IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EISAI, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 11-cv-901 (GMS)
	)	
BANNER PHARMACAPS INC. and MYLAN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	
	)	

ORDER CONSTRUSING THE TERMS OF U.S. PATENT NOs. 5,780,676 & 5,962,731

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 5,780,676 ("the '676 Patent") and 5,962,731 ("the '731 Patent"):

A. The '676 Patent

1. The term "co-transfection assay" is construed to mean "the reconstituted system in cell culture described at col. 50, lines 1-65, which can evaluate compounds for their interaction with the different Retinoid X Receptor and Retinoic Acid Receptor isoforms."[1]

[1] The court rejects the defendants' proposed construction of this term. (D.I. 53; D.I. 59.) In its Claim Construction Briefing, the defendants proposed that this term be construed to mean "the system of reconstituting ligand-dependent transcriptional control described in Ronald M. Evans, *The Steroid and Thyroid Hormone Receptor Superfamily*, 240 Science 889, 889-895 (1988)." (*Id.*) During the *Markman* hearing, the court inquired as to whether the defendants had framed a construction of the term that did not define it through reference to the Evans article, which, the defendants agree, "describes a concept." *See* Transcript of *Markman* Hearing ("Tr.") at 71:3-15. While the defendants were unable to propose a construction excluding specific reference to Evans during that hearing, they subsequently filed a letter on May 28, 2013, proposing a new construction wherein this term would be defined to mean:

> [A] system for reconstituting ligand-dependent transcriptional control that involves the introduction of two suitable plasmids by transfection into a suitable cell culture, e.g., a mammalian cell, where the first plasmid contains a cDNA that encodes for a readily quantifiable protein, e.g., firefly luciferase or CAT, under control of a suitable response element, e.g., RXRE or RARE.

(D.I. 92 at 1.) The plaintiff opposes consideration of this new construction because: (1) it has had "minimal opportunity to respond and explain to the [c]ourt the problems with [d]efendants' new arguments"; and (2) the proposal is "untimely" in that "this submission comes 12 weeks after the filing of the Joint Claim Construction Chart, 8 weeks after the close of *Markman* briefing, 3 weeks after the *Markman* hearing, and almost 2 years after [d]efendants' Paragraph IV Notice Letter regarding the '676 Patent." (D.I. 93 at 1.) The court agrees that the timing of the

defendants' proposed construction comes late in the claim construction process and, without the court granting leave for further briefing, limits the plaintiff's opportunity to fully respond to the merits of the new proposed construction. However, because the court agrees with the plaintiff's proposed construction of this term, it does not need to reach a decision on whether the defendants' second proposed construction should be considered.

In consideration of the record before it and the parties' *Markman* submissions and arguments, the court concludes that "co-transfection assay" should be construed as the plaintiff proposes. It is well established that a phrase must be understood in the context in which it appears in the claim. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*) (concluding that the context in which a term appears in a claim is "highly instructive" in construing the meaning of that term); *see also Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1347 (Fed. Cir. 2008) (noting that claim terms must be construed in "the context of the claim as a whole"). In addition, it must be construed in light of the claim language, specification, and prosecution history, and must be viewed from the perspective of one of ordinary skill in the art. *See id.* The court agrees with the plaintiff that its construction of the disputed term adheres to these requirements and, specifically, is supported by the patents' specifications, the context of the claims themselves, and their respective prosecution histories.

In the patents-in-suit, each time the phrase "co-transfection assay" appears, it is specific to the co-transfection assay that evaluates compounds for their interaction with the different Retinoid X Receptor ("RXR") and Retinoic Acid Receptor ("RXR") isoforms. For instance, Claim 7 states:

> A pharmaceutical composition comprising a compound which is more potent an activator of Retinoid X Receptor than all of Retinoid Acid Receptor isoforms α, β, and γ in a co-transfection assay and has an EC^{50} potency concentration requirement of 240 nM or less on one or more of the RXR isoforms α, β, and γ, in combination with a pharmaceutically acceptable vehicle.

'676 Patent at col. 67, ll. 32-35. Importantly, the parties are in agreement that the term "is more potent an activator of a [RXR] than all of [RAR] isoforms α, β, and γ" means "has an EC^{50} value for one or more of [RXR] isoforms α, β, and γ." (D.I. 47 at 2, 3.) In fact, the claim, by its own language, requires that the co-transfection assay be an assay that can evaluate compounds for their interaction with the different Retinoid X Receptor and Retinoic Acid Receptor isoforms, consistent with the plaintiff's proposed construction. Thus, a person of ordinary skill in the art would look to the specification of the patents-in-suit for the "co-transfection assay" that can evaluate the EC^{50} values of compounds for the different RXR and RAR isoforms, as required by the patent claim language. Indeed, even the defendants agree that "selectivity for RXR is a limitation in all of the claims being asserted." (D.I. 53 at 4.) Moreover, the defendants' discussion of the "co-transfection assay for determining the activity of a ligand for RXR and RAR" references the portion of the specifications that the plaintiff identifies as its proposed construction. In consideration of the parties' arguments during the *Markman* hearing and their submissions in connection with their Claim Construction Chart, the court concludes that a skilled artisan would find the description of the co-transfection assay in the lines of the '676 Patent that the plaintiff cites as its proposed construction.

In reaching this conclusion, the court disagrees with the defendants' assertion that the plaintiff's construction seeks to limit the claims to a "single embodiment disclosed in the patent." (*Id.* at 15.) The court finds that the claims cover multiple compounds and compositions and that the "co-transfection assay" at issue here is not an embodiment, but is, instead, the single assay disclosed in the patents-in-suit used to measure the RXR and RAR potencies of the various embodiments. *See* Joint Appendix of Intrinsic Evidence ("J.A.") Tab A at 50:66-54; J.A. Tab B at 42:20-45:14. A claim is properly construed as incorporating a specific method of measurement or evaluation where, as here, that method is the specific method disclosed in the patent specification for purposes of the claimed invention and that assay was used in distinguishing the claimed subject matter from the prior art. *See, e.g., Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1375-80 (Fed. Cir. 2005); *Genentech, Inc. v. Wellcome Found. Ltd.*, 29 F.3d 1555, 1562-63 (Fed. Cir. 1994). Thus, the court rejects the defendants assertion that the plaintiff's proposed construction is merely "illustrative," as even the defendants acknowledge that the patents-in-suit disclose a single co-transfection assay for measuring EC^{50} potency valves for RARs and RXRs—the plaintiff's cited language. *See, e.g.*, D.I. 53 at 6-7. Indeed, review of the specification makes clear that the Patent's statement that the "following example is illustrative," refers not to the co-transfection assay that plaintiff's identify in their proposed construction, but to the various compounds of the current invention. *See* (D.I. 61 at 5 (citing J.A. Tab A at 49:51-57; J.A. Tab B at 41:5-11).)

Finally, the court finds that the construction it adopts here is consistent with the prosecution histories of the '676 Patent patents-in-suit. For instance, the applicants stated in response to an Office Action that col. 50, lines 1-65 and Tables 1-3 of exemplary EC^{50} data "provide ample and excellent guidance regarding the co-transfection assay that can be used to measure the potency . . . of the compounds of interest." (*Id.* at 11 (citing J.A. Tab H at 23).) The applicants also explained that the measurements of the EC^{50} values of 3-methyl-TTNEX (i.e., bexarotene) in Table 2 "came from the specific co-transfection assay" of the Patent. (*Id.* (citing J.A. Tab H at 24-25).) Likewise, during the

B. The '731 Patent

1. The term "useful to treat skin cancer" is construed to have its plain and ordinary meaning.[2]

2. The term "co-transfection assay" is construed to mean "the reconstituted system in cell culture described at col. 41, line 2 to col. 42, line 19, which can evaluate compounds for their interaction with the different Retinoid X Receptor and Retinoic Acid Receptor isoforms."[3]

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CHIEF, UNITED STATES DISTRICT JUDGE

prosecution of the '731 Patent, the applicant explained that "[t]he specification . . . provides clear guidance on how to predictably . . . assay [compounds that selectively activate RXRs in preference to RARs] to verify their claimed activity." (D.I. 55 at 14 (citing '731 Patent File History, Sept. 5, 1997 Response and Amendment (Ex. C), at 8).) Based on these and similar statements, the court concludes that, like the patent specification, the prosecution histories it is clear that the description at col. 50, lines 1-65 in the '676 Patent and in col. 41, line 22 through col. 42, line 19, are the operational co-transfection assays used to evaluate the EC^{50} values of the claimed compounds in RXRs and RARs.

[2] The court rejects the constructions both parties propose in their Claim Construction Briefing. The defendants ask the court to construe "useful to treat skin cancer" to mean "utility as a therapeutic agent to treat a malignant neoplasm that originates in the tissues of the skin." (D.I. 53; D.I. 59.) In its briefing, the plaintiff asks the court to construe this disputed term to mean either "may be used to treat a cancer that manifests in the skin" (D.I. 55) or "may be used to treat a cancer of the skin" (D.I. 61). Moreover, during the *Markman* hearing, the plaintiff agreed, in response to a question posed by the court, that a plain and ordinary meaning construction of the term would be appropriate in its view. Tr. at 39:19-20; 92:8-17 ("In terms of the meaning of the term skin cancer, to take a step back, plaintiffs never proposed that this term actually needed construction. We were happy to stand on its plain and ordinary meaning."). The court concludes that plain and ordinary meaning is the appropriate construction for this term. *See Phillips*, 415 F.3d at 1313-14 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)) ("Words of a claim 'are generally given their ordinary and customary meaning.'").) Specifically, the court agrees with the plaintiff that the defendants' proposed construction complicates and improperly narrows the meaning of the term by importing limitations from extrinsic evidence. *Id.* at 37:19-38:2. In fact, as the plaintiff correctly notes, "useful to treat skin cancer" is not defined in the specification, intrinsic evidence, or prosecution history. (D.I. 61 at 13.) Moreover, the court finds nothing in the intrinsic evidence that excludes cancers like cutaneous T-cell lymphoma ("CTCL"), which primarily originates in the skin, but can originate elsewhere. (*Id.* 13-14.) Instead, the court concludes, based on its consideration of the specification and intrinsic record, that the patent specification does not necessarily exclude rare cancers like CTCL simply because it is not specifically listed by name in the specification. (*Id.* at 14.) In contrast, the defendants' proposed construction injects a component of "origination" of a malignant neoplasm, which is a construction unsupported by the intrinsic record. While the court agrees with the plaintiff that expert testimony at trial will aid in establishing what does and does not constitute "skin cancer," the court finds that adopting the defendants' proposed construction would inappropriately unjustifiably narrow the term's scope, which is not specifically limited by the specification. *See Phillips*, 415 F.3d at 1314-16. Thus, in view of the foregoing, the court concludes that reliance on extrinsic evidence is unnecessary and rejects the defendants' construction.

[3] *See supra* note 1. The court agrees with the parties that the construction of "co-transfection assay" should be the same in both the '676 and '731 Patents. Thus, this construction is the same as the '676 Patent's construction except for the difference in column and line references.