IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECRO TECHNOLOGY LLC, Plaintiff, v. ACTAVIS LABORATORIES FL, INC., Defendant.	Civil Action No. 14-1118-GMS
RECRO TECHNOLOGY LLC, Plaintiff, v. ALVOGEN PINE BROOK, INC., Defendant.	Civil Action No. 14-1364-GMS

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 6,228,398 and 6,902,742

After considering 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. 6,228,398 ("the '398 patent") and 6,902,742 ("the '742 patent"):

1. The term "**following oral delivery to a subject delivers the active ingredient(s) . . . in a pulsatile manner**" is construed to mean "following oral delivery to a subject provides a first pulse of an active ingredient release, followed by at least one subsequent pulse of active ingredient release, producing a plasma concentration

profile characterized by two or more peaks interspersed with low concentration troughs."[1]

2. The term "**mimics**" is construed to mean "is substantially similar to."[2]

Dated: December 29, 2015

UNITED STATES DISTRICT JUDGE

[1] The parties' disagreement centers on two issues: First, whether the court should construe "a subject" consistently with *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349 (Fed. Cir. 2014); and second, what limitations the court should use to describe the plasma concentration profile created by pulsatile delivery.

The court finds that "subjects" should be given its plain and ordinary meaning. The defendants argue that according to *Braintree*, the court should construe "a subject" to mean "the general class of persons to whom the claimed compositions are directed." The invention at issue in *Braintree* was a colon cleansing composition that "does not produce any clinically significant electrolyte shifts" in a patient. As applied to that invention, the Federal Circuit reasoned that "a patient" did not have its ordinary meaning because "such an interpretation would allow a composition to meet the claims even if 99 patients out of 100 experienced clinically significant electrolyte shifts, as long as one patient did not." Therefore, the Federal Circuit interpreted "a patient" to mean "the general class of persons to whom the patented compositions are directed, i.e. a patient population." This holding is counterintuitive in light of the strong presumption that the plain and ordinary meaning of a term governs, absent clear disavowal or lexicography by the patentee. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312, 1316 (Fed. Cir. 2005). The court is not convinced that the Federal Circuit intended *Braintree* to affect a massive change in the law of claim construction. Accordingly, the court reads its holding narrowly and declines to apply it here.

The court's construction of "pulsatile" mirrors the language in the specification. *See* '398 patent at 1:18–22 ("The plasma profile associated with the administration of a drug compound may be described as a "pulsatile profile" in which pulses of high active ingredient concentration, interspersed with low concentration troughs, are observed."). The defendants seek to also add the limitation "followed by a second period of negligible active ingredient release" based on a statement in the prosecution history. (D.I. 49 at JA-038.) The court finds that the description of peaks and troughs found in the specification is sufficient to encapsulate the claimed invention, and this further limitation is unnecessary.

[2] The court construes this term according to the specification, which uses the term "substantially similar" to describe how the release of the active ingredient mimics the release of the same active ingredient administered in two or more immediate release dosage forms given sequentially. *See, e.g.*, '398 patent at 3:32–37, 4:45–48. The court also notes, to address an issue raised by the defendants during the *Markman* hearing (D.I. 67 at 45:15–17), that "substantially similar" release profiles would include profiles which are exactly the same.