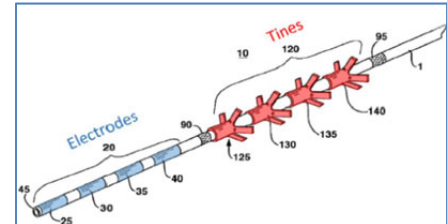


AXONICS, INC. v. MEDTRONIC, INC., Appeal Nos. 2022-1451, 2022-1452 (Fed. Cir. July 10, 2023).
Before Lourie, Dyk, and Taranto. Appealed from the PTAB.

Background:

Medtronic sued Axonics for patent infringement on sacral nerve (located above the tailbone) stimulation devices. Axonics filed for *inter partes* review (IPR) of the patents which claim at least two electrodes at the distal end of the lead with a plurality of tine elements for anchoring where all of the tines are positioned at the proximal side of the lead. Although the Field of Invention describes the invention as relating to stimulating sacral nerves, the claims were not limited to the sacral nerves.



Axonics argued that the claims were obvious based on a combination of Young and Gerber. Young disclosed a single electrode at the distal end of the lead with a plurality of tines for stimulating trigeminal nerves (located in the face). Gerber disclosed a plurality of electrodes at the distal end of the lead for sacral nerve stimulation. Axonics argued that it would have been obvious to replace the single electrode in Young with multiple electrodes in view of Gerber to arrive at the claim features, in order to provide more flexibility in activation of a wider area and possibility of bipolar electrical stimulation as stated in Young.

Medtronic argued, and the Board agreed, that a skilled artisan would not have been motivated to make the Young-Gerber combination because Young's device is for stimulation of trigeminal nerves which have a complex anatomy with very tight space that would not have allowed for a multi-electrode structure, and even if multiple electrodes were used, they would not have been placed all at the distal end of the lead due to the space constraint in the trigeminal nerve region. Axonics appealed.

Issue/Holding:

Did the Board err in its decision that the skilled artisan would not have been motivated to combine Young and Gerber? Yes, vacated and remanded.

Discussion:

The Federal Circuit said that the Board adopted a legally incorrect framing of the motivation-to-combine inquiry when it confined the inquiry to whether the Young-Gerber combination would work in the trigeminal nerve region. The trigeminal nerve region is not part of the claims. The proper inquiry is whether the skilled artisan would have been motivated to make the Young-Gerber combination to arrive at the claims' actual limitations, which are not limited to stimulating trigeminal nerves or sacral nerves. There is no evidence that the space constraint of the trigeminal nerve region exists in the context covered by the claims including the sacral nerve region.

The Federal Circuit also mentioned that the Board's motivation inquiry makes little sense given the Board's definition of the skilled artisan as a person in the "relevant art" of medical leads specifically for sacral neuromodulation. Such an artisan, focused on the sacral nerve region, would hardly read Young only for what it expressly teaches in the trigeminal nerve region but instead would consider how the features of Young and Gerber would apply in the sacral nerve region. The Federal Circuit also briefly noted that the Board erred in its definition of the relevant art as limited to the medical leads for sacral-nerve stimulation because the claims make no reference to sacral anatomy or sacral nerves, and the specification does not clearly limit the invention to such context.