Trials@uspto.gov
571.272.7822

Paper No. 7
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)

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 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.

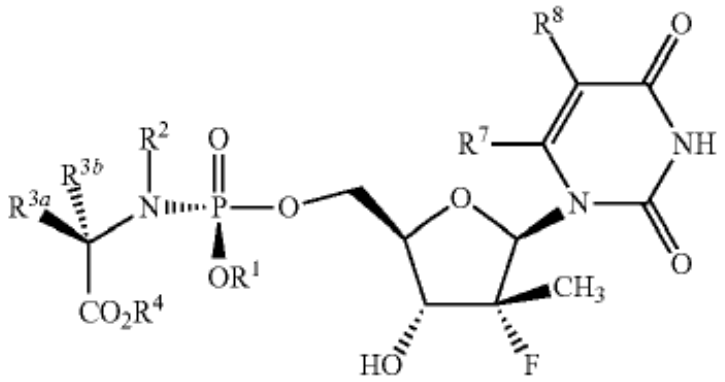
DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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

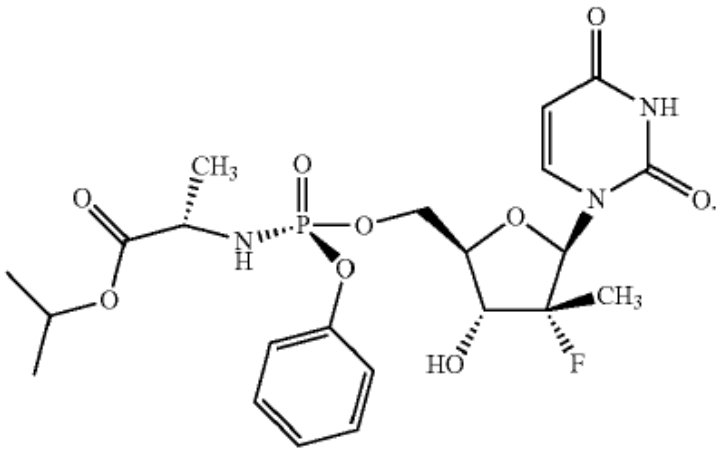
DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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

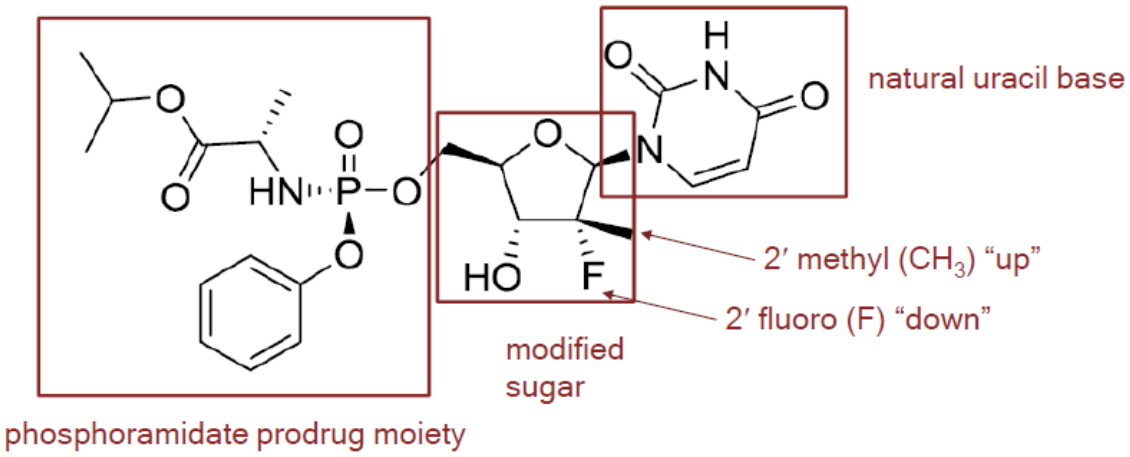


Ex. 1001, 629:64–632:20.

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

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

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).

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.