

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,
Petitioner,

v.

EXACT SCIENCES CORPORATION,
Patent Owner.

Case No: IPR2024-00459
U.S. Patent 11,634,781

PATENT OWNER'S SUR-REPLY

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Petitioner presents no substantial differences between previously-considered art and the Grounds. Petitioner also fails to explain any basis for Examiner error in allowing the claims over the exact same, and substantially the same, prior art. Incredibly, Petitioner admits this omission and asserts that it was not required to address examiner error, notwithstanding that the cited art included both of Petitioner's primary references, as well as extensive overlapping and cumulative art. These facts call for discretionary denial under § 325(d).

Discretionary denial under § 314(a) is also appropriate based on the *General Plastic* factors where the same Petitioner previously challenged the same claims of the same patent through a reexamination request that resulted in all claims being confirmed as patentable. Petitioner's serial challenge creates the inefficiencies, burden, and potential unfairness that *General Plastic* is meant to avoid.

I. PETITIONER FAILS TO SATISFY ITS BURDEN UNDER § 325(d)

To begin, none of Petitioner's three points concerning the reexamination combination of Ahlquist, DeLuca, and Olson identifies any material, substantive difference between that combination and the Grounds. Indeed, the alleged differences are either not differences at all or are additional motivation arguments to try to correct for the fact that the newly cited art is even further removed from the claimed invention than the reexamination references were. Thus, the first prong of *Advanced Bionics* applies.

First, Petitioner asserts that a single “critical difference” distinguishes its primary reference, Lenhard, from re-examination reference, Ahlquist. Reply at 2. Petitioner asserts that Ahlquist evaluated the two assays “individually” and that Lenhard provides a purported motivation to combine. *Id.* Yet, Petitioner argued in the reexamination, and the CRU agreed, that Ahlquist taught collection of fecal samples on which both types of assays discussed in Lenhard were performed. *See* POPR at 22. Thus, there was no need for the purported motivation from Lenhard when Petitioner was relying on Ahlquist. POPR at 22-27. In addition, Petitioner is wrong that Lenhard teaches “advantages” of performing the two assays in combination. POPR at 50-51. Further, to the extent Petitioner argues that seeking improved performance was a motivation to combine, that is the same general motivation that Petitioner argued in the reexamination. *See, e.g.* Ex. 1021 at 24 (a POSA would be motivated to combine “for improved diagnostic power of cancer screening in human patients.”). Any differences between the reexamination art and the Grounds are created by Petitioner ***choosing*** here to use references that disclose even ***less*** than the reexamination art. Any such differences are certainly not “substantial.”

Second, Petitioner argues that none of the reexamination references disclose “Vilkin’s use” “of a buffer to prevent degradation of blood proteins.” Reply at 2. This careful wording is telling. Petitioner necessarily argued in the reexamination

that the prior art disclosed use of a buffer to prevent degradation of blood proteins, and it relied on DeLuca to do so. Ex. 1021 at 93-96. To the extent that Vilkin discloses this element, DeLuca discloses at least as much. Vilkin states that the sample collection device tip is “put in a closed amount of Hb stabilization buffer.” Ex. 1005 at 4. Vilkin says nothing more about the buffer. *See* Ex. 1005. DeLuca discloses a buffer solution that may contain “specific” stabilizers for analytes such as hemoglobin. *See* Ex. 2006 at [0001]; [0042]. DeLuca’s disclosure of a buffer containing “specific” stabilizer for hemoglobin is substantively the same as Vilkin’s “Hb stabilization buffer.” Further, Vilkin expressly attributes stabilization to refrigeration, not to the buffer, suggesting that the Vilkin buffer does not satisfy the element. *See* Ex. 1005 at 8; Ex. 2001 at ¶ 54-55, 79-80. Finally, Petitioner argues that Vilkin’s disclosure of advantages of iFOBT provides “important motivations to combine.” Reply 2. This, too, is substantively the same as the reexamination, where Petitioner argued that Ahlquist disclosed advantages of iFOBT that would have provided motivation to combine. *See, e.g.*, Ex. 1021 at 95.

Third, Petitioner asserts generally that Ground I addresses the CRU’s Reasons for Patentability: that “[n]one of the references of record reasonably suggest ***collection at home*** with each of the fecal portion sealed in separate containers, each with a buffer therein.” Reply at 2 (emphasis added). Yet, Petitioner does not identify a single difference between any art in the Grounds and

the reexamination art that purportedly addresses the CRU's reasons. When the references are considered, Petitioner's new combination is actually further removed from the claimed invention, and from the CRU's reasons for patentability, than the failed reexamination combination. For example, Lenhard discloses only laboratory collection (POPR at 12), where Ahlquist discloses at home collection. Ex. 1022 at 8.

In addition to the reexamination references, references that were cited during prosecution also satisfy the first prong of *Advanced Bionics*. Petitioner's art and arguments are the same as and/or cumulative of the references that were discussed in detail during prosecution of the '607 Parent Application. POPR at 28-30. Although the various rejections that Patent Owner overcame during prosecution provide ample bases for discretionary denial, the Board need not delve into those details when Petitioner has relied on references that were before the Examiner but has not explained how the Examiner erred in allowing the claims over them.

Petitioner relies on a total of four references between Grounds I and IV – Lenhard, Vilkin, Itzkowitz, and Shuber. Pet. at 12. Petitioner admits that Lenhard and Shuber were submitted in an IDS. Pet. at 66-67; Reply at 5. Petitioner does not dispute that the cited Itzkowitz 2008 reference discloses everything for which it relies on Itzkowitz. *See generally* Reply. As to Vilkin, Petitioner's only argument is that none of the cited art, including Levi and Liang, is substantially the same as

Vilkin. Petitioner is incorrect. Petitioner does not dispute that the cited Levi reference concerns the same work by the same group as Vilkin. *See id.* Levi refers to the iFOBT “described by us,” and cites to Vilkin. Ex. 2007 at 3, 6 n. 25.

Further, even if Levi were not substantially the same as Vilkin, other references cited during prosecution also disclose buffers to be used in tests for hemoglobin. For example, in the '607 Parent Application, the Examiner described Liang as disclosing a device that contained a buffer and that could be used for FOBT. POPR at 31; Ex. 2003 at 641-642. Further, contrary to Petitioner's assertion, the Patent Owner did not argue otherwise. Reply at 4. Petitioner cites two partial sentences that are separated by three paragraphs in the original document. Reply at 4; Ex. 2003 at 721-722. The entirety of the second quote is that “Liang suffers from the same deficiencies as Wang, ***disclosing only collecting a small portion of feces using a ‘sampling wand.’***” Ex. 2003 at 722 (emphasis added). Petitioner omits the emphasized portion – which says nothing about buffers – in arguing that Liang is not cumulative of Vilkin. Reply at 4.

Board precedent is clear that when a Petition relies on the same or substantially the same art that was presented during prosecution, the Petitioner ***must*** demonstrate that the “Office erred in a manner material to the patentability of challenged claims.” *Ivantis, Inc. v. Sight Sciences, Inc.* IPR 2022-01540, Paper 14 at 14 (P.T.A.B. Mar. 22, 2023), *citing Advanced Bionics*. Here, Petitioner has

failed to do so. Petitioner acknowledges this failure, but brushes this requirement aside by summarily arguing that to do so would be “nonsensical.” Reply at 5-6.

That is incorrect. Far from it being “nonsensical” to require that Geneoscopy demonstrate material error (Reply at 6), the Board has repeatedly found that such a showing is precisely what *Advanced Bionics* requires.

For example, in *Ivantis* the petitioner argued that none of the asserted prior art was “applied or discussed” during prosecution, and petitioner therefore did not address the material-error prong. *Ivantis*, IPR 2022-01540, Paper 14 at 13. Here, as in *Ivantis*, even if the cited references were never applied or discussed, “it does not help Petitioner.” *Id* at 8. Indeed, the Board has expressly found, in multiple decisions, that where the Petitioner fails to demonstrate “that the examiner materially erred in considering the prior art previously presented to the Office,” the Board should exercise its discretion under § 325 (d). *Id.* at 13; *see also Google LLC v. Kewazinga Corp*, 2021 WL 3746361, *9 (P.T.A.B. Aug. 24, 2021) (exercising discretion to deny institution where petitioner did “not identify or explain sufficiently how the Office materially erred”); *Microsoft Corp. v. IPA Techs., Inc.*, 2019 WL 6999078, *8 (P.T.A.B. Nov. 12, 2019) (petitioner’s failure to explain how the examiner erred in evaluating cited references weighed “strongly in favor” of exercising discretion to deny institution). Where Petitioner has made

no attempt to show that the Examiner erred in allowing the claims over the same, or substantially the same references, the Petition should be denied.

Finally, Petitioner argues that the recent allowance of the '945 Application after Exact Sciences submitted the Petition to the Examiner is "legally irrelevant." Reply at 6. Patent Owner has not asked the Board to deny institution based on this fact. This is, however, another example of where Petitioner's arguments have been considered and rejected, and is therefore consistent with Patent Owner's position.

II. DISCRETIONARY DENIAL UNDER §314(a) IS APPROPRIATE WHERE THE SAME PARTY CHALLENGES THE SAME CLAIMS OF THE SAME PATENT AFTER A FAILED REEXAMINATION

Petitioner argues that *General Plastic* should not apply here because it has not yet been applied in the context of a petition for IPR following a reexamination. Yet, Petitioner cites no authority precluding application of *General Plastic* under the specific circumstances. To the contrary, the two cases on which Petitioner relies suggest that *General Plastic* is applicable where, as here, the same party challenges the same claims of the same patent after a failed reexamination request.

In *Toshiba*, the petitioner patterned its petition after arguments made in a reexamination. *Toshiba Memory Corp. v. Anza Tec., Inc.*, IPR2018-01597, Paper 12 at 44 (P.T.A.B. Mar. 12, 2018). There, the reexamination status undercut the patent owner's arguments because the same claims challenged in the IPR had been rejected as obvious in the reexamination. *Id.* The reexamination was terminated

due to settlement, and the rejections were never overcome on the merits. *Id.* at 45-46. Under those circumstances, the Board declined to apply *General Plastic*. *Id.* at 45. That reasoning does not apply here, where all claims were confirmed as patentable after a reexamination request by this same Petitioner.

The other cited case, *Samsung*, similarly does not support Petitioner. In *Samsung*, the reexamination was brought by a party not in privity with petitioner, and the Board determined that *General Plastic* was not applicable to the facts. *Samsung Elecs. Co. Ltd. v. Netlist, Inc.*, 2022 WL 22412095, *9 (P.T.A.B. Oct. 19, 2022). Here, the same party has challenged the same claims of the same patent based on references that it knew about at the time of the earlier challenge.

Rather than “frustrate the purpose” of IPRs (Reply at 8), denying the Petition under § 314(a) would support the goals of encouraging efficiency and discouraging gamesmanship. Petitioner made a strategic choice to first file a reexamination then file a Petition that relies on previously-cited references only after the reexamination failed. This is exactly the type of serial challenge that discretionary denial under the *General Plastic* analysis is intended to avoid.

Date: June 10, 2024

/s/ James Glass

Patent Owner's Sur-Reply

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6, I hereby certify that on June 10, 2024 the foregoing Sur-Reply from Patent Owner was served via email on the following counsel of record for the Petitioner:

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