United States Court of Appeals for the Federal Circuit

AZURITY PHARMACEUTICALS, INC.,
Plaintiff-Appellant

v.

ALKEM LABORATORIES LTD.,
Defendant-Appellee

2023-1977

Appeal from the United States District Court for the District of Delaware in No. 1:20-cv-01094-MSG, Chief Judge Mitchell S. Goldberg.

Decided: April 8, 2025

TUNG ON KONG, Wilson, Sonsini, Goodrich & Rosati, PC, San Francisco, CA, argued for plaintiff-appellant. Also represented by WENDY L. DEVINE; KELSEY CURTIS, RICHARD TORCZON, Washington, DC.

ALAN HENRY POLLACK, Windels Marx Lane & Mittendorf, LLP, Madison, NJ, argued for defendant-appellee. Also represented by KIERSTEN AMANDA FOWLER, JOSHUA I. MILLER.

Before MOORE, *Chief Judge*, CHEN, *Circuit Judge*, and MURPHY, *District Judge*.[1]

MURPHY, *District Judge*.

This appeal arises from a suit under the Hatch-Waxman Act. Azurity Pharmaceuticals, Inc. ("Azurity") brought suit against Alkem Laboratories Ltd. ("Alkem") for infringement of claims 5, 7, 8, and 9 of U.S. Patent No. 10,959,948 ("the '948 patent") following Alkem's submission of an Abbreviated New Drug Application ("ANDA"). After a two-day bench trial, the court found that Alkem's ANDA did not infringe any of the asserted claims of the '948 patent. *Azurity Pharms., Inc. v. Alkem Lab'ys, Ltd.*, 671 F. Supp. 3d 489 (D. Del. 2023). Because the district court correctly found that Azurity disclaimed any presence of propylene glycol in the prosecution history of the '948 patent, Alkem's ANDA product contains propylene glycol, and a stipulation entered by the parties during discovery does not preclude Alkem's disclaimer argument, we affirm.

BACKGROUND

Azurity's '948 patent is directed to non-sterile drinkable liquid formulations containing the antibiotic vancomycin and methods for using those formulations to treat *Clostridium difficile* infection. '948 patent, Abstract; *id.* at col. 1, ll. 21–25. Drinkable liquid drugs are particularly useful for treating pediatric and geriatric populations because they present a lower choking risk than capsules and, unlike injections, do not require sterilization. *Id.* at col. 5, ll. 31–55; *id.* at col. 6, ll. 1–17.

Claim 5 of the '948 patent is representative and is reproduced below:

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[1] Honorable John F. Murphy, District Judge, United States District Court for the Eastern District of Pennsylvania, sitting by designation.

> 5. A non-sterile stable liquid formulation formulated for oral administration, *consisting of*:
>
> > a buffering agent, wherein the buffering agent is selected from the group consisting of citric acid, sodium citrate, sodium tartarate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogen phosphate, trisodium phosphate, tripotassium phosphate, sodium acetate, potassium metaphosphate, magnesium oxide, magnesium carbonate, magnesium silicate, calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, and calcium salts,
> >
> > water,
> >
> > a sweetener,
> >
> > a preservative, wherein the preservative is selected from the group consisting of sodium benzoate, parabens, benzoic acid, potassium sorbate, benzyl alcohol or salts thereof,
> >
> > vancomycin hydrochloride, and
> >
> > *flavoring agent,*
>
> wherein the non-sterile stable liquid formulation is homogenous and stable for at least 1 week at ambient and refrigerated temperature and has a pH of 2.5–4.5.

Id. at col. 46, ll. 49–67, col. 47, ll. 1–3 (emphases added).

The application for the '948 patent, U.S. Patent Application No. 16/941,400 ("the '400 application") was allowed

without rejection. *Azurity*, 671 F. Supp. 3d at 502. But that application was a continuation of U.S. Patent Application No. 15/126,059 ("the '059 application"), which had been rejected several times by the examiner over a prior art reference known as Palepu, U.S. Patent Application Publication 2016/0101147. *Azurity*, 671 F. Supp. 3d at 497–502. Palepu discloses an intravenously administered liquid formulation containing vancomycin used to treat *Clostridium difficile* with "a polar solvent including propylene glycol." J.A. 3606–07.

The district court determined that, through amendments and arguments made in the '059 application distinguishing Palepu, Azurity "clearly and unmistakably" disclaimed propylene glycol from the invention claimed in the '948 patent. *Azurity*, 671 F. Supp. 3d at 509–10. The district court found that Alkem's ANDA product undisputedly contains propylene glycol, and accordingly ruled that Alkem's ANDA product did not infringe the '948 patent because the asserted claims used the closed "consisting of" transition. *Id.* at 510–12.

Azurity argued that a stipulation made during discovery overcame any disclaimer arising from the "flavoring agent" claim term. *Id.* at 511. The parties had stipulated that "[s]uitable flavoring agents for use in the Asserted Claims include flavoring agents with or without propylene glycol." *Id.* Azurity interpreted the stipulation to mean that products with flavoring agents that include propylene glycol could infringe the '948 patent regardless of the "consisting of" transition and any purported disclaimer. The district court found that Azurity's interpretation of the stipulation was "unpersuasive," and that the disclaimer of propylene glycol was still dispositive. *Id.*

Azurity appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

We review a judgment following a district court bench trial for legal error or clearly erroneous factual findings. *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1375 (Fed. Cir. 2022). "Infringement . . . is a question of fact." *Id.* at 1375–76. "Under the clear-error standard, we defer to the district court's findings in the absence of a definite and firm conviction that a mistake has been made." *Par Pharm., Inc. v. Eagle Pharms., Inc.*, 44 F.4th 1379, 1383 (Fed. Cir. 2022) (quotations omitted).

Claim construction is reviewed de novo, and any underlying factual determinations are reviewed for clear error. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326–27 (2015). An application of prosecution disclaimer is reviewed de novo. *Genuine Enabling Tech. LLC v. Nintendo Co.*, 29 F.4th 1365, 1372 (Fed. Cir. 2022).

"A stipulation of fact that is fairly entered into is controlling on the parties and the court is generally bound to enforce it." *Ring & Pinion Serv. Inc. v. ARB Corp.*, 743 F.3d 831, 836 (Fed. Cir. 2014). When "[r]eview[ing] . . . the district court's interpretation of the parties' pre-trial stipulations . . . this court reviews underlying factual findings for clear error and reviews the ultimate interpretation of the stipulation de novo." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 805 F.3d 1368, 1374 (Fed. Cir. 2015).

II

We will leave aside the issues raised by Azurity related to the stipulation for a later section in this opinion. Instead, we first address Azurity's argument related to disclaimer. And we begin by recapitulating the portions of the prosecution history relevant to the '948 patent.

A

The '948 patent is part of a larger patent family that includes U.S. Patent Nos. 10,959,946, 10,959,947, and 10,959,949. The following discussion will explain how Azurity's claims directed to vancomycin liquid formulations evolved during the prosecution that led to '948 patent. The earliest claims, filed in the '059 application, used the open-ended transition "comprising" to specify the formulation: "A non-sterile stable liquid formulation comprising a compounded solution of vancomycin . . . ." *Azurity*, 671 F. Supp. 3d at 498. The examiner rejected these claims over prior art including Palepu.

In early 2019, Azurity proposed several draft amendments and new claims in preparation for an interview with the examiner. Of relevance here, some included the following negative limitations: "wherein the oral liquid solution does not comprise a propylene glycol," "wherein the liquid solution does not comprise a suspending agent," and "wherein the liquid solution does not comprise a propylene glycol." J.A. 2425–27. In the interview summary, the examiner explained that the negative claim limitations excluding propylene glycol were insufficient to overcome the rejection because Palepu also disclosed polyethylene glycol. J.A. 2429. The examiner also remarked that the exclusion of suspending agents did not address Palepu's disclosure of propylene glycol because Palepu's glycols were said to be solvents, not suspending agents. *Id.* The examiner suggested that Azurity "could amend using consisting of language." *Id.*

Shortly after, Azurity formally responded, amending then claims 16 and 20 to include a negative limitation excluding propylene glycol. J.A. 2441–42. And for then claims 24 and 31, Azurity introduced the close-ended transition phrase "consisting of." J.A. 2442–43. Specifically, those two claims recited "[a] liquid solution comprising a carrier consisting of" certain ingredients—propylene glycol

not among them. *Id.* In the accompanying remarks, Azurity argued that Palepu's compositions include "a polar solvent comprising propylene glycol, polyethylene glycol, or mixtures thereof" and that "[t]he absence of propylene glycol and polyethylene glycol in the claimed invention [of then claim 20], in part, distinguish it from [Palepu]." J.A. 2435.

Along with that response, Azurity submitted a declaration by Dr. Steven Dinh, Azurity's Executive Vice President and Chief Scientific Officer. Dr. Dinh averred that "[a]s shown in the ['059] Application, the diluent and the compounded solutions do not have propylene glycol or polyethylene glycol, both of which were noted as important components in Palepu's compositions." J.A. 2448.

In the next office action, the examiner rejected the amended claims with negative limitations because there was no description for a solution that "does not comprise a propylene glycol or a suspending agent." J.A. 2467. The examiner also objected to Azurity's separation of vancomycin from the liquid solution containing the other ingredients (termed the "carrier" in these claims) because the specification "does not provide written description for a separate carrier consisting of the [other] ingredients." *Id.* (emphasis removed). And the examiner rejected the claim language that used "comprising" and "consisting of" in tandem because it was unclear "if other components can be present with the solution or not." J.A. 2469.

In response, Azurity amended its claims again, removing the putatively unsupported negative limitations and adding "consisting of" or "consists of" preambles to the claims. J.A. 2519–21. Turning to the prior art, Azurity argued that "[t]he absence of propylene glycol and polyethylene glycol in the claimed invention, in part, distinguish it from [Palepu]," and further stated that "the compositions of Palepu do not fall within the scope of the claimed invention. The claimed invention does not include the polar

solvents or lactic acid of Palepu." J.A. 2527–28. Azurity reiterated similar reasoning for the remaining claims, relying on the closed nature of the amended claims and Papelu's inclusion of other ingredients such as propylene glycol. J.A. 2528–31.

Eventually, the examiner allowed the relevant claims of the '059 application. In the accompanying reasons for allowance, the examiner explained that Palepu "teaches a non-sterile stable liquid formulation having vancomycin hydrochloride together with either propylene glycol or polyethylene glycol in the liquid formulation. The instant claims exclude the presence of propylene glycol or polyethylene glycol in view of the consisting of language, and thus overcome the teachings of Palepu which requires the propylene glycol or polyethylene glycol to be present with the vancomycin hydrochloride." J.A. 2570. After that allowance, Azurity filed the '400 application as a continuation of the '059 application. The examiner allowed those claims without rejection, and they issued in the '948 patent.

After Alkem submitted its Paragraph IV letter related to this lawsuit, on October 13, 2020—in another patent application in the same family also claiming priority to the '059 application, U.S. Patent Application No. 16/892,421 ("the '421 application")—Azurity made the following statement in the introduction of a response to an office action: "For the record, Applicant did not disclaim propylene glycol when submitting the arguments in U.S. 15/126059, and reserves the right to claim propylene glycol in the instant and future cases in this patent family." *Azurity*, 671 F. Supp. 3d at 503; J.A. 2808. The examiner allowed the claims at issue there, but did not respond to Azurity's statement. The examiner stated that the claims—which also used the "consisting of" transition—were allowed because "[n]one of the prior art teaches or suggests a composition consisting of ingredients a-f as claimed." J.A. 2822. The "ingredients a-f" were citric acid, water, a sweetener, sodium benzoate,

20–60 mg/ml vancomycin hydrochloride, and flavoring agent. J.A. 2821. The examiner also stated that "Palepu's formulations require propylene glycol present as the polar solvent with lactic acid." *Id.*

B

With a full appreciation for the relevant prosecution history, we now consider whether the district court correctly held that Azurity clearly and unmistakably disclaimed propylene glycol. We hold that it did, and that the disclaimer of propylene glycol applies to all claims of the '948 patent.

Azurity argues that the district court's interpretation of the prosecution history is overbroad. Azurity views the prosecution history as ambiguous and, even if there were a disclaimer, Azurity argues that it excludes propylene glycol only as a carrier and does not reach the claim term "flavoring agent." Alkem asks us to affirm the district court's finding that Azurity disclaimed any inclusion of propylene glycol.

One of two exceptions to the general rule of claim construction is "when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). "A patentee may, through a clear and unmistakable disavowal in the prosecution history, surrender certain claim scope to which he would otherwise have an exclusive right by virtue of the claim language." *Data Engine Techs. LLC v. Google LLC*, 10 F.4th 1375, 1382 (Fed. Cir. 2021) (quoting *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1324 (Fed. Cir. 2009)). "Any explanation, elaboration, or qualification presented by the inventor during patent examination is relevant, for the role of claim construction is to capture the scope of the actual invention that is disclosed, described, and patented." *TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1063 (Fed. Cir. 2016) (quotations omitted). Holding

patentees to their definitive statements made during prosecution protects the public and promotes the notice function of intrinsic evidence. *Data Engine Techs.*, 10 F.4th at 1383. Statements that clearly and unmistakably disavow claim scope to one skilled in the art are binding, "even if [the patentee] said more than needed to overcome a prior art rejection." *Id.* Courts must take care, however, to interpret purported disavowals in the context of the prosecution history as a whole. *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1342 (Fed. Cir. 2009), *amended on reh'g in part*, 366 F. App'x 154 (Fed. Cir. 2009). "The party seeking to invoke prosecution history disclaimer bears the burden of proving the existence of a 'clear and unmistakable' disclaimer that would have been evident to one skilled in the art." *Tri-Vascular*, 812 F.3d at 1063–64.

Here, Alkem amply met its burden by identifying Azurity's clear and unmistakable statements in the prosecution history of the '948 patent disclaiming the presence of any propylene glycol in the claimed invention.

To reach our conclusion about the scope of the '948 patent, we focus on the relevant prosecution history in the '400 application and its parent '059 application. Azurity contends that its remarks made in the '421 application are also relevant for determining the scope of the claims of the '948 patent. This is incorrect. It is true that statements in the prosecution histories of patents descended from a common ancestor application may be relevant for interpretating the claims in the related patents. But our decisions have focused on how such statements have been relevant to *later* issued patents. *See, e.g.*, *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) (discussing the relevance of the prosecution histories of two related patents where the application for the subsequently issued patent was filed as a continuation of the earlier issued patent after the first patent was allowed); *Biovail Corp. Int'l v. Andrx Pharms., Inc.*, 239 F.3d 1297, 1301 (Fed. Cir. 2001) (same); *Gemalto S.A. v. HTC Corp.*, 754 F.3d 1364, 1371

(Fed. Cir. 2014) (same); *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349–50 (Fed. Cir. 2004) (applying disclaimer in one application to related, later-issued patents).

Here, Azurity prosecuted the '421 application in parallel with the '400 application, and the '421 application was a continuation of yet another application (U.S. Patent Application No. 15/791,717) not a part of the direct line of applications that led to the '948 patent; the '421 application was in effect the '400 application's grand-nephew. *Azurity*, 671 F. Supp. 3d at 503. And Azurity made its "for the record" statement in the '421 application *after* the examiner had allowed the claims of the '400 application. Judging these circumstances through the lens of public notice, Azurity's unilateral and belated statement carries no weight.

Turning to the more pertinent '059 application, there, the examiner repeatedly cited Palepu as prior art. And at every opportunity, Azurity clearly and unmistakably distinguished its invention from Palepu by asserting that the claimed formulations did not contain propylene glycol. *See supra*, § II.A.

The evolution of the two independent claims that emerged from the '059 application, claims 20 and 24, illustrates the point. In a first amendment, Azurity added the negative claim limitation "wherein the [] solution does not comprise a suspending agent" to both claims. J.A. 2425–26. After rejection, in a second amendment, Azurity added the negative limitation "wherein *the compounded solution does not comprise propylene glycol*" to claim 20 and added "comprising a carrier consisting of" to the preamble of claim 24. J.A. 2442 (emphasis added). And in accompanying remarks about claim 20, Azurity stated that "*[t]he absence of propylene glycol* and polyethylene glycol in the claimed invention, in part, *distinguish it from [Palepu].*" J.A. 2435 (emphases added). And even the declarant, Dr. Dinh, reiterated that "[a]s shown in the Application, the

diluent and *the compounded solutions do not have propylene glycol*." J.A. 2448 (emphasis added).

At the examiner's suggestion and after another rejection, Azurity added "consisting of" to the preambles of claims 20 and 24. The "consisting of" transition is closed. With little exception, it limits the claim's scope to the recited components. *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004) ("'Consisting of' is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim."); *AFG Indus., Inc. v. Cardinal IG Co.*, 239 F.3d 1239, 1245 (Fed. Cir. 2001) ("'[C]losed' transition phrases such as 'consisting of' are understood to exclude any elements, steps, or ingredients not specified in the claim.").

The prosecution history leaves no room to doubt that Azurity adopted the "consisting of" transition specifically to narrow the claims and overcome Palepu and its disclosure of propylene glycol. Azurity confirmed as much in its remarks, arguing for claim 20 that "Palepu teaches that its *polar solvents (e.g. propylene glycol)* and lactic acid (or the lactate molecule used in some embodiments) confer its compositions with long-term stability. *The claimed invention is an oral vancomycin formulation* that . . . *does not include the polar solvents* or lactic acid of Palepu." J.A. 2530 (emphases added). And for claim 24, Azurity stated that "*the liquid solution now consists of* the ingredients (a)-(f) and vancomycin hydrochloride." J.A. 2531 (emphasis added). The examiner's reasons for allowance agree with and incorporate Azurity's arguments: "*[t]he instant claims exclude the presence of propylene glycol* or polyethylene glycol *in view of the consisting of language*, and thus overcome the teachings of Palepu which requires the propylene glycol or polyethylene glycol to be present with the vancomycin hydrochloride." J.A. 2570 (emphases added).

With immaterial changes, those versions of claims 20 and 24 from the '059 application ultimately became the two

independent claims in the '948 patent. J.A. 2562. Importantly, the claims of the '400 application included the same "consisting of" preambles added during the prosecution of the '059 application. Azurity's amendments and arguments made while prosecuting the '059 application apply directly to the '400 application and the '948 patent that followed because the '400 application is a continuation of the '059 application. *Elkay Mfg. Co.*, 192 F.3d at 980 ("When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation.").

Azurity's alternative argument that the disclaimer of propylene glycol applies only to the carrier and not to the flavoring agent is unconvincing. The record reflects that Azurity tried multiple routes to satisfy the examiner that unlike Palepu, its claimed invention lacked propylene glycol. The examiner insisted on clarity, and Azurity acquiesced by abandoning the "carrier" distinction and adopting the "consisting of" transition. And the examiner confirmed that the claims were allowed because they "exclude the presence of propylene glycol." J.A. 2570. Azurity argues that in Palepu, propylene glycol functions only as a carrier. That may be true, but what matters most is the broad language that Azurity used to distinguish Palepu. Just as the echo matches the shout, Azurity's repeated, sweeping statements—endorsed by the examiner—return an equally sweeping disclaimer. *See Tech. Props. Ltd. LLC v. Huawei Techs. Co.*, 849 F.3d 1349, 1359 (Fed. Cir. 2017) ("[T]he scope of surrender is not limited to what is absolutely necessary to avoid a prior art reference; patentees may surrender more than necessary.").

Based on the totality of the relevant prosecution history, we conclude that Azurity's disclaimer of propylene glycol in the claims of the '948 patent was clear, unambiguous, and complete.

III

We next address Azurity's argument that one of the parties' pretrial stipulations precludes any application of the disclaimer.

Before trial, the parties prepared a list of at least 143 undisputed facts that did not require proof at trial. The very last stipulation in this section is the critical one that Azurity relies on here: "Suitable flavoring agents for use in the Asserted Claims include flavoring agents with or without propylene glycol." J.A. 1773. According to Azurity, the stipulation means that Alkem surrendered its disclaimer argument at least with respect to the claimed "flavoring agent." Put another way—and consistent with how the district court understood Azurity's interpretation—"[s]uitable flavoring agents for use in the Asserted Claims" means "*infringing* flavoring agents." *Azurity*, 671 F. Supp. 3d at 511 (emphasis added). Alkem disagrees, arguing when the stipulation is understood in the context of its origin, it merely confirms that in this field, the relevant flavoring agents need not have propylene glycol.

For several reasons, we agree with Alkem and the district court. First, the undisputed facts under the heading "Infringement" begin with a statement that Alkem does not dispute infringement except that it "contends that it does not infringe the Asserted Claims due to [the] presence of propylene glycol in Alkem's ANDA Products." J.A. 1768. Azurity's view of the disputed stipulation is implausible because it would have Alkem frame the infringement dispute and then, several lines down, turn around and concede the same issue.

Second, the disputed stipulation is markedly different than the other undisputed facts under the "Infringement" heading. In a typical example, the parties agreed that "Claims 5 and 7 of the '948 Patent recite 'water'" and "Alkem's ANDA Products contain water, which meets the 'water' limitation of claims 5 and 7 of the '948 Patent." J.A.

1771. Unlike every other example, the disputed stipulation does not refer to meeting a limitation of any claim.

Third, Alkem's interpretation is more consistent with the origin of the disputed stipulation. It began with Azurity's infringement theory. Even without the disclaimer we discussed *supra*, the "consisting of" transition presumably renders any ANDA product with propylene glycol non-infringing because propylene glycol is not recited in the claims. But the parties appreciated that propylene glycol might find its way into this sort of ANDA product either incidentally—*i.e.*, as part of a flavoring agent mixture—or separately. Azurity's infringement theory was that all propylene glycol in the ANDA product, even if added separately, could be deemed part of the claimed "flavoring agent"—a view the district court dubbed Azurity's "mix-and-match" theory. *Azurity*, 671 F. Supp. 3d at 494–97, 503–05. The parties began to dispute whether propylene glycol might be found in suitable flavoring agents, and eventually, Azurity admitted "that the plain and ordinary meaning of the claim term 'flavoring agent' includes flavoring agents without propylene glycol." J.A. 1134. That admission became the disputed stipulation.

With that context, the district court correctly determined that "[t]he stipulation says nothing about whether Alkem's ANDA contains a flavoring agent with propylene glycol," a necessary link in its mix-and-match theory of infringement. *Azurity*, 671 F. Supp. 3d at 511. Azurity's position that the stipulation made infringement *fait accompli*—contrary to the rest of the infringement section of the pretrial order—cannot be sustained when a far more sensible reading is the one consistent with the stipulation's origin: making clear that in this field, the relevant flavoring agents need not have propylene glycol. The district court correctly concluded that the disputed stipulation did not preclude application of disclaimer in this case.

IV

Finally, we address the district court's finding of non-infringement. The district court's decision that the presence of propylene glycol in Alkem's ANDA established non-infringement is not clearly erroneous. Accordingly, we affirm.

In a Hatch–Waxman case, "the filing of an ANDA constitutes an 'artificial' act of infringement for purposes of creating case or controversy jurisdiction. . . . [But] the ultimate infringement inquiry provoked by such filing is focused on a comparison of the asserted patent claims against the product that is likely to be sold following ANDA approval and determined by traditional patent law principles." *Ferring B.V. v. Watson Lab'ys, Inc.-Fla.*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) (citing 35 U.S.C. § 271(e)(2)(A)). "[I]f the ANDA 'defines a proposed generic drug in a manner that directly addresses the issue of infringement, it controls the infringement inquiry.'" *Par Pharm.*, 44 F.4th at 1383 (quoting *Abbott Lab'ys. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002)) (internal quotation cleaned up).

The patented formulation is a liquid mixture that "consists of" the listed ingredients in the claims of the '948 patent: buffering agent, water, a sweetener, a preservative, vancomycin hydrochloride, and a flavoring agent. *See* '948 patent, claims 5 & 7. Alkem's ANDA recites a formulation containing: vancomycin hydrochloride, Grape Flavor 501417C (flavoring agent), FD&C Red No. 40 (coloring agent), D&C Yellow 10 (coloring agent), citric acid (pH modifier or buffering agent), *propylene glycol* (co-solvent), methyl paraben (preservative), propyl paraben (preservative), sucralose micronized (sweetener), and purified water (vehicle). J.A. 3278–79; *see also* J.A. 2915. The ANDA also lists the ingredients of Grape Flavor 501417C: *propylene glycol*, flavoring, and ascorbic acid. J.A. 3278. There is no dispute that the ANDA indicates that Alkem's proposed

generic contains propylene glycol, either through the flavoring agent or the separately listed propylene glycol.

Here, having correctly concluded that Azurity comprehensively disclaimed propylene glycol, and having correctly ignored the "suitable flavoring agents" stipulation, the district court in turn found that Azurity failed to prove infringement. That was not error. The infringement inquiry here is very simple: propylene glycol was disclaimed; the ANDA contains propylene glycol; therefore there is no infringement. To be sure, absent the disclaimer, there could have been some difficult questions to answer. Indeed, the district court held a bench trial where Azurity advanced evidence that propylene glycol would affect the flavoring of the product, and that propylene glycol and grape flavoring collectively are a flavoring agent. *Azurity*, 671 F. Supp. 3d at 496–97. But these topics turned out to be of little moment in the district court's final analysis, and we agree. Because Azurity disclaimed any presence of propylene glycol, the district court's finding that Alkem's ANDA product does not infringe the claims of the '948 patent is not clearly erroneous.

CONCLUSION

For the foregoing reasons, we affirm the district court's finding that Alkem's ANDA product does not infringe the claims of the '948 patent.

AFFIRMED

COSTS

Costs to Defendant-Appellee.