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Paper No. 7
Entered: June 20, 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 IPR2018-00211
Patent 9,393,256 B2

Before LORA M. GREEN, GRACE KARAFFA OBERMANN, 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 9,393,256 B2 (the "'256 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 '256 patent. Therefore, we do not institute an *inter partes* review for any challenged claim of the '256 patent.

A. Related Proceedings

Petitioner has 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); one petition for *inter partes* review of U.S. Patent No. 8,633,309 (Case No. IPR2018-00125); and one petition for *inter partes* review of U.S. Patent No. 9,284,342 (Case No. IPR2018-00126). Paper 3, 2.

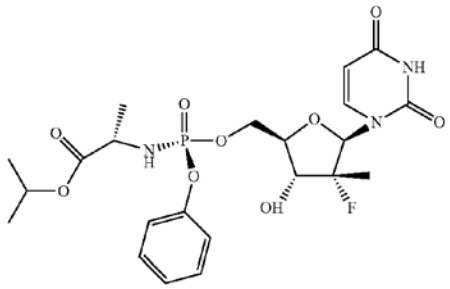
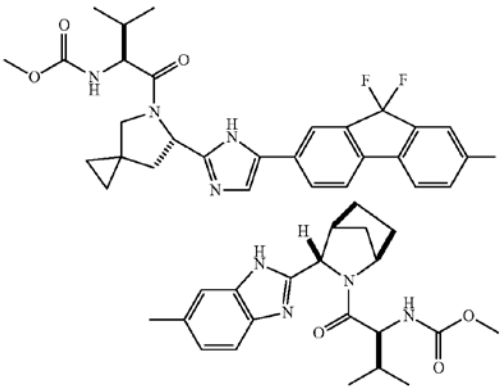
B. The '256 Patent

The '256 patent relates to compositions and therapeutic methods useful for treating viral infections, such as hepatitis C virus (HCV). Ex. 1001, 2:63–65. For

example, the ’256 patent discloses a method of treating an HCV infection in a human comprising administering two or more compounds selected from a group that includes Compound 6 and Compound 10 (*see* claim 1 below). *Id.* at 3:11–15; 139: l. 6–140: l. 21. The ’256 patent indicates that compound 10 is an NS5B nucleoside prodrug and compound 6 is an NS5A inhibitor. *Id.* at 133:55–61; 134:24–35. The ’256 patent also states that the disclosed methods “are beneficial because they provide treatments for a wide range of HCV genotypes and . . . cause fewer or less serious side effects than current HCV therapies.” *Id.* at 4:55–58.

C. Illustrative Claim

Petitioner challenges claims 1–4 of the ’256 patent, of which claim 1 is the only independent claim. Claim 1 is reproduced below:

> 1. A method of treating an HCV infection in a human, comprising administering to the human: 1) compound 10 having the structure:
>
> 
>
> or a pharmaceutically acceptable salt thereof and 2) compound 6 having the structure:
>
> 

or a pharmaceutically acceptable salt thereof, wherein the method does not include administering interferon.

Ex. 1001, 139: l. 6–140: l. 21.

Claims 2–4 depend directly from claim 1.[1] *Id.* at 140:22–27.

D. The Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. §§ 102 and 103 based on the following grounds. Pet. 3.

Reference[s]	**Basis**	**Claims challenged**
Legrand-Abravanel[2]	§§ 102(b) and 103(a)	1–4
Delaney[3]	§ 102(e)	1–4
Sofia '634[4] and Guo[5]	§103(a)	1–4

Petitioner also relies on the Declaration of Joseph M. Fortunak, Ph.D. Ex. 1012.

[1] For example, claim 4 recites "[t]he method of claim 1 further comprising administering ribavirin to the human." Ex. 1001, 140:26–27.
[2] F. Legrand-Abravanel et al., *New NS5B polymerase inhibitors for hepatitis C*, Expert Opinion Investigational Drugs 19(8), 963–75 (2010) ("Legrand-Abravanel"). Ex. 1005.
[3] Delaney, IV et al., US 2011/0306541 A1, published Dec. 15, 2011 ("Delaney"). Ex. 1010.
[4] Sofia et al., WO 2008/121634 A2, published Oct. 9, 2008 ("Sofia '634"). Ex. 1004.
[5] Guo et al., WO 2010/132601 A1, published Nov. 18, 2010 ("Guo"). Ex. 1011.

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have 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. 6.

Patent Owner "takes no position on Petitioner's proposed definition of a" person of ordinary skill in the art ("POSA"), but indicates that "a POSA also would include, or would have access to, an individual with an M.D. who has experience developing or researching antiviral treatment methods, such as treatment for HCV, or experience treating viral infections such as HCV." Prelim. Resp. 10.

On this record, for purposes of this Decision, we accept Petitioner's definition without the clarification advanced by Patent Owner. Specifically, based in the information presented, we find that a person of ordinary skill in the art would have 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. On that point, however, we agree with Patent Owner

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