NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

SCILEX PHARMACEUTICALS INC., ITOCHU CHEMICAL FRONTIER CORP., OISHI KOSEIDO CO., LTD.,
Plaintiffs-Appellants

v.

AVEVA DRUG DELIVERY SYSTEMS, INC.,
Defendant-Appellee

2025-1002

Appeal from the United States District Court for the Southern District of Florida in No. 0:22-cv-61192-WPD, Judge William P. Dimitrouleas.

Decided: August 4, 2026

JONATHAN DAVIES, Norton Rose Fulbright US LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by SANYA SUKDUANG.

JOSEPH THOMAS JAROS, Rakoczy Molino Mazzochi Siwik LLP, Chicago, IL, argued for defendant-appellee. Also represented by WILLIAM A. RAKOCZY, DYLAN SACENTI, CONLY S. WYTHERS.

Before REYNA, MAYER, and HUGHES, *Circuit Judges*.

PER CURIAM.

Scilex Pharmaceuticals Inc. ("Scilex"), Itochu Chemical Frontier Corp. ("Itochu"), and Oishi Koseido Co., Ltd. ("Oishi") (collectively, the "Scilex plaintiffs") appeal a final judgment of non-infringement entered by the United States District Court for the Southern District of Florida. For the reasons discussed below, we affirm.

I. BACKGROUND

Scilex is the exclusive licensee of U.S. Patent Nos. 9,283,174 (the "'174 patent"), 9,931,403 (the "'403 patent"), and 9,925,264 (the "'264 patent") (collectively the "asserted patents").[1] The asserted patents are directed to non-aqueous lidocaine patch compositions and methods of using such compositions.[2] *See* '174 patent, col. 9 ll. 6–13, '403 patent, col. 9 ll. 25–31, '264 patent, col. 9 ll. 19–27. For purposes of this appeal, claims 1 and 4 of the '174 patent are representative. They recite:

> 1. A non-aqueous patch comprising 0.5 to 7 mass % lidocaine and/or its reactant, and a dissolving agent consisting of an organic acid and a polyalcohol, which are contained in a plaster, wherein the amount of lidocaine and/or its reactant is 0.1 to 1 mg/cm^2 of the plaster, and wherein the proportion of dissolving agent to lidocaine and/or its reactant is 0.5 to 5 mass % of dissolving agent relative to 1 mass % of lidocaine and/or its reactant.

---

[1] Itochu and Oishi are the assignees of the asserted patents.

[2] For ease of reference, we cite only to the claims and specification of the '174 patent unless otherwise noted.

> 4. The non-aqueous patch according to claim 1, wherein the dissolving agent consists of isostearic acid and dipropylene glycol.

'174 patent, col. 9 ll. 6–13, 18–20 (emphases omitted).

In May 2022, Aveva Drug Delivery Systems, Inc. ("Aveva") notified the Scilex plaintiffs that it had filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration seeking approval of a generic version of ZTlido®, Scilex's topical lidocaine patch.[3] The Scilex plaintiffs then sued Aveva, alleging that its proposed generic formulation would infringe dependent claim 4 of each of the asserted patents.[4] They asserted infringement under the doctrine of equivalents, contending that the isostearic acid and oleyl alcohol in Aveva's patch functioned in the same way to achieve the same result as the claimed two-component dissolving agent consisting of isostearic acid and dipropylene glycol.[5] *See* J.A. 9792–94, 10475–77. Their theory of infringement was premised on

---

[3] ZTlido® is indicated for the relief of pain associated with post-herpetic neuralgia. *See Scilex Pharms. Inc. v. Aveva Drug Delivery Sys., Inc.*, No. 0:22-CV-61192-WPD, 2024 WL 4473767, at *2 (S.D. Fla. Aug. 27, 2024) ("*District Court Decision*").

[4] The Scilex plaintiffs asserted direct infringement under the doctrine of equivalents of claim 4 of the '174 and '403 patents and indirect infringement under the doctrine of equivalents of claim 4 of the '264 patent.

[5] At trial, the Scilex plaintiffs conceded that Aveva's ANDA product did not literally infringe the asserted claims. *See District Court Decision*, 2024 WL 4473767, at *11. The district court's analysis was therefore confined to whether the Scilex plaintiffs could establish infringement under the doctrine of equivalents.

the argument that the term "dissolving agent" in the asserted claims means a solubilizer or co-solubilizer that prevents crystallization of lidocaine by maintaining the lidocaine in a dissolved state in the plaster. *See* J.A. 9178, 9756, 9793.

Following a four-day bench trial, the district court held that the Scilex plaintiffs had not established infringement by Aveva's generic product. The court determined that, in view of the prosecution history, the "dissolving agent" in the claimed non-aqueous patch had to both "dissolve[] the lidocaine and prevent[] crystallization of lidocaine." *District Court Decision*, 2024 WL 4473767, at *10. The court stated that Aveva's patch "use[d] only a single solvent, n-heptane, to dissolve the lidocaine," *id*. at *12, and that "[n]-heptane, either alone or in combination with any other component, [was] not equivalent to any claimed 'dissolving agent,'" *id*. at *13. The court further determined that prosecution history estoppel and the doctrine of claim vitiation barred the Scilex plaintiffs from asserting that isostearic acid and oleyl alcohol are equivalent to the claimed two-component dissolving agent. *Id*. at *12–16.

This appeal followed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A.

We review a judgment entered by a district court following a bench trial for both legal error and clearly erroneous factual findings. *Azurity Pharms., Inc. v. Alkem Lab'ys Ltd*., 133 F.4th 1359, 1363 (Fed. Cir. 2025). "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) (citation and internal quotation marks omitted).

"The doctrine of equivalents provides a limited exception to the principle that claim meaning defines the scope of the exclusivity right in our patent system." *VLSI Tech. LLC v. Intel Corp.*, 87 F.4th 1332, 1341 (Fed. Cir. 2023). The doctrine "is limitation specific, not focused only on the claim as a whole" and "asks whether a substitute element matches the function, way, and result of the claimed element, or whether there are only insubstantial differences." *Galderma Lab'ys, L.P. v. Lupin Inc.*, 122 F.4th 902, 910 (Fed. Cir. 2024) (citations and internal quotation marks omitted); *see Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997); *Lab'y Corp. of Am. Holdings v. Qiagen Scis., LLC*, 148 F.4th 1350, 1359 (Fed. Cir. 2025).

B.

Resolution of the present appeal turns on the proper interpretation of the term "dissolving agent" in the claim limitation requiring "[a] non-aqueous patch comprising . . . lidocaine . . . and a dissolving agent consisting of an organic acid and a polyalcohol, which are contained in a plaster." '174 patent, col. 9 ll. 6–9. The parties agree that the claimed "dissolving agent" must prevent crystallization of the lidocaine by maintaining it in a dissolved state in the plaster of the patch. *See, e.g.*, J.A. 9758, 10192, 10347–48. They are at loggerheads, however, regarding whether the dissolving agent must also dissolve the lidocaine.

According to the Scilex plaintiffs, the asserted "claims say nothing about how the lidocaine is dissolved during manufacture or the order in which the lidocaine, dissolving agent and other components are combined prior to being incorporated into the plaster of the patch." Br. of Plaintiffs-Appellants 27. In essence, they contend that the asserted claims are directed to a finished patch in which the recited two-component dissolving agent functions to maintain lidocaine in a dissolved, *i.e.*, non-crystalline, state, thereby "allowing for effective delivery to the skin." *Id.* at 28. In their view, therefore, the district court erred in concluding that

a person of ordinary skill in the art "would understand the claimed 'dissolving agent' both dissolves the lidocaine and prevents crystallization of lidocaine," *District Court Decision*, 2024 WL 4473767, at *10.

We do not find this argument persuasive. As the district court correctly determined, "the asserted claims cover a topical patch where lidocaine is dissolved in a combination of an organic acid (isostearic acid) and a polyalcohol (dipropylene glycol)." *Id*. at *4. When the phrase "dissolving agent," '174 patent, col. 9 l. 7, is interpreted in view of the specification and prosecution history, it is evident that the term refers to a substance that both dissolves the lidocaine and maintains it in a non-crystalline state in the finished patch. *See, e.g.*, *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372, 1378–79 (Fed. Cir. 2025) (emphasizing that "[c]laim terms are generally given their plain and ordinary meaning, which is the meaning that one of ordinary skill in the art would ascribe to a term when read in the context of the claims, specification, and prosecution history").

C.

We turn first to the claim language. Given that the claimed therapeutic non-aqueous patch is comprised of two specified components—an active drug substance, lidocaine, which is a solid at room temperature, *see, e.g.*, J.A. 10206, and a "dissolving agent," '174 patent, col. 9 l. 7—a person of ordinary skill in the art would presumably infer that the recited dissolving agent dissolves the lidocaine. *See, e.g.*, *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1367 (Fed. Cir. 2003) (explaining that "[c]laim language generally carries the ordinary meaning of the words in their normal usage in the field of invention"). Such an interpretation is confirmed by the specification. *See, e.g.*, *Actelion Pharms. LTD v. Mylan Pharms. Inc.*, 85 F.4th

1167, 1172 (Fed. Cir. 2023) (explaining that the specification "is always highly relevant to the claim construction analysis" (citation and internal quotation marks omitted)).

The specification explains that a problem with prior art non-aqueous patches was that they "ha[d] poor permeability to the skin because the lidocaine [was] not dissolved and [was] present in a crystalline state." '174 patent, col. 1 ll. 43–45. Therefore, in the claimed invention, "a dissolving agent" and "lidocaine" are "mixed in a plaster" in order to *"produc[e] a non-aqueous patch in which the lidocaine is completely dissolved*." *Id.* col. 2 ll. 14–18 (emphasis added). This language makes clear that the lidocaine and the dissolving agent are mixed to *produce* a non-aqueous patch in which the lidocaine is dissolved. We reject, therefore, the Scilex plaintiffs' assertion that the asserted claims do not require the dissolving agent to dissolve the lidocaine.

Other portions of the specification buttress the conclusion that the claimed dissolving agent must dissolve, *i.e.*, break apart, the lidocaine. *See id.* col. 2 ll. 52–57 ("The most effective proportion of dissolving agent and lidocaine is 0.5 to 5 mass % of dissolving agent relative to 1 mass % of lidocaine. In this proportion, *lidocaine can be stably mixed in a dissolved state*, increasing the release rate of the lidocaine to the skin, and causing the drug to effectively permeate into the muscle." (emphasis added)); *see also id.* col. 2 ll. 39–40 ("According to the present invention, *a small amount of lidocaine is efficiently dissolved*." (emphasis added)). Notably, moreover, as the district court correctly recognized, "[t]he asserted patents describe six examples of the claimed patch," *District Court Decision*, 2024 WL 4473767, at *4, and "[a]ll six examples . . . describe the use of a combination of an organic acid (*e.g.*, isostearic acid) and a polyalcohol (*e.g.*, dipropylene glycol) to dissolve [the] solid lidocaine drug substance before mixing [it] with adhesives to obtain a 'plaster solution,'" *id.* at *5. *See* '174 patent, col. 4 l. 6–col. 7 l. 36.

Although this court has "cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification," *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1328 (Fed. Cir. 2002) (citation and internal quotation marks omitted), we have also recognized that disclosed embodiments and examples "can shed light on the intended scope of the claims," *Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mut. Pharm. Co.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004). Here, the fact that all six examples in the specification describe using the "dissolving agent" combination of an organic acid and a polyalcohol to dissolve the lidocaine bolsters the conclusion that the claimed dissolving agent must dissolve the lidocaine and not simply prevent crystallization of the lidocaine in the finished patch. *See, e.g.*, *In re Power Integrations, Inc.*, 884 F.3d 1370, 1377 (Fed. Cir. 2018) (concluding that the claims at issue could not "be stretched to cover a system in which a memory separates the counter and the digital to analog converter and severs the requisite control relationship between them" where "every embodiment disclosed in the [specification] show[ed] a counter that passes voltage, current, or control signals to the digital to analog converter"); *Astrazeneca*, 384 F.3d at 1341 (stating that "[t]he fact that all of the solubilizers listed in the specification and used in the working examples were surfactants adds further support to the conclusion that the term 'solubilizer' in the claims should be limited, according to the definition employed in the specification, to surfactants"). It is notable, moreover, that the specification identifies no substance or substances—other than the claimed dissolving agent consisting of an organic acid and a polyalcohol—that can appropriately be employed to dissolve the lidocaine in the claimed patch.

D.

To the extent there remains any uncertainty regarding the meaning of the term "dissolving agent," it is dispelled by reference to statements made by the applicant during

prosecution. *See Personalized Media Commc'ns, LLC v. Apple Inc.*, 952 F.3d 1336, 1340 (Fed. Cir. 2020) (explaining that "[t]he prosecution history . . . may be critical in interpreting disputed claim terms because it contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims" (citations and internal quotation marks omitted)). During prosecution of the '174 patent, the examiner rejected the original claims over two prior art references, *see* J.A. 6214–20, 6433–43, 10199, including U.S. Patent Application Publication No. 2011/0152377 A1 ("Hanma"), J.A. 6409–32, which describes patches containing lidocaine, an organic acid, and a polyalcohol, J.A. 6417–21, and further describes dissolving lidocaine in an ester solvent and/or a polyalcohol solvent, J.A. 6421, 6429–32. In response, Oishi, the applicant, stated, at least three different times, that in the claimed invention the "lidocaine *is dissolved in* an organic acid and a polyalcohol," *i.e.*, in the claimed dissolving agent. J.A. 6242–43 (emphasis added); *see also* J.A. 6244 ("In the present invention, the lidocaine *is simply dissolved in* the organic acid and a polyalcohol." (emphasis added)). Because Oishi repeatedly and unambiguously represented that the lidocaine was dissolved "in" the claimed dissolving agent, the district court correctly rejected the argument by the Scilex plaintiffs that the claimed dissolving agent need not function to dissolve the lidocaine. *See District Court Decision*, 2024 WL 4473767, at *10.

On appeal, the Scilex plaintiffs argue that during prosecution "the patentees distinguished the claimed invention from Hanma on the basis that in Hanma, the lidocaine is reacted with an organic acid to form a salt, as opposed to simply dissolving the lidocaine, which does not involve a chemical reaction." Br. of Plaintiffs-Appellants 53–54 (emphases omitted). They assert, moreover, that the prosecution history does not show that "the patentees clearly and

unmistakably distinguish[ed] the claimed invention from Hanma on the basis of the order in which the components of the invention are combined or suggest that lidocaine must be dissolved in the dissolving agent alone prior to combination with other components of the patch." *Id.* at 54 (emphasis omitted). As we have previously made clear, however, statements made during prosecution can "inform . . . claim construction" even where such "statements do not rise to the level of unmistakable disavowal." *Shire Dev., LLC v. Watson Pharm., Inc.*, 787 F.3d 1359, 1366 (Fed. Cir. 2015). Accordingly, even assuming, *arguendo*, that Oishi's repeated and consistent statements that the lidocaine is dissolved in the claimed dissolving agent are insufficient to give rise to disclaimer, they nonetheless provide cogent evidence supporting the conclusion that the claimed dissolving agent functions to dissolve the lidocaine. *See Personalized Media Commc'ns*, 952 F.3d at 1340 (explaining that even where prosecution history evidence does not rise to the level of disclaimer, "an applicant's repeated and consistent remarks during prosecution can define a claim term by demonstrating how the inventor understood the invention").

E.

In sum, we conclude that, in view of the specification and prosecution history, the district court correctly determined that the claimed "dissolving agent," '174 patent, col. 9 l. 7, must dissolve the lidocaine as well as maintain it in a non-crystalline state in the finished patch. The Scilex plaintiffs do not meaningfully dispute that they cannot show infringement by Aveva's generic product if this court affirms the district court's claim construction of the term "dissolving agent." *See, e.g.*, Oral Arg. at 24:17–33. In this regard, we note that Aveva uses a single solvent, n-heptane, to dissolve the lidocaine and, as the district court properly found, "[n]-heptane, either alone or in combination with any other component, is not equivalent to [the]

claimed 'dissolving agent.'" *District Court Decision*, 2024 WL 4473767, at *13.

Because we conclude that the district court correctly determined that Aveva's ANDA product did not infringe under a proper construction of the term "dissolving agent," we need not reach the court's alternative holdings that: (1) the Scilex plaintiffs' "doctrine of equivalents theory that a mono-alcohol (oleyl alcohol) could be equivalent to the claimed polyalcohol, dipropylene glycol, would vitiate the 'polyalcohol' and 'dipropylene glycol' claim limitations," *id.* at *16; and (2) "Oishi clearly and unmistakably disclaimed use of anything other than a dissolving agent consisting essentially of an organic acid and a polyalcohol," *id.* at *14. We have considered the Scilex plaintiffs' remaining arguments but do not find them persuasive.

III. CONCLUSION

Accordingly, the judgment of the United States District Court for the Southern District of Florida is affirmed.

AFFIRMED