

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

SPINELOGIK, INC.,
Patent Owner.

Case IPR2025-00225
U.S. Patent No. 9,730,805

**PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW
OF FINAL WRITTEN DECISION**

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CASES

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STATUTES

35 U.S.C. § 316(e)	3, 9
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REGULATIONS

37 C.F.R. § 42.75(c)	1, 3
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I. INTRODUCTION

Patent Owner Spinelogik, Inc. respectfully requests Director Review of the Final Written Decision (Paper 21, “Decision” or “Dec.”). Review is warranted under 37 C.F.R. § 42.75(c)(1)–(4) because two aspects of the Decision apply erroneous legal standards to outcome-determinative facts.

First, claims 5 and 16 require each channel of the fusion member to be curved. The hearing established that neither Blain nor any other cited document discloses a curved channel in Blain’s implant. Tr. 49:8–50:6, 51:19–52:12. Steffee discloses a curved fastener driven through bone graft, not a curved implant channel. Dec. 64–67. Petitioner’s counsel ultimately confirmed that there was no other direct evidence of curved implant channels beyond the theory in paragraph 206 of Mr. Culbert’s declaration. Tr. 51:6–52:12. The Decision nevertheless credited that expert-created redesign—supported by litigation mockups and Blain’s distinct disclosure of nonlinear external guide tubes—as proof that a skilled artisan would have created the claimed implant channels with a reasonable expectation of success. Dec. 62–67. That analysis permits expert testimony to supply the missing structural limitation without the reasoned evidentiary bridge required by *KSR*, *Magnum*, and precedential *Xerox*.

Second, the Decision held that Blain anticipates independent claims 1 and 11 even though it acknowledged that Blain does not expressly disclose a delivery mechanism extending outside the patient while coupled to an implant positioned between vertebral bodies. Dec. 23–26. The cited testimony addressed what tools are commonly designed to do, what other tools show, and what Mr. Culbert had seen in practice. Ex. 1002 ¶¶ 118–122. That may support probability or a proposed modification; it does not establish that the claimed spatial and temporal relationship is necessarily present in Blain. The Decision’s statement that Blain’s use of the guide to insert the implant “mean[s]” the handle is necessarily outside the body skips the missing premise—Blain discloses variable dimensions and a detachable handle. Dec. 25–26; PO Resp. 36–38; Tr. 54:21–55:13.

Patent Owner recognizes that the Decision also stated an alternative obviousness rationale for the external-extension limitation. Dec. 24–26. That does not insulate the anticipation error, and the rationale itself adopts a false binary—that the tool must extend outside the body or the physician must place a hand inside the incision—without analyzing Blain’s variable and detachable configurations at the claimed stage. In all events, the independent error concerning curved implant channels requires review and reversal at least as to claims 5 and 16.

II. STANDARD FOR DIRECTOR REVIEW

Director Review of a final written decision is available for an abuse of discretion, an important issue of law or policy, an erroneous finding of material fact, or an erroneous conclusion of law. 37 C.F.R. § 42.75(c). Petitioner bears the burden of proving unpatentability by a preponderance, and that burden never shifts. 35 U.S.C. § 316(e); *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015); *In re Magnum Oil Tools International, Ltd.*, 829 F.3d 1364, 1375–78 (Fed. Cir. 2016).

Anticipation by inherency requires that the missing feature be necessarily present; probability or possibility is insufficient. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268–69 (Fed. Cir. 1991); *PAR Pharmaceutical, Inc. v. TWi Pharmaceuticals, Inc.*, 773 F.3d 1186, 1195–96 (Fed. Cir. 2014). Obviousness requires articulated reasoning with a rational underpinning and a reasonable expectation of success. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007); *Magnum*, 829 F.3d at 1380–81; *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016). An expert may explain the art but may not supply a limitation missing from it through a conclusory assertion. *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15–17 (PTAB Aug. 24, 2022) (precedential).

III. DIRECTOR REVIEW IS WARRANTED

A. Petitioner's Expert Supplied the Missing Curved Implant Channels

Claims 5 and 16 recite that “each channel of the fusion member is curved.”

Dec. 13–14. The parties agreed, and the Board held, that a curved channel follows a curved trajectory. *Id.* at 14. Blain's implant uses channels for straight threaded fasteners. Steffee's curved rigid fastener passes through bone graft and does not traverse a channel in an implant. *Id.* at 61–67. Thus, no reference discloses the claimed curved channel in a fusion member.

Petitioner proposed to create that missing structure. Mr. Culbert opined that a skilled artisan would replace Blain's screws with Steffee's rigid curved anchors and then modify both Blain's external guide-tube channels and its internal implant channels to complement the anchors. Ex. 1002 ¶¶ 205–206. Paragraph 206 stated that the alteration would be “simple”; paragraphs 207 and 208 presented Petitioner-created conceptual renderings; and paragraph 210 invoked “basic machining principles.” Pet. 88–91; Dec. 62–63. None identified a prior-art implant channel following a curved trajectory, specified the geometry needed to pass a rigid curved fastener, or analyzed whether the redesigned implant retained structural integrity and alignment.

The hearing clarified the evidentiary gap. Judge Tartal asked whether Blain disclosed that the channel “in the implant itself” could be nonlinear. Petitioner answered, “No, Your Honor, there’s not.” Tr. 50:3–6. Petitioner also acknowledged that a nonlinear guide tube does not necessarily require a curved implant channel; depending on geometry, a straight fastener could be used. *Id.* at 50:19–51:5. When the panel asked whether any other reference or disclosure directly supported curved implant channels, Petitioner answered that it did not believe there was “any other direct evidence.” *Id.* at 51:6–52:12.

The Decision nevertheless relied on Blain’s statement that external guide members may be linear or nonlinear to support the different proposition that the implant itself would be machined with curved channels. Dec. 62, 66–67. But Blain explains that nonlinear guide members facilitate access to difficult anatomical sites and may be used with nonlinear or flexible drills and screwdrivers. Ex. 1004, 8:8–16; Tr. 55:13–56:1. That disclosure concerns the path of an external instrument, not the trajectory of a rigid anchor through an internal implant channel. The hearing made the distinction explicit. Tr. 49:8–50:18.

The remaining reasoning is circular: once the combination assumes Steffee's rigid curved anchor, Mr. Culbert states that Blain's implant channel "should match" the anchor and therefore should be curved. Ex. 1002 ¶¶ 205–206. But the claimed curved implant channel cannot be treated as an inevitable consequence of first selecting a curved anchor when the evidence does not establish the needed channel geometry or why a skilled artisan would undertake the resulting redesign rather than choose a straight barbed fastener, shorten the internal passage, or use a different insertion structure. PO Resp. 64–70; Tr. 55:13–57:9, 70:20–71:23.

This is the precise concern addressed by precedential *Xerox*. Where the references lack a limitation, an expert cannot supply it by asserting that a skilled artisan would have created it. Paper 9 at 15–17. The problem is not that expert testimony can never support a modification. It can. The problem is that the testimony must explain, from record evidence and technical reasoning, why the claimed structure would have resulted and why success was reasonably expected. *KSR*, 550 U.S. at 418; *Magnum*, 829 F.3d at 1380–81. Labels such as "simple" and "basic machining," coupled with claim-shaped conceptual renderings, do not provide that bridge.

The Decision recited that modifying the contours would be within ordinary skill and would yield predictable results. Dec. 66–70. But it did not identify evidence resolving the technical point the panel itself raised: how Blain’s disclosure of a nonlinear guide tube establishes a curved trajectory through the implant. Nor did it address Petitioner’s concession that the asserted implication was not necessary and lacked other direct support. A finding that the combination teaches the claimed curved implant channels therefore rests on an erroneous material fact and an erroneous application of the law governing conclusory expert testimony.

B. The Anticipation Finding Replaced Necessity with Typical Practice

Independent claims 1 and 11 require the delivery mechanism to extend outside the patient to a practitioner while the mechanism is coupled to the fusion member and the fusion member is positioned between two vertebral bodies. Dec. 20–21, 44. The limitation imposes a particular spatial relationship at a particular procedural time. Blain never states that relationship. Petitioner acknowledged the omission, and the Decision acknowledged it too. Pet. 50–54; Dec. 23–24.

The proof credited for anticipation was evidence of ordinary or preferable practice. Mr. Culbert said a skilled artisan would understand Blain’s handle was “designed” to permit manipulation from outside the body; cited other tools designed to reach outside; and testified that he had never seen an interbody delivery tool that failed to do so. Ex. 1002 ¶¶ 118–121; Dec. 24. Those propositions may make an external handle likely. They do not establish that every embodiment—or even the relied-upon embodiment—necessarily has the claimed relationship when the implant is between vertebral bodies. *Continental Can*, 948 F.2d at 1268–69; *PAR Pharmaceutical*, 773 F.3d at 1195–96.

The Decision’s asserted necessity is a non sequitur. It reasoned that because Blain attaches the guide before implantation and uses it to insert and fix the device, “the handle 20 is necessarily outside the body during this stage.” Dec. 25. Attachment and use do not establish length. Blain expressly permits the relative lengths of the proximal and distal shafts to vary. Ex. 1004, 5:4–6; Dec. 22. It also permits the protruding handle to be detached to avoid interference. Ex. 1004, 8:46–49; PO Resp. 38. A permanently attached handle remains attached; permanence alone does not determine whether it extends beyond the patient’s body. Tr. 54:21–55:13.

Nor can “unrebutted” testimony lower the inherency standard. Dec. 23–26. Petitioner always retains the burden under § 316(e). *Dynamic Drinkware*, 800 F.3d at 1378; *Magnum*, 829 F.3d at 1375–78. Patent Owner identified the variable lengths, detachable handle, and precise temporal limitation in its Response and again at the hearing. PO Resp. 36–38; Tr. 46:19–47:14, 54:21–55:13. The absence of a Patent Owner declaration does not transform evidence that a configuration is typical into proof that it is necessary.

C. The Alternative Obviousness Rationale Does Not Cure the Error

The Decision alternatively reasoned that common sense would have led a skilled artisan to lengthen Blain’s instrument guide so the physician need not insert a hand into the incision, and that an external tool could permit a smaller incision and avoid interference with fluoroscopy. Dec. 24–26 (citing Ex. 1002 ¶¶ 123–126). Those may be advantages of some external delivery tools. They do not answer the claim-specific question: why a skilled artisan would select and maintain a configuration that extends externally while the guide remains coupled and the implant is positioned between the vertebral bodies, given Blain’s variable shaft lengths and detachable-handle teaching.

The rationale also treats the design choice as binary: either the guide reaches outside or the physician inserts a hand into the patient. Pet. 53; Dec. 22, 24. The record does not establish that binary. Blain permits variable dimensions and removes the protruding handle when it interferes. Ex. 1004, 5:1–6, 8:46–49. A reason to avoid putting a hand inside an incision does not itself establish the particular length, coupling state, and procedural timing recited by the claims. *KSR* permits common sense, but it still requires an articulated, record-supported connection to the claimed arrangement. 550 U.S. at 418; *Magnum*, 829 F.3d at 1380–81.

At minimum, Director Review should vacate the anticipation determination. If the Director concludes the alternative obviousness rationale independently supports claims 1–4, 6, 11, 12, 15, and 17, the separate curved-channel error remains dispositive for claims 5 and 16.

D. The Errors Are Material and the Issues Are Important

The curved-channel issue is outcome-determinative for claims 5 and 16: the Decision did not find those claims unpatentable over Blain alone and relied on the Blain–Steffee modification for their only adjudicated basis of unpatentability. Dec. 14–15, 59–71. The external-extension limitation is common to the independent claims as analyzed by the Board, and the Decision carried its claim 1 reasoning into claim 11. *Id.* at 23–26, 44.

Both issues also concern recurring standards central to IPR practice: whether “unrebutted” expert testimony may substitute for reasoned proof of a missing structural limitation, and whether typical practice can satisfy inherency’s necessity requirement. Review will reinforce that the statutory burden remains with the petitioner and that the labels “common sense,” “simple,” and “unrebutted” do not relax the evidentiary standards for anticipation or obviousness.

IV. RELIEF REQUESTED

Patent Owner respectfully requests that the Director grant review and vacate the determination that claims 1–6, 11, 12, and 15–17 are unpatentable. The Director should determine that Petitioner failed to prove anticipation of claims 1–4, 6, 11, 12, 15, and 17 and failed to prove obviousness of claims 5 and 16. Alternatively, Patent Owner requests remand for application of the correct inherency, burden, and expert-evidence standards. At a minimum, the Director should vacate the unpatentability determination as to claims 5 and 16 because the record lacks reasoned evidence of the required curved channels in the fusion member.

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Respectfully submitted,

GARTEISER HONEA PLLC

By: /M. Scott Fuller/
M. Scott Fuller
Reg. No. 54,716
119 W. Ferguson Street
Tyler, Texas 75702
Telephone: (903) 705-7420
sfuller@ghiplaw.com

Lead Counsel for Patent Owner

René A. Vazquez
Reg. No. 38,647
SINERGIA TECHNOLOGY LAW
GROUP, PLLC
18296 St. Georges Court
Leesburg, Virginia 20176
Telephone: (703) 989-2244
rvazquez@sinergialaw.com

Back-Up Counsel for Patent Owner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on August 8, 2026, a true and correct copy of PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW OF FINAL WRITTEN DECISION was served by electronic mail on Petitioner's counsel of record at the following addresses:

Stephen D. Zinda (Reg. No. 67,272)
James H. Hall (Reg. No. 66,317)
CABELLO HALL ZINDA, PLLC
801 Travis Street
Houston, Texas 77002
Stephen@CHZFirm.com
James@CHZFirm.com

/M. Scott Fuller/
M. Scott Fuller
Reg. No. 54,716