

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

IPR2026-00194
Patent 12,102,368

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. 12,102,368 to Smith et al. ("the '368 patent")
1003	Declaration Of Steven K. Neufeld, M.D. In Support Of Petition For Inter Partes Review Of U.S. Patent No. 12,102,368
1006	U.S. Patent No. 8,882,816 to Kartalian, et al. ("Kartalian")
1007	McGlamry's Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4th Edition, 2013 ("McGlamry")
2005	McGlamry's Comprehensive Textbook of Foot and Ankle Surgery, Chapters 1 and 13, Vol. 1, 5th Edition, 2022 ("McGlamry 5ed")
2031	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 2031.

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 50-80 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 '368 patent and testimony presented by Dr. Neufeld.

III. OPINIONS REGARDING DR. NEUFELD'S DECLARATION

10. Section VII of Dr. Neufeld's Declaration (Ex. 1003) discusses the McGlamry (Ex. 1007) and Kartalian (Ex. 1006) prior art references. Every obviousness ground asserted by Dr. Neufeld relies on either McGlamry's Weber clamp or Kartalian's forceps instrument as the bone positioning guide recited in the '368 patent claims. I disagree with Dr. Neufeld's obviousness opinion because neither device satisfies the bone positioning guide claim limitation under the construction described in the Patent Owner's Preliminary Response.

11. Like Dr. Neufeld, I am also not an expert in patent law. Attorneys from the 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 bones. That is, the structure of the device (bone positioning guide) dictates the movement of the bones.

14. I also understand in the context of the Patent Owner's Preliminary Response, Treace contends that consistent with the plain and ordinary meaning of “guide,” the '368 patent claims require a device whose structure directs or regulates the bone's path of movement in both the transverse plane and the frontal plane, not merely a device capable of applying force to a bone.

15. 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.

16. 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 '368 Patent relates to a system for bunion correction.

The '368 Patent describes an integrated instrumented correction system including a bone preparation guide, a bone positioning guide, and a fixation device. The system achieves precise, reproducible correction in multiple planes, including both the transverse and frontal planes, providing the corrected metatarsal position for fusion with the cuneiform.

17. 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.

18. 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.

19. 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.

20. 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 January 2015 time period.

21. Dr. Neufeld contends that McGlamry renders a bone positioning guide configured to move the first metatarsal in a transverse plane and a frontal plane obvious. Ex. 1003 ¶¶ 137–146.

22. With respect to the McGlamry prior art reference (Ex. 1007), Dr. Neufeld states that:

McGlamry discloses an instrumented method for performing a bunion correction surgery. Ex.1007, 324-328. Chapter 31 of McGlamry—“Lapidus Bunionectomy: First Metatarsal-Cuneiform Arthrodesis”—describes a surgical method for cutting the proximal end of the first metatarsal, cutting the distal end of the medial cuneiform, correcting the position of the metatarsal in the transverse plane and frontal plane, and fixing the moved first metatarsal to the medial cuneiform. Id. McGlamry discloses the use of instruments during its surgical procedure, including (1) an osteotome to cut the first metatarsal and medial cuneiform, Ex.1007, 324 (“The recommended joint preparation techniques consist of the use of an osteotome....”); (2) Weber clamps and/or -wires to reposition the first metatarsal and/or temporarily stabilize the first metatarsal relative to the medial cuneiform prior to fixation, id., 325-326, Fig. 31.5; and (3) various combinations of screws and plates which, in combination with a drill, fix the first metatarsal to the medial cuneiform, id., 326-329.

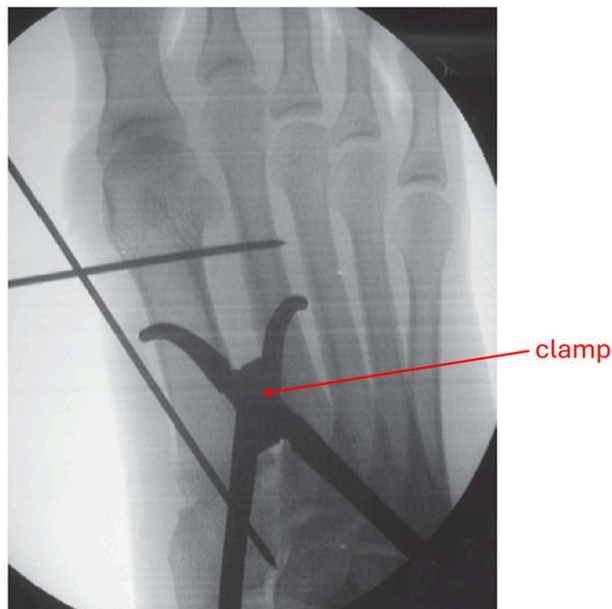
(Ex. 1003 at ¶ 107).

21. With respect to the McGlamry prior art reference (Ex. 1007), Dr.

Neufeld further states that:

138. McGlamry discloses repositioning the first metatarsal in multiple planes as part of its procedure, including the transverse plane, frontal plane, and sagittal plane, to treat a bunion deformity. Ex.1007, 325-326.

139. McGlamry discloses a Weber clamp for moving the first metatarsal in the transverse plane and rotating the first metatarsal in the frontal plane. *Id.* McGlamry discloses that “a large Weber clamp may be used to assist, increase, or maintain the reduction.” *Id.*, 325; see also *id.*, 325-326; Ex.1015, 1112 (disclosing a lateral force applied to the first metatarsal that both reduces the IMA and corrects a hallux valgus deformity). This reduction treats the bunion deformity. Ex.1007, 322-29. McGlamry’s Weber clamp is shown below:



Ex.1007, Fig.31.5 (annotated).

140. McGlamry's Weber clamp is a bone positioning guide under either construction of that term discussed above. A Weber clamp is a type of tenaculum and is used to position bones. In McGlamry's procedure, that positioning includes moving the metatarsal and the transverse and frontal planes.

141. For the transverse plane movement, McGlamry's Figure 31.5, shown above, shows an "[i]ntraoperative radiograph in a case in which a large Weber clamp was used for reduction of a large IM angle." Id., 326. McGlamry's Weber clamp is identical, or at least equivalent to the structures identified in the '368 patent for the claimed bone positioning guide. McGlamry's Weber clamp is at least an equivalent of the '368 patent's bone positioning structure (e.g., tenaculum/tong/reduction forceps-type instrument) because it uses opposing jaws/arms that engage bones (the first and second metatarsal) that are actuated through a pivot/handle/screw mechanism. This mechanism allows a surgeon to apply controlled corrective forces and hold the first and second metatarsal in a corrected relationship. Ex.1007, 325- 326. McGlamry's Weber clamp therefore performs the same function, in the same way (opposing jaws that apply/maintain a corrective clamping force), to achieve the same result of controlling the repositioning and maintenance of the correction during fixation.

142. The Weber clamp was a well-known and widely adopted surgical instrument, and it was known for use in bunion correction procedures as McGlamry describes. See Ex.1007, 325-326, Fig. 31.5; see also Ex.1008, 466 ("The first IMA was then reduced with a large, pointed, bone reduction clamp" and Fig. 2 showing use of clamp). A pointed bone reduction clamp is a Weber clamp.

143. Even if McGlamry does not disclose that the Weber clamp rotates the metatarsal in the frontal plane, it would have been obvious to use the Weber clamp to rotate the metatarsal in the frontal plane. A POSA would have recognized that a Weber clamp engaged across adjacent metatarsals (as shown by McGlamry) not only transmits compressive forces (for transverse plane correction) but also torsional movement (frontal plane derotation) as part of a controlled reduction. See Ex.1006, 9:66-10:3.

144. The first metatarsal is not cylindrical and has an asymmetric cross-section. The medial side of the first metatarsal has a ridge, which is referred to as the “metatarsal ridge.” See, e.g., Ex.1001, Fig.15B, 11:14-17. The Weber clamp in McGlamry is illustrated as being placed in the region of the metatarsal ridge. Ex.1005, Fig.31.5. A POSA would have recognized that, because the first metatarsal is not symmetrical (e.g., has the ridge on the medial side), when a bone positioning device like a Weber clamp engages the first metatarsal as shown in McGlamry, the force from the clamp would generate rotation of the first metatarsal in the frontal plane when the force is not in line with the metatarsal’s center of mass. The surgeon could increase or decrease the amount of this rotation either through the positioning of the Weber clamp or by pulling/pushing on the Weber clamp as desired when moving the first metatarsal.

145. In McGlamry’s procedure, before using the Weber clamp, the surgeon resects the connective tissue from the metatarso-cuneiform joint. Ex.1005, 324. The first metatarsal can thus rotate in the frontal plane when the surgeon uses the Weber clamp. Id., 328 (“Once the ligamentous structures of the tarsal–metatarsal joint [are] free of soft tissue attachments, rotation of the first metatarsal from a valgus position in the direction of varus and into a neutral position can demonstrate the frontal plane motion associated with the pathological hallux valgus deformity.”).

146. A POSA would have been motivated to use the Weber clamp to correct the frontal plane rotation of the first metatarsal due to the problems McGlamry discusses with failing to correct the position of the first metatarsal. Ex.1007, 322- 329. McGlamry describes that maintaining the corrected position “in all three planes” is important during temporary fixation and further provides guidance for additional frontal plane rotation: “[a] K-wire can be used as a rotation device and rotate the metatarsal into more of a neutral position.” Ex.1007, 326, 328-329. Fallin likewise discloses that, after creating increased mobility, the metatarsus and cuneiform may be freely repositioned in a “new relative orientation” and “in one or more planes” before fusion. Ex.1005, [0057]-[0058]. Selecting a familiar reduction clamp already used in McGlamry’s procedure, such as the Weber clamp,

to transmit controlled corrective forces (including a rotational component) during repositioning would have been desirable to a POSA, since such use of McGlamry's clamp would improve control and stability (e.g., freeing the surgeon's hands during temporary fixation) without modification of the clamp. A POSA would expect McGlamry's clamp to perform such a torsional rotation in the frontal plane as explained above while leaving the overall surgical approach of McGlamry's procedure unchanged. (Ex. 1003 ¶¶ 138-146).

22. Based on my experience as a foot and ankle surgeon who has evaluated and performed bunion-correction and arthrodesis procedures, including Lapidus-type procedures, I understand McGlamry to describe Lapidus joint preparation as a surgeon-controlled, freehand technique. McGlamry teaches that the joint resection should be kept "consistent and parallel with the natural occurring anatomy" and that substantial time is spent preparing the joint because that step is vital to the procedure.

23. A Weber clamp is understood in practice as a generic reduction/compression clamp that transmits surgeon-applied forces, not as an instrument whose geometry itself constrains a predefined multi-planar correction path. 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 passages cited by Dr. Neufeld as disclosing a device that regulates or directs progressive motion or action

to move bones. In McGlamry (Ex. 1007), it is the surgeon's hand that dictates the movement of the bones, not the structure of the Weber clamp.

24. In my opinion, from a surgeon's perspective, McGlamry's sequence describes surgeon-controlled reduction and stabilization, and a POSA would not read the cited Weber-clamp passage as disclosing an instrument whose structure itself performs multi-planar correction, such as intermetatarsal angle reduction and frontal-plane derotation.

25. I disagree with Dr. Neufeld's characterization of the Weber clamp's functionality because clamp placement and user-applied push/pull forces are surgeon-generated inputs, not properties of Weber clamp's device structure, and therefore do not convert such a generic clamp into a "guide" configured to produce the claimed correction of the '368 patent.

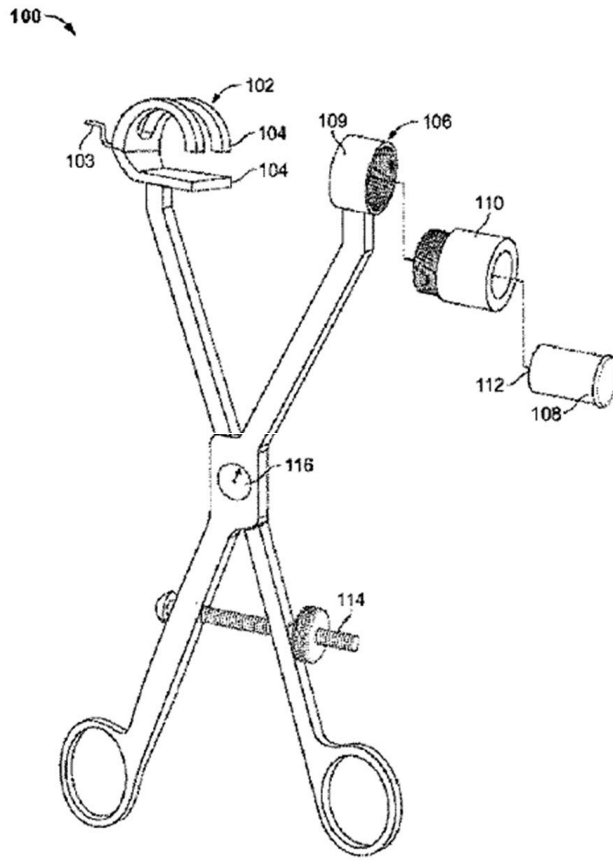
26. The later edition of McGlamry (Ex. 2005) expressly recommends making precise alignment using specialized guides and jigs. Based on my experience, when a surgical text later expressly identifies a particular instrument or technique as preferred, that typically reflects that the authors considered 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.

27. With regard to the Kartalian prior art reference (Ex. 1006), Dr. Neufeld states:

218. Kartalian also discloses correction of a bunion deformity by moving the first metatarsal in the transverse plane (Ex.1006, 10:46-51 (describing reduction of the IMA via Kartalian's instrument 100)) and rotating the first metatarsal in the frontal plane. Id., 9:66-10:3 (Kartalian's instrument 100 "correcti[ng] ... any rotational deformity (pronation)" of the first metatarsal). In the context of a bunion and a bunion correction procedure, "pronation" refers to a rotation of the metatarsal in the frontal plane.

219. Kartalian further discloses an "instrument 100" that "may act as reduction forceps to align two bones or reduce the distance between the bones, as desired" and that "allow[s] for correction of any rotational deformity (pronation) when used for surgical correction of a bunion." Id., 9:66-10:3. As shown below, Kartalian's instrument is a tenaculum (forceps):



Id., Fig.1 (excerpt).

220. Kartalian's instrument 100 functions to position the bones by moving the metatarsal in the transverse plane and rotating it in the frontal plane. Ex.1006, 9:66-10:3, 10:46-51. 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 '368 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 the transverse plane and rotational correction in the frontal plane), in substantially the same way (opposed bone-engaging ends/arms of a tenaculum (forceps) 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).

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

222. Kartalian has features that are specifically designed for bunion correction procedures and would have been desirable for use in McGlamry's procedure. Ex.1006, 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.

223. 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.1006, 2:30-39.

224. 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*, VII.C. (Claim 3).

225. A POSA would have also reasonably expected to succeed in using Kartalian's instrument in McGlamry's procedure. 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.1006, 9:66-10:3, 10:43-51; Ex.1007, 325-26, Fig.31.5.

226. Kartalian's instrument was designed for a bunion correction procedure that is, in many respects, similar to McGlamry's procedure. Ex.1006, 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.

227. Given these similarities in structure and use, a POSA would 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.

(Ex. 1003 ¶¶ 218-227).

28. Kartalian's instrument 100 suffers from the same fundamental deficiency as McGlamry's Weber clamp: it is a reduction forceps whose structure does not regulate or direct the path of bone movement in the way the claimed guide requires. And it is not configured to regulate or direct the path of bone movement to both reduce an intermetatarsal angle between the first metatarsal and a second metatarsal and rotate the first metatarsal in a frontal plane.

29. 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, not as a guide that structurally dictates frontal-plane and transverse-plane correction.

30. 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 claimed multi-planar correction path; Dr. Neufeld's assertions of equivalents to the claimed guide relate to surgeon-driven manual reduction—not guide-constrained motion produced by device geometry. Further, 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.

IV. CONCLUSION

31. All the obviousness grounds discussed in Dr. Neufeld's declaration (Ex. 1003) rely on either McGlamry's Weber clamp or Kartalian's instrument as the sole or primary disclosure of the bone positioning guide limitation in the claims of the '368 patent. However, as discussed above, neither device satisfies that limitation under the construction provided by Treace in the Patent Owner's Preliminary Response. More particularly, the McGlamry and Kartalian prior art references do not disclose a device whose structure regulates or directs the path of bone movement in the manner described and claimed by the '368 patent.

32. For the foregoing reasons, it is my opinion that Claims 1–30 of the '368 patent would not have been obvious to a POSA in January 2015 in view of the McGlamry and Kartalian prior art discussed above and the knowledge of one of ordinary skill in the art at the time of the alleged invention.

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 10, 2026

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