

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 No. IPR2018-00121
U.S. Patent No. 8,334,270

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 8,334,270 (“the ‘270 patent”) (“Decision”; Paper 10) because the Board misapprehended or overlooked that a provisional application to which the ‘270 patent claims priority failed to satisfy the written description requirement. The Board’s resulting conclusion that the ‘270 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.¹

¹ In IPR2018-00123 of U.S. Patent No. 8,735,372, a patent that relates to the ‘270 patent, the Board held that Sofia (Ex. 1004) is unavailable as a printed publication. Paper 7 (June 13, 2018). However, notably, Patent Owner did not dispute there, and has not disputed here, that Sofia was a printed publication as of September 2007, and the Internet Archive Wayback Machine confirms it was published on the website of Patent Owner’s predecessor at that time. Ex. 1016; see also <https://web.archive.org/web/20071005041918/http://investor.pharmasset.com:80/vents.cfm> (link to “View Phosphoramidates presentation” under “Sep 10, 2007”).

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 ‘270 PATENT IS NOT ENTITLED TO THE BENEFIT OF THE ‘315 APPLICATION’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.

“The ‘270 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 application” and “the ‘309 application”).” Paper 10, 3. In the Petition, I-MAK contested that the ‘270 patent is entitled to claim priority to the ‘315 application. *Id.* at 8. Specifically, although the ‘315 application discusses broad genera of compounds, “it does not discuss the specific compounds and stereochemistry around the phosphorous atom claimed in the ‘270 patent.” Pet. 22, 24; Ex. 1002 ¶ 72. As a result, the two references cited in the Petition that were published after the ‘315 application but prior to the ‘309 application constitute prior art.

Neither Patent Owner in its Preliminary Response, nor the Board in its Decision, dispute I-MAK’s assertion that the ‘315 application fails to identify the specific compounds and stereochemistry around the phosphorous atom and at the amino acid ester (*i.e.*, R^{3a} and R^{3b}) as claimed in the ‘270 patent. Rather, Patent

Owner argued, and the Board concluded, that the '270 patent is entitled to claim priority to the '315 application 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). This is despite the fact that Patent Owner did not specify the stereochemistry at phosphorous as claimed in the '270 Patent. *Id.* (the '315 states that the stereochemistry at phosphorous can be either R- or S-). The Patent Owner further did not specify the stereochemistry at positions R^{3a} and R^{3b} as claimed in the '270 Patent. *Id.* (the '315 states that the stereochemistry at R^{3a} and R^{3b} can be either R- or S-).

But the '315 application identifies 12,400 different compounds (31 structures each having 50 tables of 8 compounds), of which the '315 application 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 application, and yet claims 1, 2, 10-18 and 20-25 of the '270 patent claim at most just fifty-four specific stereoisomers of those compounds, none of which are specifically described by the '315 application.² Given the vast disclosure of the

² Claim 1 claims 12 individual stereoisomeric compounds and claims 10-15 depend therefrom. Claim 2 claims 6 individual stereoisomeric compounds. Claim 16

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