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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November 23, 2015

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).

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[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).

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