Paper No. ___
Filed: August 15, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TWINSTRAND BIOSCIENCES, INC.,
Petitioner,

v.

GUARDANT HEALTH, INC.,
Patent Owner.

Case No. IPR2022-00747
Patent No. 10,889,858

PATENT OWNER'S PRE-INSTITUTION SUR-REPLY[1]

[1] Authorized by Board Order on July 27, 2022.

I. THE PETITION SHOULD BE DENIED UNDER §325(D)

By its own terms §325(d) addresses whether "the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. §325(d). *Advanced Bionics* sets forth a two-prong test for evaluating whether discretionary denial is appropriate under §325(d). Petitioner never grapples with the full scope of the record under either prong and inappropriately concocts a scenario to invoke legal error that did not occur. The alleged legal error Petitioner imagines is not reflected in the record of this case as a basis of the Examiner's withdrawal of his rejection over the same Schmitt reference, or in the Office's prior disposals of the same art and issue of patentability (including prior IPRs evaluated and denied by the Board). Thus, the Board should exercise its discretion under §325(d) and deny institution.

As to the first prong, it is beyond dispute that the Office has considered in numerous proceedings whether a POSA would have been motivated to modify Schmitt, in view of state-of-the-art ligation techniques, with more than 10× molar excess of adapters to achieve a tagging efficiency of at least 20% in cell-free DNA with a reasonable expectation of success. POPR, 6-13. Also, Petitioner does not dispute, as it cannot, that all the same references relied upon here were previously before the Office together with extensive expert testimony from a different petitioner in considering the same issue of patentability raised here.

The Reply (p. 1) advances one dismissive sentence that some of the proceedings identified by Patent Owner involved different patent families. Petitioner identifies no authority why the Office's consideration of the same issue of patentability may be ignored under §325(d) just because it occurred in multiple different patent families, including this patent, sibling patents, and related patents. The statute addresses art and argument previously presented "to the Office," and Petitioner here provides no compelling reason demonstrating that the various decision makers at the Office all materially erred in their various prior evaluations.

II. ARGUMENTS REGARDING PERAKIS ARE WRONG AND NOT DISPOSITIVE

As to the second prong, Petitioner implies the Examiner limited his analysis to only the Perakis reference and somehow confused the time point for assessing reasonable expectation of success. To be clear, there is no evidence that the Examiner actually did so in allowing the claims over Schmitt. Rather the Examiner, like many other decision makers at the Office, examined the broader evidentiary record and determined that Schmitt in view of state-of-the-art ligation techniques did not render obvious using 10× molar excess of adapters to achieve a tagging efficiency of at least 20% in cfDNA. Similarly, in the '992 patent IPRs, the Board broadly considered Schmitt in view of state-of-the-art ligation techniques. EX1079, 12 ("various techniques known in the art"), 13 ("using various known techniques"), 14 ("using a variety of techniques"). The Board, like the Examiner

here, did not center its decision on Perakis—the Board did not even cite to Perakis. Rather, the Board reasoned Schmitt itself and the record as a whole failed to teach the claimed limitation, and a POSA would lack either motivation or reasonable expectation of success in achieving it. *Id.*, 14-15. This decision was before the Examiner in the '858 patent prosecution (EX1066, 368), and there is no indication that the Examiner reasoned differently.

With regard to legal issue argued in the Reply, Petitioner improperly conflates *when* reasonable expectation of success is determined with the different issue of *what evidence* is probative of nonobviousness. Guardant does not dispute that expectation of success is determined at the time of the invention, and nothing indicates the Office ever used any other date. Guardant is also not aware of any cases stating that only evidence prior to the filing date is probative of obviousness, and Petitioner does not point to any. To the contrary, numerous cases support use of post-filing evidence when assessing obviousness, including not only objective indicia but other factors such as enablement, the state of the art in general, and a POSA's understanding of the prior art. *See, e.g.*, *Teva Pharms. USA, Inc. v. Sandoz Inc.*, 906 F.3d 1013, 1025 (Fed. Cir. 2018) (post-filing art can be considered to show "motivations and expectations when reading the prior art at the time of the invention" and to confirm POSA's understanding of prior art); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001)

(post-critical date evidence can inform enablement of prior art); *Gould v. Quigg*, 822 F.2d 1074, 1078 (Fed. Cir. 1987) (evidence of level of ordinary skill). Thus, while the Examiner did not specifically credit Perakis as evidence corroborating his finding of nonobviousness, doing so would not constitute material error.

The cases Petitioner cites to fail to disqualify post-filing date evidence. *Amgen* and *OSI* merely state that expectation of success is assessed as of the time of invention. Indeed, *OSI* expressly considered post-filing evidence regarding trial results spanning a time period extending from before the critical date to many years afterward to infer lack of expectation of success. *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019). Petitioner concedes that *In re Koller* "permit[s] using post-filing evidence to show the state of the art," but tries to limit such use to "narrow circumstances" without arguing that such circumstances elucidate some material error here when none exists. Reply, 4.

Petitioner also concedes that the reason it was permissible to ignore post-filing evidence in *BMS* was because it reflected a *later change* in the state of the art, in contrast to the instant case where no such change is alleged. *See* Reply, 3 (toxicity issues "not known" at time of invention). *Velander*, *Gruenthal*, and *Renesas* similarly involve "later-recognized insights" (Reply, 4 (quoting *Velander v. Garner*, 348 F.3d 1359, 1377 (Fed. Cir. 2003)), as opposed to using Perakis (and Nix, and others) that corroborate POSAs' understanding of Schmitt *as of the*

critical date. Lastly, *Yeda Research v. Mylan Pharms, Inc.* approved using post-filing evidence to show "the knowledge, motivations, and expectations of a POSITA regarding the prior art," criticizing only reliance on a post-filing *event* (clinical trial success) to establish expectation of success. 906 F.3d 1031, 1041-42 (Fed. Cir. 2018).

The Reply's discussion of objective indicia of nonobviousness is of no moment. Regardless of whether Perakis relates to objective indicia, Perakis is objective *evidence* of nonobviousness. To the extent that Petitioner concedes the Examiner could have viewed Perakis as also speaking to objective indicia of nonobviousness, Petitioner has pointed to no evidence to refute such a conclusion. Petitioner was clearly aware of Perakis and that the reference, like others (e.g., Nix, etc.), was presented to the Office, yet the only objective indicia the petition discusses relates to long-felt need and commercial success in a prior IPR. *See* Pet., 72. At best, Petitioner raises an issue that fails to advance their case, and more reasonably, Perakis (*see also*, Nix, etc.) further illustrates there was no material error by the Office.

Accordingly, Petitioner fails to show that no reasonable mind could agree with this Examiner, other Examiners, or the Board. Institution should be denied under §325(d).

Respectfully submitted,

Date: August 15, 2022

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Patent Owner's Pre-Institution Sur-Reply was served on August 15, 2022, on the Petitioner at the following electronic correspondence addresses:

Ralph Wilson Powers III
David H. Holman
Kristina C. Kelly
Christopher M. Gallo
Tyler C. Liu
STERNE, KESSLER, GOLDSTEIN & FOX
tpowers-PTAB@sternekessler.com
dholman-PTAB@sternekessler.com
kckelly-PTAB@sternekessler.com
cgallo-PTAB@sternekessler.com
tliu-PTAB@sternekessler.com
PTAB@sternekessler.com

Respectfully submitted,

Date: August 15, 2022

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182