Filed: December 2, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MATERIALISE N.V.
Petitioner,
v.

OSTEOPLASTICS, LLC
Patent Owner.

Patent No. 9,330,206
Inter Partes Review No.: IPR2021-00245

PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

State Cases

Regulatory Cases

Federal Statutes

Regulations

PETITIONER'S EXHIBIT LIST

Exhibit #	*Description*
1001	U.S. Patent No. 9,292,206 ("the Patent").
1002	Prosecution history of the Patent ("File History").
1003	Declaration of Petitioner's Expert Steven Pieper.
1004	U.S. Provisional Application No. 60/148277 ("Provisional I").
1005	U.S. Provisional Application No. 60/148275 ("Provisional II").
1006	U.S. Provisional Application No. 60/148393 ("Provisional III").
1007	U.S. Provisional Application No. 60/163323 ("Provisional IV").
1008	U.S. Patent No. 5,798,924 ("Eufinger").
1009	Average African American Three-Dimensional Computer Tomography Skull Images: The Potential Clinical Importance of Ethnicity and Sex, The Journal of Craniofacial Surgery, Vol. 9, No. 4, July 1998, at 356-57 ("Dean98").
1010	U.S. Pat. No. 5,027,281 ("Rekow").
1011	Three-Dimensional Dental Imaging by Spiral CT, Oral Surgery Oral Medicine Oral Pathology, November 1997 pp. 561-570 "(Vannier").
1012	Preston, CAD/CAM in Dentistry, Oral Health; Montréal Vol. 87, Iss. 3, (Mar 1997): 17.
1013	WO 95/07509 ("D'Urso 1995").
1014	J.S.Bill, J.F.Reuther, W.Dittmann, N.Kubler, J.L.Meier, H.Pistner, G.Wittenberg: "Stereolithography in Oral and Maxillofacial Operation Planning," Int. J. Oral Maxillofac. Surg. 1995; 24:98-103.
1015	U.S. Pat. No. 4,436,684 ("White").
1016	U.S. Pat. No. 4,976,737 ("Leake").

Exhibit #	***Description***
1017	C. Cutting, et al., *Computer Aided Planning and Execution of Craniofacial Surgical Procedures*, 1992 14th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. Date of Conference: 29 Oct.-1 Nov. 1992.
1018	Wolf, M., Paulus, D., Neimann, H., "Automatic Measurement of Cusps in 2 ½ D Dental Images, SPIE Conf. on Intelligent Robots and Computer Visions XIV: Unconventional Imaging for Industrial Inspection at Intelligent Systems and Advance Manufacturing/Photonics East (1995).
1019	D.Paulus, M.Wolf, S.Meller, H.Niemann, "Three-Dimensional Computer Vision for Tooth Restoration," Medical Image Analysis (1999), Vol. 3, No. 1, pp 1–19.
1020	*Richard A. Robb*, A Software System For Interactive And Quantitative Analysis Of Biomedical Images, NATO ASI Series, Vol. F 60, 3D Imaging in Medicine*,* 1990.
1021	D. Ney, E. Fishman, D. Magid, R. Drebin, "Volumetric rendering of computed tomography data: Principles and techniques," IEEE Comput. Graphics Applicat., pp. 24–31, Mar. 1990.
1022	U. Tiede, K. Heinz, M. Bomans, A. Pommert, M. Riemer, and G. Wiebecke, "Investigation of medical 3-D-rendering algorithms," *IEEE Comput. Graphics Applicat.*, pp. 41–53, Mar. 1990.
1023	J. K. Udupa and D. Odhner, "Shell rendering," *IEEE Comput. Graphics Applicat.*, pp. 58–67, Nov. 1993.
1024	M. Levoy, "Display of surfaces from volume data," *IEEE Comput. Graphics Applicat.*, pp. 29–37, May 1988.
1025	"A hybrid ray tracer for rendering polygon and volume data," *IEEE Comput. Graphics Applicat.*, pp. 33–40, Mar. 1990.
1026	EP 0,255,797 A1 (Ahrens) (certified translation).
1027	U.S. Pat. No. 4,742,464 ("Duret").

Exhibit #	*Description*
1028	Osteoplastic's Response to 3D Systems' Opening Claim Construction Brief, Civil Action No.: 18-2565-MSK-SKC, Docket No. 39.
1029	S.Meller, M.Wolf, M.Pelka, D.Paulus, H.Niemann, Automatic Tooth Restoration via Image Warping, in H.Lemke, M.Vannier, K.Inamura (Hrsg.): Computer Assisted Radiology, N. 1134 in International Congree Series, Berlin, Juni 1997, S. 221-227.
1030	Declaration of Milan Sonka, Ph.D., In Support of Osteoplastic's Response to 3D Systems' Opening Claim Construction Brief, Civil Action No.: 18-2565-MSK-SKC, Docket No. 39-9.
1031	Declaration Of Ingrid Hsieh-Yee, PhD.
1032	Krishna Subramanyan, David Dean, "Scanned bi-orthogonal radiographs as a source for 3D cephalometric data," Proc. SPIE 2710, Medical Imaging 1996: Image Processing, (16 April 1996) doi: 10.1117/12.237976.
1033	Exhibit No. not used.
1034	M.Vannier, J.Marsh, *Craniofacial Disorders*, Diagnostic Imaging, (March 1983).
1035	Court B. Cutting M.D., Fred L. Bookstein, Betsy Haddad, David Dean, David Kim, "Spline-based approach for averaging three-dimensional curves and surfaces," Proc. SPIE 2035, Mathematical Methods in Medical Imaging II, (23 June 1993); doi: 10.1117/12.146610 ("Dean93").
1036	Exhibit No. not used.
1037	Exhibit No. not used.
1038	D.Dean, et al., "Three Dimensional MR-Based Morphometric Comparison of Schizophrenic and Normal Cerebral Ventricles," Visualization in Biomedical Computing. VBC 1996. Lecture Notes in Computer Science, vol 1131.

Exhibit #	*Description*
1039	Alan David Kalvin, Court B. Cutting M.D., Betsy Haddad, Marilyn E. Noz, "Constructing topologically connected surfaces for the comprehensive analysis of 3-D medical structures," Proc. SPIE 1445, Medical Imaging V: Image Processing, (1 June 1991); doi: 10.1117/12.45222.
1040	Exhibit No. not used.
1041	Fred Bookstein, Shape and the Information in Medical Images, A Decade of the Morphometric Synthesis," Computer Vision And Image Understanding, Vol. 66, No. 2, May, pp. 97–118, 1997, Article No. IV970607.
1042	Exhibit No. not used.
1043	Exhibit No. not used.
1044	Eufinger, H., Wehmoller, M., Machtens, E., Heuser, L., Harders, A. and Kruse, D. (1995) Reconstruction of craniofacial bone defects with individual alloplastic implants based on CAD/CAM manipulated CT-data, *J. Cranio Maxilla-facial Surgery,* 23, 175-181. ("Eufinger95")
1045	CAD-CAM in Dentistry, Francois Duret, DCD, DSO, MS, PhD, Jen-Louis Blouin, Berard Duret, CD, JADA Vol 117, Nov. 1988.
1046	Dean, D., Subramanyan, K., Kamath, J., Bookstein, F., Wilson, D., Kwon, D., and Buckley, P., "Comparison of Traditional Brain Segmentation Tools with 3D Self-Organizing Maps," Information Processing in Medical Imaging. IPMI 1997. Lecture Notes in Computer Science, Vol 1230.
1047	Fred L. Bookstein, Thin-Plate Splines And The Atlas Problem For Biomedical Images, Information Processing in Medical Imaging. IPMI 1991. Lecture Notes in Computer Science, vol 511.

I. MANDATORY NOTICES

A. Real Parties-In-Interest (37 C.F.R. § 42.8(b)(1))

The real parties-in-interest are Materialise N.V. ("Petitioner") and Zimmer Biomet Holdings, Inc. and Zimmer, Inc. .

B. Related Matters (37 C.F.R. § 42.8(b)(2))

Petitioner is not aware of any reexamination certificate or pending prosecution concerning the '206 patent.

The '206 Patent has been asserted in the following litigations ("Parallel Litigations"):

Osteoplastics, LLC v. Zimmer Biomet Holdings, Inc. and Zimmer, Inc., C.A. No. 20-407-MN-JLH (D.Del. March 23, 2020).

Osteoplastics, LLC v. Conformis, Inc., C.A. No. 20-405-MN-JLH (D.Del. March 23, 2020).

Osteoplastics, LLC v. Depuy Synthes, Inc., Depuy Synthes Products, Inc., Medical Device Business Services, Inc., and Synthes, Inc., C.A. No. 20-406-MN-JLH (D.Del. March 23, 2020).

Petitioner is not a party to the foregoing Parallel Litigations.

Two patent applications in the same family are pending as U.S. Patent Application Nos. 16/547911 and 16/119162.

Petitioner is filing concurrently requests for *inter partes* review for related patents, U.S. Patent No. 9,292,920, 9,672,617, and 9,672,302.

C. Identification of Counsel (37 C.F.R. § 42.8(b)(3))

Lead Counsel	Back Up Counsel
Patrick D. McPherson Registration No.: 46,255 Duane Morris LLP 505 9th Street, N.W., Suite 1000 Washington, DC 20004-2166 PDMcPherson@duanemorris.com	Diana M. Sangalli Registration No.: 40,798 Duane Morris LLP Las Cimas IV 900 S. Capital of Texas Hwy, Suite 300 Austin, TX 78746-5435 DMSangalli@duanemorris.com Christopher S. Kroon Registration No.: 54,241 Duane Morris LLP 100 High Street Boston, MA 02110 CSKroon@duanemorris.com Boris Zelkind Registration No.: 42,250 Duane Morris LLP 750 B Street, Suite 2900 San Diego, CA 92101-4681 BZelkind@duanemorris.com

D. Service Information (37 C.F.R. § 42.8(b)(4))

Please direct all correspondence to lead counsel and back-up counsel at the contact information above. Petitioner consents to service by electronic mail at

PDMcPherson@duanemorris.com, DMSangalli@duanemorris.com, CSKroon@duanemorris.com, and BZelkind@duanemorris.com.

II. GROUNDS FOR STANDING AND PROCEDURAL STATEMENT

As required by 37 C.F.R. §42.104(a), Petitioner certifies that the '206 patent is available for *inter partes* review and that the petitioner is not barred or estopped from requesting *inter partes* review on the grounds identified herein.

III. SUMMARY OF THE ARGUMENT

A. Introduction

Pursuant to 35 U.S.C. §§ 311 et seq. and 37 C.F.R. §§ 42.1 et seq., Materialise N.V. ("Petitioner") hereby petitions for *inter partes* review of U.S. Patent No. 9,330,206 ("the '206 patent"). Petitioner respectfully submits that Claims 1-7 (the "Challenged Claims") of the '206 patent are unpatentable under 35 U.S.C. § 103 in view of the prior art discussed herein. This Petition demonstrates by a preponderance of the evidence that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of these claims.

B. Overview

The '206 patent, titled "Producing a Three Dimensional Model of an Implant," issued on May 3, 2016. EX-1001. Despite the lengthy specification (spanning 46 columns and 49 figures), at base the Challenged Claims comprise four well-known and well-understood steps for creating a patient-specific implant:

- **Step one:** obtaining patient data of the target tissue (i.e., the defect to be repaired and surrounding tissue);
- **Step two:** rendering an image of the target tissue;
- **Step three:** superimposing a template representing non-defective (i.e., "normative") tissue onto the rendered image; and
- **Step four:** deforming the template to fit the target tissue to determine the implant shape.

Steps one and two (image acquisition and rendering) are required of virtually any 3D medical imaging method and had been performed for decades prior to the purported invention. EX-1008-EX-1011; EX-1035. The explosive development of 3D medical image acquisition modalities during the 1950's and 60's such as computer tomography (CT), magnetic resonance imaging (MRI), and ultrasound, stimulated the development of numerous technologies to display these new kinds of data. EX-1003 ¶87.

Similarly, steps three and four were routine in the art. David Dean, the lead inventor of the patent, authored numerous publications that taught the claimed steps of "superimposing" a "normative" template, and template "deformation." EX-1009;

EX-1035; EX-1038. By August 1999, these steps had become a "nearly mature branch of applied statistics" which was "sturdy enough for a wide range of scientific and biomedical applications." EX-1041 pp.116-117; EX-1003 ¶88.

Though these imaging acquisition and processing techniques were well-known since the early 1990s, the provisional applications that led to the '206 patent were not filed until August and November, 1999. EX-1004-1007. These applications detailed the work of a group of medical imaging professionals at New York University (the "NYU Group") (among which included David Dean) on a suite of 3D medical imaging tools developed in the late 1980's/early 1990's. This "NYU Toolkit," as it was referred to in the provisional applications and the corresponding published papers, was the subject of numerous publications over the decade preceding the filing of the '206 patent. EX-1009; EX-1035; EX-1038; EX-1041. The provisional applications explained that the "invention," which was embodied in three algorithms (*i.e.*, the SOFM, SASE and SSA algorithms described below), represented incremental improvements to the functionality of the NYU Toolkit, and contained citations to countless prior art demonstrating that the functionality was well-known. The provisional applications further discussed several other publicly disclosed software applications capable of performing certain steps of the Challenged Claims (including the "3DCEPH" and "MAESTRO" programs), and contained citations to countless prior art. EX-1003 ¶89.

Inexplicably, however all references to the "NYU Toolkit" were dropped from the detailed description of the '206 patent, where it was shortened to simply "toolkit." And all references to the other publicly disclosed software, and all of the detailed citations to the prior art, were likewise omitted from the patent. Despite these deletions, applicants never informed the Examiner that the "toolkit" – described at length in the '206 patent as performing all of the claimed steps – was *prior art*, or that these software applications were also publicly available. Nor did applicants submit the omitted prior art references to the Patent Office during prosecution. Worse yet, none of the alleged "incremental improvements" over the prior art NYU Toolkit are covered by the Challenged Claims, but instead the Challenged Claims are directed to the very basic steps outlined above that were prevalent in the prior art as demonstrated by the prior art cited in Grounds 1 and 2 below. EX-1003 ¶90.

IV. IDENTIFICATION OF CHALLENGES

A. Challenged Claims

Claims 1-7 of the '206 patent are challenged in this Petition.

B. Statutory Grounds for Challenges

The Challenges are set forth in detail below and summarized as follows:

Ground	Claims	Basis	Reference
1	1-7	§ 103	Rekow, in view of Vannier
2	1-7	§ 103	Eufinger, in view of Dean93 and Dean98

Ground 1:

"Rekow" is U.S. Patent No. 5,027,281 titled "Method and Apparatus for Scanning and Recording of Coordinates Describing Three Dimensional Objects of Complex and Unique Geometry," issued on June 25, 1991 ("Rekow" (EX-1010)).

"Vannier" is a publication titled "Three-Dimensional Dental Imaging by Spiral CT," published in November, 1997 in Oral Surgery Oral Medicine Oral Pathology, Vol. 84, No. 5 ("Vannier" (EX-1011)). Vannier is a printed publication that was publically accessible beginning in November 1997. EX-1031.

Rekow and Vannier are prior art under at least § 102(b), and were not cited or applied by the Examiner during the '206 patent prosecution.

Ground 2:

"Eufinger" is U.S. Patent No. 5,798,924 titled "Process for Producing Endoprostheses," published June 8, 1995 from a PCT application filed December 2, 1994, which claims priority to December 4, 1993 ("Eufinger" (EX-1008)).

"Dean93" is a publication titled "Spline-Based Approach for Averaging Three-Dimensional Curves and Surfaces," published in June 1993 in the Mathematical Methods in Medical Imaging II, SPIE Vol. 2035, ("Dean93" (EX-1035)). David Dean, an inventor of the '206 patent, is a co-author. Dean93 is a printed publication that was publically accessible beginning in August 1993. EX-1031.

"Dean98" is a publication titled "Average African American Three-Dimensional Computed Tomography Skull Images: The Potential Clinical Importance of Ethnicity and Sex," published in July, 1998 in The Journal of Craniofacial Surgery, Vol. 9, No. 4 ("Dean98" (EX-1009)). David Dean is the lead author. Dean98 is a printed publication that was publically accessible beginning in July 1998. EX-1031.

All of Eufinger, Dean93 and Dean98 are prior art under at least § 102(b), and were cited but not applied by the Examiner during the '206 patent prosecution.

V. BACKGROUND OF THE '206 PATENT

The '206 patent claims are directed to a computer-implemented technique for determining the 3D shape of an implant. EX-1001 44:66-46:3. At a high level – which is the level at which the technique is claimed – the claimed method generally corresponds to the black box flowchart of FIG. 2:

Steps A and B (image acquisition) – 3D image data corresponding to a defective and a non-defective portion of a patient's tissue is obtained;

Step C (data segmentation) – the data is segmented (digitally processed) to extract a region of the image that includes the target tissue;

Step D (surface reconstruction) – the image is mapped by identifying points corresponding to anatomical shapes on the surface of the extracted target tissue;

Steps E, F, G and H (superimposing and deforming a template) – a template representing a normative shape (i.e., a desired or average shape) of the tissue – is

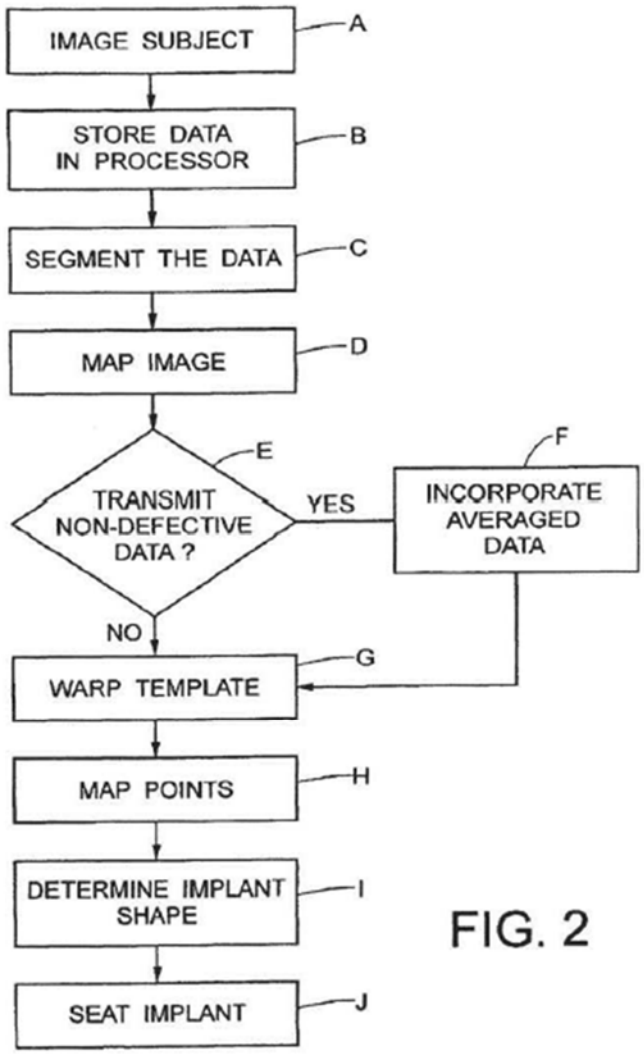


FIG. 2

superimposed on the surface of the extracted tissue and deformed by a "warping" or "best-fitting" process. Points on the deformed template are mapped to points on the surface of the target tissue; and

Step I (creating an implant) – the shape of the implant is determined based on the template that spans the defective portion, and data representing the implant shape can then be manufactured or printed on a 3D rendering device. EX-1001 10:21-11:24; EX-1003 ¶32.

In comparison to the high-level steps recited in the Challenged Claims and mirrored in FIG. 2, the patent's "Detailed Description of the Preferred Embodiments" is complex, spanning thirty-five columns and forty-nine figures. The description of FIG. 2 occupies but a *single one* of those columns. The remaining thirty-four columns are devoted to three mathematically-intensive algorithms that correspond to some of the high-level steps of FIG 2, but are not claimed: (1) an image segmentation algorithm, referred to as a "Self-Organizing Feature Map" (or "SOFM"); (2) a "Simulated Annealing-based Surface Extraction" ("SASE") algorithm for extracting and rendering surfaces from the segmented data, and performing the "superimposing" step; and (3) a surface averaging algorithm for generating an "average" template based on data from multiple subjects, referred to as "SSA". EX-1001 11:28-45:6; EX-1003 ¶33.

Despite the great detail provided for each algorithm, the provisional applications to which the patent claims priority admits that the SOFM, SASE and SSA algorithms are merely incremental improvements over "conventional" and "known" processes for performing their respective functions. EX-1004 pp.1-7, 24-25; EX-1005 pp.1-4; EX-1006 pp.1-5. Significantly, **none of the incremental improvements implemented by the SOFM, SASE and SSA algorithms are recited in the Challenged Claims**. EX-1003 ¶34.

VI. THE '206 PATENT PROSECUTION HISTORY

A. Prosecution History

1. Applicant Omits Material Information

The '206 patent claims priority to four provisional applications, three of which comprise manuscripts submitted to various scholarly journals. EX-1001; EX-1004-1007. These manuscripts cite extensively to the prior work of both the authors and their peers. Those cited materials were highly relevant to patentability. However, the PCT application that led to issuance of the '206 patent was drafted to hide that prior work. EX-1003 ¶50.

Each provisional describes one of the three purportedly new algorithms. A first provisional describes the "SASE" algorithm used for "warping the template to … a normative shape of the bone of interest." EX-1001: 20:18-21:9; EX-1004. The provisional asserts that SASE represented an improvement over well-known "NYU Methods" that had been developed in 1993 and were part of the "NYU toolkit." EX-

1004 pp.1-4; 24-25. According to the provisional, **the NYU toolkit and SASE performed the same functions**, except that SASE allegedly worked better, faster and produced more reliable results. *Id.* The SASE algorithm is not claimed. EX-1003 ¶51.

A second provisional describes the "SSA" algorithm for generating a normative or average template and admits that SSA generates these averages "by the **same method as in the NYU toolkit**." EX-1005 p.3 (emphasis added). Citing to publications from 1993, the provisional admits that the "NYU toolkit has been used previously to generate average ridge curve-based deformable template surfaces of the boney skull" and then explains that SSA improves on the NYU toolkit because SSA's analysis "is extended to the entire surface." *Id*. Average (or normative) deformable templates are limitations required by the Challenged Claims; specific details on how the average surfaces of the template are generated are not. EX-1003 ¶52.

The second provisional also describes the "apparent" utility of normative or average surface templates to generate prosthetic implants. Specifically, citing to the prior average surface template work performed by the NYU Group and the prior computer-implemented implant design work performed by Harald Eufinger, the application states:

> We now wish to use average 3D surface images to model surfaces in patient images for rapid prototyping of prosthetic implants (Dean et al., in press; **Eufinger et al., 1995**)…; and
>
> Their use for boney prosthetic design (Dean et al., in press; **Eufinger et al., 1995**) is apparent.

EX-1005 pp.3, 26; EX-1003 ¶53.

Despite the numerous comparisons to the "NYU Toolkit" throughout the first and second provisional applications, **all references to the "NYU Toolkit" were removed and shortened to simply "toolkit" in the written description of the '206 patent.** EX-1001. Applicants never informed the Examiner that the "toolkit" – which is discussed extensively throughout the specification and performs virtually every step of the Challenged Claims – was actually prior art developed and published by one of the inventors himself. Moreover, the inventors' citation to Dr. Eufinger's work on prosthetic implant design was also omitted. *Id*.; EX-1003 ¶54.

Similar omissions were made with respect to the allegedly new "SOFM" algorithm disclosed in the third provisional. EX-1006. This algorithm performs surface segmentation, which is another high-level limitation required by the Challenged Claims, but not specifically claimed. While the third provisional acknowledged that SOFM was simply an extension of prior work published in 1993, 1996 and 1997, **all references to those works were omitted from the patent.**

Compare EX-1006 at 5-6; 17-18 and FIG. 2 to EX-1001 11:28-12:22 and FIG. 4. EX-1003 ¶55.

Further still, similar deletions were made regarding disclosures in the fourth provisional. EX-1007. That provisional application discussed two prior art programs, the "3DCEPH" and "MAESTRO" programs. *Id*. at 5-6. MAESTRO was a program used to convert image data into a format suitable for use by a stereolithography machine (i.e., 3D printer), while 3DCEPH – another program Dean developed at least as early as 1996 – "could be used to warp a normalized data sampling of data [of a particular target tissue] to the scanned segmented data… to create a computer model of the implant itself." EX-1007 at p.6; EX-1032. Both of these features are limitations required by some of the Challenged Claims. ***Yet, all references to 3DCEPH and MAESTRO were omitted from the patent specification.*** EX-1003 ¶56; EX-1001.

Finally, **all** reference to the nearly 100 scholarly articles and numerous known software programs cited in all four of the provisionals were omitted from the applications that led to the '206 patent. EX-1003 ¶57.

B. Claim Construction

Petitioner proposes that each claim term in the Challenged Claims be given its plain and ordinary meaning in this proceeding, and that no specific construction

of any claim term is required because the prior art relied on in this Petition meets each of the claim terms under any reasonable construction. EX-1003 ¶83.

C. Priority Date of the Challenged Claims

The application that issued as the '206 patent was filed on May 14, 2014, and is a continuation-in-part of two patent families: (1) U.S. Application No. 10/089467 filed March 27, 2002, which purports to claim priority to U.S. Provisional Application Nos. 60/148393, 60/148277, and 60/148275 concurrently filed on August 11, 1999; and (2) U.S. Application No. 10/129308 filed September 3, 2002, which purports to claim priority to U.S. Provisional Application No. 60/163323 filed November 3, 1999.

Thus, the earliest possible priority date for the '206 patent is August 11, 1999.

VII. LEVEL OF ORDINARY SKILL IN THE ART

Based on the disclosure of the '206 patent, a POSA would have had a Master's degree in computer science, mathematics, or biomedical engineering, coupled with two-years' experience working with medical imaging in clinical applications; or by having a Doctor's degree, such as an M.D. or Ph.D. EX-1003 ¶22.

VIII. STATE OF THE ART

A. The Field of Custom 3D Medical Implant Design

By August 1999, numerous techniques for designing and creating custom implants using 3D computer modeling were practiced worldwide by healthcare professionals, including 3D (and even 4D) imaging modalities (e.g., CT, MRI,

Ultrasound). These techniques were in mainstream use by healthcare professionals across specialties requiring high-resolution 3D images. EX-1012 p. 1; EX-1013 p. 1-4; EX-1020. Methods for processing, displaying and manipulating 3D image data (including data segmentation, volume rendering, and superimposition of deformable normative templates) to design custom implants were equally known, as evidenced by multiple 3D imaging systems in widespread commercial use in the biomedical space. EX-1003 ¶58.

Over the years, the basic steps of 3D medical imaging have remained the same, with improvements directed at the algorithms that drive the acquisition, collection, processing, manipulation and display of data. EX-1013; EX-1041; EX-1029. All medical imaging universally began by obtaining computer readable image data of the target tissue that was then transferred (via a storage medium or network) to a computer for processing. *Id.* Processing typically involved reconstructing (or formatting) the data into slices stacked to create volumes (consisting of voxels, the 3D equivalent of a pixel); segmenting anatomical structures and regions to focus on the defect and surrounding non-defective tissue; rendering an image of the segmented data; and then matching the segmented data with a template representing the normative shape of the target tissue. EX-1013 pp.11-15; EX-1015; EX-1016; EX-1029. POSAs commonly used editing, such as warping or best fitting, to fit the template to the precise contours of the imaged tissue. EX-1013 pp.11-15; EX-1045

pp.715-719; EX-1029, §6. The shape of the implant could then be determined as a function of respective shapes of the target tissue and the template. EX-1013; EX-1014; EX-1029; EX-1003 ¶61.

B. Segmenting Image Data for Surface Extraction

Once image data was obtained and transferred to a computer, the data was ready for processing, which generally began with "segmentation." EX-1018; EX-1020. Segmentation is the well-known process used to locate objects and boundaries (lines, curves, etc.) in images by partitioning a digital image into multiple segments (volumes of interest, regions of interest, or 3D models). EX-1018 p.3. Each image pixel is given a segment label or logical name such that pixels can be grouped based on shared characteristics (e.g., color or intensity) or association with a particular anatomical structure (skull, bone) or body substance (blood). *Id*. Segmentation allows the target tissue to be extracted from the image data so that, for example, a visualization of a defect and adjacent non-defective tissue can be displayed. *Id*.; EX-1003 ¶63.

By the mid-1990s, segmentation was routinely used in 3D medical imaging applications, including dentistry and craniomaxillofacial (CMF) reconstructive surgery. EX-1018 p.3; EX-1019 p.6; EX-1013; EX-1020. By 1997, "neural network-based" segmentation using "ordered feature maps" (the type of segmentation discussed in the patent) had been developed. EX-1046, p.395. The

SOFM segmentation algorithm discussed in the '206 patent is simply an application of one extension of this previous work. *Id.*; EX-1006 p.5-6. Likewise, by August 1999, generating a visualization of 3D organ surfaces on a computer screen (a process called "image rendering") was common practice. EX-1038; EX-1039; EX-1041; EX-1003 ¶64.

C. Average Deformable Templates

Well before August 1999, a POSA understood that after rendering an image, the next step in designing an implant began with a model or template from which to work. EX-1012; EX-1026; EX-1045; EX-1047; EX-1029. Rather than starting from scratch, a POSA recognized that several sources of model information were readily available as a starting point. *Id.* The first resided with the patient itself. EX-1013 p.2; EX-1016; EX-1026; EX-1034. That is, in many cases the bilateral symmetry of the body (e.g., right side/left side of the skull) could be used to provide information about the undamaged half of the body. *Id.* A computer could generate a "mirror image" of the undamaged half for use as a template to design the replacement for the missing section. *Id.*; EX-1003 ¶66.

POSAs also recognized that mirror images were not always available or suitable, such as when too much tissue is missing or when patient's defect spans the midline of the head. EX-1013 p.2; EX-1016; EX-1026; EX-1034. In such cases, routine medical practice for generations had been to look at other patients or

anatomical specimens as references to effect an appropriately shaped repair. EX-1017; EX-1032; EX-1003 ¶67.

By 1993, the use of "normative" templates was well-known. EX-1045; EX-1035. By August 1999, these traditional methods had been augmented by extensive digital libraries containing normative data of virtually every anatomical structure in the body, including dental libraries. EX-1017; EX-1027; 1029; EX-1032; EX-1045. These collated digital libraries of anatomic information were referred to as "atlases" following the convention of anatomical textbooks with similar purposes. EX-1047; EX-1003 ¶68.

D. Image Registration Using Landmarks

Considerable research on "image registration" was also done in the 1990s. EX-1034; EX-1047. Image registration is the process by which a patient's data can be aligned and compared with model or reference data, such as normative or average data for a template representing a desired shape. *Id*. One well-known approach focused on the identification and extraction of "anatomical landmarks" that could be precisely located in both two images to be registered. In the literature the term "Type II Landmark" is often used, as in the '920 patent, to refer to anatomical features that can be consistently identified across sample populations of normally varying anatomy. EX-1047; EX-1039; EX-1035. Indeed, as set forth in one of the provisional applications (but omitted from the patent), "Sneath (1967) originally

proposed use of the Procrustes superimposition method to compare shapes represented as anatomical landmark coordinates." EX-1005 p.9; EX-1003 ¶69.

Thus, anatomical landmarks were commonly used to align the data of two similar images, and at least by 1993, "[t]here exist[ed] rigorous multivariate procedures for averaging the shapes of such [anatomical landmarks], describing their variability around the average, and correlating that variation with its causes or effects." EX-1035 p.30; EX-1047; EX-1039 p.248; EX-1003 ¶70.

The use of anatomical landmarks to design prosthetic implants was also in common use in dentistry by the early 1990s. EX-1018; EX-1029; EX-1045. For example, the occlusal surface of the back teeth comprises several anatomical landmarks, including cusps (ridges) separated by fossa (trenches), which make up the teeth's contoured chewing surfaces. The precise shape, height and location of these features, as well as their relative shape and orientation to the opposing tooth surface, are unique, while their number, function and location is typically consistent across all humans. EX-1018-1019; EX-1029; EX-1003 ¶72.

E. Superimposing and Deforming a Normative Template

Once anatomical landmarks were identified, the model of the target tissue and the template of the normative tissue could be digitally superimposed and manipulated based on a landmark-to-landmark correspondence. By August 1999, a POSA understood that there were numerous methods by which the model and

template could be manipulated or deformed into correspondence – including "best-fitting," "interference," "subtraction" or "warping." EX-1013; EX-1019; EX-1029; EX-1045. These techniques included superimposing a deformable template representing a normative shape onto the surface of a tissue of interest. *Id.*; EX-1041; EX-1047; EX-1003 ¶75.

Algorithms for superimposing a deformable template on a model of the patient's tissue were well defined by August 1999. As discussed above, the description of the "toolkit" in the '206 patent refers to work that was performed by the NYU Group to develop the NYU Toolkit. EX-1035. Based on work published by the NYU Group, by 1985, it had become "standard in landmark-based morphometrics" to use "shape averaging, matching of one shape to another by deformation, and description of shape variability by shape regressions and component analysis." EX-1047 p.327. One such deformation technique was called "thin-plate spline interpolation." *Id.*; EX-1003 ¶76-77.

By 1991, the NYU Group had used thin-plate spline interpolation to create a "biomedical atlas" using anatomical landmarks derived from several individuals. *Id*. By 1996, the inventors had used the NYU Group's approach to evaluate morphometric differences between different patient populations, including structural differences in the cerebral ventricles of patients diagnosed with schizophrenia. EX-1038; EX-1003 ¶78.

F. Making an Implant

The high-level techniques recited in the Challenged Claims had long been used to design prosthetics. EX-1020. And by the early 1990's, machine-controlled contour sculpting tool devices had also been widely used to reproduce 3D medical prostheses using the high-level claimed techniques. EX-1015 3:2-5; EX-1027 8:20-25. Stereolithographic modelling using CAD/CAM digital data to create 3D models of bony structures had also been used. EX-1013 p.2; EX-1003 ¶81.

IX. IDENTIFICATION OF HOW THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Ground I: All Claims are unpatentable over Rekow in view of Vannier.

1. The Rekow Reference

Rekow is directed to a computer implemented method and apparatus for constructing complex 3D medical devices by superimposing a digital 3D reference model representing the normative shape of the target tissue area onto a digitally acquired image data of a defective area of a patient, and deforming the reference model to fit the defective area using a series of anatomical landmarks as reference points. EX-1010; EX-1003 ¶93.

In particular, Rekow is directed to a CAD/CAM software that radially scans and records coordinates describing a 3D object and its surroundings, such that a computer-based model of the object can be rendered to substantially duplicate all surfaces of the object. Rekow teaches that "data acquisition is the first step in

generating a computer-based representation of a 3D object" and discloses two primary scanning methods. EX-1010 6:44-46; EX-1003 ¶94.

FIG. 1 describes a digitizer (18) comprised of a three-axis positioning head (20) with a low energy laser source and detector ("a point-by-point triangulation system"), a rotational stage (24), and a computer controller (26) is used to scan a 3D object. EX-1010 6:44-62. The computer records the head position into the database (X,Y coordinates) as a laser beam is reflected off an object placed on the rotational stage. *Id.* The Z coordinate is established by combining the position of the laser source with the determined distance between the object and the laser source. *Id.* The X,Y,Z coordinates are then recorded into the computer. The head is then re-positioned, or the object is rotated, and this process repeats, until its surface is fully recorded into the computer as a set of X,Y,Z coordinates. EX-1010 6:60-7:4. The radial scan lines are then "clipped" and "wrapped" about the Z-axis to obtain a 3D representation of the object. EX-1010 6:21-24. Each of the radial scan lines are captured at different angular increments around the center of the object. Thus, each radial scan line functions as a planar slice or cross-section of the 3D surface beginning at the center of the object and extending to the outer surface. EX-1010 8:26-31; EX-1003 ¶95.

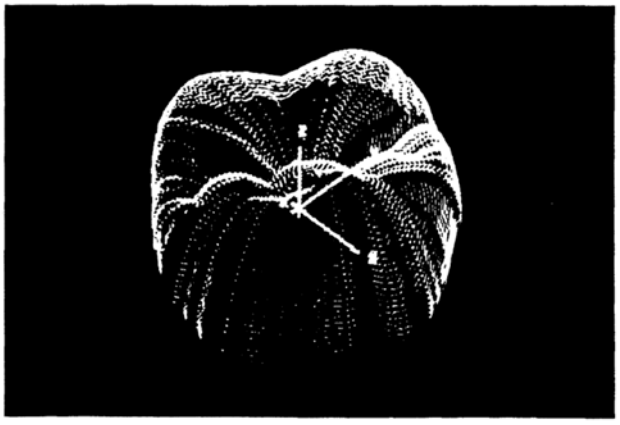
Scanning using the second embodiment is accomplished either by projecting a plurality of points onto the object which are then converted into a plurality of

profile lines by the computer software, or by projecting a plurality of profile lines directly onto the object. Under either approach, the projected points or the projected profile lines are scanned to generate X,Y,Z coordinates that are recorded into the computer. EX-1010 3:17-40. In this embodiment, profile lines, rather than scan lines, are recorded for each object. Profile lines appear to be planar slices of the 3D surface of the scanned object. EX-1010 12:29-32; EX-1003 ¶96.

The scanned computer-based model is then stored in a database. The database also contains a plurality of standardized object representations, referred to as generic forms, that permit the fabrication of prostheses based on idealized or standardized geometries. EX-1010 8:32-37. For example, when the method is used to produce dental prostheses, the database may contain a plurality of standardized generic tooth forms. "The generic tooth forms used are typically computer-based representations of standardized plaster models of teeth." EX-1010 8:50-53; EX-1003 ¶97.

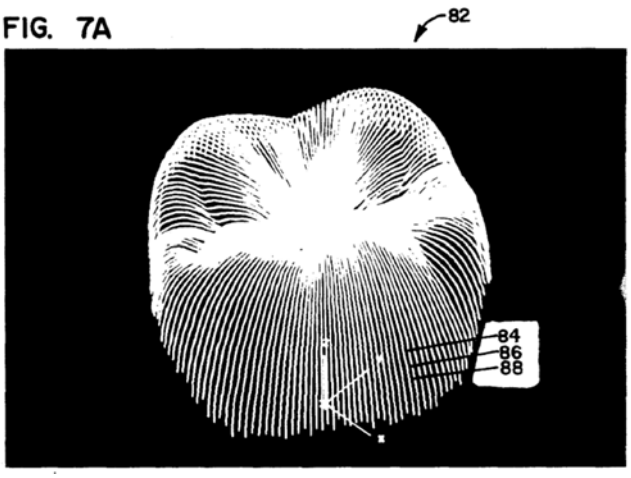
Like the scanned object, the surface of each generic form is represented as a set of (X,Y,Z) coordinates. EX-1010 8:34-35. The software superimposes the scanned coordinates onto the coordinates of a stored generic form. EX-1010 8:55-60. Landmarks on the generic form (such as fossa or cusp height) are matched with corresponding landmarks on the scanned object, thereby providing a correct

FIG. 7B



orientation and size for the generic form. EX-1010 8:55-60. FIGS. 7A and 7B, reproduced on the right, are renderings of the wrapped radial scan lines and contour lines, respectively, of a generic model. EX-1003 ¶98.

FIG. 7A



The CAD/CAM software also scales (or deforms) the generic coordinates so they are sized substantially the same as the scanned coordinates. The scaling process accounts for the height, width and gap measurements between the model prosthesis and the adjacent objects (such as adjacent and opposing teeth). This allows the implant to be sized to fit the available space for the reproduction. EX-1010 8:65-9:25. Additional coordinates can be added to emphasize features of the object or the generic form and ensure that the feature is not smoothed out, or otherwise eliminated, during processing. EX-1010 9:28-33; EX-1003 ¶99.

Rekow FIG. 11 also teaches deformation by way of homologous free form shaping. Using this method, a surface coordinate point is selected and moved to a new position (128). The surface geometry is deformed to decrease radially about the point of interest. That is, points near the moved point will move almost as much. While points further away will move less, eventually decreasing to zero movement

at the selected maximum radius. Free form shaping allows individual landmark points to be increased or decreased in size. EX-1010 9:40-53; EX-1003 ¶100.

As illustrated in FIG. 12 (right), a generic tooth form (136) stored in the database contains a local coordinate system (140), based on maximum height (in the occlusal plane) of the cusp tips. The database also contains the positions of the contact points with adjacent teeth (142 and 144) relative to that local coordinate system 140. If a landmark (146) is placed on the prepared tooth (148), a local coordinate system (150) relative to the prepared tooth (148) can be calculated. Since the two contact points (142 and 144) on the prosthesis must match the two contact points on the proximal teeth, a transformation from the generic coordinates to the prosthesis coordinates can be made, thus creating a scaled generic form (136). EX-1010 9:54-10:2; EX-1003 ¶101.

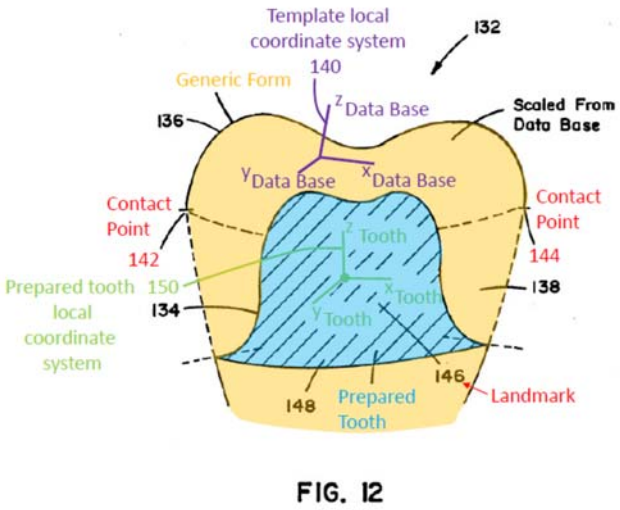


FIG. 12

Using the scaled generic form, the CAD/CAM software generates commands directing a machine tool to reproduce the object. EX-1010 5:66-6:10; 18:9-20:68. While Rekow's data acquisition techniques are well suited to the fabrication of dental prostheses, Rekow discloses that these techniques can be used to create any type of endoprosthesis. EX-1010 1:27-33 ("There are many applications that require

the reproduction or fabrication of one of-a-kind parts of complex geometry… includ[ing] dental prostheses, in-the-ear hearing aid housings, molds or implants to replace damaged bones, etc."); 2:58-63 (encompassing any "three dimensional object of complex and unique geometry"). EX-1003 ¶102.

2. The Vannier Reference

Vannier is directed to the use of spiral CT data for 3D image acquisition, display and segmentation of dental structures and lesions. EX-1011. Building on nearly two decades of work in 3D medical imaging, Vannier sought to apply spiral CT imaging to the dental arts in order to overcome limitations that were inherent to x-ray transmission-based radiographs, such as metal artifact interference. EX-1011 pp.561-562. Vannier recognized the known benefits of spiral CT over conventional radiography as a morphometric tool, including the lack of geometric distortions, higher quantitative measurement, and greater detail. *Id.*; EX-1003 ¶103.

After image segmentation and volumetric rendering of spiral CT data, the individual tooth components (enamel, pulp, and dentin) were separately displayed. EX-1011, FIG. 8. Vannier teaches that for each voxel or volume element it is possible to record information on tissue type, location within the tooth, and anatomic nomenclature, as well as the measured x-ray linear attenuation. Panoramic views of the dental anatomy (FIG. 6), are shown as conventional 3D surfaces or digital radiographs, as well as synthesized images from the spiral CT data set. By defining

multiple objects, individual teeth, such as a defective tooth, may be viewed alone or in combination with other teeth or the mandible, which may be unaffected. EX-1011, FIG. 6; EX-1003 ¶104.

3. The Motivation to Combine the Teachings of Rekow in view of Vannier

A POSA would be motivated to modify the teachings of Rekow with the teachings of Vannier to replace Rekow's optical imaging technology with Vannier's spiral CT imaging technology for several reasons. EX-1003 ¶105.

First, a POSA understood that both 3D optical image data and 3D volumetric data were used for modeling the complex and unique 3D geometry of medical devices, and Vannier expressly states that its objective was to demonstrate the feasibility of using spiral CT data for 3D image acquisition, display and segmentation of dental structures. EX-1011 p.561. While optical image data acquisition had long been applied in the dental arts due to its low cost, its ease of use, and its widespread availability, a POSA understood that optical image data represented a known and significant compromise in terms of data quality, level of detail and diagnostic value. Thus, a POSA would have been motivated to use spiral volumetric CT as it improved on these drawbacks. EX-1003 ¶106.

Second, a POSA understood that either surface scans or CT forms of 3D imaging allowed for the creation of custom prostheses across any clinical specialty. Indeed, Rekow states "[t]here are many applications that require the reproduction or

fabrication of one of-a-kind parts of complex geometry… includ[ing] dental prostheses, in-the-ear hearing aid housings, molds or implants to replace damaged bones, etc." EX-1010 1:27-33; EX-1003 ¶107.

Further, a POSA would also be confident that using Vannier's volumetric 3D image data with Rekow's method of creating custom prostheses would be a success because it was simply replacing one known technology (3D optical data) with another known technology (3D volumetric data) for its intended purpose, creating a 3D model. Indeed, the commercial software disclosed in Vannier (ANALYZE) was itself capable of operating with either source of image data to create 3D models. EX-1020; EX-1003 ¶108.

4. Detailed Application of Rekow in view of Vannier

a. Claim 1

i. A computer implemented method of obtaining data for determining the 3-dimensional shape of a medical device, the method comprising:

To the extent the preamble is a limitation, computer modeling of anatomical pathology using CT data was well known for pre-operative planning and rehearsal of procedures and in the manufacture of prosthetic devices. Rekow discloses a computer implemented method for "scanning and recording of coordinates describing three dimensional objects of complex and unique geometry." EX-1010 ABSTRACT. Rekow discloses that the "computer acquires data describing an object and its surroundings, and constructs a computer based three dimensional model of the object from that data," including "dental prostheses, in-the-ear hearing aid housings, molds or implant to replace damaged bones, etc." EX-1010 1:27-33. Thus, Rekow discloses a computer method for obtaining data for determining a 3D shape of a medical device in the form of a dental prosthesis. EX-1003 ¶109.

ii. obtaining a computer readable image data of a target wherein the target tissue comprises two portions, a portion with a defect and a portion without a defect;

Rekow discloses this limitation, alone, or in view of Vannier. Rekow discloses obtaining computer readable image data of defective and non-defective portions of target tissue. The method in Rekow rosters the scanning head of an

optical 3D surface digitizer over the entire surface of an object recording the X,Y,Z surface coordinates into the computer. EX-1010 2:65-3:11; 5-6:10. The scanned image of the tissue includes the prepared tooth surface and surrounding "gap" (collectively, the defective portion), as well as the adjacent and opposing teeth to the prepared tooth (collectively, the non-defective portions):

> The data required to produce the dental prosthesis includes: (1) the configuration of the tooth prepared by the dentist to receive the prosthesis; (2) the gap between, the heights of, and the widths of, the adjacent teeth which provides the scaling factor; (3) the surface configuration of the opposing teeth with which the prosthesis must occlude; and (4) motion of the mandible relative to the maxilla during function (in the areas where any of the teeth remain in contact and therefore guide the motion of the jaws).

EX-1010 7:24-33; 12:67-13:7; EX-1003 ¶110.

Finally, when data acquisition is complete, the "CAD/CAM software generates a set of data files so a computer-based model of the three dimensional object can be stored on the computer." EX-1010 8:15-20. Thus, Rekow discloses obtaining computer readable image data of defective and non-defective portions of a target tissue. EX-1003 ¶111.

To the extent Patent Owner asserts that this claim limitation requires the use of volumetric data, Vannier taught that using spiral CT data for dental structures provided increased sensitivity for detecting and quantifying small changes in hard

tissues and was the preferred method for imaging complex bone and tissue. EX-1011 pp.561-562. EX-1003 ¶112.

For these reasons, and those in the Motivation to Combine section, a POSA would have been motivated to modify Rekow to use 3D volumetric data as taught by Vannier and would be certain of its success. EX-1003 ¶113.

iii. rendering from the image data a computer-generated 3-dimensional representation of the target tissue;

Rekow discloses this limitation, alone, or in view of Vannier. Rekow disclose rendering a computer-generated 3D representation of the target tissue. As Patent Owner has admitted, the step of "rendering" is necessary to facilitate image interaction with a human operator. EX-1028 pp.8-9. That is, in order for the operator to "superimpose images" (discussed below), the operator must first visualize the image data to permit such interaction. While Rekow does not use the word "render" to convey the concept of displaying a 3D graphical representation of the defective and non-defective portions of the tissue, it contains several Figures illustrating rendered 3D images of tissue and generic templates which it calls "computer-based representation[s]" and describes several processing steps that require direct human interaction with such 3D rendered images. EX-1010 FIGS. 5A-B, 7A-B, 22; 7:61-8:52. As such a POSA would have understood the step of

rendering a computer-generated 3D representation of the target tissue to be disclosed. EX-1003 ¶114.

To the extent Patent Owner asserts that Rekow does not disclose this claim limitation, Vannier teaches that the ANALYZE software was used to generate "computer graphic renderings of volumetric dental images." EX-1011 p.570; 561 ("Volumetric rendering was performed to synthesize images…."); FIG. 6. As discussed above, the step of rendering a 3D image was an accepted prerequisite for subsequent image processing and, thus, a POSA would have been motivated to modify Rekow to include the step of rendering a 3D representation of the target tissue. EX-1003 ¶115.

iv. superimposing a three-dimensional template onto the 3-dimensional representation, wherein the three-dimensional template represents a normative shape of an anatomical surface of the target tissue;

Rekow discloses this limitation. Rekow discloses a database containing "a plurality of standardized object representations, referred to as generic forms." Rekow teaches that these "generic forms" comprise a "generic set of (X,Y,Z) coordinates" which a POSA understood to be a three-dimensional template, which "permit the fabrication of reproductions based on idealized or standardized geometries." EX-1010 8:32-52; EX-1003 ¶116.

Specifically, after the scanned image data has been acquired, the CAD/CAM software retrieves a generic form (i.e., a normative template) from the database. "FIG. 8 describes a method for **superimposing** the scanned coordinates onto a generic form stored in the database." EX-1010 8:55-57 (Emphasis added). Landmarks on the generic form are matched with, and compared to, corresponding landmarks on the scanned object. EX-1010 8:55-9:7. The two images are then "spatially rotated" and "positioned" until at least three landmarks on the generic form match their corresponding landmarks on the scanned object thereby confirming the correct "spatial orientation." *Id.* In other words, homologous anatomical features of the image and the template are used to align the two images. EX-1030 ¶¶ 76-78. Thus, Rekow teaches the step of superimposing a template onto the 3D representation, wherein the template represents a normative shape of an anatomical surface of the target tissue. EX-1003 ¶117.

v. deforming the three-dimensional template to the computer generated 3-dimensional representation to determine the three dimensional shape of the medical device.

In Rekow, after the homologous landmarks on the generic form and scan objected are matched (FIG. 8), the CAD/CAM software scales (deforms) the generic coordinates so they are sized substantially the same as the scanned coordinates. EX-1003 ¶118.

FIG. 9 describes the scaling operation. The space between the prepared tooth surface and adjacent teeth (i.e., the "gap measurement") is recorded. Also recorded are height and width measurements of the target tissue and/or adjacent objects. For example, these may include the "maximum height… of the cusp tips." EX-1010 9:8-65. The ratio of these values to the equivalent distances on the generic form yields a "scaling factor" that can guide transformation of the coordinates. *Id*. This scaling factor can be different in all three dimensions such that, for example, the height may be increased (or decreased) disproportionately to the width and relative position of the implant, or any combination thereof. EX-1010 23:28-24:17. In this way, the generic form can be mathematically sized (deformed) in three dimensions to fit the space available for the reproduction while maintaining the homology between the anatomical features. Rekow teaches that "a replacement part (medical device) may be created using the computer-based generic form scaled according to the 'gap' left for its placement, and from measurements of adjacent objects." EX-1010 9:18-25; EX-1003 ¶119.

Additionally, as illustrated in FIG. 10, additional coordinates can be added to emphasize features (anatomical landmarks) of the object or the generic form. The additional coordinates ensure that the anatomical feature is not smoothed out, or otherwise eliminated, either by system operators or by the CAD/CAM software. EX-1010 9:25-32. EX-1003 ¶120.

The resulting representation may be further deformed by a "free-form deformation technique." EX-1010 9:40-55. As illustrated in FIG. 11, using this method a surface coordinate "is selected and moved to a new position" thereby creating "local effects" in which the deformation to the surface geometry "decrease[s] radially about the point of interest." *Id*; EX-1003 ¶121.

Rekow discloses a dental prosthesis that "incorporates information from both the scanned tooth and from the generic tooth form." EX-1010 9:54-56. As illustrated in FIG. 12 below, the template tooth form 136 stored in the database contains a local coordinate system 140, based on maximum height (in the occlusal plane) of the cusp tips:

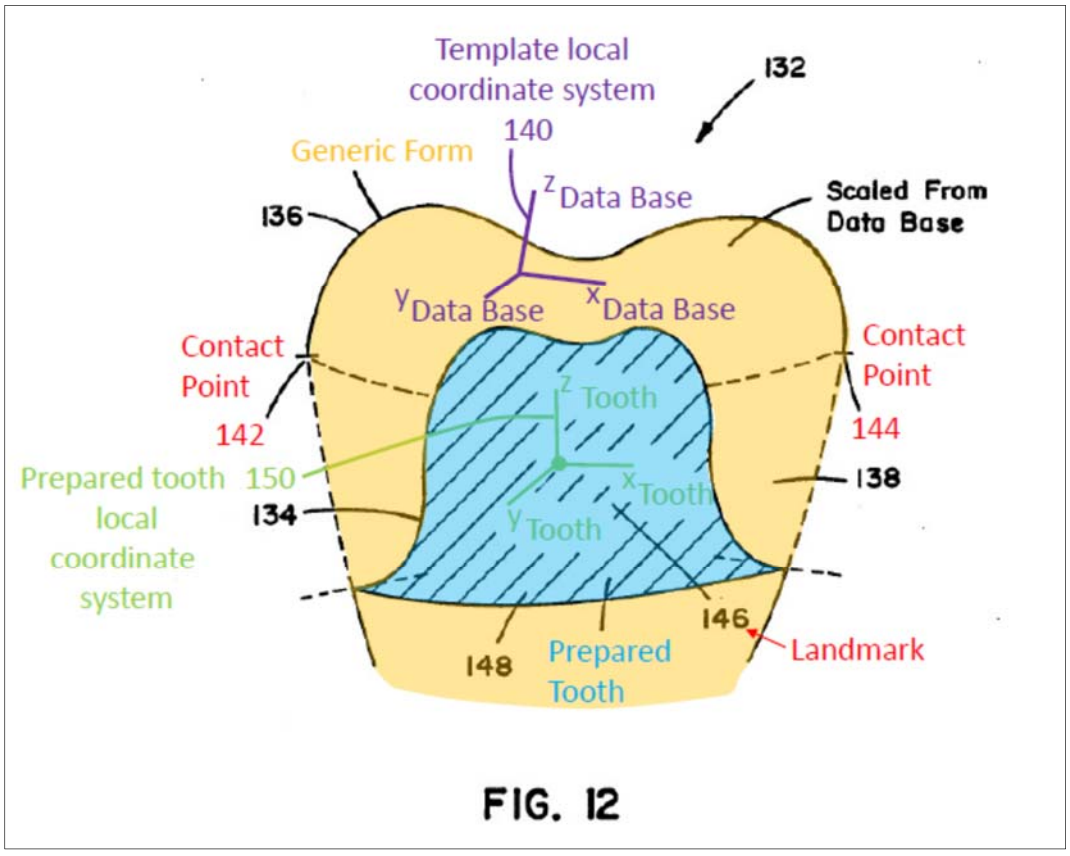


FIG. 12

EX-1010 FIG. 12; 9:57-60. The database also contains the positions of the proximal contacts 142 and 144 relative to that local coordinate system 140. If a landmark 146 is placed on the prepared tooth 148, a local coordinate system 150 relative to the prepared tooth 148 can be calculated. Since the two contact points 142 and 144 on the prosthesis must match the two contact points on the proximal teeth, a transformation from the generic coordinates to the prosthesis coordinates can be made. EX-1010 9:60-67. As a result of this transformation, the 3-dimensional shape of the dental prosthesis is determined based on the template tooth form that spans the defective portion. Thus, Rekow discloses deforming the three-dimensional template to the computer generated 3-dimensional representation to determine the three dimensional shape of the medical device. EX-1003 ¶122.

b. **Claim 2:** ***The method as set forth in claim 1, wherein the 3-dimensional image data is obtained from image slices of the target tissue.***

Rekow discloses this limitation. Rekow discloses that the surface of the scanned object of the defective portion and the non-defective portions is represented in the computer as a plurality of points and on a plurality of radial scan lines, where **each radial scan line "functions as a planar slice** or cross-section of the three dimensional surface." EX-1010 8:37-46 (emphasis added). EX-1003 ¶123.

To the extent that Patent Owner asserts that Rekow does not discloses this limitation, Vannier discloses the use of spiral 3D CT imaging where the patient

image data is "scanned transaxially with a conventional clinical spiral CT scanner (2 mm slice thickness and 2 mm/sec table motion)." EX-1011 p. 562. A POSA would be motivated to modify the teachings of Rekow with the teachings of Vannier to include spiral CT imaging for the reasons discussed in the Motivation to Combine section. EX-1003 ¶124.

c. **Claim 3:** ***The method as set forth in claim 1, wherein the 3-dimensional image data is obtained as one or more voxels of the target tissue.***

Vannier discloses this limitation. Vannier discloses that the 3D patient image data is acquired through the use of "a conventional clinical spiral CT scanner" and FIG. 8 illustrates a 3D view of an extracted molar "using software segmentation methods… [wherein] each voxel or volume element contains information on tissue type, location within the tooth, and anatomic nomenclature…." EX-1011 p. 567. Thus, Vannier discloses the use of spiral volumetric computed tomography for dental imaging which produces *a computer readable image consisting of voxels of the defective portion and the non-defective portion.* EX-1011 p.561. A POSA would be motivated to modify the teachings of Rekow to use the spiral volumetric computed tomography taught be Vannier for the reasons discussed in the Motivation to Combine section. EX-1003 ¶125.

d. **Claim 4:** ***The method of claim 1, wherein the medical device is an implant to be implanted in a subject.***

Rekow discloses this limitation. Rekow discloses a medical implant in the form of a dental prosthesis to be implanted into the subject. EX-1010 1:29-31. EX-1003 ¶126.

e. **Claim 5:** ***The method of claim 1, further comprising generating the computer-readable image data of the target tissue.***

Rekow discloses this limitation for the same reason as discussed with respect to the "rendering" step of Claim 1. EX-1003 ¶127.

f. **Claim 6:** ***The method of claim 5, further comprising fabricating the 3-dimensional shape of the medical device.***

Rekow discloses this limitation. Rekow discloses machining a dental prosthesis from a preformed blank having the 3-dimensional shape based on generic form template that spans the defective portion. EX-1010 19:30-34; 19:65-21:9. EX-1003 ¶128.

g. **Claim 7:** ***The method of claim 1, further comprising fabricating the 3-dimensional shape of the medical device.***

Rekow discloses this limitation for the same reasons as discuss with respect to Claim 6. EX-1003 ¶129.

B. Ground II: All Claims are unpatentable over Eufinger in view of Dean 93 and Dean98.

1. The Eufinger Reference

Eufinger is directed to a computer implemented method and apparatus for constructing complex custom-fit 3D medical devices. EX-1008. Like the Challenged Claims, Eufinger superimposes a 3D data model of a defective and non-defective area of a patient (generated from CT image data) with a 3D reference data model representing the normative shape of that target area, and deforms the reference model to "the special anatomical features of the patient" to determine the shape of an implant. EX-1003 ¶130.

Eufinger teaches a five-step method for producing a custom-fit endoprosthesis, using a mandibular implant as an example. EX-1008 4:50-5:40. In step A, a data block of the patient's target tissue (the "3D actual model") is acquired computertomographically preferably using spiral CT. EX-1008 4:51-59. Additionally, a data block of a 3D reference model (or "should-be" model, i.e. a normative model) is either obtained from a storage medium or acquired by a CT scan of an existing physical reference model. EX-1008 4:51-59; 1:7-21; EX-1003 ¶131.

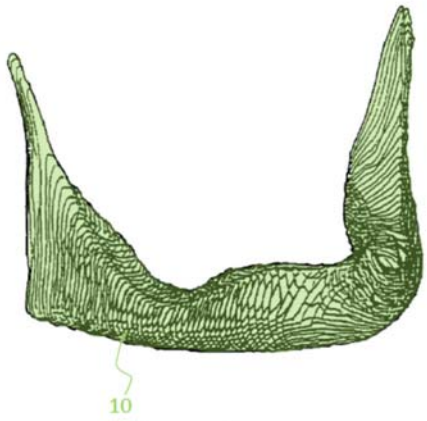


FIG. 3

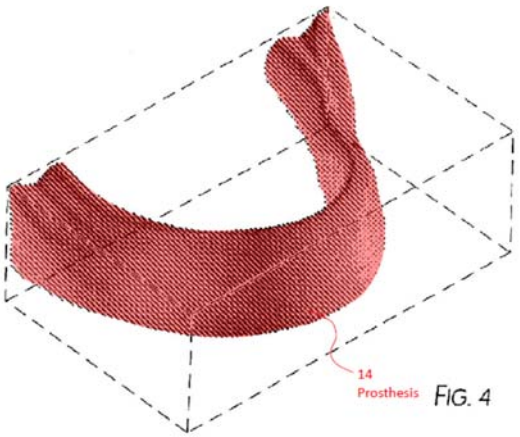


FIG. 4

In step B, the data blocks of the actual model and the reference model are converted into 3D representations displayed on the computer screen. EX-1008 4:60-5:2. The data

blocks are converted computertechnologically into a "data unit CAD free-form surface geometry through spline and Bezier functions" which are then handled using "interactive CAD-modeling and manipulating methods." *Id.* A POSA understood that this conversion step involves segmenting CT image data into groups of voxels to reconstruct 3D visualizations of the patient's mandible and the reference model. Figures 3 and 4 are the rendered 3D visualizations of the actual model and the reference model, respectively. EX-1003 ¶132.

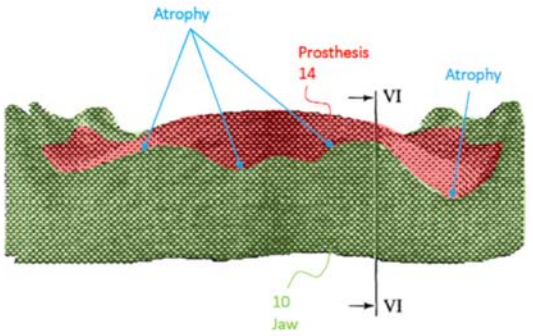


FIG. 5

In step C, "the converted data blocks of the actual model and of the reference model are shown superimposed on the video screen." EX-1008 5:3-5; *see* FIGs. 5 & 6. As shown in FIG. 6 (below, right), points of the actual model are displaced (deformed) into the volume of the reference model such that the lower surface of the reference (template) model geometrically conforms to the upper surface of the actual (patient) model, including at critical sites (e.g., nerve locations) where no contact with the patient's bone is desired. Using the difference of the data of the actual and reference models, a data block is generated in step D "which can serve as

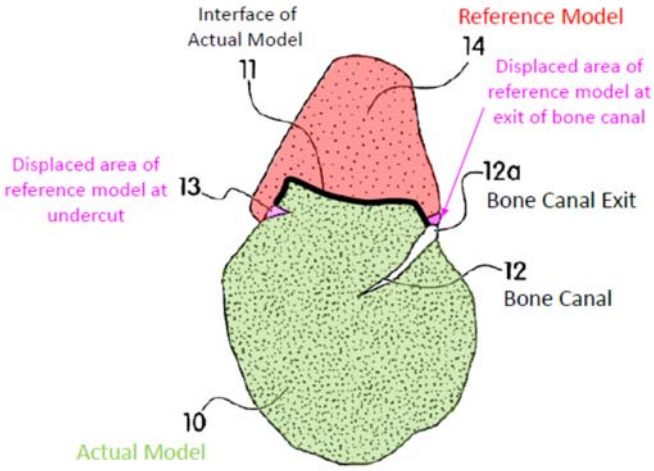


FIG. 6

the model for the computer-assisted manufacture of the endoprosthesis." EX-1008 5:15-19; EX-1003 ¶133.

Based on this data block, the finished endoprosthesis is fabricated (step E) with the help of a computer-controlled manufacturing unit. EX-1008 5:19-21; EX-1003 ¶134.

2. The Dean93 Reference

Dean93 is an article published by the NYU Group that describes a detailed approach for generating a deformable landmark-based "average" (normative) 3D template from a sample of multiple specimens. Dean93 teaches that the average template could be used to inform a surgical treatment plan, such as for reconstructive surgery. EX-1035; EX-1003 ¶135.

Dean93's average template of a skull is created using landmark-driven, spline-based algorithms. Dean93's process begins with a pre-existing template having the appearance of typical human skull with a wire frame of curving lines upon it. The curving lines consist of "ridge curves" and "geodesic" lines. EX-1035 p.33. "Ridge curves" are the lines that connect points at which the surface is, locally speaking, "most like an edge." *Id.* These ridge curves are then linked together with additional lines (called "geodesics pairs") to create a "surface patch." *Id.* In addition to the ridge curves and surface patches, Dean93's pre-existing template also included the

locations of a series of "44 commonly recognized anatomical landmarks" on the human skull.[1] EX-1035 p.34; EX-1003 ¶136.

Dean93's pre-existing template was then averaged with additional skull specimens by first manually locating the same set of landmarks on the specimen surfaces. These landmark points were used "in accordance with the landmark-to-landmark correspondence" between the template and the specimens to drive a thin-plate spline function that deformed the template to the new specimen data, thus creating an average template. EX-1035 p.34. "Such an average can be used iteratively to repeat the entire computation for a sample or to incorporate additional specimens." EX-1035 p.30. The result is a robust "average template" based on all the specimens. EX-1035 p.39; EX-1003 ¶137.

3. The Dean98 Reference

Dean98 is a continuation of the NYU Group's average template work. EX-1009 p.349. Using the same "average 'normative' 3D CT surface images of the bony skull" disclosed in Dean93, Dean98 describes the "effect of using… average 3D skull [treatment] images for comparisons with patient images at various stages of craniofacial surgical management (*i.e.,* diagnosis, treatment planning, **prosthetic**

[1] The article discusses that "landmarks are generated in two ways," and expressly refers the reader to David Dean's dissertation for additional detail on landmarking.

design, image-guided operative procedures, and outcomes assessment)." EX-1009, Abstract (emphasis added). Notably, Dean98 acknowledged that "[a]verage 3D craniofacial landmark data are already used clinically" and that these average "treatment images appear to be useful in cases where the patient's own anatomy is an incomplete basis for planning treatment," such as trauma. *Id*. According to Dean98, "a treatment image is especially useful if it can influence bone graft selection and preparation **or constrain the design of a prosthetic implant**." *Id.* (emphasis added); EX-1003 ¶138.

4. The Motivation to Combine the Teachings of Eufinger in view of Dean93 and Dean98

A POSA would have found it obvious to use Dean93 and Dean98's average templates (which Dean98 calls "treatment images") with Eufinger's computer-implemented implant design technique. EX-1003 ¶139.

Eufinger recognized that fitting an implant to the patient's anatomical features, including "a corrective adaptation of the curves of the surface" to achieve smooth transitions to adjacent bone structures, is "extremely important" to implant design. EX-1008 3:33-37. Eufinger superimposed a data model of patient tissue with a data model representing a "should-be" shape to design the implant. The patient's anatomical features were used to define the deformation of the should-be model, resulting in a precise "geometric adaptation of the endoprosthesis to the bone structure of the patient." EX-1008 4:5-7; 5:50-6:5. Eufinger recognized that

computer-implemented methods would obviate the skill and effort otherwise required to perform such adaptation manually. *Id.;* EX-1003 ¶140.

Dean93 described creating a computer-generated landmark-based 3D template representing an average of a sample of skulls. Dean93 superimposed a sample patient image onto the starting-point average template using a series of anatomical landmarks identified on both images. EX-1035 p.34. The landmarks drove deformation of the template to achieve an alignment with the images in accordance with the landmark-to-landmark correspondence. Dean93 described the deformation as "exactly mapping landmarks onto their homologues and as smooth as possible in between." *Id.* This mapping provided for computation of average landmark locations and the curving surfaces between them, which were used to generate a new average template. EX-1035 p.37. Dean93 recognized such templates provide "**useful visualizations of 'typical' or 'normative' anatomy**" that "**will be of great usefulness in many problems beyond the simple depictions of averages**," such as "**plastic surgery**." EX-1035 pp.39-40 (emphasis added); EX-1003 ¶141.

Dean98 used Dean93's technique to create average 3D skull images for use "at various stages of craniofacial surgical management" including "**prosthetic design**." EX-1009 pp.348-49 (emphasis added). Dean98 disclosed that these average images, representing an "ideal" or "norm," were "useful in cases where the

patient's own anatomy is an incomplete basis for planning treatment" (such as trauma) and were **"especially useful… [to] constrain the design of a prosthetic implant**." EX-1009 p.356 (emphasis added). Dean98 concluded that "surgical use of 'treatment' images… are likely to produce the best results when they are averages" because they "provide acceptable functional and aesthetic results with less 'disruption' to the patient's anatomy." EX-1009 pp.356-57; EX-1003 ¶142.

A POSA would have been motivated by Eufinger to try to improve the "exactness of the geometric adaptation of the endoprosthesis to the bone structure of the patient," particularly to efficiently achieve the smooth transitions to existing bone that are "extremely important" for head implants. EX-1008 3:33-37; 4:5-7; 5:50-6:5. A POSA understood that landmark-based deformable average templates would be used to "constrain the design of a prosthetic implant," as taught by Dean98, and included the benefit of "exactly mapping landmarks onto their homologues and as smooth as possible in between," as taught by Dean93. EX-1009 pp.356-57; EX-1035 p.34. Further, Eufinger, Dean93 and Dean98 each deformed normative models or templates to match a patient's anatomical features with curving surfaces therebetween. A POSA therefore expected that incorporating Dean93/Dean98's teachings into Eufinger would be successful. EX-1008 2:64-3:7; EX-1009 p.357; EX-1035 p.34. Further, Dean93 and Dean98 emphasized the utility of average models in many surgical applications, including

implant design. A POSA thus was motivated to modify Eufinger to include Dean 93/Dean98's average template to design an implant because an average would be particularly "useful in cases where the patient's own anatomy is an incomplete basis for planning treatment" and would provide acceptable functional and aesthetic results with less disruption to patient anatomy. EX-1009 pp.356-57. In other words, a POSA understood that incorporating Dean93/Dean98's average templates into Eufinger would "produce the best results" for the design of an implant. Further, the '275 provisional application to which the '920 Patent claims priority confirms that a POSA recognized the benefit of using Dean93/Dean98's average treatment images/templates in Eufinger's system. There, the inventors admitted that **"[t]he utility of average surface images… for boney prosthetic design (Dean et al., in press; Eufinger et al., 1995) is apparent**" at least as early as the '920 patent's priority date. EX-1005 pp.3, 26 (emphasis added); EX-1003 ¶143.

5. Detailed Application of Eufinger in view of Dean93 and Dean98

a. Claim 1

i. A computer implemented method of obtaining data for determining a 3-dimensional shape of a medical device, the method comprising:

To the extent the preamble is a limitation, Eufinger discloses a computer implemented method "for producing endoprostheses" comprising subtracting a

"data block" of a 3D model of "the existing bone structure of a patient" from a "data block" of a 3D "should-be model" such that "a computer-internal model is formed for the endoprosthesis from the difference." EX-1008 1:7-21. Eufinger discloses that "generating the computer-internal model for the endoprosthesis to be produced takes place in the computer." *Id.* at 5:36-38. EX-1003 ¶144.

ii. (a) obtaining computer readable image data of a target tissue wherein the target tissue comprises two portions, a portion with a defect and a portion without a defect;

Eufinger discloses this limitation. Eufinger discloses that "high-resolution computertomograph [CT] with helical data collection is used for the data acquisition." EX-1008 3:59-64. A POSA understood that data acquired using CT data collection is a computer readable image. EX-1003 ¶145.

Eufinger's computer readable image data comprises a defective portion and a non-defective portion of target tissue. For example, FIG. 3 illustrates "the idealized free-form surface geometry of an atrophied lower jaw," which includes both atrophied (*defective*) and existing bone (*non-defective*) portions. EX-1008 at 4:37-55; EX-1003 ¶146.

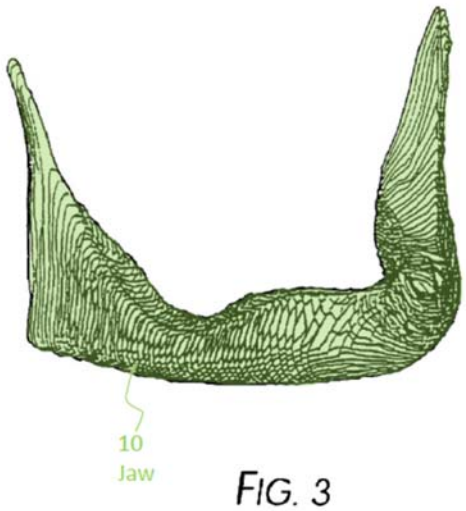


FIG. 3

iii. (b) rendering from the image data a computer-generated 3-dimensional representation of the target tissue;

Eufinger discloses this limitation. Eufinger discloses that a computer is used to convert "data blocks of the actual model [*target tissue*] and of the reference model … [into] a three-dimensional representation of the limiting surfaces of the models." *Id*. at 4:60-64; 5:29-34. FIG. 3 shows a perspective view of an atrophied jaw "as it is shown [*rendered*] on the video screen 4" of computer 3. *Id.* at 4:37-39; 5:41-43. A POSA understood FIG. 3 to illustrate a rendering of a computer-generated 3-dimensional representation of the patient's tissue. EX-1003 ¶147.

iv. (c) superimposing a three-dimensional template onto the 3-dimensional representation, wherein the three-dimensional template represents a normative shape of an anatomical surface of the target tissue; and

Eufinger discloses this limitation. Eufinger's FIG. 3 and FIG. 4 are computer-generated three-dimensional representations of the actual model and the reference

model "shown on the video screen 4." EX-1008 4:47-42; 4:60-64. In FIG. 5, the actual model and the reference model "are shown **superimposed** . . . **on the video screen 4**." EX-1008 5:41-49 (emphasis added). EX-1003 ¶148.

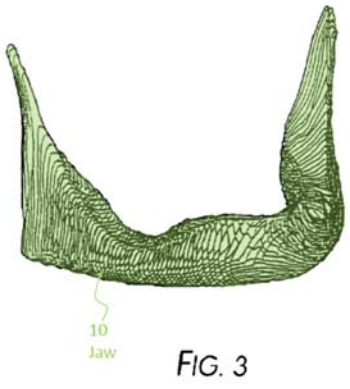


FIG. 3

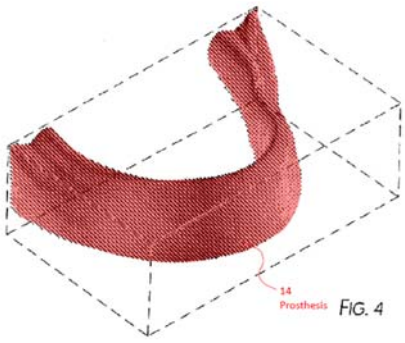


FIG. 4

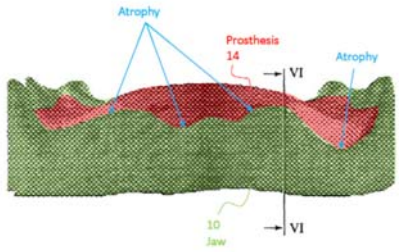


FIG. 5

Eufinger discloses that the reference model is a "should-be" model that provides "in advance" "[t]he well-rounded shaped and the sweeping curve … of the endoprosthesis to be produced." EX-1008 6:5-8. A POSA therefore understood that the "should-be" shape of the reference model would represent a *normative* (or desired) shape of the anatomical surface of the target tissue. EX-1003 ¶149.

To the extent Patent Owner asserts that Eufinger's reference model is not a normative template, Dean93 and Dean98 disclose this limitation. Dean93 discloses superimposing a landmark-based template onto a skull specimen to create an average template. EX-1035 pp.32-33. "An example of the resulting average is rendered in Figure 2," reproduced below.

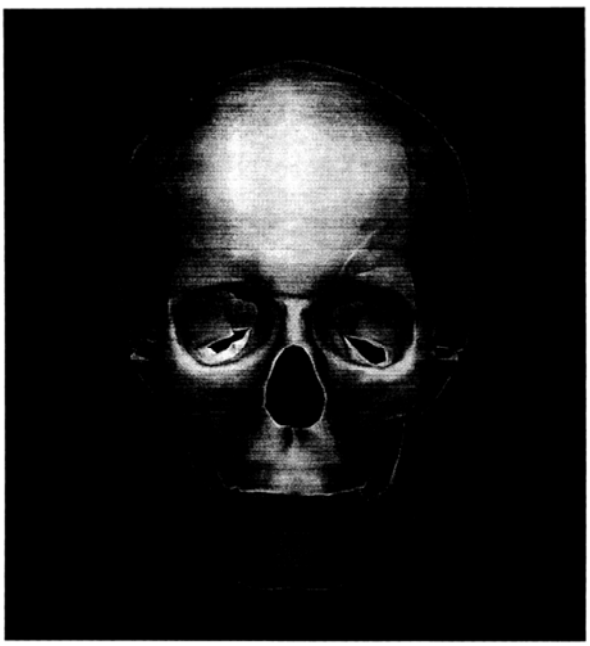


Figure 2. An early generation of the resulting average. Frontal view.

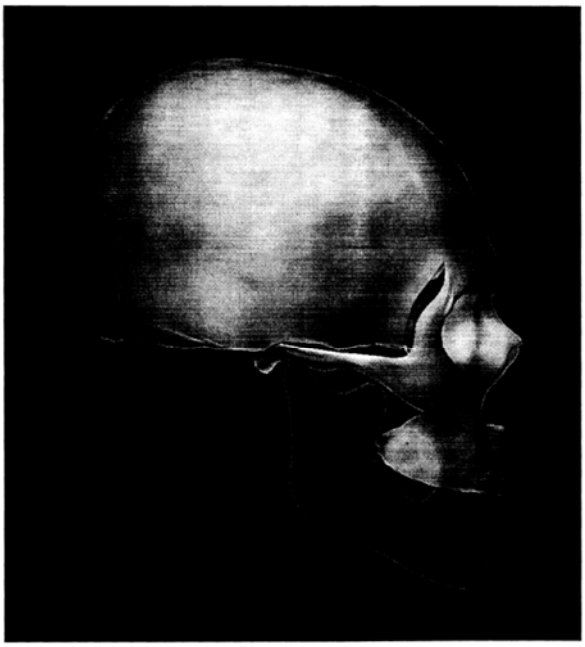


Figure 2, continued. Lateral view of the same average.

EX-1035 pp.30, 43-44. Dean93 instructs that "this useful adjunct to visualization greatly aids decision-making in all the biomedical contexts to which the **average**, or its image, might ultimately be applied." EX-1035, p.30 (emphasis added). Dean98 uses Dean93's average template technique to create average skull images based on 40 specimens. Dean98 discloses that these average images – which may be considered to represent a "'**norm**,' '**standard**,' or '**ideal**'" – "appear to be useful in cases where the patient's own anatomy is an incomplete basis for planning treatment" and are "especially useful" to "**constrain the design of a prosthetic implant**." Ex. 1009 pp.356-357 (emphasis added). A POSA therefore understood that Dean98's average treatment images correspond to a template representing a *normative shape of an anatomical surface of the target tissue*. A POSA would be

motivated to combine the teachings of Eufinger, Dean93 and Dean98 for the reasons discussed above. EX-1003 ¶150.

v. (d) deforming the three-dimensional template to the computer-generated 3-dimensional representation to determine the 3-dimensional shape of the medical device.

Eufinger discloses this limitation. Eufinger teaches that the three-dimensional actual and reference models are "adapted on the video screen of the computer by interactive manipulation of the data to the special anatomical features of the patient." EX-1008 6:35-37. The adaptation "takes place by support point displacement" of points of the actual model into the volume of the reference model and "by geometric manipulation functions (reflecting, expending [sic: expanding], turning, rounding, smoothing, etc.)" at specific anatomical locations (or landmarks) such as "the exit regions of the sensitive nerves of the lower jaw." EX-1008 5:9-11; 5:55-58. EX-1003 ¶151.

FIG. 6 is a cross-section of the actual model 10 superimposed with the reference model 14, and illustrates this adaptation of the actual and reference models to achieve "**the exactness of the geometric adaptation of the endoprosthesis to the bone structure of the patient**." EX-1008 4:6-7 (emphasis added). EX-1003 ¶152.

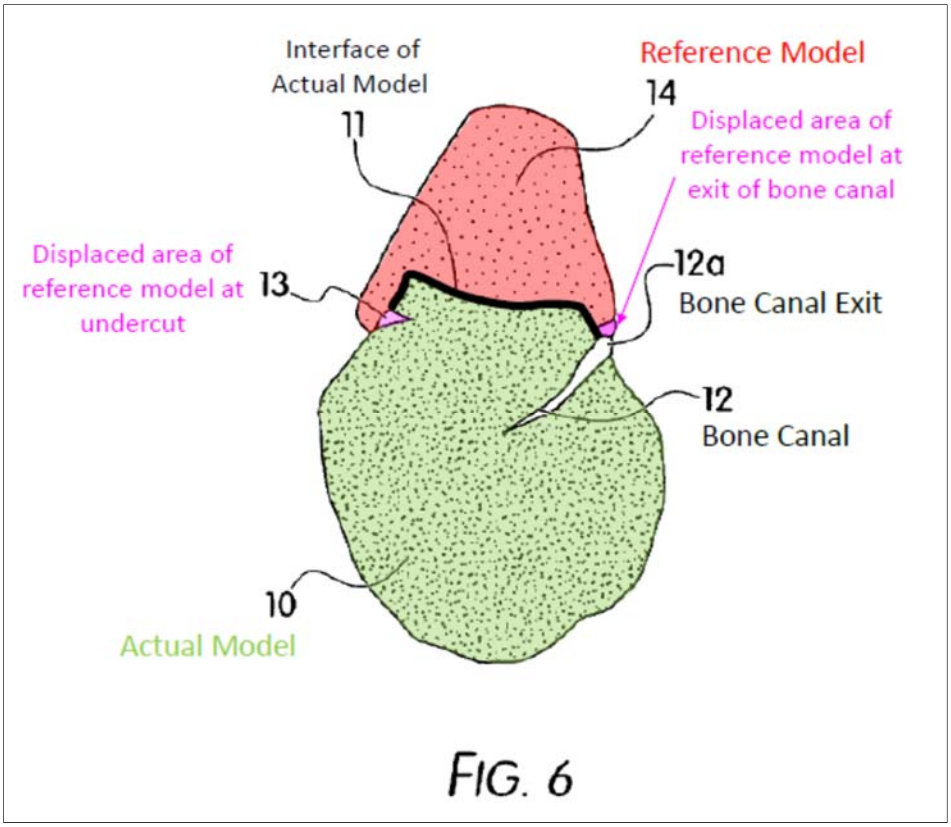


FIG. 6

A POSA understood that adapting the models by displacing the interface of the actual model into the volume of the reference model would correspond to *deforming* the normative template to the bone structure of the patient (the actual model). EX-1003 ¶153.

After the models are adapted, Eufinger teaches that "a computer-internal model is formed for the endoprosthesis from the difference" of the data blocks of the three-dimensional actual and reference models. The computer-internal model "is finally used for the computer-controlled manufacture of the endoprosthesis." EX-1008 1:10-20. Therefore, the three-dimensional shape of the endoprosthesis is determined by deforming the reference model. EX-1003 ¶154.

To the extent Patent Owner asserts that these limitations are not met by Eufinger, they are disclosed in Dean93 and Dean98. Dean93 discloses applying a landmark-based deformable template to skull specimens by first "manually locating a small set of landmark points on the specimen surface." EX-1035 p.34. Dean93 discloses that "[t]hese landmark points are used to drive a thin-plate spline map that **deforms the template in accordance with the landmark-to-landmark correspondence** supplied." EX-1035 p.34 (emphasis added). As the "landmarks of the standard wire-frame template [are warped] to match the landmarks of the specimen form, the ridge curves of the template . . . are warped right along with them." EX-1035 p.36. "The resulting map . . . is now **a deformation of one solid image onto the other** which maps landmarks onto their homologues." *Id*. (emphasis added). Dean98 uses Dean93's deformable template technique to create average treatment images that can be used "**to constrain the design of an implant**." EX-1009 pp.356-357 (emphasis added). A POSA would be motivated to combine the teachings of Eufinger, Dean93 and Dean98 for the reasons discussed above. EX-1003 ¶155.

b. **Claim 2:** ***The method as set forth in claim 1, wherein the 3-dimensional image data is obtained from image slices of the target tissue.***

Eufinger discloses this limitation. Eufinger discloses that "the part of the body of the patient to be acquired in terms of data is acquired by a helical spiral. … **The**

entire patient volume detected by the spiral can be subsequently reconstructed again layer by layer in accordance with conventional computertomographical representation, whereby **the spacing of such reconstructed layers** is not predetermined by the pitch of the spiral, but, for example, can be selected also smaller." EX-1008 3:59-4:2 (emphasis added). A POSA understood that helical CT scanning obtains a computer readable image of the target tissue in slices. EX-1003 ¶156.

c. **Claim 3:** ***The method as set forth in claim 1, wherein the 3-dimensional image data is obtained as one or more voxels of the target tissue.***

Eufinger discloses this limitation. Eufinger discloses CT helical scanning to acquire "**the entire patient volume**." EX-1008 3:59-4:2 (emphasis added). A POSA understood that helical CT scanning of the "entire patient volume" produces a computer readable image consisting of voxels. EX-1003 ¶157.

d. ***Claim 4: The method of claim 1, wherein the medical device is an implant to be implanted in a subject.***

Eufinger discloses this limitation. Eufinger discloses that "the invention is particularly suitable for the manufacture of **implants** or augments in maxillary surgery [and also] … for the construction of individual **implants** of parts of the skull." EX-1008 3:45-50; 3:11-13 (emphasis added). EX-1003 ¶158.

e. **Claim 5:** ***The method of claim 1, further comprising generating the computer-readable image data of the target tissue.***

Eufinger discloses this limitation for the same reason as discussed with respect to the "obtaining" and "rendering" steps of Claim 1. EX-1003 ¶159.

f. **Claim 6:** ***The method of claim 5, further comprising fabricating the 3-dimensional shape of the medical device.***

Eufinger discloses this limitation. Eufinger teaches that the data block representing "the difference of the data of the actual and reference models … can serve as the model for the computer-assisted manufacture of the endoprosthesis. **Based on said data block, the finished endoprosthesis is finally produced . . . with the help of a computer-controlled manufacturing unit**." EX-1008 5:15-21; 5:46-57 (emphasis added). EX-1003 ¶160.

g. **Claim 7:** ***The method of claim 1, further comprising fabricating the 3-dimensional shape of the medical device.***

Eufinger discloses this limitation. See Claim 6 above. EX-1003 ¶161.

X. The Board Should Not Exercise its Discretion to Deny Institution Under Section 325(d) and Section 314(a)

When determining whether to exercise discretion under § 325(d), "the Board uses the following two-part framework: (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of

challenged claims." *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, p. 8 (Feb. 13, 2020) (designated: March 24, 2020).

Here, the Rekow and Vannier references in Ground 1 were not cited nor applied by the examiner during prosecution and this weighs against the Board exercising discretionary denial under the first part of the test in *Advanced Bionics*. During prosecution of the '206 Patent, the Patent Owner submitted a voluminous IDS providing over 150 references, including Eufinger, Dean93 and Dean98 references of Ground 2. Ex. 1002, 10/14/15 IDS, pp.28-37. However, the examiner did not apply or discuss these references.

Importantly, although Dean93 and Dean98 were identified as particularly relevant in the provisional applications, references to these prior art documents were removed by Patent Owner in the application for the '206 Patent. The Dean93 and Dean98 references were authored by one of the inventors of the '206 Patent and directed to the same subject matters as the Challenged Claims, namely the superimposition and deformation of a normative template using anatomical landmarks. Because the examiner specifically found this feature was missing in the cited art, the Patent Owner should have specifically pointed out the relevancy of these references to the examiner, rather than putting them in an IDS after the examiner had already examined the Challenged Claims. *Armour & Co. v. Swift & Co.*, 466 F.2d 767, 779 (7th Cir. 1972) ("[W]e think that it is unfair to the busy

examiner, no matter how diligent and well informed he may be, to assume that he retains details of every pending file in his mind when he is reviewing a particular application…**[T]he applicant has the burden of presenting the examiner with a complete and accurate record to support the allowance of letters patent**.") (emphasis added).

Thus, by not considering the combination of Eufinger, Dean93 and Dean98, the examiner made a material error under the second part of the test in *Advanced Bionics*. Factors (c), (e), and (f)[2] presented in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph) ("*Becton* factors") inform the analysis of the second part of *Advanced Bionics*. *Advanced Bionics* at 9-10.

With regard to *Becton* factor (c), the examiner did not discuss any of Eufinger, Dean93 and Dean98, or the combination thereof, during prosecution of the '206

[2] Relevant *Becton* factors are: "(c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; … (e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments." *See Becton* at 17–18.

Patent. Without any statements by the examiner about these documents, factor (c) weighs against the Board exercising its discretion.

With regard to *Becton* factors (e) and (f), the examiner erred as demonstrated by the application of the prior art. The reasons not to exercise discretion are even stronger here where Petitioner urged the examiner to err by not identifying the references as it had done previously in the provisional application. *Advanced Bionics* at 10 ("[I]f the record of the Office's previous consideration of the art is not well developed or silent, then a petitioner may show the Office erred by overlooking something persuasive under factors (e) and (f).").

Accordingly, there is no basis for the Board to exercise its discretion to deny institution under § 325(d).

The Board has discretion to deny *inter partes review* under 35 U.S.C. § 314(a) in view of an earlier trial date in a parallel proceeding. Because the earliest scheduled trial date in the Parallel Litigations is four months beyond the approximate projected deadline for the Board to issue a final written decision, the Board should not exercise its discretion. Moreover, five of the six non-dispositive factors set forth in *Apple Inc. v. Fintiv, Inc.*, weigh in favor of granting institution of this IPR; the remaining factor is neutral. In view of the Board's technical and specialized expertise, proceeding with the IPR will be more efficient and will result in an earlier decision, compared to litigation. Moreover, Petitioner has presented a

substantial and robust challenge to the validity of the Challenged Claims that warrants a full review. Thus, as set forth in detail below, the considerations of efficiency, fairness, and the merits outlined in *Fintiv* weigh in favor of granting institution.

First factor. No stay has yet been requested and thus this factor is neutral.

Second factor. Only one of the three trial dates for the Parallel Litigations has been scheduled, and it is four months beyond the projected statutory deadline of the Board's final written decision. Considering this fact, as well as the inherent uncertainties of litigation scheduling and the potential for significant disruptions caused by COVID-19, the second factor weighs against discretionary denial.

Third factor. The district court and the parties have not invested substantially in the Parallel Litigations. Discovery in the Parallel Litigations is just beginning; no depositions have been noticed or taken; Patent Owner has not served infringement contentions; and defendants' invalidity contentions are not due for almost three months. Pursuant to the present scheduling orders, the institution decision will issue before the claim construction briefings are finished, and approximately two months before the earliest scheduled claim construction hearing. Thus, this factor weighs against discretionary denial.

Fourth factor. Petitioner is not a party to any of the Parallel Litigations, but is a manufacturer of some of the products accused of infringement by Patent

Owner, and thus Petitioner has concerns regarding the validity of the Challenged Claims that are separate from the individual concerns of any defendant in the Parallel Litigations. Likewise, the Petition challenges all claims of '206 Patent, irrespective of whether the Patent Owner asserts all claims against all defendants in the Parallel Litigations. Thus, this factor weighs against discretionary denial.

Fifth factor. Petitioner is not a defendant in the Parallel Litigations, thus, this factor weighs against discretionary denial.

Sixth factor. Other circumstances in this case strongly weigh in favor against discretionary denial. Here, this Petition is extremely strong. The Petition clearly demonstrates that the prior art discloses each limitation of the Challenged Claims, including highly relevant art which was identified in the provisional applications but omitted from the patent application for the '206 Patent.

Thus, when considering all of the factors together, they weigh heavily against discretionary denial.

XI. CONCLUSION

For the reasons set forth above, Petitioners have established a reasonable likelihood of prevailing with respect to all Challenged Claims of the '206 Patent and requests the Board institute *inter partes* review and then cancel all claims as unpatentable.

Dated: December 2, 2020

/Patrick D. McPherson/

Patrick D. McPherson, Reg. No. 46,255
PDMcPherson@duanemorris.com
DUANE MORRIS LLP
505 9th Street NW, Suite 1000
Washington, D.C. 20004
T: (202) 776-7800
F: (202) 776-7801

ATTORNEY FOR PETITIONER

CERTIFICATION OF SERVICE ON PATENT OWNER

Pursuant to 37 C.F.R. §§ 42.6(e), 42.8(b)(4) and 42.105, the undersigned certifies that on December 2, 2020, a complete and entire copy of this Petition for *Inter Partes* Review of U.S. Patent No. 9,330,206 and all supporting exhibits were served via Federal Express, postage prepaid, to the Mueting Raasch Group by serving the correspondence address of record for the '206 patent:

MUETING RAASCH GROUP
111 WASHINGTON AVE. S., SUITE 700
MINNEAPOLIS MN 55401

/Patrick D. McPherson/
Patrick D. McPherson, Reg. No. 46,255
PDMcPherson@duanemorris.com
DUANE MORRIS LLP
505 9th Street NW, Suite 1000
Washington, D.C. 20004
T: (202) 776-7800
F: (202) 776-7801

ATTORNEY FOR PETITIONER

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24 *et seq*., the undersigned certifies that this document complies with the type-volume limitations. This document contains 11,776 words as calculated by the "Word Count" feature of Microsoft Word 2010, the word processing program used to create it.

Dated: December 2, 2020

/Patrick D. McPherson/

Patrick D. McPherson, Reg. No. 46,255
PDMcPherson@duanemorris.com
DUANE MORRIS LLP
505 9th Street NW, Suite 1000
Washington, D.C. 20004
T: (202) 776-7800
F: (202) 776-7801

ATTORNEY FOR PETITIONER