IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civ. No. 14-829-SLR
	)	
ACTAVIS ELIZABETH LLC,	)	
	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 6th day of October, 2015, having heard argument on, and having reviewed the papers submitted in connection with, the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language of U.S. Patent Nos. 8,454,996 ("the '996 patent") and 8,940,330 ("the '330 patent") shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. **"Carrier particles:"**[1] "Particles comprising one or more pharmaceutically acceptable substances."[2] The specifications provide that carrier particles "may comprise" pharmaceutically acceptable substances.[3] ('330 patent, 7:28-30; '996 patent, 4:41-43)

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[1] Found in claims 1 and 2 of the '996 patent and in claims 1, 3-6, 10 of the '330 patent.
[2] This construction is the portion of the proposed constructions on which the parties agreed.
[3] The parties' additional proposed language seeks to define the way such carrier particles are used. This is better left to the claim language and the second disputed limitation addressed below.

2. **"Presented at the exterior surfaces of the carrier particles"[4] and "presented upon the surface of carrier particles:"**[5] "Positioned at the outside part or layer of the carrier particles by interactive forces strong enough to keep the adherent particles at the carrier surface." The parties' central disagreement regarding this limitation is the "degree" of association between the microparticles and the carrier particle. The '996 patent describes "[a] pharmaceutical composition . . . compris[ing] an essentially water-free, ordered mixture of at least one pharmaceutically active agent in the form of microparticles which are adhered to the surfaces of carrier particles which are substantially larger than the particles of the active agent or agents . . . ." ('996 patent, abstract; 2:64-67) The '996 patent explains that "a bio/mucoadhesion promoting agent . . . must be positioned at the surfaces of the carrier particles." ('996 patent, 5:58-60) In a preferred embodiment, an ordered mixture is made, with finer particles "adhered to the surfaces of the carrier particles." ('996 patent, 5:62-67)

The '330 specification describes a composition "in the form of a[n] interactive mixture comprising at least one population of carrier particles upon the surfaces of which are presented (e.g. adhered) microparticles of buprenorphine or a pharmaceutically acceptable salt thereof." ('330 patent, 6:66-7:4) The specification further explains:

> The term "interactive" mixture will be understood by those skilled in the art to include the term "ordered" mixture, and to denote a mixture in which particles do not appear as single units, as in random mixtures, but rather where smaller particles (e. g. microparticles of, for example, buprenorphine) are attached to (i.e. adhered to or associated with) the

[4] Found in claim 1 of the '996 patent.
[5] Found in claim 1 of the '330 patent.

> surfaces of larger carrier particles. Such mixtures are characterized by interactive forces (for example van der Waals forces, electrostatic or Coulomb forces, and/or hydrogen bonding) between carrier and surface-associated particles . . . . In final mixtures, and compositions comprising such mixtures, the interactive forces need to be strong enough to keep the adherent particles at the carrier surface.

('330 patent, 7:5-19)[6] The specification further recites "[b]io/mucoadhesive materials . . . may be presented upon (e.g. adhered to) the surfaces of carrier particles . . . ." (8:65-67)

The specifications do not differentiate between the terms "positioned at," "presented upon," "adhered to," "attached to," and "associated with," but use them somewhat interchangeably.[7] The court concludes that, regardless of the language chosen by either the court or the parties to describe the disputed terms "presented at" and "presented upon," the focus is properly placed on the specifications' explanation of the interaction of a carrier particle with other particles in an ordered mixture, that is, "the interactive forces need to be strong enough to keep the adherent particles at the carrier surface." ('330 patent, 7:17-19)

3. **"Pharmacologically-effective amount:"**[8] "An amount that elicits a therapeutic response." The '330 specification provides:

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[6] This explanation is the same as the extrinsic evidence relied on by defendants: "Ordered mixing may be considered to be different from random mixing since it . . . requires particle interaction, i.e. adsorption, chemisorption, surface tension, frictional, electrostatic or any other form of adhesion." J.A. Hersey, *Ordered Mixing: A New Concept in Powder Mixing Practice*, 11 Powder Tech. 41, at 41 (1975).

[7] That claim 2 contains the limitation "microparticles adhered to the surfaces of carrier particles" does not change this conclusion. Moreover, the prosecution history cited by the parties does not aid in the analysis, as the changes in the limitation are more complex than plaintiffs' description of replacing "adhered to" with "presented at." (D.I. 89, ex. 6 at JA2022)

[8] Found in claim 1 of the '330 patent.

> The term "pharmacologically effective amount" refers to an amount of an active ingredient, which is capable of conferring a desired therapeutic effect on a treated patient, whether administered alone or in combination with another active ingredient. Such an effect may be objective (i.e. measurable by some test or marker) or subjective (i.e. the subject gives an indication of, or feels, an effect).

('330 patent 9:30-36) The court adopts the agreed upon portion of the parties' construction, finding that plaintiff's additional language[9] further defining "elicit" is unnecessary.

4. **"In contact with:"**[10] "Touching at least in part." The specification explains:

> In particular, microparticles of buprenorphine or salt thereof and particles of weakly acidic, weakly-acidic buffer forming, materials are presented in associative admixture with each other in compositions of the invention. By "associative admixture" we mean that whether or not Component (i) is subsequently formulated along with Components (ii) and (iii) as hereinbefore defined, some form of mixing step (simple mixing, granulation as described hereinbefore, or otherwise) takes place as between the buprenorphine/ salt microparticles and particles of weakly acidic, weakly-acidic buffer forming, materials, rendering them in intimate contact with each other.
>
> For the avoidance of doubt, by "intimate contact", we include that microparticles of buprenorphine or salt thereof, and particles of weakly acidic, weakly-acidic buffer forming, materials, are presented in compositions of the invention in any form in which they are, at least in part, in intimate contact with each other. This includes the possibility of the inclusion of quickly dissolving coatings on one or other, or both, sets of particles.

('330 patent, 6:46-65) The limitation "in contact with" is sufficiently definite to "inform those skilled in the art about the scope of the invention with reasonable certainty," when

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[9] "I.e., is capable of conferring a desired."

[10] Found in claim 1 of the '330 patent, which recites in part: "Wherein microparticles of buprenorphine or a pharmacologically-acceptable salt thereof are in contact with particles comprising citric acid, wherein the buprenorphine or pharmaceutically acceptable salt thereof and the citric acid are not in the same particle." The parties agree that the language "are not in the same particle" means "in different." (D.I. 68 at 4)

"viewed in light of the specification and prosecution history." *Nautilus, Inc. v. Biosig Instruments, Inc.*, —— U.S. ——, 134 S.Ct. 2120, 2129 (2014).

5. The court has provided a construction in quotes for the claim limitations at issue. The parties are expected to present the claim construction consistently with any explanation or clarification herein provided by the court, even if such language is not included within the quotes

United States District Judge