Trials@uspto.gov
571.272.7822

Paper No. 10
Filed: May 21, 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.

IPR2018-00121
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)

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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, IPR2018-00122. 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.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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 (Ex. 2013), and 60/982,309, filed on October 24, 2007 (Ex. 2014), respectively, "the '315 application" and "the '309 application." Ex. 1001, 1:4–9.

C. Illustrative Claims

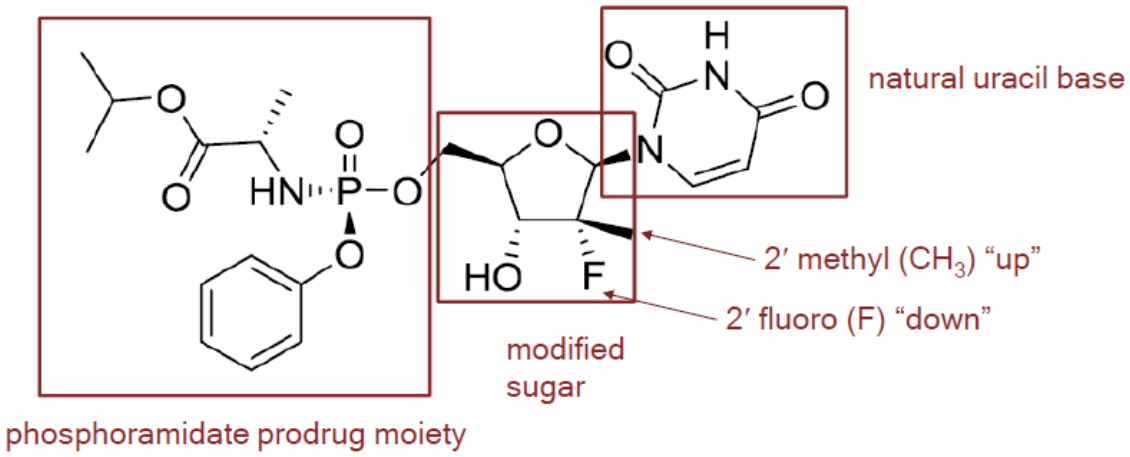
Independent claims 1 and 16, each reciting a number of different phosphoramidate nucleoside derivatives, are reproduced below in part:

> 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-tetrahy-dro-furan-2-ylmethoxy]-phenoxy-phosphorylamino}-propionic acid isopropyl ester . . . .

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

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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 3–4, 12; *see also* Pet. 28–29.

D. The Asserted Grounds of Unpatentability

Petitioner contends that "[e]ach and every feature of claims 1, 2, 10-18 and 20-25 can be found in the prior art reference[s] identified below."[1]

[1] Although Petitioner contends "[e]ach and every feature . . . can be found" in the cited references (Pet. 27), the analysis that follows of "exemplary disclosure of the cited references" (*id.*) is effectively limited to consideration of a single compound—the 5′-phosphate (phosphoramidate) prodrug of the uridine analog (2′R)-2′-deoxy-2′-fluoro-2′-*C*-methyluridine, wherein the

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

Pet. 27 (citing Ex. 1002 ¶ 92). More particularly, Petitioner asserts that claims 1, 2, 10–18, and 20–25 are unpatentable based on each of the following grounds. Pet. 3, *see also id.* at 27–55.

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

---

5′-phosphate group is the (phenyl)(isopropyl-L-alaninyl)phosphate group (*id.* at 27–55).

[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).

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

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.