

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

XENCOR, INC.,

Petitioner

v.

MERUS N.V.,

Patent Owner

IPR2025-00604

Patent No. 9,358,286

**PATENT OWNER MERUS'S REPLY IN SUPPORT OF REQUEST FOR
DISCRETIONARY DENIAL OF INSTITUTION¹**

¹ Authorized on July 7, 2025. EX3101.

TABLE OF AUTHORITIES

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Cases

<i>Dabico Airport Solutions Inc., v. AXA Power ApS,</i> IPR2025-00408, Paper 21 (P.T.A.B. June 18, 2025)	1
<i>Intel Corp. v. Proxense LLC,</i> IPR2025-00327, Paper 12 (P.T.A.B. June 26, 2025)	1, 2
<i>iRhythm Technologies, Inc. v. Welch Allyn, Inc.,</i> IPR2025-00363, Paper 10 (P.T.A.B. June 6, 2025)	<i>passim</i>

Statutes

35 U.S.C. § 271(e)(1).....	1, 3
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TABLE OF ABBREVIATIONS

Abbreviation	Definition
Merus	Patent Owner Merus N.V.
Xencor	Petitioner Xencor, Inc.
IPR	<i>Inter partes</i> review
Board	Patent Trial And Appeal Board
'286 Patent	Merus's Patent No. 9,358,286
'181 Patent	Merus's Patent No. 9,248,181
IDS	Information disclosure statement

TABLE OF EXHIBITS

Number	Description
EX2007	Xencor Form 10-K for the fiscal year ended December 31, 2017
EX2011	Xencor's IDS dated September 18, 2014
EX3101	Email authorization from the Board granting Merus permission to file a reply in support of its request for discretionary denial

The Acting Director's discretionary denial Orders since Merus filed its opening brief confirm that Xencor's IPR petition should be discretionarily denied based on the settled expectations that the '286 Patent would not be challenged. The '286 Patent has been in force since June 7, 2016, and Xencor has not provided any persuasive reason why it waited almost 9 years to challenge the '286 Patent. EX1001 at 1; *Intel Corp. v. Proxense LLC*, IPR2025-00327, Paper 12, at 2–3 (P.T.A.B. June 26, 2025) (in the absence of any persuasive reasoning for waiting over 9 years, “the Office is disinclined to disturb the settled expectations of Patent Owner.”).

Xencor does not justify its delay under *Intel*. Xencor did not identify any significant change in law that impacts the patentability of the challenged claims since the issuance of the '286 Patent. *See id.* at 2–3. Nor did Xencor claim that Merus failed to assert the '286 Patent in its relevant space. *See id.* Merus created novel bispecific antibodies covered by the '286 Patent and also licensed the '286 Patent. Instead of taking a license to the '286 Patent, however, Xencor chose to infringe.

To try to circumvent Merus's settled expectations, Xencor argues: (1) it is significant that the '286 Patent family has open continuation applications and the patent families in *iRhythm* and *Dabico* do not; (2) Merus did not show Xencor's knowledge of the '286 Patent; and (3) Xencor's potential § 271(e)(1) Safe Harbor defense to non-infringement insulates it from settled expectations. Paper 8 at 33–39. Xencor's arguments are not sufficient to disturb Merus's settled expectations.

The fact that the '286 Patent has open continuations is not germane to the settled expectations analysis. The relevant considerations are the age of the challenged patent and whether any persuasive reason exists why an IPR is an appropriate use of Board resources. *See Intel*, IPR2025-00327, Paper 12, at 3–4. The Acting Director denied institution in *Intel* without mention of the challenged patents' family, even though they are part of a family with open continuations.

Xencor was also well aware of the '286 Patent before and when it issued based on clear facts as compelling as those in the Acting Director's recent discretionary denial Orders. For example, institution was denied in *iRhythm* because petitioner cited the application that ultimately issued as the challenged patent in its own IDS. *See iRhythm Techs., Inc. v. Welch Allyn, Inc.*, IPR2025-00363, Paper 10, at 3 (P.T.A.B. June 6, 2025). Here, Xencor cited U.S. Patent Pub. No. 2013/0336981, which later issued as the '181 Patent—the parent to the '286 Patent—in its IDS in pursuit of its own patent. EX2011 at 4. Moreover, Xencor's own public 2017 Form 10-K clearly stated Xencor was aware of a “recently issued” Merus patent that would expire in 2033. EX2007 at 46. The '286 Patent issued on June 7, 2016 and will expire in 2033. It is clear that Xencor was referring to the '286 Patent when disclosing it in Xencor's first Annual Report after the Patent's issuance.

Xencor's safe harbor non-infringement defense will fail based on its incorrect theory that this defense could apply to its primary research, and in any event, there

is no justification for Xencor's failure to challenge the '286 Patent in the nine years it was aware of this patent. *First*, Xencor admits in its SEC filings that a court may not agree that its infringing development activities are protected by safe harbor. *See* EX2007 at 46 ("there can be no assurance that our interpretation of [35 U.S.C. §271(e)(1)] would be upheld."). *Second*, safe harbor only addresses issues of infringement and not validity. In fact, Xencor admits that "Xencor's 10-K expressly noted that, based on Xencor's preliminary analysis, 'there exists reasonable argument[s] of invalidity...' for Merus's patent." Paper 8 at 34 (quoting EX2007 at 46). If Xencor believed it had a reasonable basis to challenge the validity of the '286 Patent in 2017, it should have done so. *Third*, any safe harbor protection is limited to certain activities, is temporary, and would indisputably not apply to Xencor's primary research or any commercial sale of any of the drugs Xencor is developing. *See* EX2007 at 46.

The determination to exercise discretion to deny institution is based on a holistic assessment of all of the evidence and arguments presented. *See iRhythm*, IPR2025-00363, Paper 10, at 3. Xencor's untimely challenge of the '286 Patent outweighs any other considerations and favors discretionary denial of institution, particularly in view of recent Acting Director Orders.

Dated: July 9, 2025



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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing **REPLY IN SUPPORT OF MERUS' REQUEST FOR DISCRETIONARY DENIAL OF INSTITUTION** of IPR2025-00604 contains, as measured by the word-processing system used to prepare this paper, 752 words. This word count does not include the items excluded by 37 C.F.R. § 42.24 as not counting towards the word limit.

Dated: July 9, 2025

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that I caused to be served a true and correct copy of the foregoing: **REPLY IN SUPPORT OF MERUS' REQUEST FOR DISCRETIONARY DENIAL OF INSTITUTION** were served by filing this document through the Patent Trial and Appeal Case Tracking System (P-TACTS) as well as via electronic mail on July 9, 2025, in its entirety on the following:

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