

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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COSMO TECHNOLOGIES LIMITED,	:	
VALEANT PHARMACEUTICALS	:	
INTERNATIONAL, and VALEANT	:	
PHARMACEUTICALS LUXEMBOURG	:	
S.A.R.L.,	:	
	:	
Plaintiffs,	:	C.A. No. 15-164-LPS
	:	
v.	:	
	:	
ACTAVIS LABORATORIES FL, INC.,	:	
	:	
Defendant.	:	

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COSMO TECHNOLOGIES LIMITED,	:	
VALEANT PHARMACEUTICALS	:	
INTERNATIONAL, and VALEANT	:	
PHARMACEUTICALS LUXEMBOURG	:	
S.A.R.L.,	:	
	:	
Plaintiffs,	:	C.A. No. 15-193-LPS
	:	
v.	:	
	:	
ALVOGEN PINE BROOK, LLC.,	:	
	:	
Defendant.	:	

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Exhibit 1012

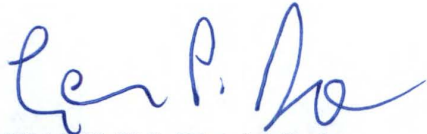
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**MEMORANDUM OPINION**

September 7, 2016  
Wilmington, Delaware



**STARK, U.S. District Judge:**

Plaintiffs Cosmo Technologies Limited, Valeant Pharmaceuticals International, and Valeant Pharmaceuticals Luxembourg S.A.R.L. (“Plaintiffs”) filed suit against Defendants Actavis Laboratories FL, Inc. and Alvogen Pine Brook, LLC, (“Defendants”) alleging infringement of U.S. Patent Nos. 7,410,651 (the “651 patent”), RE 43,799 (the “799 patent”), 8,784,888 (the “888 patent”), 8,293,273 (the “273 patent”), and 9,320,716 (the “716 patent”).<sup>1</sup> The patents are directed to formulations containing budesonide, which are used to treat ulcerative colitis. Presently before the Court is the construction of disputed terms of the patents’ claims.

The parties submitted technology tutorials (D.I. 65 and 69) and claim construction briefs (D.I. 66, 70, 75, 80, 138, 139, 145, and 147). The Court held a claim construction hearing on July 11, 2016. (*See* D.I. 163 (“Tr.”))

## **I. LEGAL STANDARDS**

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). “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) (internal quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.” *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources “in light of the

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<sup>1</sup>Plaintiffs also first sued Par Pharmaceutical, Inc. *See Cosmo Techs. Ltd. v. Par Pharm., Inc.*, C.A. No. 1:15-cv-00116-LPS. That case has since settled. (*See* D.I. 160) However, all of the docket entries cited in this Memorandum Opinion were filed in the *Par* case, so each D.I. reference herein is to C.A. No. 15-116, unless otherwise noted.

statutes and policies that inform patent law.” *Id.*

“[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 citations and quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent 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.” *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . .” *Id.* (internal citation omitted).

It is likewise true that “[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that “the specification may reveal a special definition given to a claim

term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a

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