UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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XENCOR, INC.,
Petitioner

v.

MERUS N.V.,
Patent Owner

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Case IPR2025-00604
Patent No. 9,358,286

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# PETITIONER'S SUR-REPLY IN OPPOSITION TO PATENT OWNER'S DISCRETIONARY DENIAL BRIEF

The Director should reject Merus's request to deny institution based on settled expectations. When analyzed holistically, as Xencor does in its Petition and Opposition, the discretionary denial factors favor institution. As Xencor previously explained (DDB Opp.[1]), this proceeding includes a number of unique and compelling facts that outweigh any supposed settled expectations by Merus, including that the Examiner materially erred (DDB Opp., 14-17); the district court case is in its infancy and a *Sotera* stipulation mitigates overlap (*id.*, 17-25); and the public health benefits from a review of the merits of Xencor's Petitions given the technology and circumstances (*id.*, 39-40). Xencor has thus provided "persuasive reasons why the Board should review challenged claims several years after their issuance date." *Intel Corp. v. Proxense LLC*, IPR2025-00327, Paper 12 at 2 (June 26, 2025); *see also Microsoft Corp. v. X1 Discovery, Inc.*, IPR2025-00253, Paper 13 (June 25, 2025) (Director referring the petition to a panel based on Office error and no trial date despite involving a 2008-issued patent). But even focusing on settled expectations in isolation, they favor Xencor, not Merus.

First, the settled expectations factor should be analyzed in the context of the industry and circumstances associated with the patent. *See Intel* at 2-3 (explaining that certain market-specific considerations may "weigh against a patent owner's claim of settled expectations"). In the pharmaceutical sector, companies have long

[1] Petitioner's Opposition to Patent Owner's Discretionary Denial Brief, Paper 8.

relied on the safe harbor provision under 35 U.S.C. § 271(e)(1). Xencor's expectation that they can rely on the 35 U.S.C. § 271(e) safe harbor—which is the same as Merus's (and the entire pharmaceutical industry)—outweighs any putative expectation by Merus that their patents would go unchallenged. (DDB Opp., 33-35.) Merus tries to dilute Xencor's expectation by arguing it is an "incorrect theory." (DDB Reply, 2-3.[2]) But Merus's current, self-serving belief of incorrectness does not undo the fact that the very same paragraph of Xencor's 10-K that Merus pointed to for knowledge of Merus's patents also evidences Xencor's contemporaneous safe harbor expectation. (EX2007, 46.) The Director need not resolve whether the safe harbor applies here to find it was an evidence-based expectation of Xencor. And Merus cannot call this expectation unreasonable, given Merus also invoked the safe harbor in its own 10-K submission. (EX1059, 83 (PDF page 86).)

Second, Merus ignores its own 10-K's admission that it expected "all of [its] U.S. patents, even those issued before March 16, 2013," to be subject to potential IPR challenges. (EX1059, 87 (PDF page 90).) This is particularly notable given that Merus made this proclamation to its shareholders and the public ***after*** Xencor's Petitions were filed, just a few months ago. (EX1059, 119 (PDF page 126) (10-K dated "February 27, 2025").) Xencor identified this issue in its

[2] Patent Owner's Reply in Support of Discretionary Denial, Paper 10.

opposition, yet Merus ducks it entirely. (DDB Opp., 33 ("Merus … expressly contemplated such proceedings" (citing EX1059)); *see generally* DDB Reply.)

Merus also misses the point regarding *iRhythm* and *Dabico*, incorrectly suggesting Xencor was only pointing to the fact that those challenged patent families had no open continuations. (DDB Reply, 2.) The relevance of continuations in Merus's patent family is not merely their existence, but the way Merus is using those continuations to try to capture Xencor's prior disclosures—disrupting Xencor's settled expectations. This weighs particularly strongly against discretionary denial here given the pharmaceutical technology at issue and the associated Section 271(e) safe harbor. And Merus has no response to Xencor's second point distinguishing *iRhythm* and *Dabico*—which applies equally to *Intel*—that they involved challenges to only older patents (issued more than six years ago). (DDB Opp., 36-37 ("youngest challenged patent in *iRhythm* … from 2018," and 2017 for *Dabico*).) Here, by contrast, Xencor also challenges the 2024-issued '859 patent in parallel. Because Merus has no settled expectations in the recently issued '859 patent, that petition should be referred, and thus "it is an efficient use of the Board's resources to address the related patent"—the '286 patent. *Embody, Inc. v. LifeNet Health*, IPR2025-00248, Paper 13, 2-3 (June 26, 2025).

For all of these reasons, the Director should reject Merus's argument that this IPR challenging the '286 patent should be denied for settled expectations.

Respectfully submitted,

Dated: July 11, 2025

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## CERTIFICATE OF SERVICE

I hereby certify that on July 11, 2025, I caused a true and correct copy of the foregoing Petitioner's Sur-reply in Opposition to Patent Owner's Discretionary Denial Brief to be served via email on Patent Owner at the following addresses:

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