

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTEGRATED DNA TECHNOLOGIES, INC.,
Petitioner

v.

TECAN GENOMICS, INC.,
Patent Owner

IPR2025-00016

U.S. Patent No. 10,876,108

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 and adopted erroneous findings of fact in finding that IDT had met its burden for institution here.

Acting Director Stewart’s March 26 Interim Procedures for PTAB Workload Management Memorandum (“March 26 Memo”) identified several considerations that are relevant to the petition filed in this case and should be considered on Director Review. Specifically, the Panel’s decision raises issues regarding the extent of the Petition’s reliance on expert testimony and the strength of the unpatentability challenge. *Id.* Institution of this proceeding contradicts the Board’s stated policy directives. Further, multiple petitions have been filed against the same patents, contrary to the Board’s guidance that multiple petitions create inefficiencies and

¹ The Panel also granted institution in IPR2025-00015 for substantially the same reasons, and Tecan is filing a parallel request in that proceeding.

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

Separately, the Panel's decision includes several erroneous findings of material facts and law. The Panel relied on the flawed testimony of IDT's expert witness, Dr. Sims, despite acknowledging that the underpinnings of Dr. Sims' analysis are incorrect. *See infra*, 3-5. The Panel incorrectly conflated increasing the accuracy of the output data obtained from a DNA sequencing computer (as described in IDT's primary reference) with amplifying the actual genetic material in the sample (as required by the claims). *See infra*, 8-9. The Panel ignored Patent Owner's arguments and expert testimony explaining why the amplification methods disclosed in Meyer could not result in the enrichment of the nucleic acid sequence of interest. *See infra*, 9-10. The Panel instead accepted Petitioner's assertions on their face, despite acknowledging that Tecan's expert provided testimony to the contrary. *See infra*, 11-12. Throughout its decision, the Panel ignored IDT's burden of proving a reasonable likelihood that at least one claim is invalid by refusing to consider the factual disputes and disregarding all of Patent Owner's factual challenges.

Tecan requests that the Director grant Review of the Institution Decision, vacate the Panel's decision granting institution, and 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 here, and Tecan asks the Director to consider those issues now.

A. The Petition Relies Extensively on Unsupported Expert Testimony

According to Acting Director Stewart, the Board should consider the “extent of the petition’s reliance on expert testimony” when determining whether to exercise discretion to deny a petition. 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 visited May 9, 2025). Here, the Institution Decision’s treatment of expert testimony conflicts with the explicitly stated Board policy.

As highlighted in the Preliminary Response, IDT relied extensively on the testimony of Dr. Peter Sims to support its petition. In response, Patent Owner

submitted testimony from its expert, Dr. Carlos Bustamante. In total, the parties submitted over 250 pages of expert testimony related to highly technical aspects of the prior art. For example, the experts offered conflicting testimony as to how to interpret the sequencing data disclosed in Meyer. Dr. Sims opined that the sequencing data demonstrated that the disclosed method was a selective enrichment method. *See, e.g.*, Ex. 1085, ¶ 145 (“Meyer et al. report that their selective enrichment method resulted in the specifically-targeted broken chain polyT sequence appearing in 16% of total reads, ‘slightly more than the expect[ed number of reads].’”). Dr. Bustamante challenged Dr. Sims’ interpretation of the data, explaining that the sequencing data reflected an improvement in the analysis method of the sequencer, not an enrichment of any specific nucleic acid fragments. *See, e.g.*, Ex. 2021, ¶ 130. Dr. Bustamante further provided several reasons as to why a POSA would not have relied on the stated data to determine whether Meyer disclosed a method of enrichment. *See id.*, ¶¶ 129-34. The Panel, however, did not make any credibility determinations with respect to the experts’ dispute over these material facts. Institution Decision at 19. Instead, the Panel acknowledged that the parties presented conflicting expert testimony involving “fact intensive issues better resolved after the parties fully develop the record during trial.” Institution Decision at 21.

These are precisely the circumstances that the Acting Director indicated are better deferred to an Article III court. Tecan asks the Director to exercise its discretion and deny the Petition so that an Article III court can fully vet the credibility of these expert witnesses.

B. Multiple Petitions Are Unjustified Here

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. 1:23-cv-1114-GBW (D. Del.). Tecan also asserted an overlapping set of patents against another defendant, QIAGEN. *Tecan Genomics, Inc. v. QIAGEN Sciences, LLC et al*, No. 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.*, IPR2024-01502, Paper 1 (PTAB Sept. 30, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc.*, IPR2024-01504, Paper 1 (PTAB Sept. 30, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc.*, IPR2024-01506, Paper 1 (PTAB Sept. 30, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc.*, IPR2025-00015, Paper 1 (PTAB Oct. 4, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc.*, IPR2025-00016, Paper 1 (PTAB Oct. 4, 2024). IDT's petitions were immediately followed by another four IPR petitions filed by QIAGEN on the statutory deadline. *QIAGEN*

Sciences, LLC v. Tecan Genomics, Inc., IPR2025-00026, Paper 2 (PTAB Oct. 10, 2024); *QIAGEN Sciences, LLC v. Tecan Genomics, Inc.*, IPR2025-00027, Paper 2 (PTAB Oct. 10, 2024); *QIAGEN Sciences, LLC v. Tecan Genomics, Inc.*, IPR2025-00028, Paper 2 (PTAB Oct. 10, 2024); *QIAGEN Sciences, LLC v. Tecan Genomics, Inc.*, IPR2025-00029, Paper 2 (PTAB Oct. 10, 2024).

Tecan requests that the Board take into consideration that both IDT and QIAGEN have filed petitions challenging the same patent. Compare *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc.*, IPR2024-01504, Paper 1 (PTAB Sept. 30, 2024) to *QIAGEN Sciences, LLC v. Tecan Genomics, Inc.*, IPR2025-00026, Paper 2 (PTAB Oct. 10, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc.*, IPR2024-01506, Paper 1 (PTAB Sept. 30, 2024) to *QIAGEN Sciences, LLC v. Tecan Genomics, Inc.*, IPR2025-00027, 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.*, IPR2025-00028, Paper 2 (PTAB Oct. 10, 2024); *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc.*, IPR2025-00016, Paper 1 (PTAB Oct. 4, 2024) to *QIAGEN Sciences, LLC v. Tecan Genomics, Inc.*, IPR2025-00029, 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 59 (2019) (“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. IDT and QIAGEN should not be permitted to game the PTAB process and unduly burden the Board and Tecan.

C. The Arguments Advanced in the Petition Are Weak

The Institution Decision focused on one of the four grounds asserted in the Petition—Ground 1, which argues that the claims are anticipated by Meyer. Ground 2 asserts that three dependent claims are obvious in light of Meyer alone, and Grounds 3-4 assert that certain dependent claims are obvious in light of Meyer combined with other references. IDT relies on Meyer for the disclosure of the elements of claim 1 in all of its asserted grounds. As explained in more detail below, the Panel erred in its analysis of the record in finding that all elements of the challenged claims are disclosed in the Meyer prior art reference. Critically, the Petition misconstrues Meyer in its arguments that Meyer disclosed a method of enrichment of a target sequence through amplification. As Dr. Bustamante

explained, Dr. Sims’ opinions regarding the prior art are flawed and seem to misapprehend the disclosure. *See, e.g.*, Ex. 2021, ¶¶ 109-35. The Petition rests on a single prior art reference that does not disclose or teach a method of enriching a target sequence through amplification, leaving all of IDT’s arguments without merit. 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 reached several material factual conclusions that are erroneous and internally inconsistent. The challenged claims are directed to a method that includes a step of “amplifying the ... oligonucleotide extension product ... *to enrich for the nucleic acid sequence of interest*” followed by a step of “sequencing the amplified products comprising the enriched nucleic acid sequence of interest.” Ex. 1001, 35:44-51 (emphasis added). The Panel construed the term “enrich” to have its plain meaning of “to process so as to add or increase the proportion of a desirable *ingredient*.” Institution Decision at 13 (emphasis added). The Panel also acknowledged “[t]arget enrichment was commonly used in genomic DNA sequencing to selectively capture genomic regions of interest from a DNA sample *before sequencing*” *Id.* at 5 (emphasis added); *see* POPR at 5-6, 13. Therefore, even under the Panel’s interpretation of the claims, the steps preceding sequencing (*i.e.*, the amplification step) require that the oligonucleotide with the target sequence

be enriched (increased in proportion) as compared to the rest of the oligonucleotides in the sample. The Panel, however, erroneously concluded that Meyer disclosed this element despite agreeing with Tecan that Meyer “is directed toward improving the error rate of sequencing reads.” Institution Decision at 19. The Panel’s error is based in the faulty conclusion that Meyer’s increase in the percentage of total reads observed in the sequencing data is equivalent to increasing the percentage of 3' end fragments physically present in the nucleic acid reaction mixture after amplification. *See id.*

Tecan expressly argued in its Preliminary Response that “the data reported by Meyer reflects a *perceived* decrease in sequencing artifacts caused by the 454 platform—it does not reflect the contents of the reaction mixture” and cited to the Bustamante Declaration. POPR at 29 (citing to Ex. 2021, ¶¶123-30) (emphasis added). Dr. Bustamante expressly noted that the increase in sequencing reads “does not mean that there are more sequences in the sequencing population than there might have otherwise been. It only means that more of the sequences already in that population are properly represented in the sequencing data. In other words, the relative population of the sequences remain the same.” Ex. 2021, ¶130. It was plain error for the Panel to conflate the sequencing reads with the number of fragments in the solution, especially based on the record before the Panel.

The Panel further failed to consider the evidence that Tecan presented explaining why the amplification processes in Meyer would not allow for enrichment of any target sequence. *See* POPR at 25-28; Institution Decision at 18-22. Dr. Bustamante explained in detail why the two methods disclosed in Meyer did not “disclose the use of specific primers during amplification to enrich for target sequences.” Ex. 2021, ¶¶118, 122. Instead, the Panel accepted the unsupported testimony of Dr. Sims, going so far as to acknowledge that Dr. Sims’ analysis was based on select information from two separate amplification schemes, but failing to consider the impact of the differences. Institution Decision at 20 (“Patent Owner is correct that the data reported in Meyer were generated using the method of Figure 1, whereas Petitioner relies on the method in Additional File 4 for its challenge.”).

Because of these material errors, the Panel reached the incorrect conclusion that there is a reasonable likelihood that a reference that discloses improving error rates associated with a mechanical issue caused during sequencing (Meyer) discloses all elements of the claimed method that requires that a target nucleic acid sequence is enriched through amplification. The Panel failed to meaningfully analyze Patent Owner’s evidence supporting why that conclusion is wrong. According to 37 CFR § 42.108(c), the Board’s institution decision must “take into account a patent owner preliminary response where such a response is filed, including any testimonial evidence.” 37 CFR § 42.108(c); PTAB Rules of Practice for Instituting on All

Challenged Patent Claims and All Grounds and Eliminating the Presumption at Institution Favoring Petitioner as to Testimonial Evidence, 85 Fed. Reg. 79,120 (Dec. 9, 2020). Here, however, the Panel seemingly followed the pre-2020 version of the regulations and viewed all disputed issues of fact in the light most favorable to Petitioner, akin to a motion to dismiss in district court. The Panel's Institution Decision reverses course on the Board's policies regarding Patent Owners' submission of expert testimony with their preliminary responses and significantly discourages the practice.

Despite Patent Owner providing evidence and expert testimony that demonstrated IDT's mistaken reliance on Meyer, the Panel required Patent Owner to prove its case while affording Petitioner all reasonable inferences. Petitioner bears the burden of establishing a reasonable likelihood that at least one claim is invalid; Patent Owner does not bear the burden of disproving the positions in the Petition in order to avoid institution. *See In re Magnum Oil Tool Int'l Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016) ("In an *inter partes* review, the burden of persuasion is on the petitioner to prove 'unpatentability by a preponderance of the evidence,' 35 U.S.C. § 316(e), and that burden never shifts to the patentee.") (internal citation omitted). The Panel abused its discretion by failing to meaningfully consider the record and by instituting the Petition despite it falling well below the required standard for institution. *See* Message from Chief Judge James Donald Smith,

<https://www.uspto.gov/patents/laws/america-invents-act-aia/message-chief-judge-james-donald-smith-board> (last visited May 9, 2025) (explaining that the “reasonable likelihood” standard for institution “allows for the exercise of discretion”). Deferring key factual disputes until trial—rather than engaging with them at the institution stage—is antithetical to the Board’s stated goal of promoting efficiency and runs counter to the explicit change in the regulations in 2020 regarding the treatment of pre-institution testimony. 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 grant Review of the Institution Decision, vacate the Panel’s decision granting institution, and deny the Petition.

Date: May 9, 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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CERTIFICATE OF SERVICE

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