

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.

IPR2018-00122
Patent 8,334,270 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, 2, 10–18, and 20–25 of U.S. Patent 8,334,270 B2 (Ex. 1001, “the ’270 patent”). Paper 2 (“Pet.”). Gilead Pharmasset LLC (“Patent Owner”) filed a Preliminary Response. Paper 9 (“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 a concurrently filed, second petition for *inter partes* review of the ’270 patent, IPR2018-00121. Pet. 2; Paper 4, 3. Patent Owner also identifies additional petitions for *inter partes* review of additional patents: IPR2018-00119 and IPR2018-00120 for U.S. Patent No. 7,964,580 B2; IPR2018-00103 for U.S. Patent No. 7,429,572 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. Paper 4, 3.

B. The '270 Patent (Ex. 1001)

The '270 patent is directed to, *inter alia*, phosphoramidate prodrugs of a nucleoside derivative for treatment of viral infections in mammals, its ester, or a stereoisomer thereof. Ex. 1001, Abstract. The '270 patent also addresses methods of treatment, uses, and processes for preparing such compounds. *Id.* The '270 patent claims the benefit of priority of two earlier-filed provisional applications, 60/909,315, filed on March 30, 2007, and 60/982,309, filed on October 24, 2007. Ex. 1001, 1:4–9.

C. Illustrative Claims

Independent claims 1 and 16, each reciting a number of different phosphoramidate nucleoside derivatives, are reproduced below in part:

1. A compound selected from among

...

(S)-isopropyl 2-(((S)-(((2R,3R,4R, 5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-methyl[-] tetrahydrofuran-2-yl)methoxy)(phenoxy)phosphoryl) amino)propanoate

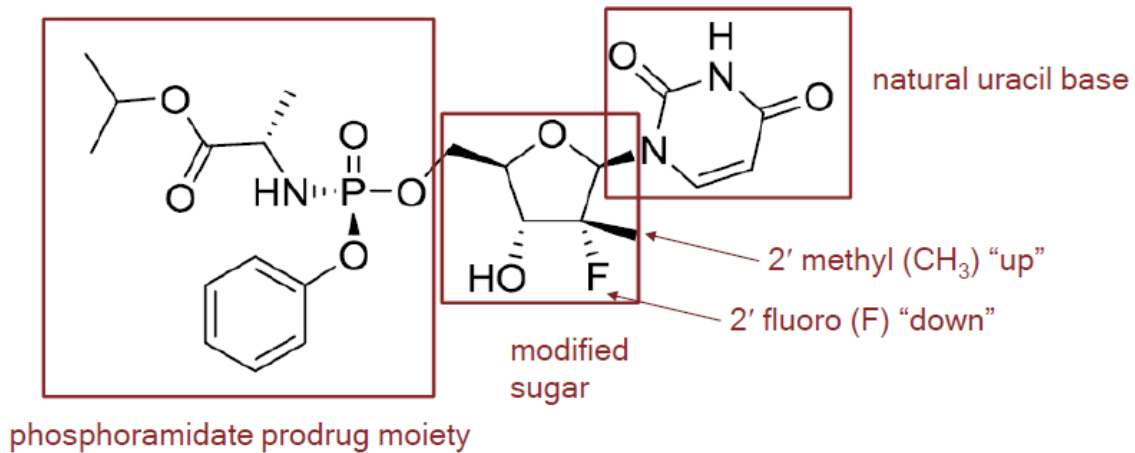
16. A compound or its stereoisomer thereof selected from among

...

(S)-2-{{{(2R,3R,4R,5R)-5-(2,4-Dioxo-3,4-dihydro-2H-pyrimidin-1-yl)-4-fluoro-3-hydroxy-4-methyl-tetrahydrofuran-2-ylmethoxy]-phenoxy-phosphorylamino}-propionic acid isopropyl ester

Ex. 1001, 605:35, 52–55, 607:58–59, 608:58–61.

The compound set forth by name in the reproduced portion of claim 1 above is the Sp stereoisomer of a phosphoramidate nucleoside derivative, known as sofosbuvir, which structure is depicted below:



Prelim. Resp. 3–4. The figure depicts the chemical structure of sofosbuvir with stereochemistry and identifies the compound's phosphoramidate prodrug moiety, modified sugar, and natural uracil base. *Id.* at 4. Claim 16 likewise, in setting forth a compound or stereoisomer of compounds identified by name, including that reproduced above, encompasses the Sp stereoisomer, the Rp stereoisomer, and mixtures of the two. *Id.* at 4, 11.

D. The Asserted Grounds of Unpatentability

Petitioner asserts that claims 1, 2, 10–18, and 20–25 of the '270 patent are unpatentable based on the following grounds. Pet. 3.

References	Statutory Basis
Clark '147, ¹ Clark 2005, ² and Perrone ³	§ 103
Clark '147, Clark 2005, and McGuigan ⁴	§ 103

¹ Clark, WO 2005/003147 A2, published January 13, 2005 (Ex. 1006).

² Clark et al., 48 J. MED. CHEM. 5504–08 (2005) (Ex. 1007).

³ Perrone et al., 50 J. MED. CHEM. 1840–49 (2007) (Ex. 1008).

⁴ McGuigan, WO 2005/012327 A2, published February 10, 2005 (Ex. 1009).

Petitioner supports the Petition with the testimony of Joseph M. Fortunak, Ph.D. (Ex. 1002). Based on Dr. Fortunak's statement of qualifications (*id.* ¶¶ 1–20) and curriculum vitae (Ex. 1003), on this record, we determine that he is qualified to opine from the perspective of a person of ordinary skill in the art.

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 ¶ 35).

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

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