IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC, et al.,

Plaintiffs,

v.

ACTAVIS LLC et al.,

Defendants.

Civil Action No. 20-804-RGA

MEMORANDUM OPINION

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January 5, 2021

/s Richard G. Andrews
ANDREWS, U.S. DISTRICT JUDGE:

Before me is a Claim Construction dispute concerning U.S. Patent No. 10,583,110 ("the '110 Patent") and U.S. Patent No. 10,716,777 ("the '777 Patent"). The parties submitted a Joint Claim Construction Brief (D.I. 183) and I heard oral argument via Skype on December 17, 2020. (D.I. 205). At the hearing, the parties agreed to a construction that resolved two of the three disputed terms: "a method of increasing survival" and "to a patient in need thereof." All that remains is to construe "increasing survival."

I. Background

The patents-in-suit disclose methods of treating metastatic castration-resistant prostate cancer with cabazitaxel. (D.I. 183 at 1). Claim 1 of the '110 Patent recites a method of administering cabazitaxel "as a new cycle every three weeks" and dexchlorpheniramine, dexamethasone and an H2 antagonist, "each administered prior to the administration of said cabazitaxel." '110 Patent 18:8-18. Claim 1 of the '777 Patent discloses a method using a "dose of 20 to 25 mg/m^2 of cabazitaxel" with an H_2 antagonist "wherein the H_2 antagonist is administered to the patient prior to administering the dose of cabazitaxel." '777 Patent 18: 54-61.[1]

[1] Why the '777 Patent, which is a continuation of the '110 Patent, refers to H_2 rather than H2 is unexplained.

The parties also have an ongoing dispute with respect to U.S. Patent No. 8,927,592 ("the '592 Patent"). The PTAB's remand decision addressing the '592 Patent is currently on appeal to the Federal Circuit. (D.I. 183 at 2).

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) (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).

III. Construction of Disputed Term

The parties dispute construction of one term that appears in claim 1 of the '110 and '777 Patents. Claim 1 of the '110 Patent reads:

> 1. A method of *increasing survival* comprising administering to a patient in need thereof (1) cabazitaxel, or a hydrate of solvate thereof, as a new cycle every three weeks and (2) dexchlorpheniramine administered at a dose of 5 mg, dexamethasone administered at a dose of 8 mg, and an H2 antagonist, each administered prior to the administration of said cabazitaxel, or hydrate or solvate thereof, wherein said patient

has castration resistant metastatic prostate cancer that has progressed during or after treatment with docetaxel.

('110 Patent 18:8-16 (disputed term italicized)).

Claim 1 of the '777 Patent reads:

1. A method of *increasing survival* comprising administering to a patient in need thereof a dose of 20 to 25 mg/m^2 of cabazitaxel, or a hydrate or solvate thereof, in combination with an H_2 antagonist, wherein the H_2 antagonist is administered to the patient prior to administering the dose of cabazitaxel, and wherein said patient has castration resistant metastatic prostate cancer that has progressed during or after treatment with docetaxel.

('777 Patent 18:54-61 (disputed term italicized)).

- **"Increasing Survival"**

  a. *Plaintiff's proposed construction:* prolonging life as compared to no treatment or palliative treatment

  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

Plaintiffs argue that the term "increasing survival" would be readily understood by a POSA as "prolonging life." (D.I. 183 at 23). In support of their definition, Plaintiffs first offer a medical dictionary definition of "survival" referring to the "persistence of life." (*Id.* at 32). With respect to the intrinsic evidence, Plaintiffs argue that the specification supports their construction based on how the term "survival" is used in the cited studies. (*Id*. at 34-36). Both the '110 and the '777 Patents cite to treatments with docetaxel wherein "the survival was improved by 2.4 months." (*Id*. at 35 (citing '110 Patent 1:65-67, 2:1-4; '777 Patent 1:66-67, 2:1-5)). When

discussing the TROPIC study, both patents state that "the median survival for patients in the cabazitaxel group was 15.1 months in comparison to 12.7 months in the mitoxantrone group. Notably, the extension of survival was observed irrespective of ECOG performance status, number of prior chemotherapy regimens and age."[2] '110 Patent 11:46-50; '777 Patent 11:43-47.

Lastly, Plaintiffs assert that their position on "increasing survival" has been consistent throughout related proceedings. They assert that they successfully disclaimed Defendants' construction (or any construction broader than the one they propose) during the prosecution of the related '592 Patent. (D.I. 183 at 36-39). Plaintiffs cite to several submissions to the PTAB and the Federal Circuit in which they offered the same construction of "increasing survival." (*See* D.I. 184, Ex. L at 8, Ex. M at 6, Ex. N at 5).[3] Additionally, they cite several statements in Plaintiffs' briefs to the Federal Circuit which they say function as disclaimers of scope. (D.I. 183 at 38). Twice in the cited materials Aventis states that it has "clearly disavowed" any reading of "increasing survival" that is not limited to prolonging life. (*Id.*). Further, Plaintiffs' brief states that "a physician administering cabazitaxel, premedication, and prednisone according to claim 31 [of the '592 Patent] to shrink a tumor, stabilize disease, or to reduce pain, but without the

[2] Eastern Cooperative Oncology Group (ECOG) performance status is a scale used by doctors that seems to assess the work and self-care abilities of a patient.

[3] Plaintiff argues that the Federal Circuit resolved the construction of "increasing survival" on consideration of the '592 Patent. (D.I. 183 at 33-34). I disagree. In *Sanofi Mature IP*, the Federal Circuit held that the preamble to claim 31 of the '592 Patent was limiting. *Sanofi Mature IP v. Mylan Labs Ltd.*, 757 F. App'x 988, 994 (Fed. Cir. 2019). In the context of the preamble, the Court held that "the proposed claims would now clearly require 'increasing survival'" but did not construe the term "increasing survival" alone. *Id.* The fact that the Court faulted Mylan for "conflat[ing] concepts of curing cancer or sending it into remission with longer survival while the cancer remains intact" when addressing Mylan's argument that the claimed doses need not "have any effect on the patient" does not amount to a claim construction of "increasing survival." *Id.*

intention of prolonging life, is not practicing the claimed method." (*Id*. (citing D.I. 184, Ex. N at 6)).

Defendants argue that the specification, which should be given dispositive weight, is clear – it defined four measures of survival. (D.I 183 at 40). Where the claims do not limit "survival" to "overall survival," the limitation of "overall survival" should not be imported from the specification. (*Id*. at 42).[4] Defendants also take issue with the asserted disavowals of scope. (*Id*. at 43). First, Defendants argue that "prolonging life" includes progression free survival so the statements cited above cannot disclaim the inclusion of progression free survival. (*Id*. at 45). Second, Defendants argue that to the extent Plaintiff has disavowed anything, what it has disavowed is the inclusion of non-time-based measurements (tumor-shrinkage, pain reduction, etc.) rather than the other, time-based survival measures discussed in the specification. (*Id*. at 45).

I agree with Defendants' construction. Beginning with the specification, the patents-in-suit discuss two forms of survival: "overall survival" and "progression free survival." '110 Patent 11:20-22, 33-36; '777 Patent 11:19-21, 32-35. Progression free survival (or "PFS") is defined 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." '110 Patent 11:33-36. The only instance Plaintiffs point to where "survival" is used to refer exclusively to "overall survival" is a citation to a review article in the specification. (D.I. 183 at 35). Further, Plaintiffs cite no

[4] I take Defendants' argument to be that "prolonging life" is equivalent to only focusing on "overall survival" as defined in the '110 and '777 Patents. '110 Patent 11:20-22; '777 Patent 11:19-20. This understanding is consistent with Plaintiffs' position that survival excludes "progression free survival."

support for the comparative aspect of their construction in the specification: "as compared to no treatment or palliative treatment." As such, I find little support for Plaintiffs' position in the specification.

The disavowals cited by Plaintiffs do not meet the standard necessary to rewrite the definitions offered in the specification. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325 (Fed. Cir. 2003) (stating that "we have required the alleged disavowing statements to be both so clear as to show reasonable clarity and deliberateness"). Twice Plaintiffs claim they "clearly disavowed" the administration of the claimed method in the '592 Patent without the intent of "prolonging life," but I am not convinced this amounted to a clear disclaimer of progression free survival as defined in the patents-in-suit. (D.I. 183 at 38). The cited briefs appear to argue that adding the language "increasing survival" to the claims of the '592 Patent is what amounted to the disclaimer. (D.I. 184, Ex. M at 7, Ex. N at 1). This is plainly not a clear disclaimer of any form of PFS discussed in the specification. Lastly, I agree that Plaintiffs' final cited disclaimer does not sufficiently address the time-based aspect of progression-free survival to constitute a disavowal of PFS metrics. (D.I. 183 at 38, 45).

I acknowledge that the Court of Appeals has clearly held that statements in an IPR proceeding may act as a disclaimer. *See Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1359-62 (Fed. Cir. 2017). I do not think any reasonable reading of *Aylus* would suggest that statements made in briefs on appeal to federal courts also may act as prosecution disclaimer.[5] To

[5] There might be other doctrines, such as judicial estoppel, that could have some applicability to statements made to courts.

the extent Plaintiffs cite statements in briefs to the Court of Appeals, I hold that they cannot be the basis for prosecution disclaimer.

I also note the reversal of the usual positions in this case, even as related solely to the IPR proceedings, which can be the basis for prosecution disclaimer. That is, usually it is the alleged infringer that is arguing for prosecution disclaimer, and the patentee that is arguing against disclaimer. This scenario makes sense in connection with one of the deep roots of the prosecution disclaimer doctrine—that it prevents the patentee from reclaiming what it had to give up in order to get issuance of the patent. *See id*. at 1359. When the positions are the other way around, the patentee is essentially arguing that it can amend the claims during an IPR without going through the process for amendment. Perhaps such ad hoc amendment during the pendency of district court proceedings in ANDA litigation—which is only forward-looking—is not a particular problem, but in non-ANDA litigation, the court would have to address the question of retroactivity, including when exactly the disclaimer became sufficient to act as a disclaimer. At least with an amendment, the date of the change in scope (if any) is known. Thus, assuming that post-issuance prosecution disclaimer asserted by the patentee is permissible, and, based on *Aylus*, I think it is, such disclaimer still has to meet the exacting standard for disavowal. I do not think it does so here.

For the reasons set forth above, I will adopt Defendants' construction of "increasing survival" which is: "Increasing any of, overall survival, tumor progression-free survival, pain progression-free survival, or prostate-specific antigen (PSA) progression-free survival."

IV. Conclusion

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion, including the terms agreed to at the Markman hearing.