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Filed: June 13, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE (I-MAK), INC.,
Petitioner,

v.

GILEAD PHARMASSET LLC,
Patent Owner.

IPR2018-00123
Patent 8,735,372 B2

Before LORA M. GREEN, GRACE KARAFFA OBERMANN, and WESLEY B. DERRICK, *Administrative Patent Judges*.

DERRICK, *Administrative Patent Judge*.

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

I. INTRODUCTION

Initiative for Medicines, Access & Knowledge (I-MAK), Inc. ("Petitioner") requests an *inter partes* review of claims 1 and 2 of U.S. Patent No. 8,735,372 B2 ("the '372 patent"). Paper 2 ("Pet."). Gilead Pharmasset LLC ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). We may not institute an *inter partes* review "unless . . . there is 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). Applying that standard, for the reasons set forth below, we decline to institute an *inter partes* review because the Petitioner has not shown a reasonable likelihood that it would prevail in establishing the unpatentability of any challenged claim.

II. BACKGROUND

A. Related Proceedings

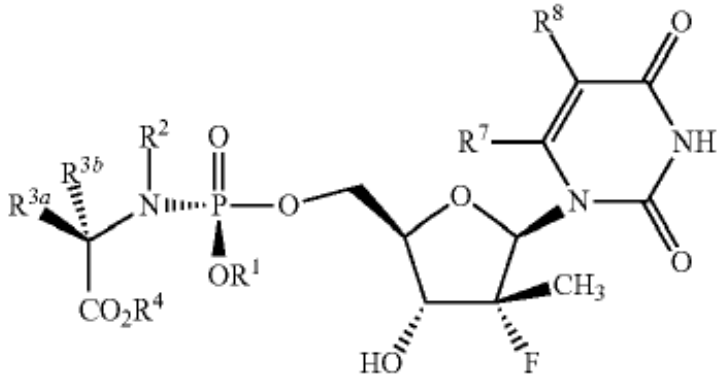
The parties identify identifies additional petitions filed by Petitioner for *inter partes* review of other patents owned by Patent Owner: IPR2018-00103 for review of U.S. Patent No. 7,429,572 B2; IPR2018-00119 and IPR2018-00120 for review of U.S. Patent No. 7,964,580 B2; IPR2018-00121 and IPR2018-00122 for U.S. Patent No. 8,334,270 B2; IPR2018-00125 for review of U.S. Patent No. 8,633,309 B2; and IPR2018-00126 for review of U.S. Patent No. 9,284,342 B2. Pet. 2, Paper 4, 2–3.

B. The ’372 Patent (Ex. 1001)

The ’372 patent is directed to a method of treating a human infected by hepatitis C virus comprising administering both an NS5a inhibitor and a prodrug of a nucleoside derivative. Ex. 1001 Abstract.

Claims 1 and 2 are reproduced below.

> 1. A method of treating a human infected by hepatitis C virus, comprising administering to the subject an effective amount of an NS5a inhibitor and an effective amount of a compound represented by the following formula:



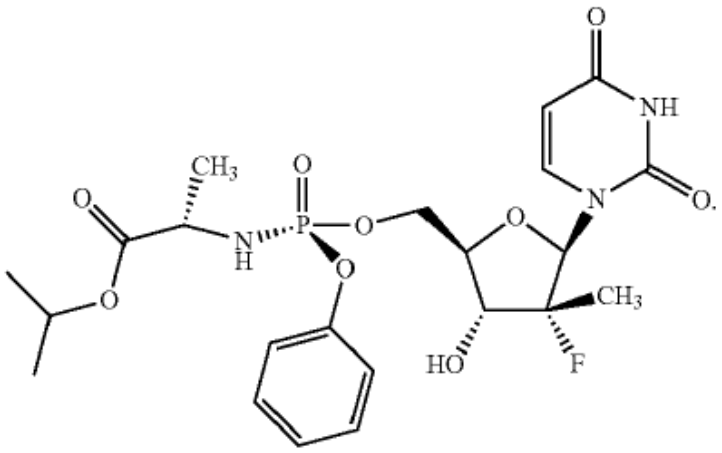
> wherein
>
> R^1 is hydrogen, methyl, ethyl, n-propyl, i-propyl, or a substituted or unsubstituted phenyl, where the substitutent [sic] of the substituted phenyl is at least one of a CH_3, OCH_3, F, Cl, Br, I, nitro, cyano, and a $CH_{3-q}X_q$, where X is F, Cl, Br, or I, and q is 1-3;
>
> R^2 is hydrogen or CH_3;
>
> R^{3a} is H and R^{3b} is H, CH_3, $CH(CH_3)_2$, $CH_2CH(CH_3)_2$, $CH(CH_3)CH_2CH_3$, CH_2Ph, CH_2 -indol-3-yl, $–CH_2CH_2SCH_3$, CH_2CO_2H, $CH_2C(O)NH_2$, CH_2CH_2COOH, $CH_2CH_2C(O)NH_2$, $CH_2CH_2CH_2CH_2NH_2$, —$CH_2CH_2CH_2NHC(NH)NH_2$, CH_2-imidazol-4-yl, CH_2OH, $CH(OH)CH_3$, CH_2((4'-OH)-Ph), CH_2SH, or lower cycloalkyl, or

R^{3a} is CH_3, $CH(CH_3)_2$, $CH_2CH(CH_3)_2$, $CH(CH_3)CH_2CH_3$, CH_2Ph, CH_2 -indol-3-yl, —$CH_2CH_2SCH_3$, CH_2CO_2H, $CH_2C(O)NH_2$, CH_2CH_2COOH, $CH_2CH_2C(O)NH_2$, $CH_2CH_2CH_2CH_2NH_2$, -$CH_2CH_2CH_2NHC(NH)NH_2$, CH_2-imidazol-4-yl, CH_2OH, $CH(OH)CH_3$, CH_2((4'-OH)-Ph), CH_2SH, or lower cycloalkyl and R^{3b} is H;

R^4 is hydrogen, CH_3, Et, ^{i}Pr, ^{n}Pr, ^{n}Bu, 2-butyl, ^{t}Bu, benzyl, cyclopropyl, cyclobutyl, cyclopentyl, cyclohexyl, N-methyl-aziridin-2-yl, N-methyl-azetidin-3-yl, N-methyl-pyrrolidin-3-yl, N-methyl-pyrrolidin-4-yl, N-methyl-piperidin-4-yl, lower haloalkyl, or di(lower alkyl)amino-lower alkyl; and

R^7 and R^8 are independently H, F, Cl, Br, I, OH, OCH_3, SH, SCH_3, NH_2, $NHCH_3$, $N(CH_3)_2$, CH_3, $CH_{3-q}X_q$, where X is F, Cl, Br, or I and q is 1 to 3, vinyl, CO_2H, CO_2CH_3, $CONH_2$, $CONHCH_3$, or $CON(CH_3)_2$, wherein R' is a C_{1-20} alkyl; a C_{1-20} cycloalkyl; a C_2-C_6 alkenyl, a C_2-C_6 alkynyl.

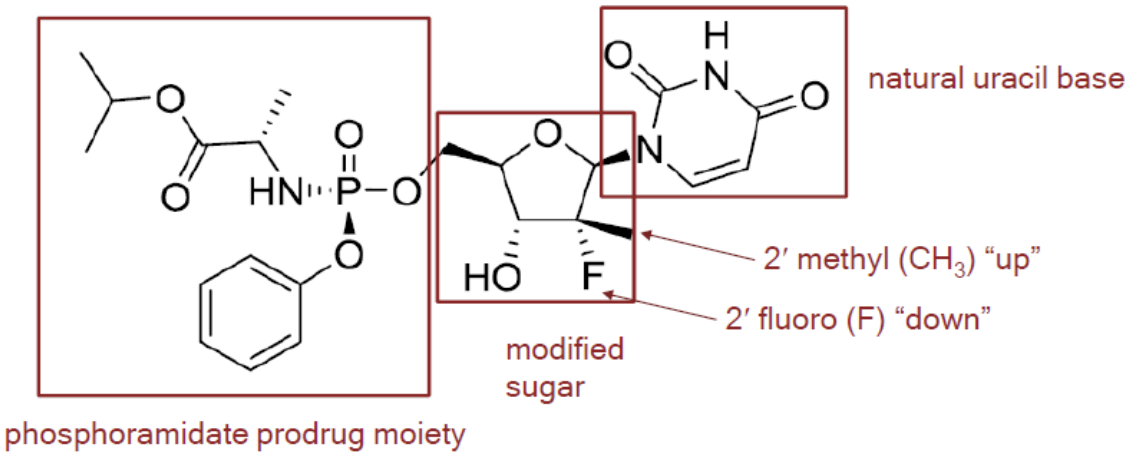
2. The method of claim **1**, wherein the compound is



Ex. 1001, 629:64–632:20.

Claim 2 sets forth a specific compound (i.e., sofosbuvir) for administration with an NS5a inhibitor, whereas claim 1 sets forth by formula and possible substituents a genus of compounds for

administration with an NS5a inhibitor. Pet. 36–38; Prelim. Resp. 4–5. The structure of sofosbuvir, as annotated by Patent Owner, is depicted below:



Prelim. Resp. 4–5. The figure depicts the chemical structure of sofosbuvir with stereochemistry and identifies the compound's phosphoroamidate prodrug moiety, modified sugar, and natural uracil base. *Id.*

C. The Asserted Ground of Unpatentability

Petitioner asserts that claims 1 and 2 of the '372 patent are unpatentable based on the following ground. Pet. 3.

References	Statutory Basis
Sofia,[1] Congiatu,[2] and Serrano-Wu[3]	§ 103

[1] Sofia et al., Poster #P-259, presented at the 14th Int'l Symposium on Hepatitis C Virus and Related Viruses, Glasgow, Scotland, UK, Sept. 9–13, 2007 (Ex. 1012).
[2] Congiatu et al., 49 J. MED. CHEM. 452–455 (2006) (Ex. 1011).
[3] Serrano-Wu et al., US 2006/0276511 A1, published December 7, 2006 (Ex. 1013).

Petitioner supports the Petition with the testimony of Joseph M. Fortunak, Ph.D. (Ex. 1002).

III. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art would have held either

> (1) a Ph.D. in chemistry or a closely related field with some experience in an academic or industrial laboratory focusing on drug discovery or development, and would also have some familiarity with antiviral drugs and their design and mechanism of action, or
>
> (2) a Bachelor's or Master's degree in chemistry or a closely related field with significant experience in an academic or industrial laboratory focusing on drug discovery and/or development for the treatment of viral diseases.

Pet. 5–6 (citing Ex. 1002 ¶ 33).

Patent Owner does not expressly contest the level of ordinary skill. *See generally* Prelim. Resp.

On this record, we adopt Petitioner's essentially uncontested definition of the level of ordinary skill. We further note that the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that "specific findings on the level of skill in the art . . . [are not required] 'where the prior art itself reflects an appropriate level and a need for

testimony is not shown'" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

B. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings). Under that standard, we interpret claim terms using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). "Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history." *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016). If an inventor acts as his or her own lexicographer, the definition must be set forth with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). Only those terms which are in controversy need to be construed and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

Petitioner contends that "there is no reason to give any of the terms of the claims of the '372 [patent] a meaning other than their ordinary and

accustomed meaning." Pet. 6. Patent Owner does not contest that the claim terms should be given their ordinary and accustomed meaning. *See generally* Prelim. Resp. We determine that no claim term requires express construction for the purpose of determining whether to institute review.

C. Prior Art Status

Under 35 U.S.C. § 311(b), in an *inter partes* review, a petitioner may only challenge the claims of a patent based on "prior art consisting of patents or printed publications," and the petitioner has the initial burden of producing evidence to support a conclusion of unpatentability under § 102 or § 103, including that an asserted reference is a printed publication. At this stage of the proceeding, Petitioner must establish that there is a reasonable likelihood that it will prevail with respect to at least one of the claims challenged. 35 U.S.C. § 314(a).

"Public accessibility" is the touchstone in determining whether a reference is a "printed publication." *In re Hall*, 781 F.2d 897, 898–99 (Fed. Cir. 1986). "Indeed, the key inquiry is whether or not a reference has been made 'publicly accessible.'" *In re Klopfenstein*, 380 F.3d 1345, 1348 (Fed. Cir. 2004). As stated by our reviewing court, "the reference must have been sufficiently accessible to the public interested in the art; dissemination and public accessibility are the keys to whether a prior art reference was 'published.'" *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989) (quoted with approval in *Klopfenstein*, 380 F.3d at 1348).

"The determination of whether a reference is a 'printed publication' under 35 U.S.C. § 102[] involves a case-by-case inquiry into the facts and circumstances surrounding the reference's disclosure to members of the public." *Klopfenstein*, 380 F.3d at 1350 (citing *Cronyn*, 890 F.2d at 1161;

Hall, 781 F.2d at 899); *see also Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016) ("Whether a reference qualifies as a printed publication is a legal conclusion based on underlying factual determinations."); *Voter Verified, Inc. v. Premier Election Sols., Inc.*, 698 F.3d 1374, 1380 (Fed. Cir. 2012) ("Public accessibility is a legal conclusion based on underlying factual determinations."). Limited distribution, even to those skilled in the art, may not amount to "publication" under the statute unless the material is otherwise so situated that "anyone who chooses may avail himself of the information it contains." *In re Bayer*, 568 F.2d 1357, 1360, 1362 (CCPA 1978) (quoting 1 W. Robinson, The Law of Patents 327 at 448 (1890)).

Petitioner fails to present an adequate basis for the Sofia poster being sufficiently accessible to the public interested in the art to be considered a "printed publication." Petitioner contends that "Sofia is prior art under 35 U.S.C. § 102(a) to the '372 patent because it was published by September 13, 2007" (Pet. 31) and, similarly, that "the September 2007 publication of Sofia makes it prior art under [§] 102(a)" (*id.* at 32). Petitioner also contends that "Sofia . . . Poster #P-259, [was] presented at the 14th International Symposium on Hepatitis C Virus and Related Viruses, Glasgow, Scotland, UK, Sep. 9-13, 2007." *Id.* at 30 (citing Ex. 1012); *see also* Ex. 1002 ¶ 83 (repeating Petitioner's contention *verbatim*). The Sofia poster (Exhibit 1012) states, *inter alia*, "[p]resented at the 14th International Symposium on Hepatitis C Virus and Related Viruses, Glasgow, Scotland, UK, September 9-13, 2007." Dr. Fortunak states that he "understand[s] that prior art for the '372 patent's claims is anything before March 21, 2008." Exhibit 1002 ¶ 85.

Petitioner's relevant contentions and showing, detailed above in full, include no evidence indicating that Sofia was published in print or electronic form, but only that it was presented as a poster. As to its presentation as a poster at the symposium, Petitioner provides nothing further as to, for example, how long it was posted, whether it was sufficiently publicized to, or placed in front of a sufficient number of, those interested in the subject matter, or as to the freedom of those viewing the poster to take notes or to copy the poster. *See generally* Pet.; Ex. 1002, Ex. 1012. Petitioner, thus, fails to provide a sufficient showing as to the "facts and circumstances surrounding the reference's disclosure to members of the public" necessary to identify it as a "printed publication." *Klopfenstein*, 380 F.3d at 1350–51; *see also Blue Calypso*, 815 F.3d at 1348–50; *Voter Verified*, 698 F.3d at 1380–81; *Cronyn*, 890 F.2d at 1160–61; *Hall*, 781 F.2d at 898–99; *Bayer*, 568 F.2d at 1360–62.

We accord little weight to Dr. Fortunak's statement that he "understand[s] that prior art for the '372 patent's claims is anything before March 21, 2008" (Ex. 1002 ¶ 85), because it is a legal opinion inapposite to, and lacking a factual basis as to, the relevant issue, that is, whether the Sofia poster is, in particular, a patent or *printed publication*, on which *inter partes* review can be instituted (35 U.S.C. § 311(b)). *Cf. Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, . . . it cannot support a jury's verdict."); *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1342 (Fed. Cir. 2007) (holding that "when an expert witness' statement of the law is incorrect, that view of the law cannot be relied upon to support the verdict."). As discussed above, the

issue is not merely whether Sofia was earlier in time than March 21, 2008, but rather, whether it was a printed publication. Dr. Fortunak's expressed opinion grounded on a contrary understanding fails to bear the weight required of Petitioner's showing.

D. Alleged Unpatentability of Claims

Petitioner contends that claims 1 and 2 are unpatentable as obvious over the combination of Sofia, Congiatu, and Serrano-Wu, identified as prior art by Petitioner. Pet. 31–46. The unavailability of Sofia undermines Petitioner's obviousness ground, which relies on Sofia alone as to the nucleoside portion of the claimed pro-drug. *Id.*

Petitioner thus fails to bear the burden required to support institution of *inter partes* review. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) ("In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable."). Petitioner should not expect the Board to search the record to piece together what may support a challenge. *See* 37 C.F.R. § 42.22(a)(2) (a petition must include "[a] full statement of the reasons for the relief requested"); *DeSilva v. DiLeonardi*, 181 F.3d 865, 866–67 (7th Cir. 1999) ("A brief must make all arguments accessible to the judges, rather than ask them to play archaeologist with the record."); *cf. In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380–81 (Fed. Cir. 2016) (rejecting an argument that the Board properly "ma[de] an obviousness argument on behalf of [petitioner]" that "could have been included in a properly drafted petition," because "petitioner . . . bears the burden of proof").

Accordingly, we are not persuaded that Petitioner establishes a reasonable likelihood of prevailing in showing that the subject matter of any challenged claim is unpatentable over Sofia, Congiatu, and Serrano-Wu.

IV. CONCLUSION

Petitioner has not established a reasonable likelihood of prevailing on its assertion that claims 1 and 2 are unpatentable.

V. ORDER

For the reasons given, it is:

ORDERED that the Petition is *denied* as to all challenged claims of the ’372 patent and no trial is instituted.

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