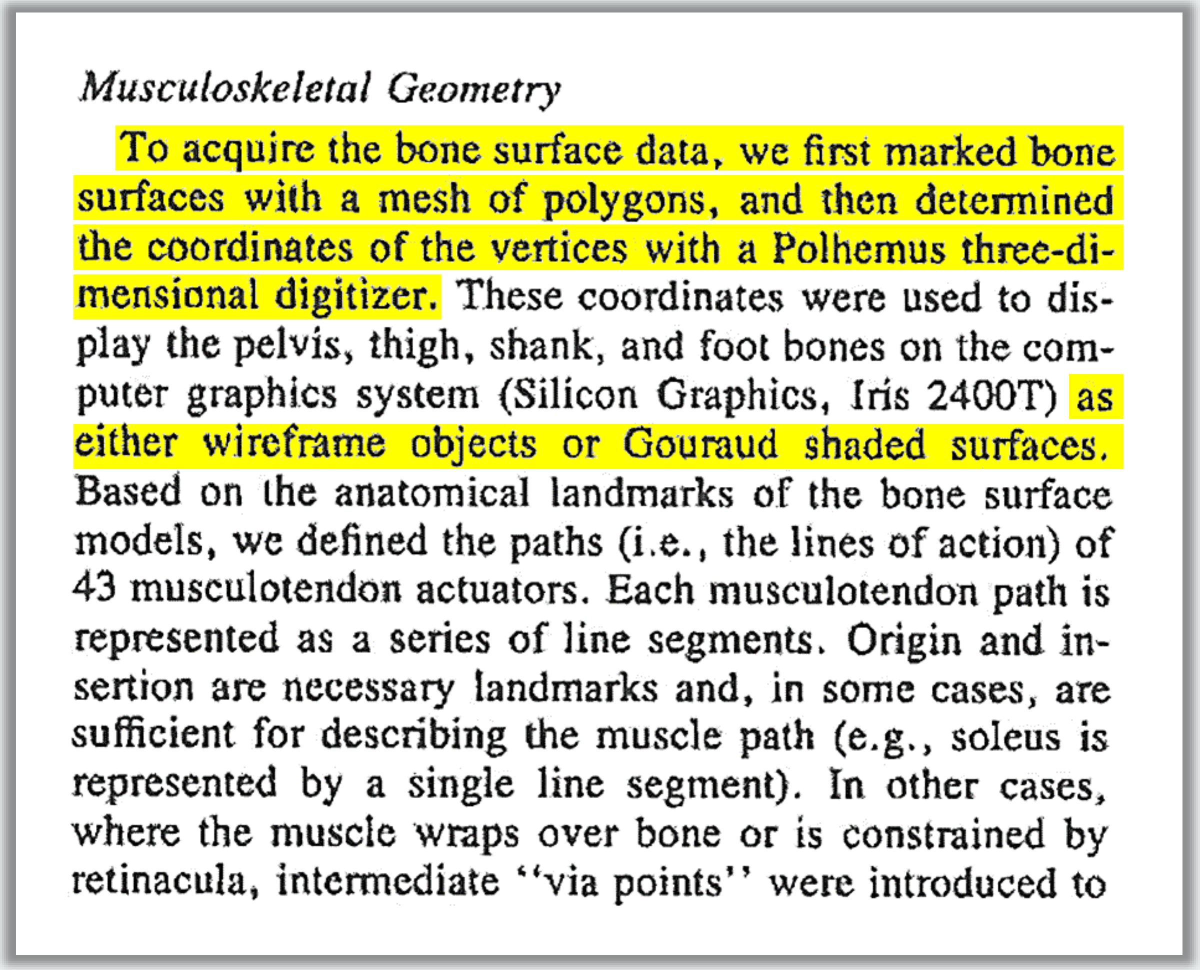


48. A method according to claim **24**, where providing a control includes increasing the size of the cutting tool image to determine whether the increased size cutting tool image intersects with the target shape in the workpiece image.

49. A method according to claim **48**, where increasing the size includes at least one of increasing the size by a fixed amount, and increasing the size based on tracking data associated with the cutting tool.

Ex. 1001, ’582 Patent at 26:48-56

Taylor and Delp Do Not Render Claims 48 and 49 Obvious



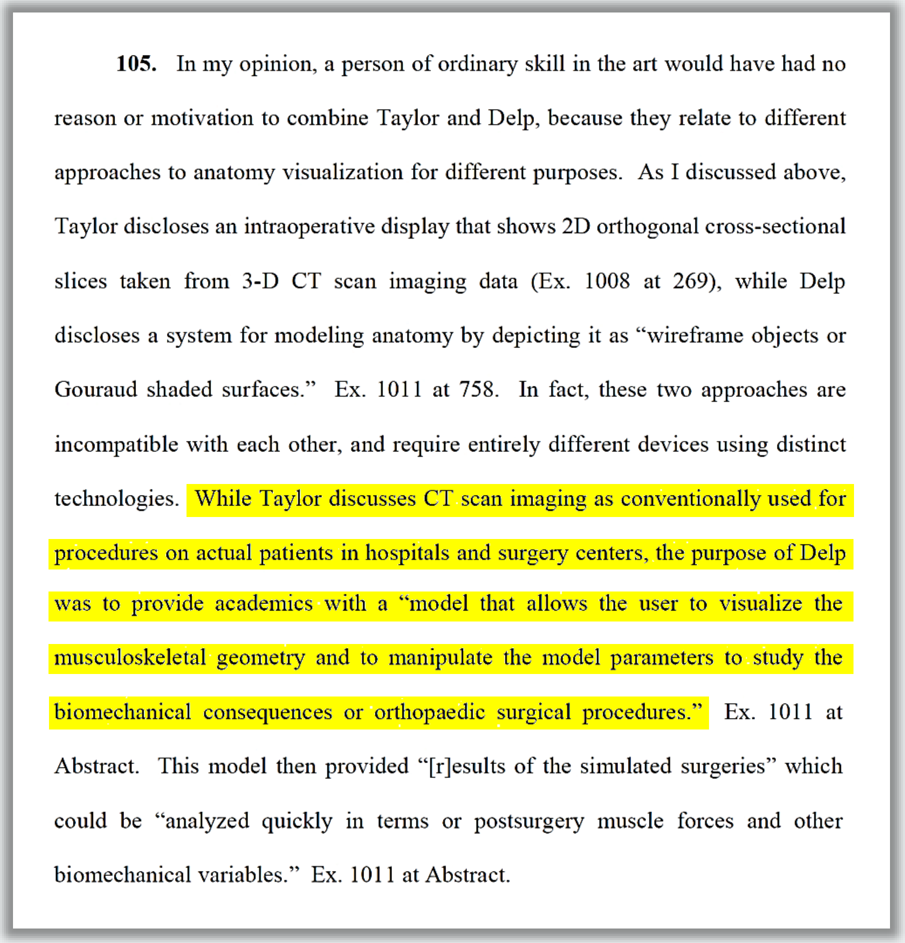
Musculoskeletal Geometry

To acquire the bone surface data, we first marked bone surfaces with a mesh of polygons, and then determined the coordinates of the vertices with a Polhemus three-dimensional digitizer. These coordinates were used to display the pelvis, thigh, shank, and foot bones on the computer graphics system (Silicon Graphics, Iris 2400T) as either wireframe objects or Gouraud shaded surfaces. Based on the anatomical landmarks of the bone surface models, we defined the paths (i.e., the lines of action) of 43 musculotendon actuators. Each musculotendon path is represented as a series of line segments. Origin and insertion are necessary landmarks and, in some cases, are sufficient for describing the muscle path (e.g., soleus is represented by a single line segment). In other cases, where the muscle wraps over bone or is constrained by retinacula, intermediate "via points" were introduced to

Ex. 1011, Delp at 758

Paper No. 10, Patent Owner Response at 59

Taylor and Delp Do Not Render Claims 48 and 49 Obvious



105. In my opinion, a person of ordinary skill in the art would have had no reason or motivation to combine Taylor and Delp, because they relate to different approaches to anatomy visualization for different purposes. As I discussed above, Taylor discloses an intraoperative display that shows 2D orthogonal cross-sectional slices taken from 3-D CT scan imaging data (Ex. 1008 at 269), while Delp discloses a system for modeling anatomy by depicting it as "wireframe objects or Gouraud shaded surfaces." Ex. 1011 at 758. In fact, these two approaches are incompatible with each other, and require entirely different devices using distinct technologies. While Taylor discusses CT scan imaging as conventionally used for procedures on actual patients in hospitals and surgery centers, the purpose of Delp was to provide academics with a "model that allows the user to visualize the musculoskeletal geometry and to manipulate the model parameters to study the biomechanical consequences or orthopaedic surgical procedures." Ex. 1011 at Abstract. This model then provided "[r]esults of the simulated surgeries" which could be "analyzed quickly in terms or postsurgery muscle forces and other biomechanical variables." Ex. 1011 at Abstract.

Ex. 2004, Cleary Decl. at ¶ 105
Paper No. 10, Patent Owner Response at 60

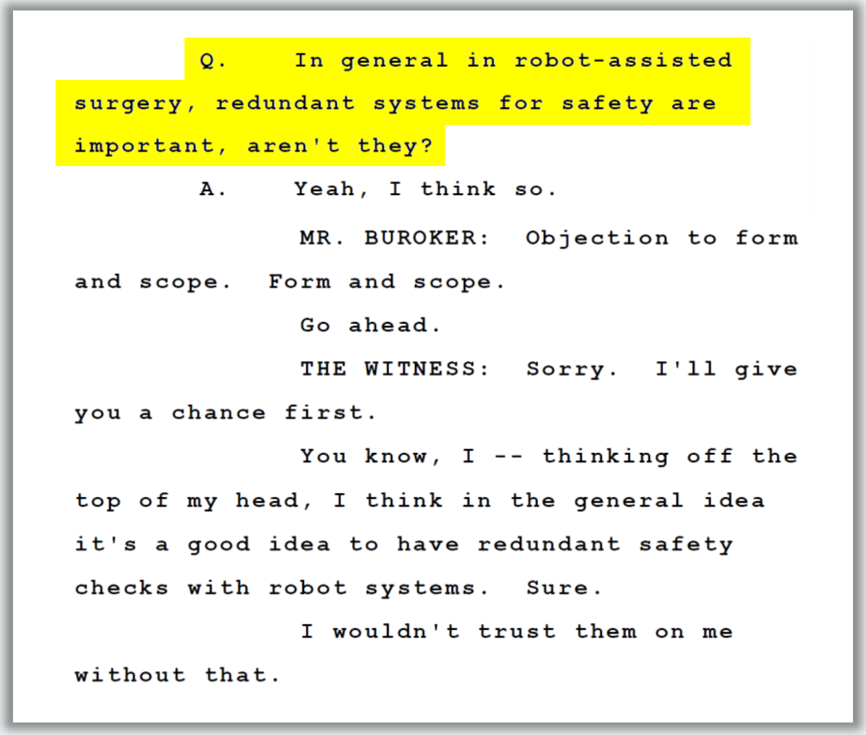
Order of Presentation – ’582 Patent

- Introduction

- Topics in Dispute

1. Claim Construction
2. Taylor Does Not Anticipate Independent Claims 1, 17, and 24 and Their Dependent Claims
3. Taylor and DiGioia Do Not Render Claim 7 Obvious
4. Taylor and Delp Do Not Render Claims 48 and 49 Obvious
5. **The Motion to Exclude Should be Granted**

Dr. Cleary's Cited Testimony Should Be Excluded



Q. In general in robot-assisted surgery, redundant systems for safety are important, aren't they?

A. Yeah, I think so.

MR. BUROKER: Objection to form and scope. Form and scope.

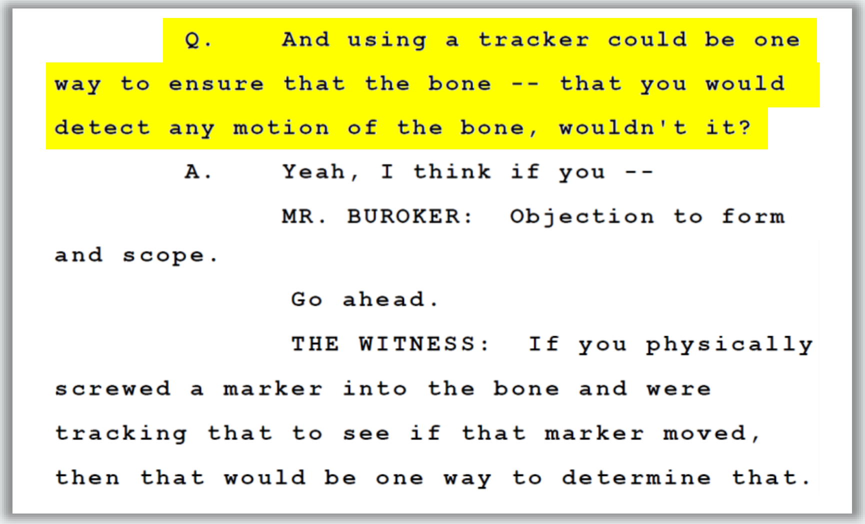
Go ahead.

THE WITNESS: Sorry. I'll give you a chance first.

You know, I -- thinking off the top of my head, I think in the general idea it's a good idea to have redundant safety checks with robot systems. Sure.

I wouldn't trust them on me without that.

Ex. 1016, Cleary Dep. at 65:22-66:11
Paper No. 17, Motion to Exclude at 1



Q. And using a tracker could be one way to ensure that the bone -- that you would detect any motion of the bone, wouldn't it?

A. Yeah, I think if you --

MR. BUROKER: Objection to form and scope.

Go ahead.

THE WITNESS: If you physically screwed a marker into the bone and were tracking that to see if that marker moved, then that would be one way to determine that.

Ex. 1016, Cleary Dep. at 66:21-67:6
Paper No. 17, Motion to Exclude at 1