Paper No. 12 Filed: July 3, 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.

IPR2018-00121 Patent 8,334,270 B2

Before LORA M. GREEN, GRACE KARAFFA OBERMANN, and WESLEY B. DERRICK, *Administrative Patent Judges*.

DERRICK, Administrative Patent Judge.

DECISION
Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71



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, 2, 10–18, and 20–25 of U.S. Patent No. 8,334,270 B2 (Ex. 1001 ("the '270 patent")). Gilead Pharmasset LLC ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp."). Having considered the Petition, the Preliminary Response, and the evidence of record, and applying the standard set forth in 35 U.S.C. § 314(a), which requires that Petitioner demonstrate a reasonable likelihood that it would prevail with respect to at least one challenged claim; we *denied* Petitioner's request and did not institute an *inter partes* review. Paper 10, 13 ("Decision" or "Dec.").

Petitioner filed a Request for Rehearing (Paper 11 ("Reh'g Req.")), requesting reconsideration of the Decision denying institution of *inter partes* review. Petitioner contends that we "misapprehended or overlooked that a provisional application to which the '270 patent claims priority failed to satisfy the written description requirement." Reh'g Req. 1.

We have considered Petitioner's Request for Rehearing, and, for the reasons set forth below, Petitioner's Request is *denied*.

II. STANDARD OF REVIEW

37 C.F.R. § 42.71(d) provides that:

A party dissatisfied with a decision . . . may file a request for rehearing, without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each



matter was previously addressed in a motion, opposition, or a reply.

See Office Trial Practice Guide, 77 Fed. Reg. 48756, 48768 (Aug. 14, 2012). Under 37 C.F.R. § 42.71(c), "[w]hen rehearing a decision on petition, a panel will review the decision for an abuse of discretion." An abuse of discretion occurs when a "decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment." PPG Indus. Inc. v. Celanese Polymer Specialties Co. Inc., 840 F.2d 1565, 1567 (Fed. Cir. 1988) (citations omitted).

III. DISCUSSION

In contending that we "misapprehended or overlooked that a provisional application to which the '270 patent claims priority failed to satisfy the written description requirement" (Reh'g Req. 1), Petitioner maintains its argument that while the '315 provisional discusses broad genera of compounds, it does not discuss the specific compounds and stereochemistry claimed in the '270 patent (*id.* at 3–4).

Petitioner further contends that "[n]either 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." *Id.* at 3.

Emphasizing the large number of compounds identified in the '315 provisional, Petitioner argues that the "two lines cited by the Board . . . do not, 'reasonably convey[] to those skilled in the art that the inventor had possession' of the compounds with the stereochemistry claimed in the '270



patent." *Id.* at 3–4 (quoting *Ariad Pharms. v. Eli Lilly*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). Citing various portions of the '315 provisional as support for certain R groups not being disclosed, Petitioner further contends that "the structures of many of the compounds claimed in challenged claims 16, 17 and 18 are not even disclosed in any of the '315 application's tables." *Id.* at 5–6. Petitioner further argues we misapprehended or overlooked that the only evidence of record is Dr. Fortunak's opinion (*id.* at 6–7, 9–10), that we erred in our application of relevant case law to this case (*id.* at 7–9), and that our reasoning is inconsistent with that in our decision denying institution in related IPR2018-00120 (*id.* at 11). Petitioner further cites to a European Patent Office (EPO) decision, dated October 31, 2016 (Exhibit 1015), filed with the Request for Rehearing, and argues it came to an opposite conclusion than we did (*id.* at 12–13).

As set forth in the Decision (*see* Dec. 7–8, 11), we fully considered Petitioner's contention that the '315 provisional "does not include a description of the specific compounds" in that "it does not discuss the specific compounds and stereochemistry around the phosphorous atom claimed in the '270 patent," even if it "discusses broad genera of compounds" (Pet. 21–22 (citing Ex. 1002 ¶ 72)).

Petitioner now builds on its original contention, raising arguments and relying on evidence not included in the Petition. *Compare* Reh'g Req. 2–13, *to* Pet. 22. Arguments raised and evidence provided for the first time in a Request for Rehearing, however, do not identify any matter that we misapprehended or overlooked in denying institution because those arguments and that evidence were not before us.



Petitioner's contention that "[n]either Patent Owner . . . nor the Board . . . dispute[d its] assertion that the '315 application fails to identify the specific compounds and stereochemistry" (Reh'g Req. 3) does not identify any misapprehended or overlooked matter. Patent Owner did contend that the '270 patent is entitled to the benefit of priority of the '315 provisional in stating, for example, that Petitioner's "conclusory assertion regarding priority is wrong" (Prelim. Resp. 13) and that "[a] review of the '315 application . . . reveals that the '315 provisional application discloses *both* the specific compounds *and* the stereochemistry . . . [of] the compounds claimed in the Sofia '270 patent" (*id.* at 15). But, although noting Patent Owner's contention that the '270 patent is entitled to the benefit of priority of the '315 provisional (Dec. 8), the Decision is grounded on "Petitioner fail[ing] to sufficiently demonstrate that the '270 patent is not entitled to the priority benefit of the '315 provisional" (*id.* at 11).

Petitioner's further arguments that various R groups are not adequately disclosed in the '315 provisional to constitute written description support similarly fails to identify any matter misapprehended or overlooked. Petitioner bears the burden required to support institution of *inter partes* review. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). No effort to remedy that failure in the Request is persuasive that we misapprehended or overlooked any matter. *See* 37 C.F.R. § 42.22(a)(2) (a petition must include "[a] full statement of the reasons for the relief requested"); *cf. DeSilva v. DiLeonardi*, 181 F.3d 865, 866–67 (7th Cir. 1999) ("A brief must make all arguments accessible to the judges, rather than ask them to play archaeologist with the record.").



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