Strategic Use of Means-Plus-Function Claiming

to Optimize Patent Protection for Biological and Chemical Inventions

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Presentation Overview

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1 The Post-*Amgen* Landscape

Amgen Inc. v. Sanofi, 598 U.S. 594 (2023)

1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody **binds to at least one** of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody **blocks binding of PCSK9 to LDLR**.

US 8,829,165 (issued in 2014)

Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021)

1. A nucleic acid polymer encoding a chimeric T cell receptor, said chimeric T cell receptor comprising

(a) a zeta chain portion comprising the intracellular domain of human CD3 ζ chain,

(b) a costimulatory signaling region, and

(c) a binding element that specifically interacts with a selected target, wherein the costimulatory signaling region comprises the amino acid sequence encoded by SEQ ID NO:6.

2. The nucleic acid polymer of claim **1**, wherein the binding element is an antibody.

3. The nucleic acid polymer of claim **2**, wherein the antibody is a single chain antibody.

4. The nucleic acid polymer of claim **3**, wherein the single chain antibody binds to prostate specific membrane antigen.

5. The nucleic acid polymer of claim **3**, wherein the single chain antibody binds to CD19.

6. The nucleic acid polymer of claim **3**, wherein the encoded T cell receptor comprises binding element-costimulatory signaling region-zeta chain portion in that order.

Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021)

"While it is true that scFvs in general were known, and even known to bind, the record demonstrates that, for even the narrowest claims at issue, the realm of possible CD19- specific scFvs was vast ***and the number of known CD19- specific scFvs was small (five at most).*** The '190 patent, however, provides no details about which scFvs bind to CD19 in a way that distinguishes them from scFvs that do not bind to CD19. Without this guidance, under our controlling *Ariad* decision, no reasonable jury could find the '190 patent satisfies the written description requirement."

2 Overview of Means Plus Function (MPF) Claiming

35 U.S.C. § 112(f): The Statutory Text

"ELEMENT IN CLAIM FOR A COMBINATION.—An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

How to Invoke 112(f):

Claim recites a "specified function" without reciting the structures or materials that perform that function.

How to Satisfy 112(f):

Make sure your specification describes **at least one** "corresponding structure, material or acts" that perform the specified function.

What Equivalents Are Covered?

Scope of your claim is extended to the equivalents that were known before your patent issued via function-way-result test*

MPEP §§ 2181–2187 = USPTO Framework for Identifying MPF Limitations

§ 2181: Three-prong test for identifying an MPF claim limitation under § 112(f)

A. The claim limitation uses “means” or “step” or a substitute for “means” that is a generic placeholder term for performing the claimed function;

B. The term “means” or “step” or the generic placeholder is modified by functional language and linked by a transition word such as “for,” “configured to,” etc.; and

C. The term “means” or “step” or the generic placeholder is NOT modified by sufficient structure, material, or acts for performing the claimed function.

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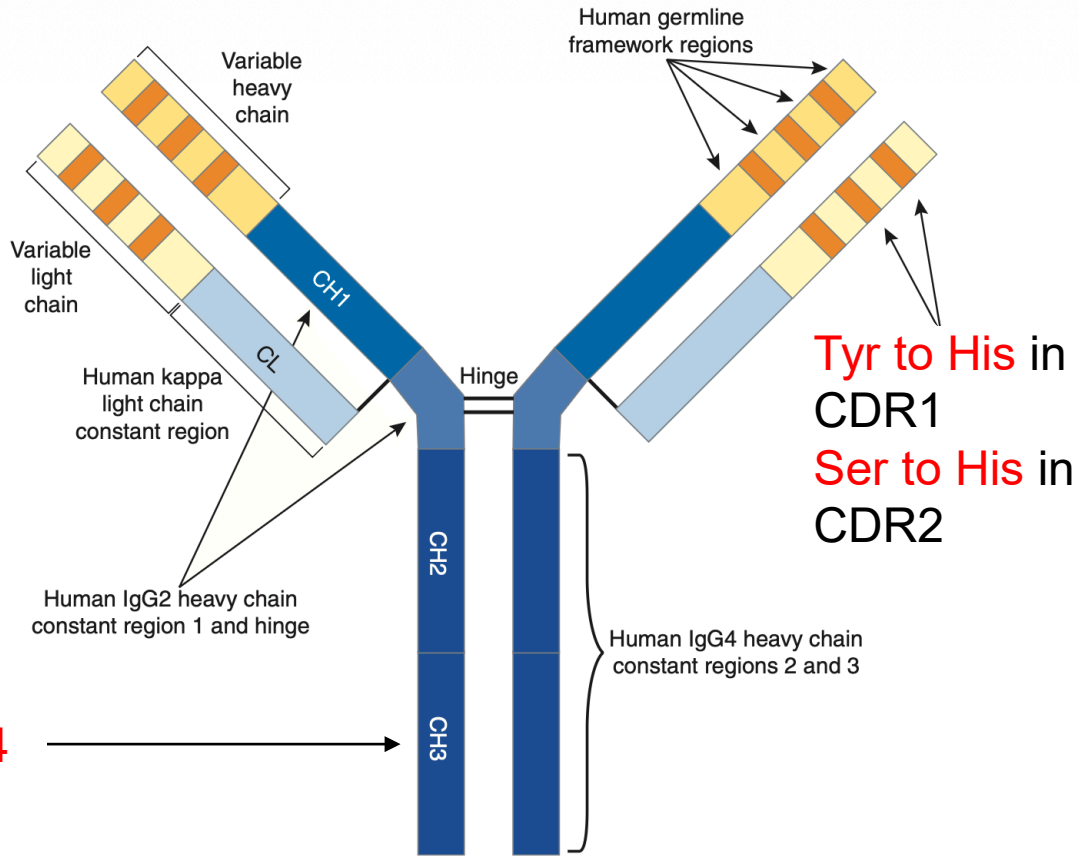
Ex Parte Chamberlain

MPF claiming for antibodies

Chamberlain is a Tale of Two Antibodies: Eculizumab and Ravulizumab



Xenor Prosecuted Just 2 Claims in its Application – Claim 8 and Claim 9

Listing of Claims:

1. – 7. Cancelled.

8. (Previously presented) In a method of treating a patient by administering an anti-C5 antibody with an Fc domain, the improvement comprising said Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide, wherein numbering is according to the EU index in Kabat et al., wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.

9. (New) A method of treating a patient by administering an anti-C5 antibody comprising:

a) means for binding human C5 protein; and

b) an Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide, wherein numbering is according to the EU index in Kabat et al., wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.

Claims 8 and 9 Targeted Alexion's Anti-C5 Antibody, Ravulizumab

REMARKS

Status of Claims

Claims 1-7 are cancelled. Claim 8 is newly added and is currently pending. Claim 20 ais supported throughout the specification and figures; the incorporation of the Fc variants (M428L/N434S) into an anti-C5 antibody is recited in [0124] and [0131] (note that 5G1.1 listed in [0131] is eculizumab, see Exhibit 1).

Applicant respectfully requests entry of the claims as amended.

Remarks

Applicants would like to draw the Examiner's attention to several references in support of the new claims. All of these references are directed to the use of the M428L/N434S amino acid substitutions in the Fc domain of eculizumab, an anti-C5 antibody marketed under the name Soliris®, resulting in a new antibody, ravulizumab, now marketed under the name Ultomiris®. Ravulizumab has a much longer half-life in serum, and thus can be dosed less frequently than eculizumab, leading to significant patient benefits.

Ravulizumab has 4 amino changes as compared to eculizumab: two amino acid changes in the CDRs, and the M428L/N434S substitutions in the Fc domain. Both changes provide benefits, but as shown in Sheridan et al., the effects are separate; see Sheridan et al., PLOS One, April 12, 2018 (https://doi.org/10.137/journal.pone.0195909), attached herein as Exhibit 2. As

Xencor's Specification Named 1 Antibody That Bound Human C5: 5G1.1

> *"…Target antigens and clinical products and candidates that are relevant for such diseases include but are not limited to anti-α4β7 integrin antibodies such as LDP-02, anti-β2 integrin antibodies such as LDP-01, anti-complement (C5) antibodies such as 5G1.1, anti-CD2 antibodies such as BTI-322, MEDI-507, anti-CD3 antibodies such as OKT3…"*

Round 1: § 112(b), § 112(f), and § 112(a)

October 2020 Final Rejection

Claim 9 (as filed Aug. 27, 2020)

"A method of treating a patient by administering an anti-C5 antibody comprising: a) means for binding human C5 protein; and b) an Fc domain comprising amino acid substitutions M428L/N434S..."

§ 112(b)	§ 112(f)	§ 112(a)
Indefiniteness	**MPF invoked**	**Written Description**
"Means for binding" vague; spec does not set forth specific structures.	Examiner acknowledged 5G1.1 as possible corresponding structure but concluded this was insufficient.	"Invocation of § 112(f) does not exempt compliance with § 112(a)."

Round 2: PTAB Affirms Both Rejections (June 2023)

Procedural History

- **Aug. 25, 2021**
  Appeal Brief filed
- **Dec. 15, 2021**
  Examiner's Answer
- **Feb. 14, 2022**
  Reply Brief filed
- **Dec. 2022 / Jan. 2023**
  PTAB original decision (vacated, rehearing)
- **June 1, 2023**
  PTAB Decision on Rehearing

PTAB Holdings on Claim 9

§ 112(a) written description: AFFIRMED

"Means for binding" is construed as a chemical genus covering the disclosed structure *and equivalents thereof*; the University of California v. Eli Lilly antibody standard applies.

§ 112(b) indefiniteness: AFFIRMED

"Failure to disclose adequate structure... results in the claim being of indefinite scope."

Core reasoning: § 112(f) compliance does not obviate independent § 112(a) analysis; naming 5G1.1 is not the same as describing 5G1.1.

Round 3: CAFC Remand → ARP Rescues the MPF Limitation

The Appeals Review Panel Decision of May 17, 2024

Jan. 23, 2024 — Fed. Cir. Remand: Director moved to remand citing "novelty and complexity" of MPF in biotech. First-ever Appeals Review Panel convened.

THE WIN: MPF Limitation

✓ 5G1.1 (= eculizumab) is adequate corresponding structure — known in prior art.

✓ Specification need NOT describe equivalents — only the corresponding structure.

✓ § 112(b) indefiniteness REVERSED on the MPF limitation.

✓ Single disclosed antibody sufficient for § 112(f) compliance.

THE LOSS: New Ground

✗ "Treating a patient" preamble held limiting and lacking written description.

✗ Spec disclosed no working example of treating any disease with 5G1.1 or any anti-C5 antibody.

✗ Therapeutic context in claim body ("increased in vivo half-life") makes preamble substantive.

✗ Claim 9 still stands rejected under § 112(a).

Round 4: Federal Circuit Affirms ARP (March 2025)

In re Xencor, Inc., No. 24-1870 (Fed. Cir. Mar. 13, 2025)

What the Court Decided:

- Affirmed "treating a patient" preamble is limiting
- Affirmed written description failure for anti-C5 antibody genus
- *Cited Juno v. Kite: WD requirement varies with "nature and scope of the invention"*

What the Court Did NOT Address:

The Federal Circuit did not reach the § 112(f) MPF issue. Claims 8 and 9 failed on written description for preamble limitations before the court needed to analyze the MPF element.

Epilogue: After Removal of Problematic Preamble, Claim 9 Was Allowed

U.S. Patent 12,492,253 — Issued December 2025

Claim 1 (sole claim)

1. **An antibody comprising:**

   a) a **means for binding human C5**; and

   b) an Fc domain comprising amino acid substitutions **M428L/N434S** as compared to a human Fc polypeptide, wherein numbering is according to EU numbering.

What Changed

Preamble amended: "A method of treating a patient by administering an anti-C5 antibody" → "An antibody"

Eliminates the written description deficiency that doomed claims 8 & 9 at the ARP and Federal Circuit.

What Survived

MPF limitation intact: "means for binding human C5" — the core doctrinal innovation from Chamberlain.

Single claim. Single corresponding structure (eculizumab). Covers equivalents by operation of law.

Epilogue: Xencor Announces Expected Royalties of $100-$120 Million

Dec 2025	US 12,492,253 issues — extends Xtend™ patent coverage for C5 antibodies to December 2028. Xencor announces it expects $100-$120 million in additional US royalties on Ultomiris®.
Mar 2026	Alexion (AstraZeneca) notifies Xencor it will cease U.S. royalty payments and disputes additional royalty obligations for Ultomiris®.
2026 - ??	Future litigation over this MPF claim may set another important precedent.

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Ex Parte Gleave

MPF claiming for antisense oligonucleotides

Gleave: Case Background & Technology

Ex Parte Gleave, PTAB Appeal 2012-004973 (App. 12/490,018)

PTAB Decision: January 22, 2014

Technology: Antisense oligonucleotides and siRNA molecules that reduce expression of heat shock protein 27 (hsp27) in cancer cells

Therapeutic Context: Hsp27 overexpression is associated with resistance to chemotherapy. Reducing hsp27 levels sensitizes cancer cells to treatment.

The MPF Claim

Claim 33:

"A pharmaceutical composition comprising ... means for reducing the amount of active hsp27 in cancerous cells ..."

Gleave: Corresponding Structures Identified

Claimed Function: "reducing the amount of active hsp27 in cancerous cells"

Structure 1: Antisense Oligonucleotides

Source: Example 1 of specification

Type: Specific antisense oligonucleotide sequences complementary to hsp27 mRNA

Mechanism: Binds hsp27 mRNA, blocks translation, reduces hsp27 protein levels

Structure 2: siRNA Molecules

Source: Example 5 of specification

Type: Specific RNA interference molecules targeting hsp27

Mechanism: Post-transcriptional gene silencing via RISC complex, degrades hsp27 mRNA

Two distinct molecular classes — both linked to the same claimed function in the specification

Gleave: PTAB Reversal & Key Holdings

PTAB Reversed Anticipation and Obviousness Rejections

The Board's critical finding:

The examiner failed to demonstrate that the prior art nucleotide sequence performed the claimed function of reducing active hsp27 in cancerous cells.

Why MPF helped:

- Under § 112(f) construction, the examiner must show prior art discloses the corresponding structure OR its equivalent performing the claimed function
- The prior art taught a nucleotide sequence but not its specific function of reducing hsp27
- MPF's narrow construction protected the applicant from broad prior art that didn't actually perform the claimed function

MPF claim construction = narrower scope = harder for examiner to find anticipatory prior art

Gleave: Prosecution Lessons

Narrow MPF claims can provide satisfactory scope

Even with narrower literal coverage, the combination of corresponding structures + equivalents gives meaningful protection.

Carefully link "means for" to specification embodiments

Clear structure-function linkage in the specification is essential. Gleave succeeded because Examples 1 and 5 were explicitly tied to hsp27 reduction.

MPF creates design-around uncertainty

Competitors cannot easily determine scope of equivalents, which creates defensive value beyond the literal claim scope.

Expect examiner resistance in biotech art units

MPF claims are uncommon in biotech prosecution. Be prepared to educate examiners on the § 112(f) framework.

Chamberlain vs. Gleave: Contrasting Outcomes

	Ex Parte Gleave (2014)	Ex Parte Chamberlain (2024)
Technology	Antisense oligos / siRNA	Anti-C5 antibodies
MPF Element	*"means for reducing active hsp27"*	*"means for binding human C5 protein"*
Corresp. Structure	Specific oligos (Ex. 1) + siRNA (Ex. 5)	Eculizumab (5G1.1)
MPF Outcome	**Anticipation & OA REVERSED**	**Indefiniteness REVERSED**
Overall Result	**CLAIM ALLOWED**	**WD rejection AFFIRMED (preamble), but MPF limitation without MOT preamble later allowed.**
Key Lesson	*Multiple corresponding structures strengthen MPF*	*MPF-based claims can add value when used strategically.*

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MPF Claiming in the Chemical Sciences

Pharmaceutical Formulation MPF Claims

US 10,413,611

1. A pharmaceutical composition comprising:
(a) at least one poloxamer selected from poloxamer 124, poloxamer 188, poloxamer 237, poloxamer 338, and poloxamer 407, or a mixture thereof; and
(b) means for keeping the pharmaceutical composition in liquid phase up to a temperature of about 40° C. in vitro,
wherein the pharmaceutical composition is for use in submucosal lift of gastrointestinal mucosal lesions in a patient undergoing a gastrointestinal endoscopic procedure.

Formulation MPF claims protect the inventor's specific solution without requiring exhaustive genus disclosure of all possible excipient combinations.

Pharmaceutical Formulation MPF Claims

Example: U.S. Patent No. 10,413,611

Claim: "means for keeping the pharmaceutical composition in liquid phase up to a temperature of about 40°C in vitro"

Corresponding Structure: Specific excipients and formulation components described in specification

Why This Works:

- Formulation function (temperature stability) clearly linked to specific disclosed components
- Scope covers disclosed excipients + equivalents that achieve same stability function
- Avoids need to claim every possible excipient combination that achieves the result

Formulation MPF claims protect the inventor's specific solution without requiring exhaustive genus disclosure of all possible excipient combinations.

Chemical vs. Biological MPF: Key Differences

	Biological MPF	Chemical MPF
Typical Structure	Antibody, oligonucleotide, protein	Small molecule, excipient, polymer
Predictability	Low: a single AA change can abolish function	Variable: SAR may be better understood
Equivalents Scope	Uncertain - no Fed. Cir. Guidance	Potentially broader if SAR is well-characterized
Best For	Target-binding claims (Chamberlain model)	Functional formulations, PROTACs, drug conjugates
Key Risk	Narrow equivalents if field unpredictable	Inadvertent invocation of § 112(f)

In chemistry, where structure-activity relationships may be better characterized, the scope of § 112(f) equivalents could be broader than in biology.

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Prosecution Strategy Recommendations

Practical guidance for drafting and prosecuting MPF claims

Specification & Claim Drafting Best Practices

Specification

- Explicitly link structures to functions
- Provide multiple corresponding structures
- Characterize why structure performs function
- Include working examples with data
- Discuss structural variants
- **Narrow therapeutic context (avoid Chamberlain trap)**

Claim Drafting: Layered Approach

Layer 1: Structural picture claims (narrowest, strongest)

Layer 2: MPF claims (medium scope, defensible)

Layer 3: Genus claims (broadest, highest risk)

Layer 4: Method / composition claims

- Use "means for [function]" deliberately
- Avoid overbroad preambles
- Draft dependent claims narrowing function

Responding to § 112 Rejections of MPF Claims

Examiner doesn't invoke § 112(f)

Request interpretation under 37 C.F.R. § 1.75(d). The USPTO’s March 18, 2024 memo on evaluating MPF claim limitations requires examiners to make their interpretation of the claim and its status under § 112(f) explicit.

§ 112(b) indefiniteness

Point to specific corresponding structure. Cite ARP's Chamberlain: single well-known antibody that performs the entire recited function suffices.

§ 112(a) written description

Distinguish MPF element (requires only corresponding structure) from other claim elements. Consider narrowing non-MPF elements.

§§ 102/103 prior art

Prior art must teach corresponding structure OR an equivalent structure, material or act that performs the entire claimed function.

Overcoming Examiner Resistance

"MPF claims are not appropriate for biological inventions."

No statutory basis. § 112(f) applies to all claim elements reciting function without structure. ARP applied it to antibodies.

"The specification must describe ALL equivalents."

ARP held otherwise: statute requires corresponding structure, not equivalents. Equivalents follow by operation of law.

"One disclosed antibody cannot be sufficient."

ARP expressly held one antibody (eculizumab) sufficed. Gleave had two molecular classes, both were deemed sufficient.

"This circumvents Amgen v. Sanofi."

Different statutory provisions with different requirements. § 112(f) is not a workaround, it is a distinct claiming tool.

7 Key Takeaways

Key Takeaways

1. MPF claiming is a legitimate, underutilized strategy that may provide meaningful protection post-Amgen.
2. The ARP's Chamberlain decision: single disclosed antibody suffices as corresponding structure.
3. Ex Parte Gleave: MPF claims can fully succeed in prosecution. Multiple corresponding structures strengthen the position.
4. A layered claiming strategy hedges against § 112 invalidity risk.
5. Chemical sciences also offer opportunities to use MPF claims: pharmaceutical formulations, PROTACs.
6. The scope of § 112(f) equivalents for biologics is uncharted territory. First litigated case will set key precedent.

Thank You!

Questions & Discussion

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