United States Court of Appeals for the Federal Circuit

ALLERGAN SALES, LLC, ALLERGAN, INC.,
Plaintiffs-Appellees

v.

SANDOZ, INC., ALCON LABORATORIES, INC.,
Defendants-Appellants

2018-2207

Appeal from the United States District Court for the District of New Jersey in No. 2:17-cv-10129-WHW-CLW, Senior Judge William H. Walls.

Decided: August 29, 2019

JONATHAN ELLIOT SINGER, Fish & Richardson, PC, San Diego, CA, argued for plaintiffs-appellees. Also represented by DEANNA JEAN REICHEL, Minneapolis, MN; SUSAN E. MORRISON, Wilmington, DE.

JOHN C. O'QUINN, Kirkland & Ellis LLP, Washington, DC, argued for defendants-appellants. Also represented by SEAN M. MCELDOWNEY, CALVIN ALEXANDER SHANK; BRYAN SCOTT HALES, Chicago, IL; BENJAMIN A. HERBERT, Los Angeles, CA.

Before PROST, *Chief Judge,* NEWMAN, and WALLACH, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* WALLACH.

Concurring opinion filed by *Chief Judge* PROST.

WALLACH, *Circuit Judge*.

Appellees Allergan Sales, LLC and Allergan, Inc. (together, "Allergan") sued Appellants Sandoz, Inc. and Alcon Laboratories, Inc. (together, "Sandoz") in the U.S. District Court for the District of New Jersey ("District Court"), asserting that Sandoz's Abbreviated New Drug Application ("ANDA") No. 91-087 for a generic version of Allergan's ophthalmic drug Combigan® infringes U.S. Patent Nos. 9,770,453 ("the '453 patent"), 9,907,801 ("the '801 patent"), and 9,907,802 ("the '802 patent") (collectively, "the Patents-in-Suit") owned by Allergan. The District Court found limiting a number of "wherein" clauses in the Patents-in-Suit, *Allergan Sales LLC v. Sandoz, Inc.*, No. 2:17-cv-10129, 2018 WL 3675235, at *7 (D.N.J. July 13, 2018) (Opinion) (J.A. 5–25), and granted Allergan's motion for a preliminary injunction, *Allergan Sales, LLC v. Sandoz, Inc.*, No. 2:17-cv-10129 (D.N.J. July 13, 2018) (Order) (J.A. 1–4).[1]

Sandoz appeals. We possess jurisdiction pursuant to 28 U.S.C. § 1292 (2012). We affirm.

BACKGROUND

Entitled "Combination of Brimonidine and Timolol for Topical Ophthalmic Use," the Patents-in-Suit share a

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[1] The parties fail to specify the asserted claims, *see generally* Appellant's Br., Appellee's Br., but they do not contest the District Court's list of disputed "wherein" clauses, *see* J.A. 2–4. Accordingly, we rely upon the District Court's undisputed list.

common specification that relates "to the topical ophthalmic use of brimonidine in combination with timolol . . . for treatment of glaucoma or ocular hypertension." '453 patent col. 1 ll. 33–35.[2] The specification explains that the combination is "preferably formulated as 0.01 to 0.5 percent by weight brimonidine and 0.1 to 1.0 percent by weight timolol solution in water at a pH of 4.5 to 8.0, e.g. about 6.9." *Id.* col. 2 ll. 40–43. The specification states, however, that "[o]ther ingredients . . . may be desirable," including "preservatives, co-solvents[,] and viscosity building agents." *Id.* col. 2 ll. 46–49.

"Example I" of the Patents-in-Suit is an exemplary "combination formulation" prepared to include 0.20% (w/v) brimonidine tartrate, 0.68% (w/v) timolol maleate,[3] 0.005% (w/v) benzalkonium chloride, an "isotonic phosphate buffer system at pH 6.9," and other ingredients. *Id.* col. 3 l. 59–col. 4 l. 6; *see id.* col. 4 ll. 7–24 (providing a Table of ingredients for the Example I formulation). The specification also describes a clinical study, referred to as "Example II," that "compare[d] the safety and efficacy of twice-daily dosed[4] brimonidine tartrate 0.2%/timolol 0.5% ophthalmic solution combination," i.e., the Example I formulation, "with that of twice-daily dosed timolol ophthalmic solution 0.5% . . . and three-times-daily dosed[5] ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2% . . . in

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[2] Because the Patents-in-Suit share a common specification, we cite to only the '453 patent for ease of reference unless otherwise specified.

[3] The specification explains that 0.68% (w/v) timolol maleate is equivalent to 0.5% (w/v) timolol, free base. '453 patent col. 3 ll. 61–63, col. 4 ll. 7–21.

[4] A twice-daily dosing frequency is referred to as "BID." *See, e.g.*, '453 patent col. 2 ll. 35–37.

[5] A thrice-daily dosing frequency is referred to as "TID." *See, e.g.*, '453 patent col. 5 ll. 20–21.

patients with glaucoma or ocular hypertension." *Id*. col. 4 ll. 29–37. The study concluded that the Example I formulation "administered BID . . . was superior to [t]imolol (timolol 0.5%) BID and [b]rimonidine (brimonidine tartrate 0.2%) TID in lowering the elevated [intraocular pressure ('IOP')] of patients with glaucoma or ocular hypertension." *Id*. col. 9 ll. 2–6. The study also concluded that the Example I formulation "administered BID demonstrated a favorable safety profile that was comparable to [t]imolol BID and better than [b]rimonidine TID with regard to the incidence of adverse events and discontinuations due to adverse events." *Id*. col. 9 ll. 6–10. The Example II results are reflected in the disputed "wherein" clauses, which may be divided into two types: efficacy and safety, i.e., adverse events.

Independent claim 1 of the '453 patent is representative and recites:

> A method of treating a patient with glaucoma or ocular hypertension comprising topically administering twice daily to an affected eye a single composition comprising 0.2% w/v brimonidine tartrate and 0.68% w/v timolol maleate, *wherein* the method is as effective as the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day and *wherein* the method reduces the incidence of one o[r] more adverse events selected from the group consisting of conjunctival hyperemia, oral dryness, eye pruritus, allergic conjunctivitis, foreign body sensation, conjunctival folliculosis, and somnolence when compared to the administration of 0.2% w/v brimonidine tartrate monotherapy three times daily.

Id. col. 9 l. 16–col. 10 l. 7 (emphases added).

DISCUSSION

I. Claim Construction

A. Standard of Review and Legal Standard

"The proper construction of a patent's claims is an issue of Federal Circuit law[.]" *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1228 (Fed. Cir. 2011) (citation omitted). "[C]laim construction must begin with the words of the claims themselves." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1301 (Fed. Cir. 2006) (citation omitted). "[W]ords of a claim are generally given their ordinary and customary meaning," i.e., "the meaning that the term would have to a person of ordinary skill in the art [('PHOSITA')] 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). "The words used in the claims are interpreted in light of the intrinsic evidence of record, including the written description, the drawings, and the prosecution history[.]" *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002) (citation omitted). The PHOSITA "is deemed to read [a] claim term not only in the context of the particular claim in which [it] appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313.[6] Prosecution history may also be looked to in order to supply additional evidence of a claim term's intended meaning. *See Home Diagnostics, Inc. v. Lifescan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004).[7] While courts

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[6] The "specification includes both the written description and the claims of the patent." *Cisco Sys., Inc. v. TQ Delta, LLC*, 928 F.3d 1359, 1362 (Fed. Cir. 2019) (internal quotation marks and citation omitted).

[7] A patent's prosecution history "consists of the complete record of the proceedings before the [U.S. Patent and Trademark Office ('USPTO')]," providing "evidence of how

may also consider extrinsic evidence in claim construction, "such evidence is generally of less significance than the intrinsic record." *Wi-LAN, Inc. v. Apple Inc.*, 811 F.3d 455, 462 (Fed. Cir. 2016) (citation omitted).[8] Where, as here, the intrinsic evidence alone determines the proper claim construction, we review the district court's ultimate legal conclusion de novo. *CardSoft, LLC v. VeriFone, Inc.*, 807 F.3d 1346, 1350 (Fed. Cir. 2015) (citing *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841–42 (2015)).

B. The District Court Properly Construed the "Wherein" Clauses as Limiting

The District Court found the disputed "wherein" clauses to constitute claim limitations. *Allergan Sales*, 2018 WL 3675235, at *7. Specifically, the District Court "f[ound] that the 'wherein' clauses are limiting because they are material to patentability and express the inventive aspect of the claimed invention," viz., "Combigan®'s ability to reduce daily administrations from TID to BID without a loss of efficacy, and with reduced adverse events." *Id.* at *5–6. On appeal, Sandoz disputes the District Court's construction, arguing, inter alia, that: (1) the "wherein" clauses "merely state the intended results of administering Combigan[®] twice daily," Appellant's Br. 36; *see id.* at 36–49; and (2) the recited results are not "material to patentability," *id.* at 50; *see id.* at 50–62. We disagree with Sandoz.

Consistent with claim construction principles, we look first to the language of the claims, followed by the language

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the [US]PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317 (citation omitted).

[8] "[E]xtrinsic evidence . . . consists of all evidence external to the patent and prosecution history." *Phillips*, 415 F.3d at 1317 (internal quotation marks and citation omitted).

of the specification and prosecution history. *See Phillips*, 415 F.3d at 1315. Independent claim 1 of the '453 patent recites both a representative efficacy "wherein" clause, '453 patent col. 9 l. 20–col. 10 l. 1 ("[W]herein the method is as effective as the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day."),[9] and a representative safety "wherein" clause, *id.* col. 10 ll. 1–7 ("[W]herein the method reduces the incidence of one o[r] more adverse events selected from the group consisting of conjunctival hyperemia, oral dryness, eye pruritus, allergic conjunctivitis, foreign body sensation, conjunctival folliculosis, and somnolence when compared to the administration of 0.2% w/v brimonidine tartrate monotherapy three times daily.").[10] Sandoz contends that these clauses "merely state . . . intended results," Appellant's Br. 36, because they reflect the results of administering the Example I formulation, viz., Combigan®, as witnessed during the Example II clinical study, *see, e.g.*, *id.* at 36 ("The asserted method claims have one and only one step: administration of the claimed composition. Everything else is literally the results observed during clinical trials of Combigan[®]."); *see also Minton v. Nat'l Ass'n of Sec.*

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[9] Independent claim 1 of the '802 patent recites a similar efficacy "wherein" clause. '802 patent col. 9 ll. 16–19 ("[W]herein the method is as effective at reducing intraocular pressure as the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day.").

[10] Independent claim 1 of the '801 patent recites a similar safety "wherein" clause. '801 patent col. 9 l. 32–col. 10 l. 3 ("[W]herein said method reduces the incidence of one or more adverse events, as compared to the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day, wherein the adverse event is selected from the group consisting of conjunctival hyperemia, oral dryness, eye pruritus, allergic conjunctivitis, foreign body sensation, conjunctival folliculosis, and somnolence.").

Dealers, Inc., 336 F.3d 1373, 1381 (Fed. Cir. 2003) ("A whereby [or wherein] clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited."); *Bristol–Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) (explaining that claim language that "is only a statement of purpose and intended result" and that "does not result in a manipulative difference in the steps of [a] claim" is generally not limiting). We disagree. While we recognize some overlap between the language of the "wherein" clauses and those results, we must read the claims in view of the "*entire* specification." *Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1145 (Fed. Cir. 2007) (emphasis added); *see Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1363 (Fed. Cir. 2016) ("[T]he specification is *always* highly relevant to the claim construction analysis and is, in fact, the single best guide to the meaning of a disputed term." (internal quotation marks and citation omitted)).

The specification of the Patents-in-Suit demonstrates that the claimed invention is ultimately a formulation (and methods of using that formulation) that allows for increased efficacy and safety, i.e., a decreased risk of adverse events. *See* '453 patent col. 1 ll. 48–53 ("[T]here is a need to increase the efficacy of many topical ophthalmic agents, without increasing the systemic concentration of such topical agents, since it is well known that many of such topically-applied ophthalmic agents cause systemic side effects, e.g. drowsiness, heart effects, etc."), col. 4 ll. 29–37 (explaining that the Example II clinical study was a comparative study of the "safety and efficacy" of the Example I formulation), col. 6 l. 2–col. 8 l. 14 (detailing "Conclusions" with regard to the "Efficacy" and "Safety" of the Example I formulation), col. 9 ll. 2–10 (explaining that the Example I formulation was found to be "superior . . . in lowering the elevated IOP of patients with glaucoma or ocular hypertension" and "demonstrated a favorable safety profile . . . with

regard to the incidence of adverse events and discontinuations due to adverse events"). These benefits are described throughout the specification with reference to prior art topical ophthalmic treatments, viz., Timolol BID and "0.2% w/v brimonidine tartrate" TID, as recited in the claims; indeed, the Example II clinical study directly compares use of the Example I formulation with those prior art treatments and concludes that the claimed method is "superior" in both efficacy and safety. Thus, the specification demonstrates that Allergan believed the increased efficacy and safety of the claimed methods to be material to patentability.

Consistent with this understanding, Allergan relied on the efficacy and safety of the claimed methods during prosecution of the Patents-in-Suit in responding to the examiner's rejections. *See Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995) ("[A]rguments made during prosecution regarding the meaning of a claim term are relevant to the interpretation of that term in every claim of the patent absent a clear indication to the contrary."). For example, in distinguishing the claimed methods over the prior art, Allergan explained that the prior art

> does nothing to teach or suggest that the claimed fixed combination of brimonidine tartrate and timolol maleate administered twice daily would be as effective as the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day, nor that administration of the claimed fixed combination would cause an unexpected reduction in adverse events.

J.A. 944; *see* J.A. 943 (disagreeing with the Examiner "that the reduction in side effects is inherently present in the prior art combination"), 944 (explaining that the prior art "does not teach or suggest that the claimed fixed combination of brimonidine tartrate and timolol maleate

administered twice daily would be as effective as the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day" or cause "the unexpected reduction of adverse effects"). Allergan therefore argued that the improved efficacy and safety of the claimed methods were "unexpected results" that "underscore[d] the patentability and non-obviousness of the . . . claims." J.A. 945; *see* J.A. 944–48.

Indeed, the Examiner explicitly relied on the "wherein" clauses in explaining why the claims of the Patents-in-Suit were "novel and non-obvious over the prior art." J.A. 977; *see* J.A. 975–77 (explaining, by the Examiner, the reasons for allowing the '453 patent application), 997–99 (explaining, by the Examiner, the reasons for allowing the '801 patent application), 1009–10 (explaining, by the Examiner, the reasons for allowing the '802 patent application). The Examiner explained that the prior art "data," consisting of "only . . . a single data point for IOP," was insufficient to teach the recited efficacy limitations, *see* J.A. 976, 998, 1009, and credited Allergan with having shown that the prior art "fail[ed] to teach the reduction in adverse events as compared to the administration of 0.2% w/v brimonidine tartrate monotherapy three times a day as claimed," J.A. 976, 998 (same), 1009 (same); *see ACCO Brands, Inc. v. Micro Sec. Devices, Inc.*, 346 F.3d 1075, 1079 (Fed. Cir. 2003) (construing the asserted claims consistent with the examiner's reasons for allowance where the examiner simply reiterated "the arguments that the patentee had presented"). The prosecution history thus demonstrates that the formulation's efficacy and safety—as reflected in the disputed "wherein" clauses—were expressly relied on to define the claimed methods and distinguish them from the prior art.

Accordingly, having reviewed the intrinsic evidence, we are persuaded that the "wherein" clauses are material to patentability and thus limiting. *See Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed. Cir. 2005) ("[W]hen [a]

'whereby' [or 'wherein'] clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention.").

We are not persuaded by Sandoz's primary counterarguments, including Sandoz's reliance on *Bristol–Myers*, 246 F.3d 1368, *In re Copaxone Consolid. Cases*, 906 F.3d 1013 (Fed. Cir. 2018), and *Georgetown Rail Equip. Co. v. Holland, L.P.*, 867 F.3d 1229 (Fed. Cir. 2017). *See generally* Appellant's Br.; Appellant's Reply Br.; Oral Arg. http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2018-2207.mp3. In *Bristol–Myers* we expressly noted that the disputed claim terms "w[ere] voluntarily made after the examiner had already indicated . . . the claims were allowable" and such "unsolicited assertions of patentability made during prosecution do not create a material claim limitation." 246 F.3d at 1375. Likewise, in *Copaxone* we held that the disputed claim terms were not "necessary or relevant to the examiner's approval." 906 F.3d at 1024. Finally, in *Georgetown Rail* we explained that the disputed claim terms were not relied upon during prosecution to "distinguish the patented invention from the prior art." 867 F.3d at 1238. Here, however, both Allergan and the Examiner explicitly relied on the "wherein" clauses to distinguish the claimed methods over the prior art during prosecution. The "wherein" clauses were neither unnecessary nor irrelevant, but were instead material to the Examiner's patentability determination.[11]

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[11] Neither Allergan nor Sandoz disputes that because we affirm the District Court's determination that the "wherein" clauses are limiting, the District Court's granting of Allergan's preliminary injunction should likewise be affirmed. *See* Appellant's Br. 34 ("The district court's preliminary injunction decision rises and falls with its claim construction."), 67 ("The district court's grant of a preliminary injunction rises and falls with its claim construction.

CONCLUSION

We have considered Sandoz's remaining arguments[12] and find them unpersuasive. Accordingly, the Opinion and Order of the U.S. District Court for the District of New Jersey is

AFFIRMED

Indeed, the court's likelihood of success analysis turns entirely on claim construction."); Appellee's Br. 56–57; Appellant's Reply Br. 35–36 ("Both the public interest and the balance of equities rise and fall with claim construction here[.]"). Accordingly, we affirm the District Court's granting of Allergan's motion for preliminary injunction.

[12] Sandoz's argument that the District Court erred by considering this Court's earlier decisions in *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286 (Fed. Cir. 2013), and *Allergan Sales, LLC v. Sandoz, Inc.*, 717 F. App'x 991 (Fed. Cir. 2017), Appellant's Br. 62–67, is mistaken. Indeed, the District Court was well within its discretion to consider those decisions concerning related patents to support its claim construction determination. *See V–Formation, Inc. v. Benetton Group SpA*, 401 F.3d 1307, 1312 (Fed. Cir. 2005) ("The district court properly referred to a related, non-binding judicial opinion to support its [claim construction] conclusion in this case.").

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PROST, *Chief Judge*, concurring.

The central question before us is whether the "wherein" clauses here are limiting. Claim 1 of the '453 patent expressly recites two "wherein" clauses, which set out specific safety and efficacy benchmarks for the claimed formulation. However, Sandoz invites us to read these requirements out of the claim. Sandoz insists that these "wherein" clauses are mere statements of inherent results or general purpose that do not meaningfully limit the scope of the invention. For the reasons below, I agree with the majority's conclusion and most aspects of its thoughtful analysis. However, I would arrive at that conclusion by following a slightly different path.

I

As an initial matter, the posture in this case is unusual. The outcome of Sandoz's appeal turns purely on an issue of claim construction. If treated as non-limiting, Sandoz argues the asserted claims are automatically rendered invalid, based on prior rulings concluding that similar claims reciting the remaining elements are obvious. In turn, Sandoz contends that there can be no likelihood of success on the merits such that the district court's decision to grant Allergan a preliminary injunction must be reversed. Allergan agrees that Sandoz's challenge on appeal here rests entirely on the issue of claim construction.

Turning to the analysis, I agree with the majority's review of our relevant law. We have a well-established set of legal standards governing claim construction and the majority has already ably articulated those standards in detail. *See* Majority Op. 5–6. Suffice it to say that "claim construction must begin with the words of the claims themselves," *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1301 (Fed. Cir. 2006), and then proceed to consider a term's meaning to one of ordinary skill in the art in light of the other intrinsic evidence, including the specification and prosecution history, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315–17 (Fed. Cir. 2005) (en banc).

In addition, our prior decisions have grappled with the more specific question of whether a particular clause in the body of a method claim is non-limiting. On one hand, we have given limiting effect to "wherein" clauses that "relate back to and clarify what is required by the count," giving "meaning and purpose to the manipulative steps." *Griffin v. Bertina*, 285 F.3d 1029, 1033 (Fed. Cir. 2002). Furthermore, if the clause "states a condition that is material to patentability, it cannot be ignored." *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed. Cir. 2005).

On the other hand, we have held that a clause that "merely states the result of the limitations" already in the

claim "adds nothing to the patentability or substance of the claim." *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1172 (Fed. Cir. 1993). Similarly, a clause in a method claim "is not given weight when it simply expresses the intended result of a process step positively recited." *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003); *see also Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) ("[W]e agree with the defendants that this language is only a statement of purpose and intended result. The expression does not result in a manipulative difference in the steps of the claim.").

II

Turning to the application of these principles to the disputed clauses in claim 1 of the '453 patent, I agree with the majority in terms of the result. The "wherein" clauses here are limiting. I also agree with the majority's well-reasoned conclusion that the specification and prosecution history confirm the recited results were "material to patentability." But I would add one narrow but crucial point about the claim language at the outset of the majority opinion.

In my view, the claim language on its face confirms that these clauses give meaning and purpose to the other manipulative steps of claim 1. *Griffin*, 285 F.3d at 1033. The majority does not address the plain language of the claim. I take the opportunity to do so here. As explained below, Sandoz's arguments concerning the claim language fail.

Sandoz's principal argument about the claim language is that the "wherein" clauses merely describe results that occur whenever the claimed dosages are administered. To support this assumption, Sandoz provides no intrinsic evidence. Instead, it summarily asserts that "nothing in the intrinsic record identifies any combination of 0.2% brimonidine tartrate/0.68% timolol maleate administered twice daily that does not satisfy the wherein clauses." Reply

Br. 25. But nothing in the claims—or the rest of the intrinsic record for that matter—states that any combination of these two compositions *will* satisfy the "wherein" clauses.

Thus, Sandoz's position falters from the start. Beginning with "the words of the claims themselves," *Amgen*, 457 F.3d at 1301, Sandoz has put forth no evidence how either clause "merely states the result of the limitations in the claim." *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1319 (Fed. Cir. 2003). In my view, no part of the plain text of claim 1 shows these benchmarks are an inherent result of the dosage limitations.

Lest there be any doubt, the other language of claim 1 further exposes the lack of support for Sandoz's position. Claim 1 is written in open format. *See* '453 patent col. 9 ll. 16–17 ("A method of treating a patient with glaucoma or ocular hypertension comprising . . . ."). Therefore, while the claimed treatment must include the two recited compositions (0.2% w/v brimonidine tartrate and 0.68% w/v timolol maleate), other compositions can be present in the formulation, such as solvents, buffers, and preservatives typical for ophthalmic solutions. *See id.* col. 2 ll. 46–65, col. 3 ll. 23–30. Sandoz provides no explanation as to how the recited dosages of brimonidine tartrate and timolol maleate will necessarily achieve these results if these other formulation parameters vary. In addition, the claims are not directed to a composition alone. Instead, they are directed to a method of "administering." *Id.* col. 9 l. 17. Without the "wherein" clauses, the only other limitation guiding the physician is that the drug is administered "twice" per day. *Id.* Sandoz provides no basis for us to conclude with any certainty that the safety and efficacy requirements of the "wherein" clauses would always result from two doses of (1) any formulation of the combination at (2) any interval in a 24-hour period.

Nor does the text of claim 1 suggest that these specific benchmarks are "only a statement of purpose and intended

result." *Bristol-Myers Squibb*, 246 F.3d at 1376. On their face, these clauses state specific requirements rather than a general purpose or aspirational result for the claimed method. The efficacy clause does not simply require some general level of therapeutic effectiveness. Instead, it specifically requires that the claimed formulation be "as effective as the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day." '453 patent col. 9 l. 20–col. 10 l. 1.

Likewise, the safety clause does not recite that the claimed method of treatment is generally intended to improve safety. Rather, with equal particularity, the safety clause of claim 1 here requires that the claimed formulation "reduces the incidence of one of more adverse events"—specifically "selected from the group consisting of conjunctival hyperemia, oral dryness, eye pruritus, allergic conjunctivitis, foreign body sensation, conjunctival folliculosis, and somnolence"—in comparison once again "to the administration of 0.2% w/v brimonidine tartrate monotherapy three times daily." *Id.* col. 10 ll. 1–7.

In light of this claim language, Sandoz's attempt to liken the clauses here to the non-limiting term in *Minton* founders. In *Minton*, we reasoned that the term "efficiently" "*on its face* does not inform the mechanics of how the trade is executed, and nothing in the specification or the prosecution history suggests otherwise." *Minton*, 336 F.3d at 1381 (emphasis added) (concluding term was a non-limiting statement of intended result of a claim directed to a system for executing securities trades). Here, Sandoz has provided no affirmative basis for us to conclude from the claim language alone that these detailed clauses—which specify clear and measurable metrics that the formulation must meet—are a mere intended result.

Therefore, I would reject Sandoz's position that the claim language on its face recites either an inherent or intended result.

III

The specification serves to reinforce the clear import of the claims. Indeed, this consistency between the claims and the specification is punctuated by the majority's own thorough review of the specification.

As explained by the majority, the specification confirms that "the claimed invention is ultimately a formulation" that meets the specific safety and efficacy outcomes in claim 1. *See* Majority Op. 8. To support this conclusion, the majority points to various parts of the specification that essentially mirror the structure of the "wherein" clauses' language in claim 1, which uses specific prior art as a clear benchmark for measuring safety and efficacy. In the majority's own words, these safety and efficacy "benefits are described throughout the specification with reference to prior art topical ophthalmic treatments, viz., Timolol BID and '0.2% w/v brimonidine tartrate' TID, *as recited in the claims*." *Id.* at 9 (emphasis added). Thus, the majority recognizes the parallel nature of the claims and specification.

Sandoz's attempts to undermine this consistency between the claims and the specification fail. The specification does not support Sandoz's position that *any* formulation involving the two compositions administered twice daily will satisfy the clauses. Indeed, Sandoz cannot point to any place in the specification that suggests these traits are inherently found in all formulations that combine 0.2% w/v brimonidine tartrate and 0.68% w/v timolol maleate.

Sandoz's reliance on *Bristol-Myers Squibb* is therefore misplaced. We have no reason to conclude that the safety and efficacy standards required by the "wherein" clauses "essentially duplicate[] the dosage amounts recited in the claims." *Bristol-Myers Squibb*, 246 F.3d at 1375 (finding claimed dosages are described in the specification as "antineoplastically effective"). Thus, these claims stand in stark contrast to the non-limiting clauses in both *Bristol-*

Myers Squibb and other cases decided on similar facts. *Id.* ("The express dosage amounts are material claim limitations; the statement of the intended result of administering those amounts does not change those amounts or otherwise limit the claim."); *see also In re Copaxone Consol. Cases*, 906 F.3d 1013, 1023 (Fed. Cir. 2018) (finding clause "does not change the express dosing amount or method already disclosed in the claims").

Given the lack of support for its position, Sandoz tries to show inherent results by redrawing the claim's scope. Sandoz implies that the scope of the claims is limited to the preferred embodiment, Combigan®. The clinical trials of Combigan® discussed in the specification (Example II) achieved the benchmarks recited in the efficacy and safety clauses of claim 1. *See* Appellant's Br. 41–42; Reply Br. 23, 25. Sandoz jumps to the conclusion that the "wherein" clauses therefore only recite inherent or intended results.

Sandoz's position fails for at least two reasons. First, Sandoz did not argue that the claims should be construed as being limited to Allergan's commercial embodiment Combigan®. Second, there is no basis in the record before us for assuming that all formulations of the combination necessarily behave like Combigan®. Combigan® is "a sterile, preserved, aqueous solution" that uses the specific solvent, preservative, and buffers listed in Table 1 of the specification. '453 patent col. 3 ll. 65–67. Thus, Sandoz's arguments based on the clinical trial data for Combigan® carry little force.

In sum, no part of the specification justifies reading out the express language of the "wherein" clauses defining the claimed invention.

IV

Finally, the prosecution history cements the view that the claim language at issue is clearly limiting. Again, one need look no further than the majority's opinion for proof.

See Majority Op. 9–10. The majority's cogent analysis of the prosecution history underscores the consistency between the claim language and the rest of the intrinsic record.

The majority opinion relies on arguments Allergan made during prosecution that were directly based on the claim language itself. As the majority observes, "Allergan relied on the efficacy and safety of the claimed methods during prosecution of the Patents-in-Suit in responding to the examiner's rejections." *Id.* at 9. In particular, the majority points to Allergan's statements to the Examiner that parrot the express language of claim 1. "Allergan explained that the prior art 'does nothing to teach or suggest that the claimed fixed combination of brimonidine tartrate and timolol maleate administered twice daily would be *as effective as the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day* . . . .'" *Id.* (quoting J.A. 944) (emphasis added); *see also* '453 patent col. 9 l. 20–col. 10 l. 1 (wherein method is "as effective as the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day").

In turn, the majority emphasizes that the Examiner credited Allergan's arguments based on the claim language, which showed that "the prior art 'fail[ed] to teach the reduction in adverse events as compared to the administration of 0.2% w/v brimonidine tartrate monotherapy three times a day *as claimed*.'" *Id.* at 10 (quoting J.A. 976–77, 998–99, 1009–10) (emphasis added).

Accordingly, I would hold that the claim language, specification, and prosecution history all consistently show that the "wherein" clauses place meaningful limitations on the scope of the invention. On its face, claim 1 is limited to only those formulations of "0.2% w/v brimonidine tartrate" and "0.68% w/v timolol maleate" administered twice daily that meet the specific safety and efficacy benchmarks. The specification and prosecution history expunge any

lingering doubts that these clauses define the scope of the invention. The "wherein" clauses are important for "giving meaning . . . to the manipulative steps," rather than simply being an "inherent result of performing the manipulative steps." *Griffin*, 285 F.3d at 1033–34.

V

I offer one final point about the importance of the plain language of the claim here. Sandoz's arguments raise general concerns about the role of claim language in claim construction.

Sandoz attempts to label over half the claim language in claim 1 as a mere "intended result." By doing so, Sandoz invites us to start from a place of uncertainty about whether most of the text in the body of the claim is limiting. Accepting that invitation threatens the broader notice function of the patent claim. "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Indeed, "[b]oth the Supreme Court and this court have adhered to the fundamental principle that claims define the scope of patent protection . . . . The claims thus give notice of the scope of patent protection." *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) (en banc).

As it is, claim construction can be difficult. For instance, litigants often encounter uncertainty over whether a claim's preamble is limiting or not. I see no reason to inject further uncertainty into the notice provided by the body of a claim. Given the specificity, clarity, and material limits the "wherein" clauses add to the scope of claim 1 on their face, Sandoz's position deserves rigorous scrutiny from the start. We should not begin with the presumption that text in the body of the claim may be meaningless and

can only be saved by clear statements in the specification or prosecution history.

Therefore, I would affirm the district court's decision for the reasons stated in the majority's opinion, except that I would start by explaining why the plain language of the claim compels us to reject Sandoz's position that the "wherein" clauses here are mere statements of inherent or intended results.