NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

SUPERNUS PHARMACEUTICALS, INC.,
Plaintiff-Appellee

v.

TWI PHARMACEUTICALS, INC., TWI INTERNATIONAL LLC, DBA TWI PHARMACEUTICALS USA,
Defendants-Appellants

2017-2513

Appeal from the United States District Court for the District of New Jersey in No. 1:15-cv-00369-RMB-JS, Judge Renee Marie Bumb.

Decided: September 6, 2018

NICHOLAS F. GIOVE, Haug Partners LLP, New York, NY, argued for plaintiff-appellee. Also represented by EDGAR HAUG, KEVIN GEORGEK, JONATHAN HERSTOFF, ANDREW SCOTT ROPER, CAMILLE YVETTE TURNER; WILLIAM CHARLES BATON, CHARLES M. LIZZA, Saul Ewing Arnstein & Lehr LLP, Newark, NJ.

DONALD J. MIZERK, Husch Blackwell LLP, Chicago, IL,

argued for defendants-appellants. Also represented by PHILIP DALE SEGREST, JR., DUSTIN L. TAYLOR.

Before O'MALLEY, CLEVENGER, and STOLL, *Circuit Judges.*

O'MALLEY, Circuit *Judge*.

TWi Pharmaceuticals, Inc. ("TWi") appeals from a decision of the United States District Court for the District of New Jersey holding, after bench trial, that Supernus Pharmaceuticals, Inc.'s ("Supernus") U.S. Patent Nos. 7,722,898 ("the '898 patent"), 7,910,131 ("the '131 patent"), and 8,821,930 ("the '930 patent) (collectively, "the asserted patents") are not invalid and would be infringed. *Supernus Pharms., Inc. v. TWi Pharms., Inc.*, 265 F. Supp. 3d 490 (D.N.J. 2017). For the following reasons, we *affirm*.

I. BACKGROUND

A. The Asserted Patents

This case involves a formulation of active ingredient, oxcarbazepine, which treats partial epilepsy seizures in adults and children over the age of six. Supernus is the holder of New Drug Application No. 202810 for an oxcarbazepine extended-release tablet, which is prescribed and sold in the United States under the trade name Oxtellar XR®. The asserted patents are listed in the *FDA's Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book," as covering Oxtellar XR®.

Supernus is the assignee of the asserted patents, which claim priority from provisional application No. 60/794,837. All three asserted patents share a common

specification,[1] the same inventors, and substantially the same claim limitations at issue on appeal.

In the common specification, the background of the invention explains that twice daily, immediate release formulations of oxcarbazepine were known in the art and were disadvantageous because they require multiple daily administrations and can result in increased side effects. '898 patent, col. 1, ll. 30–33. For these reasons, sustained release formulations were preferred, but were purportedly difficult to achieve because oxcarbazepine is poorly soluble in water. *Id.* at col. 1, ll. 33–35, 41–53.

The common specification explains that the asserted patents purport to solve these problems by "provid[ing] controlled-release oxcarbazepine formulations for once-a-day administration," and "enhanc[ing] the bioavailability of oxcarbazepine and its derivatives." *Id.* at col. 3, ll. 54–60. The asserted patents purport to achieve these objectives by (1) using matrix polymers that comprise a homogeneous matrix structure, and (2) "incorporat[ing] a combination of solubility-enhancing excipients and/or release-promoting agents into the formulations to enhance the bioavailability of oxcarbazepine and its derivatives." *Id.* at col. 5, ll. 53–55, col. 3, ll. 54–60.

Representative claim 1 of the '898 patent recites:

> 1. A pharmaceutical formulation for once-a-day administration of oxcarbazepine comprising a *homogeneous matrix* comprising:
>
> (a) oxcarbazepine;
>
> (b) a matrix-forming polymer selected from the group consisting of cellulosic polymers, alginates, gums, cross-linked poly-

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[1] For ease of reference, all citations to the common specification will refer to the '898 patent.

> acrylic acid, carageenan, polyvinyl pyrrolidone, polyethylene oxides, and polyvinyl alcohol;
>
> (c) *at least one agent that enhances the solubility of oxcarbazepine* selected from the group consisting of surface active agents, complexing agents, cyclodextrins, pH modifying agents, and hydration promoting agents; and
>
> (d) at least one release promoting agent comprising a polymer having pH-dependent solubility selected from the group consisting of cellulose acetate phthalate, cellulose acetate succinate, methylcellulose phthalate, ethylhydroxycellulose phthalate, polyvinylacetate phthalate, polyvinylbutyrate acetate, vinyl acetate-maleic anhydride copolymer, styrene-maleic mono-ester copolymer, and Eudragit L100-55 (Methacrylic Acid-Ethyl Acrylate Copolymer (1:1)), and methyl acrylate-methacrylic acid copolymers.

Id. at col. 12, l. 51–col. 13, l. 6 (emphases added).

B. Procedural History

On December 30, 2013, TWi filed Abbreviated New Drug Application No. 206576 with the FDA seeking regulatory approval to market extended-release oxcarbazepine oral tablets in 150 mg, 300 mg, and 600 mg dosages (the "proposed tablets") and certifying that the asserted patents are invalid and/or would not be infringed. Supernus sued TWi for infringement of the asserted patents, and TWi counterclaimed for invalidity. On October 7, 2015, the district court held a *Markman* hearing, during which it construed claim term "at least one agent that enhances the solubility of oxcarbazepine" (hereinafter, the

"solubility agent limitation") as "an agent, other than oxcarbazepine, that enhances the solubility of oxcarbazepine, which agent cannot also serve as the sole matrix-forming polymer in 1(b) or the sole release promoting agent in 1(d) in claim 1," and claim term "homogeneous matrix" as a "matrix in which the ingredients or constituents are uniformly dispersed."

After the *Markman* hearing in this litigation, the district court decided a related case, *Supernus Pharms., Inc. v. Actavis Inc.*, No. 13-cv-4740-RMB-JS, 2016 WL 527838 (D.N.J. Feb. 5, 2016) ("*Actavis*"), which involved the same plaintiff and asserted patents from this litigation, but different defendants and accused products. In that case, the district court concluded that the asserted patents are not invalid and would be infringed.

After its decision in *Actavis*, the district court held a four-day bench trial in this litigation from April 3–6, 2017. The parties submitted post-trial briefs. In a decision dated August 15, 2017, the district court concluded that the asserted patents are not invalid and would be infringed by TWi's proposed tablets. In particular, the district court found that TWi's proposed tablets satisfied the "homogeneous matrix" and the solubility agent limitations under its constructions of those terms, and that the common specification and prosecution histories of the asserted patents demonstrate that the "homogeneous matrix" limitation is not indefinite and does not lack adequate written description support. In making these determinations, the district court, at times, referenced its decision in *Actavis*.

TWi appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

"On appeal from a bench trial, we review a district court's conclusions of law de novo and its findings of fact

for clear error." *Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1123 (Fed. Cir. 2018). TWi contends that the district court erred because it gave its decision in *Actavis* de facto preclusive effect in this case. TWi also argues that the district court erred in concluding that the proposed tablets would infringe the solubility agent and "homogeneous matrix" limitations, and that the asserted patents are not invalid as indefinite or for lack of written description. For the following reasons, we conclude that the district court did not err in any of these respects.

A

First, the district court did not give its decision in *Actavis* de facto preclusive effect in this case. The district court explicitly stated in its post-trial decision that its decision in *Actavis* has "some relevance to this action," but that its "findings of fact and conclusions of law set forth [in this post-trial decision] are based upon the evidence and argument presented in *this* litigation." *Supernus*, 265 F. Supp. 3d at 497 n.6. The district court adhered to this position throughout its analysis. TWi disagrees and contends that the district court improperly relied on its decision in *Actavis* in three ways, each of which we address below.

TWi argues that the district court relied on its findings and conclusions from *Actavis* when it referenced the case in making its invalidity determinations. But, as Supernus points out, the district court made express findings based on the record presented in this litigation and relied on *Actavis* only to the extent that the records were similar or the parties had agreed to be bound by a subsidiary conclusion from *Actavis*. *Id.* at 519 n.13 ("The Court comes to this conclusion [of no invalidity] exclusively on the basis of the record developed in this litigation."); *id.* at 521 ("Based upon the record in this litigation, the Court sees no reason to deviate from this finding" in

Actavis "that the term 'homogeneous matrix' had adequate written description."). Thus, the district court did not err in this regard.

TWi also argues that the district court improperly relied on results from tests conducted on Oxtellar XR® tablets by Dr. Bugay, Supernus's expert, which were admitted as evidence in *Actavis* but not in this litigation. To the contrary, the district court made only a passing reference to the Oxtellar XR® tests, *id.* at 506, and based its infringement determination solely on tests and evidence admitted in this litigation, *id.* at 510 ("In sum, based upon TWi's manufacturing process, the results of the FDA uniformity testing on the TWi Tablets, and the Raman chemical imaging of the sample TWi Tablet, the Court finds that the TWi Tablets comprise a homogeneous matrix, as construed by this Court and as understood by a person of ordinary skill in the art."). We find that the district court did not rely on evidence not of record in this case.

Finally, TWi argues that the district court relied on its reasoning from *Actavis* even though the arguments and evidence presented in this case were different from that of the *Actavis* case. Indeed, had the district court attributed any failures of proof in the *Actavis* litigation to TWi, that would be error. But, as noted above, the district court referenced *Actavis* only to the extent that the records in the two cases were the same. For these reasons, the district court did not err in referencing *Actavis* in its decision in this case. The *Actavis* decision also does not color our decision-making on appeal.

B

Second, TWi argues that Supernus's admissions in the common specification preclude a finding that the accused agent satisfies the solubility agent limitation. As described above, the asserted patents require both a release promoting agent and a solubility agent. TWi

argues that the accused agent cannot satisfy the solubility agent limitation because the common specification, at Table 1, characterizes a formulation that contains the accused agent, but not a release-promoting agent, as a "non-enhanced" formulation. '898 patent, col. 9, ll. 10–33. TWi contends that the specification defines "non-enhanced" formulations as formulations that contain neither a release promoter nor a solubility agent, and "enhanced" formulations as formulations that contain a release promotor, solubility agent, or both. In other words, TWi contends that the accused agent cannot satisfy the solubility agent limitation because the common specification admits that a formulation containing the accused agent is a "non-enhanced" formulation, i.e. is a formulation that contains neither a solubility agent nor a release promoting agent.

TWi's argument turns on how the common specification defines "enhanced" and "non-enhanced" formulations. In support of its alleged definitions of the terms, TWi points to language from the common specification stating that "improvements were made to the formulations by incorporating *solubility enhancers and/or release-promoting excipients (such formulation[s] are referred to as enhanced formulations)*." *Id.* at col. 4, ll. 1–4 (emphasis added). TWi believes that the term "and/or" in this statement means "and" or "or," whereas Supernus contends that "and/or" means solely "and." The district court found that, in the context of the specification, "and/or" means solely "and."

We agree with the district court. We read "enhanced" formulations, in the context of the common specification, to require both a "combination of solubility and release promoters." *Id.* at col. 4, ll. 14–16. Indeed, as Supernus notes, even "[TWi]'s own citation to a legal style manual" describes "and/or" "as a 'grammatical abomination' that can mean 'and,' 'or,' *or* 'and/or.'" *See* Oral Arg. at 19:08–25,

http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2017-2513.mp3 (quoting Bryan A. Garner, The Redbook: A Manual on Legal Style § 1.81(d) (2d ed. 2006)) (emphasis added).

Here, the common specification indicates that the use of "and/or" must mean solely "and" because the common specification identifies both agents as essential to enhancing the bioavailability of oxcarbazepine. *Id.* at col. 4, ll. 21–31. In particular, the common specification emphasizes that, "[w]hen a formulation containing both the enteric polymer[, a type of release-promoting agent,] and solubilizer is exposed to an aqueous media . . . the enteric polymer dissolves rapidly leaving a porous structure, resulting in increased contact surface between the aqueous medium and the poorly soluble drug." *Id.* at col. 4, ll. 22–27. "This increased surface area," according to the common specification, in turn, "enhances the efficiency of the solubilizer(s), and hence, the overall solubility and release rate of the drug is enhanced to a point where it impacts the availability of the drug for systemic absorption." *Id.* at col. 4, ll. 27–31. In this way, the common specification describes the presence of *both* a solubility agent *and* a release-promoting agent as essential to formulating an "enhanced" formulation.

Accordingly, "non-enhanced" formulations can include formulations that do not contain *either* a solubility agent *or* a release promoter. Applied to Table 1, the "non-enhanced" formulation containing the accused agent does not preclude a finding that the accused agent is a solubility agent. This is because it is entirely possible that the formulation is "non-enhanced" solely because it lacks a release-promoting agent and not because it lacks a solubility agent. Thus, the district court did not err in finding that this statement in the specification does not amount to an admission of noninfringement, nor did it err in ultimately concluding, based on expert testimony, that

the accused agent infringes the solubility agent limitation.

TWi also contends that the district court failed to apply its own construction of the solubility agent limitation which the district court agreed implicitly required that the solubility agent enhance solubility by more than a de minimis amount. While the district court did not use the magic words "de minimis," we conclude that it made the necessary findings to support a conclusion of infringement of the limitation as construed. Specifically, the district court found, consistent with expert testimony, that the patents do not require any specific amount of enhancement and that the accused agent enhanced solubility by a statistically significant amount. That TWi disagrees with the district court's assessment that a statistically significant increase satisfies the claim limitation as construed is not grounds for error. Thus, we conclude that the district court did not err in this respect. We have considered TWi's remaining noninfringement arguments regarding the solubility agent limitation and find them unpersuasive.

C

TWi also argues that the district court erred in finding that the proposed tablets infringe the "homogeneous matrix" limitation. Specifically, it contends that the district court changed its construction of "homogeneous matrix" from a "matrix in which the ingredients or constituents are uniformly dispersed," as construed in the district court's *Markman* order, to "no localization of constituents," as stated in its post-trial decision.

We conclude that district court did not change the construction of the term in its post-trial decision, but rather clarified what was already inherent in its construction, as permitted. *See Cordis Corp. v. Boston Sci. Corp.*, 658 F.3d 1347 (Fed. Cir. 2011). In fact, the district court remained consistent in its use of the term throughout the

proceedings below. During the claim construction proceedings in this litigation, Supernus raised concerns that TWi may attempt to avoid infringement by arguing that the asserted patents require complete uniformity, which Supernus contends is unattainable. In response to Supernus's concerns, the district court stated that, in its view, the asserted patents do not require any specific degree of uniformity, just some degree of uniformity. J.A. 2405 ("[A] homogeneous matrix comprising A, B, C and D means that there is a uniform dispersion of A, B, C and D whatever that rate, whatever that proportion, whatever that degree is. The fact that it may vary a little here or there is of no moment.").

The district court later reiterated in its post-trial decision that this proposition is inherent in its construction of the term. Because the parties had agreed to adopt the district court's construction of the term "homogeneous matrix" from the *Actavis* matter, the district court began by incorporating its reasoning for this construction from its decision in that case, *Supernus*, 265 F. Supp. 3d at 498, including its reasoning that "everyone understands . . . that you don't get this perfect uniformity ever; it's impossible," *Actavis*, 2016 WL 527838 at *7. The district court then considered the prosecution histories and found, based on a specific office action, that "[t]he term was not added to describe the *degree* of uniformity or homogeneity of the Supernus invention or to distinguish the degree of uniformity of Supernus's invention from that of prior art formulations." *Supernus*, 265 F. Supp. 3d at 501 (emphasis added). Rather, the district court stated, the term "was added to the claims to distinguish Supernus's invention, which has all four matrix components in the tablet core, from the prior art references, which contained certain matrix constituents solely in the coating, which the Patent Examiner viewed to be part of the matrix." *Id.* Thus, the district court clarified that inherent in its construction of "homogeneous matrix" is this understand-

ing that, where the degree of uniformity is irrelevant, "uniformly dispersed" necessarily implicates an absence of localization. *Id.* at 524–25.

This is similar to our decision in *Cordis Corp. v. Boston Sci. Corp.*, 658 F.3d 1347 (Fed. Cir. 2011). There, the district court construed the claim term "undulating" to mean "rising and falling in waves, thus having at least a crest and a trough." *Id.* at 1355. When the district court entered a judgment of noninfringement as a matter of law, it clarified that "waves" implies a change in direction. *Id.* Cordis argued that the district court's characterization of "waves" improperly narrowed the construction. *Id.* On appeal, we found that the district court did not err, but merely "clarified what was inherent in the construction," because "the terms 'crest' and 'trough,' as used in district court's claim construction, implicate changes of direction, with the curve extending beyond the point of inflection." *Id.* at 1356. Similarly, here, the district court merely clarified what was inherent in its construction because uniform dispersal, in the context of the district court's finding that "homogenous matrix" does not require any specific degree of uniformity, necessarily implicates an absence of localization. Thus, the district court did not err.

D

Finally, TWi argues that the district court erred in finding that the "homogeneous matrix" limitation was not indefinite and did not lack written description support. But the specification, prosecution history, and expert testimony support the district court's conclusions. *See, e.g.*, '898 patent, col. 5, ll. 53–59; *Supernus*, 265 F. Supp. 3d at 520–21 (stating during prosecution that "one of ordinary skill in the art would appreciate that the formulations derived according to the protocol set forth in the Examples would necessarily comprise a homogeneous

matrix."). Thus, we conclude that the district court did not err.

III. CONCLUSION

For the reasons stated above, we *affirm* the district court's conclusion that the asserted patents are not invalid and would be infringed by TWi's proposed tablets.[2]

AFFIRMED

COSTS

No costs.

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[2] Prior to oral argument in this case, Supernus moved to modify the district court's protective order pursuant to Federal Circuit Rule 11(e). *Supernus Pharms., Inc. v. TWi Pharms., Inc.*, No. 17-2513, ECF No. 34, 35. TWi opposed the motion. *Id.* at ECF No. 38, 39. In an order dated July 20, 2018, this court reserved ruling on this motion pending a decision on the merits. *Id.* at ECF No. 74. Having affirmed the district court's decision without reference to the information that was the subject of the motion, we deny the motion as moot.