787 F.3d 1359
United States Court of Appeals,
Federal Circuit.

SHIRE DEVELOPMENT, LLC, Shire Pharmaceutical Development, Inc., Cosmo Technologies Limited, Giuliani International Limited, Plaintiffs–Appellees
v.
WATSON PHARMACEUTICALS, INC., nka Actavis, Inc., Watson Laboratories, Inc. Florida, Watson Pharma, Inc., nka Actavis Pharma, Inc., Watson Laboratories, Inc., Defendants–Appellants.

No. 2013–1409.
|
June 3, 2015.

Synopsis

Background: Owners of **patent** concerning controlled-release oral pharmaceutical compositions for treating inflammatory bowel diseases brought infringement action against competitor. After construing certain relevant claim language, 2013 WL 174843, the United States District Court for the Southern District of Florida, Donald M. Middlebrooks, J., 2013 WL 1912208, found the competitor's product infringed the **patent**. Competitor appealed. The Court of Appeals, 746 F.3d 1326, reversed and remanded. Patentee petitioned for writ of certiorari, and the Supreme Court granted the writ and vacated and remanded, 135 S.Ct. 1174.

Holdings: On remand, the Court of Appeals, Hughes, Circuit Judge, held that:

[1] term, "matrix," meant a macroscopically homogeneous structure in all its volume, and

[2] terms, "inner lipophilic matrix" and "outer hydrophilic matrix," required two separate matrices, such that the matrices retained their claimed properties and were consistent with their respective Markush group limitations.

Reversed and remanded.

West Headnotes (14)

[1] **Patents** Construction and Operation of **Patents**

A district court's ultimate interpretation of the **patent** claims is reviewed de novo.

5 Cases that cite this headnote

[2] **Patents** Construction and Operation of **Patents**

When the district court reviews only evidence intrinsic to the **patent**, i.e., the **patent** claims and specifications, along with the **patent's** prosecution history, the judge's determination will amount solely to a determination

of law, and the Court of Appeals will review that construction de novo; if, on the other hand, a district court resolves factual disputes over evidence extrinsic to the **patent**, the Court of Appeals will review for clear error those factual findings that underlie a district court's claim construction.

13 Cases that cite this headnote

[3] **Patents** Construction and Operation of **Patents**

De novo review applied to district court's **patent** claim constructions, since intrinsic evidence fully determined proper constructions.

14 Cases that cite this headnote

[4] **Patents** State of the art

When construing asserted **patent** claims, claim terms are given their ordinary and accustomed meaning as understood by one of ordinary skill in the art.

8 Cases that cite this headnote

[5] **Patents** Specifications and Drawings;Written Description

Intrinsic evidence, such as the specification, may shed contextual light on the ordinary and customary meaning of a **patent** claim term.

5 Cases that cite this headnote

[6] **Patents** Language of claims in general

The construction of asserted **patent** claims that stays true to the **patent** claim language and most naturally aligns with the **patent's** description of the invention will be, in the end, the correct construction.

2 Cases that cite this headnote

[7] **Patents** Rejection and Amendment of Claims;Prosecution History

In addition to the **patent** specification, a court construing a **patent** claim looks to the prosecution history.

1 Cases that cite this headnote

[8] **Patents** Prosecution disclaimer

Where the patentee has unequivocally disavowed a certain meaning to obtain his **patent**, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender; however, while the prosecution history can inform whether the inventor limited the claim scope in the course of prosecution, it often produces ambiguities created by ongoing negotiations between the inventor and the **Patent** and Trademark Office (PTO), and, therefore, the doctrine of prosecution disclaimer only applies to unambiguous disavowals.

2 Cases that cite this headnote

[9] **Patents** Prosecution history estoppel

The application of prosecution disclaimer under **patent** law is reviewed de novo.

2 Cases that cite this headnote

[10] **Patents** Expert and inventor testimony

When construing asserted **patent** claims, a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the **patent**.

Cases that cite this headnote

[11] **Patents** Drugs and medicines

Term "matrix," in **patent** concerning controlled-release oral pharmaceutical compositions for treating inflammatory bowel diseases, meant a macroscopically homogeneous structure in all its volume.

2 Cases that cite this headnote

[12] **Patents** Drugs and medicines

Terms "inner lipophilic matrix" and "outer hydrophilic matrix," in **patent** concerning controlled-release oral pharmaceutical compositions for treating inflammatory bowel diseases, required two separate matrices, such that the matrices retained their claimed properties and were consistent with their respective Markush group limitations.

8 Cases that cite this headnote

[13] **Patents** In general;utility

US **Patent** 5,593,690, US **Patent** 5,851,555, US **Patent** 6,395,300. Cited as Prior Art.

Cases that cite this headnote

[14] **Patents** In general;utility

US **Patent** 6,773,720. Construed.

Cases that cite this headnote

Attorneys and Law Firms

***1360** Edgar Haug, Frommer Lawrence & Haug LLP, New York, NY, for plaintiffs-appellees. Also represented by Nicholas F. Giove, Jonathan Herstoff, Elizabeth Murphy, Joseph Saphia Erin A. Lawrence, Jason Aaron Lief, Caroline Bercier, Andrew S. Wasson.

***1361** Steven Arthur Maddox, Maddox Edwards, PLLC, Washington, DC, for defendants-appellants. Also represented by Jeremy J. Edwards; Neil Michael McCarthy, Knobbe, Martens, Olson & Bear, LLP, Washington, DC.

Before PROST, Chief Judge, CHEN[*] and HUGHES, Circuit Judges.

Opinion

HUGHES, Circuit Judge.

This case returns to us on remand from the Supreme Court. In *Shire Development, LLC v. Watson Pharmaceuticals, Inc.*, 746 F.3d 1326 (Fed.Cir.2014), we decided an appeal by defendant-appellants (collectively, Watson) from a decision of the United States District Court for the Southern District of Florida. The district court found, among other things, that Watson infringed plaintiffs-appellees' (collectively, Shire's) **patent** under the district court's constructions of the asserted claims. We reversed the district court's constructions of two claim terms and remanded for further proceedings.

Following our decision in this case, the Supreme Court issued *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, —— U.S. ——, 135 S.Ct. 831, ——L.Ed.2d —— (2015), which clarified how this court should review a district court's construction of a claim term. The Court also vacated and remanded our *Shire* decision for further consideration in light of this new standard of review. *Shire Dev., LLC v. Watson Pharm., Inc.*, —— U.S. ——, 135 S.Ct. 1174, 191 L.Ed.2d 130 (2015). Because this case does not involve factual findings to which we owe deference under *Teva,* we again reverse the district court's constructions of the disputed claim terms and subsequent findings of infringement, and remand for further proceedings.

I

Shire owns U.S. **Patent** No. 6,773,720, which claims a controlled-release oral pharmaceutical composition for treating inflammatory bowel diseases. Shire markets these oral pharmaceutical compositions under the brand name LIALDA®. After Watson submitted an Abbreviated New Drug Application (ANDA) seeking approval to sell the bioequivalent of LIALDA®, Shire sued for infringement of the #720 **patent**. After construing certain relevant claim language, the district court found that Watson's product infringed the #720 **patent**.

The #720 **patent**—entitled "Mesalazine Controlled Release Oral Pharmaceutical Composition"—concerns controlled-release oral pharmaceutical compositions for treating inflammatory bowel diseases, such as Crohn's disease and ulcerative colitis. #720 **patent** col. 1 ll. 9–13. The active ingredient in these compositions is 5–amino–salicylic acid, which is also known as mesalazine or mesalamine (hereinafter, mesalamine). Mesalamine treats inflamed areas in the bowel by direct contact with the intestinal mucosal tissue. J.A. 9054. Thus, mesala-mine must pass through the stomach and small intestine without being absorbed into the bloodstream. J.A. 9054. And it must be administered throughout the entire length of the colon so that the mesalamine contacts all affected tissues. J.A. 9054. Given these requirements, the oral composition must contain a high percentage, by weight, of mesalamine. #720 **patent** col. 3 ll. 52–56.

The #720 **patent** teaches an inner lipophilic matrix and an outer hydrophilic matrix to address the limitations of the prior ***1362** art systems. [1] According to the #720 **patent**, the combination of a lipophilic and hydrophilic matrix in an inner-outer matrix system, respectively, is advantageous because the inner-outer matrix properties cause the mesalamine to be released in a sustained and uniform manner. #720 **patent** col. 3 ll. 57–59 ("[T]he compositions of the invention provide a release profile of [mesalamine] more homogenous than the traditional systems."); *see also id.* at col. 3 l. 60–col. 4 l. 5. The #720 **patent** also teaches the "advantageous characteristic" of a composition with up to 95% active ingredient by weight. *Id.* at col. 3 ll. 52–56.

Shire asserts independent claim 1 and dependent claim 3. Claim 1 recites:

1. Controlled-release oral pharmaceutical compositions containing as an active ingredient [mesal-amine], comprising:

a) an inner lipophilic matrix consisting of substances selected from the group consisting of unsaturated and/or hydrogenated fatty acid, salts, esters or amides thereof, fatty acid mono-, di- or triglycerid[e]s, waxes, ceramides, and cholesterol derivatives with melting points below 90° C., and wherein the active ingredient is dispersed both in said the lipophilic matrix and in the hydrophilic matrix;

b) an outer hydrophilic matrix wherein the lipophilic matrix is dispersed, and said outer hydrophilic matrix consists of compounds selected from the group consisting of polymers or copolymers of acrylic or methacrylic acid, alkylvinyl polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrins, pectins, starches and derivatives, alginic acid, and natural or synthetic gums;

c) optionally other excipients;

wherein the active ingredient is present in an amount of 80 to 95% by weight of the total composition, and wherein the active ingredient is dispersed both in the lipophilic matrix and in the hydrophilic matrix.

Id. at col. 6 ll. 7–30. Claim 3 depends from claim 1 and requires that the composition be in the form of tablets, capsules, or minitablets. *Id.* at col. 6 ll. 35–36.

The #720 **patent** teaches a three-step process to arrive at the claimed composition. *Id.* at col. 2 ll. 48–59. First, one or more low melting, lipophilic excipients [2] are mixed with mesalamine during heating. *Id.* at col. 2 ll. 50–53. Second, the mixture is cooled to form the lipophilic matrix and then reduced in size into "matrix granules containing the active ingredient." *Id.* at col. 2 ll. 54–56. Third, the lipophilic matrix granules are mixed together with hydrophilic excipients and compressed to form tablets. *Id.* at col. 2 ll. 50–53, col. 3 ll. 40–45.

During prosecution of the #720 **patent**, the examiner initially rejected the applicants' claims as obvious in view of GB 2 245 492 A (Franco); obvious and anticipated in view of U.S. **Patent** No. 5,593,690 (Akiyama); and obvious in view of the combination of U.S. **Patent** No. 5,851,555 (Sanghvi) and U.S. **Patent** No. 6,395,300 (Straub). J.A. 15469–71. The examiner explained that Franco taught a pharmaceutical composition with an active core, a ***1363** lipophilic coating, and a hydrophilic film. J.A. 15469.

In response, the applicants stated that Franco disclosed a reservoir system where "the active ingredient is confined within a core which acts as a reservoir from which the active ingredient is released via the erosion of the outer coating. However, as to the present invention, the active ingredient is dispersed in a lipophilic matrix, not in an isolated core." J.A. 15480–81.

The applicants then distinguished Akiyama based on the claimed invention's two matrices and high active ingredient concentration. The applicants argued that Akiyama "fail[s] to disclose or suggest the two matrices and the arrangement of the matrices as set forth in the claimed invention. The arrangement of the matrices in the present invention aid[s] in the combined release of an active ingredient via diffusion from a lipophilic matrix." J.A. 15479. The applicants also argued that Akiyama's composition contained the "active ingredient ... in an amount much lower than that according to the claimed invention"—Akiyama taught an active ingredient in granules in an amount ranging from 0.005–75% by weight, but the applicants' amended claim taught 80–95%. J.A. 15478–79.

To distinguish Sanghvi and Straub, the applicants again focused on a lack of two separate matrices: Sanghvi "fails to disclose a system containing two separate matrices. [It] merely discloses formulations obtained by mixing together hydrophilic and lipophilic substances into a single matrix." J.A. 15481. When discussing the combination of Sanghvi and Straub, the applicants explained that "[w]hile the publications might teach the advantageous results of using a lipophilic matrix, the publications fail to disclose or suggest a composition comprising a combination of two separate matrices. In fact, there is no mention or suggestion of a composition utilizing different control mechanisms." J.A. 15482.

The examiner maintained her rejection of the pending claims as obvious in view of Franco. The examiner also rejected the claims because "the feature upon which applicant relies (i.e., the active ingredient is dispersed in a lipophilic matrix) is not recited in the rejected claims." J.A. 15489. Further, the examiner explained that the limitation-at-the-time—"active ingredient is at least partly inglobated"—"does not limit the claim to 'active ingredient is dispersed in a lipophilic matrix' as alleged by the applicant." J.A. 15489.

In response, the applicants maintained that Franco taught a reservoir system, but that the claimed invention "relates to a 'multimatrix system' and not to a reservoir system." J.A. 15492; *see also* J.A. 15492 ("FRANCO et al. do[es] not teach an inner lipophilic matrix or an outer hydrophilic matrix.... The composition taught by FRANCO et al. is not based on an actual matrix."). The applicants also amended their claims to state that the active ingredient is dispersed in the lipophilic matrix and added a Markush group[3] for both the inner lipophilic matrix and the outer hydrophilic matrix. J.A. 15491–92, 15496, 15499. Following an interview with the examiner, the claims were amended to require the mesalamine to be dispersed in the outer hydrophilic matrix and not just the lipophilic matrix. J.A. 15546–50. The claims were then allowed and the #720 **patent** issued.

***1364** When Watson submitted its ANDA seeking FDA approval to sell the bioequivalent of LIALDA®, Shire sued Watson for infringement of the #720 **patent**. In January 2013, the district court construed several disputed terms, including "inner lipophilic matrix" and "outer hydrophilic matrix." *See Shire Dev. LLC v. Watson Pharm., Inc.,* No. 12–60862, 2013 WL 174843 (S.D.Fla. Jan. 17, 2013).

The district court held a bench trial in April 2013 and issued its opinion a month later, finding that Watson's ANDA product infringed claims 1 and 3 of the #720 **patent**; that the claims were not invalid under 35 U.S.C. § 112, ¶ 1 (2006); and that Shire was entitled to injunctive relief. *Shire Dev. LLC v. Watson Pharm., Inc.,* No. 12–60862, 2013 WL 1912208, at *16 (S.D.Fla. May 9, 2013). Specifically, the district court determined that Watson's ANDA product met the limitations of the claims at issue. In considering the disputed limitations, the district court found that the mesalamine in Watson's product was dispersed in both the lipophilic and hydrophilic matrices because the mesalamine was present in both the granules and the spaces outside the granules. *Shire,* 2013 WL 1912208, at *7–13. The district court also determined that Watson failed to prove by clear and convincing evidence that the **patent** was invalid under 35 U.S.C. § 112 for lack of written description or enablement. *Id.,* at *14–16. Watson appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II

[1] **[2]** **[3]** We review the district court's ultimate interpretation of the **patent** claims de novo. *Teva,* 135 S.Ct. at 839, 841–42. "[W]hen the district court reviews only evidence intrinsic to the **patent** (the **patent** claims and specifications, along with the **patent's** prosecution history), the judge's determination will amount solely to a determination of law, and [we] will review that construction de novo." *Id.* at 841. If, on the other hand, a district court resolves factual disputes over evidence extrinsic to the **patent**, we "review for clear error those factual findings that underlie a district court's claim construction." *Id.* at 842. In this case, we review the district court's constructions de novo, as the intrinsic evidence fully determines the proper constructions. *See id.* at 840–42; *see also In re Papst Licensing Digital Camera **Patent** Litig.,* 778 F.3d 1255, 1261 (Fed.Cir.2015) (citing *Teva,* 135 S.Ct. at 840–42).

[4] When construing asserted claims, claim terms are given "their ordinary and accustomed meaning as understood by one of ordinary skill in the art." *Dow Chem. Co. v. Sumitomo Chem. Co.,* 257 F.3d 1364, 1372 (Fed.Cir.2001); *Phillips v. AWH Corp.,* 415 F.3d 1303, 1312–13 (Fed.Cir.2005) (en banc).

[5] **[6]** Intrinsic evidence, such as "the specification, ... may shed contextual light" on the ordinary and customary meaning of a claim term. *Aventis Pharm. Inc. v. Amino Chems. Ltd.,* 715 F.3d 1363, 1373 (Fed.Cir.2013). "The

construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Phillips,* 415 F.3d at 1316.

[7] **[8]** **[9]** In addition to the specification, this court looks to the prosecution history. For example, "where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Omega Eng'g, Inc. v. Raytek Corp.,* 334 F.3d 1314, 1324 (Fed.Cir.2003); *see* ***1365** *Ekchian v. Home Depot, Inc.,* 104 F.3d 1299, 1304 (Fed.Cir.1997) ("since, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection"). "However, while the prosecution history can inform whether the inventor limited the claim scope in the course of prosecution, it often produces ambiguities created by ongoing negotiations between the inventor and the PTO. Therefore, the doctrine of prosecution disclaimer only applies to unambiguous disavowals." *Grober v. Mako Prods., Inc.,* 686 F.3d 1335, 1341 (Fed.Cir.2012) (citing *Abbott Labs. v. Sandoz, Inc.,* 566 F.3d 1282, 1289 (Fed.Cir.2009)). We review the application of prosecution disclaimer de novo. *Ecolab, Inc. v. FMC Corp.,* 569 F.3d 1335, 1342 (Fed.Cir.2009).

[10] We have also held that a court may look to extrinsic evidence, such as dictionaries and expert testimony, to "shed useful light on the relevant art" and for a variety of other purposes. *Phillips,* 415 F.3d at 1317–18 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.,* 388 F.3d 858, 862 (Fed.Cir.2004)). But "a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.' " *Id.* at 1318 (quoting *Key Pharm. v. Hercon Labs. Corp.,* 161 F.3d 709, 716 (Fed.Cir.1998)).

III

The district court construed "inner lipophilic matrix" to mean "a matrix including at least one lipophilic excipi-ent, where the matrix is located within one or more other substances." *Shire,* 2013 WL 174843, at *5. Similarly, the district court construed "outer hydrophilic matrix" as "a matrix of at least one hydrophilic excipient, where the matrix is located outside the inner lipophilic matrix." *Id.* These constructions do not reflect the ordinary and customary meaning of the claim terms in light of the intrinsic evidence and are impermissibly broad.

A

[11] When construing the disputed terms, the district court relied on the specification to first construe "matrix" to mean "a macroscopically homogeneous structure in all its volume." *Id.* at *4 (quoting #720 patent col. 3 ll. 42–45). That construction is correct. But the district court erred by construing " 'lipophilic matrix' [as] a matrix that includes at least one lipophilic excipient." *Id.* That construction erroneously focuses on the lipophilic properties of an excipient in the matrix, rather than the properties of the matrix itself.

A review of the intrinsic evidence as a whole reveals that the district court's construction of "inner lipophilic matrix"—and thus, "outer hydrophilic matrix"—is overly broad. Looking first to the language of the claims, "lipophilic" is an adjective that modifies matrix. The parties stipulated that "lipophilic" means "poor affinity towards aqueous fluids." J.A. 216. Thus, the *matrix*—not just an excipient within the matrix—must exhibit the stipulated-to lipophilic characteristic.

This conclusion is bolstered by the specification. The Background of the Invention explains that a lipophilic matrix is one "in which the main component of the matrix structure" exhibits certain lipophilic properties. #720 patent col. 1 ll. 17–20. And the specification teaches that a lipophilic matrix "generally entail[s] non-linear, but esponential [sic] release of the active ingredient." #720 patent col. 1 ll. 32–33. Thus, a "lipophilic *matrix* " is more than just a matrix with at least

one lipophilic *excipient*—the matrix itself must exhibit ***1366** lipophilic characteristics. The #720 **patent** teaches that this occurs when "the main component of the matrix structure" is lipophilic. #720 **patent** col. 1 ll. 17–18.

B

[12] In construing the matrix terms, the district court rejected Watson's position that the inner matrix and outer matrix must be "separate and distinct." *Shire,* 2013 WL 174843, at *5. Watson based its arguments on alleged disclaimers by the applicants during the prosecution. *See* Appellants' Br. 37–38. The district court acknowledged that the applicants described their matrices as "separate" to distinguish over the prior art references, but found that "no where in the prosecution history, claims, or specification does the term 'separate and distinct' appear." *Shire,* 2013 WL 174843, at *5. Explaining that the prosecution history is an ongoing negotiation and that there must be clear and unambiguous disavowal, the district court could not "say that the claim was clearly limited or disclaimed during the prosecution." *Id.*

The district court correctly found no prosecution disclaimer because the statements in the prosecution history were not "unambiguous disavowals." *Grober,* 686 F.3d at 1341. During prosecution, Shire carefully characterized the *prior art* as *not having* separate matrices but never actually stated that the *claimed invention does have* separate matrices. *See, e.g.,* J.A. 15482 ("While the publications might teach the advantageous results of using a lipophilic matrix, *the publications fail to disclose* or suggest a composition comprising a combination of two separate matrices." (emphasis added)). Although the prosecution history statements do not rise to the level of unmistakable disavowal, they do inform the claim construction.

The prosecution history, the structure of the claim itself, the ordinary meaning of the claim terms, including the Markush group limitations, and the **patent's** description of the invention compel a claim construction which requires that the inner lipophilic matrix is separate from the outer hydrophilic matrix. *See Phillips,* 415 F.3d at 1316.

Looking to the claim structure itself, the claims require the inner lipophilic matrix to be separate, if not distinct, from the outer hydrophilic matrix. Element (a) of claim 1 recites "an inner lipophilic matrix." Element (b) of claim 1 separately recites "an outer hydrophobic matrix." The separation of these elements within the claims indicates that the claim requires two separate matrices.

Shire even admits that the structure of the claim language requires two separate matrices. Oral Argument at 17:23–17:50, *Shire Dev., LLC v. Watson Pharms., Inc.,* No. 2013–1409 (Fed. Cir. Dec. 2, 2013), *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2013–1409.mp3 (Q: "It sounds like then, even though you opposed having the separate and distinct, that you agree that there has to be two different matrices? A: Correct, separate, yes.... They're separate because by the claim, itself, it says an inner and an outer, so we're talking about two different matrices. For sure, one is lipophilic, one is hydrophilic. They're separate. No question."); Appellees' Br. 34 ("[T]o the extent there is a 'separation' of matrices, the claim language addresses that by defining two matrices as opposed to one.").

Moreover, the logical reading of the claim requires separation between the matrices because the matrices are defined by mutually exclusive spatial characteristics—one inner, one outer—and mutually exclusive compositional characteristics—one hydrophilic, one lipophilic. According ***1367** to the ordinary and customary meanings of these characteristics, one matrix cannot be both inner and outer in relation to a second matrix. Nor can one matrix be both hydrophilic and lipophilic. Thus, considering "matrix" is properly construed as "a macroscopically homogenous structure in all its volume," the construction of "inner lipophilic matrix" requires the inner volume to be separate from the outer volume. *See Phillips,* 415 F.3d at 1314 ("In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.").

The compositions of the inner volume and outer volume, i.e., inner matrix and outer matrix, respectively, are further limited by the Markush groups. During prosecution, the applicants added Markush groups to claim 1 to overcome the examiner's rejection of the claims as obvious over Franco. J.A. 15491–92. For example, the inner lipophilic matrix is limited by a Markush group "consisting of unsaturated and/or hydrogenated fatty acid, salts, esters or amides thereof, fatty acid mono-, di- or triglycer-id[e]s, waxes, ceramides, and cholesterol derivatives with melting points below 90° C." #720 **patent** col. 6 ll. 11–14. The outer hydrophilic matrix is similarly limited by a Markush group consisting of hydrophilic components. *See* #720 **patent** col. 6 ll. 20–25. The lack of overlap of the components of the two Markush groups supports the requirement that the volumes be separate. Accordingly, the correct construction requires that the inner volume contain substances from the group described for the inner lipophilic matrix (which are all lipophilic substances), and that the outer volume separately contain substances from the group described for the outer hydrophilic matrix (which are all hydrophilic).

The #720 **patent** specification also teaches "separate" matrices. The specification describes five examples of forming discrete lipophilic matrix granules and compressing those granules together with the hydrophilic matrix. *See, e.g.,* #720 **patent** col. 3 ll. 31–45. The specification explains that a lipophilic matrix "opposes some resistance to the penetration of the solvent due to the poor affinity towards aqueous fluids." #720 **patent** col. 1 ll. 17–20. And under the stipulated meaning of "lipophilic," the lipophilic matrix must have a "poor affinity towards aqueous fluids." J.A. 216. Thus, the matrix that is deemed the "lipophilic" matrix cannot have hydrophilic properties. But, a matrix comprised of only one lipophilic substance and several hydrophilic substances—and thus capable of exhibiting hydrophilic properties—would meet the district court's construction of "lipophilic matrix." Such a result contradicts the customary and ordinary meaning of "lipophilic" and "hydrophilic."

Furthermore, under the district court's construction, a single mixed matrix with both hydrophilic and lipophilic components—such as the one disclosed in the Sanghvi reference, which the applicants described as "mixing together hydrophilic and lipophilic substances into a single matrix"—could contain both an "inner lipophilic matrix" and an "outer hydrophilic matrix." J.A. 15481. Indeed, any arbitrarily selected volume in a single mixed matrix would satisfy the district court's construction of "inner lipophilic matrix" because that volume would necessarily contain "at least one lipophilic excipient" and it would be "inside" the surrounding volume. Similarly, under the district court's construction, that same arbitrarily selected volume would constitute an "outer hydrophilic matrix" because it would contain ***1368** "at least one hydrophilic excipient" and would be "outside" the inner lipophilic matrix. The claims, however, require two matrices with a defined spatial relationship.

Shire argues that the intrinsic evidence does not describe any particular degree of separation and thus, such a construction would create ambiguity. Shire's argument misses the point. A court must identify "[t]he construction that stays true to the claim language and most naturally aligns with the **patent's** description of the invention." *Phillips,* 415 F.3d at 1316. Whether or not a composition infringes when there is a trace of hydrophilic molecules in the inner volume because of the mixing step inherent in the manufacturing process, for example, is a question for the fact finder. That this question may need to be resolved does not compel a claim construction that departs from the customary and ordinary meaning of the claims, i.e., that the matrices must be "separate" such that they retain their claimed properties and are consistent with their respective Markush group limitations.

C

On remand from the Supreme Court, Shire argues that because the district court "heard" testimony from various expert witnesses during a Markman hearing and at trial, we must defer to the district court's constructions of the appealed terms. *See, e.g.,* Appellees' Suppl. Br. 1.

The Supreme Court held that we "should review for clear error those factual findings that underlie a district court's claim construction." *Teva,* 135 S.Ct. at 842. The Court did not hold that a deferential standard of review is triggered any time a district court hears or receives extrinsic evidence. *See id.* Here, there is no indication that the district court made any factual findings that underlie its constructions of "inner lipophilic matrix" and "outer hydrophilic matrix." *See* J.A. 4566–67.

IV

Accordingly, we reverse the district court's constructions of "inner lipophilic matrix" and "outer hydrophilic matrix," and its subsequent infringement determination, and we remand for proceedings consistent with this opinion.

REVERSED AND REMANDED.

All Citations

787 F.3d 1359, 114 U.S.P.Q.2d 1885

Footnotes

* Pursuant to Fed. Cir. Internal Operating Procedure 15 ¶ 2(b)(ii) (Nov. 14, 2008), Circuit Judge Chen was designated to replace Randall R. Rader, now retired, on this panel.

1 Generally, a lipophilic substance has an affinity for lipids and a hydrophilic substance has an affinity for water. Thus, a lipophilic substance resists dissolving in water, but a hydrophilic substance readily dissolves in water. *See* #720 **patent** col. 1 ll. 17–26, 32–36.

2 An excipient is an ingredient other than the active ingredient, i.e., an ingredient other than mesalamine. *See Shire Dev. LLC v. Watson Pharm., Inc.,* No. 12–60862, 2013 WL 1912208, at *6 (S.D.Fla. May 9, 2013); *see also* J.A. 1425.

3 "A Markush group lists specified alternatives in a **patent** claim, typically in the form: a member selected from the group consisting of A, B, and C." *Gillette Co. v. Energizer Holdings, Inc.,* 405 F.3d 1367, 1372 (Fed.Cir.2005) (citing to *Manual of* ***Patent*** *Examining Procedure* § 803.2 (2004)).

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