United States Court of Appeals for the Federal Circuit

MEDYTOX, INC.,
Appellant

v.

GALDERMA S.A., GALDERMA LABORATORIES INC., GALDERMA LABORATORIES, L.P., GALDERMA RESEARCH AND DEVELOPMENT, S.N.C., SHDS, INC., GALDERMA HOLDINGS S.A.,
Appellees

KATHERINE K. VIDAL, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2022-1165

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. PGR2019-00062.

Decided: June 27, 2023

VISHAL C. GUPTA, Steptoe & Johnson LLP, New York, NY, argued for appellant. Also represented by TYLER DOH, JOHN J. MOLENDA; CHRISTOPHER ALAN SUAREZ,

Washington, DC.

JOSEPH A. MAHONEY, Mayer Brown, LLP, Charlotte, NC, argued for appellees. Also represented by AMANDA STREFF BONNER, ERICK J. PALMER, Chicago, IL.

ROBERT MCBRIDE, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by SARAH E. CRAVEN, THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED.

Before DYK, REYNA, and STARK, *Circuit Judges*.

REYNA, *Circuit Judge*.

Appellant Medytox, Inc. appeals a final written decision in a post-grant review proceeding of the Patent Trial and Appeal Board that denied Medytox's revised motion to amend to substitute claims 19–27 of U.S. Patent No. 10,143,728. On appeal, Medytox challenges the Board's findings on claim construction, written description, and enablement. Medytox also challenges the Board's Pilot Program concerning motion to amend practice and procedures under the Administrative Procedure Act. We affirm.

BACKGROUND

The patent-at-issue, U.S. Patent No. 10,143,728 (the "'728 patent") issued from an application filed on October 27, 2016, but claims priority from a provisional application filed on December 12, 2013. *See Galderma S.A. v. Medytox, Inc.*, PGR2019-00062, 2021 WL 3039217, at *2 (P.T.A.B. July 16, 2021) ("*Decision*"). The '728 patent is directed to the use of an animal-protein-free botulinum toxin composition that exhibits a longer lasting effect in the patient compared to an animal protein-containing botulinum toxin composition. '728 Patent, col. 2 ll. 57–62.

According to the '728 patent, the animal-protein-free botulinum toxin composition can be used to treat both cosmetic and non-cosmetic conditions, from glabellar lines and lateral canthal lines to chronic migraines. '728 Patent, col. 11 l. 5–col. 12 l. 47.

Substitute claim 19 is representative of the substitute claims:

19. A method for treating glabellar lines ~~a condition~~ in a patient in need thereof, comprising:

locally administering a first treatment of ~~therapeutically effective amount of~~ a botulinum toxin composition comprising a serotype A botulinum toxin in an amount present in about 20 units of MT10109L, a first stabilizer comprising a polysorbate, and at least one additional stabilizer, and that does not comprise an animal-derived product or recombinant human albumin;

locally administering a second treatment of the botulinum toxin composition at a time interval after the first treatment;

wherein said time interval is the length of effect of the serotype A botulinum toxin composition as determined by physician's live assessment at maximum frown;

wherein said botulinum toxin composition has a greater length of effect compared to about 20 units of BOTOX®, when ~~whereby the botulinum toxin composition exhibits a longer lasting effect in the patient when compared to treatment of the same condition with a botulinum toxin composition that contains an animal-derived product or recombinant human albumin dosed at a comparable amount and~~ administered in the same manner for the treatment of glabellar lines ~~and to the same locations(s)~~ as that of the botulinum toxin composition; and

wherein said greater length of effect is determined by physician's live assessment at maximum frown and

requires a responder rate at 16 weeks after the first treatment of 50% or greater. ~~that does not comprise an animal-derived product or recombinant human albumin, wherein the condition is selected from the group consisting of glabellar lines, marionette lines, brow furrows, lateral canthal lines, and any combination thereof.~~

J.A. 2683.[1]

The specification notes that two previous patent applications, which are incorporated by reference in their entireties into the '728 patent, disclose animal-protein-free botulinum toxin compositions. '728 Patent, col. 2 l. 63–col. 3 l. 14. The specification also describes the results of "experimental examples," i.e., two clinical trials, which compared animal-protein-free botulinum toxin composition with botulinum toxin stabilized with human serum albumin. '728 Patent, col. 13 l. 41–col. 31 l. 55. These examples were provided in "support of [the specification's] conclusion regarding longer lasting efficacy." *Decision*, at *3.

The first example is a Phase III clinical study comparing an animal-protein-free composition of MT10109L to BOTOX® in managing moderate to severe glabellar frown lines. '728 Patent, col. 13 l. 41–col. 22 l. 67. The results of example 1 demonstrated that "MT10109L treatment" led to "significant improvement" of frown line severity at week 4 and week 16. '728 Patent, col. 20 ll. 53–57.

The second example is a Phase II clinical study comparing MT10109 to BOTOX®. '728 Patent, col. 23 l. 1–col. 31 l. 55. The result of example 2 is that "lyophilized MT10109 dosed at 20 U" "displays an increased sustained

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[1] Substitute claim 19 reflects Medytox's amendments to original claim 1 through underlined text (text added to) and strikethrough text (text deleted from). Appellant's Br. 17 n.6; *Decision*, at *4.

effect compared to BOTOX®." '728 Patent, col. 31 ll. 48–52.

PROCEDURAL HISTORY

Appellee Galderma S.A., et. al., filed a petition requesting post-grant review of claims 1–10 of the '728 patent, which the Patent Trial and Appeal Board ("Board") granted on all challenged claims. *Decision*, at *1. Medytox filed a non-contingent motion to amend seeking to cancel claims 1–10 of the '728 patent and substitute claims 11–18.[2] J.A. 2635. Medytox requested that the Board issue a Preliminary Guidance in accordance with the pilot program concerning the motion to amend practice and procedures ("Pilot Program"). *Id.*[3] Galderma opposed the motion. *Decision,* at *1. Among other things, Galderma argued that the claims added new matter because the claims covered compounds with a 16-week responder rate between 50%

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[2] The Board's underlying decision refers to Appellant as "Medy-Tox" (J.A. 2), Galderma refers to Appellant as "MedyTox" (Appellee's Br. 1), but, for this opinion, we follow Appellant's spelling, that is, "Medytox" (Appellant's Br. 2).

[3] Patent owners can partake in the Pilot Program concerning motion to amend practice for motions filed in inter partes reviews, post-grant reviews, and covered business method patent reviews (i.e., AIA trials) before the Patent Trial and Appeal Board. 84 Fed. Reg. 9,497. After receiving the petitioner's opposition to its motion to amend, the Pilot Program allows a patent owner to receive a Preliminary Guidance from the Board regarding its motion or to file a revised motion to amend. *Id.* The Preliminary Guidance is an initial discussion about whether there is a reasonable likelihood that the motion to amend meets the statutory and regulatory requirements. *Id.*

and 100% but the specification only disclosed responder rates of up to 62%. J.A. 2638.

The Board issued a Preliminary Guidance, which focused on the substitute claims and amendments proposed in Medytox's motion. J.A. 2635. The Board found that, "at this stage of the proceeding, and based on the current record," Medytox had not shown a reasonable likelihood that it satisfied the statutory and regulatory requirements under 35 U.S.C. § 326(d) and 37 C.F.R. § 42.221(a) for filing a motion to amend. *Id*. at 2636. The Board gave its "preliminary view" that Medytox's proposed responder-rate limitation did not add new matter, and that it should not "necessarily be interpreted as a range of 50–100%" as opposed to simply 50% or greater. J.A. 2638–39.

In addition, the Board stated:

> We emphasize that the views expressed in this Preliminary Guidance are subject to change upon consideration of the complete record, including any revision to the Motion filed by Patent Owner. Thus, this Preliminary Guidance is not binding on the Board when rendering a final written decision.

J.A. 2636.

Medytox then filed a non-contingent revised motion to amend ("revised motion") seeking to cancel original claim 6 and replace the other original claims with substitute claims 19–27, which Galderma opposed. *Decision*, at *1. Galderma's opposition to Medytox's revised motion challenged the "50% or greater" language in the claim, the "responder rate limitation,"[4] as not sufficiently enabled or

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[4] The responder rate, in the context of the '728 patent, is "the proportion of patients who responded

described in the specification. Appellant's Br. 19 (citing J.A. 3463–66). Medytox replied that the rate was a clinically meaningful threshold such that the claims were narrower in scope, should not be treated as a range, and were adequately described, enabled, and not indefinite. *Id*. (citing J.A. 4221). Galderma reiterated its arguments in a surreply. *Id*. at 19–20 (citing J.A. 4662–63).

The oral hearing was held on March 19, 2021. *Decision*, at *2. Prior to the hearing, the Board notified the parties of a "potential *sua sponte* ground of unpatentability" for substitute claim 19 from the revised motion to amend, raising an indefiniteness issue from Medytox's use of the term BOTOX®. *Id*. During the hearing, the Board asked the parties to discuss how the responder rate limitation should be construed and to identify specific examples from the specification that would satisfy the written description requirement for the dose claims. J.A. 4487–89, 4924. Medytox's response pointed to its expert's testimony, clinical trial design, and case law, including *In re Wertheim*, 541 F.2d 257 (CCPA 1976) and *In re Fisher*, 427 F.2d 833 (CCPA 1970). J.A. 4924–49.

BOARD'S FINAL WRITTEN DECISION

The Board issued its final written decision ("FWD") on July 16, 2021. First, the Board cancelled original claims 1–5 and 7–10 because "a non-contingent [motion to amend] is one in which 'the Board provides a final decision on the patentability of substitute claims *in place of* determining the patentability of corresponding original claims.'" *Decision*, at *3 (italics in original). Second, the Board addressed the parties' dispute regarding whether the responder rate

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favorably" to the treatment with Medytox's MT10109L, a botulinum toxin composition, out of all patients to receive it, multiplied by 100 to generate a percentage. Appellant's Br. 6.

limitation should be construed as a range of 50–100% (as argued by Galderma) or a minimum threshold of 50% (as argued by Medytox). *Id.* at *6, 8–9. The Board analyzed whether Medytox's substitute claims were a reasonable number under 37 C.F.R. § 42.221(a)(3); responsive to grounds of unpatentability involved in the trial under 37 C.F.R. § 42.221(a)(2)(i); improperly broader than the original claims under 35 U.S.C. § 326(d)(3) and 37 C.F.R. § 42.221(a)(2)(ii); and introduced new matter under 35 U.S.C. § 326(d)(3) and 37 C.F.R. § 42.221(a)(2)(ii). *Id.* at *6–12. Third, the Board addressed section 112 concerns regarding a lack of written description and lack of enablement. *Id.* at *12–14.

Ultimately, the Board found that the substitute claims impermissibly introduced new matter with the inclusion of the responder rate limitation and thus, failed to meet the requirements for revised motions to amend. *Id.* In light of that finding, the Board found that the proposed substitute claims were unpatentable for a lack of written description. *Id.* After assessing Galderma's expert testimony and evidence for the factors from *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1998) ("*Wands* factors"),[5] the Board found that, by a preponderance of the evidence, the full scope of the claims was not enabled, particularly because a skilled artisan would not have been able to achieve higher than 62% for the responder rate limitation when reading the

[5] There are eight *Wands* factors that the Board considered in assessing whether the substitute claims satisfied the enablement requirement of 35 U.S.C. § 112(a): (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Decision*, at *12.

specification. *Id.* at *12–14. Recognizing that it had interpreted the claim differently in its Preliminary Guidance, the Board now rejected Medytox's argument that the responder rate limitation only requires a threshold of 50%, instead interpreting the limitation as a range with an upper limit of 100%. *Id.* at *9, 14. Accordingly, the Board found that a skilled artisan would not have been able to achieve higher responder rates under the guidance provided in the specification without undue experimentation. *Id.* Based on the foregoing, the Board thus denied Medytox's revised motion to amend. *Id.* Medytox appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

STANDARD OF REVIEW

We review Board decisions using the standards set forth in the Administrative Procedure Act. 5 U.S.C. § 706; *see also In re Sullivan*, 362 F.3d 1324, 1326 (Fed. Cir. 2004). We review the Board's legal conclusions de novo and its factual findings for substantial evidence. *ACCO Brands Corp. v. Fellowes, Inc.*, 813 F.3d 1361, 1365 (Fed. Cir. 2016). Whether a claim amendment satisfies the written description requirement or improperly adds new matter are both questions of fact reviewed for substantial evidence. *Knowles Elecs. LLC v. Cirrus Logic, Inc.*, 883 F.3d 1358, 1365 (Fed. Cir. 2018); *see also In re Lew*, 257 F. App'x 281, 285 (Fed. Cir. 2007) (referencing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)). Substantial evidence "means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000) (citations omitted).

Claim construction is an issue of law that may involve underlying factual findings. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015). Whether the scope of the claims has been enlarged is "a matter of claim construction" that is subject to de novo review. *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1580 (Fed. Cir. 1995).

Whether a claim satisfies the enablement requirement is a question of law that may be based on underlying factual findings. *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1188, 1190 (Fed. Cir. 2014).

DISCUSSION

On appeal, Medytox challenges the Board's findings on claim construction, new matter, written description, and enablement, as well as the Board's Pilot Program concerning motion to amend practice and procedures under the Administrative Procedure Act. Medytox also raises a due process claim. We address each issue in turn.

I

With this backdrop in mind, we first address the Board's claim construction of the responder rate limitation as a range. Medytox argues that the responder rate limitation should be construed as a "yes-or-no inquiry" such that it is a "threshold" for determining whether the animal-protein-free composition has a "greater length of effect" than BOTOX®. Appellant's Br. 28–29.

Galderma asserts that Medytox's claim construction argument that is based on the intrinsic record is forfeited because Medytox did not specifically point out the intrinsic evidence it now relies on before the Board issued its FWD. Appellee's Br. 25–27; Oral Arg. at 20:34–21:03. Medytox does not substantively rebut Galderma's assertion that Medytox relies on intrinsic evidence for the first time on appeal. Medytox does not point to anywhere prior to its petition for rehearing that it directed the Board's attention to intrinsic evidence in support of its claim construction. Medytox instead asserts that it relied on extrinsic evidence to support its claim construction before the Board so the Board did not address intrinsic evidence. Appellant's Br. 34 n.9; Reply Br. 14 ("Medytox relied on extrinsic evidence below in support of its claim construction argument, including evidence cited and relied on by both Medytox's and

Galderma's experts, and admissions from Galderma's experts.").

Typically, intrinsic evidence, such as the specification, is the most important consideration in a claim construction analysis. *See, e.g.*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc) ("[W]e have emphasized the importance of intrinsic evidence in claim construction . . . ."); *see also Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1217–18 (Fed. Cir. 2014) ("[In] ascertain[ing] the scope and meaning of the asserted claims, . . . [our] inquiry typically begins and ends with the intrinsic evidence."). We have held that "arguments that are based on a specification in evidence and that are in support of an existing claim construction are not barred by the doctrine of waiver for the sole reason that they were not first presented to the trial court." *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1347 (Fed. Cir. 2001); *see also Seabed Geosolutions (US) Inc. v. Magseis FF LLC*, 8 F.4th 1285, 1289 (Fed. Cir. 2021) ("The doctrine of waiver does not preclude a party from supporting its original claim construction with new citations to intrinsic evidence of record."). Medytox acknowledges that the Board did not, in the first instance, address the intrinsic record in its claim construction analysis of the responder rate limitation. Appellant's Br. 34 n.9. We note, however, that even if we agreed to analyze the intrinsic record for the first time on appeal, it would not change our holding on claim construction because the parties' constructions do not substantively differ. We, therefore, decline to decide the forfeiture issue.

There is no dispute that the responder rate limitation has an inherent upper limit. Appellant's Br. 50; Appellee's Br. 21. Medytox's expert acknowledged that a minimum threshold responder rate of 50%, 80%, and 90%, would meet the responder rate limitation. J.A. 21, 3489. The same expert also acknowledged that the responder rate limitation cannot exceed 100%. *Id.* at 3489. Accordingly,

we agree that the responder rate limitation has a natural upper limit of 100%.

The parties do not meaningfully dispute that there is not a substantive difference between a "threshold" or "range" construction of the responder rate limitation. During oral argument, Medytox explained that a minimum threshold responder rate of 95% would fall within the scope of the claims, and that any responder rate above 50% "is essentially the same." Oral Arg. 0:30–0:44, 1:21–1:38. Medytox conceded that a 95% responder rate would fall within the scope of the claims under either Medytox's "threshold" construction or Galderma's "range" construction. *Id*. at 2:05–2:20. Galderma similarly acknowledged during oral argument that there is no difference between the two constructions of the responder rate limitation. *Id*. at 16:19–58. We agree that there appears to be no substantive difference in the claim construction proposed by the parties for the responder rate limitation. *Id*. at 3:34–4:07. We thus affirm the Board's construction of the responder rate limitation as a range.

II

The Board evaluated the parties' evidence regarding the *Wands* factors and expert testimony and found that the full scope of the claims was not enabled. *Decision*, at *12–14.

Medytox argues that the specification does not need to include a working example of "every possible embodiment to enable the full scope of the claims." Appellant's Br. 46–47 (citing *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 982 (Fed Cir. 2021)). Medytox cites to its expert's testimony that there would not have been undue experimentation to practice the claims because it is "routine to clinically confirm" that similar compositions meet the duration limitation. *Id*. at 47 (citing J.A. 4313–14, 4465–66). Medytox asserts that the Board failed to provide an analysis or factual findings with respect to the *Wands* factors.

Appellant's Br. 47–48. Finally, Medytox asserts that, even under the Board's claim construction of the responder rate limitation, the claims are enabled. Appellant's Br. 46.

Addressing the *Wands* factors, Galderma asserts that Medytox needed to provide a clinical study for each formulation because clinical trials are not routine for "determining whether pharmaceutical compositions fall within the scope of a patent claim." Appellee's Br. 48. Galderma argues that the specification fails to disclose how one would modify the named formulations (MT10109L and MT10109) to achieve the claimed range. *Id.* at 49–51. Galderma points to how the Board credited its expert's testimony and analyzed the factual findings before concluding that undue experimentation would be required to practice the claims. *Id.* at 63 (citing J.A. 32, 4056–66).

To be sure, our caselaw may not require disclosure of every possible working example of responder rates, but here, there are at most three examples of responder rates above 50% at 16 weeks: 52%, 61%, and 62%. *Decision*, at *11; *see also Wyeth & Cordis Corp. v. Abbott Lab'ys*, 720 F.3d 1380, 1385–86 (Fed. Cir. 2013) (holding that undue experimentation was required to practice the full scope of the claims where the specification "disclose[d] only a starting point for further iterative research in an unpredictable and poorly understood field"); *see MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012) (holding that "a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage"). And, as the Supreme Court recently explained in *Amgen Inc. v. Sanofi*, 143 S. Ct. 1243, 1254 (2023), "[t]he more one claims, the more one must enable." Though a specification need not always "describe with particularity how to make and use every single embodiment within a claimed class," it must nevertheless "enable the full scope of the invention as defined by its claims," for example by "disclosing [a] general quality" of the class that may "reliably enable a person

skilled in the art to make and use all of what is claimed." *Id.* at 1254–55.

Here, the Board found that the arguments and evidence were insufficient to demonstrate enablement to a skilled artisan because said artisan "would not have been able to achieve" responder rates higher than the limited examples provided in the specification. *Decision*, at *14. Substantial evidence supports that finding. The Board provided adequate explanation and reasoning for its enablement finding. We see no error in the Board's factual findings and discern no legal error in its determination of lack of enablement for the substitute claims.[6]

III

Medytox asserts that the Board's revision of its claim construction of the responder rate limitation made between its Preliminary Guidance and FWD violated the Administrative Procedure Act ("APA") because it was arbitrary and capricious and deprived it of a full and fair opportunity to litigate. Appellant's Br. 51 (citing 5 U.S.C. § 706(2)(A)).

A

Medytox argues that the portion of the FWD regarding claim construction failed to analyze "key intrinsic evidence," and the Board relied on "irrelevant" caselaw that did not fix the "fundamentally flawed nature" of its "bare, conclusory" construction. *Id.* at 52. Medytox claims that

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[6] Another issue on appeal is whether the '728 patent specification supports Medytox's claim that it possessed the entire claim range of 50%–100%. Appellant's Br. 42–48. This issue was briefed and argued by the parties and the Board made related findings. In light of our decision to affirm the Board's claim construction of the responder rate limitation as a range and our holding with respect to enablement, we do not address the written description issue.

the evidence cited by the Board in changing its claim construction was not new, such that the Board's "inconsistent conclusions on a nearly identical record" renders its decision arbitrary and capricious. *Id.* at 53 (citing *BASF Corp. v. Enthone, Inc.*, 749 F. App'x 978, 985 (Fed. Cir. 2018); *Robert Bosch, LLC v. Iancu*, 778 F. App'x 871, 875 (Fed. Cir. 2019)).

Galderma asserts that Medytox's claims of "various violations of the APA" lack merit. Appellee's Br. 59. Galderma maintains that Medytox never cited intrinsic evidence to support its proposed claim construction and that, after the Preliminary Guidance was issued, the record was "significantly developed" with new evidence and arguments. *Id.* at 59–60. Galderma argues that Medytox did not even propose its "minimum threshold" construction of the responder rate limitation until after the Preliminary Guidance. *Id.* at 60.

The Director of the Patent and Trademark Office (the "Director") intervened in this appeal primarily to respond to Medytox's APA challenges. The Director asserts that the Board's Preliminary Guidance is exactly as its name suggests: preliminary. Intervenor Br. 8–9. Further, the Preliminary Guidance includes a statement that the views are "initial, preliminary, [and] non-binding" on whether the patent owner has demonstrated a reasonable likelihood that it met the requirements for filing a motion to amend. *Id.* at 9. The Director contends that the difference in the standard in the burden of persuasion on Medytox for the Board's FWD (preponderance of the evidence) from the standard for the Preliminary Guidance (reasonable likelihood) is indicative of the nature of the determinations reached in the Preliminary Guidance. *Id.* at 9–10; *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (discussing the "significant difference" and "qualitatively different standard" between the burden to establish a reasonable likelihood of success and the burden of proof by a preponderance of the evidence).

Our review of the record indicates that the extrinsic record was developed between the Board's issuance of its Preliminary Guidance and the FWD. Medytox's expert testified about the responder rate limitation, discussing which response rates (e.g., up to 100%) would fall within the scope of the claim. Intervenor Br. 13–15. Medytox explained at the oral hearing that the Board's construction of the responder rate limitation as a range would not affect its arguments. *Id.* at 15 (citing J.A. 4931 at 50:16–24). The Board was within its discretion to find this evidence relevant to its decision on claim construction for the responder rate limitation. The Board's concerns about the substitute claims were also made clear during oral argument. For example, the Board asked counsel for both written description support on the responder rate limitation, J.A. 4929, and examples of support in the specification about the variance in the response rate, J.A. 4930.

This court has explained that "the Board has an obligation to assess the question anew after trial based on the totality of the record," particularly where the standard changes. *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1377 (Fed. Cir. 2016). We have encouraged the Board to "change its view of the merits after further development of the record" if necessary, such as when a holding otherwise would "collapse" the two analyses and standards into one. *Trivascular, Inc.*, 812 F.3d at 1068. Relatedly, this court has addressed an argument about the "Board chang[ing] theories" between an institution decision and a FWD and held that, given the "different standards of proof" between the two points in a proceeding, the Board is not first required to notify parties to the possibility of changing its position. *Fanduel, Inc. v. Interactive Games LLC*, 966 F.3d 1334, 1340–41 (Fed. Cir. 2020). The court has further noted that such change "happens with some frequency." *Id.*

The Board here provided a reasoned analysis for its ultimate claim construction, a construction that we approve

under de novo review. The extrinsic record relied on by the Board was developed after the Board's Preliminary Guidance was issued. We thus hold that the Board's decision to change its claim construction for the responder rate limitation was not arbitrary and capricious.

B

Medytox argues that it was prevented from a full and fair opportunity to litigate the case because the Board's reversal was "***solely*** based on the Board's about-face on the responder rate limitation."[7] Appellant's Br. 53. Medytox asserts that it was "penalized for its good faith efforts" to comply with the Pilot Program and that the Preliminary Guidance provided "no reason or explanation" suggesting that the Board might later rule differently. *Id*. at 54.

Galderma counters, arguing that "it was not reasonable" for Medytox to rely on the Preliminary Guidance due to its preliminary nature and because it was Medytox's "obligation" to fully address the claim construction dispute, which it ultimately failed to do. Appellee's Br. 61.

The Director points to the Federal Register, where the notice on the Pilot Program was published, which reiterates the "preliminary, non-binding" nature of the guidance. Intervenor Br. 9 (citing 84 Fed. Reg. 9,497). During oral argument, counsel for the Director explained that the Preliminary Guidance was "designed to be an initial discussion." Oral Arg. at 28:22–29:14. The Director asserts that 49% of patent owners that have filed a revised motion to

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[7] Medytox also challenges the Commissioner for Patent's refusal to review the Board's FWD as improper under the Appointments Clause. Appellant's Br. 57 (citing *United States v. Arthrex*, 141 S. Ct. 1970, 1985 (2021)). This court has already rejected this argument. *See Arthrex, Inc. v. Smith & Nephew, Inc.*, 35 F.4th 1328 (Fed. Cir. 2022).

amend ("MTA") and received the Board's Preliminary Guidance file a revised MTA. Oral Arg. at 29:14–47.

The public notice of the Pilot Program contains explicit language about its non-binding and "initial" nature:

> With that in mind, the preliminary guidance will provide an initial discussion about whether there is a reasonable likelihood that the MTA meets statutory and regulatory requirements for an MTA. The preliminary guidance also will provide an initial discussion about whether petitioner (or the record then before the Office, including any opposition to the MTA and accompanying evidence) establishes a reasonable likelihood that the substitute claims are unpatentable.

See Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497 (Mar. 15, 2019). Indeed, "initial" may imply the possibility of further discussion or development.

The public notice also outlines the procedures of the Pilot Program:

> The pilot program also allows a patent owner, after receiving petitioner's opposition to the original MTA and/or after receiving the Board's preliminary guidance (if requested), to choose to submit a revised MTA. . . . [A] revised MTA includes one or more new proposed substitute claims in place of previously presented substitute claims. A revised MTA also may include substitute claims, arguments, or evidence previously presented in the original MTA,

> but may not incorporate any material by reference from the original MTA. A revised MTA may provide new arguments and/or evidence as to why the revised MTA meets statutory and regulatory requirements for an MTA, as well as arguments and evidence relevant to the patentability of pending substitute claims. A revised MTA must provide amendments, arguments, and/or evidence in a manner that is responsive to issues raised in the preliminary guidance and/or petitioner's opposition to the MTA. A revised MTA may not include amendments, arguments, and/or evidence that are unrelated to issues raised in the preliminary guidance and/or petitioner's opposition to the MTA.

Id. The Board's Preliminary Guidance also included similar language of the preliminary nature of its views in this case. J.A. 2638–39; *supra* Op. 6.

Even if we assume, without deciding, that the Board was required to provide notice of its changed approach from the Preliminary Guidance, we hold that the Board did not violate due process or the APA. Galderma disputed the claim construction of the responder rate limitation when it filed its opposition to Medytox's motion to amend. Intervenor Br. 24 (citing J.A. 2282–2319). Medytox itself proposed its claim construction in the motion to amend. *Id.* at 24–25 (citing J.A. 1783–1816). The Board then revised the scheduling order for the parties to develop new evidence and arguments stemming from Medytox's motion to amend, the Preliminary Guidance, and other evidence. *Id.* at 25 (citing J.A. 3206–12). Medytox was able to present its case on the issues before the Board, including claim construction, and again when it filed a Request for Director Review or Panel Rehearing. *Id.* at 27 (citing J.A. 4963–83). And, to the extent Medytox alleges that the Board

committed error, Medytox's concessions, *see, e.g.*, J.A. 4931 at 50:21–24, that its remaining arguments would not be impacted by an alternate claim construction show that such error, if any, would be harmless.

To be sure, the agency must inform the parties on procedures relevant to its practices, like the Pilot Program, and must respect the boundaries imposed by the APA. There must be structural integrity to the program in ensuring that the patent owners who have requested such guidance be given an opportunity to be heard and due process. On this record, such requirements were met.

CONCLUSION

The Board's claim construction of the responder rate limitation and finding of lack of enablement for the substitute claims were reasonable and supported by substantial evidence. In this case, the Board's Preliminary Guidance for the Pilot Program did not violate the APA, nor did the Board's actions constitute a due process violation. We have considered Medytox's other arguments and find them unpersuasive. We affirm the Board's denial of Medytox's revised motion to amend substitute claims 19–27.

AFFIRMED

COSTS

No costs.