

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

XENCOR, INC.,

Petitioner

v.

MERUS N.V.,

Patent Owner

IPR2025-00605
Patent No. 11,926,859

**PATENT OWNER MERUS' REQUEST FOR DISCRETIONARY DENIAL
OF INSTITUTION UNDER 35 U.S.C. §§ 314(a) AND 324(a) PURSUANT TO
THE MARCH 26, 2025 PROCESS MEMORANDUM FOR PTAB
WORKLOAD MANAGEMENT**

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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
Office	United States Patent And Trademark Office
Board or PTAB	Patent Trial And Appeal Board
'859 Patent	Merus' U.S. Patent No. 11,926,859
'427 Patent	Xencor's U.S. Patent No. 10,472,427
'935 Provisional Application	April 20, 2012 Provisional Application No. 61/635,935
POSA	Person of ordinary skill in the art
March 26, 2025 Process Memorandum	PTAB's March 26, 2025 Memorandum Regarding Interim Processes for PTAB Workload Management
March 26, 2025 Process Memorandum FAQs	FAQs for Interim Processes for PTAB Workload Management, available at https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management
Gunasekaran	Gunasekaran, <i>et al.</i> , Enhancing antibody Fc heterodimer formation through electrostatic steering effects: applications to bispecific molecules and monovalent IgG. <i>J Biol Chem.</i> 2010 Jun 18;285(25):19637-46
Moore	Moore, <i>et al.</i> , A robust heterodimeric Fc platform engineered for efficient development of bispecific antibodies of multiple formats. <i>Methods.</i> 2019 Feb 1;154:38-50
Lazar	U.S. Patent Application Publication No. US 2011/0054151
Kannan	International Patent Application Publication No. WO 2009/089004
FDA	U.S. Food & Drug Administration
SEC	U.S. Securities And Exchange Commission

Abbreviation	Definition
BTD	Breakthrough Therapy designation
Safe Harbor	35 U.S.C. § 271(e)(1)

LIST OF EXHIBITS

Exhibit Number	Description
EX2001	FDA Press release regarding accelerated approval to zenocutuzumab-zbco for non-small cell lung cancer and pancreatic adenocarcinoma, dated December 4, 2024
EX2002	Merus press release regarding petosemtamab being granted Breakthrough Therapy designation by the FDA, dated February 18, 2025
EX2003	Merus press release regarding Incyte collaboration, dated December 21, 2016
EX2004	Merus press release regarding Eli Lilly collaboration, dated January 19, 2021
EX2005	March 26, 2025 Process Memorandum
EX2006	Response to final Office Action for U.S. Pat. App. No. 12/700,618, dated August 25, 2011
EX2007	March 26, 2025 Process Memorandum FAQs
EX2008	Xencor Form 10-K for the fiscal year ended December 31, 2017
EX2009	International Publication Number WO 2011/028952 A1

I. INTRODUCTION

Xencor's petition for IPR of Merus' '859 Patent should be discretionarily denied for four independent reasons. First, Xencor withheld from the Acting Director that its petition flies in the face of its own arguments before the Office—having itself obtained a patent to the same invention, overcoming the same prior art it now raises as allegedly invalidating. Second, its arguments are extremely weak, raising four references, two of which are not prior art, and two of which the Examiner already considered. Third, there was no material error by the Examiner. And lastly, all the *Fintiv* factors favor denial or are neutral.

First, Xencor's petition fails to inform the Acting Director that Xencor ***patented the same invention*** it now attacks, ***over the same prior art*** it now asserts, ***using a later priority date*** than Merus' '859 Patent. The '859 Patent claims certain aspects of Merus' pioneering heterodimerization technology. Xencor's '427 Patent claims the same invention, but with a later priority date. Fatal to its petition, Xencor asserts two prior art references against the '859 Patent, Lazar and Kannan, both of which Merus disclosed to the Office in obtaining its '859 Patent and Xencor disclosed to the Office in obtaining its '427 Patent. The only other references Xencor asserts—Xencor's '427 Patent and Moore—are not prior art, because they post-date the '859 Patent's earliest effective filing date. Xencor's lack of candor and

contradiction in seeking to invalidate the same invention that it patented with a later priority date should not be rewarded with institution. Indeed, it may violate 37 C.F.R. § 42.11. The Acting Director should protect the Board's limited resources, which would be wasted on Xencor's contradiction, by granting discretionary denial of institution.

Second, Xencor's petition is extremely weak. Xencor's asserted prior art references, Lazar and Kannan, undisputedly fail to disclose each element of the challenged claims. Specifically, Lazar and Kannan fail to disclose a positively charged amino acid at position 364 and a negatively charged amino acid at position 368. Indeed, Lazar does not even disclose an antibody with the claimed mutations. Xencor attempts to backfill this weakness by relying on a purported expert declaration that is flatly contradicted by the facts. For example, Xencor's expert opines that Merus is not entitled to its earliest claimed priority date, in contradiction to the ***equal or less*** disclosure in his own patents.

Third, Xencor's petition should be denied institution under *Advanced Bionics*¹ because it relies on the same prior art references that were previously before the Office and the Office did not make a material error in its patentability analysis.

¹ *Advanced Bionics, LLC v. MED-EL Elektromedizinische Gertite GmbH*, IPR2019-01469, Paper 6 (Feb. 13, 2020) (precedential).

Indeed, Xencor obtained its '427 Patent over the same references, only with a later priority date. Xencor's contradictory positions before the Office when prosecuting its own patent and now in this petition render its petition simply not credible.

Finally, Xencor's petition should also be denied institution under *Fintiv*², because Xencor is both the petitioner here and the defendant in a parallel district court proceeding **and** an IPR would not dispose of that parallel proceeding. The district court proceeding includes three asserted patents, one of which is not the subject of a Xencor IPR petition.³ As a result, a stay of that proceeding is a toss-up, even if an IPR is instituted. This factor along with the other *Fintiv* factors favor denial.

At bottom, Xencor's petition runs afoul of the March 26, 2025 Process Memorandum, which aims to increase efficiency and allow the Board to focus on its important statutory duties without distraction from wasteful patent challenges. Xencor's contradictory, incredible assertion of "patentable to me, but not to them" petition would needlessly consume the Board's precious resources.

² *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (Mar. 20, 2020) (precedential).

³ The district court litigation involves the '859 Patent, U.S. Pat. No. 9,358,286, and U.S. Pat. No. 9,944,695. Xencor challenges the '859 Patent in IPR2025-00605. Xencor challenges U.S. Pat. No. 9,358,286 in IPR2025-00604. Xencor has not challenged U.S. Pat. No. 9,944,695 in any IPR.

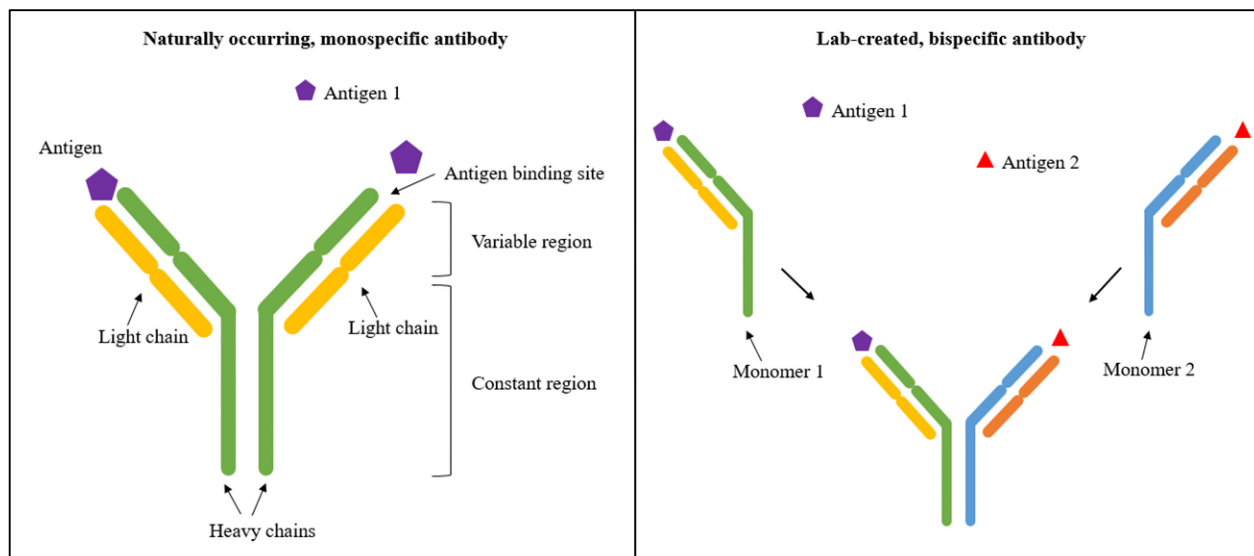
For all these reasons, as explained in more detail below, Merus respectfully requests that the Acting Director grant discretionary denial of institution.

II. BACKGROUND

Antibodies are some of the most important cancer treatments because they have the potential for high target specificity and a long half-life, which distinguishes them from conventional cancer treatments such as chemotherapy. As naturally produced by the human immune system, and as historically developed as biopharmaceuticals, antibodies are monospecific, meaning the antibody binds to one particular target (known as an antigen).

To improve upon monospecific antibodies, researchers have engineered bispecific antibodies, which unlike monospecific antibodies have two different binding domains that can therefore bind to two different targets (antigens). Compared to monospecific antibodies, bispecific antibodies can elicit superior cytotoxic effects, including by eradicating tumor cells more precisely and effectively and/or by engaging the human immune system to bring it into contact with a tumor cell to kill it in ways that a monospecific antibody cannot.

Bispecific antibodies are created by joining two different antibody monomers:



The act of joining the two different monomers is called heterodimerization.

A. Previously Known Heterodimerization Techniques

Creating stable, functional bispecific antibodies through heterodimerization has proven difficult. The heterodimerization techniques available prior to Merus' invention—including knob-into-hole and charge reversal—were plagued by stability issues, functionality issues, and low yield.

1. The Knob-Into-Hole Approach

One technique used to try to promote heterodimerization before Merus' invention was the "knob-into-hole" approach. This technique was developed circa 1996 and seeks to drive heterodimerization by introducing complementary protuberance and cavity mutations to the CH3 region of the monomer heavy chains.

See EX1001 at 46–47 (4:46 – 5:22). The knob-into-hole technique notoriously suffered low yield. See *id.* at 5:3–15.

2. Charge Reversal Strategy

At the relevant time, another known approach for seeking to promote heterodimerization was a charge reversal strategy, which was disclosed by Gunasekaran. In this approach, naturally occurring charged amino acid contact residues in the CH3 domain are replaced by amino acid residues of opposite charge (*i.e.*, a charge reversal), which creates an altered charge polarity across the Fc dimer interface in an effort to promote heterodimer formation and suppress homodimer formation. See EX1001 at 47 (5:34–49). This technique, however, also suffered inconsistent and potentially low yield—using the charge reversal strategy, “it is possible to produce a bispecific antibody in a single cell with proportions ranging between about 76% and about 96%.” See *id.* at 6:4–6.

3. The Need For Superior Heterodimerization Techniques

As of Merus' earliest effective filing date (April 20, 2012), there was a need for a superior heterodimerization technique. But that need was complicated by the fact that changes to the heavy chain—especially to the CH3 region of the heavy chain—could reduce an antibody's functionality, destabilize the antibody, and/or cause an immune response *in vivo*.

B. Merus Went Against The Grain And Created A New Approach To Heterodimerization

Merus set out to solve the problems with the two existing heterodimerization techniques by developing a new, third approach.

Merus' inventive third approach to heterodimerization defied the teachings of Gunasekaran by modifying the neutral residues in the "hydrophobic core" of the CH3 region, which plays an important role in folding and stability. Gunasekaran teaches a POSA **not to** modify the neutral residues in the "hydrophobic core" of the CH3 region, since "[i]t has long been established that the hydrophobic core of protein domains plays an important role in protein folding and stability," and "exploiting charged residues as opposed to hydrophobic residues at the CH3 domain interface may have benefits in terms of retaining the generally favorable biophysical properties of the Fc." See EX1012 at 4. Merus' patented heterodimerization technique directly contradicts Gunasekaran and **does** modify neutral residues in the "hydrophobic core" of the CH3 region, and furthermore surprisingly achieves a stable, functional heterodimer at excellent yield by doing so.

Indeed, the Merus inventors went so far against the conventional wisdom that they created a charge-charge interaction in the "hydrophobic core" of the CH3 interface. See EX1001 at 47 (5:34–49).

Merus did not use any protuberances or cavities in its approach, and thus completely differentiated itself from the “knob-into-hole” approach. It also did not use any charge reversals, and thus completely differentiated itself from the “charge reversal” strategy. Merus’ new approach to heterodimerization, as disclosed in its provisional application, surprisingly improves heterodimer yield. *See* EX1001 at 53–54 (18:67–19:17). As added benefits, Merus’ new approach generates bispecific antibodies that are stable and readily produced and purified at industrial scale, with a standard mammalian cell culture platform and a routine purification protocol.

C. The ’859 Patent

Merus was awarded the ’859 Patent (EX1001) for certain aspects of its new approach to heterodimerization. The ’859 Patent is directed to a “heterodimeric antibody” that is stabilized by certain modified amino acid residues in the “hydrophobic core” of its CH3 region. *See generally* EX1001. Specifically, the amino acid residue at position 364 of the first chain is modified from serine (S), a neutrally charged residue, to a positively charged residue, and the amino acid residue at position 368 of the second chain is modified from leucine (L), a neutrally charged residue, to a negatively charged residue. *See* EX1001 at 51 (13:44–48), 79 (claim 1).

Claim 1 of the ’859 Patent recites:

1. A heterodimeric antibody comprising a first human CH3 domain comprising a positively charged amino acid residue at position 364 according to the EU numbering system, and a second human CH3 domain comprising a negatively charged amino acid residue at position 368 according to the EU numbering system. EX1001 at 79.

According to dependent claim 2, the positively charged amino acid residue at position 364 comprises a lysine (K) or an arginine (R) residue, and the negatively charged residue at position 368 comprises an aspartic acid (D) or glutamic acid (E) residue. *Id.* According to dependent claim 3, the positively charged amino acid residue at position 364 comprises a lysine (K) residue, and the negatively charged amino acid residue at position 368 comprises an aspartic acid (D). *Id.* The modified positive amino acid interacts with the modified negative amino acid to create a strong heterodimeric bond, which can be used to create highly stable bispecific antibodies suitable for therapeutics.

D. Merus' Patented Heterodimerization Approach Led To New Commercial Bispecific Antibodies

Merus has used its new approach to heterodimerization to create and develop a broad pipeline of novel, fully human, heterodimeric bispecific antibodies for cancer therapy, both for itself and its collaborators. As one example, on December 4, 2024, FDA granted accelerated approval to zenocutuzumab-zbco (BIZENGRI®), a bispecific antibody for the treatment of adults with non-small cell lung and

pancreatic cancers driven by NRG1 fusion. *See* EX2001. Prior to its approval, the FDA granted zenocutuzumab-zbco a BTM for treatment of two different indications. *See id.* Recently, the FDA granted a second Merus bispecific antibody, petosemtamab, a BTM for treatment of certain kinds of recurrent or metastatic head and neck squamous cell carcinoma. *See* EX2002. BIZENGRI® and petosemtamab both practice patents in the same family as the '859 Patent, all of which are directed to aspects of Merus' pioneering heterodimerization technology.

Given the pioneering status of Merus' heterodimerization technologies, leading pharmaceutical and biotechnology companies, as well as academic institutions, have sought to collaborate with Merus to create and develop novel bispecific antibodies as treatment candidates. For example, in December 2016, Merus and Incyte Corporation entered into a strategic global collaboration agreement to use patented Merus technologies to create and develop novel bispecific antibodies. EX2003. Similarly, in January 2021, Merus and Eli Lilly and Company entered into a research collaboration agreement to use patented Merus technologies to create and develop novel bispecific antibodies. EX2004. These and other collaborations highlight Merus' status as a pioneer in the heterodimeric antibodies space.

III. LEGAL AUTHORITY

The Board has the authority to determine whether to institute an IPR. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.4(a). In line with this authority, the Acting Director issued the March 26, 2025 Process Memorandum, which bifurcates analysis of discretionary and merits considerations. *See* EX2005. Accordingly, the Acting Director may deny institution of an IPR based on discretionary considerations alone. *See id.*

In addition to acknowledging the existing Board precedent for discretionary denials—including *Fintiv*, *General Plastic*⁴, and *Advanced Bionics*—the March 26, 2025 Process Memorandum provides the following additional relevant considerations for the discretionary denial analysis:

- Whether the PTAB or another forum has already adjudicated the validity or patentability of the challenged patent claims;
- Whether there have been changes in the law or new judicial precedent issued since issuance of the claims that may affect patentability;
- The strength of the unpatentability challenge;
- The extent of the petition's reliance on expert testimony;
- Settled expectations of the parties, such as the length of time the claims

⁴ *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (Sept. 6, 2017) (precedential as to § II.B.4.i) pertains to serial IPR petitions challenging the same patents, which are not at issue here.

have been in force;

- Compelling economic, public health, or national security interests; and
- Any other considerations bearing on the Director's discretion.

Discretionary denial is a holistic analysis based on balancing the relevant factors, and can be based on all or a subset of these factors. *See, e.g., Arm Limited et al v. Daedalus Prime LLC*, IPR2025-00207, Paper 10, at 2 (P.T.A.B. May 16, 2025) (“Although certain arguments are highlighted above, the determination to exercise discretion to deny institution is based on a holistic assessment of all of the evidence and arguments presented”).

IV. ARGUMENT

A. Xencor's Petition Should Be Discretionarily Denied Under The March 26, 2025 Process Memorandum

Xencor's petition should be discretionarily denied under the relevant considerations of the March 26, 2025 Process Memorandum. Specifically, the Acting Director should consider: (1) Xencor's contradictory arguments and lack of candor with the Board; (2) the fatal weakness of Xencor's unpatentability challenge; (3) Xencor's excessive reliance on conclusory expert testimony; (4) the long settled expectations of the parties; and (5) compelling economic and public health interests.

1. Xencor's Contradictory Petition Lacks Candor To The Board

Xencor's contradictory positions before the Office to obtain its '427 Patent and before the Board in its current IPR petition may violate its duty of candor to the Acting Director and the Board. *See* 37 C.F.R. § 42.11(a) (2024) ("Parties and individuals involved in the proceeding have a duty of candor and good faith to the Office during the course of a proceeding."). Especially with respect to Ground 3, Xencor advances "a ***misleading*** or ***frivolous*** argument or request for relief" and the Board is authorized to order Xencor to show cause for its conduct. *See* 37 C.F.R. §42.12(a) (2024) (emphasis added); *see also* 37 C.F.R. § 42.11(d)(3) (2024).

When compared side-by-side, the claims of the '859 Patent and Xencor's '427 Patent are shockingly similar:

Claim 1 of the '859 Patent	Claim 1 of Xencor's '427 Patent
1. A heterodimeric antibody comprising a first human CH3 domain comprising a positively charged amino acid residue at position 364 according to the EU numbering system, and a second human CH3 domain comprising a negatively charged amino acid residue at position 368 according to the EU numbering system.	1. A heterodimeric protein comprising: a) a first monomer comprising a first variant Fc domain, and b) a second monomer comprising a second variant Fc domain, wherein said first and second variant Fc domains comprise amino acid variant set L368D and S364K ⁵ , according to the EU index as in Kabat.

⁵ Aspartic acid (D) is negatively charged, and lysine (K) is positively charged.

See EX1001 at 71 (claim 1); *c.f.* EX1036 at 143 (claim 1). Xencor was careful not to draw the Acting Director's and the Board's attention to the fact that Xencor's '427 Patent claims ***the same*** invention, over ***the same prior*** art, while using a ***later*** priority date. Xencor's petition to invalidate Merus' '859 patent over Lazar and Kannan is flatly contradicted by Xencor maintaining its own '427 patent over those references. Indeed, if Xencor truly believes that Lazar and Kannan invalidate the claims of Merus' patent, then Xencor should have disclaimed its '427 Patent before filing its petition.

The Acting Director should not reward Xencor's misuse of the IPR process and should exercise her discretion to deny Xencor's petition.

2. Xencor's Three Grounds For Unpatentability Are Weak And Not Likely To Invalidate Any Claim Of The '859 Patent

Xencor alleges three grounds of unpatentability that either rely on references that are not prior art (*i.e.*, Xencor's '427 Patent, which Xencor refers to as "Desjarlais," and Moore) or rely on references that were already before the Office and are clearly off-point (*i.e.*, Lazar and Kannan). Xencor's weak arguments strongly favor denying institution of Xencor's petition.

a. Grounds 1 And 2: Xencor's '427 Patent And Moore Are Not Prior Art

Merus is entitled to rely on the April 20, 2012 filing date of the '935

Provisional Application as the earliest effective filing date for the '859 Patent. The earliest possible filing date for Xencor's '427 Patent is January 14, 2013, and Moore's earliest possible publicly available date is October 23, 2018. Therefore, Xencor's '427 Patent and Moore are not prior art to the '859 Patent.

Xencor's argument that Claim 1 of the '859 Patent is not entitled to claim priority to the April 20, 2012 filing of the '935 Provisional Application is wrong on the facts and law.

First, the claims of the '859 Patent are fully supported by the '935 Provisional Application. For example, the '935 Provisional Application explicitly discloses the S364K and L368D substitutions. *See* EX1030 at 52–53 (Table 7). A POSA reading the '935 Provisional Application would know that Merus was in possession of the subject matter of the claims. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991) (“The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter”) (internal citations omitted).

Second, through his own statements, Xencor's expert admits that the disclosure in Merus' '935 Provisional Application is adequate to establish that Merus had possession of its invention on April 20, 2012. For example, during the

prosecution of one of his own patents, Dr. Presta overcame a § 112 rejection by arguing that although eight contact amino acid pairs were not explicitly disclosed in his pending specification, the skilled artisan can routinely identify these pairs without undue experimentation because “[t]he specification need not explicitly teach those in the art to make and use the invention.” *See* EX2006 at 9 (quoting *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1400 (Fed. Cir. 2003)).

Dr. Presta now hypocritically seeks to criticize the greater support found in Merus’ ’935 Provisional Application. Xencor’s (and Dr. Presta’s) principal argument appears to be that there is not a specific example. However, like Dr. Presta, Merus disclosed the claimed amino acid changes at positions 364 and 368. *See* EX1030 at 52–53 (Table 7). Furthermore, Merus disclosed that 364 and 368 are contact residues, and the neutral residues on positions 364 and 368 can be modified with charged residues. *See* EX1030 at 17 (Table A), 52–53 (Table 7), 23–24 (“now CH3 amino acids that are non-charged or neutral in wildtype CH3 are substituted with charged residues.” And as Dr. Presta has admitted in the context of his patent application, this disclosure is sufficient and Merus need not include a specific example of an antibody with amino acid changes at positions 364 and 368. *See* EX2006 at 9.

Given the above, the ’859 Patent is entitled to its earliest priority date, the April

20, 2012 filing date of the '935 Provisional Application. As a result, Xencor's '427 Patent and Moore are not available as prior art to the '859 Patent, and Xencor cannot invalidate any claim of the '859 Patent on Grounds 1 and 2.

**b. Ground 3: Lazar And Kannan Do Not Render
The Claims Obvious As They Do Not Disclose
All Of The Elements Of The Claims Of The
'859 Patent**

Xencor's obviousness argument over Lazar and Kannan fails because, among other reasons, Lazar and Kannan do not disclose or suggest "a positively charged amino acid residue at position 364" and "a negatively charged amino acid residue at position 368," as recited by independent Claim 1 of the '859 Patent. Moreover, Lazar undisputedly does not disclose an antibody with the requisite heterodimerization modifications as required by the '859 Patent.

Furthermore, as discussed in detail below, the Office already considered Lazar and Kannan during prosecution of the '859 Patent. The Office also considered Lazar and Kannan during prosecution of Xencor's '427 Patent. Both Merus and Xencor overcame Lazar and Kannan to obtain the claimed invention. The Board should not waste its resources to reach this conclusion a third time.

**3. The Extent Of Xencor's Reliance On Expert Testimony
Underscores The Weaknesses Of Its Unpatentability
Challenge**

Xencor's petition excessively relies on the conclusory and unsupported expert

testimony of Dr. Presta. Therefore, this discretionary factor also favors denial.

Significant portions of Dr. Presta's declaration are verbatim arguments and assertions made by Xencor's lawyers without offering sufficient independent analysis, supporting data, or reasoning grounded in specific, scientific evidence. For example, the entirety of Ground 3 of Xencor's petition and Dr. Presta's declaration are almost identical:

Petition at 56-58

Although the charges in the annotated example are reverse (referred to herein for convenience as a “reverse charge pair”) to the recited 364+ and 368- claim limitation, *Lazar*’s 364- and 368+ example would have conveyed to a POSA a preference for a heterodimer variant with a charge pair at position 364 in one chain and position 368 in another. (EX1002, ¶¶185-89.) In addition, a POSA would have understood from *Lazar*’s teachings that the charges in this example could have been swapped.

For example, *Lazar* teaches several preferred locations in the CH3 domain for making amino acid substitutions, including numerous locations known to be on the CH3 domain interface, such as positions 364 and 368. (EX1004, ¶¶52, 121, 123.) *Lazar* teaches specific modifications for both the 364 and 368 positions, including both positive (green) and negative (red) substitutions at both positions:

Hetero-Fc variants herein preferably comprise at least one substitution at a position in a CH3 domain selected from the group consisting of 349, 351, 354, 356, 357, 364, 366, 368, 370, 392, 394, 395, 396, 397, 399, 401, 405, 407, 409, 411, and 439, wherein numbering is according to the EU index as in Kabat. In a preferred embodiment, hetero-Fc variants comprise at least one CH3 domain substitution per heavy chain selected from the group consisting of 349A, 349C, 349E, 349I, 349K, 349S, 349T, 349W, 351 E, 351K, 354C, 356K, 357K, 364C, 364D, 364E, 364F, 364G, 364H, 364R, 364T, 364Y, 366D, 366K, 366S, 366W, 366Y, 368A, 368E, 368K, 368S, 370C, 370D, 370E, 370G, 370R, 370S, 370V, 392D, 392E, 394F, 394S, 394W, 394Y, 395T, 395V, 396T, 397E, 397S, 397T, 399K, 401 K, 405A, 405S, 407T, 407V, 409D, 409E, 411 D, 411 E, 411K, and 439D. Each of these variants can be used individually or in any combination for each heavy chain Fc region.

(EX1004, ¶123.) Thus, while the annotated example above in Table 1 makes use of 364E (negative) and 368K (positive) (a “reverse charge pair” to the substitutions recited in claim 1), a POSA reading *Lazar* would have understood that the opposite also would have been possible (e.g., 364H or 364R, as shown in green above, and 368E, as shown in red above). (EX1002, ¶¶188-89.) As such, *Lazar* expressly teaches “a positively charged amino acid residue at position 364” (364H and 364R, above) on one chain and a “negatively charged amino acid residue at position 368” (368E, above) on a second chain—also mentioning the “numbering is according to the EU index.” (*Id.*) And *Lazar* in fact identifies these modifications in the context of creating “[h]etero-Fc variants” for the purpose of “favor[ing] heterodimerization and disfavor[ing] homodimerization.” (EX1004, ¶¶119-125.)

Dr. Presta Decl. at 106-107

187. And while in Table 1, *Lazar* provides a substitution of a negatively charged amino acid residue at position 364 (insertion of the negatively charged glutamic acid (E)) on a first chain and a positively charged amino acid residue at position 368 (insertion of the positively charged leucine (K)), the teachings of *Lazar* disclose or suggest substituting in the reverse pair of charges. That is, the teachings of *Lazar* disclose (or, at the very least, suggest) exchanging the charges of the “[p]referred” “S364E” / “L368K” heterodimer and instead substituting a **positively** charged amino acid residue at position 364 on a first CH3 domain and a **negatively** charged amino acid residue at position 368 on a second CH3 domain—e.g., reversing the substitutions of the preferred heterodimer to yield a “S364K” / “L368E” variant, for example.

188. For instance, *Lazar* teaches both positively charged and negatively charged amino acid substitutions at these very positions. I have annotated the modifications provided in paragraph 52, below, to indicate substitution of a positively charged (in green) amino acid residue and a negatively charged amino acid residue (in red) at position 364 on a first chain and position 368 on a second chain:

Hetero-Fc variants herein preferably comprise at least one substitution at a position in a CH3 domain selected from the group consisting of 349, 351, 354, 356, 357, 364, 366, 368, 370, 392, 394, 395, 396, 397, 399, 401, 405, 407, 409, 411, and 439, wherein numbering is according to the EU index as in Kabat. In a preferred embodiment, hetero-Fc variants comprise at least one CH3 domain substitution per heavy chain selected from the group consisting of 349A, 349C, 349E, 349I, 349K, 349S, 349T, 349W, 351 E, 351K, 354C, 356K, 357K, 364C, 364D, 364E, 364F, 364G, 364H, 364R, 364T, 364Y, 366D, 366K, 366S, 366W, 366Y, 368A, 368E, 368K, 368S, 370C, 370D, 370E, 370G, 370R, 370S, 370V, 392D, 392E, 394F, 394S, 394W, 394Y, 395T, 395V, 396T, 397E, 397S, 397T, 399K, 401 K, 405A, 405S, 407T, 407V, 409D, 409E, 411 D, 411 E, 411K, and 439D. Each of these variants can be used individually or in any combination for each heavy chain Fc region.

(Ex. 1004 at ¶123.) *Lazar* describes these as “preferabl[e]” substitutions that “can be used individually or in any combination.” (Ex. 1004 at ¶123.)

189. Based on *Lazar*’s teachings in paragraph 123, a person of ordinary skill in the art would understand that either a complementary charge pair of amino acid residues could be substituted in at positions 364 and 368 of a first and second CH3 domain—positive/negative *or* negative/positive. Therefore, while *Lazar*

See, e.g., IPR2025-00605 Paper 1 at 56–58; c.f. EX1002 at 106–107. The above

excerpt is merely exemplary, as such copying and pasting pervades Dr. Presta's declaration. Such careless parroting of the Xencor's attorney arguments diminishes any weight to be accorded to Dr. Presta's opinion testimony.

Because Dr. Presta's conclusory opinion lacks substantive support, Dr. Presta's declaration does not add materially to Xencor's petition. *See Facebook v. Windy City Innovations, LLC*, 973 F.3d 1321, 1340-41 (Fed. Cir. 2020) (declining to re-weigh the Board's finding that expert's testimony did not add materially to petitioner's attorney argument because it "merely repeat[ed] Petitioner's argument, nearly verbatim, without citation to the basis for his testimony").

Furthermore, according to the recently published FAQs For Interim Processes For PTAB Workload Management, "[t]he failure to provide focused expert testimony may weigh against institution." EX2007 at 6 (question 21). Xencor's 52-page petition cites to Dr. Presta's 143-page declaration 131 times. For the reasons discussed above, Dr. Presta's testimony lacks the requisite "focus," lacks credibility, takes contradictory positions to his own patent prosecution, and simply parrots Xencor's attorney argument. And "[w]hile the Board may consider expert testimony, as a matter of efficiency, extensive reliance on expert testimony and/or reasonable disputes between experts on dispositive issues may suggest that the questions are better resolved in an Article III court. . . ." EX2007 at 6 (question 21).

4. The Expectations Of The Parties Have Long Been Settled

The settled expectations of the parties are that the '859 Patent family is valid and enforceable. Members of the '859 Patent family have been in force for nearly 9 years and have never before been challenged. Xencor has known about Merus' patents for years. Indeed, Xencor disclosed Merus' patents as a risk in its public Form 10-K SEC filing dated December 31, 2017. EX2008 at 46 (“[W]e are aware of a recently issued patent owned by Merus B.V. (Merus) that may relate to and claim components of our bispecific product candidates . . . and will putatively expire in 2033.”). It is telling that Xencor chose to challenge Merus' patent only after Merus filed an infringement suit and after Xencor itself obtained an ill-gotten, later-filed patent covering the same approach to heterodimerization.

5. There Are Compelling Economic And Public Health Reasons To Deny Xencor's IPR Petition

Merus is a successful oncology company with a proven track record of creating targeted antibody treatments to address the unmet needs of patients with various types of cancer. In pursuit of this goal, Merus has pioneered multiple advances in the creation and development of novel bispecific antibodies for therapeutic use, including the invention of the '859 Patent.

As discussed above, Merus is making extraordinary breakthroughs in cancer treatment using its patented heterodimerization technologies. BIZENGRI® is the

first and only therapy approved by the FDA specifically for pancreatic adenocarcinoma and NSCLC that harbor NRG1 gene fusions and are advanced unresectable or metastatic. Merus' next BTDC compound, petosemtamab, is not far behind. Merus is also actively working with collaborators, like Eli Lilly and Incyte, to continue bringing new bispecific antibody cancer treatments to the public. Merus' heterodimerization inventions are integral to its approach.

This is not a case in which the petitioner, Xencor, aims to open up to the world unfettered access to a critical area of cancer research. Instead, Xencor is attempting to invalidate Merus' '859 Patent while continuing to exclude others from this field by maintaining its '427 Patent, Xencor's later patent to the ***same heterodimerization invention—Merus' approach***.

B. Xencor's Petition Should Be Discretionarily Denied Under *Advanced Bionics*

The Board precedent of *Advanced Bionics* also supports discretionary denial of institution. Under *Advanced Bionics*, an IPR petition may be dismissed on discretionary grounds if: (1) the same or substantially same art or arguments were previously presented to the Office; and (2) if so, the Office did not make a material error in its patentability analysis. See generally *Advanced Bionics*, IPR2019-01469, Paper 6. Xencor's petition should be dismissed under *Advanced Bionics* because

Lazar and Kannan (the only two asserted references from before the priority date) were previously presented to the Office by Merus—these references are on the face of the '859 Patent—and the Office did not make a material patentability error with respect to these references by allowing the '859 Patent.

1. The Same (Or Substantially Same) Art Or Arguments Were Previously Presented To The Office

The two asserted references that are prior art were previously presented to the Office during the prosecution of the '859 Patent. International Patent Publication WO 2011/028952, which is the PCT publication of Lazar, was considered by the Examiner during the prosecution of the '859 Patent. Indeed, Xencor acknowledges that International Patent Publication WO 2011/028952 is the PCT publication of Lazar and it was considered by the Examiner. *See* IPR2025-00605 Paper 1 at 77. Both WO 2011/028952 (which was considered by the '859 Patent Examiner) and Lazar (cited in Xencor's petition) have identical twenty-nine figures and substantially the same written description with identical Examples. *See generally* EX2009 (WO 2011/028952); *c.f.* EX1004 (Lazar). The Examiner explicitly noted consideration of the references listed on the Information Disclosure Statements submitted during prosecution using the stamp: "All References Considered Except Where Lined Through." *See* Ex. 1029 at 234 (FP83).

IPR2025-00605
Patent No. 11,926,859
Patent Owner's Discretionary Denial Paper

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.D.B./		18/318,507 - GAU: 1633				
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Equivalent of Form PTO/SB-08 (07-09) Approved for use through 05/31/2014. OMB 0651-0001 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE						
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known Application Number <i>To Be Assigned</i> Filing Date <i>Herein</i> First Named Inventor Cornelis Adrian DE KRUIF Art Unit <i>To Be Assigned</i> Examiner Name <i>To Be Assigned</i> Attorney Docket Number 4096.0050007				
Sheet 9 of 17						
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.†	Foreign Patent Document Country Code ¹ -Number ² -Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Words, Relevant Passages or Relevant Figures Appear	†§
	FP82	WO-2010120204-A2	11-11-2010	ONCOMED PHARM INC [US]		
	FP83	WO-2011028952-A1	03-10-2011	XENCOR INC [US]		
	FP84	WO-2011028953-A1	03-10-2011	AMFTT INC [US]		
	FP85	WO-2011063348-A1	05-26-2011	AMGEN INC [US]		
	FP86	WO-2011097603-A1	08-11-2011	REGENERON PHARMA [US]		
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	FP89	WO-2012023053-A2	02-23-2012	NOVIMMUNE SA [CH]		
	FP90	WO-2012058768-A1	05-10-2012	ZYMEWORKS INC [CA]		
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	FP92	WO-2012141798-A1	10-18-2012	REGENERON PHARMA [US]		
	FP93	WO-2012148873-A2	11-01-2012	REGENERON PHARMA [US]		
	FP94	WO-2013134263-A1	09-12-2013	REGENERON PHARMA [US]		
	FP95	WO-2013157953-A1	10-24-2013	MERUS B V [NL]		
	FP96	WO-2013157954-A1	10-24-2013	MERUS B V [NL]		
	FP97	WO-2013184761-A1	12-12-2013	REGENERON PHARMA [US]		
	FP98	WO-2014151433-A1	09-25-2014	ALTRIA CLIENT SERVICES INC [US]		
	FP99	WO-9002809-A1	03-22-1990	PROTEIN ENG CORP [US]		
	FP100	WO-9012878-A1	11-01-1990	MEDICAL RES COUNCIL [GB]		
	FP101	WO-9100906-A1	01-24-1991	GENETICS INST [US]		
	FP102	WO-9108216-A1	06-13-1991	GENPHARM INT [US]		
	FP103	WO-9117271-A1	11-14-1991	AFFYMAX TECH NV [NL]		
	FP104	WO-9201047-A1	01-23-1992	CAMBRIDGE ANTIBODY TECH [GB]		
	FP105	WO-9203918-A1	03-19-1992	GENPHARM INT [US]		
	FP106	WO-9209690-A2	06-11-1992	GENENTECH INC [US]		
	FP107	WO-9215679-A1	09-17-1992	PROTEIN ENG CORP [US]		
	FP108	WO-9218619-A1	10-29-1992	SCRIPPS RESEARCH INST [US]		
	FP109	WO-9220791-A1	11-26-1992	CAMBRIDGE ANTIBODY TECH [GB]		
	FP110	WO-9301288-A1	01-21-1993	DEUTSCHES KREBSFORSCH [DE]		X
	FP111	WO-9312227-A1	06-24-1993	GENPHARM INT [US]		
Examiner Signature		/MICHAEL D BURKHART/		Date Considered	08/26/2023	

Kannan was also previously presented to the Office during the prosecution of the '859 Patent, and Xencor acknowledges that Kannan was cited in rejections of a parent application of the '859 Patent. See IPR2025-00605 Paper 1 at 77. The Examiner also explicitly noted consideration of the references listed on the Information Disclosure Statements submitted during prosecution using the stamp:

“All References Considered Except Where Lined Through.” See Ex. 1029 at 233 (FP77).

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.D.B/				18/318,507 - GAU: 1633	
Substitute for Form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	To Be Assigned
				Filing Date	Herewith
				First Named Inventor	Cornelis Adriaan DE KRUIF
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	8	of	17	Attorney Docket Number	4096.0050007
FOREIGN PATENT DOCUMENTS					
Examiner Initials ⁶	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Page, Column, Line, Where Relevant: Patent or Reissue Figure, Figure Appendix
	FP52	WO-03102157-A2	12-11-2003	GENENTECH INC [US]	
	FP53	WO-03106674-A2	12-24-2003	CHROMAGENICS BV [NL]	
	FP54	WO-03106684-A2	12-24-2003	CHROMAGENICS BV [NL]	
	FP55	WO-03107218-A1	12-24-2003	CELESTAR LEXICO SCIENCES INC [JP]	X
	FP56	WO-2004003211-A1	01-08-2004	IMCLONE SYSTEMS INC [US]	
	FP57	WO-2004009618-A2	01-29-2004	CRUCCELL HOLLAND BV [NL]	
	FP58	WO-2004061104-A2	07-22-2004	SYMPHOGEN AS [DK]	
	FP59	WO-2004106375-A1	12-09-2004	MERUS BIOPHARMACEUTICALS B V I [NL]	
	FP60	WO-2005000894-A2	01-06-2005	CRUCCELL HOLLAND BV [NL]	
	FP61	WO-2005068622-A2	07-28-2005	MERUS B V [NL]	
	FP62	WO-2005118635-A2	12-15-2005	NOVIMMUNE SA [CH]	
	FP63	WO-2006028936-A2	03-16-2006	GENENTECH INC [US]	
	FP64	WO-2006106905-A1	10-12-2006	CHUGAI PHARMACEUTICAL CO LTD [JP]	X
	FP65	WO-2006117699-A2	11-09-2006	INNATE PHARMA SA [FR]	
	FP66	WO-2007059782-A1	05-31-2007	GENMAB AS [DK]	
	FP67	WO-2007110205-A2	10-04-2007	MERCK PATENT GMBH [DE]	
	FP68	WO-2007117410-A2	10-18-2007	MEDAREX INC [US]	
	FP69	WO-2007147901-A1	12-27-2007	NOVO NORDISK AS [DK]	
	FP70	WO-2008027236-A2	03-06-2008	GENENTECH INC [US]	
	FP71	WO-2008054606-A2	05-08-2008	REGENERON PHARMA [US]	
	FP72	WO-2008076379-A2	06-26-2008	REGENERON PHARMA [US]	
	FP73	WO-2008119353-A1	10-09-2008	GENMAB AS [DK]	
	FP74	WO-2009051974-A1	04-23-2009	NUVELO INC [US]	
	FP75	WO-2009080251-A1	07-02-2009	HOFFMANN LA ROCHE [CH]	
	FP76	WO-2009080252-A1	07-02-2009	HOFFMANN LA ROCHE [CH]	
	FP77	WO-2009089004-A1	07-16-2009	AMGEN INC [US]	
	FP78	WO-2009098590-A2	08-13-2009	ZYMEWORKS INC [CA]	
	FP79	WO-2009157771-A2	12-30-2009	MERUS B V [NL]	
	FP80	WO-2010084197-A1	07-29-2010	GENMAB AS [DK]	
	FP81	WO-2010108127-A1	09-23-2010	GENENTECH INC [US]	
Examiner Signature: /MICHAEL D BURKHART/				Date Considered: 08/26/2023	

It is clear under *Advanced Bionics* that Lazar and Kannan were considered by the Office during prosecution of the '859 Patent.

2. The Office Did Not Make A Material Error In Its Patentability Analysis

Xencor's assertion that Lazar and Kannan were not properly considered during

prosecution of the '859 Patent—because they were not cited in an office action—is legally wrong. Discussion in an office action is not a requirement for discretionary denial. It is well-established that the absence of a rejection based on cited references does not evidence material error. *See Ivantis, Inc. v. Sight Sciences, Inc.*, IPR2022-01533, Paper 14, at 19 (P.T.A.B. Mar. 27, 2023).

Indeed, the Board has made clear that in direct contrast, grounds for denying institution can be based on the fact that prior art was “considered” but not discussed during prosecution. *See Clim-A-Tech Ind., Inc. v. William A. Ebert*, IPR2017-01863, Paper 13, at 18–19 (P.T.A.B. Feb. 12, 2018) (denying institution even though the “Examiner did not base a rejection” on the reference asserted in the petition); *Biocon Pharma Ltd. v. Novartis Pharm. Corp.*, IPR2020-01263, Paper 12, at 9 (P.T.A.B. Feb. 16, 2021) (holding that cited but unapplied references supported denying institution); *Sony Interactive Entm't LLC v. Terminal Reality, Inc.*, IPR2020-00711, Paper 15, at 11 (P.T.A.B. Oct. 13, 2020) (finding reference was previously considered by the PTO because it was listed in the Examiner's Notice of References Cited); *Agrinomix, LLC v. Mitchell Ellis Prods., Inc.*, IPR2017-00525, Paper 6, at 12–13 (P.T.A.B. Jun. 14, 2017) (denying institution for grounds based on prior art that was considered during prosecution even though the prior art reference was not relied upon to reject all the challenged claims).

Furthermore, the Board has held that examiners must receive deference, and are presumed to perform their duties and responsibilities as Examiners, understand the cited references, and issue only valid patents. *See PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008). “[I]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Advanced Bionics*, Paper 6, at 9.

In any event, the combination of Lazar and Kannan cannot render the claims of the '859 Patent obvious because these references do not disclose all of the elements of the claims, including the specific amino acid locations for substitution. Again, Xencor obtained its own patent over these very references. Having not withdrawn its '427 Patent, Xencor concedes that the Office did not make a material error in finding Merus' invention novel and not obvious over that prior art. Indeed, given that Xencor obtained its '427 Patent over the same prior art, it should be estopped from making this hypocritical argument.

The Office furthermore did not need to review Xencor's '427 Patent and Moore because they were filed after the earliest effective filing date for the '859 Patent. The '427 Patent's earliest possible filing date is January 14, 2013, and Moore's earliest possible publicly available date is October 23, 2018. The earliest

filing date of the '859 Patent is April 20, 2012, which is the filing date of the '935 Provisional Application that discloses descriptions, interface residue substitution tables, and experimental data for a heterodimeric antibody including a positively charged amino acid residue at position 364 in one heavy chain and a negatively charged amino acid residue at position 368 in the other.⁶

Because Xencor's petition presents only the same prior art and arguments previously presented during prosecution, and because Xencor has failed to make any showing of material error by the Office, the Acting Director should exercise her discretion and deny institution under 35 U.S.C. § 325(d).

C. Xencor's Petition Should Be Discretionarily Denied Under *Fintiv*

Under *Fintiv*, the Board considers multiple factors to determine whether to deny an IPR petition while a parallel district court is pending. The *Fintiv* factors include: (1) whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted, (2) proximity of the court's trial date to the Board's projected statutory deadline for a final written decision, (3) investment in the parallel proceeding by the court and the parties, (4) overlap between issues raised

⁶ There is no difference between the utility disclosure and provisional disclosure on this point, so this is really a disguised §112 attack. But even if this is viewed purely as an exercise in determining what is, and is not, prior art, the result is the same. The provisional disclosure is sufficient such that any reference dated after the provisional filing date is not prior art.

in Xencor's petition and in the parallel proceeding, (5) whether the petitioner and the defendant in the parallel proceeding are the same party, and (6) other circumstances that impact the Board's exercise of discretion, including the merits. *See Fintiv*, IPR2020-00019, Paper 11, at 6. *Fintiv* is a balancing test, so Merus does not need all factors to be present to prevail. *See id.* at 5. As discussed below, on balance the *Fintiv* factors weigh in favor of denial of institution.

As for *Fintiv* factor 1, the district of Delaware has not granted a stay in the parallel district court litigation. Further, because Xencor's IPR petitions do not cover all asserted patents in the district court litigation, if a proceeding were instituted a stay would be a coin-toss. Therefore, *Fintiv* factor 1 favors discretionary denial.

Regarding *Fintiv* factor 2, the district court litigation does not yet have a trial date—the parties are awaiting oral argument and/or a decision on Xencor's motion to dismiss Merus' complaint. Merus has requested a Rule 16 conference, but the litigation was recently reassigned from Chief Judge Colm F. Connolly to Judge John Campbell Barker of the Eastern District of Texas, who is sitting by designation in the District of Delaware. Based on past precedent, Merus expects trial to be in August 2026, roughly two years from the filing of its complaint. The projected statutory deadline for a final written Board decision is September 30, 2026

(extendable by no more than 6 months for good cause). Because the trial could potentially predate the Board's final written decision, *Fintiv* factor 2 favors discretionary denial.

Fintiv factor 3 also favors discretionary denial. Merus has reviewed thousands of pages of documents, including technical documents like laboratory notebooks, and prepared document productions to comply with Chief Judge Connolly's extensive initial disclosure requirements. And both Merus and Xencor have put significant work into the Safe Harbor briefing. Therefore, the parties have invested in the parallel district court proceeding.

Fintiv factors 4 and 5 also favor discretionary denial. Xencor is both the petitioner here and the defendant in a parallel district court proceeding **and** an IPR would not dispose of that parallel proceeding. The ongoing district court proceeding in the District of Delaware includes three asserted patents, one of which is not the subject of a Xencor IPR petition. As a result, a stay of that proceeding is a toss-up, even if an IPR is instituted. *Fintiv* factor 6 also favors discretionary denial of Xencor's IPR petition because, for the reasons discussed above, Xencor's petition is contradictory and weak on the merits.

The Acting Director should also deny institution under § 314(a) because the lack of progress in the parallel district court litigation is due to Xencor's dilatory

tactics. Xencor should not be rewarded for this behavior. The purpose of the *Fintiv* analysis is to “take[] a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.” *Fintiv*, IPR2020-00019, Paper 11, at 6. A holistic view of Xencor's actions reveals dilatory tactics, hypocrisy, and bad faith arguments. The efficiency and integrity of the system are best served by denying institution.

The District Court litigation is delayed because Xencor is engaging in tactical delay. On August 5, 2024, Merus filed a complaint for patent infringement against Xencor in the District of Delaware, alleging infringement of the three patents, including the '859 Patent. Xencor has infringed, and continues to infringe, Merus' '859 Patent, including during Xencor's independent and partnered or collaborative heterodimeric antibody creation and development work.

Instead of responding to Merus' infringement allegations, Xencor moved to dismiss Merus' Complaint, arguing that all of Xencor's infringing conduct was somehow immune under the Safe Harbor. Merus opposed, explaining that Xencor's use of Merus' patented heterodimerization technology during its early creation and development work falls outside the Safe Harbor.

Xencor's motion to dismiss based on alleged Safe Harbor immunity was meritless. Xencor ignored binding precedent, including from the Supreme Court and

the Federal Circuit, and contradicted their own prior admissions on this topic. Had Xencor earnestly responded to Merus' complaint, the District Court litigation would likely be well into fact discovery.

For the reasons discussed above, Xencor's IPR petition should be denied under *Fintiv*.

V. CONCLUSION

For at least the foregoing reasons, the Acting Director should discretionally deny institution of Xencor's petition.

Dated: May 30, 2025

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing Request for Discretionary Denial of Institution of IPR2025-00605 contains, as measured by the word-processing system used to prepare this paper, 6,022 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: May 30, 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: **PATENT OWNER MERUS' DISCRETIONARY DENIAL BRIEF** and **EXHIBITS** were served by filing this document through the Patent Trial and Appeal Case Tracking System (P-TACTS) as well as via electronic mail on May 30, 2025, in its entirety on the following:

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