EXHIBIT 18

TO THE DECLARATION OF BRIAN J.
NISBET IN SUPPORT OF DEFENDANTS'
OPPOSITION TO NUVASIVE'S MOTION
FOR PARTIAL SUMMARY JUDGMENT
AND MOTION TO EXCLUDE



UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA - SAN DIEGO DIVISION

| NUVASIVE, INC., a Delaware corporation, |) |
|--|----------------------------------|
| Plaintiff, |) |
| v. |) |
| ALPHATEC HOLDINGS, INC., a Delaware corporation, and ALPHATEC SPINE, INC., a California corporation, |) Case No. 18-cv-00347-MDD-CAB) |
| Defendants. |))) |

REBUTTAL EXPERT REPORT OF JIM YOUSSEF, MD





NUVA ATEC0341114.

- 133. Importantly, the disclosures in the Provisional Application make clear that "implant 10" is intended to be inserted laterally. NUVA_ATEC0020836 (Provisional Application) at FIG. 2. As I discussed in my Implant Opening Report (¶ 99), the receiving aperture 12 in the Figures 2, 3, and 5 of the Provisional Application engages with insertion instrument 20 and defines the distal-proximal direction as the longitudinal length. In addition, the Provisional Application describes "lateral" openings specifically for assessment of the degree of fusion from the "side" perspective of the implant—a POSA would understand that the "side" is the dimension of the implant extending proximally-distally across the disc space.
- 134. As I stated in my Implant Opening Report (¶¶ 92-114, 202-208), the Provisional Application provides sufficient written description for each of the Asserted Claims of the '334 and '156 patents.
- XI. DR. SACHS DOES NOT IDENTIFY ANY PUBLIC USE, SALE, OR OFFER TO SELL OF ANY EMBODIMENT OF THE ASSERTED CLAIMS PRIOR TO MARCH 29, 2003
- 135. Dr. Sachs opines that the NuVasive Cement Restrictor XL/PEEK CR-XL/PEEK CR-X/CoRoent XL implants meets each limitation of the Asserted Claims of the '334 and '156



patents. Sachs Implant Opening Report at ¶¶ 251-292. I agree that these devices do appear to meet the limitations of the Asserted Claims.⁴ However, as in my Opening Implant Report and below, I disagree that Dr. Sachs has pointed to any information indicating that there was a "public use" or a "sale" prior to the priority date applicable to the Asserted Claims.

- 136. First, Dr. Sachs bases his conclusion that the Asserted Claims are invalid (due to prior public use and sale) on his opinion that the Asserted Claims are entitled to a priority date no earlier than March 29, 2005. I disagree for the reasons stated in above and for the reasons stated in my Implant Patent Opening Report. Youssef Implant Opening Report at ¶¶ 91-114, 201-208. Dr. Sachs provides no evidence of a prior public use or sale/offer to sell any device that meets the limitations of the Asserted Claims prior to *March 29, 2003* (*i.e.*, more than one year before the priority date—which in my opinion is the March 29, 2004 filing date of the Provisional Application). Accordingly, for at least this reason, it is my opinion that Dr. Sachs fails to show that the Implant Patents are invalid due to prior public use or sale/offer to sell.⁵
- 137. Second, as detailed above and below, Dr. Sachs has pointed to no evidence that the claimed implant was in public use or the subject of a commercial sale or offer to sell in the United States prior to March 29, 2003 (the relevant date) or even March 29, 2004.

⁵ I note that, Dr. Sachs opines that the Cement Restrictor XL/PEEK CR-XL/PEEK CR-X/CoRoent XL implants were "ready for patenting" before March 29, 2004. Sachs Implant Opening Report at ¶¶ 304-309. I understand from counsel that "ready for patenting" means that the claimed implant was either in use or sufficient preparations had been made by the inventor to enable one of skill in the art to practice the invention. I agree with Dr. Sachs that the claimed implant of the '334 and '156 patent was enabled as of the March 29, 2004 filing date of the Provisional Application.



⁴ Dr. Sachs cites to numerous documents to support his opinion that Cement Restrictor XL/PEEK CR-XL/PEEK CR-X/CoRoent XL are embodying products of the Asserted Claims of the '334 and '156 patents and meet each claim limitation of the '334 and '156 patents. I do not address each document cited because it appears these devices meet the claim limitations.

A. Dr. Sachs Cites No Evidence of Public Use At Any Time

- 138. Dr. Sachs' opinions are flawed at least because he does not identify any evidence of <u>public</u> use. I understand from counsel that to be invalidating, such a use must be public and without confidentiality restriction.
- 139. Dr. Sachs opines that products that meet the limitations of the Asserted Claims were in public use at least as early as December 2003. Sachs Implant Opening Report at ¶ 294. As I stated above and stated in my Implant Opening Report (¶¶ 91-114, 201-208), the priority date for the '334 and '156 patents is March 29, 2004. Thus, Dr. Sachs has not cited any evidence of a public use more than one year before the priority date (*i.e.*, before March 29, 2003).
- 140. At ¶ 299 of his report, Dr. Sachs states that he has not seen evidence that the pre-March 29, 2004 "uses" of the claimed implants that he discusses "were intended to be confidential or experimental." I understand from counsel that it is Alphatec's burden to identify evidence of prior public use, not NuVasive's burden to identify the absence of public use. I disagree with Dr. Sachs that there is no evidence that the pre-March 29, 2004 "uses" were intended to be "confidential or experimental." As discussed above it is clear that Matt Copp's December 5, 2003 email discussed an ALPHA launch, not a commercial launch.
- 141. As discussed above in Section IX., Dr. Sachs cites a number of documents, none of which support his opinion that an implant that meets the limitations of the claims of the '334 and '156 patents was in "public use" more than one year prior to the priority date. I address each document in turn below.

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