FEDERAL CIRCUIT CALLS FOUL ON "SANDBAGGING" AT THE PTAB IN AXONICS V. MEDTRONIC

Joshua A. Zuchniarz* * * *

Introduction

One of the first features of the U.S. legal system taught to law students is the existence of different standards of review on appeal. Questions of law are reviewed de novo; questions of fact are reviewed for clear error. The procedural choices of the judge below are reviewed under the most lenient standard: abuse of discretion.

How far does discretion stretch before it is abused? Last August, as part of a long-running dispute between healthcare technology firms Axonics and Medtronic, the Federal Circuit provided an answer: openly ignoring a litigant's response to the other party's arguments will result in vacatur for abuse of discretion. In doing so, the court illustrated how judges should privilege the strong public policy interest in maintaining the fundamental fairness of the justice system, even when they are not formally required to do so.

In Part I of this Case Note, I briefly discuss the context of the dispute between Axonics and Medtronic and a recent outcome in their proceedings before the Patent Trial and Appeal Board (PTAB). Then, in Part II, I lay out the abuse of discretion standard and the result of <u>Axonics, Inc. v. Medtronic, Inc.</u> (Fed. Cir. 2023). Part III argues that the Federal Circuit got it exactly right, by safeguarding fundamental fairness even when the letter of the law perhaps didn't require it. Finally, Part IV offers a few concluding remarks, including advice to litigants in view of this ruling.

I. The Patent Fight Over Sacral Nerve Stimulators

In 2011, Medtronic received a <u>patent</u> for an implantable nerve stimulation device. Medtronic took advantage of its legal monopoly to market the invention as a sacral nerve modulator (SNM) to treat incontinence. By 2019, over <u>300,000</u> people had received an implant, and <u>millions</u> more had the potential to benefit from the same treatment.

Medtronic's competitors took notice. One competitor, Axonics, began <u>developing</u> its own SNM. In 2019, Axonics received <u>FDA</u>

^{*} Dr. Joshua Zuchniarz is a J.D. Candidate at the University of Chicago Law School, Class of 2025. He thanks Georgia Huang, Natalie Cohn-Aronoff and the entire *University of Chicago Law Review Online* team for productive comments and suggestions.

<u>approval</u> to market its product in the United States. In response, Medtronic <u>sued</u> Axonics for patent infringement, asserting multiple SNM patents. Axonics then <u>petitioned</u> the PTAB to review the validity of seven of Medtronic's patents via inter partes review.

Inter partes review (IPR) is an administrative proceeding that a third party can initiate in front of the PTAB to challenge the validity of a patent after it has issued. PTAB judges are <u>administrative patent</u> judges, not Article III judges, and the Board's procedures are ultimately governed by the <u>Administrative Procedure Act</u> (APA). The procedures of an IPR differ from those of district court litigation. First, the challenger files a <u>petition</u> to institute an IPR. The patent owner may file a <u>preliminary response</u> to the petition. Next, the Board issues an <u>institution decision</u>. This is analogous to a decision on a motion to dismiss for failure to state a claim. A decision not to institute an IPR does *not* <u>preclude</u> the challenger from raising the same invalidity arguments later in district court.

If the Board decides to institute an IPR, the patent owner may file a <u>response</u>. The challenger can reply, and finally the patent owner can sur-reply. Importantly for the Axonics dispute, <u>replies and surreplies</u> are not to contain new evidence or arguments. The Board then issues a final invalidity <u>decision</u>, which is appealable to the Federal Circuit. If the Board finds that the challenged patent claims are not invalid, the challenger will be <u>estopped</u> from raising the same grounds of invalidity in future litigation. That is, a party who chooses to challenge a patent's validity through IPR assumes the risk that they will never be able to have a full hearing on the merits of invalidity in district court.

Last year, the PTAB considered Axonics' <u>challenge</u> to claims in two of Medtronic's SNM patents. Axonics <u>asserted</u> in its petition that the claims at issue were invalid as anticipated by several earlier patents. Axonics' <u>petition</u> adopted a certain construction—or interpretation—of the claims in the Medtronic patents, and Medtronic did not dispute that claim construction in its <u>preliminary response</u>. The Board decided to <u>institute</u> a review.

At that point, Medtronic suddenly took a new tack, arguing in its <u>response</u> for a different claim construction. As such, it was only in the <u>reply</u> that Axonics was able to address the new Medtronic claim construction for the first time. Axonics maintained that its own claim construction was correct but also argued, in the alternative, that even if the Board adopted Medtronic's construction the patent claims would be invalid. In support, Axonics filed <u>new expert testimony</u>. Medtronic <u>sur-replied</u>, contending that Axonics' arguments under Medtronic's claim construction were improper new arguments for different grounds of invalidity. Medtronic further complained that it was prejudiced by Axonics' attempt to introduce new expert testimony, because it did not have an opportunity to submit expert testimony in response.

The Board adopted Medtronic's new claim construction. The Board also agreed with Medtronic that Axonics' reply contained improper new arguments, and the Board pointedly "[did] not give . . . weight" to those arguments or to Axonics' new expert testimony. In support of its ruling, the PTAB cited the Supreme Court's admonition that the petition is "supposed to guide the life of the litigation." Because Axonics, in its petition, "had an adequate opportunity to assess [Medtronic's patents] and to understand that [they] disclosed support for [Medtronic's preferred construction]" but did not raise those arguments, Axonics forfeited the right to make them later. Axonics' "apparent misapprehension of what is disclosed in [Medtronic's patents] does not afford [Axonics] the opportunity to present new arguments in Reply." The Board then held that Axonics had failed to show that Medtronics' patent claims were invalid. Axonics appealed, arguing that the Board erred in refusing to consider the merits of its arguments.

II. Abuse of Discretion and Axonics v. Medtronic at the Federal Circuit

On <u>appeal</u> (not to be confused with an <u>earlier disposition</u> of the same name), a panel of the Federal Circuit noted that PTAB determinations concerning the proper scope of a reply are reviewed for abuse of discretion. The Federal Circuit's position raises two questions: First, what does "abuse of discretion" mean to the Federal Circuit? Second, did the PTAB abuse its discretion in this case?

Abuse of discretion is a murkier standard than the name implies. As Judge Henry Friendly once put it: "There are a half dozen different definitions of 'abuse of discretion,' ranging from ones that would require the appellate court to come close to finding that the trial court had taken leave of its senses to others which differ from the definition of error by only the slightest nuance."¹ Part of the difficulty of defining the boundaries of this standard of review is that a finding of abuse of discretion is extraordinarily rare: one study found only nine

¹ Henry J. Friendly, *Indiscretion About Discretion*, 31 EMORY L.J. 747, 763 (1982).

instances of reversal for abuse of discretion across two years and 2,025 total decisions at the Second Circuit.²

A more fundamental source of the confusion, however, is that abuse of direction really serves as an umbrella term for several different standards. The Federal Circuit finds <u>abuse of discretion</u> when a decision is "(1) clearly unreasonable . . . [or] (2) is based on an erroneous conclusion of law," among other tests that are irrelevant here.

Back to *Axonics*: the Federal Circuit focused on the second prong of the abuse of discretion test, and distilled a rule from its precedents that "under the APA, when the Board adopts a new claim construction following institution, an IPR petitioner must have adequate notice and an opportunity to respond to the new construction." The Federal Circuit also consulted the text of the APA, which requires administrative agencies in a formal adjudication to "give all interested parties opportunity for . . . the submission and consideration of facts [and] arguments." The court concluded, as a matter of law, that when a patent owner proposes a claim construction for the first time in its response, "a petitioner must be given the opportunity in its reply to argue and present evidence . . . under the new construction." This opportunity is not unlimited: the Federal Circuit's precedents that prevent petitioners from relying on new prior art in replies remain good law. Nevertheless, since Axonics had not been allowed to argue or present evidence under the new construction, the Board's procedural decision was founded in legal error and thus it abused its discretion.

III. The Sandbagging Problem

The Federal Circuit's decision in *Axonics* is plainly correct: the Board's myopic focus on <u>the trial practice regulations</u>' instruction that replies not contain new arguments or evidence contravened the <u>specific</u> <u>requirements</u> of the APA and ignored the importance of notice and opportunity to be heard. The Board even overlooked its own power, conveniently located in a nearby <u>provision</u>, to "waive or suspend" the ordinary trial practice requirements as appropriate. Correcting that mistake was important—both for reasons the *Axonics* court discusses and for fundamental fairness.

² See Jon O. Newman, A Study of Appellate Reversals, 58 BROOK. L. REV. 629, 632, 635 (1992).

The Axonics court was concerned, as a matter of public policy, with "sandbagging."³ Basically, the court fears a scenario where patent owners spring a new claim construction on petitioners after the Board decides to institute an IPR. Under the Board's position in Axonics, the patent owner who does so would have an enormous advantage: if the patent owner convinces the Board to adopt their claim construction, they can evade the merits of the petitioner's argument simply because no new arguments are allowed in the reply. The patent owner would then receive a decision in their favor and the petitioner would be precluded under 35 U.S.C. § 315(e) from raising the same grounds of invalidity in court, and thus from ever having the merits of their arguments considered. Creating an incentive for patent owners to dissemble about the arguments they intend to make is bad policy. Such "gamesmanship" defeats one of the core purposes of U.S. civil procedure: preventing "trial by ambush" because, as Justice Lewis Powell once said, it "well may disserve the cause of truth."

There are other prudential and equitable reasons that the Federal Circuit's decision was necessary. First, the Board's confidence that Axonics received a fair opportunity in their petition to anticipate and rebut Medtronic's arguments is entirely misplaced. An IPR petition is subject to a 14,000-word <u>limit</u> and often the petitioner must explain the contents of several patents to support their invalidity arguments. Incentivizing petitioners to mention and attempt to rebut every plausible claim construction would force them to waste time and money developing many dead-end arguments to avoid forfeiture. The patent owner is ill served as well, since they would necessarily receive a less developed version of the petitioner's best arguments.

Second, such a rule is inefficient at producing useful information. The point of pretrial disclosure is to encourage the parties to reveal information they have relevant to the dispute. Demanding that the petitioner anticipate the patent owner's preferred arguments is not simply a matter of "understanding" what a patent "discloses," as the <u>Board</u> would have us believe. Counsel are not neutral truth seekers who can find the One True Claim Construction if they are simply perceptive enough. Choosing to argue one claim construction over another, like any other strategic choice in litigation, is a balancing of the client's interests with the strength of the legal arguments. A patent owner's counsel (hopefully) has the information necessary to make that determination; petitioner's counsel does not.

 $^{^3}$ The Merriam-Webster definition provides: "sandbag [(v.)] . . . : to conceal or misrepresent one's true position, potential, or intent especially in order to gain an advantage over."

Finally, the Board's preferred interpretation impairs the procedural fairness and accessibility of the justice system. There is surely some tradeoff between administrative efficiency and letting litigants occasionally introduce new matter late in the process. But our system of justice has already resolved this tradeoff against the Board's position—parties who "did not have an adequate opportunity or incentive to obtain a full and fair adjudication in the initial action" should, in general, be allowed to raise the issue again.⁴ Further, the Board's position lays yet another trap for the unwary in an already arcane process. We should worry about procedural rules that heavily advantage the well-advised, and thus tend to make adjudications turn less on merit than on ability to pay able counsel. And finally, public respect for adjudication depends in part on the intuitive fairness, to say nothing of intelligibility, of the rules to average people. Perhaps it is naïve to expect that the legal system be an even playing field for everyone regardless of the quality of counsel that one can afford, but it is downright mean-spirited to ask the average person to apprehend that success at the PTAB means reading your opponent's mind. Such a defect undermines the legitimacy of the system.

Conclusion

The Federal Circuit got *Axonics* right and defended core values of our system of justice in the process. Dishearteningly, this is not the first time they have had to weigh in on this precise issue. On <u>three</u> <u>other occasions</u> in the last seven years, the Federal Circuit has had to restrain the PTAB from adopting a claim construction and then barring one (or <u>both</u>!) litigants from mounting an effective response. Perhaps a vacatur for abuse of discretion will finally get the message across to the Board that it cannot deprive litigants of adequate procedure. In any case, litigants themselves should be on notice that the appellate court will not countenance sandbagging, so they are better off fighting fair from the start.

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⁴ RESTATEMENT (SECOND) OF JUDGMENTS: EXCEPTIONS TO THE GENERAL RULE OF ISSUE PRECLUSION § 28 (Am. L. INST. 1982).