Paper No. ___
Filed: March 2, 2020

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'S SUPPLEMENTAL SUR-REPLY**

## I. INTRODUCTION

Reply argument based on newly submitted references of Michelson '770 (EX1053) and McAfee (EX1054) is improper and should be treated accordingly.

Reply argument is improperly new where it deviates, or attempts to change, the "thrust" of the challenge set forth in the petition. *In re NuVasive, Inc.*, 841 F.3d 966, 972 (Fed. Cir. 2016) (citing *In re Leithem*, 661 F.3d 1316, 1319 (Fed. Cir. 2011) ("we have relied on the APA's requirements to find a 'new ground' where 'the thrust of the rejection' has changed."). Here, the challenges advanced in the petition relied on modifying Brantigan according the modular assembly in Figs. 18 and 19 of Michelson. Argument or evidence in the Reply that deviates from the modularity described by Michelson, or invites the Board to so deviate, is improper.

Furthermore, it is well established that attempting to fill in the gaps identified by Patent Owner in the *prima facie* case presented in the petition with new evidence and argument is improperly new. *E.g.*, Consolidated Practice Guide at 73 ("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.").

## II. PETITIONER'S ATTEMPTED RETREAT FROM THE "MODULARITY" OF MICHELSON IS IMPROPER

Petitioner repeatedly asserts, throughout the petition materials, that a POSA would have been motivated to modify Brantigan according to the modular embodiment of Michelson (EX1032). *E.g.*, Pet. 14, 72, 74 ("…combined in

modular fashion…"), 69 ("inserting the 'oversized' implant modularly"), 69 ("for insertion in a modular fashion"), 70 ("make the implants modular"), 73 ("Michelson '973 discloses the same modularity concept Brantigan describes"), 75, FN 12 (at least two 18.95 mm implants).

Petitioner's proffered rationale for adopting the modularity of Michelson to the implants of Frey or Brantigan was "to increase patient safety and minimize invasiveness." Pet. 69.

As required by statute, the Board instituted the case set forth in the petition. Paper 18, 33 ("permit[] a single implant to be inserted by a single procedure into the spine"), 33, 34-35 ("more than one spinal fusion implant 1000 may be combined in a modular fashion") 35 ("half the width dimensions for various vertebrae implants based on Brantigan's teaching to make the implants modular ").

The Reply advances several arguments indicating retreat from its previous reliance on the modularity of Michelson as illustrated in Figs. 18 and 19 in numerous respects. For example, the Reply (1) now asserts it never argued sequential insertion of modular members and combination within the disc space. Additionally, the Reply (16) claims Petitioner never suggested an implant up to 37.9 mm wide, as would result from a modular implant of two 18.95 mm wide modules (18.95 + 18.95 = 37.9). While such arguments were advanced previously, NuVasive does not oppose Petitioner's concession of such arguments going

forward. To the extent the Reply offers any argument in replacement, however, it should be rejected as untimely and improperly new.

The Reply (2-5, 6, 13) cites to McAfee (EX1054) and Michelson '770 (EX1053). Neither reference describes a modular implant as in Michelson nor does Petitioner assert otherwise. Instead, the newly cited references present independent cylindrical cages, which the Reply (5, 12) describes as a "side-by-side" arrangement. Neither reference discusses Michelson, the modular embodiment of Michelson, or even recites the term "modular." As such, McAfee (EX1054) and Michelson '770 (EX1053) are irrelevant to the modularity theory described in the petition.

The Board's Order suggests that, to the extent possible, the supplemental briefing address new evidence/argument. The Reply, however, presents no cogent argument as to how these references relate to the petition arguments based on the modularity of Michelson. Whether the modular members are combined prior to insertion as stated in Michelson or inserted sequentially, Petitioner still fails explain how modifying a single implant to a multi-component assembly increases safety and minimizes invasiveness. To the extent Petitioner envisions some pivot away from the modular embodiment of Michelson and toward newly presented "side-by-side" cylindrical cages, none is explained. To the extent Petitioner invites the Board to fashion some new theory on its behalf, that of course is prohibited.

Under the guise of responsiveness, the Reply (4) suggests the newly submitted references clarify the state of the art generally, as well as respond to specific arguments regarding the state of the art. But the Reply (*e.g.*, 1) does not address NuVasive's arguments regarding state of the art either, which are incompletely and inaccurately stated in the Reply. *See also* Paper 37, 3.

Petitioner's expert overstated and exaggerated developments in the field in numerous instances, which called into question the reliability and credibility of the direct testimony. POR 13-19; EX2055, ¶¶36-66. One of several examples of such exaggerations was the assertion that "[b]y the 1990s, the use of non-bone interbody spinal fusion implants had become common place." EX1002, ¶39. Petitioner's own expert conceded during cross-examination that the first such implant he used was one not available until the 2003. EX2022, 20-21, 31-34; EX1002, ¶45.

## III. PETITIONER'S SUBMISSION OF MCAFEE IS A BELATED ATTEMPT TO FILL A VOID IN THE PRIMA FACIE CASE

The petition relied exclusively on Baccelli as teaching the claimed arrangement of radiopaque markers. The petition states that "Baccelli instructs a POSA to include radiopaque markers in the middle of the sidewalls of the implant relative to the direction in which the implant is inserted" Pet. 31. The petition further states, based on Baccelli, that "POSA have found it obvious to position two markers in the middle (widest portion) of Brantigan's sidewalls to allow surgeons

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.