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Context Matters

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The Court of Appeals for the Federal Circuit recently decided *Axonics, Inc. v. Medtronic, Inc., 2022-1451, 2022-1452, (July 10, 2023)* (Appeals taken from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2020-00715, and IPR2020-00679), a precedential case considering the appropriate inquiry to be performed with regard to the motivation to combine reference teachings in an analysis under 35 USC 103.

At issue were various claims of U.S. Patent Nos. 8,626,314 and 8,036,756, issued to Medtronics (the 'Medtronics patents') and generally directed to a neurostimulation lead, and implantation/anchoring of the neurostimulation lead. While the Medtronics patents discussed use of the lead in connection *with sacral nerves*, none of the claims were so limited.

In the IPRs, the Court noted that the PTAB disagreed with Axonics' position that the Medtronics claims were unpatentable for obviousness "…*Axonics failed to show that a relevant artisan would have had a motivation to combine the teachings of [the prior art] and the Board rested that finding on its determination that the proposed combination 'would not be feasible in the trigeminal nerve region…'[the context with which the cited art was concerned]*…" *Axonics* at 9. Emphasis added.

On appeal, the CAFC found that "…*the Board committed a fundamental legal error in confining the motivation inquiry to whether a motivation would exist to make the proposed combination for use in [the specific context of the prior art] to which the Medtronic patents are not limited. Second, the Board was incorrect in its view that 'the relevant art is medical leads specifically for sacral neuromodulation'…as the Medtronic patents' claims are not limited to the sacral-nerve context and the shared specification, properly read, is not so limited either*…" *Axonics* at 12. Emphasis added.

The CAFC clarified that "…*the motivation-to-combine portion of the [obviousness] inquiry is 'whether a skilled artisan would have been motivated to combine the teachings…to achieve the claimed invention'."* The Court went on to explain that "…*The 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.*" In fact, the Court added, "*the real question is why a person of ordinary skill in the art would have combined elements from specific references in the way the claimed invention does*…" Id. Emphasis added.

The Court thus concluded that "…*The Board adopted a legally incorrect framing of the motivation-to-combine question when it confined the inquiry to whether a motivation would exist to make the Gerber-Young combination for use in the Young-specific trigeminal-nerve context. That context is not part of the Medtronic patents' claims. The proper inquiry is whether the relevant artisan would be motivated to make the combination to arrive at the claims' actual limitations, which are not limited to the trigeminal-nerve context*." *Axonics* at 13. Emphasis added.

Notably, the Court also found that "…*Neither the Board nor Medtronic has cited any authority for treating the relevant art as limited to a narrow subset of what the claims of a patent cover—a conclusion that would risk curtailing prior-art analysis of a claim to less than its exclusive-rights-protecting scope. And we have repeatedly ruled that what constitutes "analogous art" for section 103 purposes is tied to*

*"the claimed invention." See Sanofi-Aventis Deutschland GmbH v. Mylan Pharmaceuticals Inc., 66 F.4th 1373, 1377–78 (Fed. Cir. 2023) (citing and quoting cases)."*Axonics at 14. Emphasis added.

The *Axonics* decision, while unfavorable to the patentee due to its finding that the PTAB erred in making a determination that the claims of the Medtronics patents were not obvious, nonetheless provides some useful guidance to prosecution counsel when dealing with Examiner allegations that prior art teachings would be obvious to combine because the combination would purportedly achieve some improvement in the context of one or the other of the cited references.

Rather, as *Axonics* makes clear, the proper inquiry is whether the relevant artisan would be motivated to make the combination to arrive at the claims' actual limitations – that is, the real question is why a person of ordinary skill in the art would have combined elements from specific references in the way the claimed invention does.