

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 No. IPR2018-00119  
U.S. Patent No. 7,964,580

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**PETITIONER'S REQUEST FOR REHEARING**

## I. INTRODUCTION

Petitioner Initiative for Medicines, Access & Knowledge (I-MAK), Inc. (“Petitioner”) respectfully requests rehearing of the Board’s Decision Denying Institution of *Inter Partes* Review (“IPR”) of Gilead Pharmasset LLC’s (“Gilead”) U.S. Patent 7,964,580 (“the ‘580 patent”) (“Decision”; Paper 7) because the Board misapprehended or overlooked that a provisional application to which the ‘580 patent claims priority failed to satisfy the written description requirement. The Board’s resulting conclusion that the ‘580 patent was entitled to the benefit of the filing date of that provisional application was, thus, incorrect, as was the Board’s further conclusion that two of the references cited by Petitioner in the Petition did not qualify as prior art.

## II. LEGAL STANDARD

A party may request rehearing of a denial of institution by, “identify[ing] all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.” 37 C.F.R. § 42.71(d). The Board reviews its decision for “abuse of discretion,” *Id.* at § 42.71(c), which includes basing the decision on, “an erroneous conclusion of law or clearly erroneous factual finding.” *PPG Indus., Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988).

### III. THE '580 PATENT IS NOT ENTITLED TO THE BENEFIT OF THE '315 PROVISIONAL'S FILING DATE BECAUSE IT DOES NOT SATISFY THE WRITTEN DESCRIPTION REQUIREMENT

“[A] patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112.” *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995). “To be entitled to a parent’s effective filing date, a continuation must comply with the written description requirement of 35 U.S.C. § 112, ¶1.” *In re Owens*, 710 F.3d 1362, 1366 (Fed. Cir. 2013).

To satisfy the written description requirement, “the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate that by disclosure in the specification of the patent.” *ULF Bamberg v. Dalvey*, 815 F.3d 793, 797 (Fed. Cir. 2016) (citations and internal quotation marks omitted); *accord Ariad Pharms. v. Eli Lilly*, 598 F.3d 1336, 1351-52 (Fed. Cir. 2010) (*en banc*). “A disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations.” *Tronzo v. Biomet*, 156 F.3d 1154, 1158 (Fed. Cir. 1998); *accord Ariad*, 593 F.3d at 1352.

“[T]he '580 patent claims the benefit of priority of two earlier-filed provisional applications, 60/909,315 filed March 30, 2007 (Ex. 2013), and

60/982,309 filed on October 24, 2007 (Ex. 2014), (respectively, “the ‘315 provisional” and “the ‘309 provisional”).” Paper 7, 3. In the Petition, I-MAK “contest[ed] that the ’580 patent is entitled to the claimed benefit of priority to the ’315 provisional (id. at 23, 25).” *Id.* at n.1. Specifically, although the ‘315 provisional discusses broad genera of compounds, “it does not discuss the specific compounds and stereochemistry around the phosphorous atom claimed in the ‘580 patent.” Pet. 23, 25; Ex. 1002 ¶ 73. As a result, the two references cited in the Petition that were published after the ‘315 provisional but prior to the ‘309 provisional constitute prior art.

Neither Patent Owner in its Preliminary Response, nor the Board in its Decision, dispute I-MAK’s assertion that the ‘315 provisional fails to identify the specific compound and stereochemistry around the phosphorous atom as claimed in the ‘580 patent. Rather, Patent Owner argued, and the Board concluded, that the ’580 patent is entitled to claim priority to the ‘315 provisional because it contains one line identifying the substituents of the claimed compound (Ex. 2013, 195) and one line generically stating phosphorous can be a chiral center of the disclosed compounds (Ex. 2013, 63).

But the ‘315 provisional identifies 12,400 different compounds (31 structures each having 50 tables of 8 compounds), of which the ‘315 provisional states that they can have various chiral centers. Thus, there are tens of thousands of

possible compounds each with various particular stereochemistry identified by the '315 provisional application, and yet claims 1-7 of the '580 patent claim just eight of those compounds (those listed in table IX-25) and claims 8-14 claim not just a single compound, but a specific stereoisomer thereof, which is nowhere specifically described by the '315 provisional. Given the vast disclosure of the '315 provisional and its failure to specifically disclose the compounds and stereochemistry claimed in the '580 patent, the mere two lines cited by the Board from the 645-page long document do not, "reasonably convey[] to those skilled in the art that the inventor had possession" of the compounds with the stereochemistry claimed in the '580 patent. *Ariad*, 598 F.3d at 1351.

The Board determined that Dr. Fortunak is qualified to opine from the perspective of a person of ordinary skill in the art, Paper 7 at 5, and his testimony was quite clear, "[t]he '315 provisional application does not include a description of the specific compounds claimed by the '580 patent." This testimony supports I-MAK's position that the '580 patent is not entitled to claim the benefit of the '315 provisional. Patent Owner could have entered evidence to contradict Dr. Fortunak's testimony with its Preliminary Response, but chose not to do so. Thus, the only evidence of record is that of Dr. Fortunak's opinion.

The Board cites in its Decision *Fujikawa v. Warranasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996), for the proposition that, "It is well settled that '*ipsis verbis*

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