

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Straumann USA, LLC
Petitioner,

v.

Smart Denture Conversions, LLC,
Patent Owner.

Case No. IPR2025-00956

Patent No. 11,937,992

**DECLARATION OF KARL R. LEINSING, MSME, PE
IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND AND QUALIFICATIONS.....	1
III.	MATERIALS CONSIDERED	4
IV.	LEGAL UNDERSTANDING.....	7
	A. Anticipation	7
	B. Obviousness.....	9
	C. Claim Construction.....	12
V.	LEVEL OF ORDINARY SKILL IN THE ART.....	13
VI.	THE 992 PATENT	15
	A. The 992 Patent (EX1001).....	15
	B. Prosecution History Of The 992 Patent (EX1003)	16
VII.	PRIOR ART	18
	A. Bernhard (EX1003)	18
	B. Poovey (EX1005)	19
	C. Gracco (EX1006)	22
	D. Derey (EX1008)	24
	E. Nino (EX1020)	25
	F. Ruetschi (EX1022)	25
VIII.	SUMMARY OF OPINIONS.....	26
IX.	GRACCO, DEREY, NINO, AND RUETSCHI ARE CUMULATIVE OF PRIOR ART THAT WAS BEFORE THE PATENT EXAMINER.....	28
	A. Derey	29
	B. Gracco.....	36
	C. Nino & Ruetschi.....	41
X.	<u>GROUND 1: THE PRIORITY APPLICATIONS SUPPORT AND ENABLE INDEPENDENT CLAIMS 1 AND 9.</u>	42

I, Karl R. Leinsing, declare as follows:

I. INTRODUCTION

1. I have been retained in this matter by Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan on behalf of Patent Owner Smart Denture Conversions, LLC (“Smart Denture”) to provide technical assistance in responding to the petition for *inter partes* review (“IPR”) of certain claims of U.S. Patent No. 11,937,992 (“the 992 Patent”). The 992 Patent is generally directed to a screw-attached pick-up dental coping system and methods.

2. I understand that Petitioner Straumann USA, LLC (“Straumann”) petitions for *inter partes* review of the 992 Patent and requests that the Patent Trial and Appeal Board (“Board”) cancel Claims 1–12 of the 992 Patent.

3. This declaration is a statement of my opinions on issues related to the patentability of certain claims of the 992 Patent.

II. BACKGROUND AND QUALIFICATIONS

4. In forming my opinions, I relied upon my education, knowledge, and experience and considered the level of ordinary skill in the art as discussed below. A copy of my current *curriculum vitae* is attached to this Declaration, and it provides a comprehensive description of my academic and employment history along with papers and books that I have published and patent and patent applications of which I am listed as an inventor.

5. I received a Bachelor of Science degree in mechanical engineering from the University of New Hampshire in 1988 and a Master of Science degree in mechanical engineering from North Carolina A&T State University in 1995. I am also a Professional Engineer in the State of New Hampshire (License No. 11437). I have worked as an engineer for more than 35 years and as a medical device engineer since 1992. Since 2006, I have served as the President of ATech Designs, LLC, where I design and develop various medical devices.

6. I have experience with various types of implants and devices in the medical field. I have consulted on and have experience with bone anchors, bone screws, and bone plates. In particular, I have consulted on bone screw threads, fracture of bone screws, screw guides, drills, bone reamers, and inserters. I have invented, developed, and tested surgical anchors and other fixation devices used in the various tissues of the body and I have experience with training surgeons on use of the same.

7. I also have experience with other medical devices used during surgical intervention such as fasteners, tensioning members, and tissue anchors. I have further experience with devices that use electrodes for tissue ablation or tissue sealing/cutting devices, or to stimulate muscles such as pacemakers.

8. My experience with materials used in medical devices is quite extensive starting with my Master's Thesis on Strength of Medical Thermoplastic Female Luers Exposed to Chemicals.

9. I have gained significant experience with the development and life cycle of medical devices. This includes product conception/design, manufacturing, testing, sterilization, qualification, validation, verification, packaging, labeling, clinical trials, regulatory approval, marketing, and sales. I have worked as a Senior Product Design Engineer, Manager of Design Engineering, and Director of Biomedical Engineering. In my current role as President of ATech Designs, LLC, I have managed the development of various medical devices from conception to market. Many of my speaking engagements address the medical device product development process and include topics such as "The Science of Successful Medical Device Design."

10. Over my professional career, I have received several awards and honors. I have received a variety of awards for my medical product designs, with one design published on the cover of LIFE Magazine. One award, from Governor James B. Hunt of North Carolina, was presented for the design and development of a needle-free valve produced using completely automated manufacturing technology. In 1998, I won a Medical Design Excellence Award from the Medical Device & Manufacturing Conference and Exposition (Canon Communications). In

2000, I received a design award from the National Society of Professional Engineers for innovative use of engineering principles and materials. In 2001, I won a Prototype Design Award and in 2003, I was a Gold Winner for yet another Medical Design Excellence Award. I have been recognized as one of the top medical device professionals in the country by MD&DI Magazine, and I have won awards from the MD&M Conference for my medical devices.

11. I am listed as an inventor on forty-one (41) U.S. patents, and I am currently working on two new medical device inventions.

12. My company, ATech Designs, LLC, is being compensated for my time in connection with this matter at my standard consulting rate, which is \$600 per hour, plus reimbursement for actual expenses. My compensation is not dependent in any way upon the outcome of this matter.

III. MATERIALS CONSIDERED

13. In preparing this Declaration, I have reviewed the '992 Patent and considered the following documents in light of the general knowledge in the relevant art.

Exhibit	Description
1001	U.S. Patent No. 11,937,992
1002	Expert Declaration of John B. Brunski, Ph.D.
1003	U.S. Patent Application Pub. No. US 2017/0202649 A1 (Bernhard)

Exhibit	Description
1004	U.S. Patent No. 6,283,752 (Kumar)
1005	U.S. Patent Application Pub. No. US 2016/0045290 A1 (Poovey)
1006	A. Gracco et al., <i>Effects of Thread Shape on the Pullout Strength of Miniscrews</i> , 142 Amer. J. Orthodontics & Dentofacial Orthopedics 186–190 (2012) (Gracco)
1007	Declaration of Lindsay Allen
1008	PCT Patent Application No. WO 2013/030839 A1 (Derey)
1009	U.S. Provisional Patent Application No. 62/742,942
1010	U.S. Provisional Patent Application No. 62/774,402
1011	U.S. Provisional Patent Application No. 62/818,082
1012	U.S. Patent Application No. 16/596,361
1013	U.S. Patent No. 11,311,354 (Kofford)
1014	Smart Denture Conversions Webpage – Separable Fastener
1015	Prosecution History of U.S. Patent Application No. 18/328,730
1016	Smart Denture Conversions – Technique Guide
1017	Complaint, D.I. 1 (April 23, 2024), <i>Smart Denture Conversions, LLC v. Straumann USA, LLC</i> , No. 1:24-cv-00507-JCB (D. Del.)
1018	U.S. Patent Application No. 17/691,108
1019	NeoConvert Brochure
1020	U.S. Patent No. 7,938,046 (Nino)
1021	German Published Patent Application (Offenlegungsschrift) DE 3808238 A1 (Ruetschi)
1022	Certified English Translation of German Published Patent Application (Offenlegungsschrift) DE 3808238 A1 (Ruetschi)
1023	U.S. Patent No. 1,725,109 (Starkey)
1024	U.S. Patent No. 2,626,029 (Guttermann)
2001	First Supplemental Complaint, <i>Smart Denture Conversions, LLC v. Straumann USA, LLC</i> , No. 1:24-cv-00507-JCB (D. Del. Feb. 4, 2025), ECF No. 34

Exhibit	Description
2002	Docket sheet, <i>Smart Denture Conversions, LLC v. Straumann USA, LLC</i> , No. 1:24-cv-00507-JCB (D. Del.)
2003	Complaint, <i>Smart Denture Conversions, LLC v. Straumann USA, LLC</i> , No. 1:24-cv-00507-JCB (D. Del. Apr. 23, 2024), ECF No. 1
2004	Defendant Straumann USA, LLC's Opening Brief in Support of its Motion to Dismiss Plaintiff's Complaint for Failure to State a Claim for Relief under Fed. R. Civ. P. 12(b)(6), <i>Smart Denture Conversions, LLC v. Straumann USA, LLC</i> , No. 1:24-cv-00507-JCB (D. Del. July 29, 2024), ECF No. 13
2005	Order, <i>Smart Denture Conversions, LLC v. Straumann USA, LLC</i> , No. 1:24-cv-00507-JCB (D. Del. Jan. 30, 2025), ECF No. 31
2006	Stipulated Protective Order, <i>Smart Denture Conversions, LLC v. Straumann USA, LLC</i> , No. 1:24-cv-00507-JCB (D. Del. Mar. 4, 2025), ECF No. 44
2007	Defendant Straumann USA, LLC's Initial Invalidity Contentions, No. 1:24-cv-00507-JCB (D. Del.) (served June 2, 2025)
2008	Order Regulating Practice for civil cases assigned to The Honorable J. Campbell Barker, <i>Smart Denture Conversions, LLC v. Straumann USA, LLC</i> , No. 1:24-cv-00507-JCB (D. Del. Dec. 16, 2024), ECF No. 22
2009	Notice of Sotera Stipulation, <i>Smart Denture Conversions, LLC v. Straumann USA, LLC</i> , No. 1:24-cv-00507-JCB (D. Del. June 4, 2025), ECF No. 57
2011	Smart Denture Conversions, <i>Technique Manual</i> , available at https://shorturl.at/798cX
2012	International Patent Application No. WO 96/2019 (Sept. 26, 1996) ("Sutter 1996")
2013	U.S. Patent No. 6,332,777 B1 (Dec. 25, 2001) ("Sutter 2001")
2014	U.S. Patent No. 3,115,804 (Dec. 31, 1963) ("Johnson")
2015	U.S. Patent No. 5,904,483 (May 18, 1999) ("Wade")
2016	U.S. Patent No. 6,517,543 B1 (Feb. 11, 2003) ("Berrevoets")
2017	U.S. Patent No. 9,568,037 B2 (Feb. 14, 2017) ("Staniszewski")

Exhibit	Description
2018	Pub. No. US2002/0094255 A1 (July 18, 2002) (“Neuhengen”)

IV. LEGAL UNDERSTANDING

14. I am not an attorney, and I render no opinions on the law itself. My opinions are informed by my understanding of the relevant law as has been provided to me by counsel. I understand that the patentability analysis is conducted on a claim-by-claim and element-by-element basis.

15. I understand that, in this *inter partes* review, Petitioner ultimately has the burden of proving that each challenged claim is unpatentable by a preponderance of the evidence. I also understand that, for the Board to institute an *inter partes* review, Petitioner has the burden of showing a reasonable likelihood of that unpatentability.

16. I understand that earlier patents and publications may render a patent unpatentable as anticipated under 35 U.S.C. §102 or obvious under 35 U.S.C. § 103. I understand Petitioner is asserting both anticipation and obviousness arguments in this proceeding.

A. Anticipation

17. I understand that a patent claim is unpatentable and invalid if the claim is “anticipated” by the prior art. I understand that a claimed invention is not novel or is anticipated if:

(i) the invention was known or used by others in this country, or was patented or described in a printed publication in this or a foreign country, before the invention by the patent applicant;

(ii) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of the application for patent in the United States; or

(iii) the invention was described in a published patent application by another filed in the United States before the invention by the applicant for patent; or

(iv) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the Patent Cooperation Treaty shall serve as prior art only if the international application designated the United States and was published under the treaty in the English language.

18. I understand that anticipation occurs when a single piece of prior art describes every element of the claimed invention, either expressly or inherently, arranged in the same way as in the claim. I understand that, for inherent anticipation, it is required that the missing descriptive material is necessarily present in the prior art.

B. Obviousness

19. I further understand that a patent claim is unpatentable and invalid if the subject matter of the claim as a whole would have been obvious to a person of ordinary skill in the art (“POSA”) of the claimed subject matter as of the time of the invention at issue. I understand that obviousness may be shown by considering and combining more than one item of prior art or the knowledge of a POSA.

20. I understand that the following factors should be evaluated to determine whether the claimed subject matter is obvious: (1) the scope and content of the prior art; (2) the difference or differences, if any, between each claim of the patent and the prior art; (3) the level of ordinary skill in the art at the time the patent was filed; and 4) the objective evidence of non-obviousness, also referred to as secondary considerations (described below).

21. I understand that a prior art reference is proper to use in an obviousness analysis if the prior art is analogous art to the claimed invention. I understand that a prior art reference is analogous art if at least one of the following two considerations is met: (1) the prior art reference is from the same field of endeavor as the claimed invention, even if the prior art reference addresses a different problem and/or arrives at a different solution; (2) the prior art reference is reasonably pertinent to the problem faced by the inventor, even if it is not in the same field of endeavor as the claimed invention.

22. I understand that it must be shown that a POSA at the time of the invention would have had a reasonable expectation that a modification or combination of one or more prior art references would have succeeded. Moreover, I understand that, to establish obviousness based on combining multiple embodiments from a single reference, there must be a motivation to make the combination and a reasonable expectation that such a combination would be successful.

23. I also understand that there should be a reason, suggestion, or motivation in the prior art that would lead a POSA to combine the prior art references, and that would also suggest a reasonable likelihood of success. The reasons for combining references stem (explicitly or implicitly) from, for example: (a) the prior art references themselves; (b) the prior art as a whole; (c) the knowledge, common sense, and creativity of those of ordinary skill in the art; (d) the nature of the problem to be solved; (e) the demands in the design community and/or the market place; (f) the simple and predictable substitution of one known element for another in accordance with their known functions; (g) the application of a known technique or method to a piece of prior art ready for improvement; (h) the obviousness of trying the combination; and/or (i) the general needs and problems in the field. For example, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a POSA has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated

success, it is likely the product is not of innovation but of ordinary skill and common sense. I also understand that, if a technique has been used to improve one device, and a POSA would recognize that it would improve similar devices in the same way, using the technique is obvious unless its application is beyond his or her skill.

24. I understand that so-called “objective indicia of non-obviousness,” also known as “secondary considerations,” are also to be considered when assessing obviousness if present. These include commercial success; long-felt but unresolved need; failure of others to solve the problem that the inventor solved; unexpected results; copying of the invention by others; and industry recognition or expressions of disbelief by experts in the field of the claimed invention. I also understand that a nexus, i.e., a tie, must exist between objective indicia of non-obviousness and the novel aspects of the claimed subject matter.

25. I understand that the test of obviousness is whether the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art as of the date of the invention in light of the prior art. I understand that the use of hindsight must be avoided when considering whether the alleged invention would have been obvious to the POSA.

26. I understand that in determining obviousness, the POSA is a person of ordinary creativity, not an automaton. I understand that, when there is a design need or market pressure to solve a problem and there are a finite number of identified,

predictable solutions, a POSA has good reason to pursue the known options within his or her technical grasp.

27. I understand that a dependent claim incorporates each and every limitation of the independent claim from which it depends. Thus, I understand that if a prior art reference fails to anticipate an independent claim, then that prior art also necessarily fails to anticipate all dependent claims that depend from the independent claim. Similarly, I understand that if a prior art reference or combination of prior art reference fails to render obvious an independent claim, then that prior art reference or combination of prior art references also necessarily fails to render obvious all dependent claims that depend on that independent claim.

C. Claim Construction

28. I understand that “claim construction” is the interpretation of the meaning of patent claims. I understand that claims in this *inter partes* review proceeding are generally given their ordinary and customary meaning, which is the meaning they would have to a POSA at the time of the invention, in light of the intrinsic specification and file history.

29. I understand that many sources can be used to assist in understanding the meaning of a claim including the claims themselves, the specification, the prosecution history, and extrinsic evidence concerning scientific principles, the meaning of technical terms, and the state of the art. I also understand that intrinsic

evidence can carry more weight than extrinsic evidence particularly if claim terms are given an express definition or if the inventor(s) acted as their own lexicographer.

30. I have been asked to review the claims and ascertain the meaning of the claims from the perspective of one of ordinary skill in the art. My opinions on claim construction expressed in this declaration are from the perspective of a POSA as of October 9, 2018, the priority date of the 992 Patent, and are consistent with my understanding as stated above with regards to this *inter partes* review.

31. Opposing expert states that he has “interpreted the language of claims 1–12 of the ’992 patent to have its ordinary meaning as it would be understood by a POSA after reading the ’992 patent,” and “do[es] not believe that any language in the claims need to be further defined in order to conduct [his] analysis.” EX1002, ¶ 131. However, as I explain below, by failing to define certain claim terms, the opposing expert’s obviousness analysis overlooks certain claim limitations that are not met by the prior art.

V. LEVEL OF ORDINARY SKILL IN THE ART

32. I have been asked to analyze the 992 Patent and the references discussed herein from the perspective of a POSA at the time of invention. I understand that, for purposes of this *inter partes* review, the time of invention is assumed to be the 992 Patent’s priority date, which is October 9, 2018.

33. I understand that a POSA of the 992 Patent is a hypothetical person who is presumed to be aware of pertinent art including knowledge in the art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. I understand that this hypothetical POSA is considered to have the normal skills and knowledge of a person in the technical field.

34. I understand that factors that may be considered in determining the level of ordinary skill in the art include: (1) the education level of the inventor; (2) the types of problems encountered in the art; (3) the prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the education level of active workers in the field.

35. In my opinion, a POSA relating to the subject matter of the 992 Patent would be an individual having a bachelor's degree in mechanical engineering or equivalent technical degree with at least three years of experience in the field, such as experience with the design of bone implants, anchors, and/or screws. A person with a higher technical engineering degree and two years of experience, in a related field, would also qualify as a POSA. A person of skill in the art may consult with a dentist, oral surgeon, prosthodontist, or periodontist who has experience with dental implants and prosthetics on patients.

36. I believe that I am qualified to provide opinions about how one of ordinary skill in the art in October 2018 would have interpreted and understood the 992 Patent and the prior art relied upon by the Petitioner.

37. Dr. Brunski defines a POSA to “have at least a bachelor’s degree in mechanical engineering, biomedical engineering, materials science engineering, or an equivalent degree, plus at least five years of experience working with (i.e. researching, developing and/or designing) dental implants and prostheses.” Ex. 1002, ¶ 128.

38. Dr. Brunski also states that “[a] POSA would also have some familiarity and experience with fasteners (threaded and otherwise) used to connect prostheses, implants and related components.” Ex. 1002, ¶ 128.

39. Finally, Dr. Brunski says that “[a] POSA could also be a person with less formal education but commensurately more practical experience, or vice versa.” Ex. 1002, ¶ 129.

40. My opinions would not change under either definition.

VI. THE 992 PATENT

A. The 992 Patent (EX1001)

41. The 992 Patent describes a “temporary alignment system and method for holding a dental coping to an implant abutment using the same threads in the abutment that are used for definitive attachment.” EX1001, at 2. “The disclosed

temporary fasteners initially orient and hold a coping against an abutment,” and then “[t]he aligned coping can be picked-up in a closed-tray impression process without unscrewing the temporary fastener.” EX1001, at 2. “In this manner, the coping is held against the abutment for the pick-up process with a force oriented identically to that of the final screw mounting.” EX1001, at 32. The temporary fastener thus allows both axial and rotational attachment, which provides the same alignment force vector as the permanent screw.

42. “Embodiments” of these temporary fasteners “include threaded posts that release copings from the abutment through axial forces” as well as “a threaded post with separable cap that is picked-up with the coping.” EX1001, at 2.

B. Prosecution History Of The 992 Patent (EX1003)

43. The inventors filed several provisional applications (“Priority Applications”) in late 2018 and early 2019 regarding their inventions. *See* EX1009; EX1010; EX1011.

44. On October 8, 2019, the inventors filed U.S. Application No. 16/596,361. EX1012. As a result of this application, the Patent Office issued the Kofford patent on April 26, 2022. EX1013.

45. On June 3, 2023, the inventors filed U.S. Application No. 18/328,730, which claimed the priority dates of the nonprovisional Priority Applications.

EX1015. As a result of this application, the Patent Office issued the 992 Patent on March 26, 2024. EX1001.

46. The 992 Patent underwent a thorough review during prosecution. There were several office actions, both non-final and final, some resulting in amendments. EX1015, at 175, 200–231, 236, 283–302. In response to Examiner concerns, SDC explicitly addressed specification and disclosure issues related to those that the Petition raises. EX1015, at 295–299.

47. In two Information Disclosure Statements, SDC provided 105 prior-art references, all of which the Examiner considered. These included Bernhard (EX1003) and Poovey (EX1005), which are the basis for several Grounds in the Petition. EX1015, at 274–275, 762–774, 1068–1069, 1072–1083. It also included Sutter (1996) (EX2012), Sutter (2001) (EX2013), Johnson (EX2014), and Wade (EX2015).

48. The Examiner also independently conducted her own detailed prior-art searches, which led her to Berrevoets (EX2016). EX1015, at 1046–1066. The Examiner rejected multiple claims for obviousness in light of prior art, including Berrevoets. EX1015, at 224–236.

VII. PRIOR ART

A. Bernhard (EX1003)

49. Bernhard discloses various snap-fit designs for fasteners that temporarily connect a coping to an abutment during the dental conversion process. The “provisional connection features” disclosed “can comprise one or more fingers and/or can comprise a spring,” “can be configured to be coupled via a snap fit and/or via a friction fit,” “can include an elongate member,” “can include a plurality of protrusions and slots,” “can also include a flange,” or “can include a plurality of grooves.” EX1013, at 28. Various figures in Bernhard graphically depict some (but not all) of these embodiments. For example:

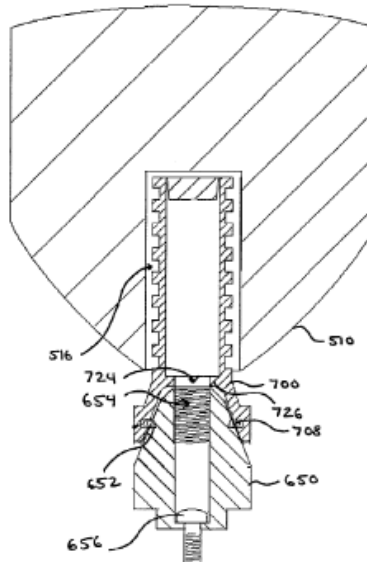


Figure 8

EX1002, at 43.

50. According to the Petition, “Bernhard also explains that a threaded screw can be used to connect the coping to the abutment in order ‘to reduce the likelihood of inadvertent detachment.’” Petition at 15. Petitioner omits, however, that this teaching refers to the permanent screw that will ultimately hold the prosthesis to the abutment, not a temporary fastener used in the pick-up process.

51. Bernhard is a reference cited during prosecution of the `992 patent and claims were likely granted over this reference because it does not describe or suggest a temporary alignment fastener with screw threading.

B. Poovey (EX1005)

52. Poovey was also a reference cited during prosecution of the `992 patent. This patent discloses an “impression coping security screw” that temporarily connects a coping to an implant during the impression phase of a conversion procedure. This “impression coping securing screw comprises threads made of metal or plastic and coated with a heat labile plastic or silicone.” EX1005, at 12. This screw would be “threaded into the internal threading in a dental implant” (not an abutment) “by exerting a rotational force on the impression coping securing screw.” EX1005, at 12.

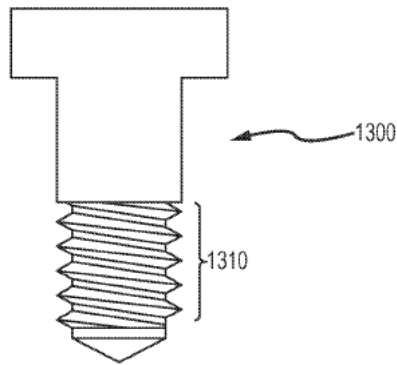


FIG.13

EX1005, at 9.

53. Then, “[a]t the time of removal, the heat labile plastic, or silicone threads (or heal labile plastic, or silicone-coated threads) are activated to allow the impression coping, secured by the impression coping securing screw, to be disengaged from the implant and removed with the impression of the patient’s dentitia.” EX1005, at 12. This action “may include” heating the heat labile plastic or silicone threads enough “to dissolve or soften sufficiently the plastic or silicone material” to allow removal. EX1005, at 12.

54. Poovey does not disclose any means of “activat[ing]” the “heat labile plastic” or “silicone threads” in the context of a dental implant procedure. In fact, using heat as a method of releasing the impression coping securing screw from the implant is impractical and likely uncomfortable for the patient. Heating the screw to “dissolve or soften the plastic or silicone sufficiently to allow removal ... without unscrewing the impression coping security screw” like Poovey describes, EX1005,

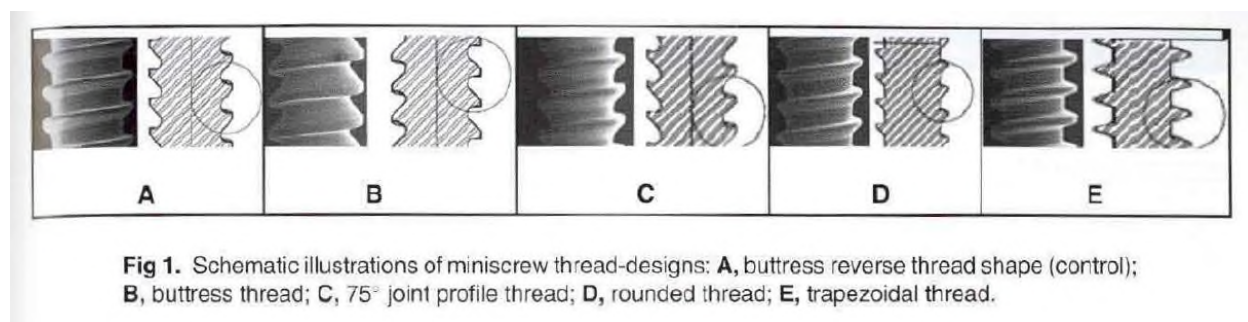
at 12, would be unworkable in a clinical setting. It would also be difficult (if not impractical) to simultaneously activate multiple such temporary screws to remove the arch. Finally, heating the temporary screws to such a temperature would likely be painful or at least uncomfortable for the patient.

55. Poovey's screws are also impractical. "[C]oat[ing]" metal or plastic threads "with a heat labile plastic or silicone" as Poovey describes, EX1005, at 12, is not practical and expensive for the extraordinary small screws used in dental implants. Poovey does not teach which type of medical grade plastic to use that could be softened at a low enough temperature to be comfortable for a patient and not degrade so much that plastic wouldn't shear off and remain in the valleys of the female thread. Poovey discusses an alternate choice of using silicone, but making threads out of silicone or coating threads with silicone would impede the initial screw insertion, or prevent it altogether. Silicone is designed as a sealant, but it is not a strong material for securing fasteners against vibration and movement. Silicone is known by a POSA to be very soft and flexible. It is also known to have very high heat resistance, which is why it is used in cookware. There is no teaching in Poovey on how these screws would be made or how they are made to be labile.

Silicone rubber, depending on precise variety, usually degrades around 250°C.¹ Boiling point of water is 100°C, so this is a high temperature for a patient to endure during a procedure.

C. Gracco (EX1006)

56. Gracco is an academic article describing an experiment to measure to force required to pull orthodontic mini-screws with different thread designs out of synthetic bone. EX1006, at 186–187. The different thread profiles tested are depicted:



EX1006, at 4.

57. Because the screws in the experiment were designed to cut into the bone itself, they were necessarily “self-drilling and self-tapping, with a cutting flute at their apex.” EX1006, at 187. Because they are self-cutting screws, by definition the

¹ https://wolife.international/blogs/news/melting-points-of-different-silicone-rubber-types?srsId=AfmBOooQbx6ydi8RDD1_PzE2FuI94fMdEO5t1pADg8jxIYmWw1MUjaxU.

screw threading matches the female threads that the screws themselves cut into the synthetic bone material.

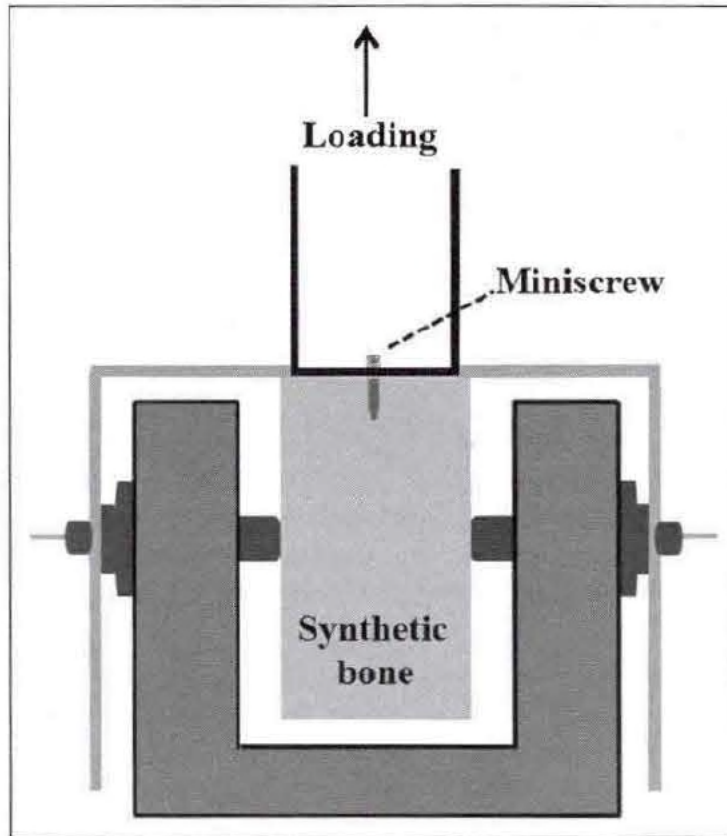


Fig 2. Configuration of testing setup.

EX1006, at 4.

58. Gracco does not teach any method for extracting a screw through axial force that would not degrade the female threading around the screw. This is a critical feature for a temporary fastener.

D. Derey (EX1008)

59. Derey teaches a plastic snap-in connector to temporarily hold elements to an implant or abutment during a denture conversion. EX1008, at 1. Derey's snap-in connector has two legs that separate to hold the connector in the female threading of the implant or abutment. EX1008, at 18–19.

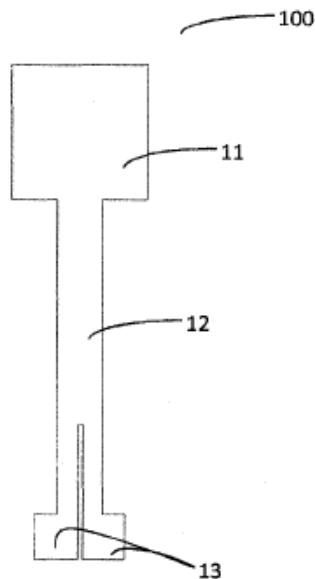


Fig. 5

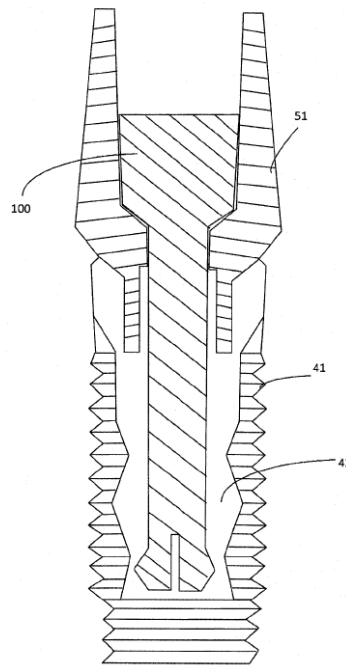


Fig. 6

EX1008, at 18, 19.

60. Derey's snap-in connector does not, however, have screw threads. Rather, the connector is pushed in and pulled out and so does not have the torquing or alignment benefits of a screw-threaded temporary fastener. Derey does not discuss rotation, a tool interface for rotation, or any threading on the fastener.

E. Nino (EX1020)

61. Nino is a 2011 patent that teaches a “torque-limiting driver that disengages at a predefined torque limit,” including in “the installation of dental ... implants.” EX1020, at 7, 9. Nino explained that “[t]orque-limiting drivers are widely used throughout the medical industry.” EX1020, at 7. These drivers are either “[r]eusable” or “disposable.” EX1020, at 7. “Reusable drivers require constant recalibration,” “a cumbersome task” that “must be done routinely.” EX1020, at 7. “Disposable drivers,” on the other hand, “are easy to use and reliable” but “have been used for low torque applications” only. EX1020, at 7. Nino therefore described a disposable driver capable of high-torque applications. EX1020, at 9.

62. Nino does not describe temporary screws that allow for stable axial positioning with ability to withstand the necessary torque, which facilitates alignment and creation of the prosthesis.

F. Ruetschi (EX1022)

63. Ruetschi is a patent application published October 27, 1988, which teaches the use of a torque-limiting driver in surgical procedures generally. EX1022, at 1–3. Previous iterations of screwing tools, Ruetschi explained, were “difficult” to handle “due to the small dimensions of the handle,” particularly when loosening screws. EX1022, at 2. Ruetschi’s driver therefore was “easy to handle” and

“ensure[d] by simple means that, on the one hand, a maximum tightening torque can be exerted for release.” EX1022, at 2.

64. Ruetschi does not describe temporary screws that allow for stable axial positioning with ability to withstand full torque, which facilitates alignment and creation of the prosthesis.

VIII. SUMMARY OF OPINIONS

65. The following is a summary of my opinions regarding the patentability of the 992 Patent’s claims.

66. Ground 1: Kofford is not prior art to the 992 Patent because the Priority Applications support and enable independent claims 1 and 9. A POSA would understand the Priority Applications to support the full scope of the thread pattern/profile limitations in those independent claims. A POSA would also understand the Priority Applications to support the full scope of the release limitations. Therefore, Kofford does not anticipate claims 1–6, 8–9, or 11–12.

67. Grounds 2–3: Kofford is not prior art to the 992 Patent for the same reasons I explain in my response to the Petition’s Ground 1. A POSA would interpret the Priority Applications to disclose numerous embodiments of the claimed invention and therefore adequately enable the full scope of the 992 Patent’s claims. For the same reasons, they adequately enable dependent claims 2–8 and 10–12 as well. Furthermore, the additional arguments that Grounds 2 and 3 include for

specific dependent claims are not persuasive. As to dependent claim 10, a POSA would understand the Priority Applications to support the full scope of the thread diameter/pitch limitations. As to dependent claim 7, a POSA would understand the Priority Applications to support the full scope of the thread-deformation limitation. Therefore, claims 4, 7, and 12 would not have been obvious based on Kofford in view of Poovey, nor does Kofford anticipate claims 7 and 10.

68. Ground 4: A POSA would not have combined Bernhard, Poovey, and Gracco to arrive at the claimed invention. Such a combination would not have had a reasonable expectation of success because coating metal or plastic threads on the temporary fastener “with a heat labile plastic or silicone” or making the threads from those materials, as Poovey teaches, is not practical for the extraordinarily small screws used in dental implants. Nor does the Petition identify any problem to be solved with any of the asserted prior art that would have motivated a POSA to look to other prior art. Therefore, claims 1, 3, 5–7, and 9–12 would not have been obvious based on Bernhard in view of Poovey and Gracco.

69. Ground 5: A POSA would not have combined Bernhard, Gracco, and Derey to arrive at the claimed invention. For the same reasons I explain in my response to the Petition’s Ground 4, such a combination would not have had a reasonable expectation of success. Furthermore, the claim 4 would not have been obvious in view of Derey because Derey discloses a snap-in system, not a screw-in

system, which does not have the key advantages that the claimed invention's screw-in system provides. Therefore, claims 4 and 8 would not have been obvious based on Bernhard in view of Poovey, Gracco, and Derey.

70. Ground 6: This relies on obviousness arguments that are similar to those in Grounds 4 and 5. For the same reasons that I set out in my responses to Grounds 4 and 5, combining Bernhard, Poovey, Gracco, and Ruetschi would not have been obvious because a POSA would not have been motivated to do so—nor would the combination have had a reasonable expectation of success. Therefore, claim 2 would not have been obvious based on Bernhard in view of Poovey, Gracco, and Ruetschi.

IX. GRACCO, DEREY, NINO, AND RUETSCHI ARE CUMULATIVE OF PRIOR ART THAT WAS BEFORE THE PATENT EXAMINER.

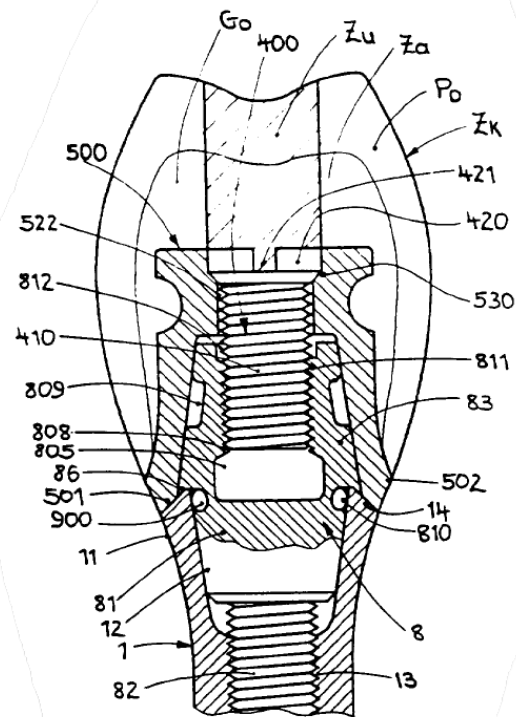
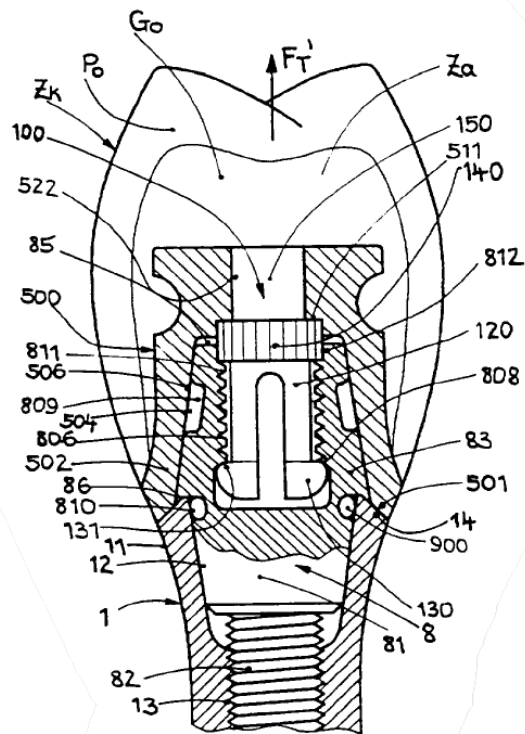
71. It is my understanding that the 992 Patent's owner is asserting that the Board should decline to institute an inter partes review in this matter because (a) the Examiner considered Bernhard and Poovey, and (b) Gracco, Derey, Nino, and Ruetschi are cumulative to the other prior art the Examiner considered. For the reasons explained below, I conclude that Gracco, Derey, Nino, and Ruetschi are cumulative to the other references the Examiner considered during the 992 Patent's prosecution.

A. Derey

72. Derey describes a snap-fit temporary fastener for the dental conversion process. EX1008, at 1. Specifically, Derey discloses a push-in fastener that uses a split-post structure to “hold[] the internal thread” of the dental implant “from the inside.” EX1008, at 1.

73. Based on the prosecution history, the examiner did not consider Derey. She did, however, consider several prior art references that are cumulative to Derey because they disclose fasteners that similarly use a split-post structure to grip the female threading of an implant abutment.

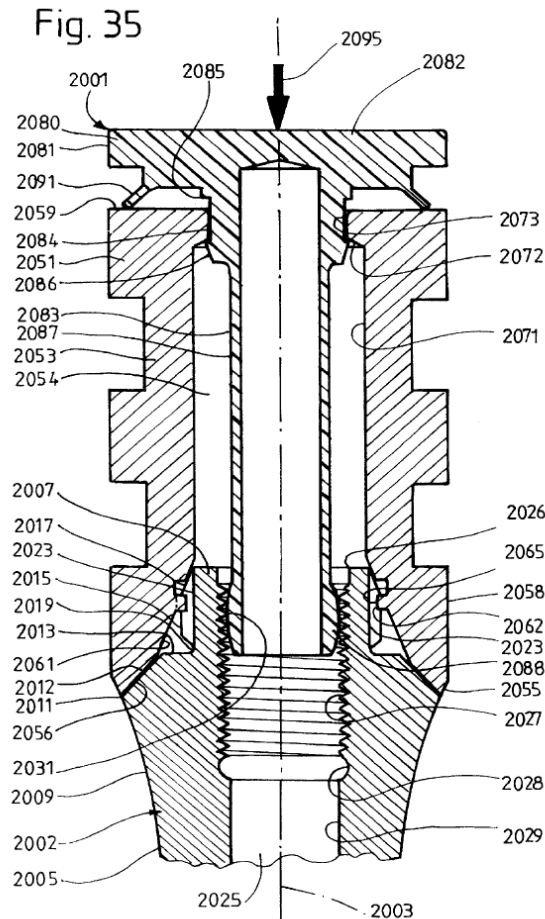
74. Sutter (1996) discloses such a fastener:



EX2012, at 76. In Figure 19, the temporary fastener has a deflecting split post which grips a circular recess below the threading of an implant abutment. This fastener does not have the same rigidity, securement, alignment, and torquing benefits as a temporary screw as taught by the '992 patent. With the temporary fastener (not a screw) removed, in Figure 20 the definitive screw with threads matching the implant abutment permanently attaches the coping and prosthesis. The fastener is much different than the definitive screw, so the fastener lacks the ability to fully mimic the definitive screw to reduce follow-up steps to prep and align the prosthetic for the

definitive screw. Sutter (1996) was provided to the examiner in an IDS; she marked it “examined” on January 2, 2024. EX1015, at 1081, 1083.

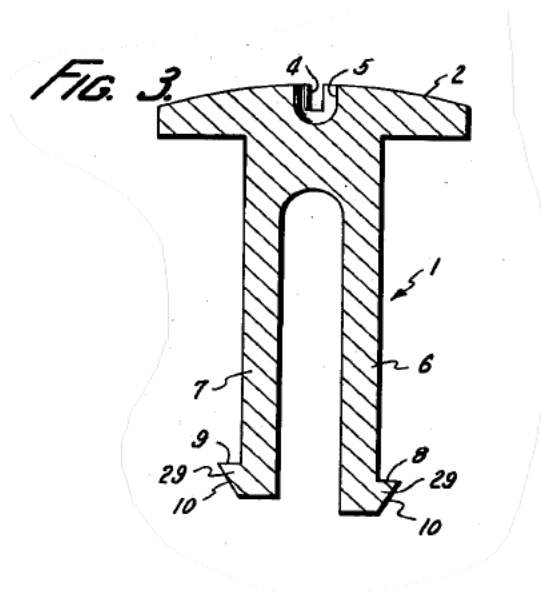
75. Sutter (2001)’s Figure 35 discloses a similar embodiment.



EX2013, at 13. In Figure 35, “[t]he anchoring part 2005 has a generally cylindrical section below, not visible, with an outer threading and a trumpet-shaped section 2009 which spreads out upwards from the generally cylindrical section.” EX2013, at 26. The hollow fastener post attaches to the implant abutment by friction fit; “[t]he interior threading 2027 of the support thus forms a fixing section and/or attachment

section 2031 on which, or in which, the fixing section 2088 of the connection element is detachably jammed fast.” EX2013, at 27. Sutter (2001) was provided to the Examiner in an IDS; she marked it “examined” on January 2, 2024. EX1015, at 1073, 1083.

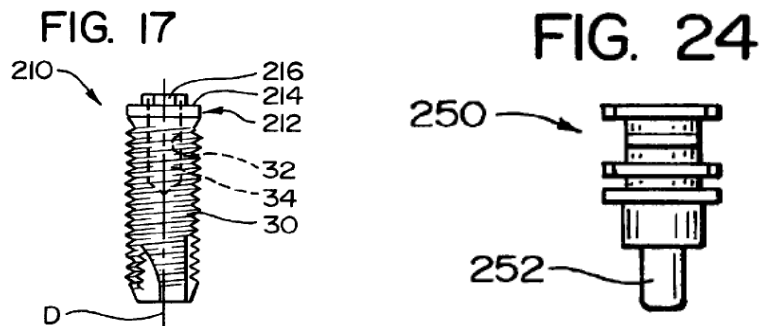
76. Johnson similarly discloses a push-in fastener with “two flexible legs or prongs” that “terminate in lips 29” that match the female threading of the base element. EX2014, at 2.



EX2014, at 1. Because the lips engage the base element’s female threading, the fastener can be torqued with screwing motion; because of the “flexible legs or prongs,” the fastener can be pushed in with an axial force. EX2014, at 2. Johnson was provided to the examiner in an IDS; she marked it “examined” on January 2, 2024. EX1015, at 1072, 1083.

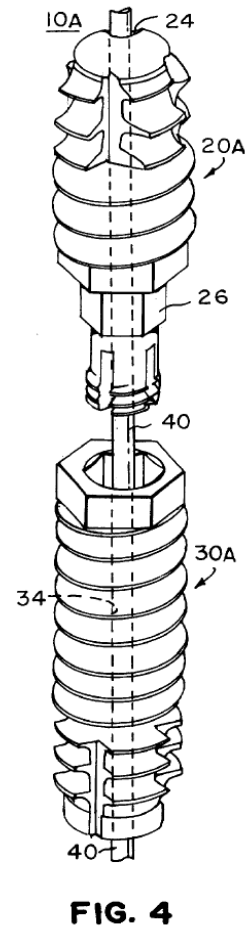
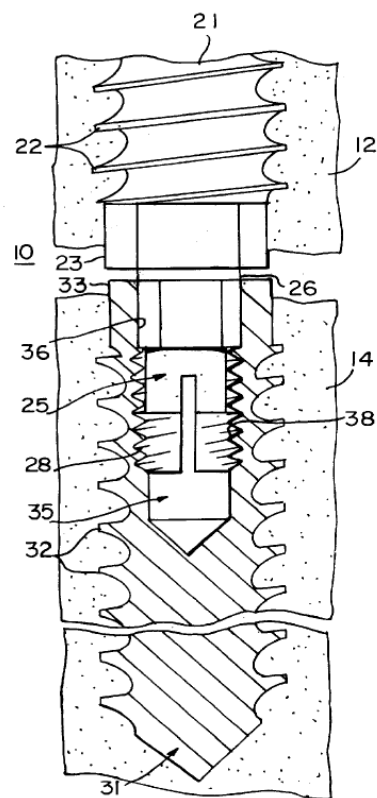
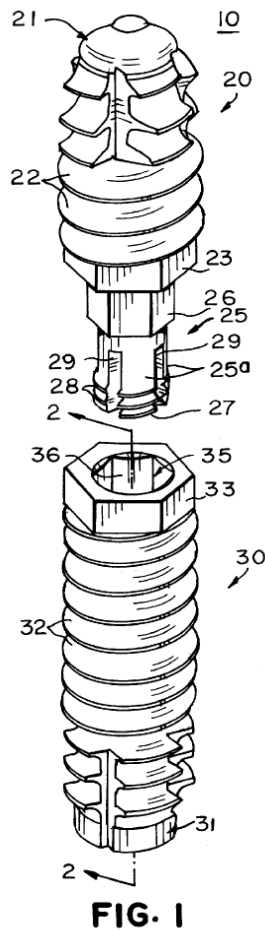
77. These push-in style fasteners may be quicker to use, but they generally lack the controlled axial alignment positioning capability and contact force of torqued fasteners because they only contact the threads at the very end of the prongs. Flexible prongs themselves also allow for this fastener to wobble or be loose in the female threads.

78. Prior art considered by the examiner also discloses temporary fasteners without a split-post structure that temporarily hold to the inside threading of a base element by friction fit. Wade’s Figure 24 discloses a “surgical impression feather” with “a lower post 252” that “enters the screw chamber 34 defined by the implant to form a friction fit that holds the feather 250 in place while the impression is being taken.”



EX2015, at 5, 7. Because “the post 252 is not threaded, however,” it “may be withdrawn when the impression is removed.” EX2015, at 16–17. Wade was provided to the examiner in an IDS; she marked it “examined” on January 2, 2024. EX1015, at 1077, 1083.

79. Finally, prior art that the examiner herself identified (Berrevoets) discloses a push-in split-bottom fastener with screw threading that matably threaded into a bone implant, rather than using a friction fit.



EX2016, at 2–3. The examiner identified Berrevoets in her own independent prior-art searches; she even rejected multiple claims for obviousness based on combinations of prior art that included Berrevoets. EX1015, at 231–236, 238.

80. Finally, the 992 Patent itself discusses the tradeoffs and disadvantages of existing snap-on options at length: “For snap-on systems, a closed impression tray

pick-up technique may be done. ... However, it is desirable to ensure that the assembly of snap-on copings can be removed without patient discomfort. ... Some snap-on systems provide features to provide different retention levels, but this complicates the installation process. Special tools have been introduced to help separate impression trays or prostheses with snap-on systems but may still result in patient discomfort. Since snap-on systems are generally physically larger than dental screws, converting an existing denture may require large clearance cavities to be bored into the existing denture before it can be used as an impression tray in a pick-up coping process. These large holes may significantly reduce the mechanical stability of the existing denture. The mechanical precision required of snap-on system elements generally makes them more expensive than screw-attached systems.” EX1001, at 3.

81. Furthermore, “[o]ther hybrid systems that use a snap-on engagement for the pick-up coping during transfer and subsequent screw-attachment have also been proposed, but detailed information on the tradeoffs in precision and associated complexity or size required for equivalent performance to open-tray impression screw techniques have not been disclosed.” EX1001, at 32. “The simplicity of screw-attached systems provides some benefits over snap-on systems beyond fabrication cost,” including “axial tension control,” “self-aligning characteristics,” and

“independence for removal since each coping can be loosened individually.”
EX1001, at 3.

82. Based on the above, Derey is cumulative because it does not teach anything more than the prior art before the Examiner. It is therefore not invalidating prior art.

B. Gracco

83. Gracco is a 2002 research study that discusses “the effects of variations in thread shape on the axial pullout strength of orthodontic miniscrews.” Pet. Ex. 1006, at 3. Specifically, the Petition points to Gracco’s “asymmetric buttress thread with a smaller proximal angle,” which “could be pulled out with less force than a reverse buttress thread.” Petition at 59. As a POSA, I can first state that the principle that different thread profiles affect the pullout force required to disengage a screw is well-known and the natural result of inherent geometry. Second, Gracco does not disclose the threads that don’t damage the female threads as discussed in the 992 Patent. The 992 Patent discusses a temporary screw that does not damage the female threads such that a permanent screw may be used later in the same female threads.

84. Regardless, Gracco does not teach anything more than the other prior art and inherent geometry disclosed to the Examiner. For example, the implant to which Berrevoets’ fastener is attached, which implant is screwed directly into bone,

appears to show asymmetric threads 32 that the Petition and Gracco would (incorrectly) call ‘reverse buttress threads.’

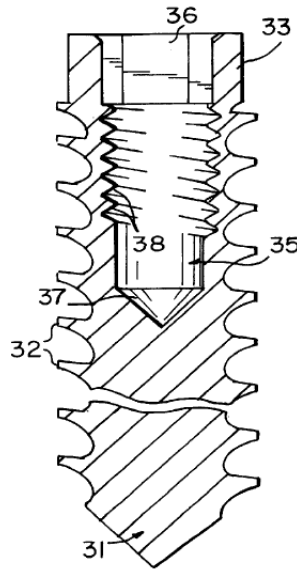


FIG. 2

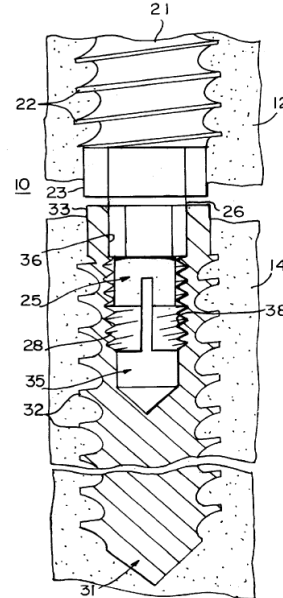


FIG. 3

EX2016, at 2–3. In common usage, these would be called buttress threads.² Berrevoets also discloses two embodiments of its push-in fastener, one (in Figure 3) with symmetric threads 28 and one (in Figure 5) with asymmetric buttress threads 67.

² Gracco identifies the control screws as “commercially available” screws from Ormco, called VectorTAS. EX1006, at 4. Ormco’s website (<https://ormco.com/en-us/vectortas-system>) describes the VectorTAS screws as having an “asymmetric buttress thread,” not a reverse buttress thread.

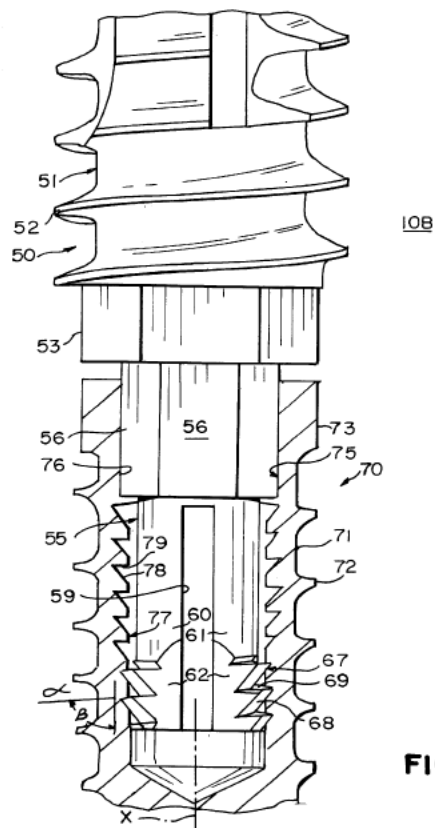
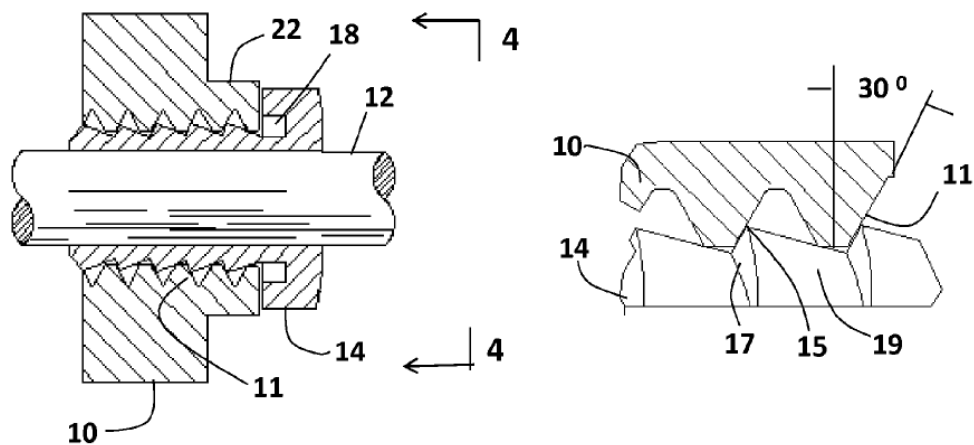


FIG. 5

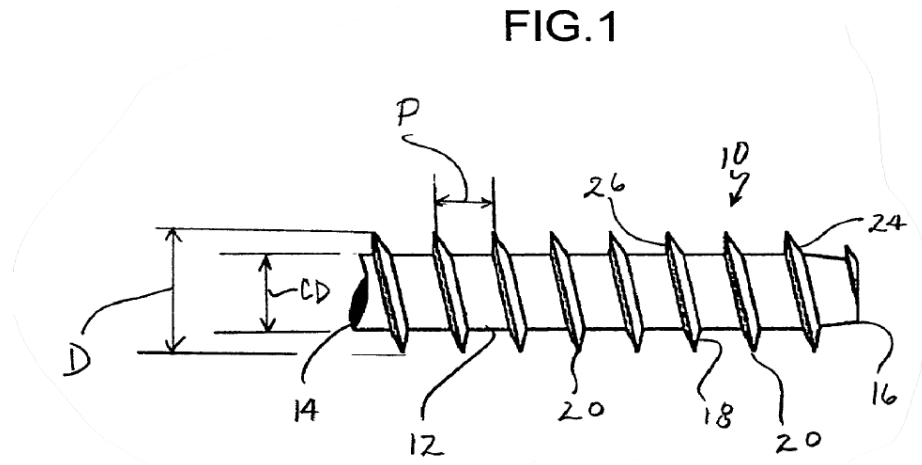
EX2016, at 4.

85. Staniszewski's threaded shaft also has an asymmetric thread profile, notably with the shallower flank towards the pulling direction.



EX2017, at 1. Staniszewski was submitted to the examiner in an IDS; the examiner marked it “considered” on January 2, 2024. EX1015, at 1068–1069.

86. Neuhengen, which the Examiner identified and considered, likewise shows a screw with an asymmetric thread profile.



EX2018, at 2. Neuhengen explains that in “self-tapping or thread forming screws,” to “increase the amount of loosening torque required to remove the screw”—i.e., “to prevent unwanted unthreading”—the engineer can “make the thread of the screw asymmetrical.” EX2018, at 3. Neuhengen explains that one “object of the present invention is to provide an improved thread forming screw which is designed to have increased resistance to pullout.” EX2018, at 3; *see also id.* at 4 (“It has been found that by providing the relatively smaller trailing angle β , that resistance to pullout is increased over prior configurations.”). The Examiner identified Neuhengen on September 7, 2023. EX1015, at 199, 238. She also rejected certain claims based on prior-art combinations that included Neuhengen. EX1015, at 229.

87. Comments that the patent owner submitted with proposed amendments during prosecution explain that “the standard definitive screw has a continuous symmetrical helical form as is well known to those of skill in the art.” EX1015, at 296. “In contrast, the thread profile 40 of the temporary screw of FIG. 75 is not the same as the illustrated profile ... of the definitive screw threading.” EX1015, at 297. “As a result of the open space from the different thread profile of the temporary screw compared to the definitive screw in FIG. 9, the temporary screw threading of FIG. 75 has less surface area contact with the female implant abutment threading.” EX1015, at 298. This smaller contact area means that less axial pull-out force is required to remove the screw from female threading.

88. Gracco itself confirms that the inherent geometric characteristics of different screw profiles are well known and Gracco’s experiment was not novel. “Measuring performance in pullout tests with axial forces is a well-established method to compare different screw designs, and the resulting pullout strength has been described in the orthopedic, maxillofacial surgery, and orthodontic fields as a fundamental biomechanical parameter contributing to the primary stability of screws.” EX1006, at 3. The “buttress reverse” threaded screw was the “commercially available control design” against which Gracco’s other configurations were measured. EX1006, at 4. Gracco attributes the “significant reduction in pullout force found between the buttress reverse and the buttress thread

miniscrews” to “the geometry of the thread that was inclined toward the tip, thus reducing the resistance to removal in an axial direction.” EX1006, at 6. “This finding was consistent with previous reports” as well. EX1006, at 6 nn. 38–40 (citing three other previous studies on mechanical properties of bone screws).

89. Gracco is therefore cumulative because it teaches nothing more than the prior art and inherent principles already before the Examiner.

C. Nino & Ruetschi

90. Nino and Ruetschi both teach using torque-limiting drivers in the medical industry generally. EX1020, at 7 (“This disclosure relates to a medical use driver tool and, in particular, to a torque-limiting driver that disengages at a predefined torque limit.”); *id.* at 9 (“Torques of this magnitude can be utilized in precision high torque environments such as the installation of dental, joint, vertebral implants and the like.”); EX1022, at 1 (“A screw-in tool 1 for surgical applications”).

91. None of the claims assert that the use of a torque-limiting driver by itself is part of the claimed invention nor do they disclose or teach the methods described by the `992 patent. As a POSA, I unequivocally confirm that the importance of torquing fasteners in surgical and dental applications, including use of torque-limiting drivers, is well-known. *See, e.g.*, Pet. Ex. 1015, at 455 (“In addition, special purpose torque drivers are required to install the screws.”), but again their use does not in any way invalidate or disclose the claims of `992 patent.

X. GROUND 1: THE PRIORITY APPLICATIONS SUPPORT AND ENABLE INDEPENDENT CLAIMS 1 AND 9.

92. I understand that, for the Board to find any claims invalid based on the Petition's Grounds 1–3, the Board must first find that Kofford is prior art to the 992 continuation patent. That is so, according to Petitioner, because “[n]one of the Priority Applications contain an adequate written description of or enable independent claims 1 and 9.” Petition at 32.

93. A POSA would understand the Priority Applications, however, to support the full scope of the thread pattern/profile limitations in independent claims 1 and 9. Furthermore, a POSA would understand the Priority Applications to support the full scope of the release limitations in those same claims.

A. A POSA Would Understand The Priority Applications To Support The Full Scope Of The Thread Pattern / Profile Limitations In Independent Claims 1 And 9.

94. Claim 1 describes “a temporary screw” that has “a distal shaft portion with threads in a pattern that is shaped differently from a pattern of the threads of the definitive screw.” EX1001, at 25:48, 53–54. Claim 9 similarly describes “a temporary screw” that has “a male threading profile that is different from the male threading profile of the shaft of the definitive screw.” EX1001, at 26:49, 52–54.

95. The Petition argues that “[t]he Priority Applications do not support this claim scope because they describe only one temporary screw embodiment with a different thread or profile: the temporary screw of Figure 75 with an ‘asymmetric’

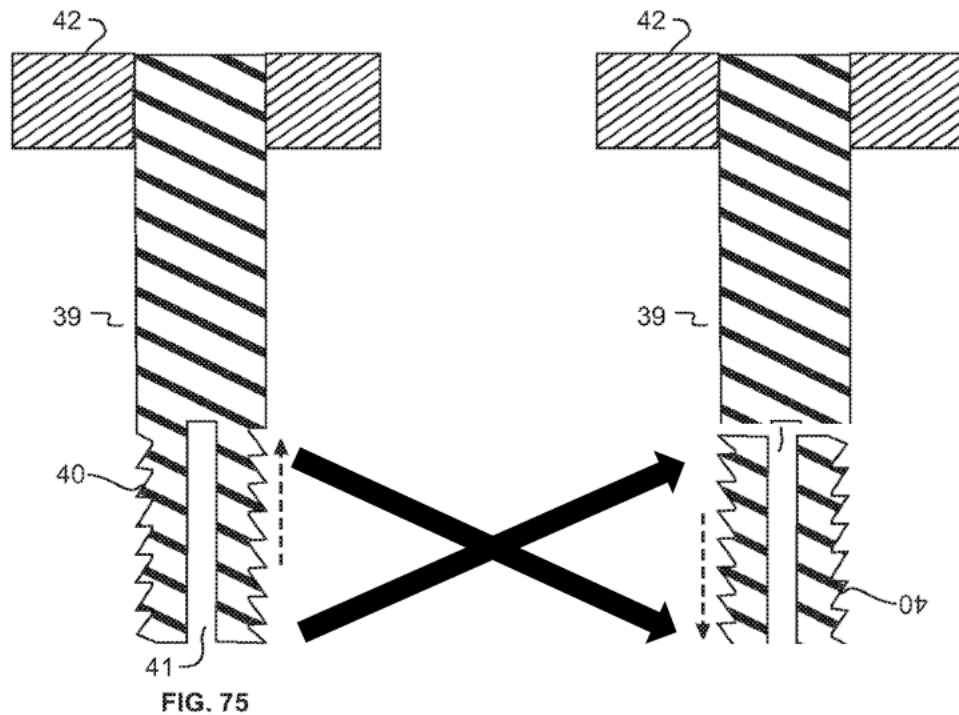
buttress thread that is different than the symmetric thread of the definitive screw of Figure 9.” Petition at 32–33.

96. I disagree. The Petition essentially ignores the written portions of the Priority Applications’ descriptions and focuses exclusively on Figure 75. A POSA would not do so because the descriptions themselves state that the descriptions should not be read that way: “[T]he drawings featured in the figures,” including Figure 75, “are for the purpose of illustrating certain convenient embodiments of the present invention and are not to be considered as limitation thereto.” EX1012, at 72. Rather, a POSA would understand the Priority Applications to disclose multiple embodiments of a one-piece temporary screw with a thread pattern or profile that is different from that of the permanent screw.

97. The 361 Priority Application, for example, says that “[t]he inventive concepts disclosed are not meant to be restricted to a temporary attachment post with standard screws that both engage and disengage the threads in the implant abutment through rotations.” EX1012, at 97. “For example, alternate separable temporary attachment posts embodiments are possible providing features that allow the post to removably hold the coping to the abutment by other means than a separable cap.” EX1012, at 97–98. “For example, as shown in FIG. 75 an alignment fastener may contain a separable threaded or serrated portion 40 that engages the screw threads in the abutment for pick-up, but that will release with axial force after.” EX1012, at

97–98. A POSA would understand this to disclose any embodiment with a threaded or serrated portion that engages the threads in the implant abutment through rotations for insertion “but that will release” the threading “with axial after.” EX1012, at 97–98. A POSA would understand the disclosure this way because the 361 Priority Application specifically instructs the reader that “the drawings featured in the figures are for the purpose of illustrating certain convenient embodiments of the present invention and are not to be considered as limitation thereto.” EX1012, at 72. A POSA would therefore understand the phrase “as shown in FIG. 75” to be illustrative, not limiting of the written description that follows.

98. As another embodiment of such a fastener, the 361 Priority Application says “the threads could be designed to provide engagement with the implant abutments threads through axial motion in the *opposite direction* to the arrow shown in FIG. 75.” EX1012, at 97 (emphasis added).



99. The illustration above left is the 361 Priority Application's Figure 75. EX1012, at 38. The illustration above right rearranges Figure 75 to show a thread pattern "designed to provide engagement with the implant abutments threads through axial motion in the *opposite direction* to the arrow shown in FIG. 75," as the 361 Priority Application describes. The Petition would call such a thread pattern a reverse buttress thread instead of the buttress thread pattern shown in Figure 75. Such an embodiment would be pushed into the abutment through axial motion in the opposite direction of the arrow in Figure 75, and its reverse buttress threads (with steep edge facing the screw head instead of the distal portion) would engage with the abutment's female threads to secure the temporary fastener.

100. Although the distal steep thread profile is preferred over the proximal steep thread profile, the 361 Priority Application implicitly teaches that both are suitable for practicing the claimed invention. A POSA would understand this language to disclose such an embodiment.

101. Because of the differences in these thread profiles, these two embodiments would likely require different levels of force for axial movement in the two directions. Tailoring these forces by adjusting the thread profile would not take undue experimentation. Such a thread profile could even be combined with the “split post bottom structure shown in FIG. 75,” which can be used both for “axial extraction” and “axial insertion.” EX1012, at 100. A POSA would understand that additional thread profiles between these two ‘extremes’ (buttress thread and reverse buttress thread) are also included within this disclosure. Furthermore, the thread profile could also be modified by serrating the thread without using a split-post structure. Removing half of the thread cresting through serration would be expected to roughly half the pullout force required.

102. This is not the only additional embodiment the Priority Applications disclose. For example, the 361 Priority Application says that “[a]lternative approaches for engaging a temporary attachment post with abutment threads through axial insertion without rotation are considered to be part of this disclosure,”

including “an interference fit between the bottom of the post with the threads.” EX1012, at 100.³

103. A POSA understands that an interference fit (sometimes called a press fit or friction fit) is a mechanical friction fit that results from inserting a large first part into a smaller hole of a second part.⁴ In the case of a first part in the form of a

³ Interference fits are introduced earlier in the 361 Priority Application as one of the possible mechanical attachment techniques for attaching a temporary fastener’s post to the separable cap: “The cap can be attached to the post through a combination of known mechanical attachment means including but not limited to interference fits, adhesives, snap fits or other elastic and inelastically deforming retention elements.” EX1012, at 66.

⁴ See, e.g., Volkan Kovan, *Separation frequency analysis of interference fitted hollow shaft-hub connections by finite element method*, 42 *Advances in Engineering Software* 644, 644 (2011) (“An interference fit is a fastening between especially cylindrical two parts which is achieved by friction.”); Seung Woo Lee, Dai Gil Lee, *Torque transmission capability of composite-metal interference fit joints*, 78 *Composite Structures* 584, 584 (2007) (“An interference fit is a mechanical retention mechanism which operates by interference of materials.”); James M. Leake et al., *Engineering Design Graphics: Sketching, Modeling, and Visualization* 258 (Wiley

cylinder making an interference fit with a circular hole in the second part, the outer diameter of the cylinder is larger than the inner diameter of the hole. The resulting compressive loading in the radial direction depends upon the magnitude of the physical size mismatch and the mechanical properties of the two parts. In some cases, for example attaching a wheel to a shaft with an interference fit, the wheel with the opening may be heated to temporarily enlarge the opening for assembling onto the shaft. Then, as the temperature returns to equilibrium, the compressive forces on the interface between the two parts increases. In less demanding cases, two parts at the same temperature are simply pressed together with elastic deformation of one or both parts at the interface providing the tensile and compressive forces and therefore increasing frictional holding for the interference fit. Because of the threading on the implant abutment, a POSA would understand that inserting a temporary fastener post with a diameter slightly larger than the abutment threads' diameter would result in an interference fit.

104. A POSA also understands that interference fits can be produced in parts without axial symmetry. The amount of elastic deformation necessary from the sizing mismatch, total contact surface area, surface finish and material properties of

2022) (“In an interference fit, the internal member is always larger than the external member.”).

both interfering materials can be adjusted in a straightforward manner (without undue experimentation, in other words) to provide the desired mechanical retention force.

105. A POSA would understand that embodiments using an interference fit would need to be designed such that the temporary screw does not alter or degrade the female threading on the abutment, and by extension, the permanent connection of the definitive screw. That is necessary to preserve the geometric precision of the definitive screw's attachment, one of the principal advantages of the claimed invention.

106. A POSA understands that pressing a polymeric post large enough to produce an interference fit into the abutment's female threading will result in the polymeric post's deformation. Because of the helical nature of the thread, a screw thread does not have axial symmetry and so the interference pressure will be localized to the crests of the threads. If the amount of interference is not too high, the deformation will be essentially elastic; in other words, there will be essentially no permanent dimensional change to the polymeric post. It will be compressed as it passes the crest of each thread but will expand essentially back to its original diameter at a time or in the areas not in contact with the implant abutment thread. This means it will be squeezed at the crests of the threads and subsequently expand

radially outward to a least some extent into the open cavity of the implant abutment's threading, where the pressure is reduced, as shown below.



107. A POSA understands that this elastic relaxation away from the crests creates a shallow male thread in the post and is a fundamental characteristic of compressing a softer or more easily deformed material with a harder material, consistent with the interference fit described in the 361 Priority Application. Although the relaxation of the post between crests may be very small, it allows sufficient engagement of a polymeric cylindrical post to be rotated into a metal abutment with female threading. This is also possible regardless of whether the rotation begins at engagement or begins after partial axial insertion.

108. Thus, a POSA would know, an interference fit between a softer polymeric post and a harder metal female threading will inherently provide some level of thread formation on the post that minimally fills the open volume of the female threading. In this sense, the interference fit's polymeric post represents a

symmetric thread profile that does not match the female thread profile of the abutment that the post was inserted or screwed into.

109. It does not matter whether one considers the thread profile to be initially flat or formed by relaxation after press-fitting; the induced threads match the pitch of the implant abutment threading and can be advanced and ultimately torqued by rotation. A shallow thread (or even a flat thread) is a different threading profile than the asymmetric thread shown in Figure 75.

110. A POSA would understand that rotating the temporary screw into position to achieve the interference fit is preferred over axial insertion without rotation, to better approximate the alignment achieved when the definitive screw is used. Torquing the temporary screw in place will also provide more axial retention since there is less risk of shearing material off of the post or male or female threads.

111. By identifying additional embodiments of one-piece temporary fasteners a POSA would consider to be disclosed in the Priority Applications, I do not suggest that other or additional embodiments are not disclosed. I simply describe the additional embodiments above to show that the Petition is incorrect to say the Priority Applications “describe only one temporary screw embodiment with a different thread or profile.” Petition at 32–33. A POSA would not understand the Priority Applications to describe only one temporary screw embodiment.

B. A POSA Would Understand The Priority Applications To Support The Full Scope Of The Release Limitations In Independent Claims 1 And 9.

112. Claim 1 describes “a temporary screw” where “an axial force in a proximal direction from pick-up processing releases the coping and the temporary screw from the implant abutment.” EX1001, at 25:48, 62–64. Claim 9 similarly describes “a temporary screw” with threads that “release from threads of the female threading of the implant abutment with a predetermined axial pick-up force in a proximal direction in response to and/or during pick-up processing.” EX1001, at 26:49, 26:65–27:2.

113. The Petition argues that “[t]he Priority Applications do not support this claim scope because they describe only one temporary screw embodiment with a different thread or profile: the temporary screw of Figure 75 with an ‘asymmetric’ buttress thread that is different than the symmetric thread of the definitive screw of Figure 9.” Petition at 32–33.

114. I disagree. As with the Petition’s assertions about the thread pattern/profile limitations, these arguments essentially ignore the written portions of the Priority Applications’ descriptions and focus exclusively on Figure 75. A POSA would not do so because (as explained above) the descriptions themselves state that the descriptions should not be read that way: “[T]he drawings featured in the figures,” including Figure 75, “are for the purpose of illustrating certain convenient

embodiments of the present invention and are not to be considered as limitation thereto.” EX1012, at 72. Rather, a POSA would understand the Priority Applications to disclose multiple embodiments of a one-piece temporary screw with and without a split post or deflecting-leg design.

115. A POSA would understand the Priority Applications to disclose embodiments that do not have a “split post with deflecting legs,” as the Petition describes them. Petition 38. The disclosure also includes (among other embodiments) those with “an interference fit between the bottom of the [temporary fastener] post with the [abutment] threads.” EX1012, at 97.

116. The Priority Applications also do not describe a split-post structure as critical to the claimed invention’s release limitations. To the contrary, the 361 Priority Application says that “[i]n *some* embodiments, the threaded end of the post portion of the temporary fastener has a deflecting feature that allows the post to engage or disengage the abutment threads through axial motion instead of a rotary screw motion.” EX1012, at 78 (emphasis added). Such a “deflecting feature” would include, but certainly would not be limited to, a split-post design.

117. Furthermore, the 361 Priority Application discloses using such a structure for both “axial extraction” as well as “axial insertion.” EX1012, at 100. Immediately after, the 361 Priority Application discloses using “an interference fit between the bottom of the post threads that may also be designed to provide

sufficient engagement to provide adequate alignment and fixing of the coping for the pick-up bonding process described earlier.” EX1012, at 100. A polymeric post with an interference fit, explained in detail above, would not require a split-post or deflecting-legs structure to provide the attachment force necessary.

118. The 992 Patent describes an “attachment post portion 39” with “a slot 41 and asymmetric threads or serrations 40.” EX1001, at 42. Limiting the description only to an embodiment with both a slot and asymmetric threads, however, is inconsistent with the 992 Patent’s own internal instructions. “The term ‘or’ as used herein is to be interpreted as an inclusive or meaning any one or any combination. Therefore, ‘A, B or C’ means any of the following: ‘A; B; C; A and B; A and C; B and C; A, B, and C.’” EX1001, at 34. Therefore, “a slot 41 and asymmetric threads or serrations 40” must be read to illustrate an attachment post portion (a) with only a slot, (b) with only asymmetric threads, (c) with only serrations, (d) with a slot and asymmetric threads, (e) with a slot and serrations, (f) with asymmetric threads and serrations, as well as (f) with a slot, asymmetric threads, and serrations.

119. These three disclosed features that allow axial extraction can thus work alone or together through sufficient elastic or inelastic deformation to allow axial movement. The description of Figure 75 does not say all three are essential for axial movement.

120. For these reasons, a POSA would not understand the Priority Applications' disclosures to be limited to a temporary fastener with a split-post structure or deflecting legs. A POSA would also not interpret such a structure as being critical to the invention. Even features that are preferred or illustrated would not be understood by a POSA to be critical or essential. It is therefore incorrect to say that the Priority Applications fail to describe or enable the full scope of the release limitations in independent claims 1 and 9.

XI. GROUND 2-3: THE PRIORITY APPLICATIONS SUPPORT DEPENDENT CLAIMS 2-8 AND 10-12.

121. As I explained above, a POSA would interpret the Priority Applications to disclose numerous embodiments of the claimed invention and therefore adequately enable the full scope of the 992 Patent's claims. For the same reasons, they adequately enable dependent claims 2-8 and 10-12 as well.

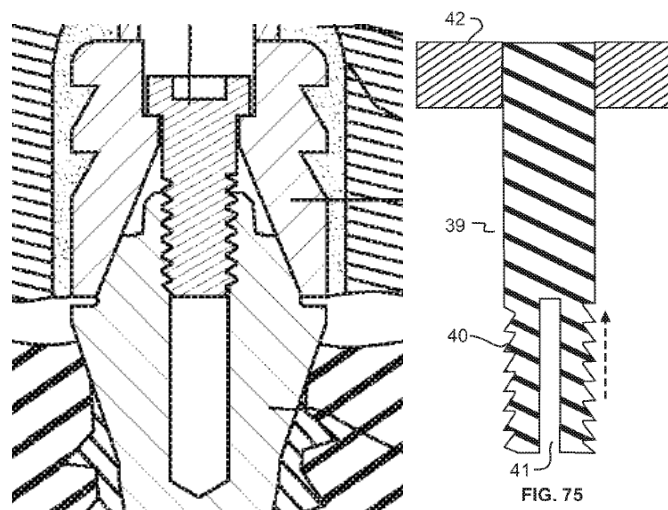
122. The Petition also presents a few additional arguments for why certain dependent claims should be found invalid. In my view and that of a POSA, these arguments are unpersuasive.

A. A POSA Would Understand The Priority Applications To Support The Full Scope Of The Thread Diameter / Thread Pitch Limitations In Dependent Claim 10.

123. The Petition argues that Claim 10 is not supported "because the threads of the temporary screw of Figure 75 have the same maximum thread diameter and

thread pitch, and therefore the same pitch angle, as the threads of the definitive screw and the abutment of Figure 9.” Petition at 42. A POSA would not understand the disclosures this way.

124. The close-up of Figure 9 (below left) depicts a permanent screw with threads that match the abutment’s female threads. The asymmetric threads in Figure 75 (below right) do not match.



EX1012, at 20, 38.

125. Nor is it accurate to say that the threads of the temporary and definitive screws in these figures “have ... the same pitch angle.” Petition at 42. The pitch-angle formula that Mr. Brunski uses shows this could not be true:

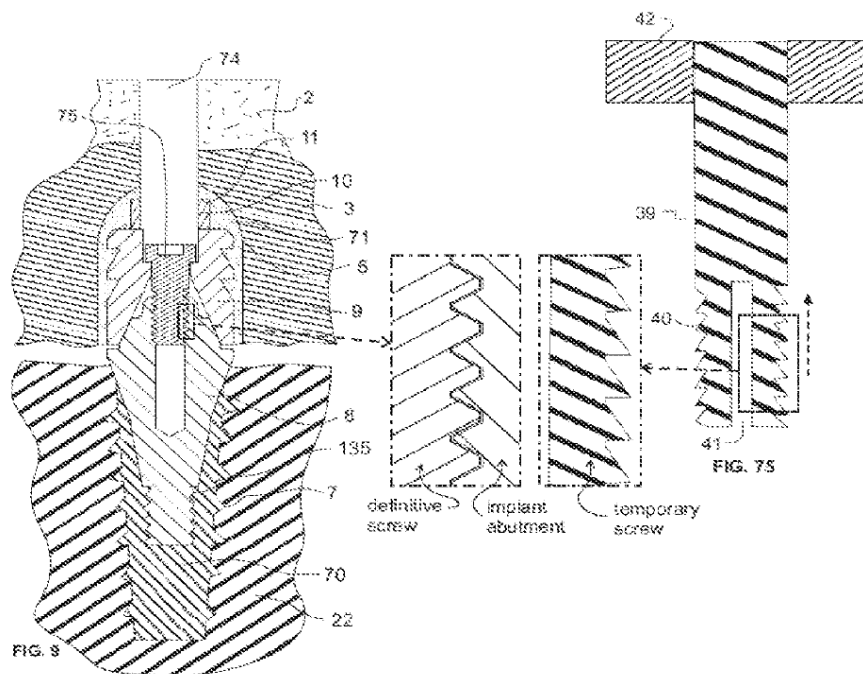
For a screw with a maximum thread diameter D and a thread pitch P , the pitch angle λ (λ) may be calculated by the following equation:

$$\tan (\text{pitch angle } \lambda) = P / \pi D$$

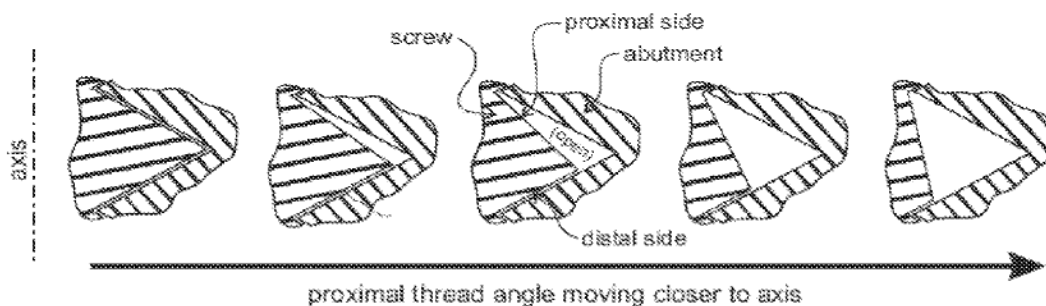
EX1002, ¶ 156.

126. A POSA would recognize that one of the two inputs (thread diameter) is different between the temporary and permanent screws depicted; therefore, the formula could not result in the same pitch angle.

127. A POSA would also understand that Figure 75's temporary screw could not possibly have the same thread diameter as the permanent screw. Based on inherent geometric principles, the temporary screw would not screw into the abutment if it had the same thread diameter. Materials that SDC submitted during prosecution illustrate this point:



EX1015, at 296.



EX1015, at 297.

128. A POSA would understand that in the case of a temporary screw with the proximal thread angle shown on the right in the top image above having the same diameter as a permanent screw with the proximal thread angle shown on the far left of the bottom image above, the temporary screw would not fit into the abutment's female threading.

B. A POSA Would Understand The Priority Applications To Support The Full Scope Of The Thread Deformation Limitation In Dependent Claim 7.

129. Finally, Petitioner argues that the Priority Applications do not support dependent claim 7's "threads deform" limitation "because they do not describe any differently-threaded temporary screw with threads that 'deform' during release." Petition at 43. This is incorrect. A POSA would understand the Priority Applications to disclose a temporary fastener that uses "an interference fit between the bottom of the post with the treads," which "[s]imilarly ... may also be designed to provide sufficient engagement to provide adequate alignment and fixing of the coping." EX1012, at 100.

130. A POSA would know that a temporary fastener with an interference fit described would need to be made of a polymeric material like PEEK or acetal so that the interference fit would not alter or degrade the female threading in the metal implant abutment. Using the threads of the implant abutment to attach the temporary fastener *without* degrading or altering those threads is one of the key advantages of all embodiments of the claimed invention because it allows the temporary fastener to be torqued down with attachment force like that of the permanent screw, for a more accurate impression. The post and thread diameter of the polymeric post would need to be large enough to provide the interference fit but shallow enough to deform (whether elastically or inelastically) and then release. Pressing a polymeric post into the abutment's female threading, inserting it by rotating it in, or pulling it out will all result in the polymeric post's deformation. Even without threading before insertion, a polymeric post within the range for an interference fit will inherently provide some level of thread deformation on the post (even if the deformation is small temporary and elastic).

131. A POSA would understand the 361 Priority Application to disclose such a fastener. For that reason, it is not correct to say that the Priority Applications do not enable dependent claim 7's thread-deformation limitation.

XII. GROUND 4: A POSA WOULD NOT HAVE COMBINED BERNHARD, POOVEY, AND GRACCO TO ARRIVE AT THE CLAIMED INVENTION.

132. The Petition argues that “it would have been obvious in view of Bernhard, Poovey[] and Gracco to modify the system of [Bernhard] Figure 8 to temporarily fasten coping 700 to abutment 650 with a temporary screw with flexible threads in a buttress thread pattern, which would be threaded into bore 654 but pulled out of abutment 650 without being unscrewed when the prosthesis is removed.” Petition at 55. According to Petitioner, a POSA would have been motivated to combine these teachings “to make the temporary connection ... more secure, reliable and stable than a snap-fit mechanism,” and that this solution “would be simpler.” Petition at 56.

133. As explained above, I understand that for an obviousness argument of this kind to succeed, Petitioner must show that a POSA at the time of the invention would have had a reasonable expectation that a modification or combination of one or more prior art references would have succeeded. Moreover, I understand that, to establish obviousness based on combining multiple embodiments from a single reference, there must be a motivation to make the combination and a reasonable expectation that such a combination would be successful.

134. Based on this understanding, I do not agree that a POSA would be motivated to successfully combine Bernhard, Poovey, and Gracco to arrive at the

claimed invention because such an invention would not have a reasonable expectation of success. There was also no mention of a problem to be solved with any of the asserted prior art to motivate a POSA to look to other prior art.

135. Specifically, “coat[ing]” metal or plastic threads on the temporary fastener “with a heat labile plastic or silicone” as Poovey teaches (EX1005, at 12) is not practical for the extraordinarily small screws used in dental implants. That is true for two reasons.

136. First, making the temporary fastener’s threads out of silicone or coating the threads from silicone would impede—or prevent altogether—the temporary fastener’s initial insertion, because of silicone’s inherent properties. It is not rigid enough to easily fit into the female threading, especially with the friction it would create. Attempting to do so would be like trying to push a gummy worm into a pencil sharpener.

137. Second, making the temporary fastener’s threads out of heat labile plastic or coating the threads with such plastic would not be successful either. For one thing, as the 992 Patent itself notes, Poovey does not teach a viable method for applying the heat necessary to sufficiently degrade the thread material or coating. *See* EX1001, at 4:17–23 (“the practicality of providing adequate alignment and seating forces with a screw diameter in the range of existing systems or overcoming the lack of disengagement independence required in melting all threads

simultaneously without patient discomfort has not been documented.”). Applying enough heat to sufficiently degrade or dissolve the thread material or coating *through the prosthesis, coping, and/or implant abutment* is likely to be inefficient and perhaps even painful for the patient. That is especially true because all temporary screws holding the prosthesis to the abutments would need to be heated simultaneously to successfully carry out pick-up processing. Finally, Poovey does not teach how one could degrade or melt the threading or thread coating and then “remov[e] any residual material in the abutment threads or in the prosthesis after the pick-up process.” EX1001, at 4:21–23. Straumann’s expert also doesn’t describe this as a problem that requires a solution provided by the other references.

138. For these reasons, a POSA would not be motivated to combine Bernhard, Poovey, and Gracco to reach the claimed invention. Nor would a POSA have a reasonable expectation of successfully doing so.

XIII. GROUND 5: A POSA WOULD NOT HAVE COMBINED BERNHARD, GRACCO, AND DEREY TO ARRIVE AT THE CLAIMED INVENTION.

139. The Petition next argues that “it would have been obvious to modify Bernhard’s system in view of Poovey and Gracco to use a temporary screw based on the design of threaded fastener 750 but with flexible buttress threads.” Petition at 78. For the same reasons explained above, however, that is not the case because a

POSA would not be motivated to combine these references nor would a POSA have a reasonable expectation of doing so.

140. Petitioner further argues that “Claims 4 and 8,” which require a portion of the distal shaft of the temporary screw to be hollow, would have been obvious in further view of Derey.” Petition at 78. But a POSA would not have been motivated to combine these because Derey discloses a snap-in system, not a screw-in system. The prior art that the Examiner reviewed demonstrated numerous versions of snap-in systems. Yet “snap-on systems are generally physically larger than dental screws,” so “converting an existing denture may require large clearance cavities to be bored into the existing denture before it can be used as an impression tray in a pick-up coping process.” EX1001, at 31. “These large holes may significantly reduce the mechanical stability of the existing denture,” and “[t]he mechanical precision required of snap-on system elements generally makes them more expensive than screw-attached systems.” EX1001, at 31. Lastly, the snap-in systems do not provide the axial alignment of a screw because the cylindrical portion of the snap post is much shorter than the cylindrical portion of the female thread.

141. Furthermore, as the 992 Patent notes, “hybrid systems that use a snap-on engagement for the pick-up coping during transfer and subsequent screw-attachment have also been proposed, but detailed information on the tradeoffs in precision and associated complexity or size required for equivalent performance to

open-tray impression screw techniques have not been disclosed.” EX1001, at 4:23–29.

142. This combination would also not result in the claimed invention; a snap-in system does not have the key advantages of a screw-based temporary fastener system. Specifically, it would not offer the ability to sufficiently torque the temporary fastener to achieve the same or similar fit as the definitive screw. Nor would it have the same stability, alignment, or resulting fit for the prosthesis.

XIV. GROUND 6: A POSA WOULD NOT HAVE COMBINED BERNHARD, POOVEY, GRACCO, AND RUETSCHI TO ARRIVE AT THE CLAIMED INVENTION.

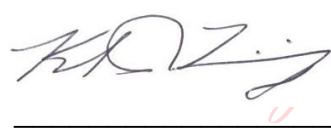
143. The Petition’s Ground 6 relies on obviousness arguments that are similar to Grounds 4 and 5. For the same reasons explained above, combining Bernhard, Poovey, Gracco, and Ruetschi would not be obvious because a POSA would not be motivated to do so, and because combining Bernhard’s system with Poovey’s silicone or heat labile plastic threads for a temporary screw would not have a reasonable expectation of success.

XV. CONCLUSION

144. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful

false statements are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: August 29, 2025

 Karl R. Leinsing
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Karl R. Leinsing, MSME, PE