UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

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PGR2026-00017
Patent 12,268,397

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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. 12,268,397 to Dayton, et al. (“the ’397 patent”)
1002	Declaration Of Steven K. Neufeld, M.D. In Support Of Petition For Post-Grant Review Of U.S. Patent No. 12,268,397
1005	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4th Edition, 2013 (“McGlamry”)
1007	English Translation of Augoyard from Ex. 1006
1013	U.S. Patent App. Publ. No. 2013/0150900 to Haddad et al. (“Haddad”)
2003	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Chapters 1 and 13, Vol. 1, 5th Edition, 2022 (“McGlamry 5ed”)
2030	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 2030.

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 50-80 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. 1002) 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 testimony presented by Dr. Neufeld.

III. OPINIONS REGARDING DR. NEUFELD'S DECLARATION

10. Section VII of Dr. Neufeld's Declaration (Ex. 1002) discusses the McGlamry (Ex. 1005) and Augoyard (Ex. 1013) prior art references. More particularly, Dr. Neufeld opines that "it would have been obvious to use Augoyard's cutting guides in McGlamry's procedure." I disagree.

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 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.

14. 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 '397 patent is directed to bunion correction methods that utilize devices and methods for, generally speaking, achieving correction of the bunion deformity by cutting the first metatarsal and cuneiform and adjusting their relative position. 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.

15. 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.

16. 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.

17. 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.

18. With respect to the McGlamry prior art reference (Ex. 1005), Dr. Neufeld states that:

> McGlamry's bunion correction procedure involves a surgeon performing freehand resection of the metatarsal and cuneiform. Ex.1005, 324-329. Freehand resections rely on the surgeon's technical ability to avoid complications, and McGlamry instructs that significant time should be spent on this step. Id.; Ex.1021, 1:31-34. Freehand cutting also creates a potential for significant misalignment of the cut surfaces when the bones are brought together for union. Ex.1015, [0005]. By 2015, it was known that freehand bone cutting can be "very difficult to perform and can be rather imprecise," and any mistakes or inaccuracies made by the surgeon during freehand resection may "lead to complications such as nerve damage, poor quality bone healing, bone resorption, …

> increased operating time and increased blood loss." Ex.1021, 1:31-37, 1:45-50. Although Armstrong discusses difficulties of freehand cutting in the context of facial bones, its rationale applies to freehand cuts of foot bones.

(Ex. 1002 at ¶ 83).

19. 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.

20. In describing the benefits of known bone cutting guides, Dr. Neufeld identifies that they were used "to ensure the accuracy and repeatability of cuts to bones" (Ex. 1002, ¶ 61), to remove the necessity of clinical judgment and guesswork by providing precision (Ex. 1002, ¶ 62), to make joint preparation predictable and repeatable, thus simplifying the procedure and reducing the time the patient spends under anesthesia (Ex. 1002, ¶ 85).

21. Based on my experience, the benefits Dr. Neufeld identifies, such as precision, reduced guesswork, simplification, repeatability, and reduced operating time, are general goals surgeons often value across many procedures. In practice, the relevant question is whether the instrument reliably fits the anatomy and the operative sequence of the particular procedure being performed. Therefore, I do not

agree with Dr. Neufeld's suggestion that those general goals would, without more information, lead a surgeon to select the MTP joint bone cutting instrument described in Augoyard for use in performing bunion correction surgery involving the TMT joint. Before selecting the Augoyard instrument for use in performing bunion correction surgery, a surgeon would first need compelling evidence that the Augoyard instrument could achieve those general goals when used to perform bunion correction surgery involving the TMT joint.

22. In my opinion, when comparing McGlamry and Augoyard, the differences in joint, surgical objective, anatomy, and workflow remain important. A surgeon familiar with both first-MTP joint replacement and Lapidus arthrodesis would therefore want procedure-specific support before using instrumentation from one context in the other. The structure of the MTP joint (Augoyard) and the TMT joint (McGlamry) are different in terms of their geometry and mobility, such that an experienced surgeon would not necessarily conclude that use of a cut guide in one type of procedure necessarily translates into use of a cut guide across other procedures.

23. Furthermore, the expectation that using Augoyard's guide in McGlamry's procedure would simplify the procedure, reduce time under anesthesia, increase repeatability, and reduce complications is not accurate. McGlamry's Lapidus procedure concerns preparation of the metatarsal and cuneiform for

arthrodesis, while Augoyard concerns preparation of the metatarsal and phalanx for prosthetic implantation. Those procedures differ in surgical objective, alignment strategy, and instrumentation requirements. The record does not identify evidence showing that Augoyard's guide would in fact simplify a Lapidus fusion, reduce operative time, or reduce complications once adapted to a different joint, different bone surfaces, and a workflow that requires intraoperative alignment of the metatarsal relative to the cuneiform before fusion. In my opinion, the asserted benefits are therefore speculative in this specific combination, not evidence-based conclusions that an experienced surgeon would have drawn from Augoyard or McGlamry themselves. For example, the use of a cut guide requires determining the appropriate positioning and attachment and would still require the same radiographic inspection discussed in McGlamry to ensure proper cut placement. Without a specific specialized cut guide for a particular procedure, an experienced surgeon would not be able to reach a general conclusion that the benefits alleged by Dr. Neufeld would necessarily flow from use a cut guide in the abstract.

24. With regard to the Augoyard prior art reference (Ex. 1013), Dr. Neufeld states:

> Augoyard's cutting guides would also reduce the risk of delayed unions, nonunions, and malunions cautioned by McGlamry. Ex.1005, 324. Delayed unions, nonunions, and malunions can occur when the cut bones, here the metatarsal and cuneiform, do not fit together properly after the first metatarsal's position is corrected. See Ex.1005, 329 (informing surgeons that

> "[m]alunions associated with the procedure can be avoided with intraoperative radiographs to establish correct positioning [of the first metatarsal] in all three planes of motion"). The use of cutting guides in McGlamry's procedure would "easily and effectively achieve a union through normal biological healing." Ex.1013, [0068]. Augoyard's cutting guides facilitate proper unions after osteotomy because the cutting guides prepare complementary joint surfaces. Id.; Ex.1007, [0034], [0070] (describing complementary cut surfaces made through use of Augoyard's guides). Based upon these disclosures and known risks associated with McGlamry's bunion correction procedure, a POSA would have recognized that Augoyard's cutting guides reduce these known risks.

(Ex. 1002 at ¶ 88).

25. McGlamry also states that malunions associated with the procedure can be avoided with intraoperative radiographs used to establish correct positioning in all three planes of motion. In my opinion, a surgeon reading McGlamry would understand those passages together to describe a Lapidus technique in which precision and alignment are achieved through careful freehand preparation and radiographic confirmation. Intraoperative radiographs are the standard of care used to establish correct positioning to avoid malunions as McGlamry explains. I also consider it significant that McGlamry discusses cutting guides in other surgical contexts, but does not recommend them for the Lapidus procedure. A practicing foot and ankle surgeon would understand from that discussion that the authors were familiar with cutting-guide technology and its use in foot surgery, yet still presented Lapidus preparation as a freehand procedure rather than as a guide-assisted cutting technique.

26. Additionally, based on my experience treating arthrodesis cases, whether fusion occurs depends on more than whether two cut surfaces are complementary. Bone preparation quality, the position in which the bones are brought together, fixation stability, and maintenance of alignment all affect the likelihood of union. For that reason, when I read the discussion presented in the Haddad prior art reference (Ex. 1013) about complementary planar surfaces promoting union, I understand that as a general principle, not as a complete description of what governs union in a TMT arthrodesis procedure such as Lapidus. Based on my reading of Haddad together with my clinical experience, I also would not understand Haddad to describe the operative workflow of a Lapidus procedure. In my opinion, a foot and ankle surgeon would read Haddad's discussion as a statement about one aspect of bone healing within its own disclosed system, not as a description of how a particular MTP implant-oriented guide system would be used for TMT fusion.

27. Dr. Neufeld testifies that using Augoyard's cutting guides in McGlamry's procedure would have been desirable. I disagree.

28. In describing McGlamry's procedure, Dr. Neufeld states:

> McGlamry's discloses how the metatarsal should be realigned to the anatomically correct position. Ex.1005, 322 ("The procedure allows for triplanar correction of first metatarsal pathology ...."), 324-326 (describing adjustment of the alignment of the first metatarsal relative to the cuneiform in the transverse, frontal, and sagittal anatomic planes). McGlamry describes how the metatarsal

> is "rotated out of valgus, and parallel in [*sic*] with the second metatarsal in both the transverse and sagittal planes." Ex.1005, 325.
>
> For example, to correct any frontal plane misalignment, "[t]he surgeon derotates the hallux out of valgus in order to get the nail plate to be parallel to the ground" and "allows for the entire hallux, sesamoid, and first metatarsal complex to be rotated from a position of valgus and into a neutral position as one unit." Id., 324. To correct any sagittal plane misalignment, the surgeon "stabiliz[es] the hind foot, while the surgeon dorsiflexes the first metatarsophalangeal joint initiating the windless mechanism," which "allows the surgeon to apply retrograde forces to the plantar tarsal-metatarsal [metatarso-cuneiform] joint and allows for the first metatarsal to plantarflex to a natural occurring level …." Id., 325. To correct transverse plane misalignment, "the surgeon can use his or her thumb against the first metatarsal to manually reduce the first intermetatarsal angle in the transverse plane." Id., 325. The movement of these bones in multiple planes establishes the moved (corrected) position of the first metatarsal for fixation and union.

(Ex. 1002 at ¶¶ 115, 116).

29. Regarding the hypothetical combining of Augoyard with McGlamry, Dr. Neufeld says:

> Using Augoyard's cutting guides in McGlamry's procedure would have been desirable to a POSA because Augoyard's cutting guides would have been nothing more than the use of a known technique for cutting bones to improve McGlamry's known technique in the same way that the guides improved Augoyard's technique. For example, as I discussed above, Augoyard's cutting guides improve resection of the metatarsophalangeal joint by precisely defining the resections of the metatarsal and proximal phalanx. See supra §IV.B.; Ex.1007, [0034].
>
> Furthermore, the use of Augoyard's cutting guide in McGlamry's procedure would have been the use of a known technique to improve a similar known procedure. The cutting steps of

> McGlamry's bunion correction procedure are similar to Augoyard's metatarsophalangeal cutting steps, as both procedures involve a joint between the first metatarsal and an adjacent bone. See generally Ex.1005, 324-330; Ex.1007. A POSA would have looked to cutting guides from other joint replacement or arthrodesis procedures to improve McGlamry's procedure as cutting guides can be adapted to other procedures. A POSA would have understood that cutting guides for other arthrodesis or joint replacement procedures would be adaptable for use in a bunion correction procedure, since a surgeon would understand that the shape, size, and configuration of the bone cutting guide could be modified to fit a particular arthrodesis procedure. See, e.g., Ex.1013, [0058] (describing use of a bone cutting guide for use in fracture or fusion (arthrodesis) application, and stating its orthopedic device "may be used with any suitable bone segments"); Ex.1017, 21:14-27 (describing a resection frame and associated guide that "can be shaped and configured in a variety of manners to suit particular anatomy and to work in conjunction with a cutting guide," including configurations for ankle joint resection, metatarsophalangeal joint resection, or an osteotomy of hand bones); see also Ex.1016, 3:10-19 (describing an "orthopaedic template system," wherein the instrumentation may be "adapted for use on a right wrist"). Thus, a POSA would have looked to cutting guides from other joint replacement or arthrodesis surgeries, such as a cutting guide for metatarsophalangeal arthrodesis like Augoyard's, to improve McGlamry's procedure.

(Ex. 1002 at ¶¶ 89, 90).

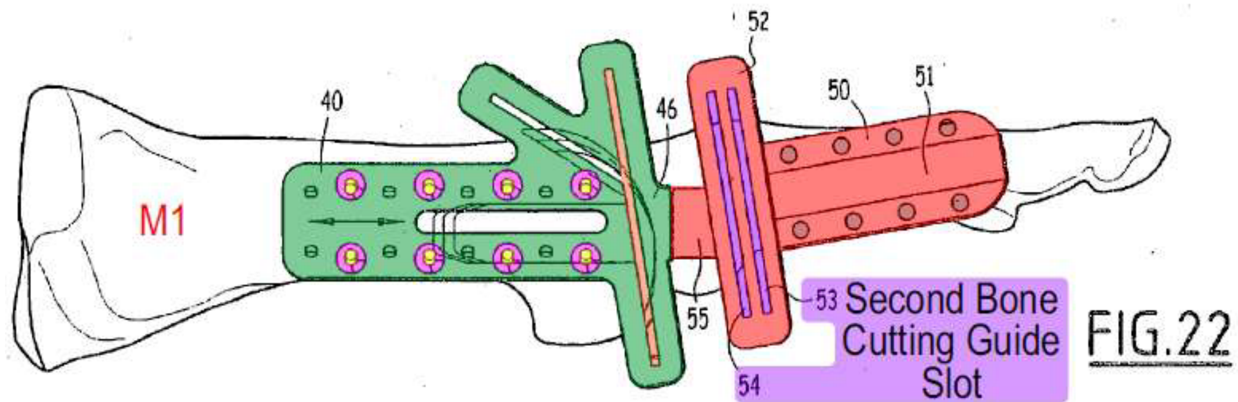
30. Based on my experience as a practicing foot and ankle surgeon, first metatarsophalangeal joint replacement (Augoyard) and first tarsometatarsal arthrodesis (McGlamry) are materially different procedures. In Augoyard, the bone preparation is described in the context of fitting a prosthesis at the MTP joint. In McGlamry, the procedure is a Lapidus fusion at the TMT joint. In surgical practice, those procedures involve different objectives and different intraoperative decisions

because one is directed to preparing bone for implant placement and the other is directed to preparing opposing bone surfaces for fusion in a corrected position.

31. Based on my experience with Lapidus and other arthrodesis procedures, the alignment step recited in the claims of the '397 patent (Ex. 1001) is an important part of that workflow. In a Lapidus procedure, the surgeon is not simply cutting two bones; the surgeon is also establishing the desired position of the metatarsal relative to the cuneiform before completing the fusion construct. I do not see in Augoyard a corresponding step in which the metatarsal is repositioned relative to the adjacent bone to establish corrected fusion alignment before the second cut is completed. For that reason, a surgeon familiar with both procedures would read McGlamry and Augoyard as addressing different operative problems and would view instrumentation through the needs of the procedure itself.

32. Dr. Neufeld testifies that "[i]t would have been obvious to use a second bone cutting guide, like the 'ancillary phalangeal cutting instrument 50' disclosed in Augoyard, to cut the distal end of the medial cuneiform in McGlamry's procedure." (Ex. 1002 at ¶ 119). I disagree. Dr. Neufeld further testifies that:

> For example, it would have been obvious to position Augoyard's second bone cutting guide's guide slot over a distal portion of the medial cuneiform to be cut as part of McGlamry's method. As shown in the figure below, Augoyard discloses a second bone cutting guide 50 (red) defining cutting guide slots 53 and 54 (purple) over a second bone adjacent to the portion of the first metatarsal to be cut.



Id., Fig.22 (annotated); see also id., [0034], [0070].

> In Augoyard, the second bone being cut is the phalanx. However, a POSA would have recognized that, when used in McGlamry's bunion correction procedure, the second bone would be the cuneiform. See supra §VII.A.
>
> The use of Augoyard's second cutting guide defining slots for cutting the cuneiform in McGlamry's procedure would be consistent with how Augoyard describes using the second bone cutting guide slots. For example, Augoyard depicts its second bone cutting guide 50 being positioned over a bone adjacent to the first metatarsal (Figs. 22 and 23), with the second bone cutting guide having an end 55 that has a tip penetrating a small recess in end 46 of the first bone cutting guide 40. Ex.1007, [0070], Figs. 22 and 23. This arrangement of the first and second cut guides "precisely determines" the respective positions of the two cutting guides. Id., [0070].
>
> Augoyard discloses that its second cutting guide body "is slightly inclined to reproduce the slight natural varus position of the first phalanx P." Ex.1007, [0070]. A POSA would have recognized that the medial cuneiform has a different natural position; however, modification of the angle between the second cut guide and the first cutting guide to accommodate the differing anatomy of the metatarsocuneiform joint would be no more than a simple design choice of straightening or slightly declining the longitudinal axis of the second cutting guide relative to that of the first cutting guide.

(Ex. 1002 at ¶¶ 120-123).

33. I specifically disagree with Dr. Neufeld's statement that "modification of the angle between the second cut guide and the first cutting guide to accommodate the differing anatomy of the metatarsocuneiform joint would be no more than a simple design choice of straightening or slightly declining the longitudinal axis of the second cutting guide relative to that of the first cutting guide." (Ex. 1002 at ¶ 123). Based on my surgical experience, changes such as moving from phalanx anatomy to cuneiform anatomy, maintaining fixation-pin relationships through a staged sequence, and using a guide after the metatarsal has been repositioned would not be details I would disregard as immaterial. Those changes would affect how the instrument registers on bone, how stable it is during the cut, whether the geometry of the guide would still produce the intended bony surfaces in the different anatomy, and whether the guide remains usable after the relative position of the bones has changed. In my opinion, those are practical surgical and instrumentation questions that matter because the usefulness of a cutting guide depends on how it functions in the actual operative sequence and on the anatomy to which it is applied.

34. In my opinion, a POSA would not have viewed Augoyard's cutting-guide system as teaching or suggesting the guide arrangement claimed in the ’397 Patent. I do not view the differences as a minor matter of relocating the same guide. The placement of the guide relative to the operative field (dorsal in the ’397 Patent

versus side in Augoyard), the underlying bones (TMT joint in '397 Patent versus MTP joint in Augoyard), and the intended cut planes is different, and the slot orientation is correspondingly different because the procedures address different bones, different joint geometry, and different surgical objectives.

35. The later 5th edition of McGlamry (Ex. 2003), the authors expressly recommend making precise cuts using a cutting jig in the Lapidus bunionectomy. 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 method. In my opinion, the later express recommendation is consistent with the earlier edition's discussion of Lapidus as merely a freehand procedure and shows that guide-assisted cutting was separately identified when the authors chose to recommend it at a later time.

IV. CONCLUSION

36. For the foregoing reasons, it is my opinion that Claims 1–2, 4–20, and 22–30 of the '397 patent would not have been obvious to a POSA in January 2015 in view of the McGlamry and Augoyard prior art discussed above and the knowledge of one of ordinary skill in the art at the time of the alleged invention.

37. 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.

38. 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