

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEOSCOPY, INC.,
Petitioner,

v.

EXACT SCIENCES CORPORATION,
Patent Owner.

IPR2024-01330
Patent 11,970,746 B2

Before RYAN H. FLAX, DAVID COTTA, and JAMIE T. WISZ,
Administrative Patent Judges.

FLAX, *Administrative Patent Judge.*

ORDER

Denying Patent Owner's Motion to Exclude Evidence
37 C.F.R. §§ 42.5, 42.7, 42.20, 42.64, 42.71

I. INTRODUCTION

Exact Sciences Corporation (“Patent Owner”) is the owner of U.S. Patent 11,970,746 B2 (Ex. 1001, “the ’746 patent”). Paper 4, 2. Geneoscopy, Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–4 and 12–19 of the ’746 patent. Paper 1 (“Pet.”). We instituted this *inter partes* review on February 14, 2025. Paper 10 (“Institution Decision” or “DI”). On May 30, 2025, Patent Owner filed a Response to the Petition (Paper 19, “Response” or “Resp.”), which was followed by Petitioner’s Reply (Paper 22, “Reply”), which was followed by Patent Owner’s Sur-reply (Paper 30, “Sur-reply”).

With its Reply, Petitioner filed Exhibits 1086 and 1090, the former being the Second Declaration of Duncan Whitney, Ph.D. and the latter being a journal article by L.G. Van Rossum et al. (“Van Rossum”).¹ On October 24, 2025, Patent Owner filed a Motion to Exclude Evidence directed to these two exhibits. Paper 32 (“Motion” or “Mot.”). Petitioner filed an Opposition to the Motion (Paper 33, “Opposition” or “Opp.”), to which Patent Owner responded with a Reply (Paper 34, “Reply”).

Having considered the parties’ arguments and support therefore, we *deny* the Motion. Our reasoning is set forth below.

II. DISCUSSION

A. LEGAL STANDARDS

Petitioners may file reply briefs to respond to issues raised in a patent owner’s response and the institution decision. 37 C.F.R. § 42.23; PTAB

¹ L.G. Van Rossum et al., *Random Comparison of Guaiac and Immunochemical Fecal Occult Blood Tests for Colorectal Cancer in a Screening Population*, 135 GASTROENTEROLOGY 82–90 (2008) (Ex. 1090).

Consolidated Trial Practice Guide, 84 Fed. R. 64280 (Nov. 21, 2019) at 73 (“CTPG”).² A party may submit rebuttal evidence in support of a reply, but may not submit new evidence or argument in a reply that it could have presented earlier, e.g., to make out a *prima facie* case of unpatentability. See *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1077–78 (Fed. Cir. 2015); CTPG at 73–75. For example, “gap-filling” for facts necessary to make a *prima facie* case for unpatentability with new evidence is inappropriate. See *Genzyme Therapeutic Prods. Ltd. v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1365–69 (Fed. Cir. 2016).

As expressed in our Consolidated Trial Practice Guide,

A motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay) but may not be used to challenge the sufficiency of the evidence to prove a particular fact. A motion to exclude is not a vehicle for addressing the weight to be given evidence—arguments regarding weight should appear only in the merits documents. ***Nor should a motion to exclude address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply.***

CTPG at 79 (emphasis added). Moreover, “[i]f a party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply, it may request authorization to file a motion to strike.” *Id.* at 80. “In most cases, the Board is capable of identifying new issues or belatedly presented evidence when weighing the evidence at the close of trial, and disregarding any new issues or belatedly presented evidence that exceeds the proper scope of reply or sur-reply.” *Id.*

² Available at www.uspto.gov/TrialPracticeGuideConsolidated.

“The moving party has the burden of proof to establish that it is entitled to the requested relief.” 37 C.F.R. § 42.20(c).

B. ANALYSIS

Petitioner argues in the Petition that the Vilkin prior art reference (Ex. 1005), in combination with other asserted prior art, renders the challenged claims obvious because, *inter alia*, it discloses that immunochemical fecal occult blood tests (iFOBT) are superior to and should replace guaiac fecal occult blood tests (gFOBT) for screening patients for colorectal cancer (CRC). *See, e.g.*, Pet. 12 (summary of grounds for unpatentability), 19–34 (ground 1).

In its Response, Patent Owner argues against Vilkin as evidence of obviousness for several reasons, including that Vilkin’s disclosed methods require sample collection for several consecutive days and storing samples in zip-lock bags in the patient’s refrigerator, which would be objectionable to patients, and make it unlikely that the ordinarily skilled artisan would have combined Vilkin’s disclosure with that of the other asserted prior art. *See* Resp. 1, 5–6, 12–14, 25–28, 33–34.

Petitioner directly responds to these arguments in its Reply. Reply 10–12. As a part of this response, Petitioner argues that Patent Owner misreads Vilkin as requiring consecutive day collection and refrigerator storage because the reference discloses that collection procedures vary by country and, in certain countries, multiple-day collection and home-refrigeration storage is not part of the process. *Id.* Petitioner also argues that, as of the ’746 patent’s priority date, the OC Sensor iFOBT (the sample analysis machine) of Vilkin’s methods was being used to test single samples collected without requiring at-home refrigeration, and it is for this point that

Petitioner cites Van Rossum (Ex. 1090) and the Second Whitney Declaration (Ex. 1086 ¶¶ 48, 50, 96–97) where it discusses this evidence. *Id.* at 10–12.

In its Motion, Patent Owner now argues that Van Rossum is improper new evidence submitted with the Reply that could have been, but was not presented with the Petition. Mot. 1–2. Patent Owner identifies that Petitioner’s Reply (at 11–12) cites Van Rossum for the reasons set forth above, but asserts that Petitioner’s argument that Vilkin’s OC Sensor iFOBT machine was being used as of the ’746 patent’s priority date to test single samples without refrigeration is an argument and evidence that should have been made and discussed in the Petition. *Id.* at 3.

Petitioner argues that Van Rossum and the respective paragraphs of the Second Whitney Declaration are rebuttal evidence challenging Patent Owner’s positions in its Response and “simply ‘confirm[s] the prima facie case’ of obviousness presented in [its] [P]etition.” Opp. 2–3 (citing *Belden*, 805 F.3d at 1079).

We find Patent Owner’s position unpersuasive.

As an initial matter, as noted above, a motion to exclude is not the proper device for a party to argue that the opposition’s evidence or arguments exceed the proper scope for a reply brief. CTPG at 79. Patent Owner neither frames its current motion as a request to strike arguments/evidence nor requested authorization to file such a motion. For this reason, alone, the Motion should be denied without reaching the merits.

In any event, even considering the merits of Patent Owner’s Motion, we find that Van Rossum (Ex. 1090) and the paragraphs of the Second Whitney Declaration citing that exhibit were submitted by Petitioner in direct response to specific arguments presented in Patent Owner’s Response.

Van Rossum was not required for Petitioner's *prima facie* case of obviousness over Vilkin, but is rebuttal evidence against Patent Owner's argument that the ordinarily skilled artisan would not have looked to combine Vilkin's disclosure with the other cited prior art because of certain aspects of Vilkin's disclosed methods. This is a proper type of evidence to be filed with a reply brief. Patent Owner has identified no gaps in Petitioner's *prima facie* case allegedly sought to be filled by Van Rossum and the objected-to paragraphs of the Second Whitney Declaration. Upon review of the Reply, we do not discern that Petitioner cites Van Rossum as teaching or suggesting any challenged claim limitations or as necessary evidence that the prior art would have been combined with a reasonable expectation of success.

C. CONCLUSIONS

For the reasons above, we find Exhibit 1090 is proper rebuttal evidence and we are not persuaded by Patent Owner's arguments for excluding Exhibit 1090 or any parts of Exhibit 1086. The Motion is, therefore, *denied*.

ORDER

Accordingly, it is hereby:

ORDERED that Patent Owner's Motion to Exclude Exhibit 1090 and paragraphs 48, 50, 96, and 97 of Exhibit 1086 is *denied*.

FOR PETITIONER:

Brendan Jones
David Shore
Sarah S. Burg
Donald R. Ware
FOLEY HOAG LLP
bjones@foleyhoag.com
dshore@foleyhoag.com
sburg@foleyhoag.com
dware@foleyhoag.com

FOR PATENT OWNER:

James Glass
Sandra Haberny
JihongLou
Anastasia Fernands
QUINN EMANUEL URQUHART & SULLIVAN, LLP
jimglass@quinnemanuel.com
sandrahaberny@quinnemanuel.com
jihonglou@quinnemanuel.com
anastasiafernands@quinnemanuel.com