IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC and SANOFI MATURE IP, Plaintiffs, v. ACTAVIS LLC, et al., Defendants.	Civil Action No. 20-804-RGA

MEMORANDUM OPINION

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August 3, 2022

ANDREWS, U.S. DISTRICT JUDGE:

Before me is the issue of claim construction of one term in U.S. Patent No. 8,927,592 ("the '592 patent"). The parties submitted a Joint Claim Construction Brief (D.I. 274), and I heard oral argument on July 5, 2022 (D.I. 280).

I. BACKGROUND

This Hatch-Waxman action concerns three patents: U.S. Patent Nos. 10,583,110 ("the '110 patent"); 10,716,777 ("the '777 patent"); and the '592 patent. All three patents are related through a series of continuation applications and have substantively identical specifications. (D.I. 183 at 1). Plaintiffs filed complaints alleging infringement of the '110 and '777 patents in June and July 2020. (D.I. 1, 62). I issued a claim construction order for these patents in January 2021. (D.I. 209, 215).

Before the '592 patent was added to this case, it was the subject of parallel proceedings in the District of New Jersey and the PTAB ("the Mylan IPR"). (D.I. 274 at 1). In the Mylan IPR, Plaintiffs filed a contingent motion to amend the '592 patent to substitute claims 31–34 for claims 27–30. (*Id.*). The PTAB ultimately granted this motion to amend because Mylan had not shown that the amended claims were obvious. *Mylan Lab'ys Ltd. v. Aventis Pharma S.A.*, No. IPR2016-00712, 2019 WL 5430242, at *13 (P.T.A.B. Oct. 22, 2019). The Federal Circuit summarily affirmed. (D.I. 236 at 2; D.I. 280 at 50:2–4). The USPTO issued the certificate of amendment adding claims 31–34 to the '592 patent on August 23, 2021. (D.I. 248-1, Ex. A at 23). Shortly thereafter, Plaintiffs filed a Second Amended Complaint adding the amended claims of the '592 patent to this case. (D.I. 248).

The '592 patent is directed to the use of cabazitaxel in the treatment of metastatic castration-resistant prostate cancer. ('592 patent, 1:19–26). The disputed term appears in claim

31, which is the only independent amended claim of the '592 patent. I have italicized the disputed term.

> **31.** (substitute for claim **27**) A method of *increasing survival* comprising administering to a patient in need thereof (i) an antihistamine, (ii) a corticoid, (iii) an H_2 antagonist, and (iv) a dose of 20 to 25 mg/m^2 of cabazitaxel, or a hydrate or solvate thereof, wherein said antihistamine, said corticoid, and said H_2 antagonist are administered prior to said dose of 20 to 25 mg/m^2 of cabazitaxel, or hydrate or solvate thereof, in combination with prednisone or prednisolone, wherein said patient has castration resistant or hormone refractory, metastatic prostate cancer that has progressed during or after treatment with docetaxel.

II. 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) (alteration in original) (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 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 Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (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 (quoting *Markman*, 52 F.3d at 980). 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.*

III. CONSTRUCTION OF AGREED-UPON TERMS

I adopt the following agreed-upon constructions:

Claim Term	**Construction**
"castration resistant or hormone refractory, metastatic prostate cancer that has progressed during or after treatment with docetaxel" (amended claim 31)	castration resistant metastatic prostate cancer that has worsened during or after treatment with docetaxel
"A method of increasing survival . . . to a patient in need thereof" (amended claim 31)	A method of increasing survival with the intentional purpose of increasing such survival in an individual patient in need of such a method of increasing survival

IV. CONSTRUCTION OF DISPUTED TERM

1. "increasing survival" (amended claim 31)

a. *Plaintiffs' proposed construction*: increasing the quantity of life (i.e., how long the patient will live) in comparison to that which would be expected with treatment with mitoxantrone and prednisone

b. *Defendants' proposed construction*: increasing any of: overall survival, tumor progression-free survival, pain progression-free survival, or prostate-specific antigen (PSA) progression-free survival

c. *Court's construction*: increasing any of: overall survival, tumor progression-free survival, pain progression-free survival, or prostate-specific antigen (PSA) progression-free survival as compared to any other treatment that may be available to the patient (including no treatment)

The parties have two disputes with respect to this term: (1) whether "survival" includes "overall survival" and "progression-free survival," or just "overall survival"; and (2) whether the proper comparator is mitoxantrone or any other treatment that may be available to the patient.

I have already resolved the first dispute. In January 2021, I construed the same term "increasing survival" for the '777 and '110 patents. I adopted Defendants' construction: "increasing any of: overall survival, tumor progression-free survival, pain progression-free survival, or prostate-specific antigen (PSA) progression-free survival." (D.I. 209 at 5–9). I see no reason to reconsider this construction. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003) ("[W]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning."); *Sentient Sensors, LLC v. Cypress Semiconductor Corp.*, 2021 WL 1966406, at *1 (D. Del. May 17, 2021) ("Motions for reargument or reconsideration should not be granted if the proponent simply rehashes materials and theories already briefed, argued and decided." (cleaned up)).

The '592 patent specification discusses two forms of survival: "overall survival" and "progression-free survival (PFS)." ('592 patent, 11:4–5, 11:21–25, 12:19–28). The patent

defines "overall survival" as "the time from inclusion to the study to the date of death" (*id.*, 11:4–5) and "PFS" as "the time from inclusion in the study and the date of progression or death when the progression is either an increase of the PSA, or of the tumour, or of the pain." (*Id.*, 11:21–25). Example 1 (the TROPIC study) reports the efficacy of treatment with cabazitaxel using both overall survival and PFS as survival metrics. (*Id.*, 11:26–12:29; Fig. 1 (Kaplan-Meier curve for overall survival); Fig. 2 (Kaplan-Meier curve for progression-free survival)). The patent reports that there were statistically significant improvements in overall survival, tumor PFS, and prostate-specific antigen (PSA) PFS as compared to treatment with mitoxantrone. (*Id.*). A POSA reading these disclosures would understand that the term "survival" as used in the '592 patent refers to both overall survival and PFS.

The prosecution history also supports this construction. During prosecution of the '777 patent, the examiner used "increased survival" to refer to an increase in either overall survival or PFS:

> While cabazitaxel was administered in combination with prednisone or prednisolone in Applicants' examples . . . it was the dose of 20 to 25 mg/m^2 cabazitaxel that led to increased survival . . . . The overall survival (15.1 months vs. 12.7 months) and progression-free survival (2.8 months vs. 1.4 months) of patients treated with cabazitaxel + prednisone or prednisolone were increased in a statistically significant manner compared to the survival of patients treated with mitoxantrone + prednisone or prednisolone. See Table 1. Accordingly, Applicants' results are considered commensurate in scope with the claimed invention.[1]

[1] Plaintiffs argue that the examiner's statements during prosecution of the '777 patent are not part of the intrinsic record of the '592 patent. (D.I. 274 at 46 n.16). This is incorrect. The Federal Circuit has held, "[T]he prosecution history regarding a claim term is pertinent when interpreting the same term in both later-issued and earlier-issued patents in the same family." *Cap. Mach. Co. v. Miller Veneers, Inc.*, 524 F. App'x 644, 649 (Fed. Cir. 2013) (citing *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004)). Thus, I find these statements to be relevant in interpreting the same term "increasing survival" in the '592 patent.

(D.I. 268-1, Ex. F at 25). The examiner's discussion of both overall survival and PFS shows that the examiner understood the term "survival" to include both overall survival and PFS.

Thus, I (again) find that "increasing survival" includes increasing overall survival and PFS.

The parties dispute the proper comparator. At the prior *Markman* hearing, Plaintiffs proposed construing "increased survival" as "prolonging life as compared to no treatment or palliative treatment." (D.I. 209 at 5). In declining to adopt their construction, I stated, "Plaintiffs cite no support for the comparative aspect of their construction in the specification: 'as compared to no treatment or palliative treatment.'" (*Id.* at 7–8). The parties had different interpretations of this statement. Plaintiffs interpreted this to mean that the claims were directed to increasing survival as compared to mitoxantrone and prednisone, which was the comparator used in Example 1 of the specification. (D.I. 280 at 9:12–17). Defendants understood this to mean that the claims are not limited to any comparator. (*Id.* at 39:21–23). Specifically, Defendants argue that the comparator should be any other treatment that may be available to the patient, including no treatment. (*Id.* at 40:7–17).

I do not see any support in the '592 patent for limiting the claimed comparator to mitoxantrone. The claim language does not specify any comparator. The specification also does not limit the specific comparator. As Plaintiffs point out, Example 1—the only comparative example in the specification—discloses the results of the TROPIC study which compared cabazitaxel with mitoxantrone. ('592 patent, 10:29–17:32). The specification, however, contemplates comparators other than mitoxantrone. For example, the specification reports that treatment with cabazitaxel did not show a statistically significant increase in pain PFS as compared to mitoxantrone. (*Id.*, 12:24–28). Because treatment with cabazitaxel does not

increase pain PFS relative to mitoxantrone, a POSA would understand that the claim encompasses other comparators. Treatment with mitoxantrone was known to increase pain PFS as compared to no treatment. (*See* D.I. 275, Ex. OO at ¶ 192; D.I. 280 at 14:18–20). Thus, a POSA would understand that cabazitaxel does increase pain PFS as compared to no treatment, even though it does not increase pain PFS relative to mitoxantrone.

Plaintiffs also argue that Defendants' construction is "irreconcilable" with the Mylan IPR. (D.I. 280 at 15:6–11). Mita—a prior art reference in the Mylan IPR—disclosed that the claimed dose of cabazitaxel demonstrated anticancer activity (i.e., PSA reductions, partial tumor responses, and decreased pain) in at least two prostate cancer patients. (*Id.* at 16:13–21). In the Final Written Decision on Remand, the PTAB concluded that the "indications of disease control" in Mita did not give rise to a reasonable expectation of success of increasing survival using cabazitaxel. (D.I. 268-1, Ex. O at 20–21; D.I. 280 at 58:11–15). Because Defendants' expert Dr. Ratain states in his obviousness opinion that in the absence of treatment, the "indications of disease control" in Mita are equivalent to increased PFS, Plaintiffs argue that a POSA reading the Mylan IPR record would understand that "increasing survival" cannot include increasing PFS as compared to no treatment. (D.I. 274 at 11–13; D.I. 280 at 63:12–16; *see also* D.I. 274 at 44 n.13 ("The logic is as follows: []if A (PSA reductions, pain relief, and antitumor responses) = B (increasing PFS as compared to no treatment) and A ≠ C (increasing survival), then B ≠ C.")).

Plaintiffs' Mylan IPR argument seems to be one of invalidity, not claim construction. This is shown by their focus on Dr. Ratain's obviousness opinion. (*See* D.I. 274 at 11–12, 43; D.I. 280 at 15:15–17:15). Further, Plaintiffs argue that Defendants' proposed construction would "create the same grounds for invalidity over the same prior art that was already considered by the PTAB." (D.I. 274 at 11). This is not a valid reason to adopt Plaintiffs' construction. *See*

Nazomi Commc'ns, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1368 (Fed. Cir. 2005) ("In thus focusing on validity, this limited approach glosses over, if it does not ignore entirely, the intrinsic evidence—the claims, specification, and prosecution history—that must inform the court's claim construction.").

I am not convinced that a POSA reading the Mylan IPR record or the '592 patent specification would understand the claimed comparator to be limited to mitoxantrone. Accordingly, I adopt Defendants' proposed comparator: any other treatment that may be available to the patient (including no treatment).

V. CONCLUSION

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