

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 IPR2019-00362
Patent 8,361,156

**PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE PURSUANT
TO 37. C.F.R. § 42.64(c)**

I. STATEMENT OF PRECISE RELIEF REQUESTED

Pursuant to 37 C.F.R. §§ 42.62 and 42.64(c) and the Federal Rules of Evidence, Patent Owner respectfully moves to exclude Exhibits 1053-1056, 1059-1062, and 1065, pursuant to 37 C.F.R. § 42.64(c).

Patent Owner timely objected to exhibits 1053-1056, 1059-1062, and 1065 and reliance thereon. Paper 35.

II. STATEMENT OF REASONS FOR THE RELIEF REQUESTED

A. Exhibits 1053 and 1054 should be excluded for being new evidence used to support new argument

Exhibits 1053 and 1054 were not submitted until after Patent Owner had filed its Patent Owner Response. Petitioner cites these exhibits in support of a *prima facie* case of obviousness raised for the first time in Petitioner's Reply. Such late evidence is improper and may not be used to support a conclusion of obviousness. 2018 Revised Trial Practice Guide ("Petitioner may not submit new evidence or argument in reply that it could have presented earlier, e.g. to make out a *prima facie* case of unpatentability."); *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1370 (Fed. Cir. 2016) ("[W]e find that the Board did not err in refusing the reply brief as improper under 37 C.F.R. § 42.23(b) because IBS relied on an entirely new rationale to explain why one of skill in the art would have been motivated to combine [the prior art references]."). As such,

exhibits 1053 and 1054 are not relevant to the grounds of review. FRE 401; FRE 402.

Petitioner relies on exhibit 1053 for the purpose of filling a gap in the *prima facie* case that Patent Owner identified in its response to the petition. In particular, the petition relies on the modularity concept of Michelson (EX1032) to supply the alleged motivation to modify the primary reference (*i.e.*, Frey or Brantigan) in both Grounds 1 and 2. *E.g.*, Pet. 4-5, 30, 47-48. In its Response, Patent Owner established, *inter alia*, that Petitioner had misapprehended Michelson as disclosing sequential insertion of modular members into the disc space. Patent Owner's experts explained that Michelson describes combining modular components before insertion in the disc space. In Reply, Petitioner does not rebut Patent Owner's evidence. Instead, Petitioner pivots to a new reference, Michelson '770 (EX1053), disclosing insertion of two independent cylindrical implants. Reply at 10 (citing EX1053, 10:10-13, 10:13-16). Other than sharing a common inventor the content of Michelson '770 (EX1053) is separate and unrelated to Michelson (EX1032) that was relied upon in the petition. Indeed, neither the term modular nor the concept of modularity is found in the newly submitted Michelson '770 patent.

Petitioner relies on exhibit 1054 also for the purpose of filling a gap in the *prima facie* case that Patent Owner identified in its response to the petition. In particular, the petition relies exclusively on Baccelli as allegedly illustrating

markers in the medial plane of the implant (central region). Pet. 45 (citing EX1002, ¶199). The petition further asserts without a shred of supporting evidence that a POSA would be motivated to add such markers to other implants (*e.g.*, Frey, Brantigan). Patent Owner established that Petitioner misapprehended the content of Baccelli and that the proffered rationale was based on nothing more than the *ipse dixit* testimony of Petitioner’s expert witness, Dr. Branch. POR 21-26. Patent Owner also established that this rationale was the same as that rejected by the Federal Circuit as being based wholly on hindsight. *Id.* In Reply, Petitioner does not rebut Patent Owner’s arguments and evidence but instead pivots to exhibit 1054 and argues that the “lateral (C) and antero-posterior (D) radiographs of a transversely oriented BAK cage show that POSAs knew the benefits of ‘aligning markers with the spinous process and the lateral ends of the vertebrae’ before the ’334 patent without ‘impermissible hindsight.’”

Exhibit 1053 and 1054 were not cited in the petition materials and do not address the grounds references actually relied upon (*e.g.*, Michelson and Baccelli). As such they are untimely, irrelevant to this proceeding, and more likely to cause confusion and unreasonable prejudice and should be excluded under FRE 401, 402, 403.

B. Exhibit 1055 should be excluded as irrelevant to any issues raised in this case

Exhibit 1055 was filed along with the Petitioner's Reply and is cited at page 5 with no substantive discussion. The significance of this reference is not explained in the briefing nor is it apparent from the document itself. As such, the exhibit is irrelevant and more likely to cause confusion and unreasonable prejudice and should be excluded under FRE 401, 402, and 403.

C. Exhibits 1056, 1059-1061, 1064, and 1065 should be excluded

Exhibits 1056, 1059-1061, 1064 and 1065 represent excerpts of transcripts, declarations, briefing, and other documents. There are numerous bases for exclusion including submission of incomplete documents and irrelevance to this proceeding more likely to cause confusion and unreasonable prejudice than add probative value. As such, these exhibits should be excluded under FRE 106, 401, 402, and 403.

Exhibits 1056, 1059-1061, and 1065 should be excluded as incomplete documents from other legal proceedings. In each instance, Petitioner submitted only select portions – cherry picked to support Petitioner's arguments. Submission of such partial documents is improper as it omits content and information that in fairness should be considered at the same time. FRE 106. Moreover, as the documents originate from other cases they are irrelevant to the present proceeding resulting in confusion and undue prejudice. FRE 401, 402, 403.

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