IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC. and ORION CORPORATION, Plaintiffs, v. EUROHEALTH INTERNATIONAL SARL and WEST-WARD PHARMACEUTICAL CORP., Defendants.	Civil Action No. 14-487-GMS
HOSPIRA, INC. and ORION CORPORATION, Plaintiffs, v. EUROHEALTH INTERNATIONAL SARL and WEST-WARD PHARMACEUTICAL CORP., Defendants.	Civil Action No. 14-1008-GMS

ORDER CONSTRUING THE TERMS OF U.S. PATENT NO. 6,716,867

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 No. 6,716,867 ("the '867 patent"):

1. The term "**dexmedetomidine**" is construed to mean "substantially pure, optically active dextrorotary stereoisomer of medetomidine, as the free base or pharmaceutically acceptable salt.[1]

[1] The parties dispute whether dexmedetomidine, in the context of the patent, includes pharmaceutically acceptable salts. The issue arises because claims 1–5 (which include both independent

2. The term "**loading dose**" is construed to mean "dose administered at the onset of therapy to achieve a target concentration."[2]

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claims) mention pharmaceutically acceptable salts, but claims 6–12 only mention dexmedetomidine. The defendants argue that the plain language of the claims excludes pharmaceutically acceptable salts from the scope of claims 6–12. The court disagrees. While the court recognizes some level of redundancy created by its construction, the court is not convinced that the patentees intended to disclaim pharmaceutically acceptable salts in claims 6–12. In spite of poor claim draftsmanship, the specification and prosecution history indicate the proper scope of this term.

In context, it seems clear that the patentee intended to claim not only dexmedetomidine, but also its pharmaceutically acceptable salts. Throughout the specification, where the patent refers only to "dexmedetomidine," the pharmaceutically acceptable salt is implicitly included. *See, e.g.*, '867 Patent at 5:5–15 ("Dexmedetomidine or a pharmaceutically acceptable salt thereof can be administered . . . . The dose range of dexmedetomidine can be described as target plasma concentrations.") The patent examples refer to administering dexmedetomidine, not a pharmaceutically acceptable salt. *See, e.g.*, '867 Patent at 5:47–49 (The efficacy, safety and titratability of dexmedetomidine in postoperative coronary bypass graft(s) patients . . . was studied.") But the form of dexmedetomidine used in the examples is the HCl salt '867 Patent at 5:53–54. Further, during prosecution, the patentees explained that when they "refer to 'dexmedetomidine' as used in the invention, that term includes pharmaceutically acceptable salts of the compound as well." (D.I. 65, Ex. 3 at 22; Ex. 4 at 35.) The court's construction of this term embodies the patentees' use of the term throughout the intrinsic record.

[2] The plaintiffs request several limitations that may be implied from the specification, but are not required by the claim. They define loading dose as "a dose that may be given at the onset of therapy with the aim of achieving the target concentration rapidly that is distinct from, and comparatively larger than, its associated maintenance dose." (D.I. 75 at 16.) The court finds that the patent does not provide any basis to evaluate the subjective portions of plaintiffs' construction. The patent does not use comparative language to define this term. Therefore, the plaintiffs' construction introduces ambiguity into the claim.

The plaintiffs cite to two dictionary definitions. The first defines loading dose as "one or a series of doses that may be given at the onset of therapy with the aim of achieving the target concentration rapidly." GOODMAN & GILMAN'S THE PHARMACEUTICAL BASIS OF THERAPEUTICS, (9th ed. 1996). The second defines loading dose as "a comparatively large [dose] given at the beginning of treatment to start getting the effect of a drug, especially one with slow clearance thus requiring a long period to achieve stable blood levels without a high initial dose." STEDMAN'S MEDICAL DICTIONARY (27th ed. 2000). From these differing definitions, the plaintiffs obtain their construction. These definitions have two important things in common—the loading dose is given at the beginning of treatment, and it is administered to obtain a target effect. The specification supports both factors. In contrast, the plaintiffs' other limitations are not grounded in a consensus between the definitions, and are not supported by the patent specification.

To support importing the "rapidly" limitation, the plaintiffs explain that the loading dose is administered over a ten-minute period in the patent examples. '867 Patent at 5:60–65, 6:61–64, 7:57–60. But the defendants correctly note that the intrinsic record does not include the term "rapidly" or provide any means to determine the meaning of "rapidly." Other than claim 9 (". . . the loading dose is administered in about 10 minutes"), the claims do not include any timing limitations. *See* '867 Patent at 14:43–44. The specification also provides a preferred embodiment in which the loading dose is "administered in about ten minutes *or slower*." '867 Patent at 5:21–25 (emphasis added). The intrinsic record provides no basis to determine what length of time would qualify as "rapid" under this claim.

To explain the "comparatively larger" limitation, the plaintiffs note that in most of the patent examples, the administered loading dose is larger than the administered maintenance dose. But both the

3. The term "**maintenance dose**" is construed to mean "dose given as a continuous infusion to maintain a target concentration or desired effect."[3]

Dated: November 3rd, 2015

UNITED STATES DISTRICT JUDGE

To explain the "comparatively larger" limitation, the plaintiffs note that in most of the patent examples, the administered loading dose is larger than the administered maintenance dose. But both the written description and the claims recite overlapping ranges for the loading and maintenance doses. *See* '867 Patent at 5:21–28, 14:41–50. Additionally, the maintenance dose is larger than the loading dose in one of the patient trial examples. '867 Patent at 11:6–10. The "comparatively larger" limitation may be implied by most of the embodiments, but is not required by the claims.

[3] The court anchors its construction on the language in the specification and claims. The specification states that "target plasma concentrations" of dexmedetomidine "can be achieved by intravenous administration by using a bolus dose and continuing it by a steady maintenance infusion." '867 Patent at 5:14–25. This indicates that the maintenance dose may be used to maintain not only a target effect, but also a target concentration. Here and elsewhere, the specification describes the maintenance dose as an intravenous infusion. Intravenous administration is by nature continuous. The dose ranges are provided in units of μg/kg/h, also evidencing a continuous, rather than periodic, dose. Finally, "maintenance dose" only appears in dependent claims that relate back to claims where the dexmedetomidine is administered intravenously. '867 Patent at 14:36–50.