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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STEPHEN **QUAKE** and HEI-MUN CHRISTINA FAN
Junior Party
(Patent 8,008,018),

v.

YUK-MING DENNIS **LO**, ROSSA WAI KWUN CHIU,
and KWAN CHEE CHAN
Senior Party

(Application 13/070,275).

Patent Interference No. 105,920 (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*.

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

Quake requests rehearing of the Decision on Remand (Paper 273 ("Decision")) in this proceeding. (*See* Quake Request for Rehearing ("Request"), Paper 276.) 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 patent 8,008,018 ("the '018 patent") lack sufficient written description support under 35 U.S.C. § 112, first paragraph and, thus, granted Lo Motion 1. (*See* Decision, Paper 273, at 3:13–17:10.) In addition, the Decision held that neither of Quake's earlier applications 11/701,686 ("the '686 application") and 60/764,420 provides a sufficient written description of the Count and, thus, denied Quake Motion 1. (*See* Decision, Paper 273, at 17:11–21:5.)

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 276, at 1:2–8.) According to Quake,

> there is testimony in the record that methods were well-known at the time the '686 application 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.

(*See* Request, Paper 276, at 6:3–8.) 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 '018 patent does not describe doing so and, thus, does not describe methods requiring such normalization. (*See* Decision, Paper 273, at 16:15–18.) 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 273, at 16:18–17:6.) 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 276, at 8:18–9:7, 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 81, at 5:1–4.) 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

high or too low relative to the norm. (*See* Request, Paper 276, at 8:18–9:7, 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 258, at 14:4–16.) 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.[2] "[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 276, at 8:12–17, citing Exh. 2078 at 34:13–35:9.) As explained in the Decision, Dr. Gabriel was

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[2] 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.").)

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 265, at 4 (identifying Example 2074 as "Lo Priority Statement, as filed in Interference No. 105,924, on July 31, 2013").) (*See* Decision, Paper 273, at 15:17–16:14.) 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 276, at 8:12–17.) 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

> 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 276, at 9:25–10:21.) 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

> 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 10:22–11:2 (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 276, at 6:9–23, citing Exh. 2049, at ¶ 151, and 7:22–26, citing Exh. 2082 at ¶¶ 28–37.) Quake does not argue that we overlooked or misapprehended this testimony, though we note that the specific portions of Dr. Detter's testimony cited by Quake (Exh. 2049 ¶ 151 and Exh. 2082 ¶¶ 28–37) were not cited in the Decision. The Decision did cite paragraph 100 of Dr. Detter's declaration (Exh. 2049), which is similar to paragraph 151. In both paragraphs 100 and 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. In neither paragraph 100 nor 159, though, does Dr. Detter 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. As explained in the Decision, "Quake cites to the testimony of Dr. Detter in support of its argument [that paragraphs 27, 59, 95, 99, 104, and 141-149 of the '686 application support step d of the Count], but neither Quake nor Dr. Detter explain how these paragraphs support the element of the Count." (Decision, Paper 273, at 19:9–17.)

In regard to Dr. Detter's second declaration, Exhibit 2082, paragraphs 28–37, cited in Quake's Request (*see* Paper 276 at 7:22–26), 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 issues on remand. (*See* Order – New Briefing and Evidence, Paper 271, 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 271.) 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 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 contigent motion is DENIED.

cc (via electronic delivery):

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Interference 105,920

Appendix

From: Danny Huntington [mailto:dhuntington@rothwellfigg.com]
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Subject: Interference Nos. 105,920 (DK); 105,923 (DK); and 105,924 (DK) - Quake request for a telephone conference to request permission to file a contingent motion to reopen the record

In connection with preparing a Request for Rehearing in the above-identified interferences, party Quake has concluded that the Board's interpretation of admissions made by Lo's expert, Dr. Gabriel, concerning the knowledge of those skilled in the art, was incorrectly limited to the context of Lo's Priority Statement. Specifically, party Quake submits that Dr. Gabriel's testimony in the 146 action removes any doubt that her statements regarding the skill in the art were general and not limited in that manner.

Counsel for party Quake would like permission to immediately file a contingent motion to reopen the record if party Quake's Requests for Rehearing are denied. That motion would explain why it would be a denial of due process if the record is not reopened to add the testimony of Dr. Gabriel on this issue developed during discovery in the intervening 35 USC 146 so that it may be considered by the Board.

Counsel for party Lo has been contacted and indicated that they will oppose party Quake's request to file this contingent motion. Party Lo will oppose the motion if authorized at least because the Board has already considered a request to reopen the record in these interferences and exercised the discretion it was afforded by the Federal Circuit, and denied that request noting that neither party argued to the Board or the Federal Circuit that it lacked an opportunity to present evidence to the Board during the interferences, and because Quake failed to timely file a request for rehearing of the Board's December 12, 2017, decision to not reopen the record.

Counsel for the Parties have conferred and are available for a telephone conference at the convenience of the Board on any day other than Monday through Wednesday, January 22-24, 2018.

Respectfully submitted,
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