

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

XENCOR, INC.,
Petitioner

v.

MERUS N.V.,
Patent Owner

Case IPR2025-00605
Patent No. 11,926,859

**PETITIONER'S OPPOSITION TO
PATENT OWNER'S DISCRETIONARY DENIAL BRIEF**

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I. INTRODUCTION

Institution is strongly favored under the traditional discretionary considerations of *Fintiv* and *Advanced Bionics*. The district court case is in its infancy—there has been no Rule 16 conference, and no case schedule has been entered. Also, a stay is likely here based on statistics for the district court. But even without a stay, a final written decision in this proceeding would likely precede trial by many months (if not longer). And for the original prosecution, Xencor’s Petition relies on newly presented anticipatory references that the Examiner never considered. Although the references for Xencor’s third ground (*Lazar* and *Kannan*) were listed in a very large IDS to the Examiner, under Merus’s current approach to priority support—mixing and matching individual mutations listed in a table—it is clear the Examiner erred in allowing the claims over *Lazar* and *Kannan*, which have similar (or greater) disclosures. Thus, *Fintiv* and *Advanced Bionics* favor institution.

Contrary to Merus’s arguments, policy also strongly favors institution. This Petition is an early challenge to the ’859 patent, which issued less than a year before the petition was filed. And Merus’s decision to pursue (and obtain) unabashedly “shockingly similar” claims to Xencor’s previously filed and previously issued claims (claims that Merus never challenged) was unexpected. Knowing the merits of Xencor’s petition are strong, Merus tries to frame the

similarity between Xencor’s and Merus’s claims as reflecting a lack of “candor.” But this reflects a fundamentally flawed characterization of the Petition that in fact cited and relied on the very “similar” claims Merus identifies.

Review of the ’859 patent is particularly important given the way Merus attempts to wield it against Xencor. Xencor is a U.S.-based biopharmaceutical company that is developing and testing novel bispecific antibodies for treating cancer and autoimmune diseases. Although Xencor’s pre-commercial activity is protected by the 35 U.S.C. § 271(e)(1) safe harbor, Merus is nevertheless attempting to use the ’859 patent to suppress Xencor’s activities based on Merus’s unsupported claims to subject matter that Xencor developed and disclosed first. An IPR challenge at the PTAB is the proper mechanism for efficiently resolving this dispute.

II. BACKGROUND

A. District of Delaware Litigation

On August 5, 2024, Merus N.V. (“Merus”) filed a patent infringement complaint in the District Court of Delaware, alleging Xencor, Inc. (“Xencor”) infringed three of Merus’s patents—U.S. Patent No. 9,944,695 (“the ’695 patent”), U.S. Patent No. 9,358,286 (“the ’286 patent”), and U.S. Patent No. 11,926,859 (“the ’859 patent”). (EX1052, ¶4.) The ’286 and ’859 patents are similarly directed to methods of heterodimerization of antibodies, whereas the ’695 patent is

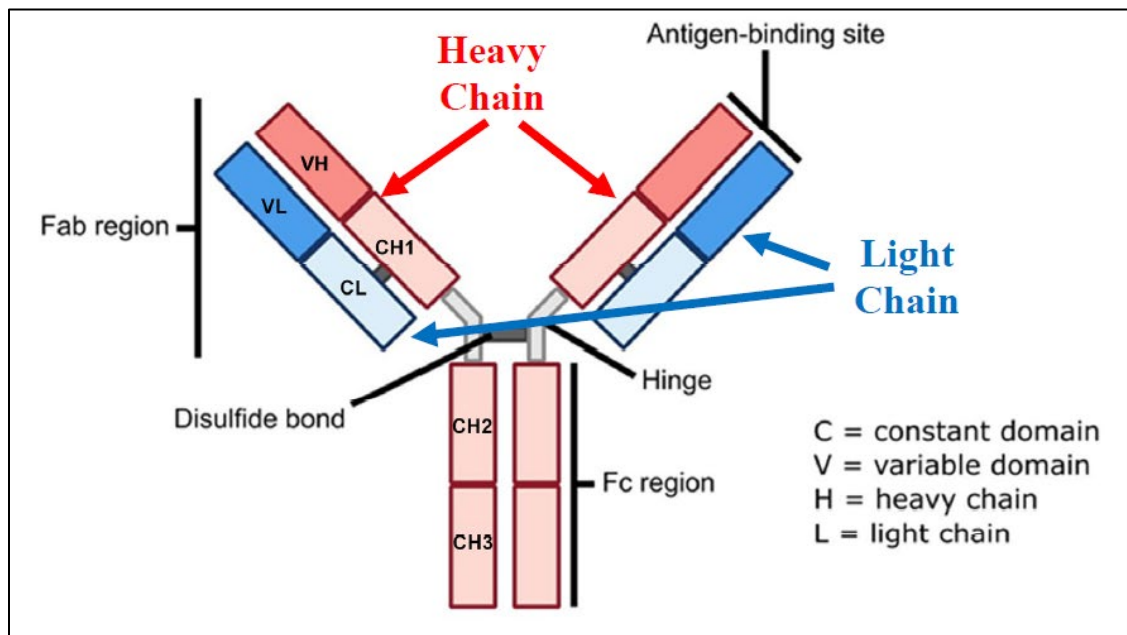
different, relating to a method of manufacturing antibodies containing a human common light chain. (EX1052, ¶¶9-11.) Merus's case was originally assigned to Chief Judge Connolly. (EX1053, 3.)

Recognizing the weakness in Merus's complaint targeting activity covered by the safe harbor provision in 35 U.S.C. § 271(e)(1), Xencor filed a motion to dismiss Merus's complaint on October 10, 2024. (EX1054.) Although Xencor does not currently have any drug products on the market, Merus seeks monetary damages from certain "developmental" activities. (EX1054, 3, 5.) Xencor has been focused on developing novel therapies that utilize bispecific antibody platforms, with the eventual goal of submitting those therapies for FDA approval. (EX1054, 3.) At present, Xencor has multiple therapies undergoing various stages of clinical trials but has yet to receive permission from the FDA to market any therapy under Xencor's developmental direction. (EX1054, 3-5, 8-9.)

Xencor's motion to dismiss was fully briefed before the district court by November 14, 2024. (EX1053, 5 (D.I. 22).) Then, on May 6, 2025, the case was reassigned to Judge Barker of the Eastern District of Texas. (*Id.*) Other than ministerial filings by the parties, no further activity in the case has occurred—there has been no Rule 16 conference and there is currently no case schedule. The motion to dismiss remains pending.

B. Technology Background

The technology at issue involves methods for making antibodies from two different parts (“heterodimeric” antibodies). One common antibody type is human IgG, which is composed of several portions, as shown below:



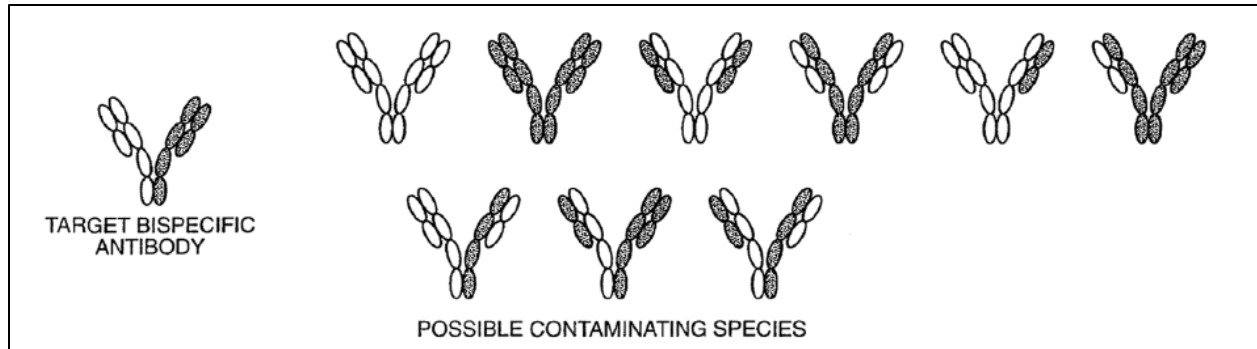
(Pet., 5-6; EX1002, ¶¶23-31.) This antibody comprises a left and a right half of the “Y,” with the antigen binding sites being on the two top sides of the “Y.” If the two halves are the same, this is known as a homodimeric antibody. (Pet., 7; EX1002, ¶27.) If they are different, it is a heterodimeric antibody. (Pet., 7-8; EX1002, ¶33.) One example of a heterodimeric antibody is shown below:



(EX1006, Fig. 1A; Pet., 8.)

One reason to make a heterodimeric antibody is to allow the antibody to be bispecific, meaning it can bind to two different antigens (or two different epitopes on the same antigen). (Pet., 7-8; EX1002, ¶¶32-36.) This allows new and more-effective treatment options for certain diseases. (Pet., 8; EX1013, 182-84; EX1004 ¶¶3, 6; EX1006, 3-4.) The black-and-white figure above shows an example of a heterodimeric, bispecific antibody, since the two halves are different and because the two antigen binding sites are different. (Pet., 7-8; EX1002, ¶¶32-33.)

Bispecific antibodies have been known for a long time. However, their use as therapeutic agents has been hampered by low yield caused by mismatching of the heavy and light chains (which are created separately in the cell that generates the antibody). (Pet., 9.) An example of such mismatching is shown below.



(EX1006, Fig. 1A.)

For this reason, several techniques have been developed to reduce mismatching to improve yield of the desired antibody. (Pet., 9-10; EX1002, ¶¶41-58.) Merus’s ’859 patent claims are directed to one such method for encouraging proper matching of the heavy chains—making substitutions in the CH3 domain¹ to introduce a charge interaction. That is, by introducing a positively charged amino acid in the CH3 domain on one heavy chain and a negatively charged amino acid in the CH3 domain on the other heavy chain, heterodimers (positive-to-negative) are favored, and homodimers (positive-to-positive and negative-to-negative) are disfavored. This is called “electrostatic steering,” and was a known technique. (Pet., 9-10; EX1002, ¶¶52-57; EX1016, 188-190; EX1007, 2:33-3:7; EX1012, 19637.)

¹ As shown in the human IgG graphic above, the CH3 domain is at the bottom of the “Y.” (Pet., 6.) The CH3 domains play a critical role in the pairing of the two heavy chains. (Pet., 7.)

The '859 patent claims are directed to two mutations made in a “first” and a “second” CH3 domain—as Xencor described in its Petition (Pet., 28), a “364+ and 368-” modification pair²:

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

(EX1001, Claim 1 (annotations added).)

C. '859 Patent Prosecution

Merus filed the application leading to the '859 patent on May 16, 2023, more than 10 years after the earliest provisional listed on the face of the '859 patent. (EX1001, Cover (fields 22 & 60).) Merus filed a preliminary amendment with this application that replaced all pending claims with nine claims newly reciting a mutation at both the 364 position on one CH3 domain and at the 368 position on a separate CH3 domain. (EX1029, 174-75.) In that preliminary amendment, Merus did not identify written description support for any individual

² The numbering refers to the amino acid position within the heavy chain according to a standardized (Kabat) numbering system. Position “364” refers to the 364th amino acid, and position “368” refers to the 368th position. The naturally occurring amino acids at positions 364 and 368 human IgG are both neutral amino acids.

claim, and instead incorrectly argued that “[s]upport for the new claims can be found throughout the specification, *inter alia*, at Example 13 and Table 7, and in the claims as originally filed” without further elaboration. (EX1029, 176; Pet., 13.) But as described below (Section III.A.3.a) and in the Petition (Pet., 23-37), Merus’s applications, including Example 13 and Table 7, do not support the claimed 364+ and 368- modification pair.

The Examiner issued only one office action during prosecution based on double patenting, which Merus overcame by cancelling certain claims and filing terminal disclaimers. (EX1029, 217-24, 249-51, 255-59; Pet., 13-14.) The Examiner never referenced or analyzed written description support or applied any prior art. As explained in Xencor’s Petition (and below), Merus’s purported priority applications do not provide written description support for the ’859 patent claims. (Pet., 23-37.) Had Merus made the priority arguments to the Examiner that it currently makes (that written description support can be found by combining individual mutations from lists (*see* DDB,³ 14-17), and had the Examiner been aware of the teachings of *Lazar* and *Kannan* that provide a similar (or greater) level of disclosure, the Examiner would have never allowed the claims.

³ Merus’s Request for Discretionary Denial (Paper 6) is cited as “DDB” herein.

III. ARGUMENT

The Director should decline Merus's request for discretionary denial. Merus is attempting to stifle and penalize Xencor's pre-commercialization development and pre-clinical/clinical testing activities that are covered under the § 271(e)(1) safe harbor based on patent claims that Merus itself suggests were copied from Xencor. Xencor's Petition challenging the '859 patent should be considered on the merits to clear the cloud that Merus has put over Xencor's protected activity.

Xencor has done everything it can to treat these IPRs⁴ as an alternative to district court litigation for the unpatentability challenges presented herein. Xencor did not wait until its statutory bar date, and instead swiftly prepared these petitions in half of the statutorily allotted time. And even though the parallel district court case has laid dormant, with virtually no activity occurring thus far, Xencor has agreed to *Sotera* stipulations to avoid any doubt of Xencor's intent to treat this proceeding as an alternative to district court litigation. Furthermore, this petition is not redundant with original prosecution. Instead, Xencor has shown in its Petition how the Xencor prior art clearly anticipated the claimed 364+ and 368- mutations

⁴ Xencor has filed a concurrent IPR petition challenging the '286 patent—
IPR2025-00604.

and why Merus’s claim to priority was faulty, leading the Examiner to overlook Xencor’s anticipatory prior art.

The Director should deny Merus’s request for discretionary denial and refer the Petition to the Board for an institution decision.

A. Interim Process Rationales Do Not Justify Denial

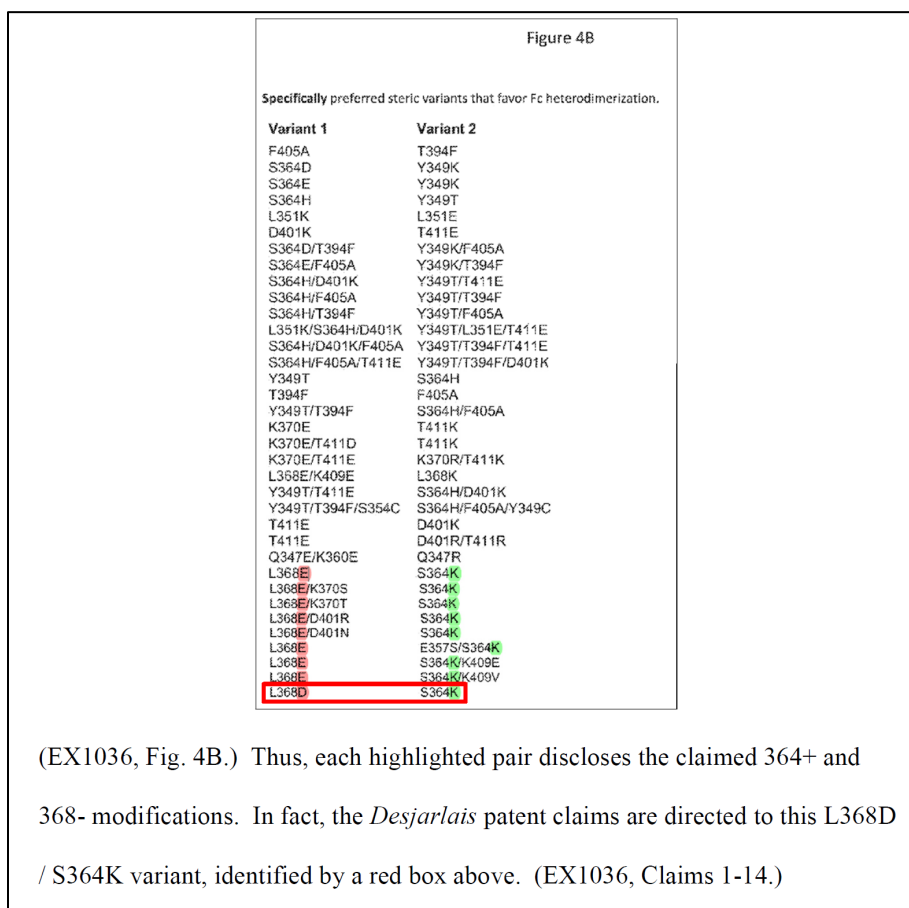
1. The District Court Case Is in its Infancy and Has Not Adjudicated Validity of the Challenged Claims

Merus ignores the first consideration in the Director’s Interim Process Memo, which favors institution here. (EX2005, 2.) Because there have been no previous PTAB challenges to the ’859 patent and because the district court case is in its infancy, this IPR would be the first opportunity to “adjudicate[] the validity or patentability of the challenged patent claims.” (*Id.*) This consideration favors institution.

2. Merus’s “Candor” Accusations Lack Merit and Misconstrue the Petition

Merus’s first argument accuses Xencor of hiding the fact that Xencor has patent claims that are “shockingly similar” to the challenged ’859 patent claims, arguing that “Xencor was careful not to draw the Acting Director’s and the Board’s attention to the fact that the [*Desjarlais*] Patent claims *the same* invention....” (DDB, 14.) But Xencor *did* draw the Board’s attention to this point. It was Xencor’s very first unpatentability argument in its Petition—*Desjarlais* anticipates. (Pet., 37-47.) Merus’s renaming of *Desjarlais* to “Xencor’s ’427 Patent”—a fact

Merus only acknowledges halfway through its brief (DDB, 14 (“Xencor’s ’427 Patent, which Xencor refers to as ‘Desjarlais’”))—does not change the fact that Xencor’s very first argument was based on *Desjarlais* disclosing the same invention and thus *Desjarlais* anticipates Merus’s “shockingly similar” claims. Xencor even expressly referenced the *Desjarlais* claims (which have § 112 support from the *Desjarlais* specification, unlike Merus’s claims):



(Pet., 41.)

Merus’s vague finger pointing at Xencor’s Ground 3 misunderstands Xencor’s Petition. Xencor’s Petition presented two strong bases for anticipation

over *Desjarlais* (Ground 1) and *Moore* (Ground 2)—anticipation which Merus seems to admit in its brief. (DDB, 1 (“*the same invention*”), 14 (same).) For those grounds, Merus only contests the prior art status of *Desjarlais* and *Moore* by arguing that an earlier Merus application supposedly provides sufficient written description support for the claims. (DDB, 14-17.) Those prior applications do not provide written description support for the reasons below and in the Petition. *See* Section III.A.3.a; (Pet., 23-37). But in any case, Xencor predicted this response by Merus, which is why Ground 3 was included.

As Xencor’s Petition explained, to the extent “Merus were allowed to stitch together disparate teachings in its priority applications” (*e.g.*, from lists of mutations such as in Table 7), such an argument by Merus would render the claims obvious over an even earlier Xencor publication (*Lazar*) that similarly disclosed such mutations in lists. (Pet., 2, 60.)

AA substitutions in CH3	construct #	Effect on homodimer formation (- = no effect; +++ = max. inhibition; NT= not tested on gel)
Q347K	8	-
Y349D	9	+-
Y349K	10	+-
T350K	11	-
T350K, S354K	12	+-
L351K, S354K	13	+-
L351K, T366K	14	++
L351K, P352K	15	+-
L351K, P353K	16	++
S354K, Y349K	17	++
D356K	18	-
E357K	19	-
S364K	20	++
T366K, L351K	21	++
T366K, Y407K	22	+++
L368K	23	NT
L368K, S364K	24	++
N390K, S400K	25	+-
T394K, V397K	26	+

Merus's Provisional Table 7

Lazar Table 1 & ¶123

“Preferred” CH3 Domain Variants from *Lazar*

TABLE 1

Preferred CH3 domain variants that favor Fc heterodimerization.

Variant 1	Variant 2
F405A	T394F
S364D	Y349K
S364E	L368K
S364E	Y349K
S364F	K370G
S364H	Y349K
S364H	Y349T
S364Y	K370G
T411K	K370E
V397S/F405A	T394F
K370R/T411K	K370E/T411E
L351E/S364D	Y349K/L351K
L351E/S364E	Y349K/L351K
L351E/T366D	L351K/T366K
P395T/V397S/F405A	T394F
S364D/K370G	S364Y/K370R
S364D/T394F	Y349K/F405A
S364E/F405A	Y349K/T394F
S364E/F405S	Y349K/T394Y
S364E/T411E	Y349K/D401K
S364H/D401K	Y349T/T411E
S364H/F405A	Y349T/T394F
S364H/T394F	Y349T/F405A
Y349C/S364E	Y349K/S354C
L351E/S364D/F405A	Y349K/L351K/T394F
L351K/S364H/D401K	Y349T/L351E/T411E
S364E/T411E/F405A	Y349K/T394F/D401K
S364H/D401K/F405A	Y349T/T394F/T411E
S364H/F405A/T411E	Y349T/T394F/D401K

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.

(Pet., 30 (annotating EX1030, 52 (Table 7, truncated)); EX1002, ¶¶90 (annotating EX1004, Table 1), 188 (annotating EX1004, ¶123).) In other words, Xencor’s position is that *Desjarlais* and *Moore* anticipate, but to the extent Merus attempts to claim an earlier priority date by cobbling together individual mutations from lists, such a position by Merus would render the claims obvious over *Lazar* alone or in view of *Kannan*.

Finally, Merus's argument that, in its view, the *Desjarlais* claims might also be unpatentable is a non-sequitur—the question for the Board is whether the '859 patent claims are unpatentable. To be sure, however, while it does appear that Merus attempted to copy Xencor's claims—which if anything speaks to Merus's lack of candor, not Xencor's—the claims are not identical, are supported by different specifications, and present unique patentability issues. And in any event, Merus's argument at best implicates only one (out of three) grounds. For all of these reasons, Merus's "candor" argument lacks merit and does not support discretionary denial.

3. The Petition's Unpatentability Merits Are Strong

Xencor's unpatentability grounds based on anticipation (Grounds 1 and 2) and obviousness (Ground 3) are strong and work in harmony. First, Merus cannot credibly assert that *Desjarlais* and *Moore* do not anticipate without arguing for an antedating priority date. But to show it is entitled to an earlier priority date, Merus must identify clear support for the claims in its prior applications. Because the disclosures in its applications are limited, however, Merus must rely on combining mutations that are listed individually in those applications. And to the extent that combining individually listed mutations is even acceptable, this bolsters Xencor's obviousness Ground 3 because *Lazar* and *Kannan* have the same types of disclosures as Merus's applications (and they both are indisputably prior art).

Thus, Merus's arguments against anticipation (to overcome *Desjarlais* and *Moore*) only strengthen Xencor's obviousness ground, and Merus's arguments that *Lazar* and *Kannan* do not render the claims obvious fundamentally undermines its basis for written description support in its applications.

a) The Strength of Grounds 1 & 2 Is Not Undermined by Merus's Weak Priority Argument

Merus does not even contest that the disclosures in *Desjarlais* and *Moore* anticipate if they are prior art. In fact, Merus affirmatively argues *Desjarlais* discloses "***the same invention.***" (DDB, 1.) Thus, the critical inquiry is whether Merus can claim priority to an antedating application. *See, e.g., Indivior UK Ltd. v. Dr. Reddy's Lab 'ys S.A.*, 18 F.4th 1323 (Fed. Cir. 2021) (affirming IPR unpatentability determination because the claims lacked written description support from the supposed priority application and thus intervening art undisputedly anticipated). As Xencor explained in its Petition, Merus's '859 patent claims cannot receive an earlier filing date because none of its applications' disclosures provide sufficient written description support for the claimed combination of a 364+ modification on one CH3 domain and a 368- modification on a separate CH3 domain. (Pet., 23-37.) This lack of support is not surprising given Merus's new claims were attempting to capture something that Xencor disclosed first.

Merus's cursory arguments for priority in its discretionary denial brief fail to rebut the Petition's thorough analysis. For instance, Merus points to Table 7, arguing it "discloses the S364K and L368D substitutions." (DDB, 15.) But Xencor addressed Table 7 in its Petition, explaining it merely discloses a list of mutations to be made on both heavy chains, not the combination of two separate CH3 domains with different mutations, as claimed. (Pet., 29-30.) This is apparent from the context in which Table 7 was created—Example 13, which was testing whether certain mutations "would result in repulsion of *identical* heavy chains." (EX1030, 51 (emphasis added); Pet., 29-30.) That is, Merus was testing the effect of these individual mutations on homodimer formation, since there was no second, different heavy chain; thus, heterodimers were not shown. Merus ignores this deficiency in their argument for support from Table 7, which shows why they are not entitled to priority.

Next, Merus tries to twist an alleged admission from Dr. Presta. (DDB, 15-16.) But the statement Merus plucks from its context was made by a Genentech prosecuting attorney, not Dr. Presta. (EX2006, 9, 14.) And the statement was a legal argument regarding enablement, not written description. (EX2006, 8-12.) This is meaningful because the case quotation that Merus repeats in its brief is a sentence immediately after distinguishing written description from the "more indulgent" enablement requirement:

The enablement requirement is often more indulgent than the written description requirement. The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without “undue experimentation.”

Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1334 (Fed. Cir. 2003) (portion quoted by Merus underlined). The Director should reject Merus’s attempt to turn a legal argument about enablement by a Genentech prosecuting attorney in a completely different case into a factual admission regarding written description by Dr. Presta for the ’859 patent.

Lastly, Merus points to two additional portions of the provisional application as supposedly supporting written description. (DDB, 16 (citing “EX1030 at 17 (Table A)” and a statement from 23-24).) But neither cures the deficiency of failing to describe two separate CH3 domains with different mutations. Table A is merely disclosing known interface residues, not different mutations on two separate CH3 domains. (EX1030, 17.) And the statement at 23-24 is merely that the supposedly “inventive” aspect of the “present invention” is “now CH3 amino acids that are non-charged or neutral in wildtype CH3 are substituted with charged residues” (EX1030, 23-24), which likewise does not support the mutations on two

separate CH3 domains at specific amino acid locations (364 and 368) that Merus claimed.

For these reasons, Merus's priority arguments are meritless. But in any case, Merus's identification of those disclosures—if sufficient for written description purposes (which Xencor contests)—further reinforces that the claims are obvious over *Lazar* and *Kannan* (Ground 3) because those references have the same level of disclosure (or greater), as described below. Merus cannot have it both ways.

b) The Strength of Ground 3 Is Not Undermined by Merus's Conclusory Attorney Argument

For Ground 3, Merus's priority arguments reinforce obviousness over *Lazar* and *Kannan*. As described above, Merus pointed to Table A for support, but this is merely a copy of *Kannan*'s disclosure of the known CH3 domain interface residues. (Pet., 28, 61-62.) Merus also identified a portion of the specification claiming neutral-to-charged CH3 domain modifications were the inventive contribution, but that was already disclosed by *Lazar*, as shown below:

“Preferred” CH3 Domain Variants from *Lazar*

TABLE 1

Preferred CH3 domain variants that favor Fe heterodimerization.

Variant 1	Variant 2
F405A	T394F
S364D	Y349K
S364E	L368K
S364E	Y349K
S364F	K370G
S364H	Y349K
S364H	Y349T
S364Y	K370G
T411K	K370E
V397S/F405A	T394F
K370R/T411K	K370E/T411E
L351E/S364D	Y349K/L351K
L351E/S364E	Y349K/L351K
L351E/T366D	L351K/T366K
P395T/V397S/F405A	T394F
S364D/K370G	S364Y/K370R
S364D/T394F	Y349K/F405A
S364E/F405A	Y349K/T394F
S364E/F405S	Y349K/T394Y
S364E/T411E	Y349K/D401K
S364H/D401K	Y349T/T411E
S364H/F405A	Y349T/T394F
S364H/T394F	Y349T/F405A
Y349C/S364E	Y349K/S354C
L351E/S364D/F405A	Y349K/L351K/T394F
L351K/S364H/D401K	Y349T/L351E/T411E
S364E/T411E/F405A	Y349K/T394F/D401K
S364H/D401K/F405A	Y349T/T394F/T411E
S364H/F405A/T411E	Y349T/T394F/D401K

(EX1002, ¶196 (annotating Ex. 1004 at Table 1 with neutral charges shown in yellow, negative charges shown in red, and positive charges shown in green).) In fact, *Lazar*’s disclosures go even further, showing the feature that is fundamentally missing from Merus’ supposed priority applications—two different modifications made in separate CH3 domains for heterodimer formation.

For its part, Merus provides only conclusory statements without any supporting rationale or citation to evidence. (DDB, 17.) First, Merus incorrectly argues “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.’” (DDB, 17.) It is unclear how Merus can even make this argument,

given Merus includes, just two pages later, a screenshot of Dr. Presta’s opinion showing where *Lazar* discloses exactly that:

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.)

(DDB, 19 (showing EX1002, ¶188 (annotating EX1004, ¶123)).) Merus’s current argument overlooking *Lazar*’s clear teachings echoes the incorrect statement Merus made during prosecution of the ancestor ’286 patent (to the same Examiner) causing that Examiner to erroneously allow the claims.

Second, Merus also argues “*Lazar* undisputedly does not disclose an antibody with the requisite heterodimerization modifications as required by the

'859 Patent.” (DDB, 17.) To the extent this is a criticism of *Lazar*'s disclosure of individual mutations in lists (rather than a specific example with both “modifications”), as Xencor explained in its Petition, that argument runs counter to Merus's priority argument that similar disclosures in its applications provide sufficient written description support. (Pet., 60; *see also* DDB, 16 (arguing the lack of a “specific example” was not disqualifying for written description purposes).) Once again, Merus cannot have it both ways.

Lastly, Merus suggests deference to the examiner is owed because *Lazar* and *Kannan* were cited in an IDS (but not applied) in the '859 patent prosecution. (DDB, 17.) But the examiner was led to error by Merus, as explained in Section III.B.

4. Xencor's Reliance on Dr. Presta's Declaration Does Not Favor Denial

Dr. Presta's declaration was appropriate in both length and content. The Director should reject Merus's conflicting arguments that Dr. Presta's declaration was somehow both too little (“parroting”) and too much (not “focused”). (DDB, 17-20.) To the contrary, this factor weighs against discretionary denial. First, Merus does not identify any portions of the expert testimony that suggests Xencor is using its expert to fill gaps in the prior art.

Second, for “parroting,” the only portion of Dr. Presta's declaration Merus identifies is a screenshot of paragraphs 187-189, which it argues is “copying and

pasting.” (DDB, 19-20.) But as is clear from Merus’s own screenshots, it is not copy pasted from the Petition. Instead of relying on gap-filling or parroting, Xencor appropriately relies on Dr. Presta to explain the background knowledge of a person of ordinary skill in the art, which Dr. Presta supports with citations to evidence. (*See, e.g.*, EX1002, ¶¶19-58 (including additional context and scientific detail).)

It is unsurprising that Xencor’s Petition and the expert declaration supporting the Petition’s unpatentability arguments point to the same portions of the prior art references and come to similar conclusions. The Director should not discretionarily deny on this basis.

5. Settled Expectations Favor Xencor, not Merus

Merus has no long-standing settled expectations in the ’859 patent because it issued recently, in 2024. (EX1001, Cover (issue date Mar. 12, 2024).) Thus, as in the Director’s recent decision in *ResMed Corp. v. Cleveland Medical Devices, Inc.*, Xencor’s Petition should be referred to a merits panel because it is an early challenge to the ’859 patent. IPR2025-00246, Paper 10, 2 (June 12, 2025) (referring petitions on patents issued in January 2024); (*see* EX1001, Cover (’859 patent issued in March 2024)).

Additionally, settled expectations in this case favor Xencor, not Merus. Xencor claimed a heterodimeric protein with a “variant set L368D and S364K” as

early as July 26, 2018. (EX1061, 776-780 (*Desjarlais* prosecution history).)

Those claims issued on November 12, 2019. (EX1001, Cover (Field 45).) Merus never challenged Xencor’s *Desjarlais* claims that issued more than five years ago. Instead, Merus simply filed “shockingly similar” claims several years later in the application that matured into the ’859 patent—filed in October 2023. Thus, to the extent the Director considers settled expectations, they favor institution here.

Merus’s contrary argument is based solely on Xencor’s 2017 10-K filing that referenced “a recently issued patent owned by Merus.” (DDB, 21 (quoting EX2008, 46).) Clearly, this was not the ’859 patent, which issued several years after this 10-K—in 2024. And knowledge of any earlier patent or application in the ’859 patent chain does not favor denial for “settled expectations” because, as Xencor described in its Petition, none of those prior applications or patents described the claimed 364+ modification on one CH3 domain *and* a 368-modification on a separate CH3 domain. (Pet., 23-37.)

Because Xencor’s Petition is an early challenge to a recently issued patent that newly claims a specific combination of modifications that Merus never previously described—and which Xencor previously published in both scientific journals and a patent application—settled expectations strongly favor institution.

6. Public Health

Public health would be benefitted by instituting Xencor's Petitions, rather than discretionarily denying them. Xencor's development activities relate to therapies for cancer and autoimmune diseases. This activity has been pre-commercial, yet Merus is attempting to shut it down through a lawsuit based on a patent that should have never been issued. Discretionarily denying IPRs in these circumstances would be bad policy, as it would increase risk and costs associated with early drug discovery, and thus ultimately hinder new drug development. For instance, even if one were to assume that pre-commercialization development activities were not covered by the § 271(e) safe harbor, requiring companies that are early in their development to file IPR challenges to all suspect patents that might potentially apply, before candidates are sufficiently advanced, would be wasteful and expensive, even if possible. This added risk and cost would lead to fewer new drug products being developed, which would be bad for public health.

For Merus's part, they fail to explain how discretionarily denying Xencor's Petition would benefit public health. Merus's argument seems to be that the '859 patent claims are beneficial because they relate to the creation of bispecific antibodies for therapeutic uses. (DDB, 21-22.) But such a general tether would apply to any patents directed to any pharmaceutical or therapeutic agent or method.

The genericness of such an argument precludes it from being a reasoned application of the Director's discretion to the specific facts of this case.

Merus also (again) tries to deflect attention from its own claims and point at Xencor's *Desjarlais* patent, arguing Xencor is using it "to exclude others from this field." (DDB, 22.) It is unclear what Merus is referring to—Xencor has not asserted the *Desjarlais* patent—and this is a blatant red herring intended to distract from the very legitimate public interest in having the PTAB consider the validity of the '859 patent.

B. Xencor's Petition Is Not Redundant with Prosecution Under 35 U.S.C. § 325(d) or *Advanced Bionics*

Under 35 U.S.C. § 325(d) and the *Advanced Bionics* framework, Xencor's Petition is not redundant with prosecution. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Gerate Ges.m.b.H*, IPR2019-01469, Paper 6 at 8 (Feb. 13, 2020). The prior art for Xencor's first two grounds was not considered by the Examiner at all, and the Examiner materially erred in overlooking the disclosures in the prior art for Xencor's third ground (which are the same or greater than the disclosures Merus pointed to for written description support).

For Xencor's first two grounds, Merus does not dispute that *Desjarlais* and *Moore* were not considered by the Examiner and thus do not even pass the first prong of the *Advanced Bionics* test. Instead, Merus argues the Office "did not need to review" those references due to Merus's argument that the claims are

entitled to an earlier priority date. (DDB, 27-28.) That is incorrect, for the reasons described in the section discussing the merits (Section III.A.3.a; *see also* Pet., 23-37). And it is beside the point for *Advanced Bionics*—there can be no dispute that the Examiner did not consider *Desjarlais* or *Moore* (two out of Xencor’s three grounds). To the extent that the Examiner limited their search of the prior art based on Merus’s incorrect assertion of priority support, that was material error. Merus’s § 325(d) argument can be rejected on this basis alone.

Xencor’s third ground involving *Lazar* in view of *Kannan* was not considered by the Examiner either and is not redundant with any rejections the Examiner applied. During prosecution, the Examiner did not apply any prior art, and instead applied only double patenting rejections. (EX1029, 215-25.) Thus, even though Merus points to an IDS showing that *Lazar* and *Kannan* individually were mentioned to the Examiner (DDB, 23-25), for the reasons the Director recently clarified in *Ecto World*, “even though the asserted prior art is listed on an IDS, the Examiner did not issue any prior art rejections during examination, so the Examiner materially erred by overlooking certain teachings in the prior art on the IDS.” *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 11 at 5-6 (May 19, 2025).

Xencor’s Petition expressly identified at least one critical teaching of the prior art that the Examiner overlooked—“*Kannan*’s teaching that its charge

modification ‘strategy can also be extended to modifying uncharged residues to charged residues at the CH3 domain interface.’” (Pet., 78 (quoting EX1007, 10:16-18).) And as discussed above for priority, Merus points to a teaching in the purported priority application emphasizing such neutral-to-charged modifications as an “inventive” aspect of the “present invention.” (EX1030, 23-24.) Thus, to the extent Merus’s arguments are credited for priority purposes, the Examiner erred in overlooking the teachings of *Lazar* and *Kannan*, which collectively have similar levels of disclosures as Merus’s applications. In other words, Xencor has shown error in the fact that *Lazar* and *Kannan* were “not a basis for rejection during examination, [are] not substantially the same as prior art the Examiner applied, and include[] specific teachings that ‘impact patentability of the challenged claims.’” *Ecto World* at 5 (quoting *Advanced Bionics* at 8 n.9).

Merus counters with a merits argument that *Lazar* and *Kannan* supposedly “do not disclose ... the specific amino acid locations for substitution.” (DDB, 27.) That is incorrect. *Lazar* discloses multiple lists where preferred charge mutations (both positive and negative) occur at the 364 and 368 positions specifically. (EX1004, ¶¶123, 241.) When viewed in combination with *Kannan*’s teachings that the 364 and 368 positions form an interface in the CH3 region (EX1007, 7:19-8:4 (Table 1)), the ’859 patent’s claims would have been obvious.

Additionally, *Becton Dickinson* factor (f)⁵ weighs against discretionary denial because *Lazar* and *Kannan* were buried in a large IDS to the Examiner. See *Ecto World* at 2, 6-7. During prosecution, Merus only referenced *Lazar* and *Kannan* in an IDS containing 376 references—fifteen times the average IDS size, per *Ecto World*. (EX1029, 182-198, 226-242); *Ecto World* at 7&n.3. The Director should consider this “volume of the references submitted to the Office” in Merus’s IDS and find it weighs against discretionary denial. *Ecto World* at 6-7.

C. Early Stage of Parallel Litigation Favors Institution Under *Fintiv*

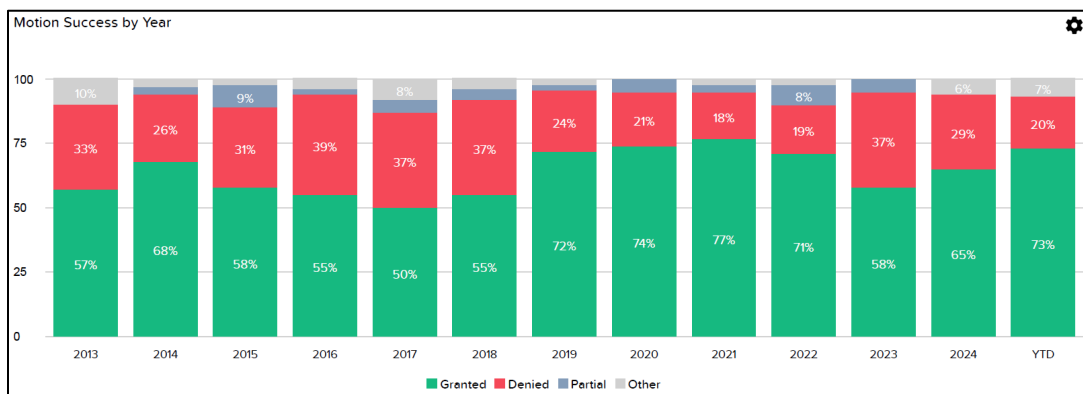
The *Fintiv* factors weigh strongly in favor of institution. The parallel district court case is in its infancy—meaning both that there has been practically no investment of resources, and that, due to Xencor’s *Sotera* stipulation, there will be no redundant work between the forums. In fact, the parallel case is so early in its life that a case schedule or even a trial date has not yet been contemplated by the court. For these reasons, and in light of the District of Delaware’s stay statistics, a stay is likely if these proceedings are instituted. The Director should decline

⁵ Factor (f) is “the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.” *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 18 (Dec. 15, 2017).

Merus’s request for discretionary denial and refer the case to a panel for a determination on the merits.

1. Factor 1 – Whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted

Factor 1 favors institution because a stay is likely based on district-wide statistics and the current early stage of the litigation. Merus’s analysis of this factor is deficient, labeling the chances that a stay will be granted a “coin-toss,” without any substantiating statistics or evidence. (DDB, 29.) The statistics show a different story—that stays in favor of IPR proceedings are commonly granted in the District of Delaware, being well above 50% in recent years:



(EX1055.) This high grant rate is sufficient evidence to show to a preponderance of the evidence that a stay is likely if this proceeding is instituted—particularly in light of Merus’s failure to provide any support for its contrary argument.

Merus argues the fact Xencor only challenged two of the three asserted Merus patents influences the chance of obtaining a stay. (DDB, 3, 30.) But Merus provides no statistics or evidence-based analysis for this particular dispute. Merus

has long been aware, even before filing its complaint, that Xencor's work with the RenLite® mice that Merus accused of infringing the '695 patent was limited and quickly discontinued. (EX1054, 8&n.4, 20.) This limited activity that terminated long ago would not be a sufficient justification to deny a stay if the other two asserted patents are instituted in IPRs. Indeed, the District of Delaware has frequently stayed cases even where not all asserted patents were instituted for review. *See, e.g., Cleveland Medical Devices, Inc. v. ResMed Inc.*, No. 1-22-cv-00794, D.I. 300 (D. Del. June 21, 2024) (granting stay despite some asserted patents not being instituted due to those patents making up a small amount of the damages claims); *Monterey Research, LLC v. Nanya Tech. Corp.*, No. 1-19-cv-02090, D.I. 84 (D.Del. June 25, 2021) (granting stay where four of six asserted patents were instituted because litigation "would be 'simplified' because it would be concluded as to four of the six asserted patents" if found unpatentable); *NEC Corp. v. Peloton Interactive, Inc.*, No. 22-987-CJB, 2024 WL 1533952 (D. Del. Apr. 9, 2024) (granting stay where one asserted patent was not at issue in the IPR); *Speyside Med., LLC v. Medtronic CoreValve LLC*, No. 1-20-cv-00361, D.I. 155 (D. Del. Sept. 30, 2021) (granting stay where IPR instituted on three of five asserted patents).

2. Factor 2 – Proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision

Factor 2 strongly favors institution because no trial date has been set in the parallel district court litigation and trial would likely be well after the projected September 2026 final written decision date for this proceeding. Because essentially no activity has occurred in the district court thus far, getting through fact discovery, expert discovery, dispositive motions, and trial within 15 months from the date of filing of this paper is utterly unrealistic.

Merus speculates, without citing to any evidence, that it expects trial to be in August 2026, roughly two years from the filing of its complaint. (DDB, 29.) But that is contrary to the most recent average time to trial statistics for the District of Delaware and ignores the current status of the case. As published on the U.S. Courts website, median time to trial in the District of Delaware is 33 months. (EX1056, 14; *see also* Pet., 76 (citing EX1046, 14 (32.2 month median time as of September 2024)).) Even ignoring the fact that the case has not even begun and simply applying the above District of Delaware median time to trial, because Merus’s complaint was filed in August 2024, trial would be May 2027—months after the projected final written decision here (September 30, 2026).

Additionally, the case was recently transferred from Chief Judge Connolly to Judge Barker (a visiting judge in the District of Delaware that ordinarily sits in the Eastern District of Texas), adding an unknown amount of additional time to the

case. (EX1053.) Judge Barker recently was assigned eleven cases from the District of Delaware (one of which being Merus's case). Furthermore, the average time to trial from the initial disclosures date (the first item in a case schedule) in patent cases before Judge Barker (although a limited data set) is 552 days, or around one-and-a-half years. (EX1057.) Thus, even if initial disclosures were made today and no stay were granted, according to Judge Barker's track record, trial would not be until December 2026—again, several months after the projected final written decision here (September 30, 2026).

Again attempting to distract from the merits, Merus accuses Xencor of being responsible for the “lack of progress in the parallel district court litigation.” (DDB, 30-31.) But Merus provides no support for this accusation, only arguing Xencor's motion is—in Merus's view—meritless. (DDB, 31-32.) Clearly the District Court does not think so, as it has been considering Xencor's motion for quite some time. And Merus cannot fairly blame Xencor for the timing of the district court's decision on Xencor's motion to dismiss—Merus, as the plaintiff, chose to litigate in the District of Delaware, which has a busy docket.

3. Factor 3 – Investment in the parallel proceeding by the court and the parties

Factor 3 strongly favors institution because the district court and the parties have invested minimally in the district court litigation. This *Fintiv* factor serves to gauge potential efficiencies—where substantial investment has already been made

in the parallel district court proceeding, it would be less efficient to institute an *inter partes* proceeding which would only increase litigation costs. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 9-10 (Mar. 20, 2020) (“Specifically, if, at the time of the institution decision, the district court has issued substantive orders related to the patent at issue in the petition, this fact favors denial.”)

The only activity by the parties has been Merus’s filing of its complaint and the briefing of Xencor’s motion to dismiss based on the 35 U.S.C. § 271(e)(1) Safe Harbor, with the court’s activity only being referring the case to another judge. Merus attempts to inflate the investment by pointing to its own required pre-suit review of “thousands of pages of documents” (DDB, 30), but this fact on its own, in view of what *Fintiv* Factor 3 aims to assess, is inconsequential. What is consequential is that the district court has yet to issue any substantive orders related to the patents at issue. Given the minimal investment by the parties and the court, efficiency favors institution.

4. Factor 4 – Overlap between issues raised in the petition and in the parallel proceeding

Factor 4 strongly favors institution due to the early stage of litigation and Xencor’s *Sotera* stipulation, which Merus fails to mention, even though it was served a month before Merus’s discretionary denial brief. (EX1058.) The submission of a *Sotera* stipulation serves to bind a petitioner to the full scope of estoppel under 35 U.S.C. § 315(e)(2), eliminating the possibility of any substantive

overlap between the proceedings should an *inter partes* review proceed to a final written decision. See *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, 18-19 (Dec. 1, 2020) (precedential as to §II.A). Because Xencor, as the defendant in the district court litigation, has yet to file an answer to Merus’s complaint and because Xencor’s motion to dismiss regards the issue of non-infringement under the 35 U.S.C. § 271(e)(1) Safe Harbor (not invalidity), no potentially overlapping substantive arguments have been made to the district court. Thus, Xencor’s *Sotera* stipulation prevents any duplicative arguments in the two forums.

Merus argues that factor 4 favors discretionary denial (DDB, 30), but Merus misunderstands the “overlap” factor. Under factor 4, “if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial.” *Fintiv*, Paper 11, 12-13. Merus argues that this factor favors denial because the district court proceeding “includes three asserted patents” and thus this IPR would not fully “dispose of that parallel proceeding.” (DDB, 30.) But this factor does not automatically favor denial any time a plaintiff asserts more than one patent (*i.e.*, where the district court proceeding could potentially cover more patents and issues than the IPR). The relevant question is whether the IPR proceeding would be redundant with the litigation due to overlap of the issues and arguments already

made during the parallel proceeding, not whether the IPR alone would dispose of the case. Here, Xencor's swift filing of its IPR early in the district court proceeding combined with its *Sotera* stipulation means that this factor favors institution because there will be no overlapping issues.

Furthermore, the third asserted patent covers a distinct technology from the two patents at issue in Xencor's IPRs, with Merus arguing infringement for that third patent based on different allegedly infringing activity. (EX1052, ¶9.) This also minimizes the likelihood of litigating overlapping issues in Xencor's IPRs and in the district court.

5. Factor 5 – Whether the petitioner and the defendant in the parallel proceeding are the same party

Factor 5 favors institution because, even though Xencor is the defendant in the parallel proceeding, this IPR is likely to proceed to final written decision before that parallel litigation would go to trial, meaning estoppel under 35 U.S.C. § 315(e)(2) would apply (not to mention Xencor's *Sotera* stipulation). *Fintiv* itself explained that where the petitioner is “unrelated to a defendant,” that factor weighs against denying an IPR petition for discretionary reasons. *Fintiv*, Paper 11, 13-14. Merus assumes the opposite is true—that the petitioner being the defendant in a parallel district court case weighs in favor of discretionary denial—but *Fintiv* did not hold that. And the Board has held that where the final written decision would precede trial, the fact that the defendant is the petitioner weighs *in favor of*

institution, not denial, because estoppel would apply. *See, e.g., BMW of N. Am., LLC v. Mich. Motor Techs. LLC*, IPR2023-01234, Paper 11, 14-15 (Jan. 26, 2024); *Huawei Tech. Co. v. WSOU Inv., LLC*, IPR2021-00225, Paper 11 at 13-14 (June 14, 2021); *Google LLC v. Parus Holdings, Inc.*, IPR2020-00846, Paper 9 at 20-21 (Oct. 21, 2020). Because a final written decision here would precede trial, *see* Section III.C.2, factor 5 favors institution.

6. Factor 6 – Other circumstances that impact the Board’s exercise of discretion, including the merits

Factor 6 favors institution because Xencor’s unpatentability merits are strong. *See* Section III.A.3. Other than the merits, Merus identifies no “other circumstances” for the *Fintiv* analysis. (*See* DDB, 30.)

* * *

The *Fintiv* factors collectively favor institution in this case. The Director should reject Merus’s request to discretionarily deny institution.

IV. CONCLUSION

For these reasons, Xencor respectfully requests that the Director reject Merus’s request for discretionary denial and refer Xencor’s Petition to a panel for an institution decision on the merits.

Respectfully submitted,

Dated: June 30, 2025

By: /Naveen Modi/
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Counsel for Petitioner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing Petitioner's Opposition to Patent Owner's Discretionary Denial Brief contains, as measured by the word-processing system used to prepare this paper, 7,038 words. This word count does not include the items excluded by 37 C.F.R. § 42.24.

Respectfully submitted,

Dated: June 30, 2025

By: /Naveen Modi/
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CERTIFICATE OF SERVICE

I hereby certify that on June 30, 2025, I caused a true and correct copy of the foregoing Petitioner's Opposition to Patent Owner's Discretionary Denial Brief to be served via email on Patent Owner at the following addresses:

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Respectfully submitted,

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