

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUSION PHARMACEUTICALS, INC.
Petitioner,

v.

UNIVERSITÄT HEIDELBERG
Patent Owner

Case No. IPR2023-00551

U.S. Patent No. 10,980,901

Issue Date: April 20, 2021

**PETITIONER'S REPLY TO PATENT OWNER'S
PRELIMINARY RESPONSE**

Petitioner submits this Reply to Patent Owner’s Preliminary Response, as authorized by the Board on June 7, 2023, to respond to Patent Owner’s arguments that the Board should deny the petition pursuant to 35 U.S.C. § 325(d). Ex. 3001. Contrary to Patent Owner’s arguments, both *Advanced Bionics* factors support institution. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Gerate GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential). The art and arguments in the Petition are not the same or substantially the same as those considered by the Examiner, but even if they were, the Examiner materially erred.

I. The Examiner Did Not Consider Arguments That Are Substantially the Same as Those in the Petition

Patent Owner’s request for denial under § 325(d) suffers two major flaws. First, Patent Owner is incorrect that the Examiner’s consideration of art focusing on a group of compounds including PSMA-617 is substantially the same as Petitioner’s arguments regarding PSMA I&T. Importantly, during prosecution, Applicant pointed to alleged evidence of secondary considerations specific to PSMA-617—not PSMA I&T—and the record lacks any evidence justifying the assumption that the Examiner interpreted these arguments to apply to every compound in the claims. Second, the Examiner considered the allegedly overlapping prior art—the ’791 and ’160 patents (“the Eder patents”)—through the lens of obviousness-type double patenting (“ODP”), not § 103. Patent Owner ignores that the ODP analysis the Examiner considered is substantially different

than the obviousness arguments in the petition.

A. The Examiner Did Not Consider Weineisen 2015 or Any Disclosure of PSMA I&T

Patent Owner admits that the Examiner did not consider Petitioner's primary reference, Weineisen 2015, nor did the Examiner consider *any* art that disclosed PSMA I&T, the sole focus of the arguments in the Petition. POPR at 16–17 (“[t]he PSMA I&T ligand [was] not specifically disclosed in the references previously before the Office”). Examiner only considered disclosures focused on a different compound—PSMA-617. *See* Ex. 1004.032–.034. Even assuming that the Examiner applied an identical legal framework as that in the petition—which Petitioner disputes, as discussed below—Patent Owner pointed to evidence of secondary considerations to overcome the ODP rejections. Specifically, Patent Owner argued data generated with PSMA-617 allegedly evidenced unexpected results. Ex. 1004.383–.384. There is, however, no data for PSMA I&T in the record showing similar results for PSMA I&T. As a result, Patent Owner is now asking the Board—without the support of expert testimony—to assume that the Examiner's consideration of evidence of unexpected results for PSMA-617 should equally support the non-obviousness to *all* other compounds in the claims, including PSMA I&T. This is not a reasonable interpretation of the prosecution history. Without the disclosure of PSMA I&T, the Examiner never considered whether the data allegedly establishing unexpected results with PSMA-617 was

commensurate in scope with the challenged claims, sufficient to overcome the obviousness arguments in the Petition. *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (“Evidence of secondary considerations must be reasonably commensurate with the scope of the claims.”). Therefore, the Examiner did not consider arguments that are substantially the same as those in the Petition, making denial under § 325(d) improper.

B. The Examiner’s ODP Rejection Involved a Different Legal Analysis Than 35 U.S.C. § 103 Obviousness

Patent Owner’s argument similarly fails because it relies on the Examiner’s ODP rejection over the ’791 and ’160 patents. The suggestion that the Examiner’s analysis of this argument is the same as the Petition’s § 103 arguments is wrong. *See* POPR at 27. While both ODP and § 103 require analyzing whether a person of ordinary skill in the art would find the claims obvious, “[i]mportant differences” exist. *See Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012). Most importantly here, the ODP analysis focuses *solely* on the claims of the cited patents and does not treat the entirety of the cited patents as prior art. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1379 (Fed. Cir. 2012) (“[T]he obviousness-type double patenting doctrine ... rests on preventing a patentee from claiming an obvious variant of what it has previously *claimed*, not what it has previously *disclosed*.”); *In re Longi*, 759 F.2d 887, 892 n.4 (Fed. Cir. 1985) (“[T]he patent principally underlying the double patenting rejection is not

considered prior art.”). The § 103 analysis, instead, examines the *entirety* of the teachings of the prior art references. *Eli Lilly*, 689 F.3d at 1379; MPEP 804 (noting that a reference patent in a § 103 rejection is “available for all that it fairly discloses to one of ordinary skill in the art, regardless of what is claimed”).

Here, the Examiner compared the *claims* of the Eder patents to the then pending claims of the '901 patent. Ex. 1004.404–.406, .408–.410. The Examiner concluded “a hypothetical *infringer* of [the claims of the Eder patents] would necessarily be an infringer of the claimed invention ... render[ing] the instant claims obvious absent a showing of unpredictability or comparative evidence suggesting otherwise.” Ex. 1004.405–.406, .410 (emphasis added). In contrast, the Petition relies on the *entirety* of Weineisen 2015, disclosing data showing PSMA I&T’s almost two-fold increase in PSMA binding compared to similar radioligands and that PSMA I&T was so promising that it was advanced into clinical studies. Pet. at 22–23, 29–30 (citing Ex. 1028.008). The Examiner’s ODP analysis cannot be “substantially the same” as Petitioner’s obviousness arguments because the Examiner’s analysis *necessarily* omitted the teachings of the specification of the Eder patents. For purposes of the § 325(d) analysis, the proper question is whether the *claims* of the Eder patents are “substantially the same” as the *entirety* of Weineisen 2015. The clear answer is that they are not.

Patent Owner attempts to gloss over the holes in the information the

Examiner considered by pointing to statements made during prosecution regarding the specification of the Eder patents and disclosures in references the Examiner failed to cite, but these arguments fall short. The Examiner did not treat the Eder patents as prior art—as evidenced by a lack of a § 103 rejection—and therefore, never considered the disclosures of their specification. *See* Ex. 1004.400–.410; *see also* 1004.382 (Patent Owner stated the Eder patents “are not prior art for the purposes of these double patenting rejections”). Additionally, there is no evidence that the Examiner considered the Eder patents in combination with other references. *See* 1004.400–410.

While Patent Owner repeatedly states that the Examiner “considered” information related to the benefits of ²²⁵Ac and dosing, the Examiner failed to cite any of these references and failed to raise even a single § 103 rejection. *Id.* As Patent Owner admits, the only prior art cited by the Examiner in a rejection were the Eder patents. POPR at 27. The Board has stated on many occasions that a reference merely cited in an IDS is not sufficient to support denial under § 325(d). *See, e.g., Sonos, Inc. v. Google LLC*, IPR2023-00118, Paper 9 at 24 (P.T.A.B. May 19, 2023); *Sci. Design Co., Inc. v. Shell Oil Co.*, IPR2022-00158, Paper 7 at 25 (P.T.A.B. Apr. 4, 2022).

Patent Owner’s reliance on *Alarm.com Inc. v. Vivint, Inc.* is similarly misguided. IPR2015-01967, Paper 12 (Mar. 30, 2016). Contrary to Patent Owner’s

characterization, the Board in *Alarm.com* did not put substantial weight on the number of references the Examiner considered. *Id.* at 15. Rather, the Board denied institution based on § 325(d) because Petitioner merely relied on its “belie[f]” that the Examiner erred and “[did] not provide any evidence in support of this belief.” *Id.* at 15. The Board, thus, assumed the Examiner properly did their job. *Id.* at 15–16. Here rather, there is evidence the Examiner did not consider the specifications of the Eder patents because they were not considered prior art. Additionally, as discussed below, there is evidence that the Examiner misinterpreted the record and improperly ignored secondary references. Therefore, the number of references cited in an IDS does not “strongly suggest” the Examiner’s “meaningful[]” consideration of the record. POPR at 27.

Unlike the Examiner’s ODP rejection, the Petition explains why the challenged claims are obvious in light of teachings in the prior art as a whole. *See, e.g.,* Pet. at 29–50. Not only does the Petition point to prior art that was undisputedly not before the Examiner, but also relies on expert testimony that explains how a POSA would have understood the prior art. *See Sonos*, IPR2023-00119, Paper 9 at 28–29 (instituting petition despite overlap with prosecution because Petition analyzed references in light of expert testimony and secondary references). These arguments go far beyond the Examiner’s limited ODP rejection. Therefore, the Petition relies on prior art and arguments that were not substantively

considered by the Examiner, strongly favoring institution.

II. The Examiner Erred in Their Analysis

Even assuming there is overlap between the arguments the Examiner considered and those in the Petition, the second *Advanced Bionics* factor also supports institution because the Examiner materially erred in allowing the patent. The clearest evidence of the Examiner's error is seen in the Notice of Allowance. Ex. 1004.033–.034. In the Notice, the Examiner did not address the ODP arguments, and stated that the claims were allowable because the claims were directed to different chemical structures than the closest prior art, citing prior art never cited previously during prosecution. *Id.* Not only did the Examiner err in ignoring the secondary references that are cited in the Petition that support a finding of obviousness, the Examiner also erred in failing to recognize that the Eder patents are prior art to the '901 patent. *See id.* Both patents claim priority to PCT application PCT/EP2014/002808, filed on Oct 17, 2014, making them prior art to the '901 patent. Ex. 1026.001; Ex. 1025.001. Thus, the Examiner materially erred by (1) not considering a fulsome § 103 rejection over these or similar references and (2) concluding that a reference with different chemical structures was the closest prior art and, as such, failing to properly consider obviousness of the claims. As a result, both *Advanced Bionics* factors favor institution here.

Dated: June 14, 2023

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that I caused to served, on June 14, 2023, a true and correct copy of the foregoing **PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE** , by email to lead counsel for Patent Owner at AHasan@LewisRoca.com with a courtesy copy to LSchneider@LewisRoca.com and PTO@LewisRoca.com, pursuant to Patent Owner's agreement to accept service by email as set forth in Patent Owner's Mandatory Notice.

Dated: June 14, 2023

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