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Paper No. 9
Entered: May 24, 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

Case IPR2018-00125
Patent 8,633,309 B2

Before LORA M. GREEN, ERICA A. FRANKLIN, and RICHARD J. SMITH, *Administrative Patent Judges.*

SMITH, *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") filed a Petition (Paper 2, "Pet.") to institute an *inter partes* review of claims 1–12 of U.S. Patent 8,633,309 B2 (the "'309 patent"). 35 U.S.C. § 311. Gilead Pharmasset LLC ("Patent Owner") filed a Preliminary Response to the Petition (Paper 6), as corrected (Paper 8). ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314. To institute an *inter partes* review, we must determine that the information presented in the Petition shows "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). For the reasons set forth below, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of any challenged claim of the '309 patent. Therefore, we do not institute an *inter partes* review for any challenged claim of the '309 patent.

A. Related Proceedings

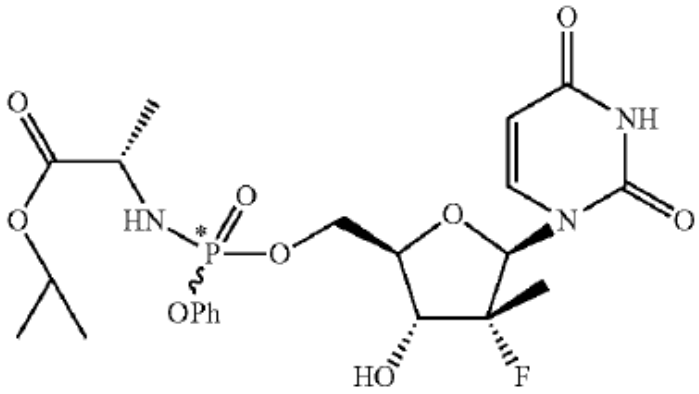
Petitioner also filed two petitions for *inter partes* review of U.S. Patent No. 7,964,580 (Case Nos. IPR2018-00119 and IPR2018-00120); two petitions for *inter partes* review of U.S. Patent No. 8,334,270 (Case Nos. IPR2018-00121 and IPR2018-00122); one petition for *inter partes* review of U.S. Patent No. 7,429,572 (Case No. IPR2018-00103); and one petition for *inter partes* review of U.S. Patent No. 9,284,342 (Case No. IPR2018-00126). Pet. 2; Paper 3, 3.

B. The '309 Patent

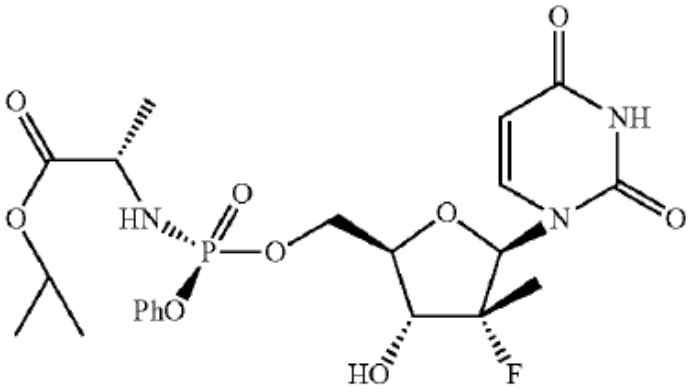
The '309 patent relates to nucleoside phosphoramidates and their use as agents in treating viral diseases, such as hepatitis C. Ex. 1001, 1:12–17. The '309

patent specifically disclose a compound represented by formula 4 and its respective phosphorous-based diastereomers represented by formulas S*p*-4 and R*p*-4, as shown below:

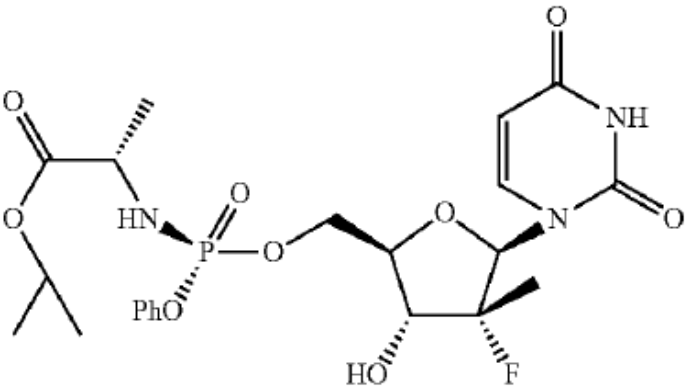
4



S_P-4



R_P-4



Id. at 4:50–5:24. The '309 patent states that "[t]he term 'P*' means that the phosphorus atom is chiral and that it has a corresponding Cahn-Ingold-Prelog designation of 'R' or 'S' which have their accepted meanings." *Id.* at 6:8–10. The compound of formula S*p*-4 is sofosbuvir. Prelim. Resp. 10.

The '309 patent discloses methods of synthesizing the formula 4 compound as a diastereomeric mixture of S_P-4 and R_P-4. Ex. 1001, 31:60–33:56. The '309 patent also discloses methods of obtaining substantially pure S_P-4 from the mixture of diastereomers by chromatography and crystallization of the individual stereoisomers. *Id.* at 36:3–12 (describing crystallization process that resulted in ">99% pure S_P-4"); *id.* at 72:34–61 (describing HPLC purification conditions that resulted in 99.5% pure S_P-4). The '309 patent teaches methods of generating substantially pure isomers by diastereoselective synthesis. *See, e.g.*, *id.* at 49:25–50:7 (describing processes for stereoselective synthesis of the S_P-4 enantiomer, resulting in about 97% chiral purity). The '309 patent also describes biological activity tests in which the potency of each of the compounds of formula 4, R_P-4, and S_P-4 was demonstrated by viral replicon assays. *See id.* at 75:30–56.

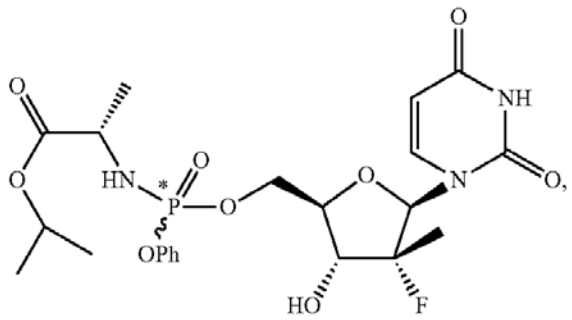
The '309 patent states that "U.S. patent application Ser. No. 12/053,015, which corresponds to WO 2008/121634 [Sofia '634, Ex. 1005] . . . discloses a number of phosphoramidate nucleoside prodrugs, many of which show activity in an HCV assay." *Id.* at 4:42–46.

C. Illustrative Claim

Petitioner challenges claims 1–12 of the '309 patent, of which claim 1 is the only independent claim. Claim 1 is reproduced below:

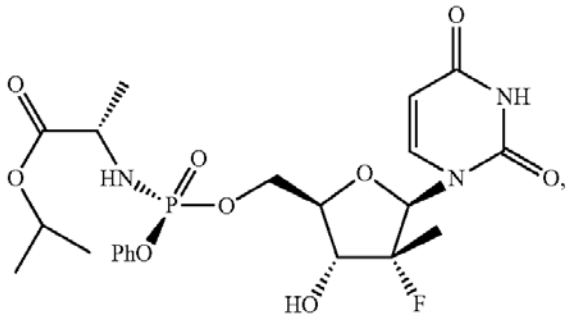
1. A compound represented by the formula (4):

(4)



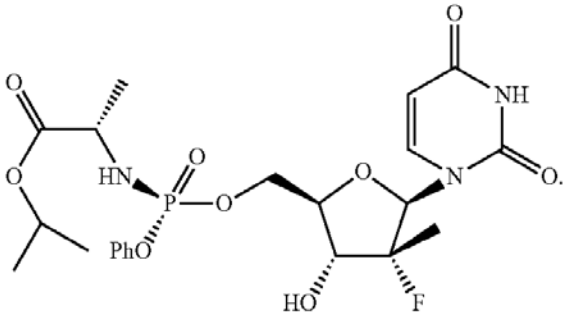
wherein P* represents a chiral phosphorus atom and wherein the compound is at least 97% of the S_P stereoisomer represented by the formula (S_P-4):

(S_P-4)



and not more than 3% of the R_P stereoisomer represented by the formula (R_P-4):

(R_P-4)



Ex. 1001, 76:1–47.

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