

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA, N.V., JANSSEN
SCIENCES IRELAND UC, GILEAD SCIENCES, INC.,
and GILEAD SCIENCES IRELAND UC

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC. and MYLAN
INC.,

Defendants.

No. 15-cv-760 (RGA)

MEMORANDUM OPINION

Steven J. Balick, Esq., Tiffany Geyer Lydon, Esq., Andrew C. Mayo, Esq., Ashby & Geddes, Wilmington, Del., Gregory L. Diskant, Esq., Irena Royzman, Esq. (argued), Jordan M. Engelhardt, Esq., Jacob Siegel, Esq., Patterson Belknap Webb & Tyler LLP, New York, N.Y., attorneys for Plaintiffs Janssen Pharmaceutica, N.V., and Janssen Sciences Ireland UC.

Brian E. Farnan, Esq., Michael J. Farnan, Esq., Farnan LLP, Wilmington, Del., Colleen Tracy James, Esq., Manuel J. Velez, Esq., Scott A. McMurry, Esq., Mayer Brown LLP, New York, N.Y., attorneys for Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Ireland UC.

James M. Lennon, Esq., Pilar G. Kraman, Esq., Young Conaway Stargatt & Taylor, LLP, Wilmington, Del., James H. Wallace, Jr., Esq., Mark A. Pacella, Esq., Brian H. Pandya, Esq. (argued), Wesley E. Weeks, Esq., Wiley Rein LLP, Washington, D.C., attorneys for Defendants Mylan Pharmaceuticals Inc. and Mylan Inc.

January 6, 2017


ANDREWS, U.S. DISTRICT JUDGE:

Plaintiffs own U.S. Patent 8,101,629 claiming the invention of a pharmaceutical compound used to treat patients with HIV and AIDs. After Defendants filed an Abbreviated New Drug Application to sell generic versions of Plaintiffs' drug Complera, Plaintiffs filed this patent infringement suit. (D.I. 1).

The '629 patent is one of eight asserted patents, and the only one containing a disputed term. (D.I. 119 at 5; D.I. 127 at 6). Parties dispute the construction of the term "wetting agent" as used in claim 1. Plaintiffs have also asserted dependent claims 2, 3, 4, 5, and 7. (D.I. 119 at 6).

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) (alteration in original). 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 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 question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312–13 (citations and internal quotation marks 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.

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 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.*

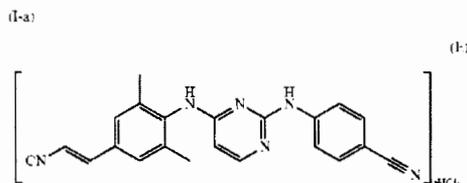
“A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude

the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

II. CONSTRUCTION OF DISPUTED TERM

The only term disputed by the parties is wetting agent as used in claim 1. Claim 1 reads:

1. A tablet comprising 25 mg base equivalent of a compound of formula (I-a)



in a pharmaceutically acceptable carrier comprising a *wetting agent*.

'629 Patent, col. 27, ll. 16–31 (disputed term italicized).

Both parties agree wetting agent includes an amphiphilic compound. Defendants add, and Plaintiffs dispute, that the compound must decrease the contact angle between the rilpivirine hydrochloride and an aqueous solution.

1. “wetting agent”

- a. *Plaintiffs' proposed construction*: “an amphiphilic compound, *i.e.*, a compound which contains polar, hydrophilic moieties as well as non-polar, hydrophobic moieties”
- b. *Defendants' proposed construction*: “an amphiphilic compound that decreases the contact angle between the rilpivirine hydrochloride and an aqueous solution”
- c. *Court's construction*: “amphiphilic compound that, when added to a liquid, reduces the surface tension of said liquid allowing the liquid to penetrate or spread over the surface of another material more easily”

The core question in this claim construction is whether the specification provides its own definition of the term “wetting agent.” The specification provides:

As for the wetting agent in the compositions of the invention, there may be used any of the physiologically tolerable wetting agent suitable for use in a pharmaceutical composition.

It is well-known in the art that a wetting agent is an amphiphilic compound; it contains polar, hydrophilic moieties as well as non-polar, hydrophobic moieties.

'629 Patent, col. 9, ll. 31–36. From this, Plaintiffs argue the complete definition of “wetting agent” is amphiphilic compound.

The plain and ordinary meaning of a term controls unless the “patentee sets out a definition and acts as his own lexicographer....” *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). “To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning.” *Id.* (internal quotation marks omitted).

While “rigid formalism is not required,” *AstraZeneca AB v. Mutual Pharma.*, 384 F.3d 1333, 1339 (Fed. Cir. 2004), the specification contains no signaling that the patent is specifying a specialized definition, *contrast with id.* (adopting specialized definition when specification read that the disputed term was “defined below”) and *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1369, 1371 (Fed. Cir. 2003) (adopting specialized definition when specification read “[the disputed term] means...”).

The patent in this case does not “clearly set forth a definition of” wetting agent. Instead the specification sets out a necessary condition, not a definition, of “wetting agent.” For example, if I say “it is well known that a mammal is a vertebrate” that does not mean I am saying a frog should be considered a mammal. A frog is a vertebrate, but it is an amphibian. Just because the patent says a wetting agent is an amphiphilic compound does not mean that all amphiphilic

compounds should be considered wetting agents. Thus, I am rejecting Plaintiffs' proposed construction.

Having rejected Plaintiffs' lexicography argument, I turn to the plain and ordinary meaning of the term "wetting agent." Plaintiffs offered no input on the definition of "wetting agent" outside of their lexicography argument. Defendants' definition specifies that the wetting agent reduces the contact angle between a liquid and the claimed compound. The patent, however, does not discuss how the wetting agent and claimed compound interact. Therefore, I decline to adopt Defendants' definition.

I am construing "wetting agent" to be an amphiphilic compound that, when added to a liquid, reduces the surface tension of said liquid allowing the liquid to penetrate or spread over the surface of another material more easily. The patent specification makes clear that the wetting agent is an amphiphilic compound. Further, technical dictionaries also embrace the idea that a wetting agent reduces surface tension and allows a liquid to penetrate or spread over the surface of another material. *See, e.g., "Wetting Agent," The Condensed Chemical Dictionary* (10th ed. 1981) ("A surface-active agent (q.v.) which, when added to water, causes it to penetrate more easily into, or to spread over the surface of, another material by reducing the surface tension of the water."); "Wetting Agent," *McGraw-Hill Dictionary of Scientific and Technical Terms* (5th ed. 1994) ("A substance that increases the rate at which a liquid spreads across a surface when it is added to the liquid in small amounts.").

III. CONCLUSION

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