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

Daniel M. Silver, Esq., McCARTER & ENGLISH, LLP, Wilmington, DE; Nicholas N. Kallas, Esq., Christopher E. Loh, Esq. (argued), Charlotte Jacobsen, Esq., Christina Schwarz, Esq., Laura K. Fishwick, Esq., FITZPATRICK, CELLA, HARPER & SCINTO, New York, NY, attorneys for Plaintiffs.

Steven J. Fineman, Esq., Katharine C. Lester, Esq., RICHARDS LAYTON & FINGER, P.A., Wilmington, DE; Daniel G. Brown, Esq., LATHAM & WATKINS LLP, New York, NY; Roger J. Chin, Esq., LATHAM & WATKINS LLP, San Francisco, CA; Marc N. Zubick, Esq., Brenda L. Danek, Esq., LATHAM & WATKINS LLP, Chicago, IL; Parker M. Tresemer, Esq., LATHAM & WATKINS LLP, Los Angeles, CA, attorneys for Defendant Par Pharmaceutical, Inc.

Richard L. Horwitz, Esq., David E. Moore, Esq., Bindu A. Palapura, Esq., POTTER ANDERSON & CORROON LLP, Wilmington, DE; Marta E. Gross, Esq., Keith A. Zullow, Esq., Michael B. Cottler, Esq. (argued), Steven J. Bernstein, Esq., GOODWIN PROCTER LLP, New York, NY, attorneys for Defendant Roxane Laboratories, Inc.

October 16, 2015

Richard G. Andrews

ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of 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 has considered the parties' Joint Claim Construction Brief. (D.I. 72).[2] The Court heard oral argument on October 14, 2015.

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).

"[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

---

[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.

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

The disputed claim term "catalytic amount" appears in claim 1 of the '703 patent and claim 2 of the '338 patent. (D.I. 72 at 8). The '338 patent is a continuation of the '703 patent and the '703 and '338 patents share the same specification. (D.I. 73-1 at 13; D.I. 72 at 8). The

parties agree that the term should be construed to have the same meaning in the claims of the '703 and '338 patents. (D.I. 72 at 8).

1. "catalytic amount"

   a. *Plaintiffs' proposed construction*: small amount as compared to the amount of the poly-ene macrolide

   b. *Defendants' proposed construction*: an amount up to 1% based on the weight of the poly-ene macrolide

   c. *Court's construction*: small amount as compared to the amount of the poly-ene macrolide

The parties agree that the term "catalytic amount" refers to an amount of antioxidant that is relative to the amount of the claimed poly-ene macrolide. (D.I. 72 at 9–10, 26). The dispute concerns how much antioxidant is a "catalytic amount" as that term is used in the asserted claims.

Plaintiffs argue that their construction is proper under principles of claim differentiation, relying on claims 1 and 2 of the '703 patent. (*Id.* at 12). Claims 1 and 2 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.
>
> 2. A mixture according to claim 1, wherein the antioxidant is present in an amount of up to 1% based on the poly-ene macrolide weight.

('703 patent, col. 8, ll. 37–44). Plaintiffs contend that "catalytic amount" in claim 1 of the '703 patent should be construed to encompass amounts greater than the amount disclosed in dependent claim 2 of that patent, "up to 1% based on the poly-ene macrolide weight," because the scope of an independent claim is presumed to be different from and broader than the scope of a claim that depends from the independent claim. (D.I. 72 at 12–14). Plaintiffs further contend that a claim term expressed in general descriptive terms typically should "not be limited to a

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.