Novartis Pharmaceuticals Corporation et al v. Par Pharmaceutical Inc. Doc. 97

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	Civil Action No. 14-1494-RGA Civil Action No. 15-78-RGA
NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. ROXANE LABORATORIES, INC., Defendant.	Civil Action No. 14-1508-RGA Civil Action No. 15-128-RGA

MEMORANDUM OPINION

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Richard G. Andrews

ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is a supplemental claim construction of a term in U.S. Patent Nos. 7,297,703 ("the '703 patent") and 7,741,338 ("the '338 patent"). Plaintiffs Novartis Pharmaceuticals Corporation and Novartis AG assert claims of the '703 patent, the '338 patent, and U.S. Patent No. 5,665,772 against Defendants Par Pharmaceutical, Inc. and Roxane Laboratories, Inc. in the above-captioned cases.[1] The Court previously construed another disputed term submitted by the parties. (D.I. 80, 84).[2] In the present matter, the Court has considered the parties' Joint Claim Construction Brief. (D.I. 89). The Court heard oral argument on November 13, 2015 (D.I. 95 [hereinafter, "Tr."]).

I. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks and citations omitted).

[1] The claim terms of U.S. Patent No. 5,665,772 are not at issue in this proceeding.
[2] Citations to "D.I. __" are citations to the docket in C.A. No. 14-1494.

> "[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."

Id. at 1312–13 (internal quotation marks and citations omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "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." *Id.* at 1314 (internal citations omitted).

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (internal quotation marks and citations omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.* "A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

II. CONSTRUCTION OF DISPUTED TERM

Claim 1 of the '703 patent and claim 1 of the '338 patent are each directed to the disputed term "solid mixture." ('703 patent, col. 8, ll. 37–41; '338 patent, col. 10, ll. 12–13). The '703 and '338 patents share the same specification.

1. "solid mixture"

   a. *Plaintiffs' proposed construction*: mixture in solid form of two or more substances, which mixture is not a pharmaceutical composition

   b. *Defendants' proposed construction*: a solid combination of two or more solid substances that are mixed, but not chemically combined

   c. *Court's construction*: a solid combination of two or more solid substances that are mixed, but not chemically combined

The parties agree that the claimed "solid mixture" is a combination of two or more solid substances that are not chemically combined. (D.I. 89 at 6, 12). The dispute concerns whether the solid mixture can be a pharmaceutical composition. (*Id.*).

Plaintiffs argue that the claimed "solid mixture" cannot be a pharmaceutical composition because claims 1 and 6 of the '703 patent and claims 1 and 3 of the '338 patent draw an "express distinction between (i) a solid mixture of a macrolide and an antioxidant, and (ii) a pharmaceutical composition that incorporates a solid mixture of a macrolide and an antioxidant." (*Id.* at 7). Claims 1 and 6 of the '703 patent read:

> 1. A solid mixture comprising a poly-ene macrolide and an antioxidant wherein the poly-ene macrolide is selected from the group consisting of rapamycin, a 16-O-substituted rapamycin, and a 40-O-substituted rapamycin and wherein the antioxidant is present in a catalytic amount.
>
> 6. A pharmaceutical composition comprising as active ingredient, a mixture according to claim 1 or 2, admixed with one or more pharmaceutically acceptable carriers or diluents.

('703 patent, col. 8, ll. 37–41, 55–58).

Claims 1 and 3 of the '338 patent read:

1. A solid mixture comprising 40-O-(2-hydroxy)ethyl-rapamycin and 2,6-di-tert-butyl-methylphenol (BHT).

3. A pharmaceutical composition comprising the solid mixture of claim 1 together with one or more pharmaceutically acceptable diluent or carrier.

('338 patent, col. 10, ll. 12–13, 16–18). Plaintiffs contend that if the claimed solid mixture were a pharmaceutical composition, "then claim 6 of the '703 patent and claim 3 of the '338 patent would cover a pharmaceutical composition comprising, as an active ingredient or element thereof, a pharmaceutical composition." (D.I. 89 at 7). Plaintiffs argue that Defendants' construction is improper because it renders claim 6 of the '703 patent and claim 3 of the '338 patent nonsensical. (*Id.*). Plaintiffs further contend that, like the claims, the specification expressly distinguishes a solid mixture of a macrolide and an antioxidant from a pharmaceutical composition that incorporates a solid mixture of a macrolide and an antioxidant. (*Id.* at 9–10).

Defendants respond that a claim directed to a pharmaceutical composition comprising, as an active ingredient or element thereof, a pharmaceutical composition is not nonsensical. (*Id.* at 14). "A pharmaceutical composition comprising a pharmaceutical composition" makes sense because a pharmaceutical composition can be one element of another pharmaceutical composition. (Tr. at 26). Defendants contend, for example, that replacing the term "mixture" in claim 6 of the '703 patent with the term "pharmaceutical composition" would not render the resulting claim nonsensical because claim 6 "would simply require admixing 'one or more pharmaceutically acceptable carriers or diluents' in addition to whatever is already in the mixture of claim 1." (D.I. 89 at 15). With respect to Plaintiffs' argument that the intrinsic evidence repeatedly distinguishes solid mixtures from pharmaceutical compositions, Defendants' view is that the fact that the claims and specification refer to "mixtures" in some instances and

"pharmaceutical compositions" in other instances suggests that "mixture" and "pharmaceutical composition" do not have identical scope, but does not preclude their having overlapping scope. (*Id.* at 15, 17). Defendants argue that their proposed construction simply gives the term "solid mixture" "the full scope of its plain meaning, which would not exclude 'pharmaceutical compositions.'" (*Id.* at 15). I agree that Defendants' proposed construction does not render the dependent claims facially nonsensical and is consistent with the patents' distinguishing "mixture" from "pharmaceutical composition."

Defendants argue that Plaintiffs' proposed negative limitation violates the principle that dependent claims must fall within the scope of the independent claims from which they depend. (*Id.* at 23 (citing *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1291–92 (Fed. Cir. 2006)). The parties agree that claim 6 of the '703 patent depends from claim 1 of the '703 patent and claim 3 of the '338 patent depends from claim 1 of the '338 patent. (*Id.* at 23–24; Tr. at 6). Defendants argue that under Plaintiffs' proposed construction claim 1 of the '703 patent cannot include claim 6 of the '703 patent within its scope and claim 1 of the '338 patent cannot include claim 3 of the '338 patent within its scope. (D.I. 89 at 23).

Relying on *Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305 (Fed. Cir. 2001), Plaintiffs respond that claim 6 of the '703 patent and claim 3 of the '338 patent properly depend on the first claims of their respective patents. (Tr. at 15–17). In *Forest Laboratories*, the court held that a claim to a "pharmaceutical composition . . . comprising . . . [the] surface active material . . . in claim 1" properly depended on claim 1, which recited a "surface active material comprising [certain material]." *Forest Labs., Inc.*, 239 F.3d at 1310, 1311 n.3. In reaching that conclusion, the court recounted the test for proper dependency in the Manual of Patent Examining Procedure, which provides: "The test [of proper dependency] is *not* whether the

claims differ in scope. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim." *Id.* at 1311 n.3. Relying on that test, the court concluded that the claims to a pharmaceutical composition properly depended on the claims to surface active material because "[a]ny pharmaceutical composition that would infringe the dependent claims must necessarily contain a surface active material that would also infringe the independent claims." *Id.*

Forest Laboratories does not support Plaintiffs' construction that "solid mixture" excludes pharmaceutical compositions. In *Forest Laboratories*, the court did not adopt a construction of "surface active material" that excluded from it "pharmaceutical compositions." To the contrary, the court held that "[w]hen the surface active material is combined with a pharmaceutically acceptable carrier, it does not necessarily cease to be the claimed surface active material." *Id.* at 1310. Applying the *Forest Laboratories* reasoning to the claims at issue in this case, the conclusion would be that when the solid mixture is combined with one or more pharmaceutically acceptable carriers or diluents, it would not necessarily cease to be the claimed solid mixture. That solid mixture, combined with one or more pharmaceutically acceptable carriers or diluents, would be the pharmaceutical composition claimed in the dependent claims. Thus, *Forest Laboratories* does not support Plaintiffs' construction.

More generally, it is simply not possible for both (1) "solid mixture" to exclude pharmaceutical compositions and (2) the dependent claims to properly depend on their respective independent claims. By the terms of the claims themselves, a substance that would infringe claim 6 of the '703 patent or claim 3 of the '338 patent would be a "pharmaceutical composition." ('703 patent, col. 8, ll. 55–58; '338 patent, col. 10, ll. 16–18). For that substance to also infringe claim 1 of either patent, according to the claims themselves, it would have to be a

"solid mixture." ('703 patent, col. 8, ll. 37–41; '338 patent, col. 10, ll. 12–13). Thus, the pharmaceutical composition would have to be a solid mixture. Alternatively, if one accepted that "solid mixture" excludes pharmaceutical compositions, then claim 6 of the '703 patent and claim 3 of the '338 patent would not properly depend on their respective independent claims because the pharmaceutical composition that would infringe claim 6 of the '703 patent or claim 3 of the '338 patent could not infringe the independent claims.

Defendants also argue that Plaintiffs' "proposed construction does not meet the Federal Circuit's high bar for adopting a negative limitation." (D.I. 89 at 13). Negative limitations will generally not be added to claim terms without "express disclaimer or independent lexicography in the intrinsic record that justifies including the negative limitation." *Vehicle IP, LLC v. AT & T Mobility, LLC*, 594 F. App'x 636, 642 (Fed. Cir. 2014). Although the claims and specification distinguish "solid mixture" from "pharmaceutical composition," Plaintiffs do not dispute that patentees did not expressly disavow or disclaim "pharmaceutical compositions" from the scope of the term "solid mixture" in the specification or during prosecution. (D.I. 89 at 14, 18–19). Patentees did not act as their own lexicographers by clearly setting forth a definition of "solid mixture" that excluded "pharmaceutical compositions" from its scope. In fact, the specification does not use the term "solid mixture."

Plaintiffs maintain that express disavowal and lexicography are not the sole means by which claim terms can be limited. (*Id.* at 19). As Plaintiffs point out, claim terms are sometimes limited in view of intrinsic evidence even absent express disavowal and lexicography. (*Id.* at 19); *see, e.g.*, *Cephalon, Inc. v. Barr Labs., Inc.*, 389 F. Supp. 2d 602, 606 (D. Del. 2005). Still, the intrinsic evidence Plaintiffs cite here is insufficient to support their proposed negative limitation in light of the lack of express disavowal and lexicography.

Further, Defendants argue that the prosecution history of the '338 patent supports their construction. (D.I. 89 at 24–25). In rejecting patentees' amendment to add as claim 3 "[a] pharmaceutical composition comprising the solid mixture of claim 1," the examiner stated that "[n]ew claim 3 is a duplicate of claim 1. Insertion of the language . . . which reads 'together with one or more pharmaceutically acceptable diluent or carrier' would overcome the objection."[3] (D.I. 90-1 at 54, 57). Patentees acquiesced to the examiner's rejection and made the suggested amendment. (*Id.* at 59). Plaintiffs argue that their proposed construction is consistent with patentees' acquiescence to the examiner's rejection because the need to add a limitation in claim 3 requiring the presence of pharmaceutically acceptable diluents or carriers demonstrates that the solid mixture in claim 1 does not contain such pharmaceutically acceptable diluents or carriers and thus is not a pharmaceutical composition. (Tr. at 19–20). That a mixture meeting the limitations of claim 1 *may* not contain pharmaceutically acceptable carriers or diluents does not mean that it must not. Consequently, Patentees' acquiescence to the examiner's objection that a pharmaceutical composition comprising the solid mixture of claim 1 is a duplicate of claim 3 defeats Plaintiffs' proposed construction.

For the reasons stated above, although "solid mixture" does not mean "pharmaceutical composition," it is possible for a pharmaceutical composition to be a solid mixture. I therefore adopt Defendants' proposed construction.

III. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.

[3] The patent examiner evidently understood the term "solid mixture" as including pharmaceutical compositions.