

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.

IPR2018-00120
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 No. 7,964,580 B2 (“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, IPR2018-00119. 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.

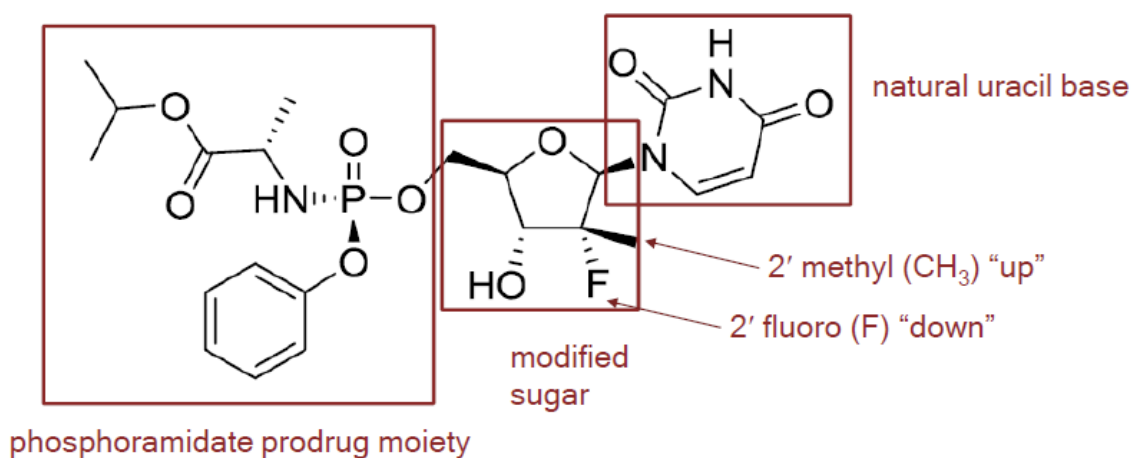
C. Illustrative Claims

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-methyl-tetrahydrofuran-2-yl)methoxy)(phenoxy)phosphoryl amino)propanoate.

Ex. 1001, 493:42–45, 495:27–80.

Claim 8 is directed to the Sp stereoisomer (i.e., sofosbuvir), whereas claim 1 covers the Sp stereoisomer, the Rp stereoisomer, and 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. at 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
Clark '147, ¹ Clark 2005, ² and Perrone ³	§ 103
Clark '147, Clark 2005, and McGuigan ⁴	§ 103

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,

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).

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

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.