NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

ROXANE LABORATORIES, INC.,
Plaintiff-Appellant

v.

CAMBER PHARMACEUTICALS INC., INVAGEN PHARMACEUTICALS INC.,
Defendants-Appellees

2016-1028

Appeal from the United States District Court for the District of New Jersey in No. 2:14-cv-04042-SRC-CLW, Judge Stanley R. Chesler.

Decided: November 17, 2016

KENNETH G. SCHULER, Latham & Watkins LLP, Chicago, IL, argued for plaintiff-appellant. Also represented by MARC NATHAN ZUBICK; GREGORY SOBOLSKI, San Francisco, CA; ROBERT J. GAJARSA, Washington, DC.

ROBERT S. SILVER, Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd., Philadelphia, PA, argued for defendants-appellees. Also represented by SALVATORE GUERRIERO, PEI-RU WEY.

Before LOURIE, MAYER, and O'MALLEY, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Roxane Laboratories, Inc. ("Roxane") appeals from a stipulated judgment of noninfringement following the decision of the United States District Court for the District of New Jersey construing the claims of U.S. Patent 8,563,032 ("the '032 patent"). *See Roxane Labs., Inc. v. Camber Pharm. Inc.*, No. 14-4042, 2015 WL 4393785 (D.N.J. July 15, 2015) (claim construction order); *Roxane Labs., Inc. v. Camber Pharm. Inc.*, No. 14-4042, ECF No. 247 (D.N.J. Sept. 9, 2015) (final judgment). Roxane also challenges an earlier decision of the United States District Court for the Southern District of Ohio transferring this infringement action to the District of New Jersey. *See Roxane Labs., Inc. v. Camber Pharm., Inc.*, No. 2:14-cv-232, 2014 WL 2812867 (S.D. Ohio June 23, 2014). Because the district courts did not err in transferring the case and in construing the claims, we *affirm*.

BACKGROUND

Calcium acetate is used to treat patients suffering from end-stage kidney failure who have abnormally high serum phosphorous levels. When taken orally, calcium acetate binds to phosphorous in foods and prevents its absorption through the gastrointestinal tract. Roxane owns the '032 patent, directed to a capsule formulation of calcium acetate granules, with each capsule containing a dose of 667 mg calcium acetate on an anhydrous basis.

Pharmaceutical capsules for human use are available in a variety of sizes, including size 5 (the smallest), 4, 3, 2, 1, 0, 00, and 000 (the largest). The claims of the '032 patent require that the calcium acetate granules be contained within "a pharmaceutically acceptable capsule . . . that is size 00 or less." '032 patent col. 6 ll. 35–41.

Claim 1, the only independent claim, is representative and reads as follows:

> 1. A calcium acetate capsule formulation comprising flowable granules comprised of a pharmaceutically acceptable amount of calcium acetate along with other pharmaceutically acceptable adjuvants, wherein said granules are filled into and contained within a pharmaceutically acceptable capsule such that 667 mg of said calcium acetate on an anhydrous basis are present in said capsule that is *size 00 or less*.

Id. (emphasis added).

Camber Pharmaceuticals, Inc. and InvaGen Pharmaceuticals, Inc. (collectively, "the Appellees") manufacture and sell calcium acetate products in elongated size 00 ("size 00el") capsules. A size 00el capsule has the same diameter as a standard size 00 capsule, but has a greater length and a larger fill volume.

In March 2014, Roxane sued the Appellees in the United States District Court for the Southern District of Ohio, alleging infringement of the '032 patent. On the Appellees' motion, in June 2014, the district court in Ohio transferred the action to the District of New Jersey pursuant to 28 U.S.C. § 1404(a). Applying Sixth Circuit law, the district court in Ohio found that the convenience of the parties and witnesses as a whole and the balance of public and private interests favored the transfer of venue to New Jersey. *Roxane*, 2014 WL 2812867, at *3–5.

In July 2015, the district court in New Jersey issued an order construing the claim limitation "size 00 or less." The court examined the intrinsic record of the '032 patent and concluded that the meaning of "'size 00 or less' is unambiguous," that "nothing in the patent . . . suggests that the applicants understood 'size 00' to mean a family of capsule sizes" that included both standard and elongat-

ed size 00 capsules, and that the intrinsic record consistently indicated that "size 00" refers to a single capsule size with a specific weight and fill capacity. *Roxane*, 2015 WL 4393785, at *4–5. The district court therefore concluded that "size 00 or less" means "precisely size 00 or less," which excludes capsules of size 00el. *Id.* at *6.

In light of that construction and the undisputed fact that the Appellees' products use size 00el capsules, which are larger than standard size 00 capsules, Roxane stipulated to a judgment of noninfringement. The district court then entered final judgment under Federal Rule of Civil Procedure 54(b). Roxane timely appealed to this court. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

We first consider whether the district court in Ohio erred in transferring the case to the District of New Jersey. In reviewing a district court's decision on a motion to transfer under 28 U.S.C. § 1404(a), we apply the law of the regional circuit in which the district court deciding the motion sits, here, the Sixth Circuit. *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 836 (Fed. Cir. 2003). The Sixth Circuit recognizes that district courts have "broad discretion" to determine "when party 'convenience' or 'the interest of justice' make[s] a transfer appropriate." *Reese v. CNH Am. LLC*, 574 F.3d 315, 320 (6th Cir. 2009) (quoting 28 U.S.C. § 1404(a)). Applying Sixth Circuit law, we reverse a district court's ruling on a motion to transfer "[o]nly when the district court clearly abuse[s] its discretion in balancing these considerations." *Id.* (second alteration in original) (internal quotation marks omitted).

Roxane argues that the district court abused its discretion in transferring the action, and that the court made two legal errors: (1) that the court afforded no weight to

Roxane's choice of forum; and (2) that the court considered the convenience of employee witnesses as the most important factor. According to Roxane, a plaintiff's choice of forum controls unless the factors of convenience strongly favor transfer. Roxane contends that those factors did not strongly favor transfer in this case.

The Appellees respond that it was within the broad discretion of the district court to transfer the action. The Appellees argue that the district court properly weighed the relevant factors, including Roxane's choice of forum, the location of the complained-of activity, the location of and ease of access to sources of proof, and the convenience of all parties in the lawsuit, and correctly found that the balance of those factors as a whole favored the transfer.

We agree with the Appellees that the district court did not abuse its discretion in transferring the case. The court recognized that Roxane's choice to litigate in Ohio is "[t]he most significant factor weighing against transfer." *Roxane*, 2014 WL 2812867, at *5. Nevertheless, the court found that other factors, including the location of the complained-of activity, greatly weighed in favor of transfer. As the district court found, the Appellees' operations and employees are located in New Jersey or nearby New York; all documentary evidence relating to the marketing and sales of the accused products was located in either New Jersey or New York; and the accused products were designed and developed in New Jersey. *Id.* at *3–4. The district court conducted a fact-specific analysis of all of the relevant factors and ultimately found that those factors on balance favored transfer. On this record, we discern no clear abuse of discretion in the district court's decision to transfer the case to the District of New Jersey.

II

We next consider whether the district court in New Jersey erred in construing the claim limitation "size 00 or less." "The proper construction of a patent's claims is an

issue of Federal Circuit law." *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1129 (Fed. Cir. 2011). We review a district court's ultimate claim constructions *de novo* and any underlying factual determinations involving extrinsic evidence for clear error. *Teva Pharm. U.S.A., Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841–42 (2015). Here, because the district court relied only on the intrinsic record to construe "size 00 or less," we review the district court's construction *de novo*. *See Shire Dev., LLC v. Watson Pharm., Inc.*, 787 F.3d 1359, 1364, 1368 (Fed. Cir. 2015) (citing *Teva*, 135 S. Ct. at 840–42).

The words of a claim "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). Because that meaning is "often not immediately apparent, and because patentees frequently use terms idiosyncratically," the court looks to the intrinsic record, including "the words of the claims themselves, the remainder of the specification, [and] the prosecution history," as well as to extrinsic evidence when appropriate, to construe a disputed claim term. *Id.* at 1314, 1319. "[W]hile extrinsic evidence can shed useful light on the relevant art, we have explained that it is less significant than the intrinsic record in determining the legally operative meaning of claim language." *Id.* at 1317 (quotation marks omitted); *see also id.* at 1318 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms, for several reasons.").

Roxane argues that the district court erred in construing the claims as excluding size 00el capsules. According to Roxane, "size 00" refers to *either* non-elongated *or* elongated size 00. Roxane maintains that capsule "size" only designates capsule diameter, not length or volume. Roxane argues, moreover, that nowhere in the intrinsic record did the patentee *re*define "size 00" as an indicator

of anything other than capsule diameter, and that the patentee did not discuss elongated capsules or consider them as constituting a separate size. Appellant's Br. 45. Roxane additionally asserts that the district court ignored the "pharmaceutically acceptable" claim language, which imposes a requirement for ease-of-swallowability that is primarily determined by capsule diameter. Lastly, Roxane contends that its proposed construction is supported by extrinsic evidence.

The Appellees respond that the district court correctly construed "size 00" as designating a capsule of one specific size—*i.e.*, one specific diameter, length, and fill volume—not a family of capsules. The Appellees argue that all descriptions of "size 00" in the written description and prosecution history of the '032 patent are limited to one specific capsule size—standard size 00, and that nothing in the intrinsic record suggests that the applicants intended a broader meaning of "size 00" to encompass size 00el. The Appellees additionally argue that the declaration filed by coinventor Dr. Uraizee ("the Uraizee declaration"), as well as the two capsule size charts in the prosecution history, resolve any remaining doubt on the meaning of "size 00."

We agree with the district court and the Appellees that "size 00" in the '032 patent means standard, non-elongated size 00, and that the limitation "size 00 or less" thus excludes the larger elongated size 00 capsules from the scope of the claims. The main dispute in this appeal is whether "size 00" in the '032 patent refers to a capsule of a specific diameter, length, and fill volume, or to a family of capsules with the same diameter but varying lengths and fill volumes. We agree with the district court that the intrinsic record of the '032 patent unambiguously indicates that the former, not the latter, is the proper construction.

The written description of the '032 patent refers to "size 00" twice. First, it states that "[a]ccording to one embodiment of the invention, the capsule is a size 00 capsule containing 667 mg of calcium acetate." '032 patent col. 3 ll. 29–31. It then describes in Example 1 that "[t]he final blend was then filled into size 00 capsules using an IMA capsule filling machine wherein the resulting filled capsules had a weight of 880 mg and contained 760 mg of the final blend, including a 667 mg dose of calcium acetate." *Id.* col. 5 ll. 53–57.

The disclosed example thus refers to size 00 capsules as having the same weight (880 mg) when filled with the same amount of the final blend (760 mg). As the district court noted, however, an empty size 00 capsule and an empty size 00el capsule share the same diameter, but have different lengths and presumably different weights. Thus, a size 00 capsule would have a different weight than a size 00el capsule when both are filled with the same amount of the final blend. Accordingly, the size-family definition now advocated by Roxane does not reconcile with the usage of "size 00" in the written description.

Importantly, the prosecution history clearly indicates that "size 00" refers to standard, non-elongated size 00 capsules. During prosecution, the Examiner rejected the claims as being obvious over Dennett, which teaches filling a size 0 capsule with 667 mg of *compressed* anhydrous calcium acetate, in view of Nakai, which teaches free flowing calcium acetate *granules*, albeit having a lower bulk density than that described in the '032 patent. J.A. 232–34. The Examiner cited Torpac, a capsule size chart, to support the rejection. J.A. 239, 241. Notably, the capsule size chart in Torpac does not list any elongated capsule sizes, such as size 00el; it only lists standard, non-elongated capsules, including size 0 and size 00 with specific fill volumes of 0.68 mL and 0.95 mL, respectively. J.A. 241. Relying on Torpac, the Examiner maintained

that "[i]t's clear from the metric table that size 00 is about 50% bigger than size 0." J.A. 233. The Examiner then reasoned that it would have been obvious to a skilled artisan to combine the teachings of Dennett, Nakai, and Torpac to arrive at the claimed capsule formulation. *Id.* The Examiner considered "size 00" to be standard size 00, not elongated size 00.

We are unpersuaded by Roxane's argument that the Examiner's statement that "size 00 capsules are 50% bigger than size 0 capsules," J.A. 286, is evidence that he referred to size 00el capsules because the volume of size 00el capsules (1.02 mL) is exactly 50% greater than standard size 0 capsules (0.68 mL). As indicated, the intrinsic record clearly shows that the Examiner relied only on Torpac as evidence of capsule sizes and referred to the fill volume of non-elongated size 00 capsules, 0.95 mL, in his analysis. *See, e.g.*, J.A. 233 (citing Torpac); J.A. 285 ("Torpac teaches various capsules and their sizes."); J.A. 292 ("The volume of a size 00 capsule . . . is 0.95 mls." (citing Torpac)); *see also* J.A. 329 (the Board's opinion stating that "[a]s the Examiner's calculation itself shows, . . . a size 00 capsule holds only 0.95 ml").

In response to that rejection and in the subsequent appeal to the Patent Trial and Appeal Board ("the Board"), the applicants did not dispute the Examiner's understanding of "size 00" as standard size 00. Rather, the applicants argued that Nakai's granules, which have a lower bulk density, cannot be filled into size 00 capsules to achieve the claimed amount of 667 mg of calcium acetate on an anhydrous basis. As support, the applicants submitted a declaration by coinventor Dr. Uraizee. J.A. 221–24. In that declaration, Dr. Uraizee explained that, although she was able to duplicate the bulk density of Nakai's granules, she was unable to fill the claimed amount of calcium acetate into "size 00 capsules" using the prior-art granules. J.A. 222. Dr. Uraizee stated that "[t]he maximum fill we could obtain using these granules

was approximately 600 mg." *Id.* Citing Lightfoot, which also provides a capsule size chart, Dr. Uraizee further explained that Nakai's granules had a tapped density of 0.65 g/cc and that "only about 592 mg of granules can be comfortably filled into the capsule." *Id.*

The Uraizee declaration therefore treated "size 00" as capsules of one size having a particular fill capacity, rather than a family of capsules having a range of fill capacities. Indeed, Roxane conceded to the district court that Dr. Uraizee only tested one capsule size—standard size 00, not size 00el. *Roxane*, 2015 WL 4393785, at *5 n.5. Although Dr. Uraizee cited Lightfoot, which provides a capsule size chart listing the fill volumes of both size 00 and size 00el capsules, J.A. 303,[1] it appears that she only used the fill volume of standard size 00, not size 00el, to calculate the amount of granules (592 mg) that can be filled into "size 00 capsules," given the known tapped density of the granules (0.65 g/cc).[2] She did not perform a similar calculation as to size 00el capsules, which would, without doubt, hold a greater amount of calcium acetate due to the larger fill volume.

Furthermore, in the Reply Brief filed at the Board, the applicants emphasized that claim 1 does not cover capsules that are larger and have more fill capacity than "size 00." J.A. 299 (stating that the applicants "have drafted claim 1 to refer to capsules of size 00 or less, i.e.,

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[1] The applicants did not provide a copy of Lightfoot to the Examiner when filing the Uraizee declaration. It only submitted a copy of Lightfoot with its Reply Brief filed at the Board sixteen months later.

[2] In the units used by Dr. Uraizee, 592 mg divided by 0.65 g/cc gives a fill volume of 0.91 cc, or 0.91 mL, which corresponds to the fill volume of standard size 00 capsules listed in Lightfoot, not that of size 00el capsules, which is 1.02 mL. J.A. 303.

capsules of size 00 or a smaller capsule than size 00." (emphasis in original)). In the Examiner's Answer, the Examiner maintained that the claims are broader than what the Uraizee declaration showed. J.A. 292. In reply, the applicants argued that "although the Uraizee Declaration only tested size 00 capsules it is commensurate with the claims," and that "[t]he Uraizee Declaration showed that *only about 592 mg* of granules could be comfortably filled in size 00 capsules using Nakai's granular material, which was far short of the claimed fill amount of 667 mg of flowable granules of calcium acetate on an anhydrous basis." J.A. 300 (emphasis added). In light of the applicants' arguments, the Board reversed the Examiner's rejection and specifically relied on the Uraizee declaration, finding that it "provides persuasive evidence to show that Nakai's process does not produce granules of calcium acetate that could provide size 00 capsules containing 667 mg of calcium acetate." J.A. 329.

Accordingly, the Uraizee declaration and the applicants' prosecution arguments clearly indicate that size 00el capsules, which have a greater fill volume than the standard size 00 capsules tested by Dr. Uraizee, are outside the scope of the claims. In order to overcome the obviousness rejection, the applicants relied on the Uraizee declaration and emphatically argued that the claims only cover size 00 capsules tested by Dr. Uraizee or smaller capsules. Because the intrinsic record unambiguously and fully resolves the proper construction of "size 00 or less," we agree with the district court that resort to extrinsic evidence is unnecessary and improper.

We therefore conclude that the district court did not err in construing "size 00 or less" as meaning standard size 00 or less, which excludes size 00el.

CONCLUSION

We have considered Roxane's remaining arguments but find them to be unpersuasive. For the foregoing

reasons, we affirm the decision of the district court for the Southern District of Ohio to transfer the action to the District of New Jersey, as well as the decision of the district court in New Jersey construing "size 00 or less." We therefore affirm the stipulated judgment of non-infringement.

AFFIRMED