

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

SHIRE LLC,

Plaintiff,

v.

NEOS THERAPEUTICS, INC.,

Defendant.

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Civil Action No. 3:13-CV-1452-N

ORDER

This Order addresses the construction of five disputed claim terms in United States Reissued Patent No. RE42,096 (the “’096 Patent”) pursuant to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). Having reviewed the relevant intrinsic and extrinsic evidence in the record, the Court construes the disputed terms and phrases as provided below.

I. CLAIM CONSTRUCTION STANDARDS

Claim construction is a question of law for the Court. *See Markman*, 517 U.S. at 391. In construing the claims of a patent, the words comprising the claims “are generally given their ordinary and customary meaning” as understood by “a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (citations and internal quotation marks omitted). Accordingly, courts must determine the meaning of claim terms in light of the resources that a person with such skill would review to understand the patented technology. *See id.* at 1313 (quoting

Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998)). First, “the person of ordinary skill in the art is deemed to read the claim term . . . in the context of the entire patent, including the specification.” *Id.* If the specification “reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess . . . , the inventor’s lexicography governs.” *Id.* at 1316. Likewise, if “the specification . . . reveal[s] an intentional disclaimer, or disavowal, of claim scope by the inventor . . . [,] the inventor’s intention, as expressed in the specification, is regarded as dispositive.” *Id.* (citation omitted).

In addition to the specification, courts must examine the patent’s prosecution history – that is, the “complete record of the proceedings before the PTO and includ[ing] the prior art cited during the examination of the patent.” *Id.* at 1317 (citation omitted). “Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent.” *Id.* (citation omitted). In particular, courts must look to the prosecution history to determine “whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.* (citations omitted). “[W]here 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).

Finally, in addition to evidence intrinsic to the patent at issue and its prosecution history, courts may look to “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 (quoting *Markman*, 52 F.3d at 980). In general, extrinsic evidence is “less reliable than the patent and its prosecution history in determining how to read claim terms.” *Id.* at 1318.

Of particular importance here is the prohibition on reading limitations from the specification into the claim. The *Phillips* Court instructed:

We also acknowledge that the purpose underlying the *Texas Digital [Systems, Inc. v. Telegenix, Inc.]*, 308 F.3d 1193 (Fed. Cir. 2002)] line of cases – to avoid the danger of reading limitations from the specification into the claim – is sound. Moreover, we recognize that the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice. *See Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-87 (Fed. Cir. 1998) (“there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification”). However, the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court’s focus remains on understanding how a person of ordinary skill in the art would understand the claim terms. For instance, although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments. *See, e.g., Nazomi Communications, Inc. v. ARM Holdings, PLC*, 403 F.3d 1364, 1369 (Fed. Cir. 2005) (claims may embrace “different subject matter than is illustrated in the specific embodiments in the specification”); *Liebel–Flarsheim [Co. v. Medrad, Inc.]*, 358 F.3d [898,] 906-08 [(Fed. Cir. 2004)]; *Teleflex [Inc. v. Ficos N. Am. Corp.]*, 299 F.3d [1313,] 1327 [(Fed. Cir. 2002)]; *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985). In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment. *Gemstar–TV Guide [Int’l, Inc. v. Int’l Trade Comm’n]*, 383 F.3d [1352,] 1366 [(Fed. Cir. 2004)]. That is not just because section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant, but also because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments.

To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. *See Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987). One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive. *See SciMed Life Sys. [Inc. v. Adv. Cardiovascular Sys., Inc.]* 242 F.3d [1337,] 1341 [(Fed. Cir. 2001)]. The manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent. *See Snow v. Lake Shore & M.S. Ry. Co.*, 121 U.S. 617, 630 (1887) (it was clear from the specification that there was “nothing in the context to indicate that the patentee contemplated any alternative” embodiment to the one presented).

Phillips, 415 F.3d at 1323.

II. BACKGROUND OF THE INVENTION

The '096 Patent discloses a formulation of amphetamine that provides for extended release into the recipient's bloodstream. Attention Deficit Hyperactivity Disorder (“ADHD”) causes behavioral symptoms in children such as inattention and impulsiveness. Paradoxically, stimulants are frequently prescribed to treat ADHD. Amphetamine is effective, but relatively short acting. Traditional continuous slow release formulation techniques have various drawbacks. The '096 Patent describes a pharmaceutical composition that combines a drug that will immediately release into the recipient's system upon ingestion with a formulation that will not release until it enters the recipient's intestines.

Plaintiff Shire LLC markets a conventional amphetamine drug under the name Adderall. It also markets an extended release formulation that practices the '096 Patent

under the name Adderall XR. Defendant Neos Therapeutics, Inc. (“Neos”) applied to the FDA to manufacture its own amphetamine-based drug. This lawsuit followed.

III. MIXED AMPHETAMINE SALTS

Term:

mixed amphetamine salts (Claims 1, 8, and 25)

Shire’s Proposed Construction:

a combination of two or more salts resulting from the reaction of an acid with different optical isomers of amphetamine or of an optical isomer of amphetamine with different acids

Neos’s Proposed Construction:

the mixture of four amphetamine salts in Adderall

The specification does not define a salt. A person of ordinary skill in the art would understand that a “salt” is an ionic compound that results from a reaction between an acid and a base. Luk Decl. ¶ 20, Shire App. A411. Neos proposes to limit the term to the four amphetamine salts in Adderall based on the prosecution history in a related patent. That other patent, however, required those four specific salts. The ’096 Patent facially has no such requirement, and the Court will not limit the scope of the ’096 Patent’s claims based on the prosecution history of a substantively different patent. The Court, therefore, adopts Shire’s construction.

IV. DISTINCT, CONTINUOUS LAYERS AND POLYMERS

Term:

covered with an immediate release coating (Claims 1, 2, 8, 13, 18–20, and 25)

Shire’s Proposed Construction:

covered with a coating intended to allow drug to dissolve without delaying or prolonging its dissolution or absorption

Neos’s Proposed Construction:

covered with a distinct, continuous layer of polymeric material that allows immediate release of the drug

Term:

covered with an enteric release coating (Claims 1, 2, 8, 13, 18–20, and 25)

Shire's Proposed Construction:

covered with a coating intended to delay release of drug until the drug has passed through the stomach

Neos's Proposed Construction:

covered with a distinct, continuous layer of polymeric material that delays release of the drug until it reaches the intestines

Term:

a protective layer over the enteric release coating (Claim 13)

Shire's Proposed Construction:

a thickness of material(s) intended to provide protection or separation over the enteric release coating

Neos's Proposed Construction:

a distinct, continuous layer of polymeric material that covers the enteric release coating

Term:

a protective layer between the at least one pharmaceutically active amphetamine salt and the enteric release coating (Claims 18–20)

Shire's Proposed Construction:

a thickness of material(s) intended to provide protection or separation between the at least one pharmaceutically active amphetamine salt and the enteric release coating

Neos's Proposed Construction:

a distinct, continuous layer of polymeric material that lies between the at least one pharmaceutically active amphetamine salt and the enteric release coating

The Court addresses the remaining four terms together as the parties' dispute is essentially the same in all four. In all four cases, Neos proposes adding the limitations (1) distinct, continuous layer, and (2) polymeric material. The Court will address these in turn.

A. Distinct, Continuous Layer

Neos essentially proposes to define the terms "coating" and "layer" as "a distinct, continuous layer." The Court suspects, in typical *Markman* fashion, that Neos's product does not meet that definition and the parties are fighting an infringement battle with the Court left

flailing around in the dark. The Court is left to speculate whether something with a gradient rather than a distinct boundary might ever be considered a coating. Or whether a covering with pores or other discontinuities might be considered a coating. Rather than speculate in a vacuum, the Court believes the better course is not to construe “layer” or “coating.” The finder of fact can then determine based on actual evidence whether Neos’s product embodies the ordinary meaning of coating and layer. The Court therefore rejects Neos’s proposed limitations.

B. Polymeric Material

This is perhaps the most audacious attempt by Neos to limit the scope of the claims in the ’096 Patent. Neos argues in favor of this limitation (1) that all of the examples in the specification are polymers and (2) that a skilled formulator desiring to practice the ’096 Patent would use a polymer. But Neos acknowledges the use of sugar and wax coatings, which are not polymers. And the specification refers to fatty acids and wax, which are not polymers. *See* col. 8, l. 62. Moreover, the fact that polymers might be the most common or even the best choice for the coatings and layers does not mean that polymers should be a limitation of claim terms that are otherwise unlimited. The Court therefore rejects Neos’s proposed polymer limitation.

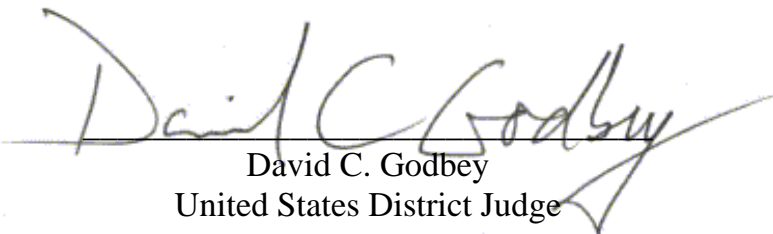
Having rejected both of Neos’s proposed limitations, the Court adopts Shire’s proposed construction of the last four disputed terms.¹

¹There is a minor terminology difference in whether “enteric” should refer to the point at which the drug has passed through the stomach or the drug reaches the intestines. The parties do not discuss this difference, and the Court cannot discern any meaningful difference

CONCLUSION

The Court orders that the various patent terms are construed as indicated. The Court will by separate order establish a schedule for resolution of the remaining issues in the case.

Signed March 20, 2014.


David C. Godbey
United States District Judge

between the two phrases. The Court will therefore adopt Shire's terminology.