UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTEGRATED DNA TECHNOLOGIES, INC.,
Petitioner

v.

TECAN GENOMICS, INC.,
Patent Owner

IPR2024-01502

U.S. Patent No. 9,546,399

PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW

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Patent Owner Tecan Genomics Inc. ("Tecan") requests Director Review of the Institution Decision, which granted Petitioner Integrated DNA Technologies, Inc.'s ("IDT") petition.[1] The Panel's decision is ripe for Director Review for two independent reasons. First, the Panel's decision raises important issues of law and policy, as it raises several issues regarding denial of petitions outlined in Acting Director Stewarts' recent comments on workload management and considerations for discretionary denial. Second, the Panel abused its discretion, misapplied the law, and adopted erroneous findings of fact in rejecting Tecan's discretionary denial arguments and finding that IDT had met its burden for institution here.

While this proceeding does not fall within the procedures for additional briefing outlined in Acting Director Stewart's March 26 Interim Procedures for PTAB Workload Management Memorandum ("March 26 Memo"), several of the considerations set forth in that memo are relevant here. Specifically, the Panel's decision raises issues regarding (1) whether the PTAB or another forum has already adjudicated the validity or patentability of the challenged patent claims, (2) the strength of the unpatentability challenge; and (3) the extent of the petition's reliance on expert testimony. *Id*. Institution of this proceeding contradicts the Board's policy

[1] The Panel also granted institution in IPR2024-01504 and 1506 for substantially the same reasons, and Tecan is filing parallel requests in those proceedings.

directives. The institution decision reduces PTAB efficiency because it adds to the burdens of the PTAB and unduly burdens Tecan.

Additionally, IDT's petition relies on references with the same gaps as the ones that were rejected during prosecution. The Panel's consideration of the merits and rejection of Patent Owner's arguments for discretionary denial pursuant to § 325(d) was misplaced and based on its fundamental misunderstanding of the claims. Under the interpretation of the claims that both parties advanced, the Panel committed a factual error by concluding that Kivioja's use of gene position for duplicate identification was the same as using the actual nucleic acid fragment, instead of using a surrogate for the target sequence. Based on this error, the Panel also erred in determining that the examiner committed a material error by not considering Kivioja during prosecution.

Tecan requests that the Director (1) grant Review of the Institution Decision, (2) vacate the Panel's decision granting institution, and (3) deny the petition.

I. The Panel's Institution Decision Conflicts With Important Policy Directives

In the March 26 Memo, the Acting Director articulated concerns that the Board should consider in determining whether to use its discretion to deny a petition. In line with prior policies, the March 26 Memo expanded the scope of issues that could be raised for consideration. Several of those issues are relevant to and strongly

favor denial of the Petition, and Tecan asks the Director to consider those issues now.

A. Parallel Litigation Results in a Waste of Judicial and Party Resources

As explained in the Petition and Preliminary Response, the parties are involved in parallel litigation. *Tecan Genomics, Inc. v. Invitae Corp., et al.*, C.A. No. 23-cv-1114-GBW (D. Del.). Tecan also asserted patents in the same family against another defendant, QIAGEN. *Tecan Genomics, Inc. v QIAGEN Sciences, LLC et al*, 1:23-cv-01115-GBW (D. Del.). IDT filed this petition along with four other IPR petitions days before the statutory deadline, despite the ongoing litigation and exchange of initial contentions and discovery. *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc*., IPR2024-1502, Paper 1 (PTAB Sept. 30, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc*., IPR2024-1504, Paper 1 (PTAB Sept. 30, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc*., IPR2024-1506, Paper 1 (PTAB Sept. 30, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc*., IPR2025-0016, Paper (PTAB Oct. 4, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc*., IPR2025-00015, Paper 1 (PTAB Oct. 4, 2024). IDT's petitions were immediately followed by another four IPR petitions filed by QIAGEN targeting four of the same five patents. *QIAGEN Sciences, LLC v. Tecan Genomics, Inc*., IPR2025-0026, Paper 2 (PTAB Oct. 10, 2024); *QIAGEN Sciences, LLC v. Tecan Genomics, Inc*., IPR2025-0027, Paper 2

(PTAB Oct. 10, 2024); *QIAGEN Sciences, LLC v. Tecan Genomics, Inc*., IPR2025-0028, Paper 2 (PTAB Oct. 10, 2024); *QIAGEN Sciences, LLC v. Tecan Genomics, Inc*., IPR2025-0029, Paper 2 (PTAB Oct. 10, 2024).

IDT has sought to stay its litigation, but QIAGEN has not. As of this filing, both the Board and a District Court will be considering overlapping issues related to the validity of the challenged patent. This is a waste of judicial resources because the District Court will need to consider the same issues as the ones before this Board, regardless of whether a stay is granted in the litigation against IDT. Therefore, the Board should exercise its discretion and deny IDT's petition.

Additionally, the Board should, at least, take into consideration that both IDT and QIAGEN have filed petitions challenging the same patent. Compare *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc*., IPR2024-1504, Paper 1 (PTAB Sept. 30, 2024) to *QIAGEN Sciences, LLC v. Tecan Genomics, Inc*., IPR2025-0026, Paper 2 (PTAB Oct. 10, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc*., IPR2024-1506, Paper 1 (PTAB Sept. 30, 2024) to *QIAGEN Sciences, LLC v. Tecan Genomics, Inc*., IPR2025-0027, Paper 2 (PTAB Oct. 10, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc*., IPR2025-0016, Paper (PTAB Oct. 4, 2024) to *QIAGEN Sciences, LLC v. Tecan Genomics, Inc*., IPR2025-0029, Paper 2 (PTAB Oct. 10, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc*., IPR2025-00015, Paper 1 (PTAB Oct. 4, 2024) to *QIAGEN*

Sciences, LLC v. Tecan Genomics, Inc., IPR2025-0028, Paper 2 (PTAB Oct. 10, 2024). The Board has repeatedly confirmed that multiple, parallel petitions can lead to undue burden on patent owners. CONSOLIDATED TRIAL PRACTICE GUIDE at 59 ("Two or more petitions filed against the same patent at or about the same time (e.g., before the first preliminary response by the patent owner) may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns. *See* 35 U.S.C. § 316(b)."). In addition, the Board has stressed that "multiple petitions by a petitioner are not necessary in the vast majority of cases." *Id*. These parties circumvented the rules cautioning against multiple petitions and avoided having to justify why multiple petitions are necessary here. Nothing about the challenged claims here require multiple petitions. The petitioners challenging these patents—IDT and QIAGEN—should not be permitted to game the PTAB process and unduly burden the Board and Tecan.

B. Petition Relies Extensively on Unsupported Expert Testimony

As stated in the March 26 Memo, the Board should consider the "extent of the petition's reliance on expert testimony." March 26 Memo at 2. Specifically, the Board's FAQs state: "While the Board may consider expert testimony, as a matter of efficiency, extensive reliance on expert testimony and/or reasonable disputes between experts on dispositive issues may suggest that the questions are better resolved in an Article III court." FAQ 21, *FAQs for Interim Processes for PTAB*

Workload Management, https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management (last accessed May 5, 2025). Here, as highlighted in the Preliminary Response, IDT relied extensively on the testimony of Dr. Peter Sims to support its petition. Yet Dr. Sims' testimony regarding the key elements of IDT's arguments is largely unsupported.

For example, IDT and the Panel relied on paragraphs 248, 276, and 277 of the Sims Declaration to support their understanding as to whether Kivioja relied on the nucleic acid fragment to determine duplicate sequencing reads. *See* Institution Decision at 27. But Dr. Sims fails to offer any support for the positions espoused in those paragraphs. Instead, Dr. Sims claims that "Kivioja described a method of using the molecular tag and sequence of the nucleic acid fragment to determine whether particular sequence reads were unique or PCR duplicates," Ex. 1079, ¶ 248, yet Dr. Sims does not explain his position. He instead focuses on how Kivioja described a method of using gene positioning—not the sequence of the nucleic acid fragment. Dr. Sims provides no explanation or support for his claim that "[t]he POSA would have understood [gene mapping] to mean that Kivioja used the 'nucleic acid fragment' to help determine a duplicate sequencing read." *See id.*, ¶ 276. Dr. Sims claims that Kivioja disclosed "mapping the entire fragment sequence to the genome" without identifying any such disclosure (for which there is none). *Id.*, ¶ 277.

IDT also relied on expert ipse dixit in arguing that a POSA would have been motivated to combine Iafrate and Kivioja in the specific manner of the claimed inventions. *See, e.g.*, Petition at 36. Dr. Sims offers no explanation or support as to why a POSA would have sought to optimize the molecular tag used in Kivioja "to a lower number." The Panel erred by dismissing this lack of support, explaining only that "Dr. Sims's testimony is consistent with the teaching in Iafrate that the amount of starting nucleic acid material may vary." Institution Decision at 31. Such a conclusion is insufficient to establish a likelihood of success as to at least one claim. Neither IDT nor the Panel explains why a POSA would be motivated to identify and optimize the length of the tag in Kivioja by reducing the number of nucleotides. This extensive reliance on expert testimony is the precise situation that the Board identified as being better resolved in district court. Therefore, the petition should be denied.

C. The Arguments Advanced in the Petition are Weak

The Panel's institution decision focused on only one of the three grounds asserted in the petition. As explained further below, the Panel erred in its analysis of the record in finding that all elements of the challenged claims are disclosed in the prior art. The Panel also glossed over the unsupported expert testimony and the scant evidence of the person of ordinary skill's motivation to combine and expectation of success. Further, even the Panel seemed to doubt Grounds 2 and 3,

going so far as to suggest that the parties further develop the issues at trial. Taken as a whole, the lack of strength of the challenge weighs in favor of the Board exercising its discretion to deny the petition.

II. The Panel Relied on Erroneous Findings of Fact and Abused Its Discretion

The Panel's assessment of the merits of the Petition and Tecan's discretionary denial arguments pursuant to § 325(d) is based on a fundamental misunderstanding of the parties' arguments and is based almost exclusively on unsupported, and unscrutinized, conclusions by IDT's expert.

Critically, the Panel analyzed an interpretation of the claims that neither party advanced, in essence rewriting the petition it was tasked with assessing. The Panel stated that "[a]ll that the claim requires is that the method identifies a duplicate sequencing read, where the sequencing read has the same identifier site and nucleic acid as another." Institution Decision at 26-27. But neither party advocated for that interpretation. Both parties' arguments are based on an interpretation of the claims where the step of identifying duplicates includes the use of both the identifier site and at least a portion of the target sequence. *See, e.g.*, Petition at 63 ("Thus, in both Example 1 and Example 3, Bielas identified duplicate sequencing reads by using the Cypher/identifier site and fragment sequence"); POPR at 1 ("As explained in more detail below, none of the cited prior art discloses or teaches using both an identifier site and at least a portion of the target sequence to identify duplicate reads in a DNA

sequencing method"). The Panel's decision is based on an argument not raised in the petition and not addressed by Patent Owner, and therefore, should be reversed for that reason alone.

Going further, however, the Panel's misinterpretation of claim 1 also led to an incorrect conclusion that Kivioja disclosed the use of an identifier site and a portion of the target nucleic acid sequence in the process of identifying duplicates. *See* Institution Decision at 26-28. The Panel's decision did not engage with the arguments actually presented in the papers. Tecan's position is that Kivioja only discusses the target sequence in a step that is ***separate*** from the process of identifying duplicates. POPR at 12. Despite this, the petition argued that Kivioja's reference to "gene" and "gene position" is sufficient to establish that Kivioja used the target sequence in the process of identifying duplicates. *See* Institution Decision at 26. Petitioner relied solely on its expert's unsupported assumptions to fill in the gaps regarding what this would mean to a POSA. The Panel failed to analyze these issues or whether Kivioja discloses the key limitation of claim 1 that the parties advanced: whether using a surrogate for the target sequence is sufficient enough to satisfy a process for identifying duplicate reads that uses both an identifier site and at least a portion of the target sequence.

As explained in the Preliminary Response, Kivioja fails to use at least a portion of the target sequence in the process of identifying duplicate reads. POPR

at 11-12. At best, Kivioja discloses the use of the identity of the gene and/or the gene position as a replacement for actually using the target sequence, which is not enough to satisfy the claim language, which requires that at least a part of the target sequence be used with the identifier sequence to identify duplicate sequence reads. *Id.* at 12-13. The Panel erred by failing to make any finding about whether the use of some other information as a surrogate for a portion of the target sequence is sufficient to disclose this element of claim 1. Instead, the Panel simply repeated or rewrote Petitioner's argument without any response or weighing of the issues. For example, it concluded, without addressing Tecan's position, that "[w]hen Kivioja states that reads with the same label were collected to one UMI, we understand that to mean that the labels have identical sequences." Institution Decision at 26 (cleaned up). The Panel provided no explanation as to how it reached that understanding that the same label must mean the identical sequence. *See id.*

As explained above, the Panel relied on unsupported expert testimony to support its statement that it understood "Kivioja to mean that the mapped position was based on the gene sequence." Institution Decision at 27. The Panel failed to meaningfully consider Patent Owner's point that "Kivioja describes only looking to the 'gene, position, and label' (i.e., the proposed chromosomal location of the original genomic sequence, the proposed mapped location of the target sequence in the reference genome, and the UMI) of mapped reads when collecting sequencing

reads. EX1012.005. ***Kivioja does not disclose, and Petitioner does not explain, when or how the gene sequence is used in Kivioja's method***." POPR at 12 (emphasis added). Despite expressing uncertainty with when and how the gene sequence is used in the Kivioja method (e.g., "[o]n this record, we cannot rule out that some additional sequences mapped to the same position even if they did not have an identical sequence"), the Panel failed to resolve the critical disputed issue: when or how the gene sequence is used in Kivioja's method and whether it is used during the process of identifying duplicates.

These errors are compounded in the Panel's analysis of Tecan's arguments for discretionary denial pursuant to § 325(d). As explained in the Preliminary Response, the references cited in the Petition suffer from the same failures as the references cited by the examiner during prosecution. POPR at 22. Namely, all of the references cited during prosecution failed to disclose a method of identifying duplicate reads using ***both*** an identifier site and at least a portion of the target sequence. *See id.* at 26. The institution decision relied on its erroneous finding that Kivioja discloses this element in rejecting Tecan's discretionary denial arguments.

In addition, the Panel's erroneous reliance on Dr. Sims' unsupported testimony extends to its assessment of the motivation to combine. Institution Decision at 29-31. In essence, the Panel relied on one conclusory statement and expert ipse dixit without further consideration. Simply because a reference says it

can generally improve NGS technology does not mean that a POSA would have had a motivation to combine the specific references. *See id.* at 29. Nor did the Panel provide any meaningful response as to why the alternative identification means in Iafrate would necessarily be replaced by the disclosure in Kivioja. *Id*. at 30-31. Although Petitioner failed to "explain why a POSA looking to improve the method of identifying genetic mutations in Iafrate would look to aspects of Kivioja," the Panel erred by instead flipping the burden of proof on its head to require Patent Owner to make a showing as to why a POSA would not be motivated to combine Iafrate and Kivioja. *See* Institution Decision at 30 ("Patent Owner argues that Iafrate is concerned with cancer mutations whereas Kivioja is concerned with karyotyping. *Id.* at 15-16. However, Patent Owner does not explain why Iafrate's method of identifying cancer mutations would not benefit from an increase in accuracy using Kivioja's method."). That is not the correct legal standard. Petitioner bears the burden of demonstrating a motivation to combine—not the other way around. *See TQ Delta, LLC v. Cisco Sys.*, 942 F.3d 1352, 1357 (Fed. Cir. 2019) (reversing Board finding of motivation to combine where petitioner proffered conclusory testimony and failed to satisfy its burden of proof). The Panel erred by accepting one cursory statement from Kivioja as enough to support a motivation to combine, and the Panel's opinion is again based on unsupported expert testimony to the final issue. *Id.* at 31. The Director has indicated that such issues are not ripe for IPR, yet the

Panel has done the exact opposite here. As a result, Tecan asks the Director to review the Institution Decision and deny the petition.

III. Conclusion

For the foregoing reasons, Tecan respectfully requests that the Director (1) grant Review of the Institution Decision, (2) vacate the Panel's decision granting institution, and (3) deny the petition.

Date: May 5, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH PAGE LIMITS

I hereby certify that Patent Owner's Request for Director Review complies with the page-count limitation because it does not exceed fifteen pages, excluding the parts of the document exempted by 37 C.F.R. § 42.24(a).

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