

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

QIAGEN SCIENCES, LLC,
Petitioner,

v.

TECAN GENOMICS, INC.,
Patent Owner.

IPR2025-00028
U.S. Patent No. 10,036,012

PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW

TABLE OF CONTENTS

	Page
I. The Panel Abused its Discretion Under 35 U.S.C. § 325(d).....	2
II. The Panel’s Institution Decision Conflicts With Important Policy Directives	5
A. The Petition Relies Extensively on Unsupported Expert Testimony	6
B. Multiple Petitions Are Unjustified Here	8
C. The Arguments Advanced in the Petition Are Weak.....	12
III. The Panel Relied on Erroneous Findings of Fact and Abused Its Discretion in Finding that the Petitioner Met its Burden	13
IV. Conclusion	15

TABLE OF AUTHORITIES

Page(s)

Cases

<i>Advanced Bionics v. Med-El Elektromedizinische Geräte GmbH,</i> IPR2019-01469, Paper 6 (Feb. 13, 2020).....	2, 3, 5
<i>Ecto World, LLC v. RAI Strategic Holdings, Inc.,</i> IPR2024-01280, Paper 13 (May 19, 2025).....	5
<i>Raytheon Co. v. Sony Corp.,</i> 727 Fed. App'x 662 (Fed. Cir. 2018)	14

Statutes

35 U.S.C. § 316.....	10
35 U.S.C. § 325	1, 2, 3, 5

Other Authorities

37 C.F.R. § 42.108(c).....	7
85 Fed. Reg. 79,120 (Dec. 9, 2020)	8
CONSOLIDATED TRIAL PRACTICE GUIDE (2019).....	10, 11
<i>FAQs for Interim Processes for PTAB Workload Management</i>	6
MPEP § 2145	14
PTAB Workload Management Memorandum (March 26, 2025)	5, 6

Patent Owner Tecan Genomics, Inc. (“Tecan”) requests Director Review of the Institution Decision, which granted Petitioner QIAGEN Sciences, LLC’s (“QIAGEN”) petition.¹ The Panel’s decision is ripe for Director Review for three independent reasons.

First, Tecan respectfully submits that the Panel abused its discretion by instituting the Petition on substantially the same prior art and arguments as were previously before the Office. The Panel declined to exercise its discretion pursuant to § 325(d) based on an argument not raised in the Petition and failed to fully assess the Office’s prior determination.

Second, the Panel’s decision raises important issues of law and policy regarding denial of petitions as outlined in Acting Director Stewarts’ recent guidance on workload management and considerations for discretionary denial—specifically, the Petition relies heavily on expert testimony and the arguments in the Petition are weak. Further, multiple petitions have been filed against the same patent, contrary to the Board’s guidance that multiple petitions create inefficiencies and fairness concerns.

Third, the Panel also abused its discretion by making several erroneous

¹ The Panel also granted institution in IPR2025-00029 for substantially the same reasons, and Tecan is filing a parallel request in that proceeding.

findings of material fact in reaching its conclusions. The Panel failed to consider whether a POSA would have been motivated to modify Shapero's MARA method to arrive at the challenged claims and do so with a reasonable expectation of success. The Panel's decision instead considered only whether a POSA would have been generally motivated to use NGS technologies for genotyping instead of hybridization arrays. In doing so, the Panel failed to consider Tecan's arguments and expert testimony explaining why NGS would not have been considered compatible with prior art methods and that accuracy concerns would have discouraged a POSA from modifying Shapero's MARA method in the way Petitioner suggests.

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 Abused its Discretion Under 35 U.S.C. § 325(d)

The Petition should have been denied under Section 325(d) because it relies on substantially the same prior art as previously considered by the Office, and the Petition does not identify any material error.

The Panel failed to fully analyze the first prong of *Advanced Bionics*. It refused to confirm that all of the references cited in the Grounds are substantially the same as those addressed by the Examiner during prosecution. As explained in the Preliminary Response, the Delseny reference cited in the Petition is substantially the same as Tucker cited during prosecution, and Shapero in the Petition is substantially

the same as Jones cited during prosecution. POPR at 16-22. The Panel agreed with Tecan that “Petitioner’s reliance on Delseny does not materially differ from the Examiner’s reliance on Tucker.” Institution Decision at 14. The Panel also acknowledged that Shapero and Jones shared authors/co-inventors and that both Shapero and Jones taught the same target preparation method now relied on in the Petition. *See id.* at 8. Yet, the Panel declined to determine whether Shapero was cumulative of Jones. *Id.* at 15. As Tecan explained—and as Petitioner admits—Shapero discloses the same invention and is being applied by Petitioner in the same manner as the Examiner applied it during prosecution. POPR at 17-20; Petition at 1-2. It was an abuse of discretion for the Panel to institute the Petition without confirming that the first prong of *Advanced Bionics* is satisfied.

Turning to the second prong of the *Advanced Bionics* analysis, the Panel erred in both procedure and substance. It is Petitioner’s burden to “demonstrate[] that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (Feb. 13, 2020). Yet the Panel here did not assess whether Petitioner met its burden and instead *sua sponte* based its decision on an issue neither party raised. The Panel’s decision not to exercise discretion under § 325(d) is based entirely on its finding that the Examiner erred in relying on Dr. Brooks’ declaration during prosecution. The Panel concluded that it found “no persuasive evidence in

either Brooks Declaration or the Examiner’s analysis on the requisite nexus” between the secondary considerations raised during prosecution and the patented inventions. Institution Decision at 16. But the Panel’s conclusion is procedurally flawed. The Petition did not argue that the nexus between the Brooks Declaration and the challenged claims was lacking. *See* Petition at 38-43, 58-59. Without notice of this argument, Tecan was precluded from addressing this issue in its Preliminary Response and was denied an opportunity to be heard. This alone justifies Director Review of the Panel’s decision.

The Panel also erred by failing to consider the entirety of the prosecution history. The Panel seems to have relied solely on Dr. Brooks’ testimony regarding unexpected results, faulting the Examiner because there was no evidence of what Dr. Brooks considered the closest prior art and no evidence of an analysis of nexus to the claims. *See id.* at 16. But Dr. Brooks’ declaration addressed issues beyond unexpected results—issues that are relevant to the Examiner’s analysis. As Tecan explained, Dr. Brooks’ testimony was relevant to whether a person of ordinary skill would have had the motivation to modify the prior art with a reasonable expectation of success in doing so and to industry skepticism. POPR at 24-25. The Examiner acknowledged that the Brooks Declaration was “sufficient to overcome the rejections,” but as Tecan explained, there is no basis to assume that the Examiner’s allowance was based solely on unexpected results. *Id.* at 25. In fact, the Applicant

relied on Dr. Brooks’ “insights about the specificity of the claimed methods” to argue that the Examiner’s prior determinations with respect to motivation to combine and reasonable expectation of success were incorrect. *Id.* at 24-25. The Panel failed to consider all of the evidence that was before the Examiner, and therefore, erred in its assessment of Tecan’s § 325(d) arguments.

Considering the Brooks Declaration as a whole, Petitioner failed to show that “no reasonable examiner could have found otherwise.” *See Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 6 (May 19, 2025) (To show that an error is material, the “petitioner must demonstrate . . . that no reasonable examiner could have” arrived at the same conclusion.). Petitioner may disagree with the Examiner’s conclusion, but none of Petitioner’s arguments identify a material error by the Examiner. *Advanced Bionics*, IPR2019-01469, Paper 6 at 9 (“If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.”). The Panel’s incomplete and erroneous analysis of § 325(d) should be vacated and reversed.

II. The Panel’s Institution Decision Conflicts With Important Policy Directives

Acting Director Stewart’s March 26 Interim Procedures for PTAB Workload Management Memorandum (“March 26 Memo”) identified concerns that the Board should consider in determining whether to exercise its discretion to deny a petition.

In line with prior policies, the March 26 Memo expanded the scope of issues that could be considered. Several of those issues are relevant and strongly favor denial of the Petition. 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 28, 2025). Here, the Institution Decision’s treatment of expert testimony conflicts with that policy.

As highlighted in the Preliminary Response, QIAGEN relied extensively on the testimony of Dr. Michael Metzker to support its petition. In response, Tecan 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 whether a person of ordinary skill in the art would have been motivated to modify the MARA

method disclosed in Shapero to be used instead with a different sequencing technology. Dr. Metzker opined that a person of ordinary skill would have been motivated to combine the prior art as Petitioner suggests because of the teachings of Delseny and the experimental data reported in Shapero. *See, e.g.*, Ex. 1003, ¶¶ 159-63. Dr. Bustamante challenged Dr. Metzker on both points, making clear that the prior art references and Shapero’s experimental data would have taught away from modifying Shapero for use with NGS. *See, e.g.*, Ex. 2028, ¶¶ 144-71. The Panel, however, did not make any credibility determinations with respect to the experts’ dispute over these material facts and failed to consider the impact of unsupported claims on Dr. Metzker’s credibility. Institution Decision at 23-24. Instead, the Panel deferred these “fact intensive issues” until “after the parties fully develop the record during trial.” *Id.* at 25. 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.

Further, the Panel’s refusal to engage with the factual disputes between experts at the institution stage discourages patent owner submissions of expert testimony. According to the current version of 37 C.F.R. § 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 C.F.R.

§ 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, which provided that all disputed issues of fact should be viewed in the light most favorable to Petitioner, akin to a motion to dismiss in district court. The Institution Decision reverses course on Board’s policies that were meant to encourage patent owners to submit expert testimony with preliminary responses. 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. Tecan requests that the Director vacate the Panel’s decision and restore the policy positions encouraging Patent Owners to submit expert testimony with their Preliminary Responses.

B. Multiple Petitions Are Unjustified Here

Tecan requests that the Board take into consideration that both QIAGEN and Integrated DNA Technologies, Inc. (“IDT”) have filed petitions challenging the

same patents.² As explained in the Petition and Preliminary Response, the parties are involved in parallel litigation. *Tecan Genomics, Inc. v. QIAGEN Sciences, LLC et al*, No. 1:23-cv-01115-GBW (D. Del.). Tecan also asserted an overlapping set of patents against another defendant, IDT. *Tecan Genomics, Inc. v. Invitae Corp., et al.*, No. 1:23-cv-1114-GBW (D. Del.). QIAGEN filed this petition along with three other IPR petitions on the statutory 1-year deadline, despite the ongoing litigation and exchange of initial contentions and discovery substantially before this deadline. *QIAGEN Sciences, LLC v. Tecan Genomics, Inc.*, IPR2025-00026, Paper 2 (PTAB Oct. 10, 2024); IPR2025-00027, Paper 2 (PTAB Oct. 10, 2024); IPR2025-00028, Paper 2 (PTAB Oct. 10, 2024); IPR2025-00029, Paper 2 (PTAB Oct. 10, 2024). QIAGEN's petitions came on the heels of another five petitions that IDT separately filed a week before. *Integrated DNA Technologies, Inc. v. Tecan Genomics, Inc.*, IPR2024-01502, Paper 1 (PTAB Sept. 30, 2024); IPR2024-01504, Paper 1 (PTAB Sept. 30, 2024); IPR2024-01506, Paper 1 (PTAB Sept. 30, 2024); IPR2025-00015, Paper 1 (PTAB Oct. 4, 2024); IPR2025-00016, Paper 1 (PTAB Oct. 4, 2024).

² In addition to the errors identified by Tecan that are specific to the Institution Decision, Tecan has requested that the Director review all institution decisions related to IDT's and QIAGEN's petitions challenging Tecan's patent so the Director may review the overlapping proceedings as a whole.

The Board has repeatedly confirmed that multiple, parallel petitions can lead to undue burden on the Board and patent owners. CONSOLIDATED TRIAL PRACTICE GUIDE at 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).”). Allowing both QIAGEN and IDT to proceed with their challenges of this patent leads to duplicative efforts by the Board and is unfair to Tecan.

If both QIAGEN’s and IDT’s petitions move forward, two different PTAB panels will be forced to separately consider the patentability of the same claims of the challenged patent. This will force two panels to analyze different prior art, consider the testimony of different experts, and review separate briefing, all to assess the same set of challenged claims. The parallel proceedings are on different schedules, meaning that the Board will hear separate arguments, approximately three weeks apart. The Board will further be forced to issue separate final written decisions addressing the same challenged claims—with the possibility of inconsistent findings. For example, the two panels will consider different claim construction issues, which will impact the scope of the claims and likely lead to different results. This duplication of work—especially where it increases the risk of conflicting results—directly contradicts the Board’s efforts to promote efficiency.

Exercising discretion to deny the Petition allows the Board to streamline the IPR process and conserve resources by minimizing unnecessary redundancies.

Further, allowing QIAGEN's petition to proceed in parallel with IDT's petition raises fairness concerns and unduly burdens Tecan. The Board has stressed that "multiple petitions by a petitioner are not necessary in the vast majority of cases." CONSOLIDATED TRIAL PRACTICE GUIDE at 59. Nothing about the challenged claims requires multiple petitions. These petitioners, however, get the benefit of two bites at the apple with each bearing the cost of only one. These parties circumvented the guidance cautioning against multiple petitions and avoided having to justify why multiple petitions are necessary here. Tecan, on the other hand, will be submitting twice as many filings, participating in twice as many depositions, and defending the patent's validity at two different oral arguments that are less than three weeks apart. Like the Board, Tecan will be forced to unfairly duplicate efforts to face both petitions in parallel.

Having two different but overlapping panels consider QIAGEN's and IDT's petitions could additionally lead to unfair cross contamination between the records of the two proceedings. If both proceedings move forward, each petitioner separately has the burden of showing that the challenged claims are unpatentable based on the record in that proceeding. Here, there is a high likelihood that the record of one proceeding will inadvertently impact the Board's consideration of the

record in the other proceeding. Despite every effort by the APJs to consider the record properly, it is impossible to simply ignore information once it is learned. Tecan will be entirely unaware of any such inadvertent cross contamination among the panels, and therefore, will not have an opportunity to be heard on those issues and will not be able to sufficiently present its positions. Because the risk of unfairness to Tecan is high, the Board should exercise its discretion and deny the Petition, either allowing the parties to proceed with this dispute in district court or at the least address the validity of this patent in a single proceeding.

C. The Arguments Advanced in the Petition Are Weak

The Institution Decision focused on one of the three grounds asserted in the Petition—Ground 1, which argues incorrectly that the claims are obvious over the combination of Shapero and Delseny. Grounds 2 and 3 erroneously allege that certain dependent claims are obvious in light of Shapero and Delseny combined with other references. QIAGEN relies on Shapero and Delseny for the supposed disclosure of the elements of claim 1 in all of its asserted grounds. In all instances, QIAGEN raises the same arguments that were already overcome during prosecution. *See* POPR at 16-22. And 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 rendered obvious by Shapero and Delseny. Critically, the Petition relies on hindsight to argue for the modification of a method specific to hybridization arrays to be used

instead with a different technology. As Dr. Bustamante explained, Dr. Metzker's opinions regarding the prior art are flawed and misapprehend the technology. *See, e.g.,* Ex. 2028, ¶¶ 143-77. The Petition fails to show the requisite motivation to modify Shapero's MARA method for use with NGS with a reasonable expectation of success, meaning that all of QIAGEN's arguments are 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.

III. The Panel Relied on Erroneous Findings of Fact and Abused Its Discretion in Finding that the Petitioner Met its Burden

The Panel's Institution Decision should also be reversed because it is based on several erroneous findings of material fact. The Panel concluded that a POSA would have had a reason to modify Shapero's MARA method with a reasonable expectation of success based on Delseny. *See* Institution Decision at 23. In doing so, the Panel erred by failing to consider the full scope of the prior art.

With respect to motivation, the Panel found that "Delseny's express teaching that NGS can substitute for microarray in genotyping sufficiently supports Petitioner's argument that a POSA would have had a reason to modify Shapero's method, i.e., using hybridization array for SNP genotyping, with Delseny's NGS technology." *Id.* This finding is erroneous for at least two reasons. First, it incorrectly frames the inquiry as a motivation to substitute hybridization arrays for SNP genotyping with NGS technology. The correct inquiry is whether the Petition

sufficiently established that a POSA would have been motivated to use Shapero's MARA library preparation method—that was used for hybridization arrays—with NGS technology. The Panel fails to reach a conclusion there. Second, the Panel ignores numerous points raised by Tecan. Tecan explained that the Petition failed to “address the concerns at the time with using a single, target-specific primer to enrich sequences for NGS.” POPR at 31. For example, Tecan explained that Shapero and Syvänen taught away from the proposed modifications. *See, e.g., id.* at 34-40. The Panel acknowledged Tecan's position that Shapero's hybridization data was inapposite to data obtained from NGS but declined to consider it, stating that it “involves fact intensive issues better resolved after the parties fully develop the record during trial.” Institution Decision at 24-25. The Panel also acknowledged Tecan's position that Syvänen taught away, noting that Tecan's arguments “appear[] to have merit,” but dismissed their impact on the motivation inquiry, stating that they do not “outweigh Delseny's express teaching that NGS can substitute for microarray in genotyping.” *Id.* at 25. It was erroneous and an abuse of discretion for the Panel to not consider the prior art as a whole in its assessment of the obviousness arguments. *See Raytheon Co. v. Sony Corp.*, 727 Fed. App'x 662, 667 (Fed. Cir. 2018) (“on the issue of obviousness, the combined teachings of the prior art as a whole must be considered.”) (cleaned up); MPEP § 2145 (“The totality of the prior art must be considered”).

With respect to expectation of success, the Panel found that the same “express teaching also lends support to the alleged reasonable expectation of success in combining [Shapero’s method] with Delseny’s NGS technology.” Institution Decision at 23. Tecan presented evidence and expert testimony that a POSA could not make inferences about the enrichment, target specificity, and off-target binding from Shapero’s MARA method given Shapero’s use of hybridization arrays. POPR at 43-47. Tecan also presented evidence that there were numerous concerns in the art that would have diminished any expectation of success, but the Panel ignored these arguments. *Id.* at 48-51. Rather, the Panel accepted Delseny’s broad and off-base statement that NGS could be used for genotyping as sufficient to show a reasonable expectation of success. As a result, the Panel’s decision does not reflect a fulsome consideration of the arguments presented by the parties and should, therefore, be vacated and reversed.

IV. 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 28, 2025

Respectfully submitted,

/Linnea Cipriano/

Linnea Cipriano (Reg. No. 67,729)

Goodwin Procter LLP

620 Eighth Avenue

New York, NY 10018

Phone: (212) 813-8800

Fax: (212) 355-3333

lcipriano@goodwinlaw.com

Counsel for Patent Owner

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).

Date: May 28, 2025

Respectfully submitted,

/Linnea Cipriano/

Linnea Cipriano (Reg. No. 67,729)

Goodwin Procter LLP

620 Eighth Avenue

New York, NY 10018

Phone: (212) 813-8800

Fax: (212) 355-3333

lcipriano@goodwinlaw.com

Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of the foregoing Patent Owner's Request for Director Review was served on May 28, 2025, by electronic mail to:

David L. Bilsker (Reg. No. 39,611)
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
50 California Street, 22nd Fl.
San Francisco, CA 94111
Tel: (415) 875-6432
Fax: (415) 875-6700
davidbilsker@quinnemanuel.com
Qe-qiagen-tecan@quinnemanuel.com

Matthew A. Traupman (Reg. No. 50,832)
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Ave., 22nd Floor
New York, NY 10010
Tel: (212) 849-7322
Fax: (212) 849-7100
matthewtraupman@quinnemanuel.com

Tara Srinivasan (Reg. No. 77,091)
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
50 California Street, 22nd Fl.
San Francisco, CA 94111
Tel: (415) 875-6600
Fax: (415) 875-6700
tarasrinivasan@quinnemanuel.com

Landon A. Smith (Reg. No. 79,248)
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
300 W. 6th Street
Austin, TX 78701
Tel: (737) 667-6116
Fax: (737) 667-6110
landonsmith@quinnemanuel.com

Andrew E. Naravage (*pro hac vice* to be applied for)
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
50 California Street, 22nd Fl.
San Francisco, CA 94111
Tel: (415) 875-6432
Fax: (415) 875-6700
andrewnaravage@quinnemanuel.com

John Yang (*pro hac vice* to be applied for)
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
3100 McKinnon St, Suite 1125
Dallas, TX 75201
Tel: (469) 902-3600
Fax: (469) 902-3610
johnnyang@quinnemanuel.com

Date: May 28, 2025

Respectfully submitted,

/Linnea Cipriano/

Linnea Cipriano (Reg. No. 67,729)

Goodwin Procter LLP

620 Eighth Avenue

New York, NY 10018

Phone: (212) 813-8800

Fax: (212) 355-3333

lcipriano@goodwinlaw.com

Counsel for Patent Owner