Trials@uspto.gov
571.272.7822

Paper No. 7
Filed: May 4, 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.

IPR2018-00119
Patent 7,964,580 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 1–14 of U.S. Patent 7,964,580 B2 (Ex. 1001, "the '580 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 a concurrently-filed, second petition for *inter partes* review of the '580 patent, IPR2018-00120. Pet., 2; Paper 4, 3. Patent Owner also identifies additional petitions filed by Petitioner for *inter partes* review of other patents owned by Patent Owner: IPR2018-00121 and IPR2018-00122 for U.S. Patent No. 8,334,270 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 '580 Patent (Ex. 1001)

The '580 patent is directed to, *inter alia*, a phosphoramidate prodrug of a nucleoside derivative for treatment of viral infections in mammals, its ester, or a stereoisomer thereof. Ex. 1001, Abstract, 493:42–45. The '580 patent also addresses methods of treatment, uses, and processes for preparing such compounds. *Id.*, Abstract.

By way of a certificate of correction (Ex. 3001), the '580 patent claims the benefit of priority of two earlier-filed provisional applications, 60/909,315 filed on March 30, 2007 (Ex. 2013), and 60/982,309 filed on October 24, 2007 (Ex. 2014), (respectively, "the '315 provisional" and "the '309 provisional").[1]

C. Illustrative Claims

Independent claims 1 and 8—reproduced below—are illustrative of the claimed subject matter.

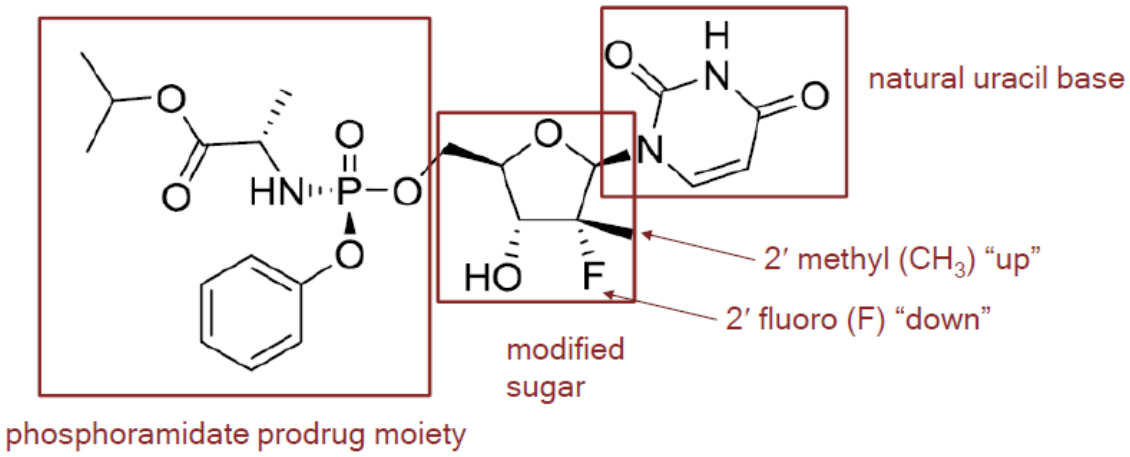
> 1. (S)-2-{[(2R,3R,4R,5R)-5-(2,4-Dioxo-3,4-dihydro-2H-pyrimidin-1-yl)-4-fluoro-3-hydroxy-4-methyl-tetrahydro-furan-2-ylmethoxy]-phenoxy-phosphorylamino}-propionic acid isopropyl ester or a stereoisomer thereof.
>
> 8. (S)-isopropyl 2-(((S)-(2R,3R,4R, 5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-meth-yltetrahydrofuran-2-yl)methoxy)(phenoxy)phosphoryl) amino)propanoate.

Ex. 1001, 493:42–45, 495:27–30.

Claim 8 is directed to the Sp stereoisomer (i.e., sofosbuvir), whereas claim 1 covers the Sp stereoisomer, the Rp stereoisomer, and

[1] Petitioner does not contest that the '580 patent claims the benefit of priority to both the '315 provisional and the '309 provisional (Pet. 5), but rather, as discussed below, contests that the '580 patent is entitled to the claimed benefit of priority to the '315 provisional (*id.* at 23, 25).

mixtures of the two. Prelim. Resp. 3–4, 12; *see also* Pet. 28–29. The structure of sofosbuvir, as annotated by Patent Owner, is depicted below:



Prelim. Resp. 4. 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.*

D. The Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–14 of the '580 patent are unpatentable based on the following grounds. Pet. 3.

References	Statutory Basis
Sofia[2]	§ 102
Sofia and Perrone[3]	§ 103
Ma[4] and Perrone	§ 103

[2] 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. 1004).
[3] Perrone et al., 50 J. MED. CHEM. 1840–1849 (2007) (Ex. 1008).
[4] Ma et al., 282 J. BIOL. CHEM. 29812–29820 (2007) (Ex. 1005).

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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