IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC., Plaintiff; v. AMNEAL PHARMACEUTICALS, LLC, Defendant.	Civil Action No. 15-cv-697-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Plaintiff brought this patent infringement action against Amneal Pharmaceuticals, LLC in 2015. (D.I. 1). At issue in this case are ready-to-use formulations of the compound dexmedetomidine. Dexmedetomidine itself is claimed in U.S. Patent No. 4,910,214 ("the '214 patent"), which is not at issue in this case. The '214 patent issued on March 20, 1990 and expired on July 15, 2013. (Trial Transcript ("Tr.") 1081:9-12, 1082:10-15; '214 patent; D.I. 96-1 at 37).[1] Dexmedetomidine, which is the d-enantiomer of racemic 4-[1-(2,3-dimethylphenyl)ethyl]-lH-imidazole, is a sedative and is the active ingredient in Hospira's Precedex products. ('106 patent at 1:26-28, 1:34-37; Tr. 5:6-9). Amneal filed Abbreviated New Drug Application ("ANDA") No. 207551, seeking to engage in the commercial manufacture, use, and sale of generic versions of Hospira's 4μg/mL dexmedetomidine products ("Precedex premix") in 50 mL and 100 mL glass vials. (D.I. 96-1 at 3-4; PTX-63 at p. 6).

Since its FDA approval in 1999, Hospira's original Precedex product (100 μg/mL dexmedetomidine hydrochloride), also known as Precedex concentrate, has been sold in a 2 mL glass vial. (Tr. 6:11-15; D.I. 96-1 at 2). Before Precedex concentrate is administered to a patient, it must be diluted to an appropriate concentration per the instructions on the Precedex concentrate label. (Tr. 6:17-20). The delay in drug administration to patients and increased risks of dosing error and contamination associated with this dilution step led Hospira to develop ready-to-use formulations of Precedex. (*Id.* at 7:7-10). In 2013, Hospira received FDA approval for 50 mL and 100 mL glass bottles containing a ready-to-use 4 μg/mL formulation of dexmedetomidine hydrochloride. (D.I. 96-1 at 2). FDA approval of the same formulation in a 20 mL glass vial followed in 2014. (*Id.* at 3).

[1] The trial transcript is available on the docket at D.I. 114-117. It is consecutively paginated.

The Court held a bench trial from August 21-24, 2017. Plaintiff asserts that Defendant's ANDA submission constitutes infringement of claims 3 and 4 of U.S. Patent No. 8,242,158 ("the '158 patent"), claim 4 of U.S. Patent No. 8,338,470 ("the'470 patent"), claim 5 of U.S. Patent No. 8,455,527 ("the'527 patent"), and claim 6 of U.S. Patent No. 8,648,106 ("the '106 patent"). (Tr. 3:15-20; D.I. 101 at 3). The asserted patents are part of the same patent family and share a common specification. (D.I. 96 at 4).

Independent claim 1 and dependent claims 2-4 of the '158 patent read as follows:

> **1.** A ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 µg/mL disposed within a sealed glass container.
>
> **2.** The ready to use liquid pharmaceutical composition of claim 1, further comprising sodium chloride at a concentration of between about 0.01 and about 2.0 weight percent.
>
> **3.** The ready to use liquid pharmaceutical composition of claim 2, wherein the sodium chloride is present at a concentration of about 0.9 weight percent.
>
> **4.** The ready to use liquid pharmaceutical composition of claim 1, wherein the composition is formulated as a total volume selected from the group consisting of 20 mL, 50 mL and 100 mL.

('158 patent at claims 1-4).

Independent claim 1 and dependent claim 4 of the '470 patent read as follows:

> **1.** A ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 0.005 to about 50 µg/mL disposed within a sealed glass container.
>
> **4.** The ready to use liquid pharmaceutical composition of claim 1, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 1 to about 7 µg/mL.

('470 patent at claims 1, 4).

Independent claim 1 and dependent claim 5 of the '527 patent read as follows:

> **1.** A method of providing sedation to a patient in need thereof, the method comprising administering to the patient an effective amount of a composition, wherein the composition comprises dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 0.005 to about 50 µg/mL, wherein the composition is a ready to use liquid pharmaceutical composition for parenteral administration to the patient disposed within a sealed glass container.
>
> **5.** The method of claim 1, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 4 µg/mL.

('527 patent at claims 1, 5).

Independent claim 1 and dependent claim 6 of the '106 patent read as follows:

> **1.** A ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof disposed within a sealed glass container, wherein the liquid pharmaceutical composition when stored in the glass container for at least five months exhibits no more than about 2% decrease in the concentration of dexmedetomidine.
>
> **6.** The ready to use liquid pharmaceutical composition of claim 1, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 4 µg/mL.

('106 patent at claims 1, 6).

I. LEGAL STANDARDS

A. Claim Construction

"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). "'[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, 979-80 (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.

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [This 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. "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 Pharms. 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. 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.*

B. Obviousness

A patent claim is invalid as obvious under 35 U.S.C. § 103 "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole

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