UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

PGR2026-00020
Patent 12,268,428

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

Paragon 28, Inc. v. Treace Medical Concepts, Inc.
PGR2026-00020
Treace Ex. 2026

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. 12,268,428 to Bays et al. ("the '428 patent")
1003	Declaration Of Steven K. Neufeld, M.D. In Support Of Petition For Post-Grant Review Of U.S. Patent No. 12,268,428
1005	McGlamry's Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4th Edition, 2013 ("McGlamry")
2028	McGlamry's Comprehensive Textbook of Foot and Ankle Surgery, Chapters 1 and 13, Vol. 1, 5th Edition, 2022 ("McGlamry 5ed")
2027	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 2027.

5. I received my Bachelor of Science 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 '397 patent and arguments presented by Dr. Neufeld.

III. OPINIONS REGARDING DR. NEUFELD'S DECLARATION

10. Dr. Neufeld's Declaration (Ex. 1003, ¶¶ 124-127) discusses the McGlamry (Ex. 1005) prior art reference, and particularly the use of the Weber clamp. With respect to Claim 8 of the '428 patent (Ex. 1001), Dr. Neufeld opines that "McGlamry anticipates claim 8" (Ex. 1003, ¶ 128). 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.

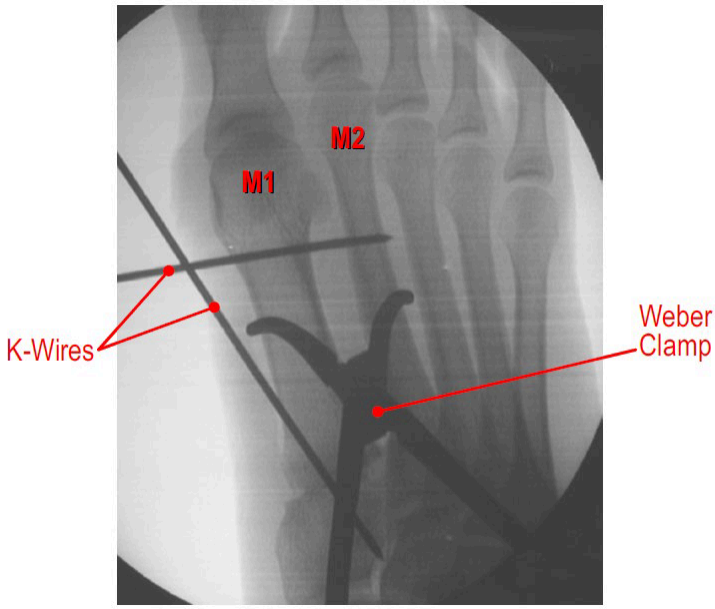
12. With respect to anticipation of a patent claim, my understanding is that anticipation in patent law means a claimed invention lacks novelty because a single prior art reference describes every element of that claim, either expressly or inherently.

13. Claim 8 depends from claim 1 and recites “wherein moving the first metatarsal in at least one plane comprises moving the first metatarsal relative to the second metatarsal in a transverse plane by applying a force to the first metatarsal with a bone positioning guide and thereby reducing an intermetatarsal angle between the first metatarsal and the second metatarsal.”

14. With respect to the McGlamry prior art reference (Ex. 1005) discussion of a Weber clamp, Dr. Neufeld states that:

> McGlamry discloses moving the first metatarsal in at least one plane relative to the second metatarsal, including movement in a

transverse plane to reduce the first intermetatarsal angle as explained above in Claim 1. See §VI.A.4, supra; Ex.1005, 325 ("[T]he surgeon can use his or her thumb against the first metatarsal to manually reduce the first intermetatarsal angle in the transverse plane"), 809 (Fig. 55.7G). McGlamry also discloses using instruments to move the first metatarsal in one or more planes, including the transverse plane. See Ex.1005, 325-326. For example, McGlamry explains that "a large Weber clamp may be used to assist, increase, or maintain the reduction" of the first metatarsal. Ex.1005, 325. McGlamry's Fig.31.5 (below) is an x-ray depicting "a case in which a large Weber clamp was used for reduction of a large [intermetatarsal] angle." Ex.1005, 326. One of the tongs is placed on the lateral aspect of the second metatarsal, and the other tong is placed on the medial aspect of the first metatarsal. See id. The clamp is then used to reduce the intermetatarsal angle, i.e. move the first metatarsal laterally toward the second metatarsal in the transverse plane. Ex.1005, 326.



Id., Fig.31.5.

A POSA would understand that clamps, like the Weber clamp, are basic surgical instruments used in bunion correction surgeries. See Ex.1005, 10. Bone holding clamps, such as the Weber clamp, are "basic [] podiatric surgical instruments" used to position bones relative to one another. Ex.1005, 3. Clamps are used in many podiatric surgeries, including bunion correction surgeries, to "grasp

> bone[s] and hold bony fragments together." Id., 10. McGlamry discloses that clamps (e.g., Weber clamps) and tenaculum are both used for similar purposes and would be considered the same class of instruments by a POSA. See Ex.1005, 10. Use of clamps to move the metatarsal in the transverse plane was common at least as of August 2015. See id., 325-326.
>
> Thus, under the ordinary meaning of bone positioning guide, McGlamry's Weber clamp is a device designed to move bones. Moreover, if a means-plus-function construction is applied, McGlamry's Weber clamp moves the first metatarsal in the transverse plane, reducing the intermetatarsal angle and maintaining the first metatarsal in the corrected position. Ex.1005, 325-326. McGlamry's Weber clamp is also identical (or at least equivalent) to the structures of the bone positioning guide identified by the '428 patent. Ex. 1005, 325-326; Ex.1001, 7:23-37. McGlamry's Weber clamp includes two shafts (e.g., tongs) that are pivotally connected. Ex.1005, 325-326. A first end of each of the tongs include a handle, and the second end of at least the first tong includes a bone engagement member. Id.

(Ex. 1003 at ¶¶ 125-127).

15. 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 Weber clamp is understood in practice to be a generic reduction/compression clamp that transmits surgeon-applied forces, and is not understood to be a device that regulates or directs progressive motion or action to move bones.

16. From the perspective of a practicing foot and ankle surgeon, the Weber clamp's effect on bone position depends entirely on surgeon-selected placement and applied force, not on any structural feature of the clamp itself. Therefore, in my

opinion, a POSA would not understand McGlamry's Weber clamp passage as disclosing a device that regulates or directs progressive motion or action to move bones. In McGlamry (Ex. 1005), it is the surgeon's hand that dictates the movement of the bones, not the structure of the Weber clamp.

17. The later edition of McGlamry (Ex. 2028) expressly recommends making precise alignment using specialized guides and jigs. Based on my experience, when a surgical text later expressly identifies a particular instrument or technique as preferred, that typically reflects that the authors considered it worth separately calling out, rather than assuming it was already part of the earlier described device. In my opinion, the later express recommendation and disclosure of specialized guides and jigs is consistent with a POSA's understanding that a Weber clamp is not a guide or jig and would therefore, not be understood as a device that regulates or directs progressive motion or action to move bones.

IV. CONCLUSION

18. For the foregoing reasons, it is my opinion that Claim 8 of the '428 patent is not anticipated by the McGlamry prior art reference discussed above.

19. 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.

20. 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: March 31, 2026 By: */s/ Daniel C. Farber*
Dr. Daniel C. Farber