

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,
Petitioner,

v.

EXACT SCIENCES CORPORATION,
Patent Owner.

Case No.: IPR2024-01330
U.S. Patent 11,970,746

**PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO
EXCLUDE EVIDENCE**

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In its Motion to Exclude Evidence, Exact asks the Board to exclude rebuttal evidence that squarely responds to arguments raised in Exact's Patent Owner's Response ("POR") and the declaration of its expert, Dr. Backman. Exact's motion misconstrues the governing legal standard and mischaracterizes Exhibit 1090 and paragraphs 48, 50, 96 and 97 of Exhibit 1086, the Second Declaration of Duncan Whitney, Ph.D. ("Second Declaration of Whitney") (collectively, "Rebuttal Evidence"). The Board should deny the motion.

I. LEGAL STANDARD

It is well-established that under 37 C.F.R. § 42.23(b), a petitioner may reply to arguments raised in a patent owner response and may submit rebuttal evidence in support of its reply "to explain, repel, counteract, or disprove the evidence of the adverse party." *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1082 (Fed. Cir. 2015). The Federal Circuit has held "there is no blanket prohibition against the introduction of new evidence during an IPR." *Rembrandt Diagnostics, LP v. Alere, Inc.*, 76 F.4th 1376, 1384 (Fed. Cir. 2023) (citing *Anacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1380 (Fed. Cir. 2018)). On the contrary, a petitioner "may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner, or if it is used to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness." *Anacor*, 889 F.3d at 1380–81.

II. ARGUMENT

Geneoscopy's Rebuttal Evidence constitutes a "legitimate reply to evidence introduced by [Exact]," and should not be excluded. *Anacor*, 889 F.3d at 1380. In its POR, Exact cites Dr. Backman's Declaration (EX2044) and a 1999 article published a decade before the Priority Date (EX2047) to argue, incorrectly, that "iFOBT testing alone routinely required sample collection on at least two consecutive days." POR 34. Geneoscopy's Reply properly rebutted Exact's argument and evidence by stating, among other things, that "[i]n contrast, by the Priority Date, the OC Sensor iFOBT of Vilkin was being used to test single samples without requiring at-home refrigeration" and citing to the Rebuttal Evidence. Reply at 11-12 (emphasis added). Geneoscopy's Rebuttal Evidence thus appropriately rebuts Exact's argument and clarifies the state of the art as of the Priority Date. *See Belden*, 805 F.3d at 1082. It should not be excluded.

Exact's motion also wrongly asserts that Geneoscopy is presenting an argument and Rebuttal Evidence "for the first time" to "make out a prima facie case of unpatentability." Mot. at 2-3. Not so. For each of the obviousness combinations at issue, Geneoscopy has pressed the same grounds of obviousness in its Reply that it advanced in its petition. Geneoscopy has consistently contended that a POSA would have replaced the gFOBT of Lenhard with the iFOBT of

Vilkin because of the known advantages of iFOBT, including that it allows for “collecting fewer fecal samples.” See POR at 33. Indeed, Exact concedes that “Exhibit 1090 discusses the same OC Sensor iFOBT as Vilkin,” Mot. at 1-2. The Rebuttal Evidence thus simply “confirm[s] the prima facie case” of obviousness presented in Geneoscopy’s petition, *Belden*, 805 F.3d at 1079, and Geneoscopy does not impermissibly rely on it “to satisfy its burden of showing a *prima facie* case of obviousness,” *Anacor*, 889 F.3d at 1380.

III. CONCLUSION

For the reasons set forth above, the Board should deny Exact’s motion to exclude.

Dated: October 31, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(c), the undersigned hereby certifies that on October 31, 2025, I caused a true and correct copy to be served on the following attorneys of record:

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