

## Medtronic v. NuVasive: Final Written Decision IPR2014-00073

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*Takeaway: Patent Owner was able to persuade the Board that features not specifically described in a priority document were necessarily comprehended in the description based, at least partly, on expert testimony that the described device in the priority document could not work without the alleged missing feature.*

In its Final Written Decision, the Board held that Petitioner demonstrated by a preponderance of the evidence that all of the instituted claims, claims 21, 22, 24, 30, and 33-37, of the '356 patent are unpatentable based on some, but not all, of the grounds upon which trial was instituted. The Petition also challenged claims 25 and 26, but no grounds on those claims were instituted. The '356 patent generally relates to "methods and apparatuses for accessing a surgical target site, such as the lumbar spine, using minimally invasive techniques."

Addressing claim construction, the Board had construed in its Decision to Institute that the "recitations in claim 21 regarding the 'lateral trans-psoas path to the lumbar spine' relate to an intended use of the claimed apparatus." Neither party disputed that interpretation. Accordingly, the Board maintained that those intended use recitations provide no particular structural limitations beyond the ability to be used in a trans-psoas path.

Also, in the Decision to Institute, the Board preliminarily found that the challenged claims of the '356 patent are not entitled to the benefit of the '214 provisional application's filing date. Petitioner had argued that the '214 provisional application "does not provide descriptive support for the blade holder apparatus being 'configured to releasably lock' with the plurality of retractor blades, as recited in claim 21." In response, Patent Owner argued that "based on images and handwritten notations in the '214 [provisional] application, and the supporting testimony of Dr. Phillips, an ordinarily skilled artisan would have understood that the releasably lacking blade holder apparatus recited in claim 21 was adequately described." Citing 35 U.S.C. § 316(e) and *Hyatt v. Boone*, 146 F.3d 1348, 1354-55 (Fed. Cir. 1998), the Board noted that although Petitioner bears the ultimate burden of showing unpatentability, "to establish descriptive support for a claim, 'the written description must include all of the limitations . . . , or the [proponent] must show that any absent text *is necessarily comprehended in the description provided* and would have been so understood at the time the patent application was filed.'"

To show that the missing text *is necessarily comprehended* in the '214 provisional application, Dr. Phillips testified that the nut and bolt assembly in the figures of the '214 provisional application show

the posterior retractor blade is “locked in place on speculum assembly.” Additionally, Dr. Phillips testified that an ordinarily skilled artisan viewing the figures of the ’214 provisional application necessarily would have understood the retractor blades to be releasably lock in place, because there is no evidence mechanism to render the blades permanently locked into place and permanently locking the blades in place would render the device unusable. Petitioner provided no persuasive arguments contradicting Dr. Phillip’s testimony. Accordingly, the Board reversed its earlier determination, and found that the preponderance of the evidence supports a finding that claim 21 of the ’356 patent, and its dependent claims, are entitled to the benefit of the ’214 provisional application.

Based on its finding that the claims of the ’356 patent are entitled to the benefit of the ’214 provisional application, all of the grounds based on “intervening” art were found to not support a finding of unpatentability.

The Board addressed the first of the obviousness grounds of unpatentability not based on a disqualified reference. Petitioner argued that it would have been obvious to equip the dilators and retractor blades of the surgical system in Cistac with the nerve-monitoring electrodes in Kelleher. Petitioner further cited Obenchain as evidence that the trans-psoas path to the lumbar spine was a known surgical approach and Mathews as evidence that it would have been obvious to consider configuring minimally invasive surgical instruments intended for lumbar spine surgery to be dimensioned so as to allow surgical implants to pass through them. Patent Owner argued that these contentions are based on improper hindsight, relying heavily on its expert’s testimony that ordinarily skilled artisans avoided traversing the psoas muscle when performing lumbar spinal surgery. However, the Board had determined that the psoas-traversing pathway recited in the claims was merely an intended use. Accordingly, the Board was not persuaded by Patent Owner’s argument, especially because Patent Owner did not provide any evidence that any feature in the prior art apparatuses would have rendered them unsuitable or unusable in such an approach.

Patent Owner also asserted several objective indicia to show non-obviousness. The Board explained that while it is Patent Owner’s burden to introduce evidence supporting objective indicia, the ultimate burden of persuasion never shifts to Patent Owner. Instead, the objective indicia are considered along with all of the other evidence in making the obviousness determination. However, the Board cited *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) when explaining that “[f]or objective evidence to be accorded substantial weight, its proponent [Patent Owner] must establish a nexus between the evidence and the merits of the claimed invention.” The Board agreed with Petitioner that the evidence provided by Patent Owner was not entitled to substantial weight, because it had not established a sufficient nexus between the claimed subject matter and that evidence.

Patent Owner’s objective indicia included arguments “that its surgical system solved a long felt need, overcame significant skepticism, elicited significant praise and recognition among practitioners in the art as being advantageous as compared to other lumbar surgical techniques, experienced significant commercial success, and was copied by competitors.” The objective evidence was centered on praise for, and success of, its “eXtreme Lateral Interbody Fusion” (XLIF) systems and methods.

First, the Board noted that the Patent Owner Response did not include any specific discussion of how the features of XLIF correspond to the limitation in claim 21, or any of the other challenged claims. Instead, Patent Owner relied solely on its expert’s declaration that included a chart mapping the features to the claims. However, because this was not included in the Patent Owner Response, it was considered improper incorporation by reference, and thus was not considered. Second, the

Board found that even if the expert's mapping were considered, because the secondary considerations were focused on the use of the XLIF technique in a lateral trans-psoas approach, which was an approach that was not required in the claims (merely intended use limitations). Third, the Board agreed with Petitioner that many of the features of the XLIF that led to its success were not claimed.

The Board also assessed Petitioner's motions to exclude certain exhibits. Petitioner argued that one set of exhibits should be excluded as hearsay. The Board agreed with Patent Owner that they were offered for non-hearsay purposes (showing what was being said about XLIF as praise and recognition by the industry, rather than the truth of the matter asserted), and thus the motion was denied with respect to those exhibits. Petitioner further argued that yet another set of exhibits should be excluded as hearsay. Again the Board agreed with Patent Owner that they were offered for non-hearsay purposes (showing industry praise and the states of minds of the declarants). The Board also agreed with Patent Owner that whether the authors of those exhibits are skilled artisans goes to the weight of the evidence, not its admissibility. Thus, the Board denied the motion with respect to these exhibits. The Board dismissed Petitioner's Motion to Exclude other exhibits as moot, because they were not relied on.

***Medtronic, Inc. v. NuVasive, Inc.*, IPR2014-00073**

Paper 48: Final Written Decision

Dated: April 3, 2015

Patent: 8,192,356 B2

Before: Francisco C. Prats, Scott E. Kamholz, and David C. McKone

Written by: Prats

Related Proceedings: IPR2014-00087 (8,005,535); IPR2014-00034 (8,000,782); IPR2014-00074 (8,192,356); IPR2014-00075 (8,016,767); IPR2014-00081 (8,005,535); *Warsaw Orthopedic Inc. v. NuVasive Inc.*, Case No. 3:12-cv-02738-CAB-MDD (S.D. Cal.)

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