NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

MELINTA THERAPEUTICS, LLC, MELINTA SUBSIDIARY CORP., REMPEX PHARMACEUTICALS, INC.,
Plaintiffs-Appellees

v.

NEXUS PHARMACEUTICALS, INC.,
Defendant-Appellant

2025-1281, 2025-1282

Appeals from the United States District Court for the Northern District of Illinois in Nos. 1:21-cv-02636, 1:21-cv-05995, Judge John F. Kness.

Decided: June 5, 2026

DAMIEN N. DOMBROWSKI, Venable LLP, New York, NY, argued for plaintiffs-appellees. Also represented by DOMINICK A. CONDE, HA KUNG WONG.

IMRON T. ALY, ArentFox Schiff LLP, Chicago, IL, argued for defendant-appellant. Also represented by HELEN H. JI, KEVIN MICHAEL NELSON, MATTHEW THOMAS WILKERSON.

Before PROST, BRYSON, and REYNA, *Circuit Judges*.

BRYSON, *Circuit Judge*.

This patent case arises under the infringement provision of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2). Melinta Pharmaceuticals, Inc. ("Melinta"), brought this action against Nexus Pharmaceuticals, Inc. ("Nexus"), alleging that a Nexus generic antibiotic infringed two of Melinta's patents. The district court found that Nexus's generic product infringed Melinta's patents and rejected Nexus's argument that the patents were invalid. We affirm the district court's decision as to the first of the two patents and decline to reach the issues raised with respect to the second.

I

The patents at issue in this case are Melinta's U.S. Patent Nos. 9,084,802 ("the '802 patent") and 9,278,105 ("the '105 patent"). The two patents are directed to methods in which the addition of magnesium to an injectable antibiotic formulation reduces hemolysis of red blood cells (i.e., cell death) at the injection site.

For the '802 patent, the claims at issue are:

> 1. A method of treating a bacterial infection in a subject, wherein the method consists of:
>
> > administering a therapeutically effective amount of a composition to a subject in need thereof via an intravenous route of administration,
> >
> > wherein the composition consists of an aqueous solution consisting of minocycline or a salt thereof, a salt that comprises a magnesium cation, and a base,

> wherein the molar ratio of magnesium cation to minocycline is greater than about 4:1, and
>
> wherein the composition has a pH that is no less than 4 and no greater than 6,
>
> whereby injection site hemolysis of red blood cells is reduced relative to intravenous administration of a composition that does not include magnesium.

7. The method of claim 1, wherein the composition has a pH between about 4.5 and 5.5.

18. The method of claim 1, wherein the total volume of the composition administered is less than 500 ml.

'802 patent col. 40, ll. 43–57; col. 41, ll. 1–2, ll. 23–24.

For the '105 patent, the claim at issue is claim 27, which depends from claim 1:

> 1. A method of treating a bacterial infection in a subject, wherein the method comprises administering a therapeutically effective amount of a composition to a subject in need thereof via an intravenous route of administration, wherein the composition comprises an aqueous solution of a 7-dimethylamino-tetracycline antibiotic and a magnesium cation, wherein the molar ratio of magnesium cation to 7-dimethylamino-tetracycline antibiotic is greater than 3:1 and wherein the solution does not comprise a pharmaceutically acceptable oil, has a pH greater than 4 and less than 7, and has an osmolality less than about 500 mOsmol/kg.
>
> 27. The method of claim 1, wherein the 7-dimethylamino-tetracycline is minocycline.

'105 patent col. 41, ll. 33–43; col. 42, ll. 47–48.

Melinta produces Minocin, "an aqueous solution consisting of minocycline and magnesium that is used to treat bacterial infections." J.A. 1. Although Minocin first entered the market in 1972, Melinta later reformulated its product to address problems with the original formulation. J.A. 6–7. The patents-in-suit relate to the reformulated Minocin, which added magnesium, increased the pH of the formulation, and decreased the size of the dose of the injected formulation. J.A. 3, 8–10.

In October 2020, Nexus filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking to develop a generic version of Minocin. J.A. 11–12. Melinta sued Nexus, alleging infringement of the '105 and '802 patents. J.A. 3–5.

After a four-day bench trial, the district court found that Nexus's generic product infringed all the asserted claims. The court also found that Nexus failed to prove the asserted claims were invalid for obviousness, indefiniteness, inadequate description, or lack of enablement. J.A. 2. The district court permanently enjoined Nexus from "manufacturing, using, offering for sale, or selling its ANDA product" until the expiration of the '802 and '105 patents. J.A. 2, 128–29. Nexus took this appeal.

II

We review issues of claim construction de novo, except that we review any factual findings underlying the court's construction for clear error. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 333 (2015). "Whether a claim satisfies the written description requirement is a question of fact that, on appeal from a bench trial, we review for clear error." *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014) (citing *Ariad Pharms.,*

Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010)).

III

Nexus raises two issues with respect to the '802 patent. First, Nexus challenges the district court's construction of the terms "composition" and "administering" as they relate to the use of a diluent in the claimed aqueous solution. *See* '802 patent col. 40, ll. 45–50. Nexus also challenges the district court's finding that the '802 patent's specification contained an adequate written description of the method of reducing "injection site hemolysis" by comparing the claimed formulation containing magnesium with "a composition that does not include magnesium." *See id.* at col. 40, ll. 55–57; J.A. 121–24.

A

The terms "composition" and "administering" refer to the process of intravenous administration of a pharmaceutical composition. In that process, a diluent is commonly added to the pharmaceutical ingredients to produce a "reconstituted solution." The reconstituted solution is then further diluted to produce the "admixture" that is injected into a patient's vein. J.A. 29. The pharmaceutical ingredients must remain dissolved in the solution in order to be administered intravenously. J.A. 9.

The district court construed the term "composition" in the '802 patent to refer to the three ingredients of minocycline, magnesium, and a base, after those ingredients are mixed together to make a solution and prior to the addition of the diluent that is required for the formulation to be administered intravenously. J.A. 23. The court construed the term "administering" to mean "to remedially give the diluted composition to a patient via an intravenous route." J.A. 31.

Nexus argues that the reference in claim 1 to "administering . . . a composition" means that a diluent cannot be

added to a composition before it is administered, because claim 1 uses the closed term "consists of" (as opposed to the open term "comprises"), and the ingredient list for the claimed composition does not include a diluent. For that reason, Nexus argues that its ANDA product, which requires the addition of a diluent prior to administration, cannot infringe the '802 patent. Appellant's Br. at 7–14. Melinta, on the other hand, argues that the term "composition" refers to the "concentrated, reconstituted solution prior to further dilution." Appellees' Br. at 10. According to Melinta, a person of ordinary skill in the art would understand that a diluent must be added to the composition before the composition is administered to a patient. *Id.* at 10–18.

We agree with the district court's construction of both terms. Although the asserted claims of the '802 patent do not refer to a diluent, both the intrinsic and extrinsic evidence support the district court's construction. The specification provides instructions for preparing an admixture by adding a diluent, which makes the solution "ready for administration by or to the patient." '802 patent, col. 13, ll. 53–56. Three expert witnesses also testified that a person of ordinary skill would understand the need to dilute the composition prior to its administration. J.A. 29. Finally, the 2010 Minocin IV prescribing information instructs that intravenous administration should include reconstitution and then further dilution. J.A. 2647. The 1973 prescribing information for Minocin likewise instructs that "[t]he drug should be initially dissolved and then further diluted to 500–1,000 cc" with various solutions for intravenous administration. J.A. 2653.

Nexus's proposed construction of the term "composition" suffers from an inconsistency. The district court noted that "[t]o simultaneously hold, as [Nexus] argues, that 'composition' includes a diluent but that 'consists / consisting of' does not include a diluent is inconsistent at

best, because both terms describe the same list of ingredients."[1] J.A. 25. A person of ordinary skill would know that it is necessary to add a diluent to the composition before administering it to the patient, as indicated in the instructions provided with the prescribing information.

Because we agree with the district court's construction of the terms "composition" and "administering," we reject Nexus's challenge to the district court's finding of infringement, which was based on Nexus's claim construction arguments.

B

The second issue raised by Nexus involves the limitation in claim 1 of the '802 patent related to the reduction of injection site hemolysis. That limitation requires that "injection site hemolysis of red blood cells is reduced relative to intravenous administration of a composition that does not include magnesium." '802 patent, col. 40, ll. 55–57. The question raised by that limitation is whether the recited composition with magnesium cations results in reduced hemolysis compared to a composition containing no metal cations, or whether the composition with magnesium cations results in reduced hemolysis compared to a composition containing other metal cations, such as calcium cations.

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[1] At oral argument, Nexus confirmed that under its construction, the term "administering" refers to administering the composition without the diluent in it. Oral Argument in Case No. 2025-1281, 2:40–51, https://www.cafc.uscourts.gov/oral-arguments/25-1281_04062026.mp3. Applying Nexus's construction would mean that Melinta's product would also fall outside the claim, because both Melinta's product and Nexus's ANDA product require the use of a diluent. *See* J.A. 2483 (2021 Minocin IV), 2541 (ANDA product).

Nexus contends that hemolysis must be reduced compared to any other administration that does not include magnesium. Under that construction, Nexus argues, the asserted claims of the '802 patent would be invalid for lack of written description because the inventors failed to show that they possessed a formulation that reduced hemolysis compared to a minocycline formulation containing calcium cations. Appellant's Br. at 14–18.

Melinta asserts that Nexus waived that argument because the argument appears in only a single sentence of Nexus's opening post-trial brief. Appellees' Br. 22. If the argument was not waived, Melinta contends that the correct comparison is between the claimed composition with magnesium and the same composition without magnesium.

We reject Melinta's contention that Nexus waived the argument regarding the proper comparator. Nexus presented that argument to the district court in its post-trial brief, where it wrote, "In addition, the patent shows hemolysis is not reduced compared to another formulation 'without magnesium' since calcium formulations had the same effect." J.A. 1114. Melinta responded to that argument at greater length, J.A. 1162, making it clear that Melinta was aware of the argument. In addition, witnesses at trial testified regarding the issue. *See* J.A. 1641 (Tr. 228:17–20); J.A. 1825 (Tr. 412:3–25). Under the applicable Seventh Circuit standard, Nexus said enough to preserve the issue for appellate review. *See United States v. Roque-Espinoza*, 338 F.3d 724, 727 (7th Cir. 2003) (argument was not waived even if it was "woefully underdeveloped").[2]

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[2] Waiver is a procedural, non-patent-related issue that is governed by regional circuit law. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1352 (Fed. Cir.

On the merits, we hold that the district court did not clearly err in finding the '802 patent not invalid for lack of written description. The most natural comparison for the claim limitation "does not include magnesium" is between a formulation that contains magnesium and one that is the same as that formulation, except without magnesium. In this case, the formulation that is otherwise the same but lacks magnesium is the prior art product, which contained minocycline without adding magnesium or any other metal cation.

The specification encompasses the administration of minocycline with various metal cations, but the focus throughout is on the differences between formulations with divalent metal cations—whether magnesium or calcium—and those without. The specification begins with a series of figures comparing formulations with such cations against formulations lacking any metal cations. '802 patent, Figs. 1–5; *see also id.* at col. 6, line 63, through col.7, line 11. The specification also contains test results showing the reduction in the incidence of hemolysis in formulations containing magnesium or calcium cations compared to formulations lacking such cations. *Id.* at col. 7, ll. 32–37, col. 29, line 56, through col. 32, line 30. Although the claims of the '802 patent are directed only to magnesium, the specification indicates that the inventors were aware that calcium could be used as the cation in the formulation as well. Nothing in the specification is directed to comparing the effect of magnesium with that of calcium. Rather, the focus of the specification is the reduction of hemolysis resulting from the inclusion of magnesium or calcium, as compared to prior art formulations, which did not include metal cations at all.

2003) (citation omitted). In this case, the applicable regional circuit is the Seventh Circuit.

To be sure, the district court's construction of the phrase "does not include magnesium" to mean simply "does not include magnesium," J.A. 40, does not expressly exclude a formulation that lacks magnesium but includes a different cation, such as calcium, in place of the absent magnesium. However, interpreting the claim language to compare a formulation containing magnesium with formulations containing other divalent cations, such as calcium, would be contrary to the overwhelming evidence that the invention of the '802 patent was directed to the advantage of adding magnesium to a minocycline formulation lacking divalent cations, and not to any advantage magnesium might have compared to other metal cations.

All the *in vitro* hemolysis tests described in the specification of the '802 patent involve comparisons between solutions containing metal cations (either magnesium or calcium) and solutions not containing metal cations. *See* '802 patent, col. 6, line 62, through col. 7, line 15. Elsewhere, the specification describes experiments showing the effect of magnesium cations on hemolysis compared to formulations containing no metal cations. *See id.* at col. 29, line 58, through col. 32, line 50. While the specification describes experiments that tested minocycline-magnesium and minocycline-calcium formulations, the point of the experiments was to demonstrate that divalent and trivalent cations reduce hemolysis, not to compare the effect of magnesium cations with the effect of calcium cations.

At the core of the patent's invention was a formulation that introduced magnesium to the existing minocycline formulation. The 1973 Minocin product included a warning against using a diluent containing calcium in its intravenous administration instructions because "a precipitate may form." J.A. 2653. The warning in the prior art against administering minocycline with calcium strongly suggests that the claim limitation was not meant

to be addressed to a comparison between magnesium and calcium with respect to their effect in reducing hemolysis.

Other evidence likewise indicates that the '802 claims were directed to a formulation without magnesium or any other cations (such as in the original minocycline formulation). David Griffith, one of the named inventors of the '802 patent, testified at trial that the new formulation was not "wildly hemolytic" compared to "minocycline in saline without magnesium." J.A. 1760 (Tr. 347:3–7); *see* J.A. 1825 (Tr. 412:5–7) ("The study [was] designed entirely to compare the divalent-cation formulations to the original formulation of minocycline."). His testimony at trial aligns with statements made during the prosecution of the application that the closest prior art was commercially available intravenous minocycline without a multivalent cation, and that experimental comparisons were to that product or minocycline without metal cations. *See* U.S. Patent Application No. 14/204,881, Declaration of David Griffith under 37 C.F.R. § 1.132 ¶¶ 4, 8 (Aug. 27, 2014) (discussing the closest prior art and experiments "comparing the effects of high molar ratios of multivalent cations with minocycline as compared to formulations lacking multivalent cations").

The district court found that a person of ordinary skill in the art "would understand this data to show that reduced incidence of injection site hemolysis occurred in a solution containing minocycline and a metal cation." J.A. 35 (citation omitted). The specification fully supports the district court's observation, as the specification states that hemolysis of red blood cells was reduced in an *in vitro* model formulated with divalent cations "compared to minocycline solutions formulated without divalent cations." '802 patent, col. 31, ll. 14–17; col. 32, ll. 27–30 (other examples). Thus, it is clear that the inventors were in possession of an invention that showed a minocycline solution with magnesium reduced hemolysis "relative to

intravenous administration of a composition that does not include magnesium." *Id.* at claim 1.

IV

In summary, we uphold the district court's judgment that the '802 patent was infringed and is not invalid. Because both the '802 patent and the '105 patent have the same expiration date, and because counsel agreed that if either patent is held not invalid, the district court's finding of infringement must be upheld, *see* Oral Arg. in Case No. 2025-1281 at 17:45–18:15, 38:58–39:12, it is unnecessary for us to address the question of the validity of the '105 patent.

AFFIRMED