

**United States Court of Appeals
for the Federal Circuit**

AXONICS, INC.,
Appellant

v.

MEDTRONIC, INC.,
Appellee

2022-1532, 2022-1533

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2020-00680, IPR2020-00712.

Decided: August 7, 2023

AARON MATTHEW NATHAN, Tensegrity Law Group LLP, McLean, VA, argued for appellant. Also represented by AZRA HADZIMEHMEDOVIC, SAMANTHA A. JAMESON, STEPHEN SHAHIDA; WILLIAM P. NELSON, MATTHEW D. POWERS, Redwood Shores, CA.

NAVEEN MODI, Paul Hastings LLP, Washington, DC, argued for appellee. Also represented by QUADEER AHMED, CHETAN BANSAL, STEPHEN BLAKE KINNAIRD, ALEXA LOWMAN.

Before LOURIE, DYK, and TARANTO, *Circuit Judges*.

DYK, *Circuit Judge*.

Appellant Axonics, Inc. appeals two *inter partes* review (“IPR”) determinations. The Patent Trial and Appeal Board held, in relevant part, that Axonics had failed to show that claims 1, 5, and 9 of U.S. Patent No. 8,457,758 (“758 patent”) and claims 3–6, 9–12, and 15–18 of U.S. Patent No. 8,738,148 (“148 patent”), in patents owned by Medtronic, Inc., were unpatentable as anticipated or obvious. In each final written decision, the Board adopted a claim construction first presented in the patent owner’s response after the institution decision and declined to consider Axonics’ reply arguments and evidence under the new claim construction. We hold that the Board’s refusal to consider the new arguments and evidence was erroneous, and we vacate and remand for the Board to consider the merits of Axonics’ responsive arguments and evidence under the new claim construction.

BACKGROUND

I

The ’758 and ’148 patents, which share a specification, relate to the transcutaneous (i.e., through the skin) charging of implanted medical devices. This charging occurs by inductive coupling, whereby energy is transferred between a primary coil in the external charger and a secondary coil in the implanted device when the two coils are placed in proximity to each other. The patents seek to improve charging efficiency by automatically varying the power output of the external charger based on various measured parameters of the current passing through the implanted device. For example, in one embodiment, the charger would decrease its charging power “if the voltage across rechargeable power source 24” in the implanted device is over 4.05 volts, J.A. 242 (’758 patent, col. 21, ll. 56–57)

(emphasis omitted); the charger would also decrease its charging power if the voltage is less than 4.05 volts but “the charging current through rechargeable power source 24 is over a current rate” of 50 milliamperes, J.A. 242 (’758 patent, col. 21, ll. 63–64) (emphasis omitted).

The patent claims at issue here require the power of the external charger to be automatically varied based on (in the language of claim 1 of the ’758 patent) a “value associated with [the] current passing through [the] internal power source” and a “measured current associated with [the] current passing through [the] internal power source.” J.A. 242 (’758 patent, col. 22, ll. 41–46). As discussed later, the parties have disagreed as to the meaning of these two clauses and whether a single disclosure, e.g., a measured charging current over 50 milliamperes, could satisfy both limitations. The parties agree that claim 1 of the ’758 patent is representative:

1. A system for transcutaneous energy transfer, comprising:
 - an implantable medical device having componentry for providing a therapeutic output, said implantable medical device having an internal power source and a secondary coil operatively coupled to said internal power source, said implantable medical device adapted to be implanted in a patient; and
 - an external power source having a primary coil, said external power source providing energy to said implantable medical device when said primary coil of said external power source is placed in proximity of said secondary coil of said implantable medical device and thereby generating a current, having a value, passing through said internal power source:

wherein said external power source automatically varies its power output based on a value associated with said current passing through said internal power source;

wherein said external power source automatically varies its power output based on a measured current associated with said current passing through said internal power source.

J.A. 242 ('758 patent, col. 22, ll. 25–46) (emphasis added). We refer to the two “wherein” limitations as the “value” limitation and the “measured current” limitation.¹

II

Axonics filed two IPR petitions challenging claims of the '758 and '148 patents as anticipated by three prior art references: Schulman (U.S. Patent No. 3,942,535), Fischell,² and Baumann (U.S. Patent No. 6,227,204). Given the parties' agreement that claim 1 of the

¹ Each challenged claim in this appeal includes (or depends from an independent claim that includes) two “wherein” clauses similar to those present in claim 1 of the '758 patent, requiring the power of the external power source to be automatically varied (1) based on a “value” associated with the current passing through the internal power source, and (2) based on a specific kind of value, e.g., a “measured current,” J.A. 242–44 ('758 patent, claims 1, 5, & 9), a “signal,” J.A. 272–74 ('148 patent, claims 3, 9, & 15), or a “measured voltage,” J.A. 272–74 ('148 patent, claims 6, 12, & 18), associated with or proportional to the current.

² R.E. Fischell et al., A Long-Lived, Reliable, Rechargeable Cardiac Pacemaker, *in* *Advances in Pacemaker Technology* 357–82 (M. Schaldach et al. eds. 1975).

'758 patent is representative, we focus on the '758 IPR and the treatment of claim 1 in that proceeding.³

In its petition, Axonics did not propose an express construction of any claim term. But in its claim charts, the petition adopted a construction of the two “wherein” clauses, stating that “[i]t is . . . clear that the second wherein clause simply narrows the ‘value’ of the first

³ The '758 petition challenged claims 1, 5, and 9 (the only claims of the '758 patent that Axonics still challenges on appeal) as independently anticipated by Schulman, Fischell, and Baumann. The petition had originally challenged all of the claims of the '758 patent (claims 1–12), but following the institution decision, Medtronic disclaimed claims 3, 7, and 11. The petition had also challenged claims 2, 4, 6, 8, 10, and 12 as anticipated by Baumann or obvious over a combination of Baumann and either Schulman or Fischell.

The '148 petition initially challenged all of the claims of the '148 patent (claims 1–18), but, following the institution decision, Medtronic disclaimed claims 1–2, 7–8, and 13–14. Axonics continues to challenge on appeal all of the remaining claims on the grounds asserted in the '148 petition. The petition, as relevant here, asserted anticipation grounds based on Schulman (claims 3–6, 9–12, and 15–18) and Fischell (claims 3–4, 9–10, and 15–16), but not Baumann, and also challenged certain claims (5–6, 11–12, and 17–18) as obvious over a combination of Fischell and another reference, U.S. Patent No. 3,888,260 (“Fischell '260”). Axonics continues to assert obviousness based on Fischell and Fischell '260 for the '148 patent. As to the obviousness ground, the same question as in the anticipation grounds is central—whether the prior art reference (here, Fischell) discloses the two “wherein” limitations.

wherein clause to ‘measured current,’ and does not require a separate measurement.” J.A. 301 (comparing the claim with Schulman); J.A. 317–18 (same with respect to Fischell); *see also* J.A. 338 (same with respect to Baumann). Axonics thus adopted a “one-input” claim construction under which both “wherein” limitations could be satisfied if the external power source automatically varied its power output using a single input based on the current in the implanted device. Under the implicit one-input claim construction, Axonics argued that Schulman, Fischell, and Baumann disclosed the two “wherein” limitations because each prior art reference disclosed varying the power output of an external charger based on some parameter of the current in the implanted device.

Medtronic filed a preliminary response to the petition arguing that Axonics had failed to show that Schulman, Fischell, and Baumann disclosed an input anticipating the “wherein” limitations under the one-input construction. In addressing Axonics invalidity arguments, Medtronic agreed that “the Board need not construe any terms because . . . construction is unnecessary to resolve any underlying controversy.” J.A. 509.

Following the parties’ lead, the Board, in its institution decision, agreed that “no term requires express construction.” J.A. 609. Indeed, the Board explicitly noted that “Patent Owner does not yet dispute Petitioner’s contention that the measured current limitation only narrows the [value] limitation.” J.A. 621. On the merits of Axonics’ invalidity arguments under the one-input construction, the Board found Axonics had shown a reasonable likelihood of prevailing and granted institution.

After the Board’s institution decision, Medtronic, in its patent owner response, for the first time advanced a claim construction that each of the two “wherein” clauses in the challenged independent claims required a separate input

(what we will refer to as the “two-input” construction). Under the two-input construction, a “measured current” that satisfied the second “wherein” clause could not also qualify as a “value” for purposes of the first “wherein” clause. In other words, the first “wherein” clause required a second “value,” other than the value of the “measured current” of the second “wherein” clause. Arguing almost exclusively under the two-input construction, Medtronic contended that the petition had not identified two separate inputs in any of the prior art references. In some respects, Medtronic went further and argued that Axonics could not have made such a showing, because the prior art references in fact did not teach two separate inputs.⁴ Unlike the preliminary response, the final response largely abandoned the argument that the petition had failed to show the prior art references satisfied the one-input construction.

In Axonics’ reply, it continued to defend the one-input construction. But Axonics also argued, under Medtronic’s new two-input construction, that each of Schulman, Fischell, and Baumann disclosed two separate inputs that would satisfy the two “wherein” limitations. In support, Axonics submitted a supplemental expert declaration. Both the reply and the supplemental expert declaration cited additional disclosures in the prior art references pertaining to the same embodiments relied on in the petition.

Medtronic filed a sur-reply continuing to argue the prior art references did not disclose two separate inputs and also arguing it would be prejudicial for the Board to

⁴ For example, Medtronic argued that “Schulman teaches that the magnetic output signal is used as the *sole* input used to regulate the external power source.” J.A. 713; *see also* J.A. 715 (“Indeed, Fischell teaches that it is this frequency modulated signal that is used as the sole input to regulate the external power source.”).

consider Axonics' new reply arguments without providing Medtronic an opportunity to submit its own supplemental expert declaration. Medtronic did not seek leave to submit a supplemental expert declaration in support of its sur-reply.

III

In the final written decision, the Board adopted the two-input construction, concluding that the one-input construction would have rendered the first "wherein" limitation superfluous. The Board then refused to consider Axonics' anticipation arguments and evidence under the two-input construction.⁵ The Board found that Axonics had not identified anywhere in the petition that the two-input anticipation arguments had originally been made and, for that reason, considered them to be improper reply arguments. The Board explained that, before filing the petition, "Petitioner had an adequate opportunity to assess the '758 patent and to understand that it disclosed support for two separate measurements, but failed to do so." J.A. 36. Although the Board agreed that "Petitioner may respond to arguments raised in the Patent Owner Response in its Reply," the Board concluded that a reply "may not offer an entirely new rationale based on a new combination of elements in the asserted references to show unpatentability based on what amounts to a new ground not set forth in the Petition." J.A. 36.

Axonics appeals. We have jurisdiction under 35 U.S.C. § 141(c) and 28 U.S.C. § 1295(a)(4)(A).

⁵ In the '148 IPR, the Board declined to consider Axonics obviousness arguments on the same grounds.

DISCUSSION

On appeal, Axonics does not argue the Board erred in adopting the two-input claim construction, only that the Board erred in refusing to consider Axonics' reply arguments and evidence under the two-input construction.

We review a determination by the Board that, under the Board's own regulations, a party exceeded the scope of a proper reply for abuse of discretion. *Apple Inc. v. Andrea Electronics Corp.*, 949 F.3d 697, 705 (Fed. Cir. 2020). "An abuse of discretion is found if the decision: (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact finding; or (4) involves a record that contains no evidence on which the Board could rationally base its decision." *Ericsson Inc. v. Intellectual Ventures I LLC*, 901 F.3d 1374, 1379 (Fed. Cir. 2018) (citation omitted). We review the Board's compliance with the procedural requirements of the Administrative Procedure Act ("APA") de novo. *Sirona Dental Sys. GmbH v. Institut Staumann AG*, 892 F.3d 1349, 1352 (Fed. Cir. 2018); 5 U.S.C. § 706(2)(D) ("The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . without observance of procedure required by law.").

An IPR is an expedited administrative procedure, driven by the invalidity theories presented in a petition. As the Supreme Court has explained, "the petitioner's petition . . . is supposed to guide the life of the litigation [in an IPR proceeding]." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018). By creating the IPR procedure, "Congress chose to structure a process in which it's the petitioner . . . who gets to define the contours of the proceeding." *Id.* at 1355. An IPR proceeds "in accordance with or in conformance to the petition," *id.* at 1356 (internal quotation marks, modification, and citation omitted), and "the petitioner's

contentions . . . define the scope of the litigation all the way from institution through to conclusion,” *id.* at 1357.

Under the statute, a petition is required to identify “in writing and with particularity . . . the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim.” 35 U.S.C. § 312(a)(3); *see also Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016). According to patent office guidance, a petitioner “may not submit new evidence or argument in reply that it could have presented earlier, e.g. to make out a prima facie case of unpatentability.” U.S. Patent Trial and Appeal Board, Consolidated Trial Practice Guide 73 (Nov. 2019).

However, under the Board’s rules and consistent with the Supreme Court’s decision in *SAS*, a petitioner is entitled to respond to new arguments made in a patent owner response. The rules provide that the petitioner may “respond to arguments raised in the corresponding opposition, patent owner preliminary response, or patent owner response.” 37 C.F.R. § 42.23(b). “As we have regularly held, the petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner.” *Apple*, 949 F.3d at 706–07 (internal quotation marks and citation omitted).

The Board’s rules do not address the specific question presented here: whether, where a patent owner offers a new claim construction for the first time in its response after the institution decision, a petitioner may introduce new arguments and evidence in reply under the newly proposed claim construction. There is no rule, for example, requiring a petition to describe all possible or reasonable claim constructions and to present invalidity theories under those constructions.

In a formal adjudication under the APA, such as an IPR proceeding, the Board must inform the parties of “the matters of fact and law asserted,” 5 U.S.C. § 554(b)(3), and “give all interested parties opportunity for . . . the submission and consideration of facts [and] arguments,” *id.* § 554(c). The Board must also permit parties “to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts.” *Id.* § 556(d); *see Fanduel, Inc. v. Interactive Games LLC*, 966 F.3d 1334, 1339 (Fed. Cir. 2020). Thus, in an IPR proceeding, “the Board must base its decision on arguments that were advanced by a party, and to which the opposing party was given a chance to respond.” *Rovalma, S.A. v. Bohler-Edelstahl GmbH & Co. KG*, 856 F.3d 1019, 1027 (Fed. Cir. 2017) (citation omitted).

Despite the Supreme Court’s admonition in *SAS* that the petition “is supposed to guide the life of the litigation,” 138 S. Ct. at 1356, we have specifically held that, under the APA, it is permissible for the Board to adopt a new construction, proposed either by the patent owner or by the Board itself, in a final written decision.⁶ But before the

⁶ *See WesternGeco LLC v. ION Geophysical Corp.*, 889 F.3d 1308, 1328 (Fed. Cir. 2018) (“[T]he Board was permitted to issue a new construction in the final written decision given that claim construction was a disputed issue during the proceedings . . . [and] is not bound to adopt either party’s preferred articulated construction of a disputed claim term.”); *Praxair Distribution, Inc. v. Mallinckrodt Hospital Prods. IP Ltd.*, 890 F.3d 1024, 1034 (Fed. Cir. 2018) (affirming the Board’s decision to adopt a claim construction for the first time in the final written decision where “the parties litigated the meaning and relevance of the [disputed] term . . . and the Board resolved the

Board decides a case under a construction adopted after the institution decision, it must give a petitioner an opportunity to respond to the new construction, whether that construction was first proposed by the patent owner or the Board.⁷

In this court’s decision in *SAS*, both parties had agreed to the claim construction adopted by the Board in the institution decision, but the Board, without notice, adopted a different construction in the final written decision. *SAS Inst., Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1351 (Fed. Cir. 2016), *rev’d on other grounds sub nom. SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348. We rejected the Board’s reasoning that its approach was permissible “because [the petitioner] could have made construction arguments for the term in its IPR petition,” *id.*, a justification similar to the one adopted by the Board in this case. *See* J.A. 36 (“Petitioner had an adequate opportunity [before filing its petition] to assess the ’758 patent and to understand that it disclosed support for two separate measurements, but failed to do so.”). In *SAS*, we held that, under the APA, the Board “may not change theories midstream” by adopting a different claim construction in the final written decision than that adopted in the institution decision “without

issue in [the petitioner’s] favor”). In general, “we have encouraged the Board to change its view of the merits after further development of the record [following an institution decision] if convinced its initial inclinations were wrong.” *Fanduel*, 966 F.3d at 1340–41 (Fed. Cir. 2020) (internal quotation marks, modification, and citation omitted).

⁷ If the ultimate construction adopted in the final written decision is sufficiently similar to a construction disputed by the parties, the Board need not give the parties prior notice of the exact construction the Board adopts. *See WesternGeco*, 889 F.3d at 1328.

giving respondents reasonable notice of the change and the opportunity to present argument under the new theory.” *SAS*, 825 F.3d at 1351 (internal quotation marks and citation omitted).

Following the Supreme Court’s *SAS* decision—which reversed our *SAS* decision solely on the ground that the Board could not institute on only some of the claims challenged in the petition—we have continued to recognize that a petitioner is entitled under the APA to respond to new claim construction arguments made by a patent owner or adopted by the Board *sua sponte* and that both parties are entitled to respond to a new construction adopted by the Board *sua sponte* after an institution decision. In that connection, we have continued to cite as authority our earlier *SAS* decision.

In *Ericsson*, after the Supreme Court’s *SAS* decision, we again addressed a new construction proposed for the first time in a patent owner response. 901 F.3d at 1378. In its institution decision, following the parties’ lead, the Board construed the relevant claim terms under the “broadest reasonable interpretation” standard. *Id.* at 1378–79. For the first time in the patent owner response, because the patent had expired, the patent owner proposed a different construction under the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).⁸ In the final written decision, the Board adopted the

⁸ *Ericsson* was decided before the U.S. Patent and Trademark Office adopted the *Phillips* standard for all IPR proceedings. See 37 C.F.R. § 42.100(b); *Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (Oct. 11, 2018). Even before that revision, the *Phillips* standard applied in IPR

new claim construction under the *Phillips* standard but refused to consider portions of petitioner’s reply containing arguments and evidence under the newly proposed claim construction, explaining “that the reply is not an opportunity for Petitioner to identify, for the first time, new and different prior art elements that are alleged to satisfy the claim requirements.” *Id.* at 1379 (internal quotation marks and citation omitted).

We vacated, disagreeing that the petitioner’s reply arguments were improper, in part because “the significance of [the arguments in the Petition] arose *after* the Petition was filed, in that the Board adopted a different construction of the [relevant] terms after the Petition instituting *inter partes* review was granted.” *Id.* at 1380. We held that, under the APA, the petitioner “should have been given an opportunity to respond” to the new claim construction in its reply. *Id.* We concluded that “[i]n light of [the] changed circumstances [regarding the correct claim construction], the Board revisited its approach to the claims in light of this error, and [the petitioner] likewise deserved an opportunity to do the same.” *Id.*

Similarly, in *Hamilton Beach Brands, Inc. v. Freal Foods LLC*, relying on our earlier decision in *SAS*, we concluded, again, that a petitioner is entitled to respond to a new claim construction. 908 F.3d 1328 (Fed. Cir. 2018). There, as here, prior to institution, neither party had proposed an express construction of the relevant terms, and the Board instituted under the parties’ implicit understanding of the terms. *Id.* at 1335. After institution the patent owner response proposed a new construction, which the Board adopted in its final written decision. *Id.* Citing

proceedings concerning expired and soon-to-be-expired patents. See *Changes to the Claim Construction Standard*, 85 Fed. Reg. at 51,341.

our *SAS* decision, we reiterated the rule that, under the APA, the Board cannot adopt a new claim construction without giving the petitioner an opportunity to respond. *Id.* at 1338. But we held that those requirements had been met because the petitioner was able to respond in its reply and at oral argument to the construction proposed in the patent owner response. *Id.* at 1338–39.

In *Qualcomm Inc. v. Intel Corp.*, we again relied on our *SAS* decision and held that, under the APA, parties in an IPR must be permitted to respond to a new claim construction adopted by the Board *sua sponte* after the institution decision. 6 F.4th 1256, 1263 (Fed. Cir. 2021). There, through the oral argument before the Board, the parties had proceeded under a shared understanding of the relevant claim term. *Id.* at 1261–62. In the final written decision, without providing any notice or opportunity to respond, the Board adopted a new claim construction. *Id.* at 1262. The patent owner appealed. Relying on our decision in *SAS*, we held that, because the Board’s construction in the final written decision “diverged from the agreed-upon” construction of the parties, the Board needed to provide notice and an adequate opportunity to respond. *Id.* at 1263.⁹

We think this case falls squarely within the rule of *SAS*, *Ericsson*, *Hamilton Beach*, and *Qualcomm*: that, under the APA, when the Board adopts a new claim construction following institution, an IPR petitioner must have

⁹ Compare *TQ Delta, LLC v. DISH Network LLC*, 929 F.3d 1350, 1356 (Fed. Cir. 2019) (affirming where the Board adopted a claim construction in the final written decision after having not adopted any construction in the institution decision, because the complaining party “had notice of the claim construction issue and the opportunity to be heard” (citing *Hamilton Beach*, 908 F.3d at 1339)).

adequate notice and an opportunity to respond under the new construction. In particular, the petitioner must be afforded a reasonable opportunity in reply to present argument and evidence under that new construction.¹⁰ Here, Axonics was not afforded that opportunity. Although the Board considered Axonics' arguments against the new claim construction, it refused to consider Axonics' evidence and argument under that construction.

That is not to say a petitioner may rely on new prior art in response to a new claim construction presented in the patent owner response. We have held that a petitioner may not in reply rely on new prior art to teach a claim limitation. See *Intelligent Bio-Sys.*, 821 F.3d at 1369 (holding a reply brief and declaration exceeded the proper scope for a reply because they cited "a number of non-patent literature references which were not relied upon to support unpatentability in the Petition"). But that is not the situation

¹⁰ Medtronic argues on appeal that Axonics "clearly anticipated" the two-input claim construction and should have presented argument and evidence under the construction in the petition. Appellee's Br. 1. The Board made no finding that Axonics clearly anticipated the two-input construction in the petition. See *SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943) ("[A]n administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained."). There is, moreover, no support for a rule that would create challenges including line-drawing and unworkability problems and consistency with the regulation that governs the content of a petition, which does not direct a petitioner to raise, address, and apply alternative possible constructions, but instead requires a petitioner affirmatively to state "[h]ow the challenged claim is to be construed." 37 C.F.R. § 42.104(b)(3).

here: Axonics did not rely on new prior art in its reply. We leave for another day the question of whether, when presented with a new claim construction, a petitioner can rely in its reply on new embodiments from the prior art references that were relied on in the petition. *See Apple*, 949 F.3d at 706 (concluding, in a case where there had not been a changed claim construction, that petitioner's reply arguments did not exceed the scope of a proper reply because those arguments did not cite new embodiments or new prior art). Here, Axonics, in the reply, relied on the same embodiments as it relied on in the petition.

Barring argument and evidence in a reply directed to a new claim construction proposed by the patent owner would create opportunities for sandbagging by the patent owner in order to create an estoppel. A patent owner has the opportunity in a preliminary response to oppose institution on the ground that the claim construction relied on by the petitioner is incorrect, and the Board may adopt the patent owner's proposed claim construction and deny institution if the petition fails to demonstrate a reasonable likelihood that a claim would be unpatentable under the correct claim construction. *See* 35 U.S.C. § 314(a). The result would be that there would be no institution and no estoppel pursuant to 35 U.S.C. § 315(e). But if instead of raising the issue in a preliminary response, a patent owner sits on its strongest claim construction arguments before institution and then raises them in response after institution, a patent owner could obtain a favorable final IPR decision and an estoppel without the Board's reaching the merits of any invalidity arguments under the newly adopted claim construction. Indeed, Medtronic admitted in this appeal that the Board's approach below would allow

for such sandbagging.¹¹ We are reluctant to adopt a construction of the APA and the Board's rules that would permit such gamesmanship.

Medtronic argues that it is unfair to permit a new expert declaration to be submitted with a reply, because a patent owner is not permitted to submit a supplemental declaration in sur-reply. *See* 37 C.F.R. § 42.23(b) (“A sur-reply . . . may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witnesses.”). But the Board “may waive or suspend” such requirements in appropriate cases. *See id.* § 42.5(b). Indeed, while the Board here recognized that declarations are not “typically” permitted with sur-replies, it also noted Medtronic had not asked for leave to submit an additional expert declaration in this case. J.A. 37 n.7. We are confident that in circumstances such as these, the Board will allow an appropriate opportunity for a patent owner to submit evidence with a sur-reply.

CONCLUSION

We hold that where a patent owner in an IPR first proposes a claim construction in a patent owner response, a petitioner must be given the opportunity in its reply to argue and present evidence of anticipation or obviousness

¹¹ The Court: “But isn’t there a risk here of sandbagging, that you realize there’s a good claim construction argument, [and] you leave it out of your preliminary response. If you argued it in your preliminary response, then maybe institution would be denied and there would be no estoppel. But if you hold back on the argument and wait to make it until the response, then you get the estoppel. Isn’t there a risk of that?” Medtronic’s counsel: “Certainly, your honor, there is a risk of that . . .” Oral Arg. at 14:24–51.

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under the new construction, at least where it relies on the same embodiments for each invalidity ground as were relied on in the petition. We vacate the Board's decisions in these IPRs and remand for the Board to consider Axonics' arguments and evidence under the two-input claim construction and, correspondingly, to consider any request by Medtronic to present new evidence in support of its sur-reply.

VACATED AND REMANDED

COSTS

Costs to Axonics.