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Paper No. 10
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MAIA PHARMACEUTICALS, INC.,
Petitioner

v.

BRACCO DIAGNOSTICS INC.,
Patent Owner.

Case IPR2019-00345
U.S. Patent No. 6,803,046 B2

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and RICHARD J. SMITH, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Maia Pharmaceuticals, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–19, 21–38, 40–55, 77–102, and 104–105 of U.S. Patent No. 6,803,046 B2 (Ex. 1001, "the '046 patent"). Paper 2 ("Pet."). Bracco Diagnostics Inc. ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has not satisfied its burden under § 314. Thus, we do not institute an *inter partes* review.

A. Related Matters

The parties identify the following litigation between the parties involving the '046 patent: *Bracco Diagnostics Inc. v. Maia Pharmaceuticals, Inc.*, Case No. 3:17-cv-13151-PGS-TJB, pending in the United States District Court for the District of New Jersey. Pet. 3; Paper 7.

B. The '046 patent

The'046 patent discloses pharmaceutically acceptable formulations of sincalide. Ex. 1001, 1:5–6. Sincalide "is a synthetically prepared C-terminal octapeptide of cholecystokinin (CCK-8), with the following amino acid sequence: Asp-Tyr(SO_3H)-Met-Gly-Trp-Met-Asp-Phe-NH_2." *Id.* at 1:12–16.

The disclosed formulations "include an effective amount of sincalide, a bulking agent/tonicity adjuster, a stabilizer, a surfactant, a chelator, and a buffer." *Id.* at Abstract. The'046 patent also discloses "kits and methods for preparing improved sincalide formulations, as well as methods for treating, preventing, and diagnosing gall bladder-related disorders using sincalide formulations." *Id.*

C. Illustrative Claims

Independent claims 1, 21, 40, 77 and 104, reproduced below, are illustrative of the challenged claims:

> 1. A stabilized, physiologically acceptable formulation of sincalide comprising:
> (a) an effective amount of sincalide,
> (b) at least one stabilizer,
> (c) a surfactant/solubilizer
> (d) a chelator,
> (e) a bulking agent/tonicity adjuster, and
> (f) a buffer.
>
> 21. A method for making a stabilized formulation of sincalide, said method comprising the step of mixing:
> (a) at least one stabilizer,
> (b) a surfactant/solubilizer,
> (c) a chelator,
> (d) a bulking agent/tonicity adjuster,
> (e) a buffer
> (f) an aqueous solution, and
> (g) sincalide.
>
> 40. A kit, comprising:
> (i) a powder mixture comprising (a) sincalide, (b) at least one stabilizer, (c) a surfactant, (d) a chelator, (e) a bulking agent/tonicity adjuster, and (f) a buffer;
> (ii) a container to hold said powder mixture; and

(iii) optionally, a physiologically acceptable fluid.

77. A method for imaging the hepatobiliary system of a subject, said method comprising:

(a) administering a hepatobiliary imaging agent to said subject;

(b) before or after step (a), administering to a subject a sincalide formulation comprising: (i) sincalide, (ii) at least one stabilizer, (iii) a surfactant, (iv) a chelator, (v) a bulking agent/tonicity adjuster, and (vi) a buffer; and

(c) detecting said imaging agent in said subject with a detection device.

104. A method for imaging the hepatobiliary system of a subject, said method comprising:

a) administering to a subject a sincalide formulation comprising: (i) sincalide, (ii) at least one stabilizer, (iii) a surfactant, (iv) a chelator, (v) a bulking agent/tonicity adjuster, and (vi) a buffer; and

b) scanning the subject using a diagnostic imaging modality.

D. Evidence Relied Upon

Petitioner relies upon the following prior art references:

Ex. 1005, Physicians' Desk Reference for Radiology and Nuclear Medicine, 1977/78 (1977) ("PDR").

Ex. 1006, PCT Publication No. WO 00/51629 to Sato (English Translation with affidavit) ("Sato").

Ex. 1017, Nema et al., "*Excipients and Their Use in Injectable Products*," 51 PDA J. OF PHARMA. SCI. AND TECH. 166 (1997) ("Nema").

Ex. 1030, Essentials of Nuclear Medicine Science (Hladik, et al., eds., 1987) ("ENMS").

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 38):

Ground	Claims	Basis	References
1	1–4, 6–11, 13, 15, 16, 19, 21–24, 26-31, 33, 35, 36, 40–42, 44–49, 51, 53, 55, and 104	§ 103(a)	PDR and Sato
2	5, 12, 14, 17, 18, 25, 32, 34, 37, 38, 43 50, 52, and 54	§ 103(a)	PDR, Sato, and Nema
3	77-88, 90-95, 97, 99, 100, and 105	§ 103(a)	PDR, Sato, and ENMS
4	89, 96, 98, 101, and 102	§ 103(a)	PDR, Sato, ENMS, and Nema

In support of its patentability challenge, Petitioner relies on the Declaration of Christian Schöneich, Ph.D. Ex. 1003.

II. DISCUSSION

A. Claim Construction

For petitions filed after November 13, 2018, such as the case here, we interpret the claims of a challenged patent using the same claim construction standard used in a civil action under 35 U.S.C. 282(b), which is the standard articulated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).[1] Under the *Phillips* standard, the "words of a claim are generally

[1] The claim construction standard used in an *inter partes* review changed. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective

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