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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALPHATEC HOLDINGS, INC. and ALPHATEC SPINE, INC.
Petitioners,

v.

NUVASIVE, INC.,
Patent Owner.

Case No. IPR2019-00362
Patent No. 8,361,156

PATENT OWNER PRELIMINARY RESPONSE PURSUANT TO 37 C.F.R. § 42.107

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I. INTRODUCTION

The Petition should be denied because it fails to establish a reasonable likelihood of proving the challenged claims are unpatentable. This is the ***fourth*** petition to challenge the same claims. Petitioners enjoyed years of hindsight (including decades as NuVasive employees) and used prior Board decisions, NuVasive's briefing, and the Federal Circuit's decision as a roadmap for drafting their Petition. Despite this advantage, the present Petition suffers from the same fatal errors that previously led the Federal Circuit to vacate the prior Board decision finding the same challenged claims unpatentable. *In re NuVasive, Inc.*, 842 F.3d 1376, 1383-85 (Fed. Cir. 2016). The Board should exercise its discretion to deny institution instead of rehash the same hindsight-driven arguments that the Federal Circuit already rejected.

Even if considered on the merits, Petitioners' Grounds both fail. Petitioners' argument that "[t]here was nothing new in the '156 patent" (Pet. at 1-2) is contradicted by the content of the Petition, which does not even assert the claims are anticipated (they are not). Moreover, none of the references identified by Petitioner discloses first and second radiopaque markers located respectively in the first and second sidewalls of the spinal fusion implant wherein each marker is located at a position ***proximate to the medial plane*** as required by all claims of the '156 patent. Likewise, no reference identified by Petitioner articulates a

rationale for incorporating this untaught feature into any implant, much less into an implant with the several, remaining claimed features.

Both Grounds 1 and 2 also fail specifically with respect to claim 9. Ground 2 fails because Petitioners ignore the Board's prior findings about the maximum lateral width of a lateral implant as disclosed by Michelson '973, the very reference Petitioners rely upon again here. The Patent Office has repeatedly considered Michelson '973 when evaluating the patentability of claim 18, including during prosecution and in two prior IPRs. When it previously evaluated claim 18 over Frey '550 (Ex. 1040) in view of Michelson '973 (Ex. 1032) and vertebral body dimensions, the Board rejected the argument that a POSA would enlarge the implant to match vertebral body dimensions and instead concluded that a POSA would use the same longitudinal length and maximum lateral width that Michelson'973 disclosed for lateral lumbar implants. The Board thus concluded that a modular member for Michelson's preferred lumbar implant would have a maximum lateral width of, "at most," 13 mm. The Federal Circuit agreed.

Even at the top end of Michelson's width range for a lumbar implant (32 mm), the modular member formed by cutting the implant in half would be at most 16 mm, not approximately 18 mm. Petitioners fail to present any reason why the Board should abandon its earlier reasoning and adopt an inconsistent conclusion;

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