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Paper No. 7
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 IPR2018-00126
Patent 9,284,342 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 1–4 of U.S. Patent 9,284,342 B2 (the "'342 patent"). 35 U.S.C. § 311. Gilead Pharmasset LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("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 '342 patent. Therefore, we do not institute an *inter partes* review for any challenged claim of the '342 patent.

A. Related Proceedings

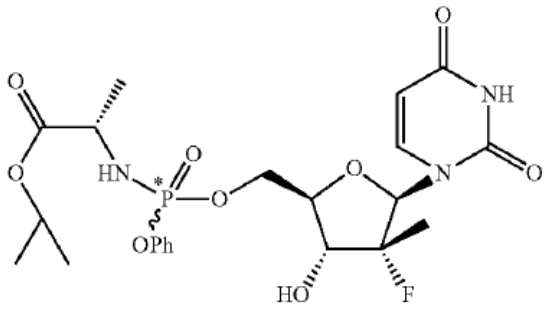
Petitioner also filed two petitions for *inter partes* review of U.S. Patent No. 7,964,580 (Case Nos. IPR2018-00119 and IPR2018-00120); two petitions for *inter partes* review of U.S. Patent No. 8,334,270 (Case Nos. IPR2018-00121 and IPR2018-00122); one petition for *inter partes* review of U.S. Patent No. 7,429,572 (Case No. IPR2018-00103); and one petition for *inter partes* review of U.S. Patent No. 8,633,309 (Case No. IPR2018-00125). Pet. 2; Paper 3, 3.

B. The '342 Patent

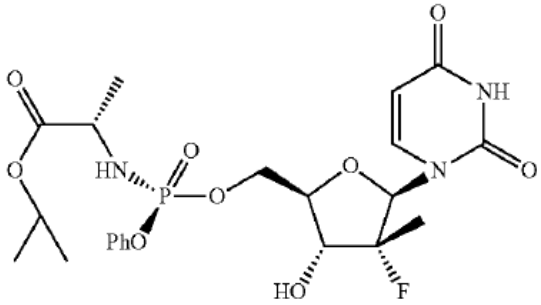
The '342 patent relates to nucleoside phosphoramidates and their use as agents for treating viral diseases, such as hepatitis C. Ex. 1001, Abstract; 1:21–26. The '342 patent discloses a compound represented by formula 4 and its respective

phosphorous-based diastereomers represented by formulas S*p*-4 and R*p*-4, as shown below:

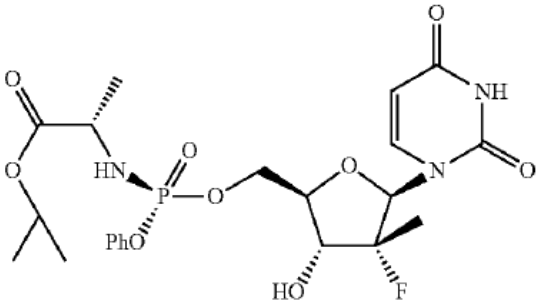
4



S_P-4



R_P-4



Id. at 4:65–5:34. The '342 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 6:28–30. The compound of formula S*p*-4 is sofosbuvir. Prelim. Resp. 9.

The '342 patent discloses six crystalline forms of S*p*-4 (Forms 1–6). Ex. 1001, 73:51–76:43. X-ray powder diffraction (XRPD) 2θ-reflections are attributed to Form 6, and recited in claim 1. *Id.* at 76:10–43. The '342 patent

characterizes Form 6, such as by X-ray powder diffraction, and describes methods for preparing Form 6. *Id.* at 73:10–50; 82:1–11, 41–42.

The '342 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 4:55–59. During prosecution, the Examiner expressly addressed Sofia '634, stating in the Notice of Allowance that:

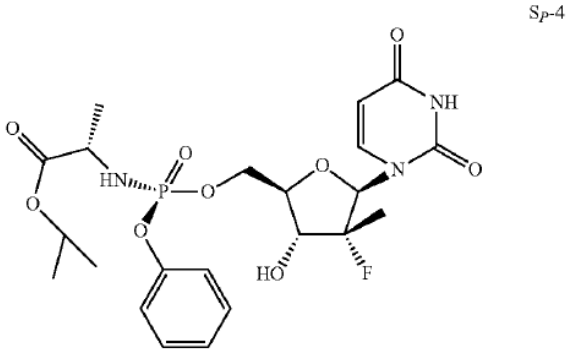
> The claimed invention is seen to be novel and non-obvious over the prior art. The prior art does not disclose a crystalline composition of the claimed compound having the claimed XRPD peaks. References to the claimed compound in the prior art (see for example [Sofia '634]) [do] not disclose the specific crystal structure described in the claims, or a method of preparing a crystalline form of the compound that would have resulted in that particular crystal. Because of the unpredictability of crystalline polymorphs, one of ordinary skill in the art would not have been able to, based on the prior art disclosure, predict or make this particular crystal form.

Ex. 1004, 183–184.

C. Illustrative Claim

Petitioner challenges claims 1–4 of the '342 patent, of which claim 1 is the only independent claim. Claim 1 is reproduced below:

1. A crystalline compound represented by the formula (S*p*-4):



having XRPD 2θ-reflections (°) at about: 6.1 and 12.7.

Ex. 1001, 89:42–65.

Claims 2–4 depend directly or indirectly on claim 1.[1] *Id.* at 90:1–9.

D. The Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. §103(a) based on the following specific grounds. Pet. 3.

Reference[s]	**Basis**	**Claims challenged**
Sofia '634[2] and Sofia 2010[3]	§ 103(a)	1–4
Sofia '634 and Ma[4]	§ 103(a)	1–4
Clark '147[5] and Ma	§103(a)	1–4

Petitioner also relies on the Declaration of Joseph M. Fortunak, Ph.D. Ex. 1002.

[1] For example, claim 3 recites "[a] method of treating a hepatitis C virus infection in a human comprising administering to the human an effective amount of the crystalline compound according to claim 1." Ex. 1001, 90:4–6.
[2] Sofia et al., WO 2008/121634 A2, published Oct. 9, 2008 ("Sofia '634"). Ex. 1005.
[3] M.J. Sofia et al., *Discovery of a β-D-2'-Deoxy-2'-α-fluoro-2'-β-C-methyluridine Nucleotide Prodrug (PSI-7977) for the Treatment of Hepatitis C Virus*, J. MED. CHEM. 53, 7202–18 (2010) ("Sofia 2010"). Ex. 1014.
[4] H. Ma et al., *Characterization of the Metabolic Activation of Hepatitis C Virus Nucleoside Inhibitor β-D-2'-Deoxy-2'-fluoro-2'-C-methylcytidine (PSI-6130) and Identification of a Novel Active 5'-Triphosphate Species*, J. OF BIOLOGICAL CHEM., 282, 29812–20 (2007) ("Ma"). Ex. 1010.
[5] Clark, WO 2005/003147 A2, published Jan. 13, 2005 ("Clark '147"). Ex. 1007.

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