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| QUARLES & BRADY LLP ATTN: IP DOCKET 411 E. WISCONSIN AVENUE SUITE 2350 MILWAUKEE, WI 53202-4426 | | | CHONG, YONG SOO | |
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte IGOR B. RONINSON and DONALD C. PORTER

Appeal 2019-006086
Application 15/065,083
Technology Center 1600

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and
ELIZABETH A. LAVIER, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from Examiner's decision to reject claims 42, 44, 45, and 49 (*see* Br. 1). We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as "SENEX BIOTECHNOLOGY INC." (Appellant's October 16, 2018 Appeal Brief (Br.) 2).

STATEMENT OF THE CASE

Appellant's disclosure "relates to the treatment and prevention of cancer" (Spec.² 1). Appellant's claims are reproduced below:

42. A method for preventing breast cancer recurrence or metastasis in a breast cancer patient who has undergone debulking treatment for a tumor, comprising administering to the patient a small molecule compound that specifically inhibits CDK8/19 following debulking.

44. A method for preventing tumor invasion in a breast cancer patient, comprising administering to the patient a small molecule compound that specifically inhibits CDK8/19.

45. A method for treating a breast cancer patient comprising administering to the patient a small molecule compound that specifically inhibits CDK8/19 in combination with a DNA damaging agent.

49. A method for treating breast cancer in a patient, comprising administering to the patient a small molecule compound that specifically inhibits CDK8/19.

(Br. 7.)

Claims 42, 44, 45, and 49 stand rejected under the written description provision of 35 U.S.C. § 112(a).

ISSUE

Does the preponderance of evidence on this record support Examiner's finding that Appellant's Specification fails to provide written descriptive support for the claimed invention?

² Appellant's December 2, 2016 Specification.

ANALYSIS

Examiner finds that Appellant’s “claims are not drawn to compounds that selectively inhibit[] CDK8/19, but are drawn to methods of preventing and treating breast cancer by administering a compound, not defined by its structure, but by its mechanism of action, specifically selective inhibition of CDK8/19” (Ans. 10–11 (emphasis omitted)). In this regard, Examiner finds that “there is no established method of preventing breast cancer in the art, let alone using compounds that selectively inhibit[] CDK8/19 for this purpose” (*id.* at 11). Thus, Examiner finds that “[a] showing of compounds that selectively inhibit[] CK8/19 is not sufficient to satisfy the written description standard for claims drawn to a method of preventing and treating breast cancer” (*id.* (emphasis omitted)).

Appellant contends, however, that “a bioinformatics discovery . . . correlated breast cancer outcome with the expression of CDK8, its paralog CDK19 and their binding partner Cyclin C in clinical breast cancer samples,” which led Appellant “to hypothesize that specific CDK8/19 inhibitors^[3] would be effective against breast cancer” (Br. 2; *see* Spec. 9; *see also* Roninson Decl.⁴ ¶ 3). Appellant further contends that although it could have used any specific inhibitor of CDK8/19⁵ to test this hypothesis, it used its specific CDK8/19 inhibitor, Senexin B (SNX2-1-165)

³ Appellant contends that its Specification discloses “that ‘specific inhibitors of CDK8/19’ are ‘small molecule compounds that inhibit one or more of CDK8 and CDK19 to a greater extent than it inhibits certain other CDKs” (Br. 2).

⁴ Declaration of Dr. Igor B. Roninson, signed May 17, 2017.

⁵ Roninson declares “that inhibitors of CDK8/19 already existed and had been publicly disclosed by . . . [Appellant] and by others” (Roninson Decl. ¶ 4; *see generally* Spec. 9–13 and 18).

(Br. 2–3; *see* Roninson Decl. ¶¶ 3–4). Roninson declares that, although Appellant used Senexin B to test its hypothesis, it “could have used any other specific inhibitor of CDK8/19 and obtained the same result” (Roninson Decl. ¶ 3). Thus, Appellant contends that “the record supports that any other specific inhibitor of CDK8/19 would work in the method according to the invention, and this fact remains unrebutted” (Br. 3; *see also* Roninson Decl. ¶ 3 (Roninson declares that Appellant “could have used any other specific inhibitor of CDK8/19 and obtained the same result”)).

Examiner acknowledged Appellant’s contention that specific inhibitors of CDK8/19 existed in the art, publicly disclosed by Appellant and others, prior to Appellant’s claimed invention (Ans. 9). Nonetheless, looking no further than to three patents commonly assigned to the real party in interest on this record, Examiner found that the prior art “disclose[d] only a variation of . . . [Appellant’s] lead compound, Senexin B (also called SNX2-1-165), and its amino quinazoline structural core” (Ans. 9). Thus, Examiner found that because Appellant used Senexin B to test its hypothesis that specific CDK8/19 inhibitors would be effective against breast cancer, this “single data point of a CDK8/19 inhibitor (Senexin B) for treating breast cancer does not render all CDK8/19 inhibitors enabled for treating or preventing breast cancer” (Ans. 9–10). We are not persuaded.

The first paragraph of 35 U.S.C. § 112 “requires a ‘written description of the invention.’” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). To comply with the written description requirement, the Specification must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the invention.” *Id.* at 1563–64. In addition, “[t]he ‘written description’

requirement must be applied in the context of the particular invention and the state of the knowledge. . . . As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.” *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005).

On this record, Examiner’s focus on Appellant’s own work, as discussed above, failed to establish an evidentiary basis to support a finding that the prior art, as a whole, is limited to only those specific inhibitors of CDK8/19 that are a variation of Appellant’s lead compound, Senexin B, and its amino quinazoline structural core (*see* Ans. 9; *cf.* Roninson Decl. ¶ 4; Br. 3 (citing a number of U.S. Patents and other documents to support Appellant’s contention that “the state of the prior art regarding specific inhibitors of CDK8/19 is not very limited, but is in fact, rather extensive”)). Examiner further failed to establish an evidentiary basis on this record to support a finding that those of ordinary skill in this art would have reasonably expected that other specific inhibitors of CDK8/19 would not work in the methods of Appellant’s claimed invention (*see generally* Ans. 9–10; *cf.* Br. 3 (Appellant contends that “the record supports that any other specific inhibitor of CDK8/19 would work in the method according to the invention, and this fact remains unrebutted”); *see* Roninson Decl. ¶ 3 (Roninson declares that Appellant “could have used any other specific inhibitor of CDK8/19 and obtained the same result”)).

For the foregoing reasons, we find that the weight of the evidence on this record weighs in favor of Appellant.

CONCLUSION

The preponderance of evidence on this record fails to support Examiner’s finding that Appellant’s Specification fails to provide written

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descriptive support for the claimed invention. The rejection of claims 42, 44, 45, and 49 under the written description provision of 35 U.S.C. § 112, first paragraph is reversed.

DECISION SUMMARY

In summary:

| Claims Rejected | 35 U.S.C. § | Reference(s)/Basis | Affirmed | Reversed |
|------------------------|--------------------|---------------------------|-----------------|-----------------|
| 42, 44, 45, 49 | 112(a) | Written Description | | 42, 44, 45, 49 |

REVERSED