UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CURIUM US LLC,
Petitioner

v.

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

Case No. IPR2025-01582

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

PETITIONER'S OPPOSITION TO DISCRETIONARY DENIAL OF INSTITUTION

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I. INTRODUCTION

Patent Owner's Discretionary Denial brief filed on March 5, 2025 ("DD Brief") repeats arguments that the PTAB previously addressed and found unpersuasive in the Institution Decision issued in IPR2023-00551 (the '551 IPR Institution Decision). *Fusion Pharm. v. Universität Heidelberg et al.*, IPR2023-00551, Paper No. at 8 (PTAB Aug. 15, 2023). The merits of the instant IPR are objectively strong in light of the PTAB's prior institution decision over these same arguments. Moreover, the '551 IPR Institution Decision creates settled expectations for Petitioner and the public that there is a reasonable likelihood that the challenged claims of the '901 Patent are unpatentable and should not have been issued.

Patent Owner's rebuttal to the '551 IPR Institution Decision is premised on an unfounded assertion that the prior "institution was in error." DD Brief at 1. Importantly, the '551 IPR Institution Decision considered the same facts and arguments that Patent Owner relies on in its Discretionary Denial brief. For instance, the PTAB considered Patent Owner's arguments on the merits of the prior art but dismissed them in finding the prior art "demonstrated a reasonable likelihood of success." '551 IPR Institution Decision at 28. With respect to whether the prior art in this IPR was previously considered during prosecution, the PTAB "determine[d] that the Weineisen 2015 reference…is not the same or substantially the same art that was previously presented to the Office" and thus "the first part of the *Advanced*

Bionics framework is not satisfied." *Id*. at 13. These facts have not changed and Patent Owner's arguments are no more compelling now than they were when the PTAB first considered them in the '551 IPR.

Furthermore, the instant Petition also relies on a new argument based on Patent Owner's admissions about Kratochwil 2016 made in the '551 IPR proceeding. *See* Petition at 51-56. These admissions show that Kratochwil 2016 is prior art and anticipate the claims of the '901 Patent confirming a material error by the examiner in allowing the claims over Kratochwil 2016. Indeed, in response to Petitioner identifying the relevance of these admissions to the Office for the first time via this IPR, Patent Owner has been forced to submit two declarations from the inventors of the '901 Patent and a third declaration from a co-author of Kratochwil 2016 to attempt to argue that Kratochwil 2016 should not be considered prior art. *See* Ex. 2004, 2007 and 2008. Patent Owner's failure to be forthcoming about this issue during prosecution (and addressing it only in response to this IPR petition) further favors institution of this IPR so that the Office can determine if Kratochwil 2016 is prior art or not.

Finally, Patent Owner's allegations about nebulous investment in the '901 Patent are not persuasive. The '901 Patent issued five years ago and Patent Owner's provides scant details about the amount of investment, the relationship of the investments to the '901 Patent, or if those investments occurred in the United States,.

In view of these facts, as explained in more detail below, the Director should not invoke his discretion to deny this IPR.

II. STRENGTH OF PETITION IS STRONG AS CONFIRMED BY THE ’551 IPR INSTITUTION DECISION

One of the factors weighed by the Director is “[t]he strength of the unpatentability challenge.” *See* Memorandum on Interim Processes for PTAB Workload Management (March 26, 2025).[1] Here, Grounds 1 and 2 of the instant IPR Petition assert the same prior art against the same claims that was asserted in the ’551 IPR, which the PTAB found “demonstrated a reasonable likelihood of success in proving that at least one challenged claim of the ’901 patent is unpatentable.” ’551 IPR Institution Decision at 28.

Ground 3 supporting institution is similarly strong given that the Patent Owner has admitted that Kratochwil 2016 would anticipate the claims if it is prior art. IPR2023-00551, Paper No. 15 at 57 (Patent Owner stating that Kratochwil 2016 “describes an embodiment of the [’901] patent.”). Kratochwil 2016 has four co-

[1] Available at:

https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf.

authors that are not inventors of the ’901 Patent and Patent Owner fails to provide evidence that Kratochwil 2016 should be disqualified as prior art.

A. Grounds 1 and 2 – Previously Accepted by the PTAB

The PTAB previously found the art and arguments for Grounds 1 and 2 were objectively strong when it instituted IPR on these grounds. *See* ’551 IPR Institution Decision at 28. In making that determination, the Board considered Patent Owner’s arguments on why the claims were not obvious and found them unconvincing. *Id*. at 23-26.

In its discretionary denial brief, Patent Owner makes demonstrably false statements about the previously instituted IPR, including “the PTAB never found any of these references teach the ’901 Patent’s claimed effective dose.” DD Brief at 18. In reality, however, the Board expressly held that the prior art teaches this limitation:

> Supplying the Ac-225-DOTATOC in multiple fractions allowed for a lower dose with each administration. Kratochwil, therefore, reasonably suggests that the alpha emitter 225 Ac may be administered at doses of 40 MBq, 25 MBq, or 18.5 MBq. We, therefore, agree with Petitioner that **the 225 Ac doses applied in the dose escalation studies of Kratochwil overlap with the claimed “unitary dosage of from 3 MBq to 30 MBq.”** Pet. 43 (citing *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003)). Kratochwil, therefore, suggests using the alpha emitter 225 Ac for administration to patients **within the dosage range claimed in the ’901 patent**.

’551 IPR Institution Decision at 24 (emphasis added).

Indeed, in its response filed after institution, the Patent Owner did not dispute that the dosage limitation (or any other limitation) was taught by the prior art but instead only argued the motivation to combine and secondary considerations. *See* IPR2023-00551, Patent Owner Response, Paper No. 15 at i (Table of Contents headings of arguments). The ’551 IPR settled shortly thereafter and before a final written decision could be issued by the Board. Hence, Petitioner filed the instant IPR to seek final resolution of this objectively strong challenge to claims 1, 2, and 4-13 of the ’901 Patent.

To the extent relevant, the Patent Owner’s post-institution arguments in the ’551 IPR are also weak. Patent Owner’s rationale challenging the motivation to combine was rejected in the ’551 Institution Decision. *See* ’551 IPR Institution Decision at 23-26. In addition, the instant Petition cites extensive evidence in the form of expert declaration testimony and background references providing a strong rationale and scientific basis supporting the motivation to combine. *See* Petition at 27-42 (citing Exhibits 1002, 1006-1008, 1011, 1013-1015, 1017, 1018, 1021, 1022 1027-1029, 1031, 1033, 1034, 1039, 1041, 1043).

Patent Owner’s arguments on secondary consideration are likewise weak as explained in the Petition. Petition at 56-63. In particular, Patent Owner relies on alleged praise and success tied to Kratochwil 2016, not the ’901 Patent. However,

Kratochwil 2016 discloses treating a singular disease (prostate cancer), using a singular radiopharmaceutical formula (^{225}AC-PSMA-617) at a singular dosage (100 kBq of body weight) while the challenged claims of the ’901 Patent are not limited to any specific disease, encompass multiple radiopharmaceutical formulas and recite broad dosage ranges. Thus, Kratochwil 2016’s specific treatment is not “reasonably commensurate with the scope of the claims” and thus lacks a nexus to the claims of the ’901 Patent. *In re Huai-Hung Kao,* 639 F.3d 1057, 1068 (Fed. Cir. 2011).

In short, Patent Owner hopes to leverage Kratochwil 2016’s specific treatment to gain a broad monopoly via the ’901 Patent encompassing using ^{225}Ac radiopharmaceutical formulas to treat any disease and using dosages never suggested by Kratochwil 2016. Yet, Patent Owner never attempts to explain why the alleged success attributable to the specific and narrow treatment procedure in Kratochwil 2016 has a nexus to the broad scope of the ’901 Patent. Notably, Petitioner did not challenge claim 3 of the ’901 Patent that affirmatively recites “Ac-225-PSMA-617”, which is the radiopharmaceutical formula actually used in Kratochwil 2016. It is only the broader claims not limited to “Ac-225-PSMA-617” that Petitioner has challenged.

B. Ground 3 – Kratochwil 2016 Anticipation

In addition, the third ground supporting IPR institution based on Kratochwil 2016, is also objectively strong on the merits given that Patent Owner has admitted that Kratochwil 2016 would anticipate the claims if it is prior art since it discloses an embodiment of the '901 Patent.[2] IPR2023-00551, Paper No. 15 at 57 (Patent Owner stating that Kratochwil 2016 "describes an embodiment of the ['901] patent."). As such, the only issue to decide for Ground 3 is whether or not Kratochwil 2016 is prior art. Kratochwil 2016 has four co-authors that are not named inventors of the '901 Patent. In an effort to rebut a finding that Kratochwil 2016 is prior art, Patent Owner has filed three declarations. *See* Ex. 2004, 2007 and 2008.

Yet only one of the three declarations is from a co-author of Kratochwil 2016 not listed as an inventor of the '901 Patent. There is no testimony from the three other non-inventor co-authors of Kratochwil 2016 leaving substantial gaps in the facts regarding their contributions to Kratochwil 2016. In addition, the two declarations of the '901 inventors alleging a lack of contribution of the non-inventor

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[2] Kratochwil 2016 can anticipate the claims since it discloses an embodiment within the scope of the broad ranges claimed, but it does not serve as evidence for secondary considerations since its limited disclosure is not commensurate with the expansive breadth of the claims. *See* Petition at 57-58 (citing *Allergan, Inc. v Apotex, Inc.*, 754 F.3d 952, 963 (Fed. Cir. 2014)).

co-authors of Kratochwil 2016 are self-serving and conclusory. *See* Ex. 2004 (Declaration of Dr. Morgenstein) and 2007 (Declaration of Dr. Kratochwil). These inventor declarations should be subject to cross-examination via this IPR to explore the accuracy and completeness of their testimony. The sole declaration from a non-inventor co-author of Kratochwil 2016 is directed only towards his own participation regarding Kratochwil 2016 and does not discuss the participation of any of the other three non-inventor co-authors. *See* Ex. 2008 (Declaration of Dr. Kopka).

III. MATERIAL ERROR DURING PROSECUTION SHOWN BY PATENT OWNER'S ADMISSION THAT KRATOCHWIL 2016 ANTICIPATES CLAIMS OF THE '901 PATENT

Kratochwil 2016 was submitted in an Information Disclosure Statement (IDS) during prosecution of the '901 Patent. Yet, not once during prosecution did the Patent Owner inform the examiner that Kratochwil 2016 "describes an embodiment of the ['901] patent" as Patent Owner has now admitted. IPR2023-00551, Patent Owner Response, Paper No. 15 at 57. Instead, that admission only came about because of the '551 IPR where Patent Owner made it in a misguided attempt to rely on the Kratochwil 2016 for secondary considerations. Patent Owner's deliberate omission of this critical information during prosecution lead to a material error by the Office in issuing claims for the '901 Patent that Patent Owner knew were anticipated by a reference "published by Kratochwil's lab *just before the Patent filing*." *Id*. at 51 (emphasis in original by Patent Owner).

Furthermore, it is only because of the instant IPR that Patent Owner has now submitted the three declarations in an attempt to demonstrate that Kratochwil 2016 is not prior art. *See* Ex. 2004, 2007, and 2008. Indeed, Patent Owner acknowledges in its discretionary denial brief that in order to disqualify Kratochwil 2016 as prior art it must submit declarations "explaining the role of the reference co-authors." DD Brief at 14.

Yet, these three declarations should have been submitted during the original prosecution of the '901 Patent so that the examiner could have weighed this information in determining whether to issue the claims of the '901 Patent. Patent Owner provides no explanation why it waited until this IPR proceeding to provide this material information to the Office. At most, Patent Owner contends it was not required to file the declarations before the prior art was asserted. DD Brief at 14 (citing MPEP §2155). Yet, that argument rings hollow where the Patent Owner was well aware that a prior art reference anticipates the claims absent any declarations as is the case here. *See* 37 C.F.R. §1.56(a) ("The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability.").

Importantly, if Petitioner had not filed this IPR, it is likely that Patent Owner would never have provided these three material declarations to the Office for

consideration. Since the sufficiency of these declarations have never been considered by the Office, this IPR should be instituted so that the Office can rectify the material error that resulted in these declarations never being considered during prosecution.

IV. PRIOR ART WAS NOT PREVIOUSLY CONSIDERED BY THE OFFICE AS PREVIOUSLY CONFIRMED BY THE '551 IPR INSTITUTION DECISION

Patent Owner asserts that Weineisen 2015 "is cumulative of the Eder Patents" cited during prosecution. Patent Owner DD Brief at 9. This was the exact same argument Patent Owner unsuccessfully raised in the '551 IPR. '551 IPR Institution Decision at 11 (Board stating that "Patent Owner asserts that Weineisen 2015 is cumulative of the claims recited in Eder '791 and Eder '160,…"). The PTAB considered Patent Owner's cumulativeness argument but found it was not supported by the underlying facts for the below reasons:

> Having considered the record, we disagree with Patent Owner that Weineisen 2015 is substantially similar or cumulative. Just because the Eder '160 patent claims disclose many of the members of the Markush group recited in the '901 patent claims does not mean that *all* the members of the Markush group are represented or encompassed by the Eder '160 claims. Sur-reply 3 ("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").

> Here, the species disclosed in the Weineisen 2015 reference is not present in the Eder '160 patent claims. Accordingly, we determine that the Weineisen 2015 not substantially similar or cumulative to the art previously presented to the Office.

'551 IPR Institution Decision at 13 (emphasis in original). This difference in teachings identified by the Board is relevant because the Patent Owner provided evidence during prosecution to overcome the species disclosed in Eder, PSMA-617, but *not* for the species disclosed in Weineisen 2015, PSMA I&T. *See* Ex. 1004 at 383-384 (providing data regarding PSMA-617). Thus, the Board found the differences in disclosed species between Weineisen 2015 and the Eder patents meant they were not substantially similar.

Patent Owner does not dispute the PTAB's central fact finding above, namely that "the species disclosed in the Weineisen 2015 reference is not present in the Eder '160 patent claims." *Id*. Rather, Patent Owner argues the "PTAB erred by requiring that Weineisen 2015 and the Eder Patents have identical species to apply § 325(d)." DD Brief at 13. Yet, the Board never said two references needed to be "identical" as Patent Owner asserts. Rather, the Board repeatably noted that § 325(d) applies to "substantially similar" prior art and arguments. '551 IPR Institution Decision at 9 ("In evaluating matters under § 325(d), the Board uses the following two-part framework: (1) determining whether the same *or substantially the same*,…"), 10 ("We first consider whether Petitioner asserts the same *or substantially the same* art

or arguments that previously were presented to the Office."), 13 ("we disagree with Patent Owner that Weineisen 2015 is *substantially similar or cumulative*") (emphasis added).

Notwithstanding the Board's findings above, Patent Owner's argument on why Weineisen 2015 and the Eder patents are similar is unconvincing. Patent Owner argues that Weineisen 2015 and the Eder patents are similar because they both allegedly have an "efficacy" that is less than what is disclosed in the examples provided in the specification of the '901 Patent. DD Brief at 10-11. Yet, the supposed similarity in efficacy is irrelevant since it would not overcome the differences in disclosed species as identified by the PTAB. Moreover, the claims of the '901 Patent do not recite any level of efficacy, let alone the specific requirement of "decreased PSA levels from three- and four-digit levels to undetectability" that Patent Owner alleges is shown by the '901 Patent. *Id*.; *see also* Ex. 1001 at Claims 1, 2, 4-8, and 10-13.

Yet, even if efficacy were relevant, Patent Owner's own analysis shows that Weineisen 2015 has much greater efficacy than Eder. *Id*. (Patent Owner asserted that Weineisen 2015 discloses going from 40.2 ng/ml to 0.7 ng/ml [98.2% reduction] while Eder discloses going from 38 ng/ml to 8 ng/ml [78.9% reduction]). Thus, even when considering only efficacy (albeit irrelevant to the claims), Weineisen 2015 is not substantially the same as the Eder patents.

In view of the above the Director should not discretionarily deny this IPR based on a theory that the Office previously considered substantially similar art and arguments during prosecution.

V. SETTLED EXPECTATIONS FAVOR INSTITUTION

A. Petitioner has settled expectations in view of the recent issuance and the PTAB's findings in IPR2023-00551

The '901 Patent issued five years ago and there is no presumption that it would not be subject to a patentability challenge. Moreover, the '551 IPR Institution Decision put Patent Owner and the public on notice that patentability of the '901 was questionable and likely subject to future IPR challenges. Although, the settlement of the '551 IPR may have resolved the private dispute between Patent Owner and Fusion Pharmaceuticals, it did nothing to resolve the cloud of unpatentability attached to the '901 Patent in light of the '551 IPR Institution Decision. After the '551 IPR settled, the Patent Owner could have filed a reexamination or reissue on the '901 Patent to ask the Office to clear up this uncertainty, but Patent Owner failed to take those steps.

In light of the still unresolved patentability issues raised in the '551 IPR Institution Decision, Petitioner has settled expectations that the Office would institute this IPR in order to address the issuance of a patent with claims where the

Office believes there is a "a reasonable likelihood" of unpatentability. '551 IPR Institution Decision at 28.

B. Patent Owner's Alleged Investments are Vague and Not Tied to the '901 Patent

Patent Owner argues that the inventors have run a decades-long clinical study on 233 patients related to the '901 Patent. DD Brief at 18. Yet, Patent Owner provides no details of the financial impact of this alleged investment. Moreover, based on the inventor's testimony this investment appears to be entirely based in Europe rather than the United States and Patent Owner fails to explain their significance to institution of this IPR. *See* Ex. 2004 at 8, 20 and 25; Ex. 2007 at 20.

Next, Patent Owner mentions clinical studies being performed by Novartis and Fusion Pharmaceuticals. DD Brief at 18-19. Yet, Patent Owner does not explain how these studies are tied to the '901 Patent, what the investment has been in these studies, or where that investment is expected to take place. At most, Patent Owner cites to expected costs about clinical trials generally, but that merely indicates what others are spending on clinical trials – not what has been invested into the '901 Patent.

In any event, the majority of these trials indicate a start date in 2025 or later, which was after the PTAB issued the '551 IPR Institution Decision in 2023. Parties were on notice after the '551 IPR Institution Decision of the questionable validity of

the ’901 Patent and must reasonably assume the risk that claims of the ’901 Patent are not patentable.

VI. CONCLUSION

The Petitioner presents a strong case on the merits that the PTAB has previously found is likely to render the challenge claims unpatentable. The PTAB rejected Patent Owner’s arguments that the prior art was weak or already considered. Moreover, Patent Owner failed to provide the examiner during prosecution with the declaration evidence it now says is needed to overcome Kratochwil 2016 necessitating this IPR to consider that evidence. Further, Patent Owner has not shown it has settled expectations in a five-year old patent that has already been found to be likely unpatentable by the PTAB.

In view of the above facts, the Director should not discretionarily deny institution of this IPR and should consider the IPR petition on its merits.

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on March 9, 2026, a copy of the forgoing document is being served via email on the following counsel of record for Patent Owner:

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