

Keywords: Doctrine of obviousness; motivation for the combination of prior art, modification of prior art.

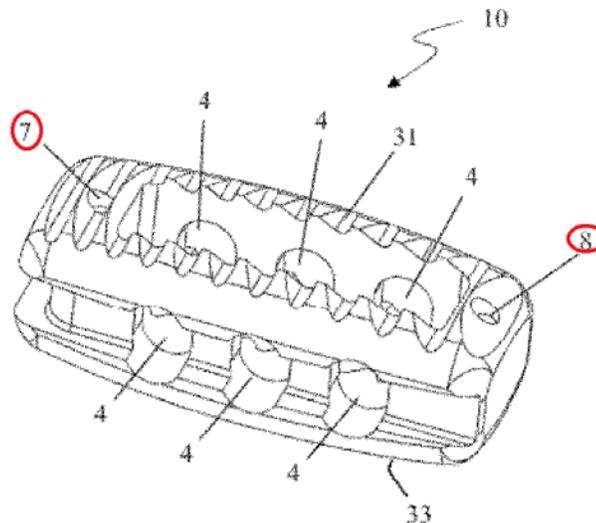
General: A determination of obviousness based on a combination of prior art references must include an “adequately explained findings” as to why a person of ordinary skill in the art would have been motivated to combine and modify the prior art references.

In re: NuVasive, Inc.
(2015-1670 Fed. Cir. 2016)
December 7, 2016

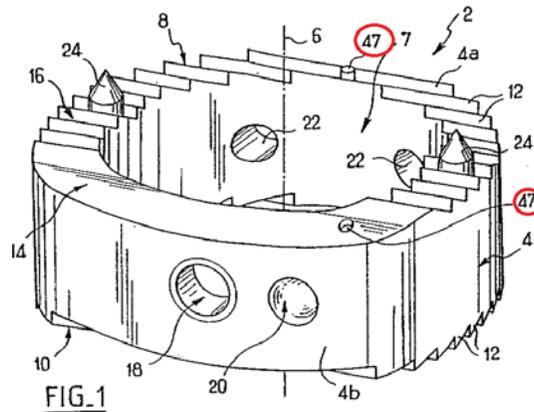
I. Facts and Procedural History

NuVasive, Inc. (hereinafter, “NuVasive”) is the assignee of a patent 8,361,156 (hereinafter, “‘156 patent”) for a spinal fusion implant. The spinal fusion implant as claimed in a single independent claim 1 includes “...at least first and second radiopaque markers oriented generally parallel to a height of the implant, wherein said *first radiopaque marker* extends into said first sidewall *at a position proximate to said medial plane*, and said *second radiopaque marker* extends into said second sidewall *at a position proximate to said medial plane*.” Emphasis added.

One embodiment of the spinal fusion implant with two radiopaque markers labeled ‘7’ and ‘8’ is illustrated below:



The ‘156 patent was challenged by Medtronic, Inc. (hereinafter, “Medtronic”) by initiating inter partes review (IPR) proceedings with the Patent Trial and Appeal Board (PTAB). Medtronic introduced various prior art references, including a U.S. patent publication No. 2003/0028249 (hereinafter, “Baccelli”) that taught a spinal fusion implant with two radiopaque markers labeled ‘47’ shown below.



Medtronic argued that the combination of Baccelli with other submitted references relating to radiopaque markers in implants and marker importance in general rendered the '156 patent obvious. More specifically, Medtronic's alleged that a person of ordinary skill in the art would combine and modify Baccelli to add radiopaque markers proximate to a medial plane because the person of ordinary skill in the art "would have considered it to be common sense" to place radiopaque markers along the medial plane "to provide additional information regarding the orientation or location of an implant." *Medtronic*, 2015 Pat. App. LEXIS 2496, 2015 WL 996352, at *6-7 (citing Medtronic's expert). NuVasive had also argued that in some modifications of the prior art the placement of the radiopaque markers proximate to the medial plane may lead to some confusion. The PTAB agreed with Medtronic and additionally invoked the high level of skill in the art to buttress Medtronic's position, stating that NuVasive's argument against the combination "vastly underestimates the ordinary skill of surgeons in this field." *Id.* NuVasive appealed to the Federal Circuit arguing that the combination of references was improper because the PTAB's Final Written Decision did not adequately explain why a person of ordinary skill in the art would have been motivated to combine the references to place the radiopaque markers proximate to the medial plane.

II. Issues

Did the PTAB adequately provide an explanation for the proposed combination of references?

III. Discussion

No. The Federal Circuit noted that the PTAB must 1) articulate a reason for why a person of ordinary skill in the art would combine and modify the proffered references; and 2) have an adequate evidentiary basis for its finding. The Federal Circuit stated the PTAB improperly relied on Medtronic's statement that the motivation to combine would be to provide for "additional information" to the surgeon, and found that the statement amounted to a cursory statement. The statement was cursory because it lacked an explanation as to why the additional information would benefit a person of ordinary skill in the art, what type of information would be obtained, and how the information would be used.

Further, the Federal Circuit stated that while in *KSR Int'l co. v. Teleflex Inc.*, 50 U.S. 398 (2007), the Supreme Court held that the motivation to combine references need not be found expressly in the prior art but may be explained by a fact finder using common sense, the PTAB cannot solely rely on common sense to support its findings and that common sense cannot be used “as a wholesale substitute for reasoned analysis and evidentiary support.” Additionally, the Federal Circuit stated that the PTAB cannot invoke a high level of skill in the art “as proof positive of its findings” without more.

IV. Conclusion

When combining prior art references, a cursory statement is insufficient. Instead, a reasoned analysis and evidentiary support stating a reason for why a person of ordinary skill in the art would combine and modify the prior art is required. Invoking common sense and/or high level of skill in the art cannot be used as a substitute for the reasoned analysis and evidentiary support.