IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: SITAGLIPTIN PHOSPHATE
('708 & '921) PATENT LITIGATION

MDL No. 19-2902-RGA

Civil Action Nos. 19-311-RGA,
19-312-RGA,
19-313-RGA,
19-314-RGA,
19-317-RGA,
19-318-RGA,
19-319-RGA,
19-347-RGA,
19-1489-RGA.

MEMORANDUM OPINION

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November 17, 2020

/s/ Richard G. Andrews
ANDREWS, U.S. DISTRICT JUDGE:

Before the Court in this multi-district litigation is the issue of claim construction of various terms in U.S. Patent Nos. 7,326,708 ("the '708 patent") and 8,414,921 ("the '921 patent"). The Court has considered the parties'[1] Joint Claim Construction Brief, accompanying exhibits, and a supplemental expert declaration. (D.I. 136; D.I. 137; D.I. 138; D.I. 193).[2] The Court heard oral argument on August 18, 2020. (D.I. 192 [hereinafter, "Tr."]).

I. BACKGROUND

The '708 patent and '921 patent are directed to the dihydrogenphosphate salt of a dipeptidyl peptidase-IV inhibitor for the prevention and treatment of Type 2 diabetes. The invention claimed in the '708 patent relates to a crystalline monohydrate of the dihydrogenphosphate salt as well as a process for its preparation and pharmaceutical composition. ('708 pat., Abstract). The '921 patent describes pharmaceutical compositions of the dihydrogenphosphate salt of a dipeptidyl peptidase-IV inhibitor and metformin, as well as methods of preparing such pharmaceutical compositions. ('921 pat., Abstract).

The following claims are relevant for the purposes of this Markman:

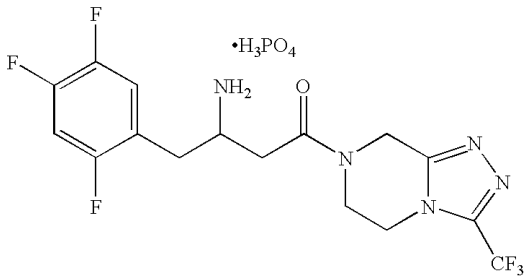
[1] Merck entered into consent judgments with some Defendants before the Markman briefing. Merck has since entered into consent judgments with other Defendants that participated in the Markman hearing. There are newer Defendants that did not participate in the Markman hearing. And, due to the pending IPR in connection with the '708 patent, Mylan did not join in any of Defendants' proposed claim constructions. (D.I. 136 at 2 n.3).

[2] All citations to the docket refer to the docket for Civil Action No. 19-md-2902-RGA. The parties submitted a Joint Appendix, referred to herein as "J.A." It is located at D.I. 137 & 138. The patents-in-suit are on the docket at D.I. 137-1, Exhibits 1 and 2.

Claim 1 of the '708 Patent[3]

1. A dihydrogenphosphate salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine of structural formula I:

(I)

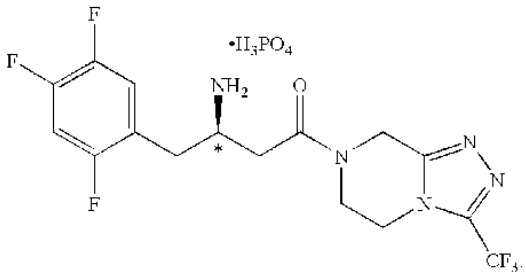


or a hydrate thereof.

Claim 2 of the '708 Patent

2. The *salt of claim 1* of structural formula II having the (R)-configuration at the chiral center marked with an *

(II)

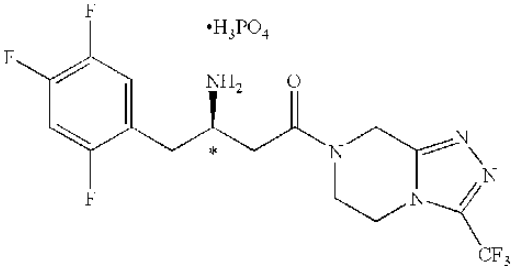


Claim 24 of the '708 Patent

24. A process for preparing the crystalline monohydrate of claim 4 comprising the steps of:

(a) *crystallizing the dihydrogenphosphate salt of structural formula (II):*

(II)



[3] Claim 1 of the '708 patent is not directly in dispute. It is included here as it is relevant for understanding disputes between the parties pertaining to '708 patent claims 2, 3, and 21, which depend from claim 1.

at 25° C. from a mixture of isopropanol and water, such that the water concentration is above 6.8 weight percent;

(b) recovering the resultant solid phase; and

(c) removing the solvent therefrom.

Claim 1 of the '921 Patent

1. A pharmaceutical composition comprising:

(a) about 3 to 20% by weight of *sitagliptin*, or a pharmaceutically acceptable salt thereof;

(b) about 25 to 94% by weight of metformin hydrochloride;

(c) about 0.1 to 10% by weight of a lubricant;

(d) about 0 to 35% by weight of a binding agent;

(e) about 0.5 to 1% by weight of a *surfactant*; and

(f) about 5 to 15% by weight of a diluent.

II. LEGAL STANDARD

"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) (internal quotation marks omitted). "'[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). 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, 977–80 (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,

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