IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, *Plaintiffs and Counterclaim Defendants*, v. AMGEN INC., *Defendant and Counterclaim Plaintiff.*	Civ. No. 18-924-CFC
GENENTECH, INC. and CITY OF HOPE, *Plaintiffs and Counterclaim Defendants*, v. SAMSUNG BIOEPSIS CO., LTD., *Defendant and Counterclaim Plaintiff.*	Civ. No. 18-1363-CFC

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MEMORANDUM OPINION

June 14, 2019

Wilmington, Delaware

CONNOLLY, UNITED STATES DISTRICT JUDGE

This action arises under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. § 262, and involves biosimilar versions of Herceptin®, a drug used to treat breast cancer. Pending before me is the matter of claim construction pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). Plaintiffs Genentech, Inc. and City of Hope (collectively, "Genentech") and Defendants Amgen, Inc. ("Amgen") and Samsung Bioepsis Co., Ltd. ("Samsung," and collectively with Amgen, "Defendants") have asked me to construe the meaning of terms set forth in U.S. Patent Nos. 7,993,834 ("the '834 patent"); 8,076,066 ("the '066 patent"); 8,574,869 ("the '869 patent"); 8,512,983 ("the '983 patent"); and 7,390,660 ("the '660 patent"). D.I. 60; D.I. 121.[1]

I held a *Markman* hearing on April 24, 2019.[2] D.I. 182. I ruled from the bench with respect to one of the disputed terms. *See Id.* at 12:3-14:14 (adopting Genentech's proposed construction of "A method for increasing likelihood of

[1] All citations are to the docket for C.A. No. 18-924 unless stated otherwise.

[2] Two of the terms at issue in this case are also at issue in *Genentech v. Amgen*, C.A. 17-1407 (the "Avastin case"). Oral argument on the overlapping terms was held in the Avastin case on April 2, 2019 and April 23, 2019. *See* C.A. 17-1407, D.I. 340 at 5:8-83:10 ("following fermentation") and D.I. 345 at 18:18-96:21 ("glutamine-free"). Samsung appeared in the Avastin case to state that it has "the same position as Amgen" on glutamine-free, "so we don't need to … argue it on [April] 24th." D.I. 345 at 96:5-8.

effectiveness of breast cancer treatment with humanized anti-ErbB2 antibody huMAb4D5-8"). The parties also agreed during the hearing that I could assign another disputed term ("Pre-Harvest [Culture Fluid]") its plain and ordinary meaning. *See id.* at 90. I address in this Memorandum Opinion the remaining disputed terms.

I. STANDARD OF REVIEW

"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). "'[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). Construing the claims in a patent is a question of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388–90 (1996).

Unless a patentee acts as his own lexicographer by setting forth a special definition or disavows the full scope of a claim term, the words in a claim are to be given their ordinary and accustomed meaning. *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). "[T]he ordinary and customary

meaning of a claim term 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." *Phillips*, 415 F.3d at 1313. A person of ordinary skill in the art ("POSITA") "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. "[T]he 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. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).[3]

The court may also consider 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.

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[3] Section 112(b) of Title 35 provides that "[t]he specification shall conclude with one or more claims[.]" This language makes clear that the specification includes the claims asserted in the patent, and the Federal Circuit has so held. *See Markman*, 52 F.3d at 979 ("Claims must be read in view of the specification, of which they are part"). The Federal Circuit and other courts, however, have also used "specification" on occasion to refer to the written description of the patent as distinct from the claims. *See, e.g., id.* ("To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history."). To avoid confusion, I will refer to the portion of the specification that is not the claims as "the written description."

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