

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 Owners

IPR2025-01582
Patent 10,980,901 B2

Before ZHENYU YANG, TAWEN CHANG, and BRIAN D. RANGE,
Administrative Patent Judges.

YANG, Administrative Patent Judge.

ORDER
Denying Patent Owner's Motion
to Compel Routine Discovery
37 C.F.R. § 42.51(b)(1)(iii)

With our authorization (Paper 19), Patent Owner filed a Motion to Compel Routine Discovery (Paper 20, “Mot.”). In its Motion, Patent Owner requests that Petitioner produces:

- Non-privileged communications such as emails, presentations, web sites, and publications by, or on behalf of, Dr. Michael Zalutsky, concerning Petitioner’s Exhibit 1045 . . . between July 2016 and September 25, 2025; and
- Non-privileged communications such as emails, presentations, web sites, and publications by, or on behalf of, Dr. Michael Zalutsky, describing the disadvantages of using radioactive actinium in therapeutics.

Id. at 1. Petitioner filed an Opposition to the Motion (Paper 21, “Opp.”). For the following reasons, we deny Patent Owner’s Motion.

I. BACKGROUND

Petitioner filed the Petition, challenging the patentability of claims 1, 2, and 4–13 of U.S. Patent No. 10,980,901. Paper 2, 7.

Claim 1 of the ’901 patent recites

A method for treating PSMA expressing cancers, wherein the method comprises administering to a patient in need thereof an effective amount of one or more Ac-225-radiopharmaceuticals, said one or more Ac-225-radiopharmaceuticals comprising Ac-225 chelated with a targeting compound of Formula (A), (B), (C), (D) or (E)

. . .

wherein the effective amount of said one or more Ac-225-radiopharmaceuticals is administered as a dosage of from 25 kBq to 400 kBq/kg of body weight of said patient or wherein the effective amount of said one or more Ac-225-radiopharmaceuticals is administered as a unitary dosage of from 3 MBq to 30 MBq to said patient.

Petitioner argues that the challenged claims are unpatentable over prior art because, among other reasons, an ordinarily skilled artisan “would

have been motivated to use PSMA I&T with ^{225}Ac and would have had a reasonable expectation of success.” Pet. 30. Petitioner contends that an ordinarily skilled artisan would have used an alpha emitter and would have recognized specific advantages of ^{225}Ac . *Id.* at 30–34. Petitioner also asserts that an ordinarily skilled artisan would have had a reasonable expectation of success in making ^{225}Ac -PSMA I&T. *Id.* at 35. Petitioner further argues that there is no evidence of objective indicia of non-obviousness. *Id.* at 56–63.

Petitioner relies in part on the testimony of its declarant, Dr. Michael R. Zalutsky, to support its arguments. *See* Ex. 1002. Dr. Zalutsky testifies that “a person of ordinary skill in the art would have been motivated to use ^{225}Ac with PSMA I&T.” *Id.* ¶ 86. According to Dr. Zalutsky, “at the time of filing, a POSA would have been aware that the potential benefit of ^{225}Ac -labeled radiopharmaceuticals for the treatment of cancer likely outweighed potential side effects, including those related to the daughter recoil effect.” *Id.* ¶ 29. Dr. Zalutsky testifies that “alpha-particle emitters were known for their potentially improved therapeutic efficacy as compared to beta emitters.” *Id.* ¶ 93. Dr. Zalutsky further testifies that he disagrees with the applicant’s statement during prosecution that the difference in efficacy would be surprising or unexpected. *Id.* ¶ 50.

Patent Owner argues that, “although Petitioner claims that there are no secondary factors supporting the non-obviousness of the patent . . . , embodiments of the patented product, as exemplified by Exhibit 1045,^[1]

¹ Kratochwil et al., *225 Ac-PSMA-617 for PSMA-Targeted α -Radiation Therapy of Metastatic Castration-Resistant Prostate Cancer*, 57 J. Nucl. Med. 1941–44 (2016) (Ex. 1045, “Kratochwil 2016”).

received public praise from Petitioner’s own expert.” Mot. 1 (footnote added). In addition, Patent Owner asserts that

while [Dr. Zalutsky] stated in his Declaration that using ^{225}Ac as claimed in the invention would be the “common-sense solution” because “the potential benefit of ^{225}Ac -labeled radiopharmaceuticals for the treatment of cancer likely outweighed potential side effects” (Exhibit 1002 at ¶¶29-30), he has actually spent the last decades arguing against the use of ^{225}Ac with PSMA, both before and after the patent-in-suit, demonstrating significant skepticism in its use and countering his sworn testimony.

Mot. 1–2.

II. ANALYSIS

As the moving party, Patent Owner bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c).

Under our Rules, in an *inter parte* review proceeding, “a party must serve relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents or things that contains the inconsistency.” 37 C.F.R. § 42.51(b)(1)(iii).

A. Alleged Inconsistencies

Patent Owner contends that Dr. Zalutsky “praised an embodiment of the patent and publicly discussed the difficulties of using the ^{225}Ac , which contradicts views that he has expressed in his expert declaration.” Mot. 3; *see also id.* at 4–5 (discussing Exhibits 2108 and 2134, both of which were co-authored by Dr. Zalutsky, as “evidence that Dr. Zalutsky’s opinions before becoming an expert for Petitioner are inconsistent with those he is expressing now”). In addition, Patent Owner asserts that Dr. Zalutsky’s previous praise of an embodiment of the patented product and skepticism towards use of ^{225}Ac are inconsistent with Petitioner’s positions that (1)

there is no evidence of objective indicia and (2) ^{225}Ac was the obvious choice for a radionuclide. *Id.* at 6. We are not persuaded by Patent Owner's arguments.

1. Exhibit 2108

Exhibit 2108 discusses “[p]rostate-specific membrane antigen (PSMA)-targeted radiopharmaceutical therapy.” Ex. 2108, 3. It recognizes “accumulating evidence that α -particle emitting radionuclides may outperform β -emitters.” *Id.* It states that comparing with β -emitters, which already “increased overall survival compared with standard of care,” “[t]argeted α -particle therapy (TAT) has shown even more dramatic results in some studies.” *Id.* Exhibit 2108 then cites Kratochwil 2016 as “a study using the ^{225}Ac -labeled analogue of PSMA-617 [that] demonstrated significant responses.” *Id.*

Read in context, we agree with Petitioner that “calling the treatment response in Kratochwil 2016 dramatic and significant does not contradict Dr. Zalutsky's opinion that the response was also predictable based on principles known prior to Kratochwil 2016.” Opp. 5. Indeed, before Kratochwil 2016, “it ha[d] already been demonstrated that targeted α -therapy can break radioresistance to β -radiation.” Ex. 1045, 3; *see also id.* at 1 (“It has already been demonstrated that targeted α -radiation therapy . . . could break radioresistance to β -emitters while simultaneously reducing hematologic toxicity in patients.”). Specifically, Kratochwil 2016 states that because “sufficient tumor retention of the ^{225}Ac daughter nuclides has already been demonstrated in vitro . . . radioligand therapy with ^{225}Ac -PMSA-617 ideally matches the theoretic considerations for targeted α -therapy.” *Id.* at 3.

Thus, on this preliminary record, we find that the statements in Exhibit 2108 that α -particle therapy had shown “even more dramatic results,” or that Kratochwil 2016 “demonstrated significant responses” are not inconsistent with Dr. Zalutsky’s opinion that an ordinarily skilled artisan would have pursued ^{225}Ac treatment with reasonable expectation of success.

2. Exhibit 2134

Exhibit 2134 is titled “Astatine-211: Production and Availability.” Ex. 2134, 1. The Exhibit mentions ^{225}Ac three times. First, it notes that ^{225}Ac is a product of natural decay, whereas ^{211}At requires a cyclotron for production. *Id.* Second, it states that ^{211}At possesses favorable decay properties in comparison to ^{225}Ac because ^{225}Ac has “much longer half life α -particle emitting radioactive daughters,” whereas the intermediate of ^{211}At , which is “not a daughter created by α -decay,” has a shorter half life. *Id.* at 2. Third, Exhibit 2134 states that the intrinsic cost of producing ^{211}At is lower than that of producing ^{225}Ac . *Id.* at 6.

At no time does Exhibit 2134 suggest against the use of ^{225}Ac , as Patent Owner alleges. *See* Mot. 4. More importantly, Exhibit 2134 teaches that, despite its two advantages, ^{211}At has a major disadvantage: limited availability because “the need for a medium energy α -particle beam for its production.” Ex. 2134, 1. Thus, Exhibit 2134 states that many researchers and clinicians believe that “ ^{211}At would be the most important α -particle emitting radionuclide,” but only “if it were widely available.” *Id.*

Exhibit 2134 identifies 36 cyclotrons “as having α -particle beam characteristics consistent with the production of ^{211}At , with the majority of these potentially capable of generating sufficient activity *levels to permit at least single patient doses* of ^{211}At -labeled targeted radiotherapeutics.” *Id.*

at 8 (emphasis added). Even that number may be higher than reality due to “the decommissioning of some of these machines.” *Id.* Moreover, “at the present time, only a few of these cyclotrons routinely produce ²¹¹At on a routine basis.” *Id.*

In sum, Exhibit 2134 discusses not only advantages, but also a “critical issue” with ²¹¹At. Ex. 2134, 8. On this preliminary record, we are not persuaded by Patent Owner’s argument that, in Exhibit 2134, Dr. Zalutsky argued in favor of ²¹¹At over ²²⁵Ac. *See* Mot. 4. In other words, we find that the statements in Exhibit 2134 are not inconsistent with Dr. Zalutsky’s opinion that an ordinarily skilled artisan would have been motivated to use ²²⁵Ac with PSMA I&T.

B. Routine Discovery

Under the Board’s precedents,

[r]outine discovery under 37 C.F.R. § 41.51(b)(1)(iii) is narrowly directed to specific information *known to the responding party to be inconsistent* with a position advanced by that party in the proceeding, and not broadly directed to any subject area in general within which the requesting party hopes to discover such inconsistent information.

Garmin Int’l, Inc. v. Cuozzo Speed Techs. LLC, IPR2012-00001, Paper 26, 4 (PTAB Mar. 5, 2013) (precedential).

Patent Owner seeks to compel discovery because “there appears to be more behind the scenes that Dr. Zalutsky knows about.” Mot. 5–6. In other words, Patent Owner “is not referencing information known to [Petitioner] to be inconsistent with positions taken in the petition.” *Garmin*, Paper 26 at 4. Instead, Patent Owner “casts a wide net directed to broad classes of information which may not include anything inconsistent with positions taken by” Petitioner. *Id.*

For example, in his declaration, Dr. Zalutsky acknowledges that ^{225}Ac “has multiple alpha emitting daughters which due to the recoil effect separate the daughter radionuclides from the chelator.” Ex. 1002 ¶ 28. According to Dr. Zalutsky, “[t]he recoil effect can potentially lead to toxicity because the daughter radionuclides produced from the initial alpha decay are no longer bound to the targeting compound, and therefore may travel to other areas of the body and cause damage to healthy tissues.” *Id.*

Patent Owner seeks to compel the production of “[n]on-privileged communications such as emails, presentations, web sites, and publications by, or on behalf of, Dr. Michael Zalutsky, describing the disadvantages of using radioactive actinium in therapeutics.” Mot. 1. These documents, if exist, however, are not inconsistent with Dr. Zalutsky’s opinion, which already discusses the disadvantages of ^{225}Ac .

III. CONCLUSION

In sum, on this record, we find Patent Owner has not met its burden to show that statements in Exhibits 2108 and 2134 are inconsistent with Dr. Zalutsky’s opinion or Petitioner’s positions. In addition, under *Garmin*, Patent Owner’s request for routine discovery is not narrowly directed to specific information known to Petitioner to be inconsistent. In view of Petitioner’s representation that it “has fully complied with its routine discovery obligations and is not aware of any information inconsistent with a position advanced in this proceeding” (Opp. 1),² we deny Patent Owner’s Motion to compel routine discovery.

² We remind the parties and counsel of the duty of candor and good faith to the Office during the course of a proceeding. *See* 37 C.F.R. § 42.11.

IV. ORDER

For the foregoing reasons, it is:

ORDERED that Patent Owner's Motion to Compel Routine
Discovery is denied.

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Patent 10,980,901 B2

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