United States Court of Appeals for the Federal Circuit

EYE THERAPIES, LLC,
Appellant

v.

SLAYBACK PHARMA, LLC,
Appellee

2023-2173

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2022-00142.

Decided: June 30, 2025

JAMES R. BARNEY, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for appellant. Also represented by BRYAN DINER, JUSTIN JAMES HASFORD, CHRISTINA JI-HYE YANG; CHARLES E. LIPSEY, Reston, VA.

KEVIN P. MARTIN, Goodwin Procter LLP, Boston, MA, argued for appellee. Also represented by ELAINE BLAIS, WILLIAM EVANS, ROBERT FREDERICKSON, III; LINNEA P. CIPRIANO, New York, NY.

Before TARANTO and STOLL, *Circuit Judges*, and SCARSI, *District Judge*.[1]

SCARSI, *District Judge*.

Appellant Eye Therapies, LLC ("Eye Therapies") appeals from a final written decision of the Patent Trial and Appeal Board (the "Board") holding all claims of U.S. Patent No. 8,293,742 ("the '742 patent") unpatentable. Eye Therapies challenges (1) the Board's construction of the phrase "consisting essentially of" and (2) the Board's conclusion that all claims of the '742 patent would have been obvious over the prior art. For reasons explained below, we reverse the Board's claim construction of the "consisting essentially of" limitation, vacate its obviousness finding, and remand for further proceedings.

BACKGROUND

Eye Therapies owns and licenses the '742 patent, which teaches a method to reduce eye redness using a low-concentration dose of brimonidine.[2] '742 patent col. 22 ll. 17–21, 25–32. As relevant to the appeal, independent claims 1 and 3 recite:

> 1. A method for reducing eye redness *consisting essentially of* administering brimonidine to a patient

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[1] Honorable Mark C. Scarsi, District Judge, United States District Court for the Central District of California, sitting by designation.

[2] Brimonidine is an alpha-adrenergic receptor agonist, a category of compounds known to cause vasoconstriction. '742 patent col. 1 ll. 60–63. Vasoconstriction counteracts vasodilation, or "[d]ilation of small blood vessels," a condition that "causes many clinically undesirable events" including "surface hemorrhage and hyperemia following Lasik surgery" and "eye redness (conjunctival hyperemia)." *Id.* col. 1 ll. 6–9.

> having an ocular condition, wherein brimonidine is present at a concentration between about 0.001% weight by volume and about 0.05% weight by volume.
>
> 3. A method for reducing eye redness *consisting essentially of* topically administering to a patient having an ocular condition a composition *consisting essentially of* brimonidine into ocular tissue, wherein pH of said composition is between about 5.5 and about 6.5, wherein said brimonidine concentration is between about 0.001% and about 0.025% weight by volume and wherein said composition is formulated as an ocular drop.

'742 patent col. 22 ll. 17–21, 25–32 (emphases added).

During patent prosecution, the examiner rejected prior versions of these claims that used "comprising" instead of "consisting essentially of." The examiner found that the claims that used "comprising" were anticipated by U.S. Patent No. 6,242,442 ("Dean"), which discloses the administration of brimonidine and brinzolamide to treat ocular diseases. J.A. 1033–35. In response, the applicant replaced "comprising" with the phrase "consisting essentially of," among other amendments. J.A. 1049. The applicant then argued that Dean only disclosed the use of brimonidine in combination with brinzolamide. J.A. 1053. Whereas Dean required brinzolamide as "an active ingredient" in addition to brimonidine, the applicant explained that the revised claims "*do not require the use of any other active ingredients* (emphasis added) in addition to brimonidine." *Id.* The examiner allowed the amended claims, citing the applicant's representation "that the presently claimed methods *do not require the use of any other active ingredients* (emphasis added) in addition to brimonidine." J.A. 1082.

On petition by Appellee Slayback Pharma, LLC ("Slayback"), the Board instituted an inter partes review of

claims 1–6 of the '742 patent and entered a final written decision determining all challenged claims were unpatentable. J.A. 2–3, 166. On claim construction, "the parties dispute[d] whether the scope of the claims includes the use of additional drugs along with low-dose brimonidine." J.A. 12. The Board noted that "the use of 'consisting essentially of' 'signals that the invention necessarily includes the listed ingredients [but] is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention,'" in accordance with the phrase's typical meaning. *Id.* (alteration in original) (quoting *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998)). The Board rejected Eye Therapies' arguments that the prosecution history demonstrated that "consisting essentially of" in this context should be read to claim a method for administering brimonidine as the sole active ingredient, reasoning:

> During prosecution, the patentee asserted that "[o]ne of the basic and novel characteristics of the presently claimed methods is that they *do not require the use of any other active ingredients* (emphasis added) in addition to brimonidine." But, unlike Patent Owner, we do not read the prosecution history as prohibiting the use of any other active ingredients besides brimonidine. To do so would construe the semi-open-ended transition phrase "consisting essentially of" to have the same scope as the closed transition phrase "consisting of."

J.A. 14 (alteration in original) (citations omitted). Instead, the Board concluded that "under the proper scope of the claims and consistent with the prosecution history, the claimed methods cannot include additional active ingredients that are *required* to perform the method." *Id.* (emphasis added).

Applying our decision in *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009), the Board reasoned that "because the Specification states that low-dose brimonidine alone can significantly reduce hyperemia, if there are additional agents beyond low-dose brimonidine administered to a patient that may also reduce eye redness . . . those additional agents would not materially affect the basic and novel characteristics of the invention." J.A. 15. Accordingly, the Board held that "the transitional phrase 'consisting essentially of' does not preclude the use of additional active agents that may also cause vasoconstriction and reduction of hyperemia along with low-dose brimonidine." J.A. 15–16.

Applying this construction, the Board concluded "that the combination of [the prior art] teach[es] or suggest[s] each limitation of the challenged claims and a [person of ordinary skill in the art] would have had a reason to combine the references with a reasonable expectation of success." J.A. 52–53.[3]

Eye Therapies timely filed this appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

STANDARD OF REVIEW

"We review de novo the Board's ultimate claim constructions and any supporting determinations based on intrinsic evidence," and "[w]e review any subsidiary factual findings involving extrinsic evidence for substantial evidence." *Personalized Media Commc'ns, LLC v. Apple Inc.*, 952 F.3d 1336, 1339 (Fed. Cir. 2020).

Obviousness is a "mixed question of law and fact." *Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357, 1361 (Fed. Cir. 2018). We review the Board's ultimate

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[3] The Board also resolved other issues not relevant to this appeal. J.A. 16–40.

obviousness determination de novo and its underlying findings of fact for substantial evidence. *Id.*

DISCUSSION

We conclude the Board erred in its construction of the phrase "consisting essentially of" as allowing the coadministration of active ingredients other than brimonidine. Given the prosecution history, we interpret the phrase as used in the '742 patent to preclude the use of active ingredients other than brimonidine. Because the Board's obviousness analysis materially relied on its erroneous claim construction, we cannot affirm the Board's unpatentability determination. We reverse the Board's claim construction, vacate the Board's decision, and remand the matter to the Board.

A. Claim Construction

The central dispute on appeal is the meaning of limiting claim language "consisting essentially of." Eye Therapies contends that this transition phrase "should be construed to exclude active ingredients other than brimonidine in the claimed method." Appellant's Br. 29. Slayback argues that the Board properly construed "consisting essentially of" in line with our caselaw interpreting the phrase and the patent prosecution history. Appellee's Br. 25.

Claim terms "are generally given their ordinary and customary meaning" as understood by "a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (internal quotation marks and citation omitted). "Claim construction requires a determination as to how a person of ordinary skill in the art would understand a claim term 'in the context of the entire patent, including the specification.'" *Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1362 (Fed. Cir. 2016) (quoting *Phillips*, 415 F.3d at 1313).

Generally, the term "comprising" is an open-ended transitional term that allows for additional steps. *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003). On the other hand, the transitional phrase "consisting essentially of" generally "has long been understood to permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'" *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1239 (Fed. Cir. 2003) (quoting *PPG Indus.*, 156 F.3d at 1354). However, "a patentee can alter that typical meaning"; for example, the patentee can make the intended meaning clear in the specification or disclaim an alternative meaning in the prosecution history. *Ecolab*, 569 F.3d at 1343–44. Limiting statements in the patent prosecution history can "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

Eye Therapies contends the prosecution history supports an atypical meaning of "consisting essentially of," as the applicant "expressly argued that the amended claims preclude the use of other active ingredients and that a basic and novel property of the invention is the administration of brimonidine without other therapeutic drugs." Appellant's Br. 30. We agree with Eye Therapies that the prosecution history informs an atypical meaning of "consisting essentially of" in the '742 patent.

Following the examiner's rejection of the '742 patent over Dean, the applicant amended the claims, replacing "comprising" with "consisting essentially of." J.A. 1049. The applicant explained that the amendment distinguished the claims from Dean, which "does not disclose a method . . . which consists *essentially of* administering to a patient with an ocular condition brimonidine . . . or a pharmaceutical composition *consisting essentially* of

brimonidine." J.A. 1053. The applicant explained that the innovation in the "claimed methods is that they *do not require the use of any other active ingredients* (emphasis added) in addition to brimonidine." *Id.* In allowing the claims, the patent examiner echoed the applicant's representation "that the presently claimed methods *do not require the use of any other active ingredients* (emphasis added) in addition to brimonidine, thereby instating the 'consisting essentially of' language." J.A. 1082 (citation omitted).

Even if these representations to the examiner "do not rise to the level of unmistakable disavowal, they do inform the claim construction." *Shire Dev., LLC v. Watson Pharms., Inc.*, 787 F.3d 1359, 1366 (Fed. Cir. 2015). "[A]n applicant's amendment accompanied by explanatory remarks can define a claim term by demonstrating what the applicant meant by the amendment." *Personalized Media Commc'ns*, 952 F.3d at 1340. For example, arguments advanced in prosecution "to convince the examiner that the claimed invention meets the statutory requirements of novelty, utility, and nonobviousness" can limit claim interpretation. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985).

The only material difference in the language circumscribing the scope of the rejected claims and the allowed amended claims is the replacement of the open-ended term "comprising" with the less-open phrase "consisting essentially of." As confirmed by the examiner's repetition of and maintained emphasis on the applicant's representations, the applicant secured allowance of the amended claims by arguing that the claimed methods were novel because they "*do not require the use of any other active ingredients*." This promotes a more restrictive interpretation of "consisting essentially of" than our precedents interpreting the typical use of the phrase would prescribe. Whereas an interpretation applying the standard meaning might permit additional unlisted active ingredients, the applicant persuaded

the examiner of the novelty of the claims by underscoring the *absence* of other active ingredients in the claimed methods.

The strongest indicators of a more-restrictive-than-typical interpretation of the phrase "consisting essentially of" are the applicant's arguments on amendment contrasting the claimed methods and Dean's:

> Dean is directed to the combinational use of brimonidine and brinzolamide, and there is nothing in the reference that would lead a person having ordinary skill in the art to omit one of the two essential components of the Dean's compositions to arrive at the claimed methods. Moreover, Dean *teaches away* from methods consisting essentially of administering brimonidine (*i.e., methods which do not include administering other active agents*).

J.A. 1061–62 (second emphasis added); *see also* J.A. 1055 ("Thus, Dean . . . does not teach any methods of treating any conditions by administering a pharmaceutical composition consisting essentially of brimonidine (*i.e., a pharmaceutical composition which does not include any other active agents*)." (emphasis added)). "[U]se of 'i.e.' signals an intent to define the word to which it refers." *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1334 (Fed. Cir. 2009); *see also Rembrandt Wireless Techs., LP v. Samsung Elecs. Co., Ltd.*, 853 F.3d 1370, 1376 (Fed. Cir. 2017) ("A patentee's use of 'i.e.,' in the intrinsic record . . . is often definitional."). The applicant's use of "i.e." here indicates an intent to define the claimed "methods *consisting essentially of brimonidine*" as "methods *which do not include administering other active agents*." In this way, the standard meaning of "consisting essentially of" is incompatible with the more restrictive meaning the applicant ascribed to the phrase.

Ecolab, which the Board analogized to reach a different result, is consistent with our conclusion. In *Ecolab*, we

interpreted a method for sanitizing fowl using a solution "which consists essentially of . . . peracetic acid" not to be limited to compositions containing peracetic acid as the sole antimicrobial agent. 569 F.3d at 1342–44. We rejected a party's argument for departing from the typical interpretation of "consisting essentially of," reasoning that the patent specification provided examples describing compositions that contain antimicrobial agents other than peracetic acid. *Id.* at 1343–44. In other words, we found that the intrinsic evidence was irreconcilable with the alternative meaning the party advanced.[4] In contrast, the prosecution history here strongly evinces a restrictive meaning of "consisting essentially of." Admittedly, other aspects of the intrinsic record are less conducive to the construction. Our construction would not embrace some embodiments in the '742 patent specification that describe compositions containing active ingredients other than brimonidine. *E.g.*, '742 patent col. 9 ll. 35–42. But an atypically restrictive construction of "consisting essentially of" remains compatible with other embodiments that describe compositions in which brimonidine is the only active ingredient. *E.g.*, *id.* col. 10 ll. 3–8. And it is hardly surprising or unusual that a specification written with broader claim language ("comprising") would contain embodiments no longer compatible with narrowed claim language adopted

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[4] The Board rested its *Ecolab* analogy on the specification's statement "that low-dose brimonidine alone can significantly reduce hyperemia," reasoning that "*if* there are additional agents . . . those additional agents would not materially affect the basic and novel characteristics of the invention." J.A. 15 (emphasis added). The contingency the Board identifies extends well beyond the text of the specification. And while the Board's logic is consistent with the typical meaning of "consisting essentially of," it does not foreclose the more restrictive meaning the prosecution history supports.

during prosecution ("consisting essentially of") accompanied by a clear narrowing explanation, as here. Such actions, post-dating the filing of the specification, naturally can and often do result in claims that do not cover all embodiments in the specification. The fact that our construction does not encompass all alternative embodiments does not foreclose its application, especially given its compelling support in the prosecution history. *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008); *see also Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1026 (Fed. Cir. 2015) ("[W]here the patent describes multiple embodiments, every claim does not need to cover every embodiment.").

Slayback argues that the applicant told the examiner only that the amended claims *do not require* the use of any other active ingredients, not that they *preclude* the use of such ingredients. Appellee's Br. 29. We rejected a similar argument in *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353 (Fed. Cir. 2017). There, a patentee made "repeated statements" in an inter partes review proceeding that its claims "require that . . . only the [CPP logic] be invoked." 856 F.3d at 1363 (ellipsis in original). We dismissed the patentee's argument that these statements could "reasonably be interpreted to mean that 'only' the CPP logic is *required* to be invoked in those claims—not that the [conceptually distinct] *CP logic* is *precluded* from being invoked." *Id.* We found the patentee's interpretation unreasonable given the context in which it made its concessions, which did "not change the plain meaning of [the] disavowing statements." *Id.*[5] So too here. Given the applicant's

[5] We applied prosecution history estoppel in *Aylus*, 856 F.3d at 1362–64. We do not apply that doctrine here, even as we employ the prosecution history to inform the claim construction. *See Shire Dev.*, 787 F.3d at 1366 (distinguishing between prosecution history statements that

arguments distinguishing Dean and definitional use of "i.e." to equate its claimed "methods consisting essentially of administering brimonidine" with "methods which do not *include* administering other active agents," J.A. 1055, 1061–62 (emphasis added), the appropriate interpretation of the applicant's representation that the claimed methods "*do not require*" agents other than brimonidine, J.A. 1053, 1082, is that its claimed methods *preclude* the use of such agents.

Accordingly, we reverse the Board's claim construction. We read the transition phrase "consisting essentially of" as used in claims 1 and 3 of the '742 patent to exclude use of active ingredients other than brimonidine.

B. Obviousness

The Board's erroneous claim construction infected its consideration of facts in its obviousness analysis. For example, the Board considered Dean and two other prior art references—Richard A. Norden, *Effect of Prophylactic Brimonidine on Bleeding Complications and Flap Adherence after Laser in situ Keratomileusis*, 18 J. REFRACTIVE SURGERY 468 (July/Aug. 2002) ("Norden"), and U.S. Patent No. 6,294,553 ("Gil")—all of which involved compositions including active agents other than brimonidine, as teaching toward the use of brimonidine alone. J.A. 42, 54. The Board reasoned that "[a]lthough Norden and Gil may also teach the possibility of co-administering pain medication, steroids, and antibiotics, . . . the claims—when properly construed—do not preclude administering other drugs that do not materially affect the basic and novel characteristics of the claims." J.A. 54. Under the appropriate construction of "consisting essentially of," the claimed methods exclude

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constitute "unmistakable disavowal" and those that "inform the claim construction"). Notwithstanding, our reasoning in *Aylus* is helpful to address Slayback's argument.

compositions that contain active agents other than brimonidine, undermining the Board's conclusion.

One final point bears discussion. As Slayback points out, the Board was careful to note that "even if the claim term 'consisting essentially of' were construed to preclude agents that reduced eye redness, Norden suggests that those additional agents do not affect brimonidine's redness-reducing action and, would therefore, still satisfy the 'consisting essentially of' limitation." J.A. 54 n.24. But this fallback position still relies upon a construction of "consisting essentially of" inconsistent with the prosecution history. After all, Dean teaches co-administration of brimonidine with an active ingredient that does not reduce redness, brinzolamide. Dean col. 2 ll. 21–29, col. 3 ll. 26–43. By amending the claims to include the phrase "consisting essentially of" to overcome Dean, the applicant intentionally sought to limit the claims to exclude applications with *any* other active agent, whether or not the agent addresses eye redness.

We do not prejudge whether the correct claim construction permits the same factual findings or obviousness conclusion. We do note, however, that because the Board applied an erroneous claim construction, it had no occasion to consider whether, under the prior art, a person of ordinary skill in the art would have been motivated to employ a method with the properly understood limitation signified by the '742 patent's use of "consisting essentially of." "We conclude that the appropriate course in this case, as in so many others involving a reversal of a Board claim construction, is to vacate the Board's decision and remand the matter." *Kaken Pharma. Co., Ltd. v. Iancu*, 952 F.3d 1346, 1355 (Fed. Cir. 2020).

CONCLUSION

For the foregoing reasons, we reverse the Board's claim construction, vacate the Board's final written decision, and

remand the matter to the Board for further proceedings consistent with the construction provided above.

Costs awarded to appellant.

REVERSED IN PART, VACATED, AND REMANDED