UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE (I-MAK), INC.,
Petitioner

v.

GILEAD PHARMASSET LLC,
Patent Owner.

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Case IPR2018-00390
Patent 8,889,159 B2

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Before ERICA A. FRANKLIN, GRACE KARAFFA OBERMANN
and RICHARD J. SMITH, *Administrative Patent Judges.*

OBERMANN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Petitioner filed a Petition for *inter partes* review of claims 1–37 of U.S. Patent 8,889,159 B2 ("the '159 patent"). Paper 2 ("Pet."). Patent Owner filed a Preliminary Response. Paper 6 ("Prelim. Resp."). We have authority to institute an *inter partes* review only upon a showing that Petitioner is reasonably likely to prevail with respect to at least one challenged patent claim. 35 U.S.C. § 314(a). Applying that standard, we conclude that Petitioner has not established the threshold showing for review and, accordingly, we deny the Petition and do not institute review of any challenged claim.
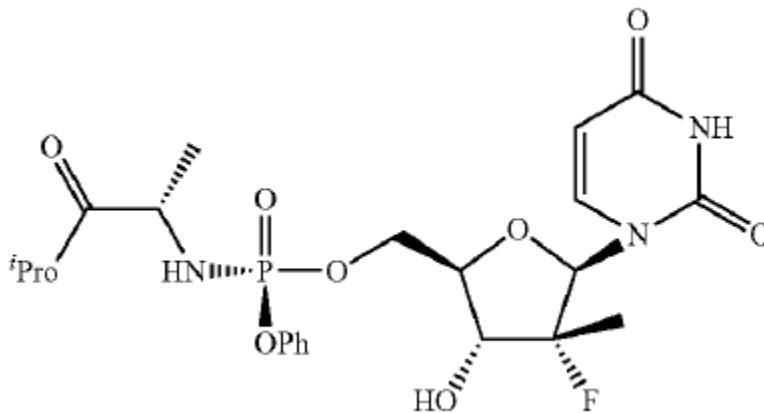
A. Related Proceedings

Petitioner identifies as a related matter a pending patent application (U.S. Patent Appl. No. 15/410,438) that claims priority through the '159 patent. Pet. 2. Petitioner avers that it "is not aware of any other matter that would affect, or be affected by, a decision in this proceeding." *Id.*

Patent Owner identifies the same pending application under a heading titled "Related Matters." Paper 3, 2. Patent Owner also identifies a second pending application (U.S. Patent Appl. No. 14/538,736) as a related matter and, further, "notes" that Petitioner filed eight prior petitions for *inter partes* review, none of which was directed to any claims of the '159 patent. *Id.* at 2–3 (citations omitted). "Patent Owner does not concede that any" of those identified matters— "aside from" the '159 patent—"would affect, or be affected by this proceeding." *Id.*

B. The '159 Patent

The '159 patent relates to a pharmaceutical composition and unit dosage form of a specific agent for treating hepatitis C virus ("HCV"). Ex. 1001, Abstract. The specification discloses that (S)-isopropyl 2-(((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3 -hydroxy-4-methyltetrahydrofuran-2-yl)methoxy)(phenoxy)phosphoryl)amino)propanoate is "available from Gilead Sciences, Inc." and, further, is disclosed and claimed in U.S. Pat. No. 7,964,580. Ex. 1001, 7:65–8:2.

The specification states that this HCV agent is, or has been, known variously as "GS-7977," "sofosbuvir," and "PSI-7977." *Id*. at 7:67; 5:20–21. We refer to that agent in this decision as sofosbuvir. According to the '159 patent specification, sofosbuvir has the following general structure:

Id. at 7:65–8:15. Patent Owner directs us to information that sofosbuvir may exist in different crystalline forms known as "polymorphs," which "can, and often do, exhibit different properties." Prelim. Resp. 5–6 (and evidence cited therein).

The '159 patent discloses a polymorphic form of sofosbuvir identified as "Form 6." Ex. 1001, 8:42; 32:24, 31. According to the specification, Form 6 is

characterized by an X-ray powder diffraction ("XRPD") pattern of "2θ-reflections (°) at about: 6.1, 8.2. 10.4, 12.7, 17.2, 17.7, 18.0, 18.8, 19.4, 19.8, 20.1, 20.8, 21.8, and 23.3." *Id*. at 8:18–26, 40–56; *see id*. at 9:51–55 (disclosing "preferred subembodiment" of "crystalline" sofosbuvir having that characteristic XRPD pattern of 2θ-reflections); 11:40–12:55 (disclosing embodiments having that characteristic XRPD pattern of 2θ-reflections).
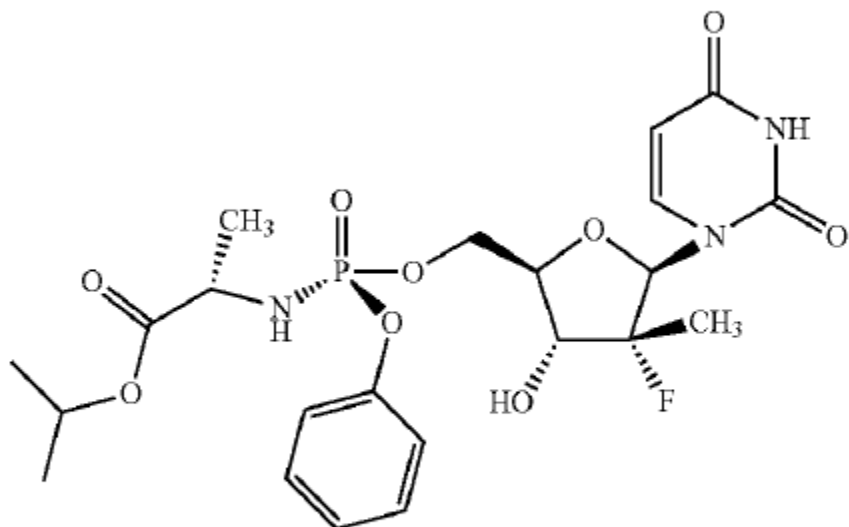
The specification discloses an example that includes instructions for forming "polymorphic Form 6" into a 400 mg tablet dosage form. *Id*. at 32:6–63. Specifically, the '159 patent describes milling Form 6 "with extragranular excipients (microcrystalline cellulose, croscarmellose sodium, colloidal silicon [dioxide], magnesium stearate) to yield a powder blend comprising 33.33% w/w" sofosbuvir, which "was compressed to a target tablet weight of 1200 mg, with each tablet comprising about 400 mg of" sofosbuvir. *Id*. Patent Owner avers that Form 6 is used in its commercial pharmaceutical product known as Sovaldi. Prelim. Resp. 6.

C. Illustrative Claims

Petitioner challenges claims 1–37 of the '159 patent, of which claims 1 and 16 are the only independent claims.

Claim 1 is reproduced below:

1. A pharmaceutical composition comprising:
a) about 25% to about 35% w/w of crystalline GS-7977
having the structure

and
b) at least one pharmaceutically acceptable excipient,
wherein the crystalline GS-7977 has XRPD 2θ-reflections
(°) at about:
6.1 and 12.7.

Ex. 1001, 46:36–56. Claims 2–15 and 33 depend directly or indirectly from
claim 1. *Id.* at 46:57–47:50; 49:15–17.

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