

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 No. 11,634,781

**PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE**

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Patent Owner's Preliminary Response (POPR) makes two tenuous arguments for discretionary denial, first under § 325(d) and *Advanced Bionics*, and then under § 314(a) and *General Plastic*. Neither has merit. Denial of institution under § 325(d) is inappropriate because the Petition's art and arguments are substantially different from any previously considered, and hence the first condition of the *Advanced Bionics* framework is not met. The Board should also reject Exact's invitation to expand *General Plastic* to include discretionary denial of institution based on a prior *ex parte* reexamination as contrary to precedent and the America Invents Act ("AIA"). Denying institution here would prevent the Patent Office from ever considering the new invalidity grounds raised in the Petition. Instead, these grounds would be evaluated for the first time by a jury in pending patent litigation, thereby defeating Congress' intent in enacting the AIA.

I. The Petition's Prior Art and Arguments Are Not Substantially the Same as Those Previously Considered

Exact argues incorrectly that the prior art cited in the Petition is substantially the same as certain previously considered references. In each case, Exact identifies superficial similarities between the compared references, but ignores key disclosures found only in the Petition's references. The art and arguments in the Petition are meaningfully distinct from any previously considered.

Exact asserts that the art and arguments in Ground I are substantially the

same as those presented in a SNQ submitted in a prior reexamination proceeding, despite the fact the SNQ applied a completely different set of references. POPR, 22 and 32. Exact's arguments fail for at least three reasons.

First, none of the SNQ references teaches that combining a DNA assay with an FOBT improves assay sensitivity over either test alone, a key teaching of Lenhard. Pet., 21, 25-26. Ahlquist, for example, compares performance of a DNA assay and FOBT to evaluate the comparative efficacy of the two assays individually. Unlike Lenhard, Ahlquist does not teach any advantages to performing the two assays in combination. This disclosure in Lenhard represents a critical difference between the Petition's arguments and those in the SNQ.

Second, none of the SNQ references discloses Vilkin's use, in his iFOBT assay, of a buffer to prevent degradation of blood proteins. DeLuca, for example, merely discloses a sealable tube into which a generic buffer is introduced, without describing a buffer that prevents blood protein degradation. POPR, 25. Moreover, none of the SNQ references discloses the numerous advantages of Vilkin's iFOBT, which provide important motivations to combine in Ground I. Pet., 21-22.

Third, the Reexamination Decision states in its Reasons for Patentability that "[n]one of the references of record reasonably suggest collection at home with each of the fecal portions sealed in separate containers, each with a buffer therein." Ex. 1023, 4-5. In contrast, Ground I explains how Lenhard, Vilkin and Itzkowitz

render obvious this exact process. Pet., 25-26.

Exact next argues incorrectly that the Ground I references are substantially similar to art submitted in an IDS but never discussed during prosecution. POPR, 28-29. This argument fails at least because Levi (the reference Exact argues is substantially the same as Vilkin), lacks Vilkin's most relevant disclosures. For example, Ground I relies on Vilkin's disclosure of an iFOBT in which a portion of a fecal sample is separated into a sealable container containing a buffer that prevents blood protein degradation. Pet., 21-22, 25-26, 30. Levi, in contrast, never mentions a blood protein stabilization buffer, let alone its use in a separate sealable container. Ex. 2007. Levi therefore lacks key disclosure found in Vilkin that is a critical part of Ground I's obviousness argument.

Exact also mistakenly contends that the Ground I references and arguments are substantially the same as those used in an obviousness rejection made during prosecution of the parent '607 Application that was based on four different references: Wang, Liang, Olek and Kutzner. POPR, 30, 33. Exact's position contradicts its own successful arguments, made during prosecution, that key disclosures are *not present* in the '607 Application references. For example, during an examiner interview, Exact argued that "none of the cited references disclose a method comprising collection of a fecal sample at home by the human subject by defecation directly into a sealable collection vessel," a method disclosed in

Itzkowitz. Ex. 2003, 715; Pet., 27. Exact also asserts that Kutzner is substantially the same as Lenhard, but whereas Lenhard teaches the advantages of combining DNA assays with FOBT, Exact argued during prosecution that “Kutzner specifically states that it is not obvious to the authors of the reference that combining testing of DNA markers with fecal blood detection will yield any particular result...” Ex. 2003, 723 (emphasis in original). Exact relies on Wang and Liang to “fill the role for which Petitioner uses Vilken,” and argues that Wang discloses “mixing the sample with a ‘preserving fluid’.” POPR, 31. However, during prosecution Exact argued to the contrary that Wang *does not disclose* “a buffer that prevents denaturation or degradation of blood proteins found in a fecal sample,” and that “Liang suffers from the same deficiencies as Wang.” Ex. 2023, 721, 722. (Neither Wang nor Liang was made of record by Exact in this IPR).

Indeed, the rejection made during the ’607 Application’s prosecution that Exact identifies bears little resemblance to Ground I. The subject matter of the primary reference used in this rejection, Wang, is completely different from that of Lenhard, the primary reference of Ground I. Ex. 2003, 640. Moreover, as admitted by Exact during prosecution, the references used in the ’607 rejection lack many of the key claim elements that Ground I demonstrates to be obvious, including direct defecation into a sealable vessel, use of a blood protein stabilization buffer, and use of a DNA stabilizing buffer. Ex. 2003, 715, 721-723; Pet. 20-26.

Exact's misguided assertions regarding Ground IV fail for similar reasons. For example, in contrast to the SNQ, Ground IV presents extensive evidence and argument that a POSA would be motivated to combine performance of a DNA assay with an iFOBT. Pet., 48-50. Moreover, as explained above, none of the SNQ's references is substantially the same as Vilkin. Ground IV also explicitly sets forth how the cited references "suggest collection at home with each of the fecal portions sealed in separate containers, each with a buffer therein," the sample processing steps the Office found were lacking in the references of record in the reexamination proceeding. Ex. 1023, 4-5; Pet., 50. Finally, none of the other references identified in the POPR is substantially the same as Vilkin. This includes Levi and Liang, neither of which discloses the use of a buffer to prevent blood protein degradation, a key disclosure in Vilkin. POPR, 35-36; Pet., 47, 53-54.

Because the second factor of the *Advanced Bionics* framework is triggered only when substantially the same art or arguments were previously considered during prosecution, that factor is not relevant here. Likewise, the fact that Lenhard and Shuber were individually submitted in an IDS during prosecution does not trigger the second factor because the Petition's grounds only use these references in combination with previously uncited references, presenting arguments distinct from any previously considered. In the present case, where the Office has never considered the combinations of references and arguments presented in the Petition,

it would be nonsensical to require Geneoscopy to demonstrate material errors made by the Office when it assessed different arguments based on different references.

Finally, the fact that Exact *later* submitted this Petition and its references in a continuation application's IDS is legally irrelevant to discretionary denial under § 325(d). (The Office did not comment on any of them.) That provision authorizes the Director to reject institution of a petition only where “the same or substantially the same art or arguments *previously* were presented to the Office.” § 325(d), emphasis added. This provision does not apply where the petition's art and arguments were first presented to the Office only *after* the filing of the petition.

II. *General Plastic* Does Not Apply Because There Is No Serial Petition

Exact's invitation to expand *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, No. IPR2016-01357, 2017 Pat. App. LEXIS 9839 (P.T.A.B. Sept. 6, 2017) to permit discretionary denial of this Petition under § 314(a) based on a prior *ex parte reexamination* has no support in precedent. Applying *General Plastic* here, moreover, would subvert the legislative purpose of IPR proceedings.

Exact cites no authority, and Geneoscopy is aware of none, holding that a request for *ex parte* reexamination constitutes a “prior petition” within the meaning of *General Plastic*. *General Plastic* lists factors the Office can consider in determining whether to exercise discretion under § 314(a) to deny an IPR petition that challenges the same patent based on the previous filing of an IPR, PGR, or

CBM petition. *Id.* at *26. *General Plastic* expressed concern about potential “harassment of patent owners” through “multiple petitions” challenging the same patent. *Id.* at *25 n.14. Nothing in that decision suggests that these factors apply to a prior request for reexamination, much less an *ex parte* reexamination based on different art and arguments. *See Toshiba Memory Corp. v Anza Tec., Inc.* (declining to apply *General Plastic* to a previous *inter partes* reexamination request); *Samsung v. Netlist*, IPR2022-00615, Paper 20, 58 (declining to deny under § 314(a) and stating “[n]o authority has been provided to support application of *General Plastics* in the context [of a prior *inter partes* reexamination]”). Exact’s citation to *In re Vivint, Inc.*, 14 F.4th 1342 (Fed. Cir. 2021), is inapposite. There, a reexamination request was denied ***under § 325(d)*** (not under § 314(a)) when a party had filed 14 prior IPR petitions and “vast swaths” of the denied request were “copied, almost word for word” from a prior IPR petition. *Id.* at 1347. Here, the Petition is based on different art and different arguments.

The *General Plastic* factors do not apply here. Geneoscopy has not “previously filed a petition” (Factor 1) and there is no “second petition” (Factors 2-5). When Congress amended the Patent Act through the AIA, it distinguished between “petitions” for post-grant review—adversarial proceedings that have the associated procedural safeguards—and “requests” for *ex parte* reexamination, non-adversarial proceedings that do not. *Ex parte* reexaminations are fundamentally

different from IPR proceedings. Indeed, Congress imposed estoppel rules for IPRs but chose not to do so for *ex parte* reexaminations. These are distinctions with a difference. While it may be reasonable in some cases to hold a challenger to a single IPR petition under § 314(a), it would be manifestly unfair to deny a challenger the right even to one petition based on an earlier request for *ex parte* reexamination. Moreover, institution of this first IPR would not be a waste of Board resources, but rather would efficiently address patent validity. (Factors 6, 7).

Denying Geneoscopy's Petition under § 314(a) would frustrate the purpose of IPRs "as providing quick and cost effective alternatives to litigation." *General Plastic*, at *24. Doing so would force the district court to resolve patentability without any prior Board review of Geneoscopy's invalidity grounds. Treating Geneoscopy's earlier reexamination request as justification for avoiding a patentability determination by this Office would subvert that objective. While Exact attempts to raise the specter of harassment, Geneoscopy filed this single Petition only after Exact initiated a federal court proceeding. The parties should not have to spend years litigating issues in court that are ripe for resolution now.

III. Conclusion

Exact's request for discretionary denial of the petition should be rejected.

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(c), the undersigned hereby certifies that
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