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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

YUK-MING DENNIS **LO**, ROSSA WAI KWUN CHIU, and
KWAN CHEE CHAN
Junior Party
(Application 12/178,181; 13/070,240; 12/614,350; and 13/070,251),

v.

STEPHEN **QUAKE** and HEI-MUN CHRISTINA FAN
Senior Party
(Application 12/393,833).

Patent Interference No. 105,923 (DK)
(Technology Center 1600)

Decision on Request for Rehearing

37 C.F.R. § 41.125(c)

Before, SALLY GARDNER LANE, JAMES T. MOORE, and
DEBORAH KATZ, *Administrative Patent Judges*.¹

KATZ, *Administrative Patent Judge*.

¹ Judge Richard E. Schafer is not available for this decision.

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Quake requests rehearing of the Decision on Remand (Paper 246 (“Decision”)) in this proceeding. (*See* Quake Request for Rehearing (“Request”), Paper 248.) To prevail, Quake must identify, with specificity, both the matters believed to have been misapprehended or overlooked and the place where the matters were previously addressed in a motion, opposition, or reply. (*See* 37 C.F.R. § 41.125(c)(3).)

The Decision held that the claims of Quake’s involved application 12/393,833 (“the ’833 application”) lacks sufficient written description support under 35 U.S.C. § 112, first paragraph and, thus, granted Lo Motion 1. (*See* Decision, Paper 246, at 3:19–17:19.)

Quake argues that the Decision overlooked testimony by Lo’s witness, Dr. Stacy Bolk Gabriel, Ph.D., regarding the knowledge in the art at the time of Quake’s filing, including alleged admissions showing that the Quake specification adequately describes the invention of the Count. (Request, Paper 248, at 1:2–8.) According to Quake,

there is testimony in the record that methods were well-known at the time the ’686 application^[2] was filed that utilized sequence/statistical analyses on individually sequenced samples, and that those methods would have been equally applicable to the sequence data obtained in Quake’s sequenced mixed sample.

²The ’833 application involved in this interference is a continuation of application 11/701,686 (“the ’686 application”). Upon declaration, Quake was accorded the benefit of the filing date of the ’686 application as a constructive reduction to practice of the Count. (*See* Declaration, Paper 1, at 6:10–11.)

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(*See* Request, Paper 248, at 6:9–13.) We are not persuaded that such testimony indicates anything was overlooked or misapprehended or that the Decision should be modified.

The Decision was based on the finding that even if it would have been known how to use statistical methods to normalize the frequency of random sequence reads by the size of the chromosome, the '833 application does not describe doing so and, thus, does not describe methods requiring such normalization. (*See* Decision, Paper 246, at 16:25–17:3.) As explained in the Decision, the failure to describe normalization to chromosome size would have indicated to one of ordinary skill in the art that the inventors had not contemplated the methods of determining aneuploidy from massively parallel sequencing of randomly selected DNA fragments recited in Quake's claims and the Count. (*See* Decision, Paper 246, at 17:4-16.) Quake fails to direct us to evidence or argument we overlooked or misapprehended indicating that either normalization to chromosome size was described in the Quake specifications or that such analysis was not necessary to the methods recited in Quake's claims or the Count.

Quake argues that we overlooked portions of Dr. Gabriel's cross-examination testimony in Exhibit 2078. (*See* Request, Paper 248, at 8:26–9:15, citing Exh. 2078 at 73:22–74:18.) The cited portion was relied upon in Quake Reply 1 for an argument about the "t-test," which is a test used to determine statistical significance. (*See* Quake Reply 1, Paper 57, at 4:8–11.) Quake argues that Dr. Gabriel's testimony indicates one of skill in the art would have known how to use a t-test (or a "z-test") to determine the normal ratio and determine if the observed ratio was too

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high or too low relative to the norm. (*See* Request, Paper 248, at 8:26–9:32, citing Exh. 2078, at 73:22–74:18.)

The Decision addressed this portion of Dr. Gabriel’s testimony and found it to be unpersuasive. (*See* Decision, Paper 246, at 14:7–15:2.) As explained, Dr. Gabriel’s testimony does not indicate that the Quake specification discloses using the t- or z-test for normalization to chromosome size as required when using sequences from randomly selected DNA fragments.³ “[W]ritten description is about whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described; it is not about whether the patentee has proven to the skilled reader that the invention works, or how to make it work, which is an enablement issue.” *Alcon Research Ltd. v Barr Laboratories, Inc.*, 745 F.3d 1180, 1191 (Fed. Cir. 2014). Accordingly, this argument does not persuade us that the Decision overlooked anything indicating it should be modified.

Quake also argues that the Board improperly concluded that a specific portion of Dr. Gabriel’s statements on cross-examination was limited in scope to what was disclosed in the Lo Priority Statement. (*See* Request, Paper 248, at 8:20–25, citing Exh. 2078 at 34:13–35:9.) As explained in the Decision, Dr. Gabriel was

³ We note that the portion of Dr. Gabriel’s testimony cited by Quake was in response to questions about “predetermined target sequencing” not random sequencing. (*See* Exh. 2078 at 73:7–21 (“Q. Okay. The question was, the sentence that reads, ‘PCR reactants are added to each well to amplify at least predetermined target sequencing.’ And my question was: Why did you say, ‘at least two’? A. Because there's a test in the reference. Q. Okay. In multiplex PCR, are there more than two predetermined target sequences? A. There can be. Q. And multiplex PCR is disclosed in the '018 patent, isn't it? A. Where? Q. Look at column 12, lines 32 to 35. (Witness reviewing) A. Yes.”).)

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directed to Example 3 of Exhibit 2074 prior to the specific testimony highlighted by Quake. (*See* Exh. 2078, 30:17–31:8 (“So now going back to Exhibit 2074”); *see* Quake Exhibit List, Paper 239, at 4 (identifying Example 2074 as “Lo Priority Statement, as filed in Interference No. 105,924, on July 31, 2013”).) (*See* Decision, Paper 246, at 16:4–24.) She testified that Example 3 of Exhibit 2074 “actually says you've got to take into account the chromosome size of things you're comparing.” (*See* Exh. 2078, at 34:17–19.) Because Dr. Gabriel testified to what Exhibit 2074 “actually says,” we are not persuaded that it was an error in the Decision to determine that the testimony was limited to that document. Quake does not explain what was overlooked or misapprehended in the record of the interference by this determination. Nor does Quake point to similar testimony by Dr. Gabriel regarding that language of Quake’s specifications. Because the determination of whether there is sufficient written description support is made on the basis of what is described in the specification in question, we are not persuaded by Quake’s argument that the Decision should be modified. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (“the hallmark of written description is disclosure. . . . the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.”).

Quake also argues that paragraph 80 of Exhibit 2099, a declaration by Dr. Gabriel in the *inter partes* review of patent 8,195,415, was not considered in the Decision. (*See* Request, Paper 248, at 9:16–32.) In paragraph 80, Dr. Gabriel testifies that “a t-statistic is a statistical method known in the art.” (Exh. 2099, ¶ 80.) Dr. Gabriel also testifies that

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a person of ordinary skill in the art at the time of the invention of the '415 patent would have applied conventional statistical analyses, such as a t-test statistic, to the methods disclosed in *Lo II* with a reasonable expectation of success. A person of ordinary skill in the art would have been motivated to use the confidence intervals derived from t statistics when evaluating sequence tag density data to determine the disomy of chromosomes in a mixed sample.

(Exh. 2099, ¶ 80.) It is not clear how this statement is relevant to the issue of written description in the involved Quake specifications because patent 8,195,415 has a different specification and no prior applications in common with the involved '018 Quake patent. Furthermore, Quake fails to explain how this testimony indicates that the currently involved Quake specifications describe using statistical tests for normalization to chromosome size in order to determine aneuploidy from massively parallel sequencing of randomly selected fragments. The testimony appears to relate to the obviousness of claims from patent 8,195,415 over the prior art, but Quake has not explained how those claims or the prior art are relevant to the issue of written description or benefit in the current interference.

Quake argues further that we overlooked Dr. Gabriel's testimony in Exhibit 1076. (*See* Request, Paper 248, at 9:33–10:29.) Quake does not indicate where Exhibit 1076 was cited in its original briefs and we do not find any citation. If the testimony was not cited, we could not have overlooked it. Accordingly, we are not persuaded that the Decision should be modified in light of this testimony.

Quake also argues that

[i]n the related Quake patent that was the subject of Interference 105,922, normalization is done by counting sequence tags per 50kb bins. However, normalization could just as easily be performed by dividing sequence tag reads by chromosome length (number of bases) and using the t-test disclosed

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in the Quake specification to determine with statistical significance whether there were more sequence tags aligning to a chromosome suspected of being aneuploid than one believed to be euploid, as discussed by Dr. Gabriel above [in Exhibit 1076].

(Request, Paper 276, at 10:30–11:4 (footnote omitted).) This argument is unpersuasive because Interference 105,922 involved Quake patent 8,195,415, which, as explained above, is not related to the currently involved '018 Quake patent involved in this interference. Whether or not “normalization could just as easily be performed by” a method does not indicate that the method is described sufficiently in the Quake specifications. *See Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (“The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.”). Quake’s argument fails to persuade us that the Decision should be modified.

Quake also refers to the testimony of its own witness, Dr. Detter, in its Request. (*See* Request, Paper 248, at 6:14–28, citing Exh. 2049, at ¶ 151, and at 7:30–34, citing Exh. 2082 at ¶¶ 28–37.) Quake does not argue that we overlooked or misapprehended this testimony, though we note that paragraph 151 of Dr. Detter’s first declaration (Exh. 2049) was not cited in the Decision. In paragraph 151, Dr. Detter states that certain portions of the '686 application, including paragraphs 104 and 141–149, support step (d) of the Count, which recites using the data obtained in the other steps to compare the amounts of identified chromosomes and determine the presence or absence of fetal aneuploidy. Dr. Detter does not

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explain how normalization is described in the specification, beyond a conclusory statement. Dr. Detter testifies that “[t]hese paragraphs describe the concept of counting chromosomes, normalization and using statistical significance to determine the presence or absence of a fetal aneuploidy” (Exh. 2049, ¶ 151), but does not discuss normalization any further. Accordingly, even if this paragraph of Dr. Detter’s declaration was not cited in the Decision, it does not persuade us that the Decision should be modified.

Paragraph 29 of Dr. Detter’s second declaration (Exh. 2082) was cited in the Decision. (*See* Decision, Paper 246, at 14:10–17.) It was not persuasive because it refers to Dr. Gabriel’s testimony about statistical methods in general, not the disclosures of the ’833 application. (*See id.*) As explained above, discussion of the t-test does not persuade us that the method of Quake’s claims or the Count was sufficiently described in Quake’s specifications.

Because Quake has failed to persuade us that the Decision should be modified, Quake’s request for rehearing is DENIED.

Quake’s request for a contingent motion

In an e-mail sent on 19 January 2018 to the Board, Quake requested a conference call to discuss authorization to file a contingent motion for reopening the record in this interference. (*See* Appendix.) Specifically, Quake requests that Dr. Gabriel’s testimony during the prior civil action under 35 U.S.C. § 146 be added to the record of this proceeding. (*See id.*) Quake previously requested additional briefing in light of information and evidence developed during discovery in the intervening 35 U.S.C. § 146 action that was asserted to be relevant to the

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issues on remand. (*See* Order – New Briefing and Evidence, Paper 244, at 2–3.) A conference call was not considered to be necessary.

Information obtained during the § 146 action was not considered by the Federal Circuit, which held that the district court did not have subject matter jurisdiction to review the Board's interference decisions in the § 146 proceeding because the America Invents Act abolished the rights of parties to bring such actions. *See Bd. of Trustees of Leland Stanford Junior Univ. v. Chinese Univ. of Hong Kong*, 860 F.3d 1367, 1374 (Fed. Cir. 2017). The Federal Circuit also determined that “the activities in the district court are a nullity when the district court lacks subject matter jurisdiction to consider a matter.” *Id.*

Quake’s request to present additional briefing and evidence on the remand of this interference to the Board was denied in light of the court’s decision and because Quake did not show that it lacked an opportunity to present evidence during the interference before the Board or that the arguments and evidence originally presented were incomplete. (*See* Order – New Briefing and Evidence, Paper 244.) Quake did not request rehearing of that decision.

In the current request, Quake asserts that the Board’s interpretation of Dr. Gabriel’s testimony regarding Lo’s Priority Statement (Exh. 2074) was incorrectly limited to the context of that document and that Dr. Gabriel’s testimony during the § 146 action would “remove any doubt that her statements regarding the skill in the art were general and not limited in that manner.” (*See* Appendix.) As explained above, Quake has not persuaded us that there was any error in the determinations made about Dr. Gabriel’s testimony regarding Lo’s Priority Statement. We are not persuaded that testimony about the skill in the art, beyond

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the evidence Quake has already presented on that issue, will shed sufficient further light on whether the disclosures in Quake's involved specifications provide sufficient written description as to warrant re-opening these proceedings when each party has had its chance to place evidence in the record.

Quake asserted that it would be a denial of due process to not reopen the record to add Dr. Gabriel's testimony. (*See Appendix.*) Because Quake has failed to show why it did not have a full and fair opportunity to present evidence and argument with its original briefs, including from the cross-examination of Dr. Gabriel conducted during the interference, it is not clear what due process was denied.

Accordingly, Quake's request for authorization to file a contingent motion is DENIED.

cc (via electronic delivery):

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