

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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XENCOR, INC.,  
Petitioner

v.

MERUS N.V.,  
Patent Owner

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

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**PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE**

## TABLE OF CONTENTS

	<b>Page</b>
I. Introduction.....	1
II. The Challenged Claims Are Not Entitled to a Priority Date Before Their Actual Filing Date.....	2
A. The Tests and Examples in the '935 Provisional Point Away from the Claimed Pair of 364 and 368 Mutations.....	3
B. The Board Should Reject Merus's Chain of Inferences that Starts with Table 7 and Further Narrows Based on Hindsight Justifications Not Disclosed in the '935 Provisional .....	5
C. Dr. Presta Applied the Correct Legal Standard for Written Description .....	13
III. <i>Desjarlais</i> and <i>Moore</i> Anticipate The Challenged Claims .....	14
IV. <i>Lazar</i> Alone or <i>Lazar</i> in View of <i>Kannan</i> Render Obvious The Challenged Claims.....	14
A. Merus's Arguments Fail to Rebut that <i>Lazar</i> , Alone or in Combination with <i>Kannan</i> , Renders Obvious Claims 1-7.....	14
1. <i>Lazar</i> Alone.....	14
2. <i>Lazar</i> in View of <i>Kannan</i> .....	19
3. Merus's Secondary Considerations Do Not Establish Nonobviousness of the Claims .....	20
4. Merus Fails to Undermine That the Dependent Claims Are Obvious over <i>Lazar</i> and <i>Lazar</i> in View of <i>Kannan</i> .....	24
V. Conclusion .....	27

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Cases</b>	
<i>Ariad Pharms., Inc. v. Eli Lilly &amp; Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010) ( <i>en banc</i> ) .....	2, 18
<i>Cytiva BioProcess R&amp;D AB v. JSR Corp.</i> , 122 F.4th 876 (Fed. Cir. 2024) .....	16
<i>In re Dembiczak</i> , 175 F.3d 994 (Fed. Cir. 1999) .....	17
<i>Duke University v. Sandoz Inc.</i> , 160 F.4th 1305 (Fed. Cir. 2025) .....	4
<i>Google LLC v. Uniloc 2017 LLC</i> , IPR2020-00447, Paper 21 (May 11, 2021).....	25
<i>Guardant v. Univ. of Wash.</i> , No. 2024-1129, 2026 WL 184334 (Fed. Cir. 2026).....	16, 26
<i>Regents of the Univ. of Minnesota v. Gilead Scis., Inc.</i> , 61 F.4th 1350 (Fed. Cir. 2023) .....	6
<i>In re Ruschig</i> , 379 F.2d 990 (C.C.P.A. 1967) .....	6
<b>Other Authorities</b>	
37 C.F.R. § 42.65(a).....	23

## LIST OF EXHIBITS

Exhibit	Document	Previously Submitted
EX1001	U.S. Patent No. 11,926,859 to De Kruif <i>et al.</i> (“the ‘859 patent”)	X
EX1002	Declaration of Leonard G. Presta, Ph.D.	X
EX1003	Curriculum Vitae of Leonard G. Presta, Ph.D.	X
EX1004	U.S. Patent Application Publication No. US 2011/0054151 A1 to Lazar <i>et al.</i> (“Lazar”)	X
EX1005	International Patent Application Publication No. WO 2012/058768 A1 to Cabrera <i>et al.</i> (“Cabrera”)	X
EX1006	International Patent Application Publication No. WO 1998/050431 A2 to Arathoon <i>et al.</i> (“Arathoon”)	X
EX1007	International Patent Application Publication No. WO 2009/089004 A1 to Kannan <i>et al.</i> (“Kannan”)	X
EX1008	File History for U.S. Patent No. 9,358,286	X
EX1009	<i>Reserved</i>	
EX1010	Georges Köhler & César Milstein, <i>Continuous culture of fused cells secreting antibody of predefined specificity</i> , NATURE, Aug. 7, 1975, 256(5517), at 495-497	X
EX1011	<i>Excerpts from</i> Kenneth Murphy <i>et al.</i> , <i>Janeway’s Immunobiology</i> (7th ed. 2008)	X
EX1012	Gunasekaran Kannan <i>et al.</i> , <i>Enhancing Antibody Fc Heterodimer Formation through Electrostatic Steering Effects</i> , J. BIOLOGICAL CHEM., 285(25), 19637-19646 (2010) (“Gunasekaran”)	X

<b>Exhibit</b>	<b>Document</b>	<b>Previously Submitted</b>
EX1013	Roland Kontermann, <i>Dual targeting strategies with bispecific antibodies</i> , MABS, 4(2), 182-197 (2012)	X
EX1014	<i>Reserved</i>	
EX1015	John Ridgway <i>et al.</i> , “Knobs-into-holes” engineering of antibody CH3 domains for heavy chain heterodimerization, PROTEIN ENGINEERING, 9(7), 617-621 (1996)	X
EX1016	Ameurfina Santos & Eduardo Padlan, <i>Development of More Efficacious Antibodies for Medical Therapy and Diagnosis</i> , PROGRESS IN NUCLEIC ACID RESEARCH AND MOLECULAR BIOLOGY, 1998:60, 169-194 (1998)	X
EX1017	A. Margaret Merchant <i>et al.</i> , <i>An efficient route to human bispecific IgG</i> , NATURE BIOTECH., 167(7), 677-81 (1998)	X
EX1018	Maria A. Angela <i>et al.</i> , <i>Effects of engineering charged amino acids in the CH3 domains on antibody heavy chain dimerization</i> , PHILIPPINE SCI. LETTERS, 4(1), 48-55 (2011) (“Diaz”)	X
EX1019	U.S. Provisional Patent Application No. 61/019,569	X
EX1020	U.S. Provisional Patent Application No. 61/120,305	X
EX1021	U.S. Patent No. 5,731,168 to Carter <i>et al.</i>	X
EX1022	<i>Reserved</i>	
EX1023	Tae Kyung Kim & James Eberwine, <i>Mammalian cell transfection: the present and the future</i> , ANALYTICAL AND BIOANALYTICAL CHEM., 397(8), 3173-3178 (2010)	X

<b>Exhibit</b>	<b>Document</b>	<b>Previously Submitted</b>
EX1024	Hui F. Liu <i>et al.</i> , <i>Recovery and purification process development for monoclonal antibody production</i> , MABS, 2(5), 480-499 (2010)	X
EX1025	<i>Reserved</i>	
EX1026	<i>Excerpts from Jan-Christer Janson &amp; Lars Rydén, Protein Purification (2nd ed. 1998)</i>	X
EX1027	Jonathan Marvin & Zhenping Zhu, <i>Recombinant approaches to IgG-like bispecific antibodies</i> , ACTA PHARMACOLOGICA SINICA, 26(6), 649-658 (2005)	X
EX1028	<i>Reserved</i>	
EX1029	File History for U.S. Patent No. 11,926,859	X
EX1030	U.S. Provisional Patent Application No. 61/635,935 (“the ’935 provisional”)	X
EX1031	U.S. Patent Application No. 16/934,925	X
EX1032	U.S. Patent Application No. 16/417,379	X
EX1033	U.S. Patent Application No. 15/155,743	X
EX1034	U.S. Patent Application No. 14/081,848	X
EX1035	U.S. Patent Application No. 13/866,747	X
EX1036	U.S. Patent No. 10,472,427 to Desjarlais <i>et al.</i> (“ <i>Desjarlais</i> ”)	X
EX1037	U.S. Provisional Patent Application No. 61/780,310	X
EX1038	Gregory L. Moore <i>et al.</i> , <i>A Robust Heterodimeric Fc platform engineered for efficient development of bispecific antibodies of Multiple Formats</i> , METHODS, 154, 38-50 (2018) (“ <i>Moore</i> ”)	X

<b>Exhibit</b>	<b>Document</b>	<b>Previously Submitted</b>
EX1039	<i>Reserved</i>	
EX1040	John R. Birch & Andrew J. Racher, <i>Antibody production</i> , ADVANCED DRUG DELIVERY REVIEWS, 58(5-6), 671-685 (2006)	X
EX1041	Florian M. Wurm, <i>Production of recombinant protein therapeutics in cultivated mammalian cells</i> , NATURE BIOTECH., 22(11), 1393-1398 (2004)	X
EX1042	<i>Excerpts from Bruce Alberts et al., Molecular Biology of the Cell</i> (5th ed 2008)	X
EX1043	<i>Monoclonal Antibody</i> , National Cancer Institute, <a href="https://www.cancer.gov/sites/g/files/xnrzdm211/files/styles/cgov_enlarged/public/cgov_image/media_image/2019-12/Monoclonal-antibodies-illustration.gif">https://www.cancer.gov/sites/g/files/xnrzdm211/files/styles/cgov_enlarged/public/cgov_image/media_image/2019-12/Monoclonal-antibodies-illustration.gif</a> (last visited Feb. 7, 2025)	X
EX1044	<i>Reserved</i>	
EX1045	Prosecution History for U.S. Patent Application No. 13/866,747 – Application Data Sheet Dated Apr. 19, 2013.	X
EX1046	<i>United States District Courts – National Judicial Caseload File</i> , <a href="https://www.uscourts.gov/sites/default/files/2024-12/fcms_na_distprofile0930.2024.pdf">https://www.uscourts.gov/sites/default/files/2024-12/fcms_na_distprofile0930.2024.pdf</a> (last visited Feb. 7, 2025)	X

<b>Exhibit</b>	<b>Document</b>	<b>Previously Submitted</b>
EX1047	<i>Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings With Parallel District Court Litigation</i> , <a href="https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf">https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf</a> (last visited Feb. 7, 2025)	X
EX1048	Docket Sheet, <i>Merus N.V. v. Xencor, Inc.</i> , Civil Action No. 24-913-CFC (D. Del.)	X
EX1049	Hongcheng Liu & Kimberly May, <i>Disulfide bond structures of IgG molecules</i> , MABS, 4(1), 17-23 (2012)	X
EX1050	Bibliographic Data, U.S. Patent Application No. 13/866,747, Patent Center, USPTO	X
EX1051	<i>Reserved</i>	
EX1052	<i>Merus N.V. v. Xencor, Inc.</i> , D.I. 1 (D. Del. Aug. 5, 2024) (“Complaint”)	X
EX1053	Docket Sheet, <i>Merus N.V. v. Xencor, Inc.</i> , Civil Action No. 24-913-JCB (D. Del.) (updated June 27, 2025)	X
EX1054	<i>Merus N.V. v. Xencor, Inc.</i> , Civil Action No. 24-913-JCB, D.I. 13 (D. Del. Oct. 10, 2024) (Defendant Xencor, Inc.’s Opening Brief in Support of Its Motion to Dismiss Pursuant To Federal Rule of Civil Procedure 12(b)(6)) (“Motion to Dismiss”),	X
EX1055	<i>Docket Navigator – Motion Success Statistics – Motions to Stay Pending IPR in the District of Delaware</i> , retrieved June 27, 2025	X

<b>Exhibit</b>	<b>Document</b>	<b>Previously Submitted</b>
EX1056	<i>United States District Courts – National Judicial Caseload File</i> , <a href="https://www.uscourts.gov/sites/default/files/document/fcms_na_distprofile0331.2025.pdf">https://www.uscourts.gov/sites/default/files/document/fcms_na_distprofile0331.2025.pdf</a> (last visited June 25, 2025)	X
EX1057	Case scheduling orders from Civil Action Nos. 6:24-cv-00263 (D.I. 40), 6:19-cv-00133 (D.I. 28), 1:24-cv-00620 (D.I. 21), 1:24-cv-00507 (D.I. 31), and 1:23-cv-00772 (D.I. 55)	X
EX1058	Email correspondence dated April 30, 2025 ( <i>Sotera Stipulation</i> )	X
EX1059	<i>Reserved</i>	
EX1060	<i>Reserved</i>	
EX1061	File History for U.S. Patent No. 10,472,427	X
EX1062	Deposition Transcript of Brian J. Sutton, Ph.D. (March 19, 2026)	

## I. INTRODUCTION

Faced with the reality that the '859 patent's priority applications fail to show possession of an S364+/L368- mutation pair, Merus argues there are "blaze marks" because these mutations would have purportedly been obvious to a POSA reading the specification. Aside from being legally deficient, that analysis, if accepted, would compel a finding of obviousness over the more detailed disclosure of *Lazar*. Merus's positions are irreconcilable, and the Board should cancel claims 1-7 of the '859 patent as unpatentable.

The '859 patent claims a heterodimeric antibody with amino acid substitutions at positions 364 and 368 to make an oppositely charged pair of residues between two CH3 domains. (Pet., 27-37.) But none of the applications to which the '859 patent claims priority provides adequate support for this pair of mutations, let alone the specific S364K and L368D substitutions of claim 3. (*Id.*) The claims are therefore not entitled to a priority date earlier than the actual filing date of the '859 patent. (*Id.*) In contesting priority, Merus constructs hindsight-driven rationales for cobbling together two separately disclosed substitutions, both of which the inventors abandoned after initial testing and never evaluated as a "pair." This approach is infected with legal error because written description demands *more* disclosure than obviousness, not less. And even under Merus's defective framework, its rationales are contradicted by the priority

application itself. Merus's priority arguments therefore fail, and because Merus does not contest that the claims are anticipated by both *Desjarlais* and *Moore* if the Board finds no priority (as it should), that finding would be dispositive of the IPR.

Merus's obviousness-style approach to written description cannot be reconciled with its nonobviousness arguments over *Lazar*. To the extent disclosing the individual mutations in a list suffices for written description (*see* EX1030, Table 7), *Lazar* does that too (*see* EX1004, ¶123). (*See also* EX1062, 240:20-241:4.) But *Lazar* even goes further, disclosing an oppositely charged 364/368 pair as a “[p]referred CH3 domain variant[] that favor[s] Fc heterodimerization.” (EX1004, Table 1.) Because obviousness is a lower bar than written description, and because *Lazar* provides more disclosure than Merus's provisional application, Merus's obviousness-style priority arguments show that the claims are unpatentable over both *Lazar* and *Lazar* in view of *Kannan*.

## **II. THE CHALLENGED CLAIMS ARE NOT ENTITLED TO A PRIORITY DATE BEFORE THEIR ACTUAL FILING DATE**

Merus's priority arguments approximate an obviousness analysis rife with improper hindsight, which “does not satisfy the [written description] requirement.” *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010)

(*en banc*). For the reasons below, the '935 provisional<sup>1</sup> fails to provide sufficient written description support, and the claims of the '859 patent are not entitled to a priority date earlier than their actual filing date.

**A. The Tests and Examples in the '935 Provisional Point Away from the Claimed Pair of 364 and 368 Mutations**

Merus begins its search for written description support with an artificially narrow focus on Table 7 of the '935 provisional and continues narrowing from there. (POR, 18.) But a POSA examining the '935 provisional's disclosure for possession of mutations for heterodimer formation would not have ignored the inventors' actual *heterodimer* testing to look only at the threshold *homodimer* test in Table 7. As Dr. Sutton admitted, "what a POSA wants and what the inventor[s] want is not just a decrease in homodimer rate, but rather an increase in heterodimerization." (EX1062, 97:16-98:7.) Here, the inventors' heterodimer testing confirms they were focused on other substitutions<sup>2</sup>—not on 364 and 368 together as a pair—when identifying what they considered to be their invention.

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<sup>1</sup> Merus does not assert that priority applications other than the '935 provisional provide written description support for the '859 patent.

<sup>2</sup> See, e.g., EX1002, ¶118 (identifying, in the table bridging pages 67-68, T366K+L351D, V397D+T366D, C354K/Y349K+S354D/Y349D, T394K+V397D, and Q347K+K360D as mutation pairs tested as heterodimers).

(See, e.g., EX1030, Tables 11-15.) Just as in *Duke Univ. v. Sandoz Inc.*, “the only blaze marks provided by the specification . . . point *away* from the combinations as recited in” Merus’s claims. 160 F.4th 1305, 1314 (Fed. Cir. 2025). As Dr. Sutton acknowledged, “the inventors would have a good understanding of what would and would not be promising constructs to move forward with for identifying good mutations that promote heterodimerization,” making the path *actually taken* by the inventors particularly salient here. (EX1062, 73:3-16.)

As Xencor explained in its Petition (Pet., 31), the results of the homodimer testing in Table 7 led to eight “promising” candidates, none of which are 364 or 368. (EX1030, 54:8-10.) The ’935 provisional followed up on those candidates by incorporating them into constructs that were tested as heterodimers, none of which involved paired mutations at residues 364 and 368. (Pet., 31-33.) When identifying “preferred combination[s] of mutations according to the present invention,” the ’935 provisional pointed to mutations involving “a T366K/L351’D pair mutation,” not a pair of changes at positions 364 and 368. (EX1030, 24:31-26:20.) Other examples tested several pairs of mutations, but never 364 and 368. (Pet., 34 (citing EX1030, 38, 59-64, 66-67).) Unsurprisingly, Dr. Sutton agreed during his cross-examination that “the ’935 provisional application does not explicitly disclose an antibody having a positively charged amino acid residue at

position 364 and a negatively charged amino acid residue at position 368.”

(EX1062, 29:7-13, 65:14-16, 66:10-13.)

A POSA would have considered the disclosure of the '935 provisional as a whole and observed that L351 and T366 variants were favored by the inventors. (See EX1030, 25:21-26:20 (part of “preferred combination of mutations”), 54:7-10 (“promising”), 57:5-6 (part of transfection ZO with “the highest proportion of heterodimers”), 58:1-67:4 (Examples 14-17).) As explained below, Merus inexplicably ignores this preference for L351 and T366 variants, despite T366 appearing just as frequently as S364 in Table 7, and L351 appearing *even more* frequently. (EX1030, Table 7; EX1062, 92:3-93:14.)

All of these disclosures point away from the claimed pair of 364 and 368 modifications and instead toward other mutation pairs listed as “preferred” or “promising,” but are ignored by Merus.

**B. The Board Should Reject Merus’s Chain of Inferences that Starts with Table 7 and Further Narrows Based on Hindsight Justifications Not Disclosed in the '935 Provisional**

Merus constructs a seven-step chain of inferences to artificially lead a POSA to one of the claimed substitutions (S364K), claiming that narrow focus would have led to only four possibilities for a charge pair. (POR, 12-31.) It is clear from this contrived path that Merus is impermissibly “[w]orking backward from a knowledge” of the claimed 364 and 368 pair, showing a hindsight path “one would

travel through the forest of the specification to arrive at it.” *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967). But merely describing a “maze-like path” that a POSA *could* take is insufficient. *See Regents of the Univ. of Minnesota v. Gilead Scis., Inc.*, 61 F.4th 1350, 1357 (Fed. Cir. 2023). Dr. Sutton laid bare Merus’s hindsight-ridden approach when he admitted that “what a POSA wants and what the inventor[s] want is . . . an increase in heterodimerization,” (EX1062, 98:3-7), but that “we don’t know” from the ’935 provisional “the percent of heterodimer formed when you have a bispecific antibody that has 364K/368D [mutations] on the two corresponding CH3 domains,” (EX1062, 212:8-13). That the ’935 provisional includes heterodimer percentages for numerous other combinations only reinforces that the inventors were focused elsewhere. (*See, e.g.*, EX1030, Table 15.)

While Merus’s misguided obviousness-style approach is legally improper, even following it would not lead where Merus needs it to because, as shown below, each step in Merus’s chain misreads the ’935 provisional.

**Table 7:** For its first step, Merus argues that a POSA would have looked to Table 7 of the ’935 provisional for guidance on which out of the forty-six listed CH3 domain variants “met the inventors’ stated preference for preventing homodimerization when expressed alone.” (POR, 18.)

AA substitutions in CH3	construct #	Effect on homodimer formation (- = no effect; +++ = max. inhibition; NT= not tested on gel)	AA substitutions in CH3	construct #	Effect on homodimer formation (- = no effect; +++ = max. inhibition; NT= not tested on gel)	AA substitutions in CH3	construct #	Effect on homodimer formation (- = no effect; +++ = max. inhibition; NT= not tested on gel)
Q347K	8	-	T394K, F405K	27	+++	Y407D		
Y349D	9	+-	T394K, Y407K	28	+++	Y349D, S364K, S400K, T407D	47	+
Y349K	10	+	P395K, V397K	29	+-	D399K	48	+-
T350K	11	-	S400K	30	-	D399R	49	+-
T350K, S354K	12	+-	F405K	31	+++	D399H	50	+
L351K, S354K	13	+	Y407K	32	++	K392D	51	+-
L351K, T366K	14	++	Q347K, V397K, T394K	33	+	K392E	52	+
L351K, P352K	15	+	Y349D, P395K, V397K	34	+	K409D	53	+
L351K, P353K	16	++	T350K, T394K, V397K	35	NT			
S354K, Y349K	17	++	L351K, S354K, S400K	36	+			
D356K	18	-	S354K, Y349K, Y407K	37	+-			
E357K	19	-	T350K, N390K, S400K	38	+-			
S364K	20	++	L368K, F405K	39	++			
T366K, L351K	21	++	D356K, T366K, L351K	40	+++			
T366K, Y407K	22	+++	Q347K, S364K	41	+++			
L368K	23	NT	L368D, Y407F	42	+			
L368K, S364K	24	++	T366K	43	+			
N390K, S400K	25	+-	L351K, S354K, T366K	44	+			
T394K, V397K	26	+	Y349D, Y407D	45	+			
			Y349D, S364K, Y407D	46	+			

(EX1030, Table 7.)

But as Xencor explained in its Petition, this table does not show possession of a “pair” of mutations as claimed because it is testing *homodimer repulsion* involving only *identical* heavy chains. (See, e.g., Pet., 29; EX1062, 75:15-17.) Merus’s logic thus fails at the outset—looking for identical mutations to make in opposing heavy chains does not show possession of a specific pair of different mutations in those heavy chains. (See EX1062, 97:16-98:7.)

Merus’s argument here is also in stark tension with its nonobviousness arguments for *Lazar*, which specifically lists in a single paragraph individual 364+ and 368- mutations as preferred substitutions, explaining they can be made “individually or in any combination for each heavy chain Fc region.” (EX1004,

¶123; POR, 52 (focusing on both 364+ and 368-).) To the extent Merus is correct that a POSA would have combed through the '935 provisional's specification to find individual mutations to work from, the same is true (and stronger) for *Lazar*.

**++ or +++ Only**: Even if a POSA were to follow Merus and focus on Table 7, Merus's next step contradicts the '935 provisional's disclosure. According to Merus, a POSA would have "understood" that the 14 variants in Table 7 with a "++" or "+++" rating "best embodied the inventors' stated preference." (POR, 21 (citing EX2019, ¶53).) Neither Merus nor Dr. Sutton gives any basis for focusing only on those ratings. Even if they had, this test should be rejected because it excludes five of the eight positions the '935 provisional expressly identifies as "promising for further testing," none of which are 364 or 368. (EX1030, 54:8-10 (listing as "promising for further testing in combination . . . residues Q347, S354, Y349, L351, K360, T366, T394, and V397").) For instance, using Merus's arbitrary "++ or +++" yardstick would exclude V397 (attaining a single "+" rating (at best) in its combinations) and K360 (not tested at all). (EX1030, Table 7.) Merus's test would also counsel against Q347, Y349, and T366, each of which attained no better than a single "+" rating when tested as a single substitution (another metric Merus argues a POSA would have focused on, (POR, 22-23)).

**Eliminating F405 and Y407**: After focusing on Table 7, then further on "++" or "+++" results only, Merus next attempts to carve out F405 and Y407.

(POR, 21-22.) But here, Merus’s rationale defeats its own argument that the ’935 provisional supposedly pointed to S364 and L368. Merus says the ’935 provisional warns against further testing of F405 and Y407 variants because they “have multiple interactions at the CH3-CH3 interface, including interactions with residues that are already charged, which may be problematic after introduction of multiple charge mutations among these interacting residues (see Table A).” (POR, 21 (quoting EX1030, 54:10-16).<sup>3</sup>) Dr. Sutton admitted otherwise in deposition, agreeing that “it is not a concern to put a positive charge” at position 405 even though it is known to interact with positions 392 and 409 “because positions 392 and 409 are already part of . . . the known salt bridges.” (EX1062, 52:13-53:5.) Dr. Sutton even agreed that a POSA reviewing the ’935 provisional application would have considered F405K and Y407K “very likely” to show an increase in heterodimer formation, and promising for further consideration. (EX1062, 78:22-79-10, 79:19-80:10, 95:15-97:1; *cf. id.*, 76:20-78:13.) To the extent this “warning” did teach away from substitutions at F405 and Y407, as Merus argues, it would also point away from S364 and L368, which also have “multiple interactions at the

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<sup>3</sup> Notably, even Merus ignored this supposed “warning”—the ’935 provisional describes numerous constructs that include substitutions at either the 405 or 407 positions. (*See* EX1030, Table 7, Table B, Table 1, Table 11.)

CH3-CH3 interface, including interactions with residues that are already charged.”  
 (EX1030, 54:10-16; *see also* EX2015, 166:2-168:17 (Dr. Presta testifying that “the same applies to S364”).)

Table A: List of CH3 domain interface residues

Interface residue in chain A	Contacting residues in chain B
Q347	K360
Y349	S354, D356, E357, K360
T350	S354, R355
L351	L351, P352, P353, S354, T366
S354	Y349, T350, L351
R355	T350
D356	Y349, K439
E357	Y349, K370
K360	Q347, Y349
S364	L368, K370
T366	L351, Y407
L368	S364, K409
K370	E357, S364
N390	S400
K392	L398, D399, S400, F405
T394	T394, V397, F405, Y407
P395	V397
V397	T394, P395
D399	K392, K409
S400	N390, K392
F405	K392, T394, K409
Y407	T366, T394, Y407, K409
K409	L368, D399, F405, Y407
K439	D356

(EX1030, Table A (annotations added).)

Merus’s response to Dr. Presta’s testimony that this “warning” would apply equally to S364, (EX2015, 162:2-168:17), is unsupported and contradicts itself. (POR, 30.) Merus first argues that there are “fewer possible complications” with S364 because there are fewer contacting residues. (*Id.*) But the portion of Dr. Sutton’s declaration on which Merus relies for support simply copies the POR word-for-word, cites nothing, (*compare* POR, 30, *with*, EX2019, ¶82; *see also* EX1062, 52:13-53:5), and is contradicted by Dr. Sutton’s untimely and questionable theory from deposition that homodimerization repulsion would be

expected to increase heterodimerization *regardless* of the mutations on the other chain (EX1062, 70:1-7; *see also id.*, 69:8-18, 71:2-18). Merus also suggests that “just because the inventors noted potential problems with certain residues, that does not mean they did not invent or possess them.” (POR, 30.) But these supposed “potential problems” are what Merus relies on to exclude F405 and Y407 from consideration. Merus cannot ask the Board to simultaneously credit and discredit these “potential problems.” To the extent the statement is credited, it points away from the claimed substitutions. To the extent the statement is discredited, Merus’s artificial narrowing of the ’935 provisional fails.

**Frequency:** Merus next attempts to carve a path to S364K by arguing it is one of two substitutions that “occur most frequently” (three times) in its already narrowed set of Table 7 → “++” or “+++” only → not F405 or Y407. (POR, 22.) That is simply wrong. L351K appears four times—in constructs 14, 16, 21, and 40. (EX1062, 92:3-93:4.) Merus’s path thus inexplicably ignores the most frequent mutation in its narrowed set—L351K—which Dr. Sutton confirmed a POSA would have viewed as “promising.” (EX1062, 93:5-14.) Furthermore, Merus provides no basis to conclude that “frequency” in the Table 7 homodimer testing chart would indicate possession for heterodimerization purposes. (POR, 22 (citing EX2019, ¶¶55-56).) Merus’s citation to Dr. Sutton’s declaration is unhelpful, as he merely parrots the POR without support or rationale. (EX2019,

¶¶55-56.) In fact, Dr. Sutton admitted that he “offered no opinion for why a POSA would not have considered L351K at least as promising as mutations to T366 or S364.” (EX1062, 95:7-14.)

**Ignoring T366:** Even after recognizing that T366K is listed the same number of times (three) as the only other residue in Merus’s narrow set (S364K), (POR, 22), Merus ignores T366K without explanation. Given the ’935 provisional’s express preference for “T366” and “T366K/L351’D” variants (EX1030, 54:8-10, 24:31-31:11; Tables 11-15), this oversight does not support a blaze mark to S364K.

**Eliminating K370:** Going further down the hindsight funnel, Merus next attempts to carve out K370 variants as a potential charge pair for S364K. (POR, 24-25.) Merus’s rationales at this step are not explained in the ’935 provisional, and are ultimately undermined by the fact that the inventors themselves were not dissuaded from modifying K370. In fact, a charged K370 mutation is part of a “particularly preferred” combination involving “E356K, E357K, K439D, and **K370D.**” (EX1030, 33:3-5 (emphasis added).) Recognizing they cannot credibly argue a POSA would be led away from K370 modifications (and thereby led only towards pairing S364 with S368), Merus abandoned this argument one page after making it and included K370 in its list of “only four possibilities.” (POR, 23-24.)

**Four Options**: Merus’s contorted path ultimately results in four options—S364K/L368D, S364K/L368E, S364K/K370D, S364K/K370E—none of which are listed as matched pairs in the ’935 provisional. (POR, 26.) Merus’s arguments amount to an insufficient obvious-to-try rationale and should be rejected.<sup>4</sup>

**C. Dr. Presta Applied the Correct Legal Standard for Written Description**

Merus’s argument that “[i]t is simply not possible for [Dr. Presta] to provide reliable written description opinions without knowing the legal standard to apply to [his] analysis” is doubly flawed. (POR, 63.) Dr. Presta opined as to technical issues, not legal issues. And in any event, as stated in his declaration, Dr. Presta applied the correct legal standard, considering whether “a person of ordinary skill in the art would . . . have understood the inventors of the ’859 patent to be in possession of the antibody claimed in claims 1-7, based on the disclosures of the specifications of the provisional and non-provisional applications identified on the cover of the ’859 patent.” (EX1002, ¶105.)

\* \* \*

Merus’s priority arguments apply an incorrect obviousness standard, rely on fabricated blaze marks, and ignore what the inventors actually disclosed in the ’935

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<sup>4</sup> In fact, Merus’s obvious-to-try rationale for priority directly supports Xencor’s obvious-to-try argument for *Lazar*. (See *infra*, Section IV.A.4.)

provisional. Because the '935 provisional does not provide written description support for the '859 patent claims, those claims are entitled to their filing date and no earlier.

### **III. *DESJARLAIS AND MOORE* ANTICIPATE THE CHALLENGED CLAIMS**

Merus does not dispute that if the claims lack written description support in the priority applications, *Desjarlais* and *Moore* anticipate.

### **IV. *LAZAR ALONE OR LAZAR IN VIEW OF KANNAN* RENDER OBVIOUS THE CHALLENGED CLAIMS**

If the Board finds the '859 patent claims have written description support based on Merus's circuitous chain of inferences (which should be rejected for the reasons above), the much shorter path to obviousness over *Lazar* or *Lazar* and *Kannan* is undeniable. *Lazar* teaches a preferred, oppositely-charged 364/368 pair and teaches preferred positive and negative mutations at positions 364 and 368 that would have immediately led a POSA to a 364+/368- pair. Making obviousness even more apparent, *Kannan*'s "charge swap" technique would have been straightforwardly applied to *Lazar*'s preferred 364/368 combination.

#### **A. Merus's Arguments Fail to Rebut that *Lazar*, Alone or in Combination with *Kannan*, Renders Obvious Claims 1-7**

##### **1. *Lazar* Alone**

Merus urges that "the Board correctly acknowledged in its institution decision [that] *Lazar* does not disclose 'a positively charged amino acid residue at

position 364’ and ‘a negatively charged amino acid residue at position 368’” (POR, 48-49), but this mischaracterizes *Lazar* and the Board’s decision. Merus acknowledges, as it must, that the Board found “Lazar teaches that preferred variant Fc regions include those having a positive charge at 364 (*e.g.*, 364H and 364R) as well as those having a negative charge at 368 (*e.g.*, 368E).” (POR, 52 (quoting Paper 13, 47).) Pivoting, Merus frames the Board’s acknowledgement of *Lazar*’s disclosure as “overread[ing], including because Lazar never shows a positive charge at 364 ***paired with*** a negative charge at 368.” (POR, 52 (emphasis added).) But this is an argument against anticipation, and does not make claim 1 of the ’859 patent nonobvious. As Dr. Sutton acknowledged, a POSA would have understood that, if they made a “positive modification at 364, [they] should then make a negative mutation at position 368.” (EX1062, 62:1-6.) In any case, Merus’s argument ignores that the ’935 provisional also “never shows a positive charge at 364 ***paired with*** a negative charge at 368.” (POR, 52.) If Xencor’s obviousness arguments fail for this reason, Merus’s written description arguments do, too.

Merus oddly argues that “[t]here is no data or other reason for a POSA to have selected either residue 364 or 368 from this list” of preferred substitutions for hetero-Fc variants in paragraphs 52 and 123 of *Lazar*. (POR, 51.) But there was: residues 364 and 368 were known contact residues in the CH3 domain. (*See, e.g.*,

EX1007, Table 1; EX1062, 34:2-9, 34:22-35:4, 36:10-14, 157:9-158:8.) As Dr. Sutton admitted, a POSA would have known that, as contact residues, positions 364 and 368 were “very promising” amino acid residues to form a positive-negative pair, (EX1062, 61:11-22), and that creating an oppositely charged 364/368 pair would have been “relatively straightforward” because 364/368 was one of the “simplest” pairs on which to focus. (EX1062, 58:19-59:8; *cf. id.*, 54:15-55:13.) In fact, an oppositely charged S364-L368 variant was listed specifically in *Lazar*’s Table 1 and was one of only nine single-modification variants listed. (EX1004, Table 1.) Because these “elements of [claim 1] are disclosed in a single embodiment in a single reference, no finding regarding a motivation to combine to arrive at those claimed elements is required.” *See Guardant Health, Inc. v. Univ. of Wash.*, No. 2024-1129, 2026 WL 184334, at \*4 (Fed. Cir. 2026).

Merus also argues that a POSA would “not have been motivated to pick the 364/368 pair for further modification; a POSA would have focused on the variants in *Lazar* with higher heterodimerization yields, which in *Lazar* reached 100%.” (POR, 50.) Merus’s invitation to apply a “lead compound”-style analysis should be rejected. First, a POSA does not need any motivation to consider what is explicitly taught in *Lazar*. *See Cytiva BioProcess R&D AB v. JSR Corp.*, 122 F.4th 876, 884 (Fed. Cir. 2024) (“A lead-compound analysis is not required where the prior-art references expressly suggest the proposed modification.”); *Guardant*,

2026 WL 184334, at \*4. Second, to the extent a POSA would have needed some motivation to select the 364/368 paired substitution in *Lazar*, this motivation is explicitly provided by *Lazar*'s labeling of this variant as "preferred" in Table 1. (EX1004, Table 1); *see In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999) ("motivation to combine may flow from the prior art references themselves"). In fact, Dr. Sutton admitted that *Lazar*'s S364E/L368K variant produced "an improvement in heterodimer formation" (EX1062, 219:21-220:6; *compare* EX1004, Fig. 5, row 11, *with*, EX1004, Fig. 5, row 1), and that he would expect the same result for an S364+/L368- variant, as well, (EX1062 169:22-170:7; *see also id.*, 168:8-169:16). Merus's and Dr. Sutton's arguments that a POSA would have instead focused on other variants based on the heterodimerization data in *Lazar*'s Figure 6 cannot supplant *Lazar*'s disclosure that the 364/368 substitution was "preferred."

There is a deeper irony in Merus's argument that a POSA would have avoided the 364/368 pair in *Lazar* because other substitutions showed higher heterodimerization yields. If the claimed substitutions were truly non-obvious over *Lazar*—requiring a POSA to bypass multiple "preferred" variants including the 364/368 charge pair—that same reasoning confirms that the '935 provisional, which lacks *Lazar*'s explicit 364/368 charge pair disclosure, cannot provide written description support for the claims. Merus cannot simultaneously argue that the

inferential leap from the '935 provisional to the claimed substitutions is adequate for written description while arguing that the stronger, explicit disclosures of *Lazar* are insufficient for obviousness. *See Ariad*, 598 F.3d at 1352.

Merus also makes a passing argument that Dr. Presta did not consider the *Graham* factors. Not true. Dr. Presta considered the level of ordinary skill in the art (EX1002, Sections IV-V), the scope and content of the prior art (*id.*, Sections VII.C-D), and the differences between the claims and the prior art (*see, e.g., id.*, ¶¶187-189). Dr. Presta did not explicitly consider secondary considerations because Merus had raised none at that time. Merus's accusation that Dr. Presta undermined his analysis by acknowledging that prior heterodimerization efforts "have been fraught with difficulty" is also pure distraction—particularly where, as here, Merus does not argue unpredictability as a basis for patentability. (POR, 64.) Dr. Presta's statement merely acknowledged background difficulties in the field, which varied depending on the specific context, and does not detract from his specific opinions regarding the prior art teachings at issue here. (*See* EX2015, 130:14-21 ("depends on the context").) Furthermore, Merus's own expert acknowledges the straightforward nature of introducing a charge pair at the 364 and 368 positions, making any generalized statements of difficulty in antibody engineering inapplicable to the relevant inquiry. (EX1062, 58:19-59:8.)

## 2. *Lazar* in View of *Kannan*

The addition of *Kannan* to *Lazar* only reinforces the obviousness of claim 1. Merus's motivation to combine and reasonable expectation of success arguments should be rejected.

**Motivation to combine:** Merus argues that “[a] POSA, based on *Kannan*, would not have made further changes to any of the already-substituted residues in *Lazar*.” (POR, 54.) But *Lazar* itself expressly suggests the combination, teaching that “[o]ther Fc variants that favor heterodimerization” (such as those in *Kannan*) “may find use in the creation of the antibody analogs of the invention” disclosed by *Lazar*. (EX1004, ¶125 (citing *Kannan*); Pet., 66.) Furthermore, *Lazar* and *Kannan* are both directed to modifying amino acid sequences in the CH3 domains of two heavy chains to promote heterodimerization. (EX1004, ¶¶119-125; EX1007, 2:33-3:13.) Moreover, *Kannan* teaches the benefits of charge-swapping in promoting heterodimerization, (EX1007, 2:35-37), and, according to Dr. Sutton, “it was known that you could combine different strategies that were known to improve the rate of heterodimerization to increase that rate even further,” (EX1062, 90:12-16; *see also id.*, 89:19-22, 168:8-170:7).

**Reasonable Expectation of Success:** Merus argues that a POSA would have understood from the *Gunasekaran* paper (EX1012) that “[i]ntroducing additional substitutions to wild-type neutral residues that had already been

modified by Lazar’s substitution processes would create a high risk of failure and, at a minimum, of decreasing the degree of heterodimerization.” (POR, 57.) To the extent Merus argues here that *Gunasekaran* teaches away, that argument is unpersuasive for the reasons below. (*See infra* Section IV.A.3.a.) Moreover, Merus’s argument that modifying *Lazar* in view of *Kannan* requires “additional substitutions” to “residues that had already been modified by Lazar’s substitution processes [and] would create a high risk of failure” is a red herring. (POR, 57.) A POSA combining the teachings of *Lazar* and *Kannan* would make only one set of substitutions by changing the neutral S364 and L368 wild-type residues to charged residues, as taught by *Lazar*. *Kannan* simply teaches a POSA that, instead of making the S364E/L368K modification explicitly taught by *Lazar*, making the opposite substitution (*i.e.*, S364K/L368E) would have also been desirable.

### **3. Merus’s Secondary Considerations Do Not Establish Nonobviousness of the Claims**

Merus argues that two secondary considerations support nonobviousness. First, Merus argues that “Dr. Gunasekaran Kannan’s [2010] paper . . . specifically warns against substituting the neutral residues of the hydrophobic core,” thereby teaching away from the claimed modifications. (POR, 46.) Second, Merus argues that it was unexpected that “the claimed inventions produce heterodimeric antibodies with increased stability.” (POR, 47.) Merus’s arguments should be

rejected because they misread *Gunasekaran* and lack evidence showing unexpected stability, let alone evidence tied to the claimed mutations.

**a) *Gunasekaran* Does Not Teach Away**

Merus argues that *Gunasekaran* teaches away from the modifications expressly taught in *Lazar* (and *Kannan*) involving neutral-to-charged substitutions in the “hydrophobic core” of the CH3 domain. (POR, 46; EX1062, 224:3-8.) Merus emphasizes that *Gunasekaran* is incorporated by reference into *Lazar*, arguing this shows an “incorporated” warning. (POR, 46.) But this incorporation actually cuts against teaching away. The *Lazar* inventors were clearly aware of *Gunasekaran*’s teachings, but still made numerous neutral-to-charged substitutions in the hydrophobic core of the CH3 domain. (EX1004, Tables 1-2; EX1002, ¶115 (annotating those tables); *see also* EX1062, 236:8-12, 240:20-241:4.)

This makes sense because the actual wording of *Gunasekaran* does not teach away. (See EX1012, 19640.) The statement Merus cites in no way discourages modification of neutral-to-charged substitutions; it notes only the potential “benefits” of using a charged-residue strategy. (*Id.*) In fact, other portions of *Gunasekaran* recognize that modifications to the hydrophobic core may be necessary to facilitate increased heterodimerization. For example, *Gunasekaran* praises the “pioneering . . . knobs-into-holes strategy” that “increased the production of heterodimer significantly” using “mutations involv[ing] structurally

conserved buried residues at the core of the interface.” (EX1012, 19645; EX1062, 224:16-20.) In fact, the same author, around the same time, expressly disclosed using “electrostatic steering effects” by “modifying uncharged residues to charged residues at the CH3 domain interface.” (EX1007, 10:16-18, 2:35-37; EX1062, 229:17-230:1.) As Dr. Sutton admitted, this teaching is inconsistent with the reading of *Gunasekaran* urged by Dr. Sutton and Merus. (EX1062, 228:11-19.)

**b) Merus Presents No Evidence That the Claimed Antibody Has Increased Stability**

Merus argues that “the claimed inventions produce heterodimeric antibodies with increased stability.” (POR, 47.) This argument lacks support and should be rejected.

Merus points to the '859 patent at 18:45-46 as allegedly supporting its claim of unexpected results. But this portion of the '859 patent includes only a general statement that “the dimers according to the invention are generally more stable as compared to the wild type dimers.” (EX1001, 18:45-56.) This general statement does not support unexpected results of the claimed S364+/L368- variants specifically.

The absence of written description for the claims is dispositive of unexpected results, as well. Merus cannot claim that an S364+/L368- pair produced unexpected stability results when those specific substitutions were not even disclosed as a pair—let alone tested—in any application predating Merus's

application for the '859 patent. There can be no unexpected results from an experiment the inventors did not conduct.

The disclosure of the '859 patent as a whole also shows that Merus's reliance on the general statement above does not show unexpected results of the claimed variants. For example, the '859 patent explains that "[t]he bispecific molecules from combinations 3-6 and 9-12 [of Table 15] (diamonds) also demonstrated a reduced thermal stability as compared to wildtype [bispecifics]." (EX1001, 53:17-21, 18:53-56.)

Merus points to paragraphs 155-156 of Dr. Sutton's declaration as allegedly supporting Merus's claim of unexpected results. (POR, 47.) These paragraphs of Dr. Sutton's report merely state, without evidence, that "Merus' heterodimerization methodology surprisingly achieves heterodimeric antibodies capable of higher yield and increased stability, especially in light of the teachings of the Gunasekaran Paper and the data from Lazar and Kannan." (EX2019, ¶155.) But according to Dr. Sutton, the "data from Lazar" showed that *Lazar's* charge swap variant achieved 100% heterodimeric purity. (*Id.*, ¶130.) Surely, Merus's heterodimerization methodology does not achieve yields higher than 100%, and Dr. Sutton's conclusory remarks do not support any unexpected results of the claimed S364+/L368- modifications. *See* 37 C.F.R. § 42.65(a).

**4. Merus Fails to Undermine That the Dependent Claims Are Obvious over *Lazar* and *Lazar* in View of *Kannan***

**Claims 2-3:** Merus argues that *Lazar* and *Kannan* fail to render claims 2 and 3 obvious because “*Lazar* and *Kannan* fail to disclose a single example or embodiment with a positively charged residue at position 364 and a negatively charged residue at position 368” and “do not provide any motivation for a POSA to arrive at this claimed subject matter with any reasonable expectation of success.” (POR, 59-60.) This argument is unpersuasive. *Lazar*, alone or in combination with *Kannan*, renders obvious a positively charged residue at position 364 and a negatively charged residue at position 368 for at least the reasons set forth above.

Moreover, *Lazar* and *Kannan* render obvious the specific mutations set forth in claims 2 and 3 because *Lazar*’s teachings would have motivated a POSA to switch the disclosed S364E/L368K and S364D/L368K residues (*i.e.*, to arrive at S364K/L368E and S364K/L368D). (*See* Pet., 55-69; *see also* EX1062, 168:8-169:17, 169:22-170:7.) In fact, Xencor’s Petition explained that *Lazar* alone suggested charge swapping based on various examples, including charge swaps at other pairs of positions (such as 364/370). (Pet., 59-60 (citing EX1002, ¶¶194-99).) Although Merus weakly contested this assertion in its POPR, (Paper 7, 25)—which the Board noted in its Institution Decision, (Paper 13, 45-46)—Merus forfeited this argument by not raising it in its Patent Owner’s Response, leaving un rebutted Xencor’s explanation (supported by Dr. Presta’s declaration). (*See*

Paper 14, 10); *see, e.g., Google LLC v. Uniloc 2017 LLC*, IPR2020-00447, Paper 21 at 9-10 n. 6 (May 11, 2021). *Kannan's* charge reversal modifications only reinforce *Lazar's* teachings. (Pet., 9-72.)

As Xencor's Petition explained, charge swapping at the 364 and 368 positions (which Dr. Sutton conceded would have been "a very promising example" set of locations for forming a charge pair based on the known CH3 domain interface alone, (EX1062, 61:11-22; *see also id.*, 58:19-59:8)) would have led to a finite number of predictable substitutions, rendering each obvious to try. (Pet., 64-65 (citing EX1002, ¶¶194-204, 220-23); *see also* EX1062, 62:1-6, 168:8-169:16, 169:22-170:7; *cf.* POR, 26.) Merus has no rebuttal to this specific point, and its obviousness-style priority arguments bolster this rationale—suggesting that a POSA would not differentiate between residues having the same charge, but instead would try all of them to make a charge pair. (*See* POR, 26-27; *see also* EX1062, 93:15-96:7.)

**Claim 4:** Merus's argument that "Lazar's alternative bispecific moieties . . . do not need Fc heterodimerization" is equally unpersuasive. (POR, 60.) *Lazar's* Figure 8 shows CH3 modifications to promote heterodimerization in *Lazar's* mAb-Fv and mAb-Fab alternative antibody formats, and *Lazar* teaches that "variants that favor Fc heterodimerization and disfavor Fc homodimerization"—including the S364+ and L368- substitutions listed in paragraphs 52 and 123—should be

incorporated into the mAb-Fv and mAb-Fab formats. (See EX1004, ¶¶52, 107, 123.) Because these “elements of [claim 4] are disclosed in a single embodiment in a single reference, no finding regarding a motivation to combine to arrive at those claimed elements is required.” See *Guardant*, 2026 WL 184334, at \*4.

**Claims 5-6:** Merus argues that “[t]he only substitutions tested in an IgG or IgG-like molecule in Lazar are Y349T/T394F in one chain and S364H/F405A in the other. Lazar does not disclose, teach, or suggest any substitutions at positions 364 and 368 of a human IgG or a human IgG1.” (POR, 61 (citing EX2019, ¶163).) Not so. *Lazar*’s Figure 8 shows CH3 modifications in a human IgG1 background to promote heterodimerization in *Lazar*’s mAb-Fv and mAb-Fab alternative antibody formats. (See EX1004, ¶46, Fig. 8, Table 3.) And, as explained above, *Lazar* teaches that the S364+ and L368- substitutions in paragraphs 52 and 123 should be incorporated into mAb-Fv and mAb-Fab formats. (See EX1004, ¶¶52, 107, 123.) Moreover, *Lazar*’s Example 2 expressly describes applying preferred and most preferred neutral-to-charged substitutions (which include the substitutions in paragraphs 52 and 123, as well as the obvious S364E/L368K and S364D/L368K charge-swapped variants) in a heterodimer based on IgG1. (EX1004, ¶239.)

**Claim 7:** Merus only argues that dependent claim 7 is not obvious because claim 1 is not obvious. (POR, 62.) This argument fails for the same reasons that Merus's arguments for the nonobviousness of claim 1 fail.

**V. CONCLUSION**

For at least the above reasons, Xencor respectfully requests that the Board find the challenged claims unpatentable.

Respectfully submitted,

Dated: April 3, 2026

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**CERTIFICATE OF COMPLIANCE**

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing Petitioner's Reply contains, as measured by the word-processing system used to prepare this paper, 5,586 words. This word count does not include the items excluded by 37 C.F.R. § 42.24.

Respectfully submitted,

Dated: April 3, 2026

By: /Naveen Modi/  
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**CERTIFICATE OF SERVICE**

I hereby certify that on April 3, 2026, I caused a true and correct copy of the foregoing Petitioner's Reply to be served via email on Patent Owner at the following addresses:

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