Filed: December 29, 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. 9,275,191
Inter Partes Review No.: IPR2021-00352

PETITION FOR *INTER PARTES* REVIEW

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i. A method for fabricating a 3-dimensional implant to be implanted into a subject, the method comprising: 28

ii. obtaining a computer readable image including a defective portion and a non-defective portion of tissue in a subject; 28

iii. identifying anatomical landmarks on the image; 30

iv. superimposing on the image a three dimensional template to span the defective portion; 31

v. deforming the template to match the anatomical landmarks on the image; and 32

vi. determining a 3-dimensional shape of the implant based on the template that spans the defective portion; and 33

vii. fabricating the implant having the 3-dimensional shape. 35

b. **Claim 2:** ***The method of claim 1, wherein the superimposing on the image the template to span the defective portion includes: mapping highly curved portions of surfaces of at least one of: the subject and another individual, or the subject and an average, wherein the average comprises an average of the surfaces of more than one individual[;] and establishing correspondence between the mapped highly curved portions.*** 35

c. ***Claim 3: The method as set forth in claim 1, wherein the computer readable image consists of slices of the defective portion and the non-defective portion.*** 37

d. **Claim 4:** ***The method as set forth in claim 1, wherein the computer readable image consists of scan lines of the defective portion and the non-defective portion.*** 37

e. **Claim 5:** ***The method as set forth in claim 1, wherein the computer readable image consists of voxels of the defective portion and the non-defective portion.*** 37

f. **Claim 6:** ***The method as set forth in claim 1, further including determining a position for optimal adjacency between the medical device and the nondefective portion of the subject.*** 38

g. **Claim 7:** ***The method as set forth in claim 1, wherein the template that spans the defective portion in the subject represents an average shape of corresponding normal tissue in the patient.*** 39

h. **Claim 8:** ***The method as set forth in claim 1, wherein fabricating the implant comprises printing with a 3D rendering device.*** 39

i. **Claim 9:** ***The method as set forth in claim 1, wherein the template that spans the defective portion is drawn on the image as the image is displayed by the computer.*** 40

j. **Claim 10:** ***The method as set forth in claim 9, wherein the template that spans the defective portion represents a right-left mirror image of a portion of the subject's anatomy that includes the defective portion.*** 41

k. **Claim 11:** ***The method of claim 10, wherein the determining the 3-dimensional shape of the medical device is determined as a function of respective shapes of the defective portion and the template.*** 42

l. **Claim 12:** ***The method as set forth in claim 1, wherein the template that spans the defective portion in the subject represents corresponding normal tissue in at least one other individual.*** 42

m. **Claim 13:** ***The method as set forth in claim 12, wherein the determining the 3-dimensional shape of the medical device determined as a function of respective shapes of the defective portion and the template.*** 43

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a. **Claim 1** 51

i. ***A method for fabricating a 3-dimensional implant to be implanted into a subject, the method comprising:*** 51

ii. ***obtaining a computer readable image including a defective portion and a non-defective portion of tissue in the subject;*** 51

iii. ***identifying anatomical landmarks on the image;*** 52

iv. ***superimposing on the image a 3-dimensional template to span the defective portion;*** 55

v. ***deforming the template to match the anatomical landmarks on the image;*** 56

vi. ***determining a 3-dimensional shape of the implant based on the template that spans the defective portion; and*** 58

vii. ***fabricating the implant having the 3-dimensional shape.*** 58

b. **Claim 2:** ***The method of claim 1, wherein the superimposing on the image the template to span the defective portion includes: mapping highly curved portions of surfaces of at least one of: the subject and another individual, or the subject and an average, wherein the average comprises an average of the surfaces of more than one individual and establishing correspondence between the mapped highly curved portions.*** 60

c. **Claim 3***: The method as set forth in claim 1, wherein the computer readable image consists of slices of the defective portion and the non-defective portion.* 62

d. **Claim 4:** ***The method as set forth in claim 1, wherein the computer readable image consists of scan lines of the defective portion and the non-defective portion.*** 63

e. **Claim 5:** ***The method as set forth in claim 1, wherein the computer readable image consists of voxels of the defective portion and the non-defective portion.*** 63

f. **Claim 6:** ***The method as set forth in claim 1, further including: determining a position for optimal adjacency between the implant and the non-defective portion of the subject.*** 63

g. **Claim 7:** ***The method as set forth in claim 1, wherein the template that spans the defective portion in the subject represents an average shape of corresponding normal tissue in the patient.*** 64

h. **Claim 8:** ***The method as set forth in claim 1, wherein fabricating the implant comprises printing with a 3-dimensional rendering device.*** 65

i. **Claim 9:** ***The method as set forth in claim 1, wherein the template that spans the defective portion is drawn on the image as the image is displayed by a computer.*** 65

j. **Claim 10:** ***The method as set forth in claim 9, wherein the template that spans the defective portion represents a right-left mirror image of a portion of the subject's anatomy that includes the defective portion.*** 65

k. **Claim 11:** ***The method of claim 10, wherein determining the 3-dimensional shape of the implant is determined as a function of respective shapes of the defective portion and the template.*** 66

l. **Claim 12:** ***The method as set forth in claim 1, wherein the template that spans the defective portion in the subject represents corresponding normal tissue in at least one other individual.*** 67

m. **Claim 13:** ***The method as set forth in claim 12, wherein the determining the 3-dimensional shape of the implant is determined as a function of respective shapes of the defective portion and the template.*** 68

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37 C.F.R. § 42.8(b)(4).....2
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PETITIONER'S EXHIBIT LIST

Exhibit #	*Description*
1001	U.S. Patent No. 9,292,191 ("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.
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 is Materialise N.V. ("Petitioner").

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

Petitioner is not aware of any reexamination certificate or pending prosecution concerning the '191 patent.

The '191 Patent has been asserted in the following litigations ("Parallel Litigations"):

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 8,781,557 and 9,626,756. Petitioner has previously filed requests for inter partes review for related patents 9,292,920, 9,330,206, 9,672,302, and 9,672,617.

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

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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 '191 patent is available for IPR and the Petitioner is not estopped from requesting IPR.

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") petitions for *inter partes* review of U.S. Patent No. 9,275,191 ("the '191 patent"). Petitioner respectfully submits that Claims 1-13 (the "Challenged Claims") are unpatentable under 35 U.S.C. § 103 in view of the prior art. This Petition demonstrates by a preponderance of the evidence that there is a reasonable likelihood Petitioner will prevail on at least one of these claims.

B. OVERVIEW

The '191 patent, titled "Methods and Systems for Producing an Implant," issued on March 1, 2016. EX-1001. Despite the lengthy specification (spanning 36 columns and 44 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.

EX-1003 ¶85.

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 imaging modalities during the 1950's and 60's such as computer tomography (CT), magnetic resonance imaging (MRI), and ultrasound, stimulated development of numerous technologies to display these new kinds of data. EX-1003 ¶86.

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… sturdy enough for a wide range of scientific and biomedical applications." EX-1041 pp.116-117; EX-1003 ¶87.

Though these imaging acquisition and processing techniques were well-known since the early 1990s, the provisional applications that led to the '191 patent were not filed until August 1999. EX-1004-1006. These applications detailed the

work of a group of medical imaging professionals at New York University (the "NYU Group") (among which included 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 corresponding published papers, was the subject of numerous publications over the decade preceding the filing of the '191 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. However, the Challenged Claims are not directed to alleged incremental improvements, but instead to the very basic steps outlined above that were prevalent in the prior art as demonstrated by Grounds 1 and 2 below. EX-1003 ¶88.

IV. IDENTIFICATION OF CHALLENGES

A. Challenged Claims

Claims 1-13 of the '191 patent are challenged in this Petition.

B. Statutory Grounds for Challenges

The Challenges are summarized as follows:

Ground	Claims	Basis	Reference
1	1-13	§ 103	Rekow, in view of Vannier
2	1-13	§ 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 '191 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 June 1993 in the Mathematical Methods in Medical Imaging II, SPIE Vol. 2035, ("Dean93" (EX-1035)). David Dean 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.

Eufinger, Dean93 and Dean98 are prior art under at least § 102(b), and were cited but not applied by the Examiner during '191 patent prosecution.

V. BACKGROUND OF THE '191 PATENT

The Challenged Claims are directed to a computer-implemented technique for determining the 3D shape of an implant. EX-1001 35:17-36:37. 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 of 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

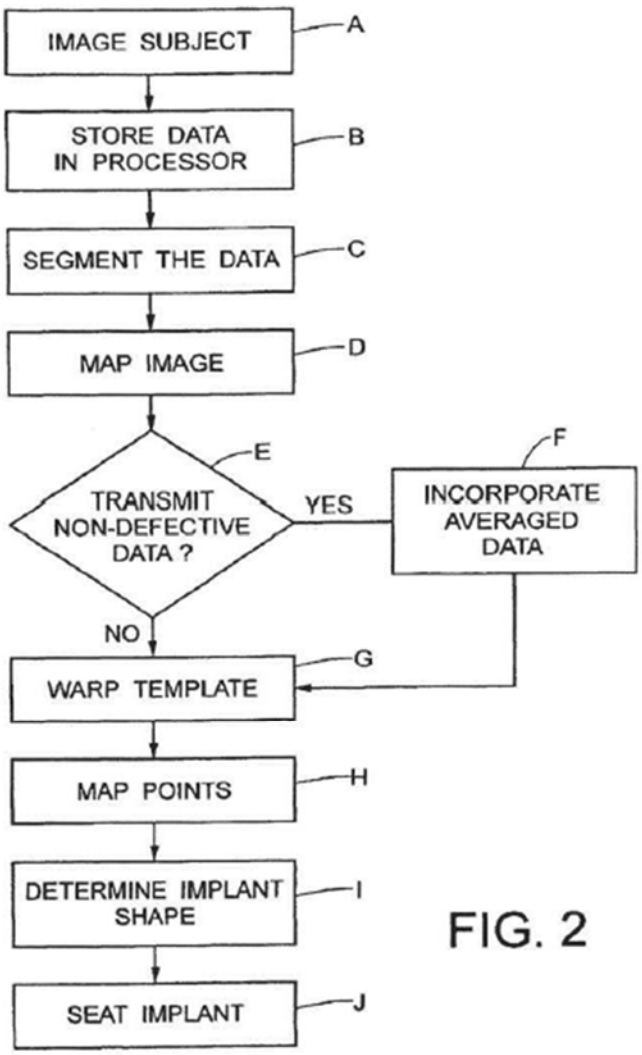


FIG. 2

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 8:44-9:47; EX-1003 ¶32.

In comparison to the high-level steps recited in the Challenged Claims, the patent's "Detailed Description of the Preferred Embodiments" is complex, spanning twenty-six columns and forty-four figures. The description of FIG. 2 occupies but a *single one* of those columns. The remaining twenty-five 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 9:51-35:16; 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 '191 PATENT PROSECUTION HISTORY

A. Prosecution History

1. Applicants Omit Material Information

The '191 patent claims priority to three provisional applications which comprise manuscripts submitted to various scholarly journals. EX-1003, ¶50; EX-1001; EX-1004-1006. 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 '191 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 18:45-19:37; EX-1004. The provisional asserts that SASE represented an improvement over well-known "NYU Methods" that were 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 of 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 extensive discussion of 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 '191 patent.** EX-1001. Applicants never informed the Examiner that the "toolkit" – which is discussed 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 9:54-10:47 and FIG. 4. In fact, **all** reference to nearly 100 scholarly articles cited throughout the provisionals were omitted from the application that led to the '191 patent. EX-1003 ¶55-56.

B. Claim Construction

Petitioner proposes that each claim term 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 '191 patent was filed on September 14, 2012, and purports to claim priority through a series of continuations to U.S. Provisional Application Nos. 60/148393, 60/148277, and 60/148275 concurrently filed on August 11, 1999. EX-1004-1006.

Thus, the earliest possible priority date for the '191 patent is August 11, 1999.

VII. LEVEL OF ORDINARY SKILL IN THE ART

Based on the '191 patent disclosure, 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). EX-1012 p.1; EX-1013 pp.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 ¶59.

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. Once a computer image is obtained, processing typically involved formatting the data into slices stacked to create volumes; 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-1003, ¶60; 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 transferred to a computer, the image 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 '191 patent is simply 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-1003 ¶68; EX-1047.

D. Image Registration Using Landmarks

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. EX-1034; EX-1047. 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 '191 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.

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 '191 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. 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 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 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 object's center. Thus, each radial scan line functions as a planar slice or cross-section of the 3D surface beginning at the object's center 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. 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 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. 7B

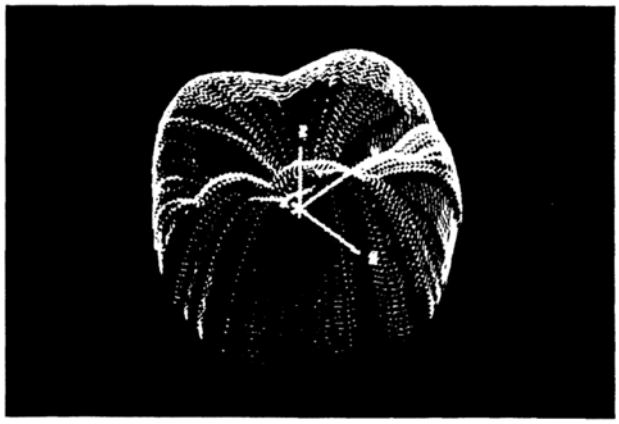
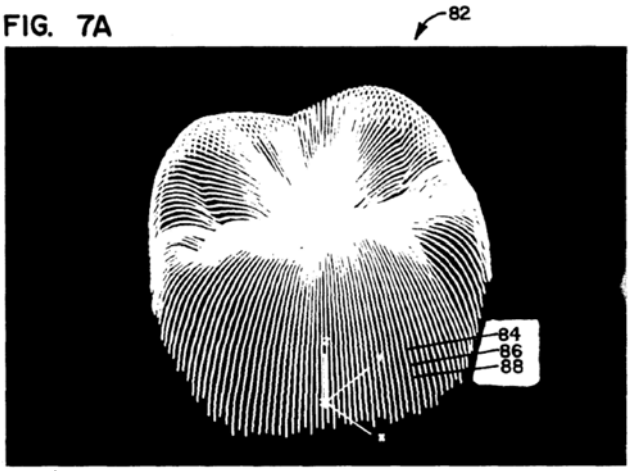


FIG. 7A



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

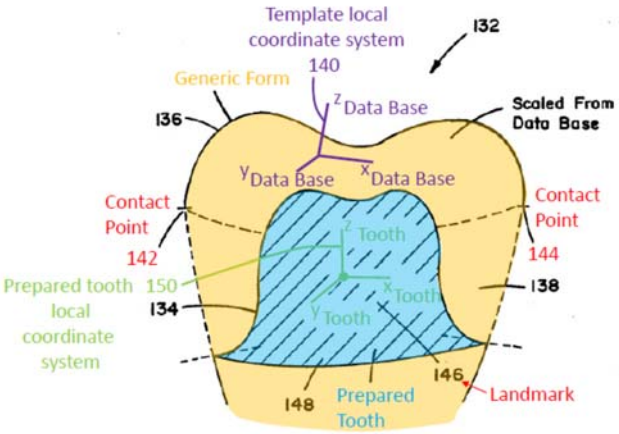


FIG. 12

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.

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 method for fabricating a 3-dimensional implant to be implanted into a subject, the method comprising:

To the extent the preamble is a limitation, Rekow discloses a 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 method for determining a 3D implant shape in the form of a dental prosthesis to be implanted in a subject. Rekow discloses manufacturing the dental prosthesis using CAD/CAM software to control the machine tool for cutting in three dimensions. EX-1010 19:65-20:7. EX-1003 ¶109.

ii. obtaining a computer readable image including a defective portion and a non-defective portion of tissue in a subject;

Rekow discloses this limitation, alone, or in view of Vannier. Rekow discloses rastering the scanning head of an optical 3D surface digitizer over the entire object surface and recording the X,Y,Z surface coordinates into the computer. EX-

1010 2:65-3:11; 6:43-7:18. The scanned image 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; 12:66-13:7; EX-1003 ¶110.

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 tissue. EX-1003 ¶111.

To the extent Patent Owner asserts that this 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 Section IX.A.3, a POSA would have been motivated to modify Rekow to use 3D volumetric data as taught by Vannier. EX-1003 ¶113.

iii. identifying anatomical landmarks on the image;

Rekow discloses this limitation. Rekow discloses a database containing "a plurality of standardized object representations, referred to as generic forms." These "generic forms" comprise a "generic set of (X,Y,Z) coordinates" which "permit the fabrication of reproductions based on idealized or standardized geometries." EX-1010 8:32-52; EX-1003 ¶114.

Rekow discloses identifying anatomical landmarks on the scanned image to match with landmarks on the generic form. Specifically, after acquiring the scanned image data, the CAD/CAM software retrieves a generic form (i.e., a template) from the database. Landmarks on the generic form are matched with, and compared to, "**corresponding landmarks on the scanned object**." EX-1010 8:55-9:7 (emphasis added). 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.*; EX-1003 ¶115.

Additionally, as illustrated in FIG. 10, coordinates can be added to emphasize features (anatomical landmarks) of the object or generic form. The additional

coordinates ensure that the anatomical feature is not smoothed out, or otherwise eliminated, during processing. EX-1010 9:25-33; EX-1003 ¶116.

Thus, Rekow discloses this limitation. EX-1003 ¶117.

iv. superimposing on the image a three dimensional template to span the defective portion;

Rekow discloses this limitation. Rekow's process for storing and retrieving a "generic set of (X,Y,Z) coordinates" that are "typically computer-based representations of standardized plaster models of teeth" in order to "permit the fabrication of reproductions based on idealized or standardized geometries" as described above. EX-1010 8:32-52. Specifically, after acquiring the scanned image data, the CAD/CAM software retrieves a generic form (i.e., a template) from the database. 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 by superimposing the generic form on the scanned object, where the scanned image includes a defective portion. EX-1030 ¶¶ 76-78. Thus, Rekow teaches this limitation. EX-1003 ¶118.

v. deforming the template to match the anatomical landmarks on the image; and

Rekow discloses this limitation. Rekow discloses that after the homologous landmarks on the generic form and scanned object 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-1010 8:55-9:7; EX-1003 ¶119.

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. EX-1003 ¶120.

Additionally, FIG. 10 describes adding coordinates to emphasize features (anatomical landmarks) of the object or the generic form. "The CAD/CAM software

plurally represents the feature coordinate by computing a plurality of parametric curves extending through the feature coordinate (126). These parametric curves are used to provide additional coordinates, thereby preventing the feature from being smoothed out or eliminated." EX-1010 9:25-39; EX-1003 ¶121.

Finally, 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 ¶123.

vi. determining a 3-dimensional shape of the implant based on the template that spans the defective portion; and

Rekow discloses this limitation. Rekow discloses a dental prosthesis that "incorporates information from both the scanned tooth and from the generic tooth form." EX-1010 9:54-56. FIG. 12 illustrates 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:

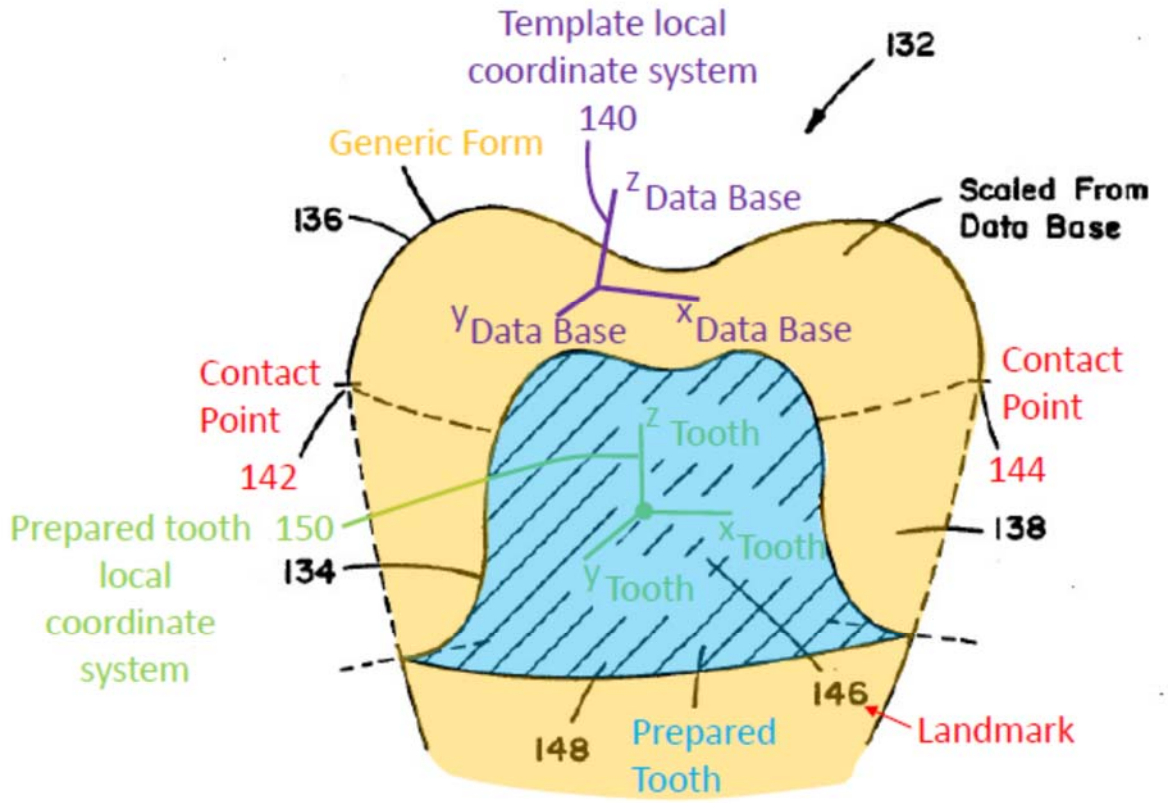


FIG. 12

EX-1010 FIG. 12; 9:57-60. The database also contains the positions of the proximal contacts 142, 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, 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

9:60-68. As a result, the 3-dimensional shape of the dental prosthesis is determined based on the template tooth form that spans the defective portion. EX-1003 ¶124.

vii. fabricating the implant having the 3-dimensional shape.

Rekow discloses this limitation. Rekow discloses fabricating the dental implant using CAD/CAM software to control the machine tool for cutting in three dimensions. EX-1010 19:30-34; 19:65-21:9.

b. **Claim 2:** ***The method of claim 1, wherein the superimposing on the image the template to span the defective portion includes: mapping highly curved portions of surfaces of at least one of: the subject and another individual, or the subject and an average, wherein the average comprises an average of the surfaces of more than one individual[;] and establishing correspondence between the mapped highly curved portions.***

Rekow discloses this limitation. Rekow discloses that the database contains a plurality of templates in the form of "computer-based representations of standardized plaster models of teeth" which a POSA understood corresponds to the normal tissue of other individuals or manually synthesized composite averages of other people's teeth. EX-1010 8:33-52. For example, as discussed in Section VIII, the use of "normative" templates was well-known including extensive digital libraries containing normative data of virtually every anatomical structure in the body, including dental libraries. EX-1017; EX-1027; EX-1029; EX-1032; EX-1045. Rekow discloses in detail "superimposition of generic form" where the generic form is "typically computer-based representations of standardized plaster models of teeth"

which, as discussed above, may be based on another individual or of an average of individuals. A POSA knew that to function as the basis for an implant, the superimposed generic form (or "template") spanning the defective portion must represent the highly curved portions of the tooth, such as the cusps and fossae of the occlusal surface. Rekow teaches that in addition to deforming the template to "contact the adjacent teeth", it is essential that "the coordinates representing the fossae and cusps of the occlusal surface be altered to raise or lower the cusps" in order to properly align with the "surface configuration of the opposing teeth with which the prosthesis must occlude." EX-1010 14:53-15:5. This is critical because these highly curved surfaces constrain the "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)". *Id.* Hence Rekow discloses how the highly curved surfaces of the template (e.g. cusps and fossae) to span the defective portion must be mapped and a proper correspondence established to ensure a functional implant, which satisfies the limitation of *establishing correspondence between the mapped highly curved portions*. EX-1003 ¶125.

c. Claim 3: The method as set forth in claim 1, wherein the computer readable image consists of slices of the defective portion and the non-defective portion.

Rekow discloses this limitation. Rekow discloses that the surface of the scanned object's defective and 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 8:37-47. To the extent Patent Owner argues this limitation requires CT data, Vannier discloses performing "conventional CT scanning" with "image slice" from "1 to 10 mm thick, and the distance between them are from 1 to 10 or 20 mm." EX-1011 p.561. A POSA would be motivated to modify the teachings of Rekow to use the spiral volumetric computed tomography taught by Vannier for the reasons discussed in Section IX.A.3. EX-1003 ¶126.

d.* Claim 4: *The method as set forth in claim 1, wherein the computer readable image consists of scan lines of the defective portion and the non-defective portion.

Rekow discloses this limitation for the same reason as discussed for Claim 3. EX-1003 ¶127.

e.* Claim 5: *The method as set forth in claim 1, wherein the computer readable image consists of voxels of the defective portion and the non-defective portion.

Rekow in view of 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 by Vannier for the reasons discussed in Section IX.A.3. EX-1003 ¶128.

f. **Claim 6:** ***The method as set forth in claim 1, further including determining a position for optimal adjacency between the medical device and the nondefective portion of the subject.***

Rekow discloses this limitation. Rekow discloses that the surfaces of dental prosthesis must contact the adjacent teeth, and thus the CAD/CAM software scales the generic tooth form so that the mesial-distal distance between adjacent proximal teeth matches the distance between contact points of the generic form. The scaling factor used is the ratio of actual mesial-distal length over the mesial-distal length of the generic form. Thus, the size of the generic form can be altered by checking the gap between the adjacent teeth 152, 154. The width and height of the generic form can be determined by measuring the thickness and height of the adjacent teeth 152, 154. EX-1010 10:3-19. EX-1003 ¶129.

g. **Claim 7:** ***The method as set forth in claim 1, wherein the template that spans the defective portion in the subject represents an average shape of corresponding normal tissue in the patient.***

Rekow discloses this limitation for the same reason as discussed for Claim 2. A POSA understood that the normative templates would include an average shape of the corresponding normal tissue in the patient. EX-1003 ¶130.

h. **Claim 8:** ***The method as set forth in claim 1, wherein fabricating the implant comprises printing with a 3D rendering device.***

Rekow renders this limitation obvious. Rekow discloses manufacturing the dental prosthesis using CAD/CAM software to control the machine tool for cutting in three dimensions as discussed in Claim 1. Although Rekow does not expressly describe using the CAD/CAM software to control a 3D printer, a POSA understood that such computer assisted manufacture including the well-known process of converting image data into a format suitable for a stereolithography machine (i.e., 3D printer), were commonly used to create implants. EX-1007 p.6; EX-1032; EX-1003 ¶131.

i. Claim 9: *The method as set forth in claim 1, wherein the template that spans the defective portion is drawn on the image as the image is displayed by the computer.*

Rekow discloses this limitation. Rekow discloses that the CAD/CAM software retrieves a generic form from the database. The generic form is "spatially rotated" and positioned so that it corresponds to a spatial orientation of the set of coordinates scanned from the object. This orientation is performed by matching at least three landmarks on the generic form with corresponding landmarks on the scanned object. The CAD/CAM software also scales the generic coordinates so they are sized substantially the same as the scanned coordinates. Further Rekow discloses that the "resulting representation" may be shaped if desired and also checked for interferences with other objects adjacent to where the reproduction will reside. EX-1010 8:60-9:7. Rekow 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. Thus, Rekow uses the term computer-based representation to refer to a rendered image and, thus, a POSA understood that the "resulting representation" would include the generic form (template) that spans the defective portion drawn on the image as the image is displayed by the computer. EX-1003 ¶132.

j. **Claim 10:** ***The method as set forth in claim 9, wherein the template that spans the defective portion represents a right-left mirror image of a portion of the subject's anatomy that includes the defective portion.***

Rekow renders this limitation obvious. Although Rekow uses a dental prosthesis as the primary embodiment, it discloses that its technique of using a generic form as a template is equally applicable to "implants to replace damaged bones." Ex-1010 1:29-31. As discussed in the Section VIII, a POSA understood that, rather than starting from scratch, several sources of model templates were readily available as a starting point, including the subject patient's anatomy. EX-1013 p.2; EX-1016; EX-1026; EX-1034. Thus, a POSA understood that 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.* Thus, it was known to generate a "mirror image" of the undamaged half of a bone, which could then be used as a starting point to design the replacement for the missing defective portion. *Id*. A POSA would be motivated to modify the teachings of Rekow when the defective portion represents a right-left mirror image of a portion of the subject's anatomy because the "mirror image" of the undamaged half of a bone provides a template that more closely matches the anatomy of the patient than a generic template from a database and, thus, its use as a starting point would be expected to require less deformation. Further, a POSA would expect this

modification to be successful because it uses a well-known technique. EX-1003, ¶133.

k. **Claim 11:** ***The method of claim 10, wherein the determining the 3-dimensional shape of the medical device is determined as a function of respective shapes of the defective portion and the template.***

Rekow discloses this limitation. As discussed above with respect to Claim 1, Rekow discloses a dental prosthesis that "incorporates information from both the scanned tooth and from the generic tooth form." EX-1010 9:54-56; EX-1003 ¶134.

l. **Claim 12:** ***The method as set forth in claim 1, wherein the template that spans the defective portion in the subject represents corresponding normal tissue in at least one other individual.***

Rekow discloses this limitation. Rekow discloses that the database contains a plurality of templates in the form of "computer-based representations of standardized plaster models of teeth" which a POSA understood corresponds to the normal tissue of other individuals or manually synthesized composite averages of other people's teeth. EX-1010 8:33-52. For example, as discussed in Section VIII, the use of "normative" templates was well-known including extensive digital libraries containing normative data of virtually every anatomical structure in the body, including dental libraries. EX-1017; EX-1027; EX-1029; EX-1032; EX-1045; EX-1003 ¶135.

m. **Claim 13:** ***The method as set forth in claim 12, wherein the determining the 3-dimensional shape of the medical device determined as a function of respective shapes of the defective portion and the template.***

Rekow discloses this limitation for the same reason as discussed with respect to Claim 11; EX-1003 ¶136.

B. Ground II: All Claims are unpatentable over Eufinger in view of Dean93 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 fit "the special anatomical features of the patient" to determine the shape of an implant. EX-1003 ¶137.

Eufinger teaches a five-step method for producing an endoprosthesis, using a mandibular implant as an example. EX-1008 4:50-5:40. First, 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 ¶138.

Second, 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 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 ¶139.

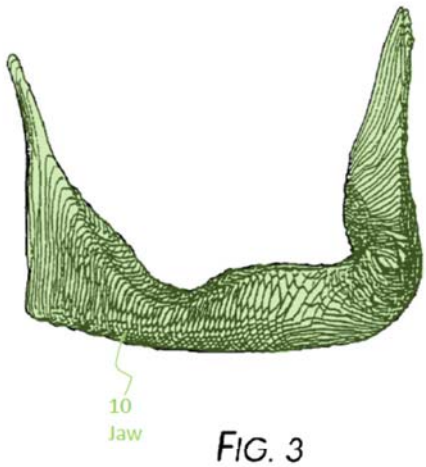


FIG. 3

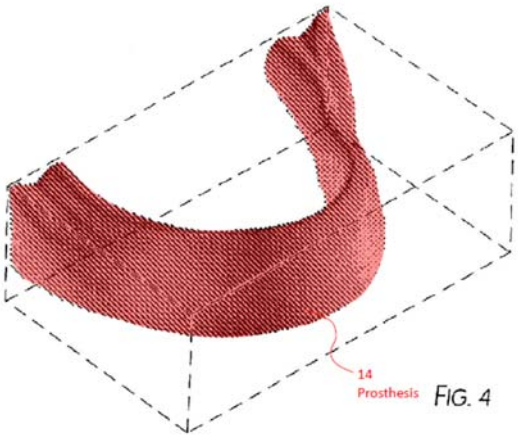


FIG. 4

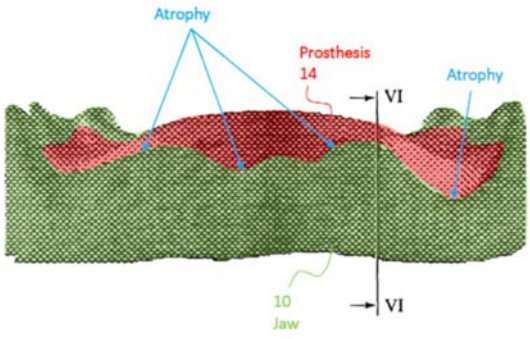


FIG. 5

Next, "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; FIGs. 5 & 6. FIG. 6 illustrates points of the actual model 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 then generated "which can serve as the model for the computer-assisted manufacture of the endoprosthesis." EX-1008 5:15-19; EX-1003 ¶140.

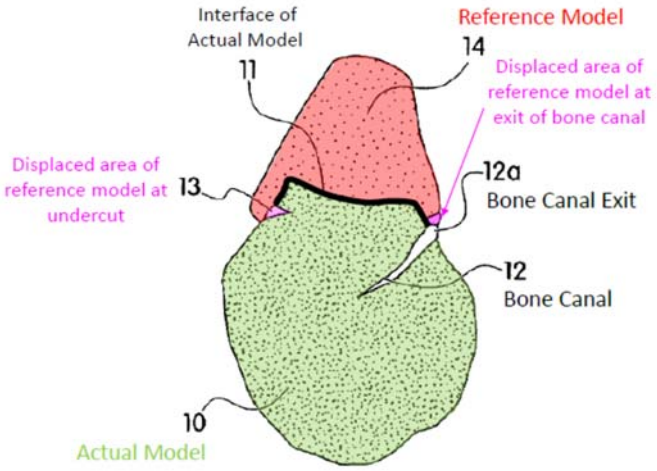


FIG. 6

Based on this data block, the finished endoprosthesis is fabricated using a computer-controlled manufacturing unit. EX-1008 5:19-21; EX-1003 ¶141.

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 can be used to inform a surgical treatment plan, such as for reconstructive surgery. EX-1035; EX-1003 ¶142.

Dean93's average skull template is created using landmark-driven, spline-based algorithms. Dean93 begins with a pre-existing template having the appearance of typical human skull with a wireframe 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 ¶143.

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 specimens. EX-1035 p.39; EX-1003 ¶144.

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

4. The Dean98 Reference

Dean98 is a continuation of the NYU Group's average template work. EX-1009 p.349. Using Dean93's technique to generate "average 'normative' 3D CT surface images of the bony skull," Dean98 describes using these average images as treatment "images for comparisons with patient images at various stages of craniofacial surgical management (*i.e.,* diagnosis, treatment planning, **prosthetic design**, image-guided operative procedures, and outcomes assessment)." EX-1009, Abstract (emphasis added). 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 ¶145.

5. 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 ¶146.

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 ¶147.

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 ¶148.

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 ¶149.

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 '191 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 '191 patent's priority date. EX-1005 pp.3, 26 (emphasis added); EX-1003 ¶150.

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

a. Claim 1

i. A method for fabricating a 3-dimensional implant to be implanted into a subject, the method comprising:

To the extent the preamble is limiting, 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. "[G]enerating the computer-internal model for the endoprosthesis to be produced takes place in the computer." EX-1008 5:36-38; EX-1003 ¶151.

ii. obtaining a computer readable image including a defective portion and a non-defective portion of tissue in the subject;

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 ¶152.

Eufinger's computer readable image comprises defective and non-defective portions of target tissue. For example, FIG. 3 illustrates "the idealized free-form surface geometry of an atrophied lower jaw," which includes both atrophied (defective) portions and existing bone (non-defective) portions, "as it is shown on the video screen 4" of computer 3. EX-1008 4:37-55, 5:41-43; EX-1003 ¶159.

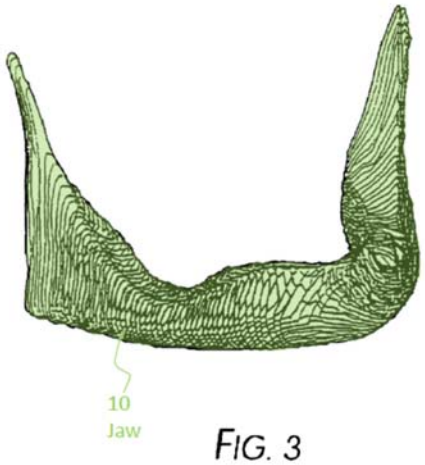


FIG. 3

iii. identifying anatomical landmarks on the image;

Eufinger discloses this limitation, alone or in view of Dean93 and Dean98. Eufinger discloses that the endoprosthesis is "adapted on the video screen of the computer to the **special anatomical features** of the patient by an interactive manipulation of the data" representing images of the actual and reference models. EX-1008 1:6-20; 1:46-55 (emphasis added). 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, 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 ¶161.

FIG. 6 is a cross-section of the actual model 10 superimposed with the reference model 14, and shows this adaptation to anatomical features:

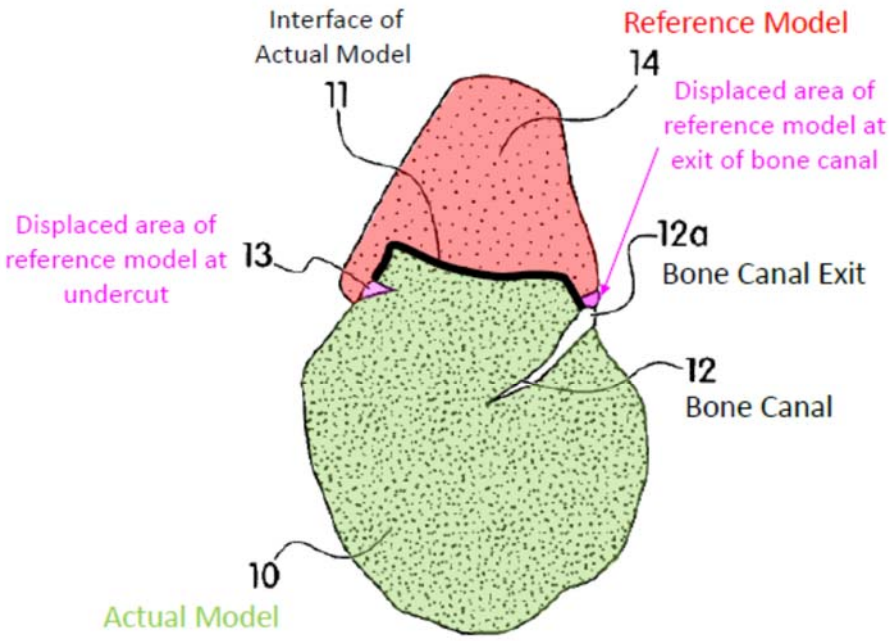


FIG. 6

EX-1003 ¶162.

In FIG. 6, "the interface 11 of the actual model 10 has been displaced within the region of the exit 12a of the bone canal 12 and the undercut 13" (highlighted in magenta) to create recesses so that "in the range of such recesses or cavities, the manufactured endoprosthesis does not rest against the surface of the bone structure of the patient (=actual model)." EX-1008 6:13-24; EX-1003 ¶156.

A POSA understood that anatomical features of the patient, such as bone canals and undercuts, are "anatomical landmarks." A POSA further understood that

adapting the shape of the endoprosthesis to these anatomical landmarks on the video screen (such as by creating recesses at these sites) would first require identifying those landmarks on the image of the actual model. EX-1003 ¶157.

To the extent Patent Owner asserts that Eufinger does not disclose this limitation, Dean93 and Dean98 disclose identifying anatomical landmarks on a 3-dimensional representation (image) of a skull.

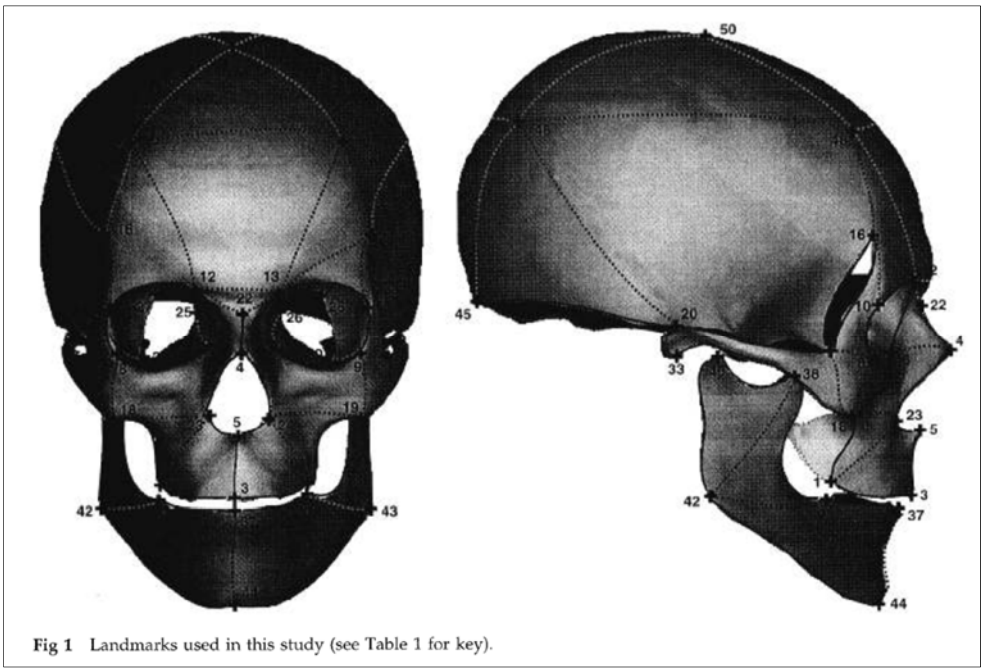


Fig 1 Landmarks used in this study (see Table 1 for key).

EX-1003 ¶158.

Dean93's anatomical landmarks are "discrete geometric points presumed to correspond in some meaningful fashion from specimen to specimen of a data set." EX-1035 p.29. Dean93's process begins with "a previously computed average [template] with all landmark locations and patch boundary curves specified." EX-1035 pp.32-33. That template is then averaged with images of additional skull

specimens by first "manually **locating a small set of landmark points on the specimen surface,**" which "are used to drive a thin-plate spline map that deforms the template in accordance with the landmark-to-landmark correspondence supplied." *Id*. (emphasis added); EX-1003 ¶159.

Dean98 uses Dean93's landmark-based template technique to create average skull templates that can be used as treatment images "to constrain the design of a prosthetic implant." EX-1009 pp.356-357. A POSA would have been motivated to combine the teachings of Eufinger, Dean93 and Dean98 for the reasons discussed in Section IX.B.4. EX-1003 ¶160.

iv. superimposing on the image a 3-dimensional template to span the defective portion;

Eufinger discloses this limitation, alone or in view of Dean93 and Dean98. FIG. 3 and FIG. 4 of Eufinger are computer-generated 3-dimensional representations of the actual and reference models "shown on the video screen 4." In FIG. 5, the actual reference models "are shown superimposed… on the video screen 4." EX-1008 5:41-49.

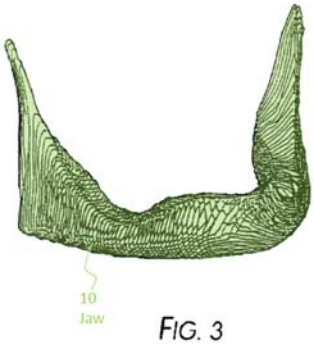


FIG. 3

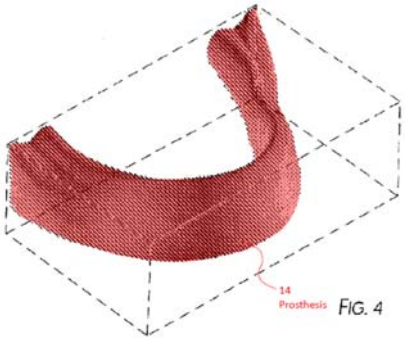


FIG. 4

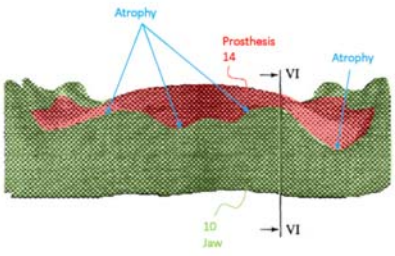


FIG. 5

EX-1003 ¶161.

When superimposed, the reference model 14 (red) spans the atrophied (defective) portion of the jaw (green). Eufinger teaches that "[t]he well-rounded shaped and the sweeping curve" of the reference model is used to obtain the shape "of the endoprosthesis to be produced." EX-1008 6:5-8. A POSA therefore understood that the reference model is a 3D representation of the desired shape to be created and, thus, is a 3D template. EX-1003 ¶162.

To the extent Patent Owner asserts that Eufinger's reference model is not a template, Dean93 and Dean98 disclose this limitation. Dean93 discloses superimposing a landmark-based wireframe template onto a skull image to create an average template. EX-1035 pp.32-33. Dean98 uses Dean93's average template technique to create average treatment images that can be used "**to constrain the design of an implant**" and discloses that "treatment images appear to be useful in cases where the patient's own anatomy is an incomplete basis for planning treatment." 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 in Section IX.B.4. EX-1003 ¶163.

v. deforming the template to match the anatomical landmarks on the image;

Eufinger discloses this limitation, alone or in view of Dean93 and Dean98. Eufinger teaches that the actual and reference data 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 6:26-49. Eufinger's FIG. 6 shows that the interface 11 of the actual model 10 "has been displaced within the region of the exit 12a of the bone canal 12 and the undercut 13 into the volume of the reference model 14." EX-1008 6:9-24; 3:8-13. In other words, the reference model (template) has been deformed to match the bone canal exit and undercut (anatomical landmarks) identified on the image of the actual model of the patient.

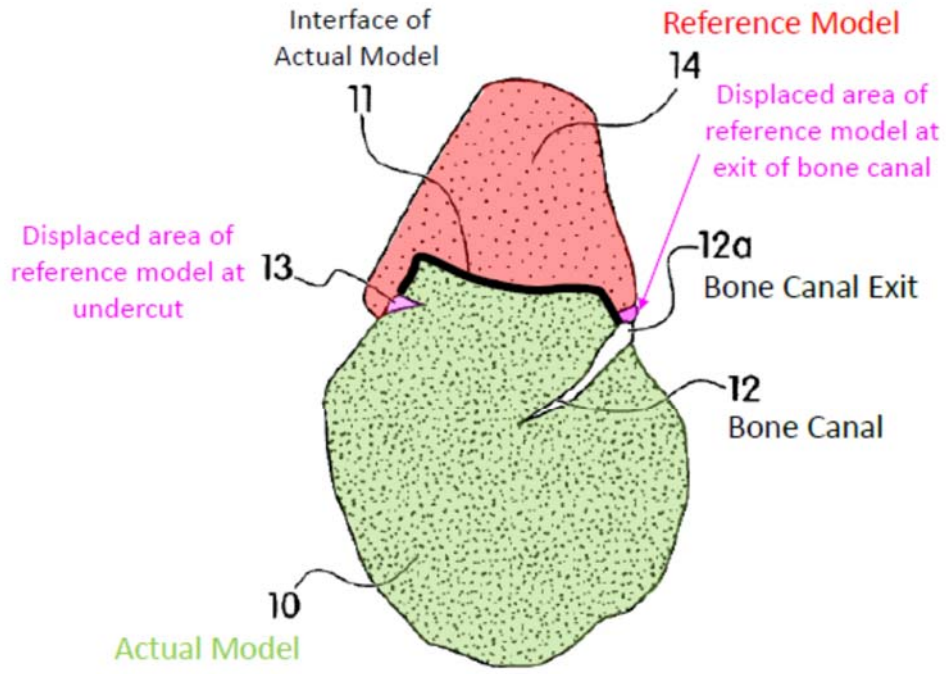


FIG. 6

EX-1003 ¶164.

To the extent Patent Owner asserts that Eufinger does not disclose this limitation, Dean93 and Dean98 disclose superimposing a landmark-based standard

template with skull specimens on which the landmarks have been located. 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." *Id*. (emphasis added). Dean98 uses Dean93's 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 in Section IX.B.4. EX-1003 ¶172.

vi. determining a 3-dimensional shape of the implant based on the template that spans the defective portion; and

Eufinger discloses this limitation. Eufinger teaches that "a computer-internal model is formed for the endoprosthesis from the difference" of the data blocks of the actual model and reference model. That computer-internal model "is finally used for the computer-controlled manufacture of the endoprosthesis." EX-1008 1:10-20. As discussed above, the reference model is a template that spans the actual model's defective portion. Therefore, the 3-dimensional shape of the endoprosthesis is determined based on the template that spans the defective portion. EX-1003 ¶173.

vii. fabricating the implant having the 3-dimensional shape.

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; 5:39-40. Therefore, Eufinger discloses this limitation. EX-1003 ¶189.

b. Claim 2: ***The method of claim 1, wherein the superimposing on the image the template to span the defective portion includes: mapping highly curved portions of surfaces of at least one of: the subject and another individual, or the subject and an average, wherein the average comprises an average of the surfaces of more than one individual and establishing correspondence between the mapped highly curved portions.***

Eufinger discloses this limitation, alone or in view of Dean93 and Dean98. Eufinger discloses that the reference model is a "should-be" model that provides "in advance" the "well-rounded shape and the sweeping curve… of the endoprosthesis to be produced." EX-1008 6:5-8. A POSA understood that the "should-be" shape of the reference model would represent corresponding normal surfaces in an individual other than the patient or an average of the surfaces of multiple individuals. EX-1003 ¶168.

Eufinger further teaches superimposing the reference model with the actual model and manipulating the models so that the highly curved portions of the template are exactly geometrically adapted to fit the corresponding highly curved portions of the actual model. EX-1008 4:4-8. Fine adaptions also are made to the endoprosthesis design, for example, to map out "the recesses of exit regions of the sensitive nerves of the lower jaw" so they are "adapted to the shape of the endoprosthesis" and will not rest against the patient's highly curved bone structure in those mapped out regions. EX-1008 5:55-6:5. Achieving this exact fit of the

endoprosthesis to the patient's highly curved bone structure necessarily includes establishing correspondence between the models' mapped highly curved surfaces. EX-1003 ¶169.

Should Patent Owner assert that Eufinger does not meet these limitations, Dean93 and Dean98 disclose these features. Dean93 discloses mapping highly curved portions of surfaces by tracing "ridge curves" where the surface curvature is at a local maximum, such as along the line of the jaw or around the eye socket, that are comparable across human skulls. EX-1035 p.34. Dean93 teaches how to establish the correspondence of these mapped highly curved surfaces between a subject and another individual (or average) using landmarks to create or update an average template. EX-1035 pp.34-35. A POSA understood that these average templates represented an average of the surfaces of more than one individual. Dean93 further teaches the use of "a thin plate spline map that deforms the template in accordance with the landmark-to-landmark correspondence supplied". EX-1035 pp.34-35. Dean98 teaches the use of Dean93's average template technique to create average skull images that are "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; EX-1003 ¶170.

A POSA understood that Dean93's thin-plate-spline-map deformation technique is a mapping of the highly curved surfaces of the specimen to another

individual or to an average, where the average comprises an average of the surfaces of multiple specimens. A POSA also understood that this deformation required establishing a correspondence between the specimen's mapped surfaces and the template's average mapped surfaces. A POSA would be motivated to combine the teachings of Eufinger, Dean93 and Dean98 for the reasons discussed in Section IX.B.4. EX-1003 ¶182.

c. **Claim 3***: The method as set forth in claim 1, wherein the computer readable image consists of slices of the defective portion and the non-defective portion.*

Eufinger discloses or renders obvious 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." EX-1008 3:59-4:5 (emphasis added). A POSA understood that helical CT scanning obtains a computer readable image of the patient volume in slices, including the defective and nondefective portions. EX-1003 ¶171.

d. **Claim 4:** ***The method as set forth in claim 1, wherein the computer readable image consists of scan lines of the defective portion and the non-defective portion.***

Eufinger discloses this limitation for the same reason as discussed with respect to Claim 3 because a POSA knew that scan lines are simply rows of pixels in a slice. EX-1003 ¶172.

e. **Claim 5:** ***The method as set forth in claim 1, wherein the computer readable image consists of voxels of the defective portion and the non-defective portion.***

Eufinger discloses CT helical scanning to acquire "the entire patient volume." EX-1008 3:59-4:5. As discussed in Section VIII (State of the Art), it was well known that processing of 3D medical images, including images obtained by a CT scan, typically involved reconstructing the data into slices stacked to create volumes consisting of voxels. *See* Section VIII(A). A POSA therefore understood that helical CT scanning of the "entire patient volume" produces a computer readable image consisting of voxels of the defective portion and the non-defective portion. Eufinger thus discloses this limitation. EX-1003 ¶173.

f. **Claim 6:** ***The method as set forth in claim 1, further including: determining a position for optimal adjacency between the implant and the non-defective portion of the subject.***

Eufinger discloses this limitation. Eufinger teaches that, to avoid "painful pressure phenomena," "the surface of the endoprosthesis has to be shaped within the region of contact with nerval structures… by recessing such surface within said

region of the surface" and creating "softly rounded transitions" to the existing bone structure." EX-1008 1:33-60. Eufinger also teaches that after the images of the actual and reference models are superimposed on the video screen, "part areas of the interface of the actual model are recessed by displacing points of support in the direction of the volume of the reference model." EX-1008 2:64-3:13. Thus, when implanting the endoprosthesis, the "hollow spaces formed" by the displacement "are in **exactly the sites** whether the adaptation was made." *Id*. (emphasis added). Eufinger, therefore, teaches "determining a position for optimal adjacency" between the endoprothesis and the patient's non-defective portion (i.e., the existing bone and nerval structures). EX-1003 ¶174

g. **Claim 7:** ***The method as set forth in claim 1, wherein the template that spans the defective portion in the subject represents an average shape of corresponding normal tissue in the patient.***

Eufinger discloses this limitation, alone or in view of Dean93 and Dean98. Eufinger's FIG. 5 shows the reference model 14 spanning the atrophied (defective) portions of the patient's jaw. EX-1008, FIG. 5. A POSA understood that the well-rounded shape and sweeping curve of the reference model 14 represents the "average shape" the patient's normal jaw should have. EX-1008 6:5-8; EX-1003 ¶175.

Should Patent Owner assert that this limitation is not met by Eufinger, Dean93 and Dean98 disclose this limitation. Dean98 uses Dean93's average template technique to create average treatment images based on 40 specimens. EX-1009

p.349. Dean98 discloses that these average images represent a "'norm,' 'standard,' or 'ideal'" which can be "especially useful" to "constrain the design of a prosthetic implant." EX-1009 pp.356-357. A POSA would have been motivated to combine the teachings of Eufinger, Dean93 and Dean98 for the reasons discussed in Section IX.B.4. EX-1003 ¶176.

h. **Claim 8:** ***The method as set forth in claim 1, wherein fabricating the implant comprises printing with a 3-dimensional rendering device.***

Eufinger renders this limitation obvious because a POSA understood that computer assisted manufacture of an endoprosthesis included the well-known process of printing on a 3D rendering device. EX-1003 ¶190; EX-1032; EX-1003 ¶177.

i. **Claim 9:** ***The method as set forth in claim 1, wherein the template that spans the defective portion is drawn on the image as the image is displayed by a computer.***

Eufinger discloses this limitation. The reference model is a template that spans the defective portion of the atrophied jaw. EX-1003 ¶174; EX-1008 4:37-59; 5:41-43. Eufinger's FIG. 5 illustrates "the actual model 10… and the reference model 14… superimposed… on the video screen 4" of the computer 3. EX-1008 5:46-50. Thus, Eufinger discloses drawing the template on the actual model's image as the image is displayed on the computer screen. EX-1003 ¶178.

j. **Claim 10:** ***The method as set forth in claim 9, wherein the template that spans the defective portion represents a***

right-left mirror image of a portion of the subject's anatomy that includes the defective portion.

Eufinger renders this limitation obvious. Eufinger explicitly lists "reflection" as an example of the interactive adaptations that can be made to a template. EX-1008 5:55-58. Further, as discussed in Section VIII, a POSA understood that, rather than starting from scratch, several sources of model templates were readily available as a starting point, including the subject patient's anatomy. EX-1003, ¶175; EX-1013 p.2; EX-1016; EX-1026; EX-1034. Thus, a POSA understood that 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.* Thus, it was known to generate a "mirror image" of the undamaged half of a bone, which could then be used to design the replacement for the missing defective portion. *Id*. A POSA would be motivated to use a mirror-image reflective adaptation because it would provide a better template that more closely matches the anatomy of the patient than an average template from a database. Thus, a POSA would expect a mirror-image template to require less deformation and, further, would expect this modification to be successful because it uses a well-known technique. EX-1003, ¶179.

k. **Claim 11:** ***The method of claim 10, wherein determining the 3-dimensional shape of the implant is determined as a function of respective shapes of the defective portion and the template.***

Eufinger discloses this limitation. As discussed above for to Claim 1, Eufinger teaches that the 3D shape of the implant is determined based on the difference between the shape of the actual model (which includes a defective portion) and the reference model. EX-1008 1:6-20. EX-1003 ¶180

l. **Claim 12:** ***The method as set forth in claim 1, wherein the template that spans the defective portion in the subject represents corresponding normal tissue in at least one other individual.***

Eufinger discloses this limitation, alone or in view of Dean93 and Dean98. Eufinger discloses that the reference model is a "should-be" model that provides "in advance" the "well-rounded shape and the sweeping curve… of the endoprosthesis to be produced." EX-1008 6:5-8. A POSA understood that the "should-be" shape of the reference model would represent corresponding normal tissue in an individual other than the patient. EX-1003 ¶181.

To the extent Patent Owner asserts that this limitation is not met by Eufinger, Dean93 and Dean98 disclose this limitation. 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. A POSA understood that Dean98's average treatment images would correspond to

normal tissue in at least one other individual, and would have been motivated to combine the teachings of Eufinger, Dean93 and Dean98 for the reasons discussed in Section IX.B.4. EX-1003 ¶181.

m. **Claim 13:** ***The method as set forth in claim 12, wherein the determining the 3-dimensional shape of the implant is determined as a function of respective shapes of the defective portion and the template.***

Eufinger discloses this limitation for the same reasons discussed for Claim 11. EX-1003 ¶179.

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 a 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 or applied by the examiner during prosecution and this weighs against the Board exercising discretionary denial under part one of the *Advanced Bionics* test. During prosecution

of the ’191 Patent, Patent Owner submitted a voluminous IDS providing over 150 references, including Eufinger, Dean93 and Dean98 references of Ground 2. Ex. 1002, pp.280-287. However, the examiner did not apply or discuss these references.

Importantly, although Dean93 was identified as particularly relevant in the provisional applications, references to this prior art document was removed by Patent Owner in the application for the ’191 Patent. The Dean93 and Dean98 references were authored by one of the inventors of the ’191 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 these features missing in the cited art, the Patent Owner should have specifically pointed out the relevancy of these references, 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 *Advanced Bionics*

test. 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 during prosecution of the '191 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 Patent Owner urged the examiner to err by not identifying Dean93 and the inventors' prior work, which it had done previously in the provisional application. *Advanced Bionics* at 10 ("[I]f the record of the Office's

[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.

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 first 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 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 '191 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 '191 Patent.

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

XI. CONCLUSION

For the reasons set forth above, Petitioner requests the Board institute *inter partes* review and then cancel all Challenged Claims as unpatentable.

Dated: December 29, 2020

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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 29, 2020, a complete and entire copy of this Petition for *Inter Partes* Review of U.S. Patent No. 9,275,191 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 '191 patent:

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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 13,992 words as calculated by the "Word Count" feature of Microsoft Word 2010, the word processing program used to create it.

Dated: December 29, 2020

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