

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUSION PHARMACEUTICALS, INC.,
Petitioner,

v.

**UNIVERSITÄT HEIDELBERG AND THE EUROPEAN ATOMIC
ENERGY COMMUNITY (EURATOM), REPRESENTED BY THE
EUROPEAN COMMISSION,**
Patent Owners

Case No. **IPR2023-00551**
Patent No. **10,980,901 B2**

**PATENT OWNERS' SUR-REPLY TO PETITIONER'S PRE-INSTITUTION
REPLY**

Patent Owners submit this Sur-Reply to Petitioner's Reply to Preliminary Response (Paper 6), as permitted by the Board's email order dated June 7, 2023. The *Advanced Bionics* factors do not support institution. Fusion narrowly focuses on an immaterial legal distinction **given the facts in this case** between obviousness-type double patenting (ODP) and §103 analyses. The ODP and §103 analyses are analogous, both requiring the same analysis of the obviousness factors, though focusing on different parts of the cited reference – claims vs. full disclosure. Here, the recitations in the claims the Examiner undisputedly considered during prosecution are cumulative in all material respects to the disclosure of the primary reference Fusion relies on in this Petition.

Separately and independently, Fusion's hyper-narrow focus on irrelevant distinctions between ODP and §103 analyses is an attempt to create a red herring to deflect away from the fact that it cannot demonstrate material error.

I. ODP ANALYSIS IS ANALOGOUS TO AND COEXTENSIVE WITH §103 ANALYSIS BASED ON THE FACTS OF THIS CASE

Fusion alleges that the ODP analysis is “substantially different than the obviousness arguments in the petition” due to the focus on the claims in an ODP rejection versus the “entire” disclosure in a §103 rejection. Reply, pp.1-2. This distinction is immaterial in the context of this case, and is an oversimplification.

Legally – as confirmed by Fusion’s own cases – ODP analysis is analogous to and “parallels” §103 analysis. *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012)(“[ODP] analysis is analogous to that undertaken under [§103]”); *In re Longhi*, 759 F.2d 887 (Fed. Cir. 1985)(stating an ODP rejection is “analogous to” and “parallels” the “guidelines for a §103 rejection”)(citing *In re Braithwaite*, 379 F.2d 594, 600, n. 4, (1967) and *In re De Blauwe*, 736 F.2d 699, (Fed. Cir. 1984)).

To meet this legal standard, the language and teachings of the reference claims themselves must be considered in the ODP analysis. MPEP §804. But “those portions of the specification which provide support for the reference claims may also be **examined and considered** when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the reference patent.” MPEP §804(II)(B)(1) (emphasis added). In the chemical context, to “ascertai[n] the scope of the reference’s claim(s) to a compound, the [E]xaminer **should consider** the reference’s specification, **including all of the compound’s uses that are disclosed**.” MPEP §804(II)(B)(1)(citing *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1386-88 (Fed. Cir. 2010)(emphasis added)). Fusion’s assertions that the ODP analysis puts a black box around the claims, precluding a more robust review is a misleading simplification, and should be discounted.

A. Weineisen 2015 is cumulative of the CLAIMS of the Eder patents themselves without needing to consider the Eder specifications

In this case, the Eder specifications are not necessary to render *Weineisen 2015* cumulative. Each portion of *Weineisen 2015* Fusion relies on in its Grounds is substantially the same as the disclosure of the considered Eder **claims**.

And while Fusion once again emphasizes the lack of disclosure in the Eder claims of PSMA I&T specifically, Fusion fails to appreciate that the Examiner's analysis of the challenged claims **necessarily involved** analysis of the entire recited Markush group of PSMA-targeting ligands – including PSMA I&T. Though they may not have specifically recited PSMA I&T, the Eder claims did specifically recite nearly all other members of the recited Markush group. Ex. 1001, claims 1, 3. As such, the Examiner already considered whether the use of known PSMA-targeting ligands – those recited in the Eder claims – rendered the challenged claims obvious.

Weineisen 2015, at best, adds yet another known PSMA-targeting ligand. But the Examiner has already considered – and answered – the question of whether ligands known in the art and recited in the challenged claims render the claims obvious. The addition of yet another known ligand does not alter this outcome.

Significantly, *Weineisen 2015* discloses chelation of ¹⁷⁷Lu or ⁶⁸Ga to the PSMA I&T ligand. Ex. 1028. Both of these radionuclides are also recited in claim 7 of Eder '160. And since claim 7 of Eder '160 also recites ²²⁵Ac, the Eder claims

are more relevant to the patentability inquiry than Weineisen 2015. Weineisen 2015 simply does not provide any new information to the examination, and is “the same in all material respects” to the Eder **claims**. See *R.J. Reynolds Vapor Co. v. Fontem Holdings I B.V.*, IPR2017-01642, Paper 10, *11 (Jan. 16, 2018).

B. The unexpected results were commensurate in scope with the claims, and were not the only proffered theory of non-obviousness

Fusion also asserts “the record lacks any evidence justifying the assumption that the Examiner interpreted [the evidence of secondary considerations] to apply to every compound in the claims,” and that application of this evidence to all compounds in the claims is an unreasonable interpretation of the prosecution history. Reply, pp.1, 2. On the contrary, it is entirely reasonable to conclude from the Examiner’s allowance following Patent Owner’s detailed presentation of unexpected results that he found the evidence to apply to all compounds.

Further, the presented evidence highlighted the unexpected results achieved using the ^{225}Ac radionuclide **coupled with the low dosages** recited in the challenged claims – not the selection of a specific, recited targeting ligand. Ex. 1004.383-.384. Thus, to the extent the Examiner allowed the claims due to this evidence, he likely found the surprising results to be achieved from the **combination** of the specific ^{225}Ac radionuclide with the recited low dosages, and that PSMA-617 was sufficiently representative of the entire recited group of PSMA-targeting ligands. Given this presentation of the surprising results from the combination of the ^{225}Ac

radionuclide with the recited low dosages, Fusion’s arguments – at best – allege that “reasonable minds can disagree regarding the purported treatment of the art or arguments.” *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469 (PTAB Feb. 13, 2020)(Paper 6)(*precedential*)(“if reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability”). As this is insufficient to establish material error, Fusion’s arguments with respect to the unexpected results do not support institution.

But these unexpected results were also **not the only presented theory of non-obviousness**. Patent Owners also argued that the Eder claims (and specifications) do not recite or disclose the recited dosages. Ex. 1004.382-.384. In fact, the Eder patents do not **claim** any dosages, and otherwise disclose significantly higher dosages – 100-fold higher – than those recited in the challenged claims. *Id.* Thus, contrary to Fusion’s implications, unexpected results were not the only available theory for allowance. And as the absence of the recited dosage ranges is sufficient by itself to support allowance, whether the unexpected results were also considered to apply to all ligands recited in the claims is immaterial.

II. THE EXAMINER DID NOT ERR

Fusion advances two main theories of material error: 1) the Examiner failed to consider a “fulsome” §103 rejection; and 2) the Examiner identified a reference

with different chemical structures as the closest prior art (“the NOA reference”). Reply, p. 7. Fusion also argues the Examiner overlooked secondary references, and failed to identify the Eder patents as prior art.

In arguing the Examiner did not consider a “fulsome” §103 rejection, Fusion fails to identify any material aspects of the Eder disclosures that were not adequately considered in making the ODP rejections, and does not identify how such a §103 rejection would differ in analysis or conclusions from the conducted ODP inquiry and analysis. The claims of the Eder patents disclose all of the elements Fusion relies on in *Weineisen 2015* – save only the specific structure of PSMA I&T. Fusion therefore fails to articulate any error – material or otherwise – resulting from the alleged failure to consider a “fulsome” §103 rejection. At best, “reasonable minds can disagree regarding the purported treatment of the art or arguments,” which is insufficient to establish material error. *Advanced Bionics, LLC*, IPR2019-01469.

The Examiner's identification of the NOA reference also does not constitute error. Statements of reasons for allowance are only warranted in instances in which “the record of the prosecution as a whole does not make clear [the] reasons for allowing a claim or claims.” 37 CFR § 1.104(e). Here, the prosecution record included Applicant’s detailed comments in response to the ODP rejection, and Examiner comments regarding withdrawal of the rejection were not required.

But because no rejection issued over the NOA reference, comments regarding

that reference were warranted and proper in light of 37 CFR §1.104(e). **Also, the Examiner's comments on this reference evidence a comprehensive analysis of the technical attributes, features, and structural parallels between the prior art and the challenged claims.** The Examiner's clear consideration of this reference also contradicts Fusion's earlier argument that "there is no evidence that the Examiner considered the Eder patents in combination with other references." Reply, p. 5. Here again, at best, "reasonable minds can disagree regarding the purported treatment of the art or arguments," which is not sufficient to establish material error. *Advanced Bionics, LLC*, IPR2019-01469.

As demonstrated above, Weineisen 2015 is merely cumulative of the art or arguments already considered by the Examiner, and Fusion has not established any material error. Thus, both *Advanced Bionics* factors support **denial** of institution.

Fusion's mudslinging and "see what sticks" approach is evidenced by the fact that its Petition relies upon over 30 references not presented in the Grounds. These 30-plus additional references are relied upon in inconsistent ways and in contradiction to its own expert's report demonstrating that it has no coherent theory of obviousness. Fusion should not be rewarded for its singular focus on a difference between ODP and §103 analyses that is immaterial in this case. Patent Owners submit that the Petition should be rejected.

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Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2023, a copy of this **PATENT OWNERS’
SUR-REPLY TO PETITIONER’S PRE-INSTITUTION REPLY**, was served
by email on the following correspondence addresses of record for Petitioner,
pursuant to 37 C.F.R. § 42.6(e):

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