

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

PGR2026-00022
Patent 12,274,481

DECLARATION OF DANIEL C. FARBER, MD
IN SUPPORT OF THE PATENT OWNER'S PRELIMINARY RESPONSE

I, Daniel C. Farber, do hereby declare:

1. I am making this declaration (the "Declaration") at the request of Treace Medical Concepts, Inc. ("Treace").

2. I am being compensated for my work in this matter, and I am being reimbursed at cost for any expenses. My compensation in no way depends upon the outcome of this proceeding.

3. In preparing this Declaration, I considered the following materials:

Exhibit No.	Description
1001	U.S. Patent No. 12,274,481 to Santrock, et al. ("the '481 patent")
1003	Declaration Of Steven K. Neufeld, M.D. In Support Of Petition For Post-Grant Review Of U.S. Patent No. 12,274,481
1004	McGlamry's Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4th Edition, 2013 ("McGlamry")
1005	U.S. Patent No. 8,882,816 to Kartalian et al. ("Kartalian")
2028	Curriculum Vitae of Daniel C. Farber, M.D.

I. BACKGROUND AND QUALIFICATIONS

4. I am an orthopaedic surgeon specializing in foot and ankle surgery. My current CV is being submitted as Exhibit 2028.

5. I received my Bachelor of Arts undergraduate degree in 1992 from Dartmouth College and my Doctor of Medicine degree in 1997 from the University of Maryland School of Medicine. In 2002, I completed my residency in Orthopaedic Surgery at Penn State Milton S. Hershey Medical Center. In 2003, I held a fellowship in Orthopaedic Surgery, Foot and Ankle Surgery, at the Mayo Clinic in Jacksonville, Florida. I am board certified in Orthopaedic Surgery by the American Board of Orthopaedic Surgery.

6. My primary practice is with the Lehigh Valley Health Network where I am the Vice Chair, Academic Affairs, for the Lehigh Valley Orthopedic Institute.

7. For over the past 22 years, I have performed between 250 and 350 surgeries per year, of which, roughly 50 to 80 per year involved bunion correction.

II. NATURE OF MY ASSIGNMENT

8. I have been asked to provide my opinion regarding certain arguments presented by Steven K. Neufeld, M.D., in his Declaration (Ex. 1003) that Paragon 28, Inc. ("Paragon") submitted in this matter.

9. The opinions I am expressing in this Declaration are based on the application of my training and technical knowledge and experience to the evaluation of certain prior art to the '481 patent and arguments presented by Dr. Neufeld.

III. OPINIONS REGARDING DR. NEUFELD'S DECLARATION

10. Dr. Neufeld's Declaration (Ex. 1003, ¶¶ 99-132) discusses the McGlamry (Ex. 1004) prior art reference and the Kartalian (Ex. 1005) prior art patent. With respect to Claims 1, 3-8, 10, 11, 13, 27, and 29 of the '481 patent (Ex. 1001), Dr. Neufeld opines that those claims "would have been obvious to a person of ordinary skill in the art as of August 14, 2015 in view of McGlamry and Kartalian." (Ex. 1003, ¶ 99). I disagree.

11. Like Dr. Neufeld, I am also not an expert in patent law. Attorneys from McCaulley Law Group provided me with guidance as to the applicable patent law in this matter.

12. It is my understanding that in determining whether a patent claim is obvious in view of the prior art, the Patent Office construes the claim by giving the claim language its ordinary and customary meaning ascribed to it by a person of ordinary skill in the art ("POSA") at the time of the invention, consistent with the descriptive language contained in the other parts of the patent. I also understand that in reading the claim, I must not add into the claim other language that appears in the description portion of the patent; in other words, I must not restrict the scope of the claim terms by adding to the claim other parts of the patent's descriptive language that are not expressed literally in the claim.

13. I understand that for purposes of the Patent Owner's Preliminary Response, Treace has agreed that “bone positioning” corresponds to “bone moving.” Accordingly, when addressing the plain and ordinary meaning of the claim language, a “bone positioning guide” is a device that regulates or directs progressive motion or action to move a bone. That is, the structure of the device (bone positioning guide) dictates the movement of the bone for correction of the bunion deformity.

14. The '481 Patent describes the bone positioning guide as a device that, when actuated by a mechanism (e.g., turning knob 120), corrects bone alignment. Ex. 1001, 9:26–34. The correction is dictated by the geometry of the device. *Id.* at 11:20–27. This is the defining characteristic of a “guide”: the device’s structure constrains and directs the path of motion. A clamp that merely applies compressive force at a location chosen by the surgeon, with no structural feature that regulates the direction or path of bone movement, is not a guide under the plain and ordinary meaning.

15. The specification of the '481 patent repeatedly attributes the correction to the guide’s actuation and geometry. Ex. 1001, 9:26–34, 11:20–27.

16. In analyzing the prior art references that Dr. Neufeld discusses in his Declaration (Ex. 1003), I have assumed that “bone positioning guide” is given its plain and ordinary meaning as a device that regulates or directs progressive motion

or action to move bones (i.e., the structure of the device (bone positioning guide) dictates the movement of the bones).

17. I understand that a claim is “obvious,” and therefore unpatentable, if the claimed subject matter as a whole would have been obvious to a POSA at the time of the invention. I also understand that an obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

18. In determining the scope and content of the relevant prior art, I understand that a reference is considered relevant prior art if it falls within the field of the inventor’s endeavor. The ’481 Patent describes a guide/actuator arrangement in which actuation of the knob/shaft relationship produces the claimed correction. That is, the bone positioning guide 10 guides the bone for the correction itself by turning the knob 120 (i.e., dialing the bunion away). To avoid confusion, it is worth noting that although Figures 9A and 9B show the bone positioning guide itself displaced from one figure to the next, this is the result of the controlled motion of that guide from turning the knob and the interactions of the guide geometry with the foot as explained above. See Ex. 1001, 9:25–29 (“As shown, as the bone positioning guide 10 is actuated it rotates with the first metatarsal 210 about an axis extending

through the frontal plane as it pushes the first metatarsal 210 laterally in the transverse plane and plantarly in the sagittal plane.”).

19. In addition, a reference is relevant prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor’s attention in considering their problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

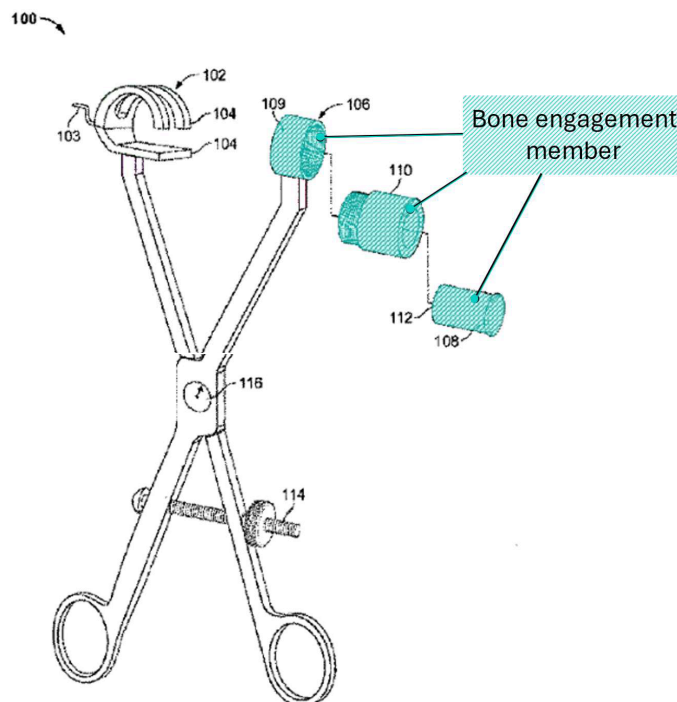
20. To assess the differences between prior art and the subject matter claimed in the patent, I understand that the law requires the claimed invention to be considered as a whole. Thus it must be shown that a POSA at the time of the invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have been motivated to select the elements from the prior art and combine them in the claimed manner, and had a reasonable expectation of success in doing so.

21. I further understand that the obviousness analysis must be performed from the perspective of a POSA at the time of the invention. This is to avoid using impermissible hindsight in the analysis. The claims of the patent must not be used to provide a road map for obviousness.

22. It is my opinion that a POSA would be an orthopedic surgeon or podiatrist with experience performing bunion correction surgery using the surgical procedures and mechanical tools corresponding to the standard of care in the August 2015 time period.

23. With respect to the Kartalian prior art patent (Ex. 1005), Dr. Neufeld states that:

108. Kartalian also discloses using a bone positioning guide with a bone engagement member to engage a first metatarsal. Kartalian discloses an “instrument 100” that “may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.” Ex.1005, 9:66-67. As shown below, Kartalian’s instrument is a tenaculum (forceps):



Ex.1005, Fig.1 (excerpt) (annotated).

109. Kartalian’s instrument 100 functions to position the bones by moving the first metatarsal in the transverse plane. Ex.1005, 9:66-

67. Accordingly, Kartalian's instrument is a bone positioning guide under the plain and ordinary meaning of that term discussed above. Further, it is identical or at least equivalent to the structures identified in the '481 patent for the claimed bone positioning guide because it is a tenaculum or structure that performs the same function (positioning metatarsals including through IMA reduction), in substantially the same way (e.g., opposed bone-engaging ends/arms of a tenaculum (forceps) or C-shaped frame) manipulated by the surgeon to apply controlled corrective forces and hold alignment), to achieve the same result (moving the bones to the desired alignment and stabilizing them while fixation is performed).

110. Kartalian's bone positioning guide includes an end 106 that is a bone engagement member. Kartalian discloses that end 106 "may be placed on the proximal first bone (first metatarsal)." Ex.1005, 10:49-51. Accordingly, Kartalian's end 106 is a bone engagement member under the plain and ordinary meaning of that term discussed above.

111. A POSA would have been motivated to use Kartalian's bone positioning guide in McGlamry's procedure.

112. Kartalian has features that are specifically designed for bunion correction procedures and would have been desirable for use in McGlamry's procedure. Ex.1005, 9:58-10:15. For example, Kartalian includes a feature for locking bones during movement of the first metatarsal. Id., 10:4-6 (describing structure to "hold the instrument 100 in position once the final alignment of the bones has been achieved"). This locking feature would prevent unwanted transverse plane movement after repositioning of the first metatarsal.

113. Kartalian's instrument 100 also includes "an automatic angle indicator 116 to provide the surgeon with an estimate of the angle of the bones requiring correction." Id., 10:8-16. Kartalian explains that "one skilled in the art appreciates that trigonometry may be used to estimate the angle between the two bones using known data regarding the length of the bones from x-rays or from anthropomorphic averages along with the final distance between

the instrument arm 118 and instrument arm 120 to estimate the [IM] angle. The instrument 100 then may be suitably calibrated to show the angle between the bones.” Id., 10:8-18. This feature would provide the surgeon with additional guidance on the final position of the bone, which could improve the success rate of a surgery that was known, in 2015, for having a relatively high failure rate. Ex.1005, 2:30-39.

114. Kartalian’s instrument also includes a sleeve that would have been useful for inserting the K-wires that McGlamry uses for temporary fixation. See *infra*, §VI.G. (Claim 10).

115. This would have been nothing more than the substitution of one known element (McGlamry’s Weber clamp) for another (Kartalian’s instrument), and the results would have been predictable. Both Kartalian’s instrument and McGlamry’s clamp are a form of a tenaculum/tongs. Kartalian’s instrument and McGlamry’s clamp are both disclosed as engaging the first and second metatarsals for the purpose of moving the first metatarsal during a bunion correction procedure. Ex.1005, 9:66-10:3, 10:43-51; Ex.1004, 325-326, Fig.31.5.

116. A POSA would have also reasonably expected to succeed in using Kartalian’s instrument in McGlamry’s procedure. Kartalian’s instrument was designed for a bunion correction procedure that is, in many respects, similar to McGlamry’s procedure. Ex.1005, 9:58-10:18, 10:29-62. The operational principles of Kartalian’s instrument would not be changed when used in McGlamry’s procedure given the similarities between the procedures described in McGlamry and Kartalian.

117. Given these similarities in structure and use, a POSA would have recognized that substituting Kartalian’s instrument for McGlamry’s clamp would have been nothing more than the substitution of one known instrument for another. The results of this substitution would have been predictable as both instruments perform the function of moving and maintaining the position of bones, and Kartalian’s instrument is described for use in procedures like McGlamry’s.

118. A POSA likely would not need to modify Kartalian's instrument for McGlamry's procedure. However, to the extent any modification would need to be made to Kartalian's instrument for use in McGlamry's procedure, such modification(s) would have been within the skill of a POSA capable of modifying basic surgical equipment. McGlamry's clamp and Kartalian's instrument are each simple mechanical tools, and thus any modification, if needed, would only involve easy-to-implement dimensional modifications.

Ex. 1003 ¶¶ 108-118.

24. The Kartalian instrument is a form of a tenaculum. (Ex. 1003 ¶115; Ex. 1006, 9:66–10:3). Specifically, Kartalian's instrument 100 is a reduction forceps (i.e., a device used by a surgeon to apply compressive force across two bones) whose structure does not regulate or direct the path of bone movement in the way the claimed guide requires.

25. In my opinion, Kartalian's instrument would be understood by surgeons as a reduction forceps whose effect depends on surgeon-selected placement and force application.

26. The functions Dr. Neufeld attributes to Kartalian arise, if at all, from user manipulation during surgery, and Kartalian does not disclose structure that would be understood to constrain or guide the correction path. Dr. Neufeld's allegations of equivalence to the claimed guide relate to surgeon-driven manual reduction—not guide-constrained motion produced by device geometry. And Dr. Neufeld's discussion of Kartalian's angle indicator 116 does not transform a tenaculum into a guide. Rather, it further shows that a skilled surgeon would

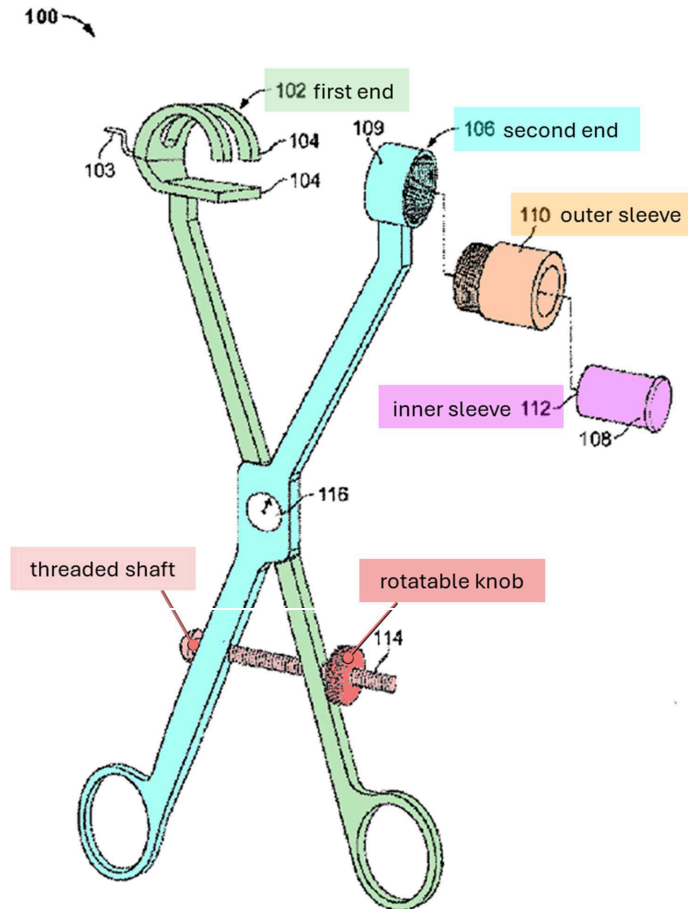
understand Kartalian's tenaculum as a surgeon-driven manual reduction tool, where the angle indicator simply indicates the manual reduction performed by the surgeon's manipulation of Kartalian's tenaculum.

27. Based on my experience as a foot and ankle surgeon who has evaluated and performed bunion-correction and arthrodesis procedures, including Lapidus-type procedures, a tenaculum is understood in practice to be a generic reduction/compression clamp that transmits surgeon-applied forces, and is not understood to be a guide that regulates or directs progressive motion or action to move bones.

28. Dr. Neufeld states that:

129. Limitation 1[e] recites "rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity." McGlamry in view of Kartalian renders obvious limitation 1[e].

130. Kartalian's instrument 100 has a rotatable knob connected to a threaded shaft, as shown in Figure 1, Panel I below:



Ex.1005, Fig.1 (excerpt) (annotated).

131. A POSA would understand that rotation of the knob would cause the knob to move down the threaded shaft, thereby causing a reduction of the distance between the first end 102 and the second end 106. This would move the bone engagement member and the tip relative to one another. Accordingly, Kartalian's IMA reduction mechanism includes a knob connected to a threaded shaft.

132. When Kartalian's instrument is used in McGlamry's procedure and engaged with the first and second metatarsals, the surgeon would rotate the threaded nob to bring the handles toward each other, thereby causing the arm 106 (bone engagement member) to move toward the end 102. Kartalian explains that the movement of the arm 106 toward end 102 pushes the first metatarsal laterally toward the second metatarsal, reducing the

IMA between the two metatarsals. Ex.1005, 9:66-67 (“The instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.”), 10:8-18 (describing operation of the “automatic angle indicator 116” for estimating the IMA between the “bones requiring correction” (the first and second metatarsals)), 10:46-62 (“After the instrument 100 is placed on the bones and the bone is set in the desired orientation, the reduction or realignment may occur to the desired angle as estimated by angle indicator 116.”). This IMA reduction corrects the bunion deformity.

(Ex. 1003 ¶¶ 129-132)

29. It is my opinion that Kartalian’s instrument would be understood by surgeons as using the locking clamp 114 in a manner consistent with Kartalian’s disclosure at 10:4–6 (i.e., to lock the clamp in position once the surgeon achieves a desired manual reduction) in the normal course of its operation.

30. Based on my experience as a foot and ankle surgeon who has evaluated and performed bunion-correction and arthrodesis procedures, including Lapidus-type procedures, the normal use of the locking clamp in Kartalian is not to effect bunion correction via rotation of the knob as identified by Dr. Neufeld. Rather, the tenaculum is adjusted manually by hand followed by the subsequent use of the locking mechanism 114 to hold the tenaculum in the position caused by the surgeon’s hand, consistent with the discussion of its use in Kartalian at column 10, lines 4–6.

31. From the perspective of a practicing foot and ankle surgeon, the Kartalian instrument’s effect on bone position depends entirely on surgeon-selected placement and applied force, not on any structural feature of the reduction forceps

itself. Therefore, in my opinion, a POSA would not understand Kartalian as disclosing a guide that regulates or directs progressive motion or action to move bones. In Kartalian, it is the surgeon's hand that dictates the movement of the bones, not the structure of the tenaculum (i.e., the reduction forceps) and the tenaculum would not be understood by skilled surgeons as being actuated by rotating the knob of the locking mechanism 114.

IV. CONCLUSION

32. For the foregoing reasons, it is my opinion that Claims 1-30 of the '481 patent are not obvious in view of McGlamry (Ex. 1004) and Kartalian (Ex. 1005).

33. I reserve the right to supplement my opinions in the future to respond to any arguments or positions that Petitioner Paragon may raise, taking account of new information as it becomes available to me.

34. I 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 and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on: April 15, 2026

By: /s/ Daniel C. Farber
Dr. Daniel C. Farber