

***Axonics, Inc. v. Medtronic, Inc.*, 73 F.4th 950 (Fed. Cir. 2023) (Lourie, Dyk, Taranto)**

BY JENNIFER MEYER CHAGNON

Axonics petitioned for IPR of two patents owned by Medtronic. The challenged claims relate to a neurostimulation lead and a method for implanting and anchoring the lead. The patents' "Field of the Invention" section states that "invention relates generally to a method and apparatus that allows for stimulation of body tissue, particularly sacral nerves." The "Summary of the Invention" section, however, "describes the 'present invention' in terms that are not confined to the sacral nerves," and states that "[a]pplication to 'sacral nerve stimulation' is one 'preferred embodiment.'" The claims do not mention and are not limited to sacral nerves.

In the IPRs, the Board found that Axonics had not shown the challenged claims to be unpatentable. The Board determined that Axonics had not demonstrated a sufficient motivation to combine the asserted references. This determination was based, at least in part, on the Board's limitation of the relevant art to "medical leads specifically for sacral neuromodulation." The Board found that one of the asserted references addresses "stimulation of the *trigeminal* sensory root" as opposed to the *sacral* nerve. The Board also found that a skilled artisan would not have been motivated to make the modifications proposed by Axonics to this reference because of space constraints in the trigeminal-nerve region.

On appeal, the Federal Circuit held the Board committed two non-harmless errors. First, the court held that the motivation-to-combine inquiry "is not whether a relevant artisan would combine a first reference's feature with a second reference's feature to meet requirements of the first reference that are not requirements of the claims at issue," but rather "whether a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the *claimed invention*." Thus, the court found that, by limiting consideration of the proposed combination to the trigeminal-nerve context,

the Board adopted a legally incorrect framing of the motivation-to-combine question.

Second, the court held that the Board erred in limiting "the relevant art" to medical leads for sacral-nerve stimulation. The court reiterated that "what constitutes 'analogous art' for section 103 purposes is tied to 'the claimed invention.'" And "[t]he Medtronic patent claims make no reference to sacral anatomy or sacral neuromodulation, and they cannot be properly construed as so limited." The court further determined that no reasonable reading of the specification could limit the relevant field of art to the sacral-nerve context.

Accordingly, the court vacated the Board's final written decisions and remanded for further proceedings.

RELATED:

- *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373 (Fed. Cir. 2023) (Newman, Prost, Hughes) (affirming Board's finding that there was sufficient motivation to combine where the Board identified a known technique to address a known problem using "prior art elements according to their established functions," and clarifying that the known technique only need be a *suitable* option, not necessarily the *best* option).