

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS LLC,

Defendant.

Civil Action No. 15-697-RGA

MEMORANDUM ORDER

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 8,242,158 (“the ’158 patent”); 8,338,470 (“the ’470 patent”); 8,455,527 (“the ’527 patent”); and 8,648,106 (“the ’106 patent”) (collectively “the patents-in-suit”). The Court has considered the parties’ Joint Claim Construction Brief. (D.I. 44).

“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 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 Pharms. 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). 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) (internal quotation marks and citation omitted).

The parties agree that the term “effective amount,” found in claim 1 of the ’527 patent, should be construed as “amount sufficient to produce the desired effect.” (D.I. 44 at p. 4). The Court adopts this construction.

The parties dispute the construction of four terms: (1) “dexmedetomidine;” (2) “no more than about 2% decrease in the concentration of dexmedetomidine;” (3) “critically ill;” and (4) “intensive care unit.” (*Id.*). The Court addresses each term separately.

1. “dexmedetomidine” (all asserted claims)

a. *Plaintiff’s proposed construction*: “substantially pure, optically active dextrorotary stereoisomer of medetomidine, as the free base or pharmaceutically acceptable salt”

b. *Defendant’s proposed construction*: “substantially pure, optically active dextrorotary stereoisomer of medetomidine, as the free base”

c. *Court’s construction*: “substantially pure, optically active dextrorotary stereoisomer of medetomidine, as the free base or pharmaceutically acceptable salt”

The specification of each of the patents-in-suit sets forth an explicit definition for this term. *See, e.g.*, ’158 patent at 3:21-24. That definition aligns with Plaintiff’s proposed construction. “When a patentee explicitly defines a claim term in the patent specification, the patentee’s definition controls.” *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009). Thus, here, the inventor’s lexicography governs. I therefore construe “dexmedetomidine” to mean “substantially pure, optically active dextrorotary stereoisomer of medetomidine, as the free base or pharmaceutically acceptable salt.”

2. “no more than about 2% decrease in the concentration of dexmedetomidine”
(’106 patent, claim 1)

- a. *Plaintiff’s proposed construction*: Plain meaning
- b. *Defendant’s proposed construction*: Indefinite
- c. *Court’s construction*: Plain meaning

A patent must “inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). Defendant’s first indefiniteness argument depends on its proposed construction of “dexmedetomidine.” Since the Court rejected that construction, this argument is also rejected. Defendant’s second argument focuses on the word “about.” “When ‘about’ is used as part of a numeric range, . . . [that use] avoids a strict numerical boundary to the specified parameter [and] [i]ts range must be interpreted in its technologic and stylistic context.” *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1368 (Fed. Cir. 2008) (quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995)). The ’106 patent’s specification explains that “‘about’ . . . as used herein means within an acceptable error range for the particular value as determined by one of ordinary skill in the art.” ’106 patent at 5:31-33. The specification further states that this “will depend in part on how the value is measured or determined, i.e., the limitations of the measurement system.” *Id.* at 5:33-35. In context, a PHOSITA would understand the scope of the “about” limitation with reasonable certainty. Therefore, Defendant’s indefiniteness argument is rejected. The term is afforded its plain and ordinary meaning.

3. “critically ill” (’527 patent, claim 10)

- a. *Plaintiff’s proposed construction*: Plain meaning
- b. *Defendant’s proposed construction*: Indefinite
- c. *Court’s construction*: Plain meaning

“[A] patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014) (quoting *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1384 (Fed. Cir. 2005)). The term “critically ill” has a recognizable meaning to those having skill in the art. Further, the ’527 patent provides examples of medical conditions that may satisfy the “critically ill” limitation. ’527 patent at 10:62-11:1. Therefore, Defendant’s indefiniteness argument is rejected. The term is afforded its plain and ordinary meaning.

4. “intensive care unit” (’527 patent, claim 8)

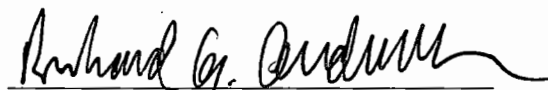
a. *Plaintiff’s proposed construction*: “any setting that provides care to critically ill patients, typically characterized by high nurse-to-patient ratios, continuous medical supervision, and intensive monitoring”

b. *Defendant’s proposed construction*: “any setting that provides intensive care”

c. *Court’s construction*: Either “any setting that provides care to critically ill patients” or “any setting that provides intensive care”

The latter part of Plaintiff’s proposed construction—“typically characterized by high nurse-to-patient ratios, continuous medical supervision, and intensive monitoring”—is rejected. This language finds no support in the intrinsic record. I cannot discern any material distinction between “any setting that provides care to critically ill patients” and “any setting that provides intensive care.” I therefore decline to construe the term further at this time. The parties are permitted to bring up any additional arguments pertaining to this term at the pretrial conference.

Entered this 25 day of May, 2016.


United States District Judge