

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,

Petitioner,

v.

NOVARTIS PHARMA AG, NOVARTIS TECHNOLOGY LLC,

NOVARTIS PHARMACEUTICALS CORPORATION,

Patent Owner.

IPR2021-00816

Patent 9,220,631 B2

Before ERICA A. FRANKLIN, ROBERT L. KINDER, and
JAMIE T. WISZ, *Administrative Patent Judges*.

KINDER, *Administrative Patent Judge*.

ORDER
Conduct of the Proceeding
37 C.F.R. § 42.5

A conference call in this proceeding was held on May 18, 2022, among counsel for Petitioner, Anish Desai, counsel for Patent Owner, Elizabeth Holland, and Judges Franklin, Kinder, and Wisz. The purpose of the call was to address Patent Owner's request to file additional evidence with its Sur-reply. During the conference call, Patent Owner stated that it requests authorization to file an expert declaration in response to arguments and evidence it asserts were newly presented in the Reply. Petitioner opposed the request.

Patent Owner contends that three declarations each contain several paragraphs of testimony that "contain new arguments and/or evidence." Ex. 3002. Specifically, the Reply Declaration of Horst Koller (Ex. 1105), the Declaration of Dr. Kenneth S. Graham (Ex. 1102), and the Declaration of Joel M. Cohen (Ex. 1108) allegedly each contain some form of new argument or evidence. *Id.* During the conference call, Patent Owner highlighted the alleged issues with each of these exhibits, including: introduction of new expert testimony (toxicology report) that should have accompanied the Petition, introduction of secondary considerations evidence (such as related to long-felt need) that Patent Owner could not have anticipated, and new expert testimony as to the function and teachings of the prior art. Patent Owner seeks to file a Sur-reply declaration responding to the alleged new arguments and evidence.

During the call, Petitioner argued that the declarations supporting its Reply merely provided evidence that directly rebut contentions raised by Patent Owner in the Response. Petitioner discussed the challenged declarations submitted with its Reply and its position how each either responded directly to an argument made in the Patent Owner Response or

was consistent with Petitioner’s original arguments set forth in the Petition. Petitioner also noted that Patent Owner was aware of its positions as they were developed and briefed in the related International Trade Commission proceeding that progressed through discovery to the eve of trial. *See, e.g.*, Decision on Institution (Paper 13), 3, 9; Ex. 1006, 1.

“A petitioner may file a reply to a patent owner response,” but, “[g]enerally, a reply . . . may only respond to arguments raised in the preceding brief.” Patent Trial and Appeal Board Consolidated Trial Practice Guide (“CTPG”) 73–74 (Nov. 2019).¹ “‘Respond,’ in the context of 37 C.F.R. § 42.23(b), does not mean proceed in a new direction with a new approach as compared to the positions taken in a prior filing.” *Id.* at 74. “A party also may submit rebuttal evidence in support of its reply.” *Id.* at 73. However, a petitioner “may not submit new evidence or argument in reply that it could have presented earlier, e.g. to make out a prima facie case of unpatentability.” *Id.* Further, “[i]f a party submits a new expert declaration with its reply, the opposing party may cross-examine the expert, move to exclude the declaration, and comment on the declaration and cross-examination in any sur-reply.” *Id.*

Our Trial Practice Guide further notes that “[t]he sur-reply may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness.” *Id.* As with a reply, “a . . . sur-reply that raises a new issue or *belatedly presents evidence* may not be considered,” and “[t]he Board is not required to attempt to sort proper from improper portions of the reply or sur-reply.” *Id.* at 74 (emphasis added). Based on the

¹ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

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circumstances before us, we see no need to deviate from our standard practice of not allowing any new evidence other than deposition transcripts of the cross-examination of any reply witness to accompany Patent Owner's Sur-reply.

Patent Owner is free to respond to Petitioner's arguments and purported new evidence in its Sur-reply and may reiterate such response at oral hearing. To the extent Petitioner presented new evidence in its Reply that may be deemed improper (*see* 37 C.F.R. § 42.23(b); CTPG 73–74), we will consider such arguments upon a completed record. However, introducing additional new evidence at this phase of the proceeding is not the proper recourse for Patent Owner. Accordingly, Patent Owner's request to file a declaration with its Sur-reply is *denied*. *See* CTPG 73 (“The sur-reply may not be accompanied by new evidence.”).

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