2023-2048

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE: XENCOR, INC.,

Appellant

Appeal from the United States Patent and Trademark Office Patent Trial and Appeal Board in Application No. 16/803,690
(Before Richard M. Lebovitz, Tawen Chang, and John E. Schneider, Administrative Patent Judges)

BRIEF OF *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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October 6, 2023

CERTIFICATE OF INTEREST

Case Number 2023-2048

Short Case Caption In re: Xencor, Inc.

Filing Party/Entity American Intellectual Property Law Association

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 10/6/2023 Signature: /s/ Barbara A. Fiacco

Name: Barbara A. Fiacco

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☒None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☒ None/Not Applicable
American Intellectual Property Law Association		

4. **Legal Representatives**. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☒None/Not Applicable ☐Additional page attached

5. **Related Cases**. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☐ Yes (file separate notice; see below) ☐ No ☒ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). Please do not duplicate information. This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. Ap. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☒ None/Not Applicable ☐ Additional pages attached

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STATEMENT OF *AMICUS CURIAE*

The American Intellectual Property Law Association ("AIPLA") is a national bar association representing the interests of approximately 7,000 members engaged in private and corporate practice, government service, and academia. AIPLA's members represent a diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trade secret, trademark, and copyright law, as well as other fields of law relating to intellectual property. Our members represent both owners and users of intellectual property. AIPLA's mission includes providing courts with objective analyses to promote an intellectual property system that stimulates and rewards invention, creativity, and investment while accommodating the public's interest in healthy competition, reasonable costs, and basic fairness. AIPLA has no stake in either of the parties to this litigation or in the result of this case.[1] AIPLA's only interest is in seeking correct and consistent interpretation of the law as it relates to intellectual property issues.

AIPLA states that, pursuant to Federal Rule of Appellate Procedure 29(a), all parties consented to the filing of this brief.

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[1] No person, party, or party's counsel, other than *amicus curiae* or its counsel, authored this brief in whole or in part, or contributed money that was intended to fund preparing or submitting this brief.

SUMMARY OF ARGUMENT

In its decision on the Request for Rehearing, the Patent Trial and Appeal Board ("PTAB") correctly viewed the "means for binding human C5 protein" as a means-plus-function claim invoking 35 U.S.C. § 112(f),[2] under which the means element must be "construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." Appx50. Appellant Xencor, Inc. argued that it disclosed one embodiment with known structure, antibody 5G1.1. Appx52. The PTAB disagreed, finding "no structure" was disclosed for 5G1.1. Appx52. Whether its structure was sufficiently known to persons of ordinary skill in the art, as Appellant argues, is a question of fact, and AIPLA takes no position on that question. But the PTAB went further, reasoning that even if the structure of 5G1.1 was adequately disclosed, Appellant may not meet the written description requirement of 35 U.S.C. § 112(a) to support ***a claimed genus*** of 5G1.1 and "equivalents thereof." Appx51-52.

AIPLA submits this brief as *amicus curiae* to urge the Court not to adopt a bright-line rule that disclosure of an antibody's structure is insufficient to support a

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[2] While the PTAB's decision cites 35 U.S.C. § 112(f), the application claims priority to 2008 and is governed by pre-America Invents Act ("AIA") law, including 35 U.S.C. § 112 ¶ 6. There is no substantive difference between pre-AIA 35 U.S.C. § 112 ¶ 6 and current Section 112(f). *See, e.g.*, *Egenera, Inc. v. Cisco Sys.*, 972 F.3d 1367, 1372 n.1 (Fed. Cir. 2020).

means-plus-function claim merely because, under the statute, the "means" element includes the corresponding antibody structure(s) described in the specification and "***equivalents thereof***." Under Section 112(f), inventors who publicly disclose the structure of an antibody and recite that disclosure as the "means" for performing a function should have the same right as other inventors to a means-plus-function claim that covers both the disclosed structure and statutory "equivalents thereof." Existing precedent analyzing structural equivalence under Section 112(f) and the closely-related doctrine of equivalents provides appropriate guidance for the determination of "equivalents thereof" in the antibody context.

While the analysis of what constitutes a structural equivalent of a disclosed antibody may, in some instances, be complicated and fact-intensive, our patent system should not shut the door on antibodies or any other technologies. Rather, as the stewards of this system, the courts and the Patent Office must ensure that it continues to incentivize innovation and public disclosure of inventions so that others may build upon them.

PROCEDURAL BACKGROUND

This is an appeal from the PTAB's decision and denial of rehearing that rejected two claims in Appellant's U.S. Patent Application No. 16/803,690. Claims 8 and 9 are directed to methods of treating a patient by administering an

anti-C5 antibody containing certain substitutions in its Fc domain that increase the antibody's half-life.

I. CLAIMS AT ISSUE

Claim 8 is in Jepson-claim format, and claim 9 is in means-plus-function format. Claim 9 recites:

> 9. 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 of Kabat, wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.

Appx3.

In a Final Office Action, the Examiner maintained rejections of both claims on obviousness-type double patenting grounds. The Examiner also rejected the claims as failing to comply with the written description requirement under Section 112(a). In a subsequent Answer, the Examiner maintained the obviousness-type double patenting rejections and withdrew the rejection based on Section 112(a) after reconsidering certain previously-submitted exhibits. Appx2.

II. THE BOARD'S DECISION

On appeal, the Board rejected both claims under Section 112(a) for lack of written description and made a new rejection of claim 9 under 35 U.S.C. § 112(b) as indefinite. Appx2. Although AIPLA's brief focuses on claim 9, the Board's overlapping analysis of both claims is set forth below.

A. Claim 8

The Board noted that claim 8 is a Jepson claim, having a preamble reciting what is conventional or known. The preamble admits that "a method of treating a patient by administering an anti-C5 antibody with an Fc domain" was known in the art. The improvement, recited in the body of the claim, consists of the substitution of specific amino acids in the Fc domain to increase the in-vivo half-life of the antibody. Appx3.

The Board construed "anti-C5 antibody" as an antibody that binds to the C5 complement protein in the "normal way" (i.e., through the variable region of the antibody) and noted that the claim does not in any way limit the structure of the variable region or the function of the antibody. The Board stated that the anti-C5 antibody "represents a broad genus of antibodies unrestricted in their variable region structure, epitopes to which they bind, function, mechanism of action in treatment, etc." Appx6.

The Board noted that the Specification discloses one anti-C5 antibody, 5G1.1, which was known in the art before the effective filing date.[3] Based on the submitted publications and a declaration, the Board found that the "5G1.1" designation refers to a specific antibody that binds human C5 and includes both the mouse and humanized forms. Although 5G1.1 was known to prevent the generation of C5a and C5b proteins from a C5 protein, the Board concluded that the claim term "anti-C5 antibody" should not be so limited in function. The Board also concluded that the claimed antibody treatment is not confined to a specific mechanism of action. Appx7-8.

The Board construed "treating a patient" as not limited to any particular condition or to human patients. The Board further noted that the term "anti-C5 antibody" is "a genus of antibodies because any antibody that binds to the C5 protein and is 'treating a patient' is encompassed by the claim (so long as it has the Fc domain substitution recited in the claim)." Appx10.

The Board then concluded that written description support was lacking for claim 8 because the only C5 antibody disclosed in the specification is 5G1.1. The

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[3] Indeed, the antibody eculizumab, marketed by Alexion as Soliris®, is a long-acting, anti-C5 antibody approved by the FDA in 2007. *See* Janus Asbjørn Schatz-Jakobsen et al., *Structural Basis for Eculizumab-Mediated Inhibition of the Complement Terminal Pathway*, 197 J. Immunology 337 (2016).

Board reasoned that "one of ordinary skill would be unable to distinguish which anti-C5 antibodies having the claimed Fc domain substitution would fall within the scope of claim 8 and which would not." Appx11-12. In response to the written description rejection, the Applicant had argued that there was a "plethora" of anti-C5 antibodies known in the art and treatment methods using such antibodies were well-known as of the filing date. The Board disagreed, concluding that "there is no limitation on the variable region structure of the claimed anti-C5 antibody and no correlation disclosed in the Specification between the function of the antibody to bind C5 and treat a patient and antibody structure." Appx18-20.

B. Claim 9

The Board determined that the claimed "means for binding human C5 protein" renders the claim a means-plus-function claim. It also determined that the function of the recited means is to bind human C5. The Board then analyzed what structure, if any, disclosed in the specification corresponds to the claimed function. Appellant argued that the disclosure of "anti-complement (C5) antibodies such as 5G1.1" is the disclosed structure. Although the Board had recognized in its analysis of claim 8 that 5G1.1 was the only anti-C5 antibody disclosed in the Specification, the Board rejected Appellant's argument that 5G1.1 was the corresponding structure for the "means" element. The Board reasoned that "anti-complement (C5) antibodies" is generic, and that there was inadequate disclosure

of an antibody structure that binds to the C5 protein. The Board noted that "[e]ven were the antibody structure of the 5G1.1 antibody sufficient, the claimed 'means for' is not restricted by the Specification to this specific antibody species." Appx29. The Board found that "the Specification does not disclose sufficient structure corresponding to the claimed function for the reasons discussed above for claim 8" and held that claim 9 both lacks written description and is indefinite. Appx30.

The Board also affirmed one of the two grounds for the Examiner's obviousness-type double-patenting rejection. Appx34.

III. THE BOARD'S DECISION ON REQUEST FOR REHEARING

On January 10, 2023, the Board denied Appellant's Request for Rehearing. With respect to claim 9, Appellant argued that an applicant need only disclose one embodiment with a structure in order to have a valid means-plus-function claim. Appx50. The Board disagreed, looking to Section 112(a) law as applied to antibodies and considering the "means" to be a chemical genus claim. It reasoned that Section 112(f) construes the recited means as including the structure disclosed in the Specification "and equivalents thereof." Appx51. According to the Board, "and equivalents thereof" broadens any structure disclosed in a specification to a group or genus of structures:

> In sum, we do not agree with Appellant that a different standard for compliance with the written description requirement should be applied to an antibody claim simply because the claim is written in means-plus-function format. It is inconsistent to arrive at a different result for an antibody claim comprising a means-plus-function element than for claim reciting the same antibody element without invoking §112(f). *See Juno Therapeutics, Inc. v. Kite Pharma, Inc.,* 10 F.4th 1330 (Fed. Cir. 2021); *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Ltd.,* 759 F.3d 1285 (Fed. Cir. 2014) for their discussion of written description for antibody claims).

Appx52.

The Board found that only one example for the "means for binding human C5 protein" (5G1.1) was disclosed in the Specification, and that no structure was disclosed for 5G1.1. The Board further ruled that the Appellant failed to establish that the structure of 5G1.1 was known at the time of the application. The Board then stated, "Equivalence under section 112(f) cannot be determined for claim 9 because there is no disclosed structure to make that determination." Appx52.

The Board found no error in the rejection of claim 9 based on indefiniteness. It also reaffirmed the obviousness-type double-patenting rejection. Appx53-54.

ARGUMENT

I. THE PATENT ACT STRIKES A BALANCE, REWARDING DISCLOSURE IN EXCHANGE FOR A LIMITED PATENT GRANT

A. The U.S. Patent System's *Quid Pro Quo*

Our patent system aims to incentivize and reward innovation while encouraging public disclosure of inventions. *See Pfaff v. Wells Elecs., Inc*., 525 U.S. 55, 63 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time."). In exchange for disclosing one's invention to the public when applying for a patent, an inventor receives a limited term of "protection from competitive exploitation." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc*., 489 U.S. 141, 151 (1989). The underlying premise of this *quid pro quo* is that timely disclosure of inventions and innovations will benefit the public by allowing others to learn from and build on the disclosed inventions. *Id*.; *Kendall v. Winsor*, 62 U.S. 322, 327-28 (1858). The goal of the patent laws is to confer a limited monopoly of the patent grant in a scope commensurate with the disclosure, striking that balance of rewarding innovation through limiting competition.

B. Section 112(f) Allows for Limited Functional Claiming

Limited functional claiming has been part of the fabric of U.S. patent law since the passage of the 1952 Patent Act. With the enactment of 35 U.S.C. § 112 ¶ 6, Congress abrogated the Supreme Court's 1946 decision in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), which prohibited purely functional claiming. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 27 (1997). Walker's patent was directed to an apparatus for determining the distance between an oil pump and the fluid surface of oil in a well by measuring the time required for a particular sound wave—an echo wave—to travel from the surface to the pump. *Halliburton*, 329 U.S. at 6-7. This patent was an improvement over the prior art because it incorporated a resonator, which amplified the desired echo wave and eliminated undesired waves to better detect the echo wave sought to be measured. *Id.* at 7. Rather than describing the physical characteristics of the resonator, the claims used the phrase, a "means . . . for tuning . . . to clearly distinguish the [desired] echoes." *Id.* at 8. The Court found this functional claim language invalid for failing to satisfy "the statutory requirement for a clear description of claims," noting:

> What he claimed in the court below and what he claims here is that his patent bars anyone from using in an oil well any device heretofore or hereafter invented which

> combined with the [prior art] machine performs the function of clearly and distinctly catching and recording echoes from tubing joints with regularity. Just how many different devices there are of various kinds and characters which would serve to emphasize these echoes, we do not know. . . . In this age of technological development there may be many other devices beyond our present information or indeed our imagination which will perform that function and yet fit these claims. And unless frightened from the course of experimentation by broad functional claims like these, inventive genius may evolve many more devices to accomplish the same purpose.

Id. at 11-12 (internal citation omitted).

Six years later, as part of the 1952 Patent Act, Congress enacted Section 112, paragraph 6, overturning *Halliburton*'s prohibition on purely functional claims. That provision, retained in the America Invents Act and now codified in Section 112(f), provides:

> 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.

In doing so, "Congress struck a balance"—"allowing patentees to express a claim limitation by reciting a function to be performed rather than by reciting structure for performing that function" but "restricting the scope of coverage to only the structure, materials, or acts described in the specification as corresponding to the claimed function and equivalents thereof." *Williamson v. Citrix Online, LLC*,

792 F.3d 1339, 1347 (Fed. Cir. 2015) (en banc). A patentee who recites a claim limitation in means-plus-function format thus is choosing a limited scope of protection.

To ensure that Section 112(f) applies to a particular claim limitation, a patent applicant uses the word "means" or another nonce word as a substitute for "means" to signal to the patent examiner and the public that the applicant intends to limit the scope of their claim to the structure(s) disclosed in the specification and "equivalents thereof." By contrast, when the claim language does not invoke Section 112(f), the scope of the patentee's protection is not so limited, and the "broadest reasonable interpretation" of the claim language may extend to structures beyond those disclosed in the specification and their equivalents. A patent applicant's invocation of Section 112(f) streamlines the claim construction analysis—examiners must "construe the 'means' language . . . as limited to the corresponding structure disclosed in the specification and equivalents thereof." *In re Donaldson Co.*, 16 F.3d 1189, 1194-95 (Fed. Cir. 1994) (en banc); *see, e.g.*, *Mettler-Toledo, Inc. v. B-Tek Scales, LLC*, 671 F.3d 1291, 1295-96 (Fed. Cir. 2012) (upholding district court's construction of "means for producing digital representations of loads applied to said counterforce" as "a multiple slope integrating analog-to-digital (A/D) converter, and equivalents thereof").

If the specification does not disclose the corresponding structure for performing the function specified in the claim, it may be found to be invalid for indefiniteness under Section 112(a). *See, e.g., Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1352 (Fed. Cir. 2015); *Advanced Ground Info. Sys. v. Life360, Inc.*, 830 F.3d 1341, 1346 (Fed. Cir. 2016); *Bosch Auto. Serv. Sols., LLC v. Matal*, 878 F.3d 1027, 1039-40 (Fed. Cir. 2017).

C. For Claims Invoking Section 112(f), the Specification Need Only Disclose a Single Structure for Each Means Limitation, Not "Equivalents Thereof"

While a patent claim invoking Section 112(f) "is still subject to the requirement that a claim 'particularly point out and distinctly claim' the invention," *In re Donaldson Co.*, 16 F.3d at 1195 (citation omitted), the specification need only disclose a structure for performing the specified function such that "a person of skill in the field of the invention would 'know and understand what structure corresponds to the means limitation.'" *See Typhoon Touch Techs., Inc. v. Dell, Inc.*, 659 F.3d 1376, 1383-84 (Fed. Cir. 2011) (citation omitted). "[T]he amount of detail that must be included in the specification depends on the subject matter that is described and its role in the invention as a whole, in view of the existing knowledge in the field of the invention." *See id.* at 1385. General terms may be used to describe structures that are well-known in the

art. *See, e.g.*, *Telcordia Techs., Inc. v. Cisco Sys.*, 612 F.3d 1365, 1377 (Fed. Cir. 2010) (finding generic description sufficient for well-known structure).

For a means-plus-function claim to satisfy the requirements of 35 U.S.C. § 112, the specification need only disclose "some structure" corresponding to the means limitation. In *In re Hayes Microcomputer Products Patent Litigation*, 982 F.2d 1527, 1535 (Fed. Cir. 1992), this Court noted that "[w]hile [patentee] was required to disclose some structure in the specification for all 'means' recitations in the claims, he was not required to disclose every means for implementing the stated function." The Court further held that, in light of expert testimony that structure for the claimed timing means was provided, "the jury could have determined that the specification reasonably conveyed to one of ordinary skill in the art that [the inventor] invented the subject matter of the [] patent." *Id*.

Likewise, in *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574 (Fed. Cir. 1985), this Court explained that "[p]atentees are required to disclose in the specification some enabling means for accomplishing the function set forth in the 'means plus function' limitation. At the same time, there is and can be no requirement that applicants describe or predict every possible means of accomplishing that function." Indeed, as this Court further explained, "§ 112-6[] was written precisely to avoid a holding that a means-plus-function limitation must be read as covering only the means disclosed in the specification." *Id.* Rather,

adequate disclosure of a single structure corresponding to the means limitation satisfies the requirements for "the apparatus disclosed . . . and [the] equivalents thereof." *In re Knowlton*, 481 F.2d 1357, 1362 (C.C.P.A. 1973).

The disclosure requirement for claims invoking Section 112(f) contrasts with the disclosure requirement for genus claims, *i.e.*, "[a] claim encompassing two or more disclosed embodiments." *Billups-Rothenberg, Inc. v. Associated Reg'l & Univ. Pathologists, Inc.*, 642 F.3d 1031, 1037 (Fed. Cir. 2011). Unlike a claim invoking Section 112(f), a genus claim may be construed to encompass structures that are not structural "equivalents." *See id*. As a result, "a sufficient description of a genus [] requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc).

By contrast, a claim invoking Section 112(f) need only disclose a single structure for each means limitation because the disclosed structure is necessarily representative of and/or has structural features common to its "equivalents." *See, e.g.*, *D.M.I.*, 755 F.2d at 1574; *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999) ("Structural equivalence under § 112, ¶ 6 is met only if the differences are insubstantial . . . ; that is, if the assertedly equivalent structure

performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification."); *Valmont Indus. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1043 (Fed. Cir. 1993) ("[A]n equivalent results from an insubstantial change which adds nothing of significance to the structure, material, or acts disclosed in the patent specification.").

II. MEANS-PLUS-FUNCTION CLAIMING SHOULD REMAIN AVAILABLE FOR ALL TYPES OF INVENTIONS

Nothing in the language of Section 112(f) limits the availability of a means-plus-function claim to specific technologies. Indeed, as a matter of policy, it is critical that U.S. patent law continues to be technology-neutral, both to encourage innovation across all technology fields (including where such fields are emerging or where existing fields may intersect, such as artificial intelligence and biotechnology) and to ensure the availability of patent protection for innovations in technical fields that are unforeseeable today.

A. Means-Plus-Function Claiming Should be Available to Protect Antibody Inventions

The option to pursue the more limited protection of a means-plus-function claim for antibody technology should continue to be available to innovators who develop novel antibodies and improvements to antibodies, such as extending the half-life of known antibodies described in the application at issue in this case.

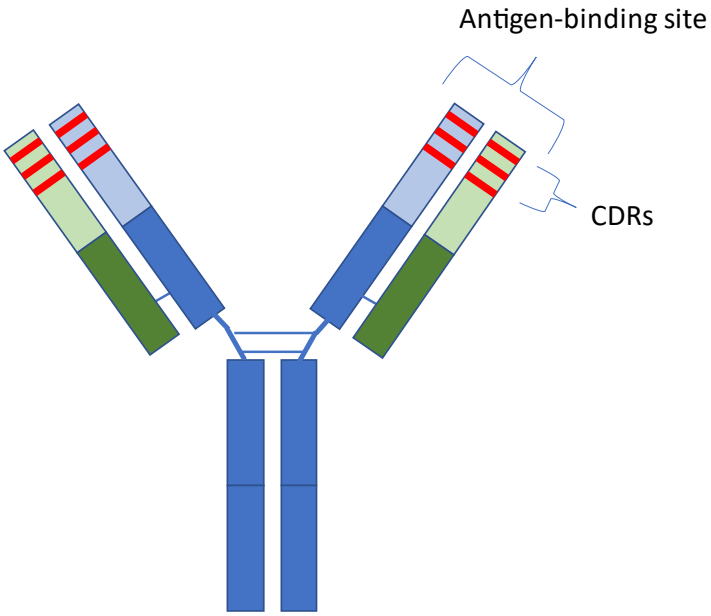
Antibodies are a class of immune system proteins widely used in many applications of biotechnology. They have specific structures and functions that the courts and the Patent Office can use to determine the meaning of structural "equivalents thereof" under Section 112(f). In nature, an antibody's primary function is to bind to an antigen on a pathogen such as bacteria, facilitating the immune system's destruction and clearance of the pathogen. *See* Kenneth Murphy & Casey Weaver, *Janeway's Immunobiology* 139-68 (9th ed. 2016). While all antibodies have the same general structure, they have structural variations in target-binding regions that allow them to bind specifically to their corresponding antigen. *Id.*

Most antibodies have a basic "Y" shape formed by four chains of amino acids, as depicted schematically in Figure 1: two longer, identical "heavy" chains (blue), and two shorter, identical "light" chains (green).[4] *Id.* at 140-145. Each chain has two regions: a "variable" region (light blue and light green) and a "constant" region (dark blue and dark green). *Id.* The variable regions of the light chain and heavy chain create a "binding site" that can bind to an antigen. *Id.* Each variable region on an antibody has three "complementarity determining regions" or

[4] Figure 1 herein is derived from Figures 4.1, 4.2 and 4.7 on pages 141 and 147 in *Janeway's Immunobiology*.

"CDRs." *Id.* at 147. The CDRs are responsible for most of the antibody's specificity for a particular antigen. *Id.* at 146-152.

FIG. 1



The specific part of an antigen to which an antibody binds is called an "epitope." *Id.* at 14. An antigen can have many different epitopes, and different antibodies can bind the same epitope. *Id.*

Antibody structure can be described in a variety of ways. Like other proteins, antibodies are comprised of amino acid building blocks. The antibody's amino acid sequence determines how it folds into a three-dimensional structure, which in turn determines how the antibody interacts with its antigen. *Id.* at 140-145. Antibodies make contact with their antigen primarily through CDRs,

although certain other amino acids in the variable regions can also play a role in binding. *Id.* at 146-152.

The interaction between an antibody and its antigen can be characterized in a number of ways. For example, the strength of the binding of an antibody to its antigen, known as "affinity" is a measurable characteristic. *See id.* at 141. Likewise, the specific amino acids in the antibody that make contact with the antigen can be identified. *See id.* at 148.

As the Supreme Court observed in *Amgen v. Sanofi*, 143 S. Ct. 1243, 1249 (2023), "aspects of antibody science remain unpredictable" and "scientists cannot always accurately predict exactly how trading one amino acid for another will affect an antibody's structure and function." However, advances in the structural basis of antibody-antigen recognition continue, and persons skilled in the art have an increasing number of tools available to predict the effect of changes in an antibody sequence on its ability to interact with an antigen. *See, e.g.,* Rahmad Akbar et al., *A Compact Vocabulary of Paratope-Epitope Interactions Enables Predictability of Antibody-Antigen Binding*, 34 Cell Reps. 1 (2021); Inbal Sela-Culang et al., *The Structural Basis of Antibody-Antigen Recognition*, 4 Frontiers Immunology 1 (2013). In some circumstances, a person of ordinary skill can apply those tools to a disclosed antibody sequence and be confident that particular

changes to the sequence would not affect the ability of the antibody to bind its antigen.

B. Existing Law Provides Guidance for the Assessment of an Antibody's Structural Equivalents

Under Section 112(f), a means-plus-function claim must be "construed to cover the corresponding structure, material, or acts described in the specification ***and equivalents thereof***" (emphasis added). Literal infringement of a means-plus-function claim "requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267. To date, there are no reported decisions of a court applying Section 112(f) in the context of an antibody claim. However, the case law informs the "equivalents thereof" analysis.

The determination of whether a structure is "equivalent" under Section 112(f) is "closely related" to infringement analysis under the doctrine of equivalents. *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus.*, 145 F.3d 1303, 1310 (Fed. Cir. 1998). Indeed, the Supreme Court has explained that structural equivalence under Section 112(f) is "an application of the doctrine of equivalents in a restrictive role." *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 28 (1997).

The Supreme Court established the doctrine of equivalents in 1950, just two years before the enactment of Section 112, paragraph 6, and set out two tests for equivalence: (1) the insubstantial differences test, and (2) the function-way-result test. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608-09 (1950). Under the insubstantial differences test, the analysis is "whether the differences between the structure in the accused device and any disclosed in the specification are insubstantial." *Chiuminatta*, 145 F.3d at 1309. Under the function-way-result test, an element in the accused device or method is equivalent to a claim limitation if it "performs 'substantially the same function in substantially the same way to obtain the same result.'" *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 866 (Fed. Cir. 2017) (quoting *Graver Tank*, 339 U.S. at 608).

The test for structural equivalence under Section 112(f) and the test for the doctrine of equivalents involve "similar analyses of insubstantiality of the differences." *Chiuminatta*, 145 F.3d at 1310. In the *Odetics* case, this Court described the test for structural equivalence in means-plus-function claims as a modified function-way-result test. The statutory equivalents test is narrower than the doctrine of equivalents' function-way-result test because ***functional identity*** is a requirement for equivalence in means-plus-function claims, whereas the doctrine of equivalents requires "substantially" the same function. *Odetics,* 185 F.3d at

1267. Once the function has been established, the statutory equivalents test "reduces to 'way' and 'result.'" *Id.* More specifically, the Section 112(f) structural equivalents analysis "requires a determination of whether the 'way' the assertedly substitute structure performs the claimed function, and the 'result' of that performance, is substantially different from the 'way' the claimed function is performed by the 'corresponding structure, acts, or materials described in the specification,' or its 'result.'" *Id.* at 1267. "Structural equivalence under § 112, ¶ 6 is met only if the differences are insubstantial; that is, if the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification." *Id.* (citation omitted).

There is another way in which the assessment of statutory equivalence in means-plus-function claims differs from—and, in some respects, is narrower than—application of the doctrine of equivalents. Under this Court's precedent, structural equivalents under Section 112(f) "must have been available at the time of the issuance of the claim." *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1320 (Fed. Cir. 1999). This Court has explained that "[a]n equivalent structure or act under § 112 cannot embrace technology developed after the issuance of the patent because the literal meaning of a claim is fixed upon its issuance." *Id.* Therefore, "[a]n 'after arising equivalent' infringes, if at all, under the doctrine of

equivalents."[5] *Id.* In sum, "[a]n 'after-arising' technology could [] infringe under the doctrine of equivalents without infringing literally" as a Section 112(f) equivalent. *Id.*

C. Application of Equivalence Tests to Means-Plus-Function Antibody Claims

Application of the insubstantial differences or function-way-result tests to antibody claims would allow patentees to capture structural "equivalents" of disclosed antibodies as permitted under Section 112(f).

Both tests for equivalence (or a combination of the two) can be applied to antibodies. The inquiry is fact-specific. *See, e.g.*, *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1575 (Fed. Cir. 1985). Structural differences between a disclosed antibody and an accused antibody would be assessed to determine whether they are "insubstantial." At one extreme, a single amino acid change in the non-binding portion of a well-characterized antibody could, in certain circumstances, be viewed as insubstantial. That same antibody is also likely to bind to an antigen in the same "way" and with the same "result" under the function-way-result test. A skilled artisan might find that two antibodies having identical CDRs are insubstantially

[5] The Court has held that "the doctrine of equivalents may be applied to a means-plus-function limitation to afford that limitation a somewhat broader scope of equivalents than it would otherwise receive under § 112 ¶6." *Wi-LAN, Inc. v. Apple Inc.*, 811 F.3d 455, 463 (Fed. Cir. 2016).

different because the part of the antibody contacting the antigen is unchanged and thus the antibody binds in the same "way" with the same "result." On the other hand, changes to amino acids that are part of the antigen binding pocket, or changes to an antibody's CDRs, might be considered "substantial," particularly if those changes result in an antibody that binds a different epitope on the antigen, or binds the same epitope but causes a different result, such as a significant increase in affinity.

Whether the accused antibody is an "after-arising technology" that does not literally infringe under Section 112(f) but may infringe under the doctrine of equivalents is also fact-specific, based on the understanding of a person of ordinary skill in the art. *See, e.g.*, *D.M.I.,* 755 F.2d at 1575. There likely are circumstances where an antibody would not be considered "after-arising technology"—for example, one with minor structural changes, such as conservative amino acid substitutions to non-binding amino acids, or even more significant structural changes that do not change the way an antibody binds to its target. Based on the historic development of monoclonal antibodies over the past 40-plus years, there have been and likely will continue to be changes that would represent a new technology altogether. For example, it has become standard practice to "humanize" mouse antibodies for the purpose of developing human therapeutics. If a mouse antibody had been patented before the process of humanization had

been invented, a humanized version of that antibody might be viewed as an "after-arising technology," even if it bound in the same way to the same amino acids on the target antigen.

AIPLA recognizes the challenges of applying long-standing legal doctrines to new forms of technology. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40 (noting that while the function-way-result test "may be suitable for analyzing mechanical devices, it often provides a poor framework for analyzing other products or processes" but nevertheless declining to dictate which test to use for doctrine of equivalents analysis). But rising to that challenge ensures that inventors will be incentivized to share their inventions with the public, leading to a balanced cycle of innovation and patent protection. In its 2017 *Mylan* decision, this Court noted that while the function-way-result test "may not be well-suited" in cases involving "the chemical arts," it aptly observed that "as technology evolves, that may change" and suggested that if, on remand, the district court, "determines that it should still utilize that test, also consider whether an evaluation of equivalence under the substantial differences test may be better suited to the particular facts of this case." 857 F.3d at 867, 869-70.

For all these reasons, AIPLA urges the Court to make clear in its decision that an applicant may obtain a means-plus-function claim covering an antibody disclosed in the specification as the corresponding structure, even though what

constitutes a structural equivalent thereof, in some instances, may be a technical and fact-intensive inquiry. Our patent system has not—and should not—shut the door on new technologies. As the stewards of our patent system, the courts and the Patent Office must ensure that the system continues to incentivize both innovation and public disclosure of inventions so that others may build upon them.

D. Ensuring Means-Plus-Function Claims Are Available to Protect Disclosed Antibodies Advances Sound Patent Policy

Permitting the use of means-plus-function claiming in the antibody space incentivizes innovation. It grants inventors a time-limited monopoly in exchange for disclosing antibodies and their equivalent structures that achieve a specified function without precluding others from developing their own novel antibodies to achieve that same function in a different or improved way. *Cf. Amgen Inc. v. Sanofi*, 143 S. Ct. 1243 (2023). The narrow penumbra of protection afforded to equivalent structures under Section 112(f) protects an inventor from unscrupulous copyists who would otherwise circumvent claim scope by making minor, non-functional changes to patented antibody sequences.

Such protection is particularly important for inventions covering biologics. In that space, competitors can potentially benefit from an innovator's regulatory data to obtain regulatory approval of non-identical but structurally equivalent "biosimilar" products. *See* 21 U.S.C. § 355; Wanli (Lily) Tang, *Revitalizing the*

Patent System to Incentivize Pharmaceutical Innovation: The Potential of Claims with Means-Plus-Function Clauses, 62 Duke L.J. 1069, 1100-01 (2013) (advocating for greater use of means-plus-function claims in biopharmaceutical context to address problem of inadequate claim scope).

Means-plus-function claiming for antibodies provides an efficient mechanism for obtaining reasonable claim scope that more accurately reflects an inventor's contribution to the field where, as may be true in this case, the claimed means is not the point of novelty. *See IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1436 (Fed. Cir. 2000) ("[W]hen in a claimed 'means' limitation the disclosed physical structure is of little or no importance to the claimed invention, there may be a broader range of equivalent structures than if the physical characteristics of the structure are critical in performing the claimed function in the context of the claimed invention."). In antibody claiming, target binding may be an element of the invention but not a point of novelty. For example, it is not unusual for an invention directed to a new use of existing antibodies to be broadly applicable to any antibody able to bind to a specific target. Examples of such inventions may include: (a) therapeutic methods that use known target-specific antibodies to treat a new disease; (b) diagnostic methods that use existing antibodies to detect a particular biomarker; and (c) pharmaceutical manufacturing

methods in which antibodies are used to purify desired products from contaminants.

Under current law, the written description and enablement requirements can prevent the inventor from claiming useful antibodies in purely functional terms. *See Amgen*, 143 S. Ct. at 1246-47 (finding patent directed to antibodies "defined by their function" insufficiently enabled where claims encompassed "a vast number of additional antibodies" beyond those described in the specification); *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1342 (Fed. Cir. 2021) (invalidating claim directed to a genus of antibodies capable of binding a target, finding no limit as to the particular target and insufficient detail for skilled artisan to determine which species bind which targets). While inventors could, in theory, pursue claims directed to the use of each known antibody useful in their invention in a single patent application, the Patent Office would likely issue a restriction requirement, requiring the inventors to pursue each such claim in a separate application. *See, e.g.*, MPEP § 803.04 ("Absent evidence to the contrary, each . . . sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement."). The need to pursue separate patent applications for each antibody identified by the inventor would be inefficient, burdensome, and costly, both to the inventor and the Patent Office. Instead, by reciting means-plus-function claims, the inventor can disclose the structures of multiple antibodies able

to perform the function of binding the relevant target, thereby covering the use of those structures and their structural equivalents in a single claim, greatly simplifying prosecution.

In sum, means-plus-function claiming may provide an opportunity for an applicant to protect the scope of their contributions to the field by disclosing antibody structures that achieve a particular function. The applicant may be unable to identify a structure-function relationship entitling him to claim a genus, but means-plus-function claiming could enable them to claim a "means" element linked to disclosed antibody structures and "equivalents thereof," to be determined based on the understanding of those skilled in the art. There is no reason why the means-plus-function format should not be available to protect disclosed antibodies and equivalents thereof.

October 6, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE
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Case Number 2023-2048

Short Case Caption In re: Xencor, Inc.

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CERTIFICATE OF SERVICE

I hereby certify that service on all parties was made through electronic filing the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the court's electronic-filing system on October 6, 2023 pursuant to Federal Circuit Rule 25(e).

October 6, 2023

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