Use of Means-Plus-Function Claiming to Evade the Enablement Requirement

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Abstract

Monoclonal antibodies are an important class of pharmaceuticals that represent a significant portion of pharmaceutical spending. These high costs can be moderated through competition from alternative products that can drive down prices and offer more effective alternatives for patients. The patent system, however, can pose significant hurdles for competitors. Specifically, broad functional genus claims can prevent competitors from entering the market by blocking new therapies based on old targets.

A recent Supreme Court case invalidated patents with broad functional genus claims for failing to meet the enablement requirement. This decision promotes competition and innovation by ensuring that patents are commensurate with the inventors' contributions. In response, however, pharmaceutical firms are now using "means-plus-function" claim language in an attempt to recapture broad functional genus claims. We suggest that courts should not allow a claim drafting tool to supersede the substantive enablement requirement for patents. We argue that courts should apply the Amgen enablement requirement to limit overly broad claims even when applicants use means-plus-function claim language.

Table of Contents

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I. Introduction

Biologic medications (hereafter "biologics") include monoclonal antibodies, insulin, mRNA-based vaccines, and CAR-T therapies.[1] They represent fewer than 2% of prescriptions but generate 46% of American pharmaceutical spending.[2] They are primarily responsible for the surge of drug prices, contributing 93% of the growth in total drug spending between 2014 and 2020.[3] The average biologic costs between $10,000 and $30,000 per year, while the most expensive ones exceed half a million

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[1] A biologic is a type of medication that is derived from living organisms. The sources for biologics include humans, animals, or microorganisms such as bacteria or viruses. In a pharmaceutical context, they are contrasted against small molecules, which typically contain 20–100 atoms. Biologics are comparatively large and complex, consisting of 200–50,000 atoms. *See What Are "Biologics" Questions and Answers*, FDA (Feb. 6, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers; *see also* Liang Zhao et al., *Clinical Pharmacology Considerations in Biologics Development*, 33 ACTA PHARMACOL. SIN. 1339, 1341 (2012).

[2] Scott Biggs & Doug Long, *Insights Into the 2023 U.S. Pharmaceutical Market*, IQVIA (Jul. 25, 2023), https://www.iqvia.com/locations/united-states/blogs/2023/07/insights-into-the-2023-us-pharmaceutical-market; Joel Lexchin, *Affordable Biologics for All*, 3 JAMA NETW. OPEN 4753, 4753 (2020).

[3] Lexchin, *supra* note 2, at 4753.

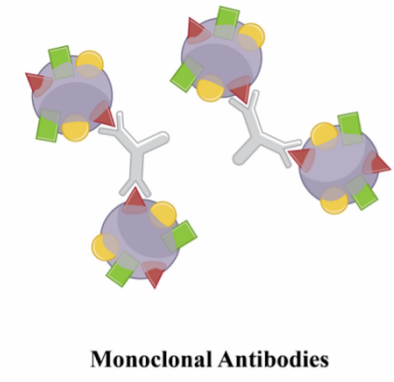
dollars annually.[4]

The cost of biologics can be moderated when there are multiple similar products available on the market.[5] New alternative drugs often cost less than reference pharmaceuticals, and the introduction of alternatives can pressure a reference drug maker to lower prices. This dual benefit on drug costs may be further enhanced as the number of competing products grows.[6] Controlling prices is not the only benefit of competition; an alternative biologic may be significantly more effective than the reference product for certain patients and vice versa.[7] To allow for the benefits of this competition, the patents on reference biologics must have a reasonable scope.

A. What is a Monoclonal Antibody?

Monoclonal antibodies, an important subset of biologic therapies, have become mainstays in the treatment of diseases ranging from high cholesterol to breast cancer, rheumatoid arthritis, and Crohn's disease.[8] Antibodies work by selectively binding to an antigen (a particular protein or other type of biomolecule), which can disrupt or enhance the normal function of a target antigen.[9] Importantly, each antigen can have millions of different epitopes for which an antibody can target. (Figure 1)

Figure 1[10]



Monoclonal Antibodies

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4 Brian K. Chen, Y. Tony Yang, & Charles L. Bennett, *Why Biologics and Biosimilars Remain So Expensive*, 78 DRUGS 1777, 1777 (2018).

5 Chintan V. Dave et al., *Prices of Generic Drugs Associated with Numbers of Manufacturers*, 377 NEW ENG. J. MED. 2597, 2598 (2017).

6 The addition of one generic competitor reduces prices by 10%, two competitors by 17%, and more competitors occasion further decreases. *See* Dave et al., *supra* note 5, at 2598; *see also* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. BIOSCS. 590, 601 (2018) (suggesting that prices decline by 80% to 85% once several generics enter).

7 *See infra* Section I.A.

8 S. Sean Tu et al., *Broad Patent Claims Come Before the Supreme Court in Amgen v. Sanofi*, 329 JAMA 1641, 1641–42 (2023).

9 *See* David Zahavi & Louis Weiner, *Monoclonal Antibodies in Cancer Therapy*, 9 ANTIBODIES 34, 34 (2020).

10 S. Sean Tu & Christopher M. Holman, *Antibody Patents: Use of the Written Description and Enablement Requirements at the Patent and Trademark Office*, 38 BERKELEY TECH L.J. 1, 44 (Figure 2A) (2023).

Figure 1: Monoclonal antibodies (grey Y-shaped) bind to an antigen (grey circle) directly to an epitope (red triangle). Each antigen can have millions of different epitopes (red triangles, green squares and yellow circles). These epitopes can be the target of many different antibodies, and each epitope can result in different functional changes to the target.

Millions of different antibodies can be generated towards a single antigen. Some antibodies may have nearly identical properties to other antibodies that target the same antigen, but different to different epitopes. These new antibodies may have distinct structures and unique biochemical attributes.[11] In this article, the term "alternative epitope antibodies" is used for monoclonal antibodies that target the same antigen but target different epitopes on that same antigen.

Monoclonal antibodies were historically awarded broad patents that encompassed a reference antibody and alternative epitope structures, but more recently, narrower claims have permitted alternative epitope drugs to be commercialized.[12] Narrow patent protection has benefited patients and the pharmaceutical industry alike. Alternative epitope antibodies can offer improved efficacy due to differences in their pharmacokinetics and binding properties on the target antigen compared to a reference drug. Alternative antibodies directed towards the same antigen provide patients with alternative therapies, which is particularly important if the first antibody does not work for the patient or if the patient becomes refractory to the first antibody treatment. Additionally, when alternative biologic firms are able to design around older biologic treatments, these new competitors can reap financial rewards associated with these new treatments.

This is not a hypothetical situation. For example, some patients with high cholesterol responded to Sanofi's Praluent® after failing to respond to Amgen's Repatha®, two distinct antibodies that target the same antigen (the PCSK-9 antigen).[13] Another example is Herceptin®, which was more effective than the biologic drug (Margenza®) in pre-treated patients with ERBB2-positive advanced breast cancer. Herceptin® and Margenza® both target the HER-2 antigen.[14] The repeated administration of an antibody can also elicit immunogenicity, decreasing its effectiveness and requiring providers to use an alternative epitope drug.[15] Alternative epitope antibodies can also expand indications sought for drug approval. For example, the TNF-alpha inhibitor Remicade® was approved initially for treating Crohn's disease while an alternative epitope drug (Enbrel®), which is also a TNF-

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11 *See* Amgen Inc. v. Sanofi, 598 U.S. 594, 600 (2023) (explaining how one antigen can have millions of complement antibodies).

12 S. Sean Tu & Christopher M. Holman, *Antibody Claims and the Evolution of the Written Description/Enablement Requirement*, 63 IDEA 84, 88 (2022).

13 S. Sean Tu et al., *supra* note 8, at 1641.

14 *Id.* at 1642.

15 Brief of Sir Gregory Paul Winter and Interested Scientists as Amici Curiae in Support of Respondents at 30–31, Amgen Inc., et al., v. Sanofi, et al., 598 U.S. 594 (2023) (No. 21-757), 2023 WL 2167707, at *30–31.

alpha inhibitor, was approved for treating rheumatoid arthritis. (Remicade® was ultimately also approved for treatment of rheumatoid arthritis.)[16]

B. Functional Genus Patents and Caselaw

In an attempt to obtain broad patent power over the entire market, drug companies try to protect their products using "functional genus claims." Functional genus claims attempt to claim the antibody by describing the antigen that it binds, and not the antibody itself. Functional genus claims allow patentees to prevent competitors from exploiting alternative epitope antibodies because these claims cover all antibodies that target the same antigen. For example, AbbVie once held a patent that claimed nearly all antibodies binding to human interleukin-12 (Il-12) that surpassed a threshold of minimum affinity and neutralizing capacity. The functional genus patent prevented its competitors from marketing any potentially effective anti-Il-12 antibodies, including alternative epitope examples with unique pharmacokinetic properties and a distinct biological lineage and structure.[17]

AbbVie's patent was invalidated by the Court of Appeals for the Federal Circuit (hereafter "Federal Circuit") in 2014. A more conclusive rejection of functional genus claims for antibody technologies occurred when the Supreme Court decided *Amgen v. Sanofi* in 2023. The Court upheld the invalidation of Amgen's functional genus claim directed to a class of monoclonal antibodies that bound to the protein PCSK9. Amgen's product (Repatha®) faced competition from Sanofi's (Praluent®, a distinct PCSK9 inhibitor), leading Amgen to sue Sanofi for infringement.[18]

Sanofi responded, arguing that Praluent® did not infringe because Amgen failed to meet the enablement requirement codified in §112 (a) of the Patent Act. The Federal Circuit (and later the Supreme Court) agreed with Sanofi, invalidating Amgen's patents. The courts did not seek to narrow the scope of permissible claims; rather, they agreed that Amgen's patents did not satisfy the enablement requirement.[19] Comparing Amgen's claims to overbroad genus in the epochal patent case *O'Reilly v. Morse*, Justice Gorsuch explained, "Much as Morse sought to claim all telegraphic forms of communication… Amgen seeks to claim, 'sovereignty over [an] entire kingdom' of antibodies," (internal citations omitted).[20] The courts concluded that Amgen's claims were too broad to meet the statutory requirements even though

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16 Richard Melsheimer et al*., Remicade(®) (Infliximab): 20 Years of Contributions to Science and Medicine*., 13 BIOLOGICS 139, 146 (2019).

17 AbbVie Deutschland GMBH & Co, v. Janssen Biotech, Inc., 759 F.3d 1285, 1291 (Fed. Cir. 2014). AbbVie discovered only a few hundred nearly identical examples of anti-Il-12 antibodies, all of which were closely related. The described antibodies shared 90% or more sequence similarity in their variable regions, and over 200 of those antibodies differed from the antibody that AbbVie began its research with by only one amino acid. *See* Tu & Holman, *supra* note 12, at 94 (2022) for analysis of structural similarity in the claims in *AbbVie*. *See also AbbVie*, 759 F.3d at 1300 (Fed. Cir. 2014).

18 Amgen Inc. v. Sanofi, 598 U.S. 594, 599 (2023).

19 *Id.*; Amgen, Inc. v. Sanofi, 987 F.3d 1080, 1088 (Fed. Cir. 2021).

20 *Amgen*, 598 U.S. at 613 (2023) (quoting Consol. Elec. Light Co. v. Mckeesport Light Co. (The Incandescent Lamp Patent), 159 U.S. 465, 476 (1895)).

Amgen provided a relatively sophisticated disclosure.[21]

The development and marketing of these alternative epitope antibodies can only happen in the presence of narrow patent rights and the absence of broad patent rights. This is not a hypothetical problem. As shown in both the *AbbVie* and *Amgen* cases, firms routinely attempt to gain broad patents to block competition and new market entrants.[22] The Amgen decision should help promote the continued availability of alternative epitope drugs by placing a substantive limit on overbroad functional claims.[23] The Amgen decision should help patients who need alternative therapies and pharmaceutical firms who wish to develop and market these alternative therapies. Importantly, the Amgen decision upholds the long-held quid quo pro balance of patent law, where the inventor must disclose how to make and use the invention, and the public grants that inventor a limited exclusive right to that invention. When inventors do not enable the full scope of the invention, the public gives away too much to the inventor.

The industry has responded to these judicial limits to broad antibody claims by trying to reclaim patent scope with procedural workarounds. *In re Xencor* (now docketed as *Ex parte Chamberlain*) concerns an attempt by a drug company to secure a broad monoclonal antibody patent through a means-plus-function claim format, a drafting technique that was previously rare for biological patents.[24] Rather than directly claiming all or nearly all antibodies that bind to a particular antigen and disclosing a few dozen examples, Xencor claims, "[a] method of treating a patient by administering an anti-C5 antibody comprising: a) *means for* binding human C5 protein . . . ." (emphasis added), with a few functional limitations.[25] Xencor disclosed only one example antibody (at best, as the disclosure was questioned), which was in the prior art.[26]

The patent Examiner and the Patent Trials and Appeals Board (hereafter "PTAB") both rejected Xencor's means-plus-function claim. They recognized that it would operate in practice like a functional genus claim. They agreed that Xencor, like

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21 *Id.*

22 *Id.* at 599; *See also* S. Sean Tu et al., *supra* note 8, at 1641.

23 *See* S. Sean Tu et al., *supra* note 8, at 1641.

24 Motion of Appellee Katherine K. Vidal to terminate appeal through remand, *In re* Xencor, Inc., 2024 U.S. App. LEXIS 1462 at *3 (Fed. Cir. 2024) (No. 2023-2048).

25 U.S. Patent Application No. 16/803,690 (filed Feb. 27, 2020).

26 When the PTAB reviewed Xencor's request for a rehearing, the Board suggested that no structure was disclosed for the means-plus-function claim because the only antibody Xencor clearly mentioned, called 5G1.1, was insufficiently described in the specification. *See* Corrected Opening Brief Filed by Appellant at 22, *In re* Xencor, Inc., 2024 U.S. App. LEXIS 1462 (Fed. Cir. 2024) (No. 2023-2048). The Appeals Review Panel had a different interpretation, finding that 5G1.1 was adequately disclosed and could serve as a corresponding structure for the means plus function claim. *See Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, available at https://www.uspto.gov/sites/default/files/documents/2022001944_order_20240521.pdf, at 28–29, 33 (P.T.A.B. May 17, 2024).

Amgen, provided too little disclosure for such broad claims.[27] Xencor's case has since been reviewed by the Appeals Review Panel (hereafter "ARP"), the supreme internal tribunal of the Patent and Trademark Office (hereafter "PTO") for reviewing *ex parte* cases. Although the ARP upheld the rejection of Xencor's claim, it signaled that means-plus-function claims could be an acceptable approach for claiming antibodies, even when patentees provide little disclosure.[28] The case is now awaiting review by the Federal Circuit.[29]

If Xencor's means-plus-function claim issues, it would set a dangerous precedent that could slow progress in antibody science, leave patients with fewer options, and stifle innovation in the important therapeutic class of biologic drugs. Part II of this article examines the legal background of the Xencor case, including the principle of means-plus-function claiming, and why the format may run afoul of the fundamental disclosure requirements of patent law. Part III introduces Xencor's procedural posture and elucidates the history of the case. Finally, Part IV explains the problems with Xencor's means-plus-function approach which the PTO almost completely overlooked, namely the failure to satisfy the enablement requirement of 35 U.S.C. § 112 (a). Finally, Part IV presents a normative solution, illustrating how the enablement requirement can ensure that means-plus-function antibody patents protect the best interests of patients and the pharmaceutical industry.

II. Legal Background

A. Enablement and Written Description

The enablement and written description requirements have been the primary legal issues in many antibody cases. Both stem from § 112 (a) of the Patent Act, which requires:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.[30]

Meeting the enablement requirement is a question of law. A skilled artisan should be able to make and use the invention from the disclosure in the patent's

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[27] *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, 2022 Pat. App. LEXIS 5961, at *1, *4 (P.T.A.B. Dec. 19, 2022).

[28] *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, available at https://www.uspto.gov/sites/default/files/documents/2022001944_order_20240521.pdf, at 35 (P.T.A.B. May 17, 2024).

[29] Dani Kass, *New Antibody IP Ruling Still Needs To Be Tested In Courts,* LAW360 LEGAL NEWS - CORPORATE (May 31, 2024, 4:04 PM), https://www.law360.com/articles/1839866/new-antibody-ip-ruling-still-needs-to-be-tested-in-courts.

[30] 35 U.S.C. § 112 (a).

specification without engaging in "undue experimentation," and the patent cannot claim embodiments beyond the enabling disclosure.[31] A patent does not need to disclose specifically how to make and use *every* embodiment of its claims, but it must provide sufficient detail to teach a skilled artisan how to practice the full scope of the claims without undue experimentation.[32] In this way, the enablement requirement protects against granting overbroad rights to the inventor and limits patent rights to only those embodiments of the invention that they disclosed to society.

Determining whether experimentation is "undue" is a fact-based inquiry, heavily dependent on the breadth of claims and state of the art.[33] The Federal Circuit established the "go to" [34] tests for identifying undue experimentation in an early monoclonal antibody case *In re Wands*.[35]

By contrast, meeting the written description requirement is a question of fact. In general, a patent meets the written description requirement when it discloses either "a representative number of species falling within the scope of the genus" claim 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 [claim]."[36] Written description disputes have generally arisen in cases (1) when the inventor amends their claims and adds elements that are not described in the original patent or (2) when the claims are overbroad.[37]

These disclosure requirements ensure the patent system serves its social purpose: "promot[ing] the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[38] The enablement requirement forces inventors to publicize instructions for making and using their innovations to expand the technical literature. This quid-pro-quo, where inventors provide useful knowledge in exchange

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31 *See, e.g.*, Invitrogen Corp. v. Clontech Labs., 429 F.3d 1052, 1070–71 (Fed. Cir. 2005) (quoting Koito Mfg. Co., Ltd v. Turn-Key Tech, LLC, 381 F.3d 1142, 1155 (Fed. Cir. 2004)); *see also* Warner-Lambert Co. v. Teva Pharms. USA, Inc., 418 F.3d 1326, 1337 (Fed. Cir. 2005).

32 Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576–77 (Fed. Cir. 1984); *In re* Wands, 858 F.2d 731, 735 (Fed. Cir. 1988); AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003); *see also* Amgen Inc. v. Sanofi, 598 U.S. 594, 600–01 (2023) (reinforcing principle that the full scope of the claims must be enabled).

33 McRO, Inc. v. Bandai Namco Games Am. Inc., 959 F.3d 1091, 1100 (Fed. Cir. 2020).

34 Amgen, Inc. v. Sanofi, 987 F.3d 1080, 1085 (Fed. Cir. 2021).

35 *In re* Wands, 858 F.2d at 737 (Fed. Cir. 1988). The so-called *Wands* factors "include I) the quantity of experimentation necessary, II) the amount of direction or guidance presented, III) the presence or absence of working examples, IV) the nature of the invention, V) the state of the prior art, VI) the relative skill of those in the art, VII) the predictability or unpredictability of the art, and VIII) the breadth of the claims."

36 Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc).

37 ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY 491, 501 (8th ed. 2021).

38 U.S. CONST. art. 1, § 8, cl. 8.

for temporary exclusive rights, is sometimes referred to as the "patent bargain."[39] Further, the enablement and written description requirements both constrain the scope of the claims; they achieve this by ensuring the scope of the claims is in parity with scope of the disclosure and by providing a tool for determining what an inventor has truly created.[40] (In the words of Justice Fortas, a patent is a reward for completing an invention, not a "hunting license."[41]). Finally, the written description provides notices of the metes and bounds of invention, allowing inventors to design around a patent by delineating the monopoly's limits.[42]

The enablement and written description requirements are distinct. The Federal Circuit has stressed the difference between enabling and describing an invention.[43] As one judge put it, "[c]onsider the case where the specification discusses only compound A…This might very well enable one skilled in the art to make and use compounds B and C, yet the class consisting of A, B, and C has not been described."[44] Conversely, courts regularly invalidate claims for lack of enablement and leave the written description question unaddressed.[45]

B. Enablement and Written Description for Antibodies and Biologics

1. The Evolution of Antibody and Biologics Patents

Patenting monoclonal antibodies has long been technically challenging due to their structural complexity and diversity.[46] Some scientists have speculated that there are as many unique antibodies as stars in the Milky Way.[47] One antigen may be

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[39] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001); Patent Act of 1790, Ch.7, §2, 1 Stat. 109, 110 (requiring patents "to enable a workman or other person skilled in the art or manufacture . . . to make, construct, or use the same."); *see also* United States v. Dubilier Condenser Corp., 289 U.S. 178, 187 (1933).

[40] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002); *see also* Schriber-Schroth Co. v. Cleveland Trust Co., 305 U.S. 47, 59 (1938).

[41] Brenner v. Manson, 383 U.S. 519, 536 (1966).

[42] *See, e.g.,* The Incandescent Lamp Patent, 159 U.S. 465, 472 (1895).

[43] Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc) (showing that § 112 contains both a written description and enablement requirement); Vas-Cath Inc. v. Mahukar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (citing *In re* Wilder, 736 F.2d 1516, 1520 (Fed. Cir. 1984)).

[44] *In re* Dileone, 436 F.2d 1404, 1405 (C.C.P.A. 1971), *in dicta.*

[45] *See, e.g.,* Amgen, Inc. v. Sanofi, 987 F.3d 1080, 1088 (Fed. Cir. 2021). *Contra* Juno Therapeutics, Inc. v. Kite Pharma, Inc. 10 F.4th 1330 (Fed. Cir. 2021).

[46] *Small-Molecule Drug Discovery and Development*, BECKMAN COULTER, https://www.beckman.com/resources/applied-science/small-molecule-drug-discovery (explaining that small molecule drugs weigh under 900 daltons); *Eculizumab*, PUBCHEM, https://pubchem.ncbi.nlm.nih.gov/substance/135288438 (explaining that eculizumab, the antibody in Xencor's patent, weighs approximately 150,000 daltons).

[47] *See* Enkelejda Miho et al., *Computational Strategies for Dissecting the High-Dimensional Complexity of Adaptive Immune Repertoires*, 9 FRONTIERS IMMUNOLOGY Art. 224, 1, 3 (2018) ("A fraction of the potential diversity is represented at any point in time in any given individual: the number of B- and T-cells is restricted (human: $10^{11–12}$)."); Maggie Masetti, *How Many Stars in the*

targeted by millions of structurally distinct antibodies.[48] Thus, the requirements for describing and enabling antibody claims developed as scientists discovered applications and techniques for analyzing them.

In the early days of antibody technology, patents were based only on antigen structure and awarded a broad scope.[49] This was consistent with the primary historical application of antibodies as diagnostic tools to determine the presence or absence of an antigen. Such binary antibody-based diagnostics (where the mechanism of binding is not relevant) required only a description of the target antigen and sometimes incorporate general limitations of the antibody's binding affinity.[50] The broadest claim upheld by the Federal Circuit in *In re Wands* is illustrative:

> 1. An immunoassay method utilizing an antibody to assay for a substance comprising hepatitis B-surface antigen (HBsAg) determinants which comprises the steps of: contacting a test sample containing said substance comprising HBsAg determinants with said antibody; and determining the presence of said substance in said sample; wherein said antibody is a monoclonal high affinity IgM antibody *having a binding affinity constant for said HBsAg determinants of at least* 10^9 M^{-1} (emphasis added).[51]

Importantly, Wands's invention used antibodies to ***detect*** the presence or absence of hepatitis B. To achieve this function, any antibody that binds anywhere to the hepatitis-B antigen would work. This is an important distinction from the current use of antibodies to ***treat*** disease, where an antibody needs to bind to a specific location of the antigen to create a desired effect.

The specification in Wands's patent did not describe the antibody, nor did it provide a detailed enabling disclosure. Rather, as with most early inventors of antibodies, Wands deposited the cell line that generated the antibody to an international depositary authority.[52] The deposit combined with the specification allowed skilled artisans to make the antibodies used in Wands's invention without requiring disclosure of the antibody's structure (a technical impossibility at the time). At the time, granting broad protection of antibodies through the description of only the antigen made sense because most antibodies were not functional antibodies but

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Milky Way?, NASA BLUESHIFT (Jul. 22, 2015), https://asd.gsfc.nasa.gov/blueshift/index.php/2015/07/22/how-many-stars-in-the-milky-way/ ("[T]here are 100 billion stars in the Milky Way on the low-end and 400 billion on the high end.").

48 Amgen Inc. v. Sanofi, 598 U.S. 594, 599 (2023).

49 Tu & Holman, *supra* note 12, at 96.

50 *Id.* at 98–99.

51 *In re* Wands, 858 F.2d 731, 735 (Fed. Cir. 1988) (reviewing U.S. Patent Publication No. 06/188,735 (filed Sep. 19, 1980) later maturing to U.S. Patent No. 4,879,219 (issued Nov. 7, 1989)).

52 *Id.*; Mark Lemley & Jake Sherkow, *The Antibody Patent Paradox*, 132 YALE L. J. 994, 1013 (2023); Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure, Apr. 28, 1977, 32 U.S.T. 1241; *see also Budapest Treaty*, USPTO, (Feb. 11, 2021, 3:26 PM), https://www.uspto.gov/ip-policy/patent-policy/budapest-treaty.

only used to help detect the presence/absence of a protein.

In the 1990s, courts began demanding structural disclosure in biological patents by applying a robust written description requirement.[53] Antibodies, however, were exempted from this shift; from the late 1990s until 2018, the PTO carved out what became known as the "antibody exception," permitting antibody patents that used functional limitations,[54] including the target antigen, "binding affinity, binding specificity, molecular weight, and length."[55] The Federal Circuit endorsed the PTO's Guidelines, noting (in dicta) that the PTO "would find compliance with [35 U.S.C. §112 (a)], for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody."[56] This occurred even while drug companies began commercializing antibody-based therapeutics. An antibody's structure is much more important in therapeutic applications than diagnostic applications.[57]

Antibody exceptionalism proved short-lived as antibodies transitioned from use in diagnostics to being widely applied in therapeutic contexts. The Federal Circuit moved away from it beginning in the mid 2000s. In *Chiron Corp. v. Genentech, Inc.*,[58] the Court invalidated a sprawling functional antibody claim (including murine, chimeric, and humanized antibodies) for lack of enablement because the patent did not specifically teach chimeric or humanized antibodies. In *Centocor v. Abbott Laboratories*,[59] the Court retracted the antibody exception by clarifying that only antibodies directed against newly characterized antigens could be described functionally. In *AbbVie v. Janssen*,[60] the Court used the written description requirement to strike down an antibody patent for overbreadth, holding that valid antibody genus claims needed a common, distinguishing trait, presumably something structural.

Patent examiners also demanded increasing levels of structural disclosure even as the PTO continued to include the "antibody exception" in official guidelines. Section 112 (a) rejections for antibody patent applications doubled from 20% in 2003–06 to 40% in 2018, when the PTO finally removed the "antibody exception" from its guidelines.[61]

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53 *See e.g.*, Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997) (holding that an adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties.").

54 Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 "Written Description" Requirement; Request for Comments, 64 Fed. Reg. 71427, 71435 (Dec. 21, 1999).

55 *Id.* at 71439 n.39.

56 Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002).

57 Tu & Holman, *supra* note 12, at 102.

58 Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1251–52 (Fed. Cir. 2004).

59 Centocor Ortho Biotech, Inc. v. Abbott Lab'ys, 636 F.3d 1341, 1352 (Fed. Cir. 2011).

60 AbbVie Deutschland GMBH & Co, v. Janssen Biotech, Inc., 759 F.3d 1285, 1310 (Fed. Cir. 2014).

61 Tu & Holman, *supra* note 12, at 84.

2. Amgen v. Sanofi and Juno v. Kite

Broad antibody patents have been invalidated as failing to meet both the enablement and written description requirements of 35 U.S.C. 112(a). Two recent cases, *Amgen v. Sanofi* and *Juno v. Kite*, exemplify the use of these patentability requirements in the context of broad functional genus claims.

The shift toward detailed structural disclosure in antibody and biologics patents was confirmed in *Amgen, Inc. v. Sanofi*. In *Amgen*,[62] the Federal Circuit invalidated a functional monoclonal antibody patent for lack of enablement, emphasizing the enablement problem caused by the scale and diversity of the functional genus claim. In 2023, the Supreme Court granted certiorari in *Amgen* and upheld the Federal Circuit's ruling. The Court noted that "the patent's specification must enable a person skilled in the art to make and use the entire class...the more one claims, the more one must enable."[63] Functional antibody claims thus became essentially unpatentable; even a narrow functionally defined genus would be too broad to enable under *Amgen*.[64]

Similarly, in *Juno Therapeutics, Inc. v. Kite Pharma, Inc*,[65] the Federal Circuit held that the written description requirement demanded structural disclosure for every component of the patent's claims. In *Juno*, the Court invalidated a claim for a genetic immunotherapy for lack of written description. The Court found the disclosure inadequate because it did not disclose sufficient common structural features of the genus and provided an incomplete structural description of the non-novel part of the invention.[66]

The enablement and written description rulings in *Amgen* and *Juno* were controversial but established a clear standard for antibody and biologics patents that reflected the evolution of antibody science.[67] An antibody inventor is owed protection commensurate with the scale of their contribution to the field. Monoclonal antibodies are neither platform technologies nor rudimentary diagnostic tools. Different antibodies targeted to the same antigen can have dramatically different effects for therapeutic applications.[68] Narrow biologics patents permit inventors to design around existing claims, potentially creating new (and possibly superior) drug options.[69] These bright-line rules help competitors understand the scope of protection afforded by antibody patents and allow for investment in new alternative epitope antibodies. Thus, narrow biologic patents allow other pharmaceutical firms to design around the older inventions, which benefits patients who may receive superior

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62 Amgen, Inc. v. Sanofi, 987 F.3d 1080, 1087 (Fed. Cir. 2021).
63 Amgen, Inc. v. Sanofi, 598 U.S. 594, 610 (2023).
64 *See* Lemley & Sherkow, *supra* note 52, at 1032–33.
65 Juno Therapeutics, Inc. v. Kite Pharma, Inc. 10 F.4th 1330, 1340 (Fed. Cir. 2021).
66 *Id.* at 1337–38.
67 Tu & Holman, *supra* note 12, at 123.
68 Tu et al., *supra* note 8, at 1641.
69 *Id.*

treatments or who may need alternative therapies.

Manufacturers of these older therapies, however, would like to prevent market competition to keep their revenues high. To reclaim the functional genus claims that were invalidated in *Amgen* and *Juno*, a new patent strategy based on "means-plus-function" claiming has emerged.

C. Means-Plus-Function Claims

1. History and Background

In the wake of *Amgen* and *Juno*, inventors were no longer able to file functional antibody genus claims, leading some to attempt to protect their inventions using means-plus-function claims. Means-plus-function claims have their basis in 35 U.S.C. § 112(f), which provides that:

> 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.[70]

Section 112(f) provides an alternative format that can reward inventors in fields where functional language is the only practical approach for disclosure. Means-plus-function claiming, however, is designed to narrow the scope of functional claims by limiting the protection to the specific structure or materials disclosed in the specification.[71]

Section § 112 ¶ 6 [now Section 112(f)] was likely added to the 1952 Patent Act to abrogate the Supreme Court's 1946 decision in *Halliburton Oil Well Cementing Co. v. Walker*,[72] which proscribed functional claiming.[73] In *Halliburton*, the Supreme Court invalidated a patent covering an apparatus for measuring the depth of the fluid surface of oil under a well. The improvement, a novel kind of resonator, was described as a "means…for tuning said receiving means to the frequency of echoes…to clearly distinguish the echoes from said couplings from each other."[74] The Court explained that claims which "describ[e] th[eir] most crucial element…in terms of what it will do rather than in terms of its own physical characteristics or its arrangement," were invalid.[75] Congress cured this six years later in the 1952 Patent Act. To access a functional claim, a patentee usually signals they are invoking §

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70 35 U.S.C. § 112(f).

71 David J. Kappos & Christopher P. Davis, *Functional Claiming and the Patent Balance*, 18 STAN. TECH. L. REV. 365, 366 (2015).

72 Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1, 8–9 (1946), *superseded by statute*, 35 U.S.C. § 112(f), *as recognized in* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 18 (1997).

73 *Warner-Jenkinson Co.*, 520 U.S. at 27.

74 *Halliburton Oil Well Cementing Co.*, 329 U.S. at 8–9.

75 *Id.* at 9.

112(f) by using "means for" or a similar nonce word in the claim.[76] When § 112(f) is determined to apply to a claim,[77] examiners must "construe the 'means' language . . . as limited to the corresponding structure disclosed in the specification and equivalents thereof."[78]

2. The Enablement Requirement for Means-Plus-Function Claims

Despite the language in the Manual of Patent Examining Procedure (MPEP), the specific criteria needed for a means-plus-function claim to meet the enablement requirement are unclear. The PTO provides limited guidance on how comprehensive the enabling disclosure must be or how an examiner should identify "undue experimentation."[79] Furthermore, there is limited precedent because the issue has rarely come before the Federal Circuit, and thus opposing parties in validity cases have taken different views.[80] Parties looking to protect their claims have asserted that only one mode of practicing a means-plus-function claim must be enabled,[81] but the Federal Circuit has implied that every embodiment of a means-plus-function claim must be enabled for a claim to be valid.[82] For example, in *Auto. Techs., Int'l., Inc. v. BMW of N. Am., Inc.*,[83] the Federal Circuit invalidated 44 claims directed to novel vehicle crash sensors for lack of enablement. Most were dependent claims based on

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76 *See* MPEP § 2181.I (9th ed. Rev. 7, 2022) ("DETERMINING WHETHER A CLAIM LIMITATION INVOKES 35 U.S.C. 112(f) or PRE-AIA 35 U.S.C. 112, SIXTH PARAGRAPH").

77 Courts analyze claim construction before applying any validity doctrine. *See* Kevin Emerson Collins, *Patent Law's Functionality Malfunction and the Problem of Overbroad, Functional Software Patents,* 90 WASH. U. L. REV. 1399, 1453–54 (2023). Determining whether a claim should be interpreted under 35 U.S.C. § 112(f) follows a three-prong analysis. A claim is assumed to invoke 35 U.S.C. § 112 (f) when it explicitly uses the term "means" or "step." *See* TriMed, Inc. v. Stryker Corp., 514 F.3d 1256, 1259–60, (Fed. Cir. 2008). A claim not using "means" or "step" triggers the rebuttable presumption that 35 U.S.C. § 112(f) does not apply. *See* Phillips v. AWH Corp., 415 F.3d 1303, 1311 (Fed. Cir. 2005) (en banc). The second prong is the means or step should be modified by a transition word, usually "means for" or "step for." The third prong is that the "means" or "step" should not be modified by a structure, material, or act for performing the function. During prosecution, the applicant should indicate whether they intend to invoke § 112(f), or else their claim may be held as indefinite. If ambiguity exists about the application of § 112(f) during litigation, courts determine the applicability of § 112(f) based on the judgment of "a person with ordinary skill in the relevant field." *See* 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, 1102 (2013).

78 *In re* Donaldson Co., 16 F.3d 1189, 1194–95 (Fed. Cir. 1994) (en banc).

79 *See* MPEP § 2185 (9th ed. Rev. 7, 2022); *See also* MPEP § 2181.II.a (9th ed. Rev. 7, 2022) ("The Corresponding Structure Must Be Disclosed In the Specification Itself in a Way That One Skilled in the Art Will Understand What Structure Will Perform the Recited Function").

80 *See infra* Section II.C. The plaintiffs in *Auto. Techs., Int'l.* and *Sitrick* both argued that their entire means-plus-function claim was enabled because one mode of practicing the invention was enabled. Sitrick made this argument despite clear precedent from *Auto. Techs., Int'l.* that every mode of practicing the invention needed to be enabled for the claim to be valid.

81 *Id.*

82 *See id.* Enablement challenges rarely occur in means-plus-function cases (accused infringers more often seek to invalidate means-plus-function claims for indefiniteness under 35 U.S.C. § 112(b)). These authors found two Federal Circuit cases addressing this issue.

83 Auto. Techs., Int'l., Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1279–80, 1285 (Fed. Cir. 2007).

independent claims that included a means-plus-function limitation: "means responsive to the motion of said mass upon acceleration of said housing in excess of a predetermined threshold value, for initiating an occupant protection apparatus."[84]

The district court identified the corresponding structure as both electronic and mechanical switch assemblies. The Specification included a detailed description of the mechanical switch, but only "vague" detail of an electronic switch.[85] When Automotive Technologies International sued several defendants in the automotive industry for infringement, some defendants won a judgement of invalidity for lack of enablement. They successfully argued that the "means responsive" limitation included both mechanical means and electronic means (and thus the full scope of the claims included both types of sensors). However, the specification enabled only mechanical sensors.[86] The Federal Circuit upheld the judgment, finding that practicing electronic sensors would require undue experimentation under the *Wands* factors.[87] The Court disputed Automotive Technologies International's defense that the claims were enabled because one mode of practicing the invention (mechanical sensors) was enabled.[88]

Furthermore, in *Sitrick v. Dreamworks*, *LLC*,[89] the Federal Circuit upheld the invalidation of ten claims (three of which followed a means-plus-function format) for lack of enablement because the corresponding structure enabled only one mode of practicing the invention. The patents covered technology for integrating a user's input data into preexisting media. The means-plus-function claims are reproduced in-part below:

From U.S. Patent No. 5,553,864:

> 56. A video interface system comprising: means for coupling to an existing video system comprising software providing requests for predefined images…[90]

From U.S. Patent No. 6,425,825:

> 1. A system comprising… means for mapping the user image to the selected predetermined character function[91]
>
> 20. A display integration system comprising: apparatus providing display signals for a display presentation…[92]

The district court identified the corresponding structure as a module (called the

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84 U.S. Patent No. 5,231,253 col. 10 l. 65 (filed June 2, 1992).
85 *Auto. Techs., Int'l.*, 501 F.3d at 1278–79 (Fed. Cir. 2007).
86 *Id.* at 1280.
87 *Id.* at 1281–82.
88 *Id.* at 1285.
89 Sitrick v. Dreamworks, LLC, 516 F.3d 993, 1000, 1000 n.1, 1002 (Fed. Cir. 2008).
90 U.S. Patent No. 5,553,864 col. 35 l. 51 (filed May 22, 1992).
91 U.S. Patent No. 6,425,825 col. 41 l. 43 (filed Nov. 2, 1998).
92 *Id.* at col. 43 l. 45.

IAIS) and construed these claims to include video games and movies. The enablement problem arose because the specification did not teach how the IAIS module would work on a movie.[93] Citing *Auto. Techs. Int'l., Inc.*, the Federal Circuit explained that the full scope of every means-plus-function claim must be enabled, invalidating Sitrick's claim because only one embodiment was enabled.[94]

3. The Written Description Requirement for Means-Plus-Function Claims

The criteria for compliance with the written description requirement are clearer than for enablement. However, the standards for means-plus-function claims to satisfy the written description requirement are not sufficiently rigorous to achieve its policy objectives. The written description requirement is designed to ensure that an inventor possesses the full scope of their invention, thereby constraining the limits of the invention as asserted in the claims.[95] Means-plus-function claims, however, need only be described by a clear corresponding structure, regardless of the exact scope of the claims.[96] From a public policy perspective, this represents a similar problem as a regular functional claim—the scope is not clearly limited even when the disclosure is limited.[97]

The Federal Circuit recognized this problem outside of the means-plus-function context. In *Ariad*, it explained "genus claims that use functional language…may simply claim a desired result, and may do so without describing species that achieve that result."[98] Similarly, in *Juno*, the Court explained that Juno's claims "'cover[ed] any compound later actually invented and determined to fall within the claim's functional boundaries,' which fails to satisfy the written description requirement," (internal citation omitted).[99] As a result, the Court mandated "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," (citation omitted) for functional claims in the biological arts.[100]

The bar appears to be lower for means-plus-function claims. For means-plus-function claims, that standard for compliance with the written description does not significantly differ from the standard for compliance with the definiteness requirement of 35 U.S.C. § 112(b), namely the disclosure of a corresponding structure

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93 *Sitrick*, 516 F.3d at 998 (Fed. Cir. 2008).

94 *Id.* at 999.

95 *See, e.g.,* Juno Therapeutics, Inc. v. Kite Pharma, Inc. 10 F.4th 1330, 1340 (Fed. Cir. 2021).

96 *See* MPEP § 2181.IV (9th ed. Rev. 7, 2022) (Explaining that "the means- (or step-) plus- function claim must still be analyzed to determine whether there exists corresponding adequate support for such claim limitation under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph.").

97 *See infra* Section II.D. (Arguing that the Federal Circuit has applied an inconsistent approach for determining the equivalents of a means-plus-function claim).

98 Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc).

99 *Juno*, 10 F.4th at 1339 (quoting *Ariad*, 598 F.3d at 1353).

100 *Id.* at 1335 (quoting *Ariad*, 598 F.3d at 1350); *Id.* at 1338.

clearly linked to the claimed function.[101] As the Federal Circuit generalized in *Medical Instrumentation and Diagnostic Corp. v. Elekta AB*,[102] "the requirement that structure must be clearly linked or associated with the claimed function is *the* quid pro quo for the convenience of claiming in functional terms," (emphasis added).

D. Determining Equivalence and Infringement on a Means-Plus-Function Claim

1. Statutory Equivalence and the Doctrine of Equivalents

Determining infringement on a means-plus-function claim can be difficult. Functional limitations are poor at indicating the metes and bounds of an invention, and the courts have used inconsistent approaches for establishing equivalence under 35 U.S.C. § 112(f).

By statute, the scope of means-plus-function claims includes the disclosed structure and "equivalents thereof." Thus, determining whether an invention infringes on a means-plus-function claim requires identifying those equivalents. The form of equivalence is sometimes called "statutory equivalence" or "§ 112 equivalence."

Statutory equivalence is based on an "insubstantial difference" standard, much like the "doctrine of equivalents," another judicial doctrine used determine the unwritten scope of the claims. Under this doctrine, an accused product or process that performs substantially the same function in substantially the same way to achieve substantially the same result as the patented invention can be deemed equivalent to the claimed elements, and thus infringes the patent. The doctrine of equivalents is applied through the function/way/result test: equivalence is not established if the function, way, or result of the assertedly substitute structure is substantially different from that described by the claim limitation.[103] The purpose of the doctrine is to prevent an infringer from taking the benefit of a patented invention by changing only minor or insubstantial details of the invention while retaining the same functionality.

Courts have repeatedly stressed that the doctrine of equivalents is distinct from statutory or § 112 equivalence.[104] Statutory equivalence has generally been held to be

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[101] *See* MPEP § 2181.IV (9th ed. Rev. 7, 2022) ("Whether a claim reciting an element in means- (or step-) plus-function language fails to comply with 35 U.S.C. 112 (b) . . . because the specification does not disclose adequate structure (or material or acts) for performing the recited function is closely related to the question of whether the specification meets the description requirement in 35 U.S.C. 112(a)."); *see also* Tech. Licensing Corp. v. Videotek, Inc. 545 F.3d 1316, 1338 (Fed. Cir. 2008) (requiring only the unambiguous disclosure of a corresponding structure, as judged from the vantage point of one skilled in the art, for a means-plus-function claim to satisfy the definiteness requirement).

[102] Medical Instrumentation and Diagnostic Corp. v. Elekta AB, 344 F.3d 1205, 1219 (Fed. Cir. 2003).

[103] Chad S.C. Stover, *Deciphering Means-Plus-Function Claim Limitation Infringement under 112, Paragraph 6: Finding Certainty in the Uncertain Case Law*, 3 N.C. J.L. & TECH. 101, 106 (2001); *see also* Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42 (1929).

[104] *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 28 (1997) (characterizing the

narrower because equivalence under 35 U.S.C. § 112(f) emphasizes functional identity; the asserted substitute's structure must perform the same function, and only after functional identity is established can equivalence be considered on the basis of the result and way it performs that function. Thus, the tripartite function/way/result test reduces to a way/result test in means-plus-function cases; equivalence is met if the assertedly equivalent structure performs the identical function in substantially the same way to achieve substantially the same result as the corresponding structure in the specification.[105]

There is also a temporal distinction between these two inquiries. The literal meaning of claims is fixed upon issuance. Therefore, equivalence under § 112(f) (which is looking for *literal* infringement) can embrace only technologies that existed at the time of invention.[106] By contrast, the doctrine of equivalents allows a patent to capture after-arising technologies if the after-arising technology is insubstantially different because it is a test for *nonliteral* infringement.[107]

This temporal difference could over-reward the holder of a means-plus-function claim. Means-plus-function claims are evaluated for compliance with the written description and enablement requirements based on the art at the time of filing, just like all other claims.[108] When means-plus-function claims are analyzed for infringement, the equivalents are determined based on the state of the art at the time of *issuance*, not the time of filing.[109] As a result, means-plus-function limitations may claim technologies that were developed by other inventors after the patent was filed without any need for the patentee to disclose, describe, or possess the technologies developed during prosecution. The risk for an over-reward is nontrivial; patent prosecution lasts nearly 26 months on average, and is increasing.[110] At the same time, significant scientific advancements can occur before the patent prosecution is complete.

2. The Caselaw for Determining the Equivalents of a Means-Plus-Function Claim is Inconsistent

This analysis should, in theory, provide a clear approach for determining the equivalent and, thus, the scope of a means-plus-function claim. The Federal Circuit,

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"function and equivalents" provision of 35 U.S.C. § 112 (f) as "an application of the doctrine of equivalents" but "in a restrictive role.").

105 Odetics, Inc. v. Storage Tech. Corp., 185 F.3d 1259, 1267 (Fed. Cir. 1999); *see also* Stover, *supra* note 103, at 106.

106 Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1320 (Fed. Cir. 1999).

107 Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus. Inc., 145 F.3d 1303, 1310 (Fed. Cir. 1998) (explaining that the doctrine of equivalents "is necessary because one cannot predict the future.").

108 *See* MPEP § 2183 (9th ed. Rev. 7, 2022 ("Making a Prima Facie Case of Equivalence.").

109 Ring & Pinion Serv. Inc. v. ARB Corp., 743 F.3d 831, 835 (Fed. Cir. 2014); *Al-Site Corp.*, 174 F.3d at 1320.

110 James Singer, *How long does U.S. patent and trademark prosecution take? (2022 edition),* NEWSTEX BLOGS JD SUPRA (December 30, 2022), https://www.jdsupra.com/legalnews/how-long-does-u-s-patent-and-trademark-8285966/.

however, has not been consistent in applying this doctrine and even conflated the doctrine of equivalents and statutory equivalence.[111]

At times, means-plus-function claims have been awarded a narrow scope based on restrictive, highly structural requirements for statutory equivalence. For example, in *Kemco Sales, Inc. v. Control Papers Co.*,[112] the Federal Circuit found no infringement between two security envelopes that both used double adhesive layers because the accused infringing product had a double lip rather than a single lip. The Court narrowly construed the statutory equivalents of the single lip envelope, explicitly applying a dual-pronged test of identical function and comparison of physical structure.[113]

Similarly, in *Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc.*,[114] the Federal Circuit overturned a judgement of infringement on two patents to a concrete cutting apparatus that had (among other inventive features) a skid plate for applying pressure to the concrete. The accused device met almost all the limitations in the original patents except it used wheels instead of a skid plate. Relying on a detailed comparison of the two structures (including the textures of the wheels and the skid plate), the Federal Circuit held that they were not structurally equivalent.[115] The Federal Circuit has summarized this approach, writing (in some cases) that the "sole question" in analyzing statutory equivalence is a comparison of the structures, whether the accused device performing the identical function is "the same as or an equivalent of the corresponding structure described in the patentee's specification."[116]

By contrast, the Federal Circuit has used a broader approach for finding equivalents in other means-plus-function cases, interpreting the statute's reference to structural equivalence as not actually requiring *equivalent structure*. For example, the same year the Court decided *Kemco*, it ruled in *IMS Technology., Inc. v. Haas Automation, Inc.*,[117] overturning a lower court's finding of nonequivalence between two methods of operating a computerized numerical control (CNC) machine, one which saved user inputs in analog on a cassette and one which saved them digitally via floppy disc. The Court established functional identity, but then pursued a different analysis from *Kemco* or *Chiuminatta*; it considered the context of the art instead of simply comparing structure.[118] The Court held that the floppy disc infringed on the cassette because the physical structure of the means in the asserted claim (using a

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[111] Stover, *supra* note 103, at 107.
[112] Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 1355–58, 1365 (Fed. Cir. 2000); *see also* Stover, *supra* note 103, at 107–09.
[113] *Kemco Sales*, 208 F.3d at 1356.
[114] Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus. Inc., 145 F.3d 1303, 1305–06, 1313 (Fed. Cir. 1998).
[115] *Id.* at 1309.
[116] Valmont Indus. v. Reinke Mfg. Co., 983 F.2d 1039, 1042 (Fed. Cir. 1993); D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1575 (Fed. Cir. 1985).
[117] IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1436, 1440 (Fed. Cir. 2000).
[118] *Id.* at 1436–37.

cassette tape to control a CNC machine) was not important to its purpose or operation.[119] It explained that two statutorily equivalent structures need not be *structurally equivalent,* depending on the nature of the art.[120] The Federal Circuit used the same approach in *Minks v. Polaris Industries, Inc.*,[121] where it upheld infringement between a device for regulating the speed of a reversing vehicle and a Polaris brand ATV, asserting that the statute "requires two structures to be equivalent, but it does not require them to be 'structurally equivalent.'" This has been referred to as the "contextual" approach because it calibrates the meaning of "equivalent structures" based on the nature of the art.[122]

Complicating means-plus-function infringement cases further, the Federal Circuit has written that a finding of nonequivalence under § 112 would preclude a finding of equivalence under the doctrine of equivalents[123] but has also held that it is still possible for a court to find indirect infringement on a means-plus-function claim by applying the regular doctrine of equivalents.[124] Judges of the Federal Circuit have noted this lack of clarity; they have divided on the legal propriety of applying the doctrine of equivalents to means-plus-function claims and publicly disagreed on the appropriate test for statutory equivalence.[125]

This confusion reveals the public policy problem with means-plus-function claims. They are not only prone to being under-described but unclear at indicating to an inventor who wishes to design around them whether they are infringing. The

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[119] *Id.* at 1437.

[120] *Id.* at 1436. (In a footnote, the court explained: "The difference between 'equivalent structures' and 'structural equivalents' can be demonstrated with a simple example borrowed from the late Judge Rich. A claim includes part A, part B, and 'means for securing parts A and B together in a fixed relationship.' The written description discloses that parts A and B are made of wood and are secured together by nails. For purposes of the invention, it does not matter how parts A and B are secured; nails are not a critical part of the invention. A screw is not a nail, but for purposes of § 112, P 6, it is equivalent structure in the context of the invention, though it is not the 'structural equivalent' of a nail.").

[121] Minks v. Polaris Indus., 546 F.3d 1364, 1379 (Fed. Cir. 2008).

[122] Stover, *supra* note 103, at 112; *see also IMS Tech.*, 206 F.3d at 1426, 1436 ("[T]he context of the invention should be considered when performing a § 112, 6 equivalence analysis just as it is in a doctrine of equivalents determination.").

[123] Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus. Inc., 145 F.3d 1303, 1310 (Fed. Cir. 1998).

[124] Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 1364 (Fed. Cir. 2000) ("If an accused structure is not a 35 U.S.C. section 112, paragraph 6 equivalent of the disclosed structure because it does not perform the identical function of that disclosed structure and hence does not literally infringe, it may nevertheless still be an 'equivalent' under the doctrine of equivalents."). *See also* WMS Gaming Inc. v. Int'l Game Tech., 184 F.3d 1339, 1353 (Fed. Cir. 1999). In *WMS Gaming Inc.,* the Federal Circuit reversed a district court's finding of noninfringement on means-plus-function claims to a slot machine. The Federal Circuit agreed that there was no structural equivalence under § 112 ¶ 6, but determined that the accused device did infringe under the doctrine of equivalents.

[125] Dawn Equip. Co. v. Kentucky Farms, Inc., 140 F.3d 1009, 1015, 1018–23 (Fed. Cir. 1998) (Federal Circuit Judge Plager's, Newman's, and Michel's additional views); *see also* Julia Hodge, *§112, ¶6 Claim Interpretation and the Doctrine of Equivalents: An Invitation to Confused Thinking?*, 17 SANTA CLARA HIGH TECH L. J. 203, 210–11 (2000).

Federal Circuit's inconsistency about statutory equivalence represents only one problem. Another is the complexity of identifying the corresponding structure in the disclosure. Parties often disagree (including in infringement cases) about what the corresponding structure is, which adds uncertainty because determining the corresponding structure is the first step in identifying the statutory equivalents.[126]

In addition, the function/way/result test used to identify equivalents (both in the doctrine of equivalents and, in restricted form, the test for statutory equivalence) is ambiguous. The Supreme Court, while not disavowing the test, has noted that function/way/result tests "'often provides a poor framework for analyzing' non-mechanical products or processes…"[127] It may be especially poorly suited for antibodies and biologics. Most fundamentally, functional limitations, are inherently poor at indicating the metes and bounds of an invention. As the PTO has explained, "[t]he principal function of claims is to provide notice of the boundaries of the right to exclude by defining the limits of the invention and means-plus-function claims rely on the disclosure to define those limits."[128]

III. Case Summary and Analysis

A. Xencor Claims a Broad Genus by Using Functional Limitations

Xencor's application (U.S. patent application no. 16/803,690) involves a modification to the Fc domain of antibodies that target complement component 5 (hereafter "C5").[129] Xencor claims all anti-C5 antibodies with certain structural qualities, but the specification discloses only one example, known as 5G1.1, and a few references to anti-C5 antibodies in the prior art.[130]

C5 is a protein created in the complement system (also known as the "complement cascade"), a process of the immune system consisting of proteins and protein complexes (numbered C1, C2, etc.), which interact sequentially to facilitate a

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[126] *See Chiuminatta Concrete Concepts*, 145 F.3d at 1308. The defendant argued that the district court erroneously identified as the corresponding structure as a passage of broad functional language in the Specification rather than a different physical structure described in the Specification. The Federal Circuit agreed with the defendant that the structure was misidentified and thus the scope of the claims was interpreted too broadly by the district court. The Federal Circuit therefore reversed the lower court's judgement of infringement.

[127] Tomita Techs. USA, LLC v. Nintendo Co., 681 Fed. Appx. 967, 971–72 (Fed. Cir. 2016) (quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39–40 (1997)).

[128] *See* MPEP § 2181.IV at 510 (9th ed. Rev. 7, 2022).

[129] U.S. Patent Application No. 16/803,690 (filed Feb. 27, 2020). Antibodies are Y-shaped. Fundamentally, they are divided into two components: the Fab and Fc regions. The Fab region (representing the diagonals of the Y) recognizes the antigen. The Fc ("fragment crystallizable" region (representing the stem of the Y) interacts with other parts of the immune system, including the complement system. *See* Mikel García-Alija, *Modulating Antibody Effector Functions by Fc Glycoengineering*, 67 BIOTECHNOLOGY ADVANCES 1, 1 (2023).

[130] U.S. Patent Application No. 16/803,690 at [0133] (filed Feb. 27, 2020) (including the phrase "anti-complement C-5 antibodies such as 5G1.1."); *see also Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, 2022 Pat. App. LEXIS 5961, at *6–7 (P.T.A.B. Dec. 19, 2022) (describing the "Exhibits" Xencor submitted).

healthy immune response. During the complement cascade, C5 splits into fragments, C5a and C5b.[131] In patients with autoimmune diseases, such as rheumatoid arthritis, the complement cascade, particularly C5a, contributes to autoimmunity, a harmful self-directed immune response.[132]

Anti-C5 antibodies, like those in Xencor's application, work by preventing C5 from splitting into C5a and C5b.[133] Xencor did not invent anti-C5 antibodies nor discover their therapeutic properties; in fact, an anti-C5 antibody called eculizumab was marketed since 2002.[134] Rather, Xencor's invention is a two amino acid substitution in a region of the antibody called the Fc domain. According to Xencor, the substitutions improve the antibody's half-life, prolonging the therapeutic benefit.[135] At issue are two claims: Claim 8, written in a Jepson format, and Claim 9, written in a means-plus-function format. The claims are reproduced below:

> 8. 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 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.[136]
>
> 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 Fe 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.[137]

The written description for both claims in the specification is a passing reference to "anti-complement C-5 antibodies, such as 5G1.1."[138]

The patent Examiner rejected both claims for failing to meet the written description requirement and for obviousness-type double patenting in view of two of Xencor's earlier patents and a Xencor patent application, U.S. Patent Nos. 10,336,818

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131 CHARLES A. JANEWAY, ET AL., IMMUNOBIOLOGY: THE IMMUNE SYSTEM IN HEALTH AND DISEASE 54–55 (5th ed. 2001).

132 P. J. Jose et al., *Measurement of the chemotactic complement fragment C5a in rheumatoid synovial fluids by radioimmunoassay: role of C5a in the acute inflammatory phase*, 49 ANN RHEUM DIS. 747, 747 (1990).

133 *Id.*

134 Corrected Opening Brief Filed by Appellant at 26, *In re* Xencor, Inc., 2024 U.S. App. LEXIS 1462 (Fed. Cir. Jan. 23, 2024) (No. 2023-2048) [hereinafter *Xencor's Appeal Brief*].

135 *See id.* at 7–8.

136 U.S. Patent Application 16/803,690, at Claim 8 (filed Feb. 27, 2020).

137 *Xencor's Appeal Brief*, *supra* note 134, at i.

138 U.S. Patent Application 16/803,690 at [0133] (filed Feb. 27, 2020).

and 8,546,543, and U.S. Patent application 2006/0018896.[139] The written description rejections both reflected the patent Examiner's determination that the claims encompassed a broad scope because phrases like "method of treating a patient" and "administering" did not narrow the genus.[140] The Examiner found the specification inadequate for the "complex" claims because it mentions only one anti-C5 antibody but claims any "means for binding human C5 protein."[141]

The Examiner determined referencing the 5G1.1 antibody provided too little disclosure for the scope of the claims.[142] They determined that 5G1.1 connotes "'the anti-C5 antibody 5G1.1' which 'is the original mouse anti-C5 antibody'" and that the other antibodies referenced through prior art publications were also mouse and rat antibodies that "would not be expected to treat humans who are encompassed by the claims to treating a 'patient.'"[143]

B. Appeal to Patent Trial and Appeals Board

Xencor appealed the Examiner's rejection to the Patent Trial and Appeals Board (PTAB).[144] The appeal brief argued that Claim 9 met the written description requirement because means-plus-function claims do not need to satisfy an equally rigorous written description requirement as other claims.[145] In addition, the Brief made the case that the preamble of Claim 8 was a statement of the prior art, not of claim limitations, and defended relying on prior art in the Specification.[146] Xencor submitted additional "exhibits" of anti-C5 antibodies to bolster the disclosure.[147]

The Examiner was persuaded to withdraw the written description rejections.[148] However, the PTAB overlooked the withdrawal in its proceedings, publishing an opinion in December 2022 upholding the written description rejections that had been withdrawn. It quickly recognized its error, *sua sponte* vacating the opinion, and issuing a new opinion in January 2023 that reiterated the written description rejections

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[139] *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, 2022 Pat. App. LEXIS 5961, at *1–2 (P.T.A.B. Dec. 19, 2022).

[140] *Id.* at *4–5.

[141] *Xencor's Appeal Brief*, *supra* note 134, at 4 n.1.

[142] *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, 2022 Pat. App. LEXIS 5961, at *9–10 (P.T.A.B. Dec. 19, 2022).

[143] *Id.* at *8–9.

[144] *Id.* at *1.

[145] *Id.* at *34.

[146] *Id.* at *14 (citing *Xencor's Appeal Brief*, *supra* note 134, at 13) (arguing that "information that is 'well known in the art' may be used to support written description," and that "what is conventional or well-known to one of skill in the art need not be disclosed in detail.").

[147] *Id.* (citing *Xencor's Appeal Brief*, *supra* note 134, at 14). Most antibodies have Fc domains, though some do not. Because modern technology allows biochemists to replace, switch, or remove amino acids in an antibody sequence, adding the claimed modifications to existing anti-C5 antibodies with Fc represents a fairly routine process. *See* Aaron L. Nelson, *Antibody Fragments: Hope and Hype*, 2 MABS 77, 77 (2022).

[148] *Xencor's Appeal Brief*, *supra* note 134, at 12.

but described them as new grounds.[149]

In its final opinion, the PTAB agreed with the Examiner's original decision. It found that both Claims 8 and 9 were broad and generic since neither limited the diseases that can be treated or significantly narrowed the structure and function of the claimed antibodies.[150]

The Board found that Xencor's method of providing disclosure (mentioning 5G1.1) did not provide an adequate written description. It emphasized the requirement's social purpose (ensuring an inventor possesses the full extent of their claims) and explained that a skilled artisan should be able to distinguish the members of a genus by using the guidance in the disclosure.

According to the Board, Xencor failed to disclose information that is required to meet this standard, such as a clear structure-function relationship or enough representative species.[151]

In addition, the Board questioned whether the additional exhibits submitted in the Appeals Brief demonstrate that a range of relevant anti-C5 antibodies were known in the prior art,[152] questioning "how [the exhibits plus 5G1.1] provide a written description of the claimed broad genus of anti-C5 antibodies and treatment indications."[153] The PTAB also found that Claim 9 was indefinite under 35 U.S.C. §112 (b), arguing that the specification did not include enough structural disclosure for a skilled artisan to know what structure corresponded to the claimed means.[154]

Xencor requested a rehearing before the PTAB.[155] It reasserted that disclosing 5G1.1 met the written description requirement because means-plus-function claims are subject to a distinct standard for compliance.[156] It argued that the preamble of

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[149] *Id.*

[150] *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, 2022 Pat. App. LEXIS 5961, at *4–5 (P.T.A.B. Dec. 19, 2022).

[151] *Id.* at *23–27 (quoting Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc) ("[S]ufficient 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.").

[152] *Id.* at *19–21. According to the PTAB, the exhibits describe only four distinct examples, including single-chain antibodies without Fc regions.

[153] *Id.* at *21.

[154] *Id.* at *36–37 ("Sufficient structure must simply 'permit one of ordinary skill in the art to know and understand what structure corresponds to the means limitation' so that he may 'perceive the bounds of the invention.' *In re* Aoyama, 656 F.3d 1293, 1298 (Fed. Cir. 2011) (citing Finisar Corp. v. DirecTV Grp., Inc., 523 F.3d 1323, 1340–41 (Fed. Cir. 2008))").

[155] An appellant may file a single request for rehearing within two months of the Board's original decision. Regulations require the appellant to describe with "particularity" points that the Board "misapprehended or overlooked." *See* 37 C.F.R. § 41.52 (2024).

[156] *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, available at https://www.uspto.gov/sites/default/files/documents/2022-

Claim 8 ("a method of treating a patient by administering an anti-C5 antibody with an Fc domain") was not limiting because the phrase 'treating a patient' defines only the "intended purpose."[157] It also argued that its disclosure of 5G1.1 would be adequate even for a limiting preamble because "treating a patient" does not imply a threshold effectiveness.[158]

The PTAB denied the rehearing. It clarified its initial holding that the preamble of Claim 8 was limiting and needed written description support.[159] Specifically addressing Xencor's assertions about the written description requirement for means-plus-function claims, the PTAB explained that the same standard for compliance with the written description requirement applies to any antibody genus claim (including a means-plus-function claim like Claim 9) regardless of format.[160]

The Board dismissed the precedent for adequate disclosure in patents invoking 35 U.S.C. § 112 (f) that Xencor submitted.[161] It cited the written description criteria from other cases involving biological genus claims, which included: "'a precise definition, such as by structure, formula, or chemical name'" that can "distinguish [the invention] from other materials"[162] or "a disclosed correlation between function and structure," neither of which Xencor provided.[163]

The PTAB also introduced the idea that 5G1.1 was insufficiently described, but its comments appeared to conflict with its original opinion. In its original opinion, the PTAB, like the Examiner, recognized that Xencor described 5G1.1 as a structural

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001944_reconsideration_denied_20230601.pdf, at 12 (P.T.A.B. June 1, 2023). Xencor cited Cardiac Pacemakers, Inc. v. St. Jude Med, Inc., 296 F.3d 1106, 1113 (Fed. Cir. 2002) and Crea Products, Inc. v. Presstek, Inc., 305 F.3d 1337, 1346 (Fed. Cir. 2002).

157 *Id.* at 3. The Federal Circuit has held that terms connoting purpose are not limiting; *see, e.g.*, Bristol Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1375–76 (Fed. Cir. 2001); *see also In re* Copaxone Consol. Cases, 906 F.3d 1013, 1023 (Fed. Cir. 2018).

158 *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, available at https://www.uspto.gov/sites/default/files/documents/2022-001944_reconsideration_denied_20230601.pdf, at 8, 10–11 (P.T.A.B. June 1, 2023).

159 *Id.* at 8 (citing Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002)). The Board clarified its initial review, explaining that the phrases "treating a patient" and "administering" define the "essence of the invention" (rather than an "intended purpose") because they recite "essential structure or steps" for the claimed improvement (enhancing the antibody's effectiveness as a therapeutic drug). Moreover, according to the PTAB, the cases cited by Xencor address whether preambles are limiting for obviousness analysis, not written description analysis. *Id.* at 3. The PTAB further argued that preambles in Jepson claims are typically limiting, citing Rowe v. Dror, 112 F.3d 473, 479–80 (Fed. Cir. 1997). *Id.* at 8. *See also id.* at 11, (disputing Xencor's statement that the preamble does not suggest a threshold effectiveness because the Specification recites "improved pharmacokinetic properties.") (citing U.S. Patent Application No. 16/803,690, at ¶ 14 (filed Feb. 27, 2020)).

160 *Id.* at 13.

161 *Id.* at 12.

162 *Id.* at 12 (quoting Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc)).

163 *Id.* at 13 (quoting Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002)).

example of an anti-C5 antibody.[164] The patentability issue arose because 5G1.1 "d[id] not establish that [Xencor] invented the full scope of the claim."[165] In the decision on rehearing, however, the Board found that "the structure of the 5G1.1 antibody is not defined or described."[166] In its opening brief at the Federal Circuit, Xencor noted the PTAB's inconsistency about whether the structure of 5G1.1 would have been known to a skilled artisan.[167]

C. Appeal to the Federal Circuit and Remand

Xencor appealed to the Federal Circuit after the PTAB denied rehearing, but the Federal Circuit has yet to review the case. Instead, the PTO successfully requested a remand so the case could be evaluated by the Appeals Review Panel (hereafter "ARP"), a newly formed Director-led tribunal for examining the PTAB's decisions.[168]

Xencor's opening brief modified its earlier arguments and rebuked the PTAB. It once again criticized the Board for interpreting Claim 9 as a functional genus claim, emphasizing that its scope is restricted to the corresponding structure, 5G1.1, and equivalents.[169] It also disputed the Board's approach of evaluating Claim 9's compliance with the written description requirement by benchmarking other chemical genus claims, accusing it of "novel" and "radical" reasoning that "misunders[tood]" the statute's reference to "equivalents thereof."[170]

While Xencor agreed that § 112 (a) applied equally to means-plus-function claims, it emphasized the means-plus-function format makes its claim narrow, including for written description analysis.[171] Xencor submitted additional evidence showing "the relevant structure—5G1.1—is known to skilled artisans" and defended the principle of relying on the prior art in place of a sequence for 5G1.1.[172] Xencor also recapitulated its arguments that Claim 8 satisfied the written description requirement.[173]

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164 *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, 2022 Pat. App. LEXIS 5961, at *27, *30 (P.T.A.B. Dec. 19, 2022).

165 *Id.*

166 *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, available at https://www.uspto.gov/sites/default/files/documents/2022-001944_reconsideration_denied_20230601.pdf, at 15 (P.T.A.B. June 1, 2023).

167 *Xencor's Appeal Brief*, *supra* note 134, at 22.

168 *In re* Xencor, Inc., No. 2023-2048, 2024 U.S. App. LEXIS 1462, at *1 (Fed. Cir. Jan. 23, 2024).

169 *Xencor's Appeal Brief*, *supra* note 134, at 22–33.

170 *Id.* at 31.

171 *Id.* at 32.

172 *Id.* at 29.

173 Xencor argued that Claim 8 complied with *Ariad*'s requirements to disclose a relationship between structure and function because it specified which amino acid substitutions improve in-vivo half-life. *Id.* at 37 (citing Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc)). Xencor also reasserted that "treating a patient" in the preamble should be read as a purpose, *id.* at 43, that "treating a patient" has written description support regardless, *id.* at 46–47, and that Jepson claim preambles do not need written description support. *Id.* at 41–42.

The PTO requested a remand without submitting a reply brief. It explained that it wanted to address "novel questions involving the application of the Supreme Court's and this Court's precedent for both Jepson-format and means-plus-function claims in the field of biotechnology, and in particular the antibody art."[174] Xencor resisted, but the Federal Circuit remanded in January 2024.[175]

This was a rare procedural outcome, underscoring the importance of *Xencor*. *Xencor* was the first case the ARP reviewed (the ARP was established recently in 2023),[176] but only seven cases underwent Director-led review between the institution of Director-led review in 2021 and October 2023, none of which were *ex parte* appeals or convened *sua sponte*.[177] This distinctive treatment reflects *Xencor*'s status as the first case where means-plus-function claims have been tested in antibody or biologic patents.

D. The Appeals Review Panel Denies Inherent Written Description Flaws in Claim 9

The ARP upheld Claim 8's written description rejection. Like the PTAB, the ARP concluded that Claim 8 is a functional genus claim because "treating a patient" could refer to any kind of patient and disease.[178] It found that the preamble has "patentable weight" because the preamble explains the "essence of the invention," "administering"[179] and "treating a patient"[180] and that disclosing only one representative species was insufficient in an unpredictable art like biotechnology.[181]

The panel criticized Xencor for failing to describe a relationship between structure and function[182] and explained that the prior art references did not compensate for the sparse disclosure.[183] The ARP suggested that Xencor would need to demonstrate possession of methods for "treating any and all human and non-human patients having any and all diseases" to support Claim 8, yet Xencor failed to show possession of a method for treating any disease.[184]

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174 Appellee's Motion for Remand at 3, *In re* Xencor, Inc., 2024 U.S. App. LEXIS 1462 (Fed. Cir. Jan. 23, 2024) (No. 2023-2048).

175 Opposition to Motion to Remand, *In re* Xencor, Inc., 2024 U.S. App. LEXIS 1462 (Fed. Cir. Jan. 23, 2024) (No. 2023-2048).

176 *Appeals Review Panel Status*, USPTO (May 17, 2024, 12:41 PM), https://www.uspto.gov/patents/ptab/decisions/appeals-review-panel-status.

177 James M. Glass & Christopher Smith, *How patent office director review has reshaped the rehearing landscape*, REUTERS (Feb. 7, 2024, 1:25 PM), https://www.reuters.com/legal/legalindustry/how-patent-office-director-review-has-reshaped-rehearing-landscape-2024-02-07/.

178 *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, available at https://www.uspto.gov/sites/default/files/documents/2022001944_order_20240521.pdf, at 15 (P.T.A.B. May 17, 2024).

179 *Id.* at 9.

180 *Id.* at 10.

181 *Id.* at 19–20, 23–24.

182 *Id.* at 22.

183 *Id.* at 28.

184 *Id.* at 38.

The review of Claim 9 was mixed. Although the ARP maintained the written description rejection, it did so only because Claim 9, like Claim 8, used the broad language of "treating a patient."[185]

The rest of the PTAB's analysis was reversed. The Panel discredited the idea that patents using means-plus-function claims must provide written description support for the statutory equivalents and resisted applying precedent from other biotechnology written description cases.[186] It also reversed the indefiniteness rejection, finding that a skilled artisan would recognize 5G1.1 as a particular structure (a murine antibody and the humanized version in eculizumab).[187]

Xencor has appealed. Its case was docketed at the Federal Circuit in May 2024.[188]

IV. Discussion

A. Xencor's Means-Plus-Function Claim has the Same Enablement Problems as Amgen's Claims

In its opinion, the ARP left a footnote querying whether Xencor's patent met the enablement requirement. Enablement was not an issue the Panel was able to consider directly, but it suggested that "increased *in-vivo* half-life" (recited in both claims) and "an anti-C5 antibody" (in Claim 8) may not be sufficiently enabled, recommending these matters for review by a future Examiner.[189] The ARP raised an important concern; Claim 9 may pass the written description requirement by disclosing and linking a corresponding structure, but comparison to *Amgen* underscores its enablement problems.

Amgen depended on functional claims, which created a broad genus that raised the bar for enablement.[190] Its disclosure of twenty-six species and a "roadmap" for amino acid substitution provided too little guidance for an artisan to reproduce the

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185 *Id.* at 38.

186 *Id.* at 36–37 (finding that the statute does not imply this requirement to describe the equivalents) (citing Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech., 521 F.3d 1328, 1331 (Fed. Cir. 2008) (showing that equivalents are structures beyond anything explicitly described in the specification)).

187 *Id.* at 33–34.

188 Notice of Docketing, *In re* Xencor, Inc., Fed. Cir. Docket No. 2024-1870 (Fed. Cir. May 28, 2024, Filed) (No. 2024-1870).

189 *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, available at https://www.uspto.gov/sites/default/files/documents/2022001944_order_20240521.pdf, at 40 n.16 (P.T.A.B. May 17, 2024).

190 Amgen Inc. v. Sanofi, 598 U.S. 594, 602 (2023); Amgen, Inc. v. Sanofi, 987 F.3d 1080, 1087 (Fed. Cir. 2021) ("Regardless of the exact number of embodiments, it is clear that [Amgen's] claims are far broader in functional diversity than the disclosed examples…the use of broad functional claim limitations raises the bar for enablement…"); *see also* Brief of Sir Gregory Paul Winter and Interested Scientists as Amici Curiae in Support of Respondents, Amgen Inc., et al., v. Sanofi, et al., 598 U.S. 594 (2023) (No. 21-757), 2023 WL 2167707, at *22. ("The relevant claims are thus so broad that they 'cover the entire genus of antibodies that bind to specific amino acid residues on PCSK9 and block PCSK9 from binding…'").

full scope of its patent without undue experimentation.[191] The problem was exacerbated by the unpredictable relationship between an antibody's structure and function.[192]

Claim 9 of Xencor's application has similar flaws. Although Claim 9 includes a structural limitation (a two amino-acid substitution on the Fc domain), the rest of the claim is functional. Xencor disclosed even less than Amgen: just one structure, 5G1.1, without a Seq ID or amino acid sequence.[193] Producing a range of C5-complement antibodies from this disclosure would be viable only if the amino acid substitutions yielded the claimed results on *every* C5-complement antibody, which Xencor has not proved. Practicing anything other than modified 5G1.1 would require testing, reformulating, and retesting each candidate if the modifications are not universally effective (as is likely). As the *Amgen* panel explained, trial and error analysis "in identifying, from among the many . . . compounds that meet the structural requirements, the compounds that satisfy the functional requirement[s]" constitutes "undue experimentation."[194]

Admittedly, Amgen's claims and Claim 9 are imperfect analogues because Xencor invokes 35 U.S.C. § 112 (f). The means-plus-function format, however, does not rectify the enablement issues. Unless the "equivalents" of 5G1.1 are extremely narrow, some experimentation in identifying antibodies that satisfy the functional requirements would be required to practice the full scope of the claim. Moreover, *Sitrick* and *Auto. Techs. Int'l., Inc.* suggest that statutory equivalents need enablement support and that the framework of "undue experimentation" applies fully to means-plus-function claims.[195]

Claim 8 underscores the enablement challenges in Claim 9. While Claim 9 uses a means-plus-function format, Claim 8 is more precisely analogous to Amgen's claims: it does not invoke 35 U.S.C. § 112 (f), so it is not narrowed by the specification; the ARP and PTAB both classified it a functional antibody genus claim[196]; and it likely encompasses an enormous genus because the functional

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[191] *Amgen*, 987 F.3d at 1087.

[192] *Id.*

[193] A "Seq ID" is a unique identifier used to identify a sequence record in a database. In the context of biotechnology patents, a "SEQ ID NO" is used to recognize a gene or protein in a sequence listing and provides the whole amino acid sequence.

[194] *Amgen*, 987 F.3d at 1087 (quoting McRO, Inc. v. Am. Inc., 959 F.3d 1091, 1100 (Fed. Cir. 2020)).

[195] *See* Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008); Auto. Techs., Intl'l. v. BMW of N. Am., Inc., 501 F.3d 1274, 1285 (Fed. Cir. 2007).

[196] *See Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, 2022 Pat. App. LEXIS 5961, at *3, *4 (P.T.A.B. Dec. 19, 2022) (where the PTAB explains that under Claim 8, "a broad genus of antibodies, indications, and patients to be treated are claimed. The antibody genus especially is claimed functionally and by the result that it treats an unidentified condition or disease."); *see also Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, available at https://www.uspto.gov/sites/default/files/documents/2022001944_order_20240521.pdf, at 18 (P.T.A.B. May 17, 2024) ("Claim 8 uses functional language to claim a genus because it claims all antibodies that bind to C5.").

limitations (such as "treating a patient") are broad.[197] Given how little Xencor discloses (less than Amgen), Claim 8 almost certainly fails the enablement requirement set out in *Amgen*.

This comparison reveals the enablement problems in Claim 9 because Claim 8 and Claim 9 are nearly identical. They have the same functional limitations, the same solitary structural limitation, and rely on the same passage in the specification for enablement support.[198] The means-plus-function format should not cure such fundamental enablement issues merely because it uses claim language guided by 112(f). Unless Claim 9 is limited to 5G1.1 (in which case, it would likely be orders of magnitude narrower than Claim 8), practicing the full scope of either claim would require trial, error, and testing. These are the same issues previously addressed by *Amgen v. Sanofi*.

B. Xencor's Means-Plus-Function Claim has the Same Enablement Problems as Single Means Claims

A caveat on means-plus-function limitations is that they cannot be the only element in claim. Such claims (known as "single means claims") are not permitted by 35 U.S.C. § 112 (f) and are automatically rejected.[199] The single means claim rejected in *Ex parte Nesbitt* is illustrative:

> 22. An apparatus for determining a route using a computer-implemented mapping system, the apparatus being configured to…receive a designation of a point on a map… use the designation of the point to influence determination of a route… and enable presentation of the route to the user."[200]

This claim essentially described the function of a GPS route computer and claimed any "apparatus" performing that function. By contrast, Claim 34 of Nesbitt's application, which was highly similar but drafted with several means-plus-function elements, was not rejected:

> 34. An apparatus for determining a route using a computer-implemented mapping system, the apparatus comprising…"means for receiving a designation of a point on a map… means for using the designation of the point to influence determination of a route…

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[197] *Ex parte* Aaron Keith Chamberlain et al., No. 2022-001944, available at https://www.uspto.gov/sites/default/files/documents/2022001944_order_20240521.pdf, at 22 (P.T.A.B. May 17, 2024) (agreeing that "the claimed 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.").

[198] *Id.* at 29–30.

[199] *See* MPEP § 2181.V (9th ed. Rev. 7, 2022) ("Single Means Claims").

[200] *Ex parte* Nesbitt, No. 2011-000501, available at https://developer.uspto.gov/ptab-web/#/search/documents?proceedingNumber=2011000501, under "Decision" at 5 (P.T.A.B. June 10, 2014).

> and means for enabling presentation of the route to the user."[201]

Single means claims are prohibited by the Patent Act, which provides that "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," (emphasis added).[202] Indeed, the statute's authors sought to exclude single means claims.[203] The policy rationale for this is that single means are overbroad; read literally, they encompass every way of performing their stated function.[204] Moreover, a single means claim, if issued today, would not be limited to the disclosed structure and equivalents thereof (like a means-plus-function claim) because single means claims cannot invoke 35 U.S.C. § 112 (f).[205]

In *In re Hyatt*,[206] the Federal Circuit clarified that the overbreadth of single means claims is an enablement problem: "the proper statutory basis for the rejection of a single means claim is the requirement…that the enabling disclosure of the specification be commensurate in scope with the claim." The *Hyatt* panel explained that the breadth of single means claims makes them *impossible* to enable: "The long-recognized problem of a single means claim is that it covers every conceivable means for achieving the stated result, while the specification discloses at most only those means known to the inventor [citations omitted]. Thus, the claim is properly rejected for what used to be known as 'undue breadth,' but has since been appreciated as being, more accurately, based on the first paragraph of § 112."[207] Hence, no enablement analysis is required to reject a single means claim.[208]

The prohibition of single means claims is not an isolated rule; it reflects the general problem that functional claims are prone to failing the enablement requirement. Indeed, courts have explicitly applied the principles behind the prohibition of single means claims to restrict functional claims that do not have a single means format. In its decision on rehearing *Amgen v. Sanofi,* the Federal Circuit cited *Hyatt*:

> Claims defining a composition of matter by function raise special problems because one may not know whether a species is within the

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[201] *Id.* at 5–6.

[202] 35 U.S.C. § 112 (f). Some defendants have argued that the Patent Act merely sanctions means-plus-function claims in combination but does not *prohibit* single means claims. This reasoning has been dismissed by the Federal Circuit. *See In re* Gilbert P. Hyatt, 708 F.2d 712, 713 (Fed. Cir. 1983).

[203] P.J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. 1, 26 (1954), *reprinted in* 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 186 (1993) (printed as a prologue to 35 USCA § 1 from 1954 to 1993) ("The language [of the final paragraph of § 112] does not go so far as to permit a so-called single means claim, that is a claim which recites merely one means plus a statement of function and nothing else.").

[204] *See* MPEP § 2181.V (9th ed. Rev. 7, 2022) ("Single Means Claims").

[205] *Id.*

[206] *In re* Hyatt, 708 F.2d 712, 714 (Fed. Cir. 1983).

[207] *Id.*

[208] Enfish, LLC v. Microsoft Corp., 9 F. Supp. 3d 1126, 1129 (C.D. Cal. 2014).

> scope of a generic claim until one has made it and one can ascertain whether it possesses the claimed function, hence that it has been enabled…this court has already considered the impact of functional means claim limitations on whether a disclosure is commensurate in scope with the claim. The answer is that single means claims claim too much."[209]

Similarly, in *Fiers v. Revel*,[210] where § 112 (a) was applied to deny Revel—who used highly functional claims—priority to a DNA coding invention, the Federal Circuit found that Fiers's claim was "analogous to a single means claim," and therefore failed "to comply with" § 112(a). The Panel explained that single means claims "'attempt to preempt the future before it has arrived' by claiming all results without describing all the means to do so."[211]

Xencor's means-plus-function claim is not a single means claim,[212] but it shares the same problem, a scope that is broader than the enabling disclosure. Xencor's specification teaches only modified 5G1.1, but Claim 9 encompasses a range of C5-complement antibodies. Xencor's means-plus-function limitation does not claim *all* embodiments like a single means claim, but it claims *many* embodiments. An inadequate specification should not be enabling whether the scope encompasses every embodiment or just many of them.

Xencor does not solve this enablement problem by invoking 35 U.S.C. § 112 (f). While the *Hyatt* panel did note that 35 U.S.C. § 112 ¶ 6 "saves" means-plus-function claims used in combination "by providing a construction of that format narrow enough to avoid the problem of undue breadth," it did not suggest that any means-plus-function claim meets the enablement requirement merely because it uses claim language guided by 112(f).[213] As discussed in § IV.A, Xencor's means-plus-function claim encompasses more than its specification enables even considering the statute's limits on the scope of means-plus-function claims (restricting them to the disclosed structure and equivalents thereof). The discrepancy between the scope of Xencor's functional claim and the enabling disclosure is same the enablement issue associated with single means claims.

C. Reviewing the Arguments for Means-Plus-Function Antibody Claims

We believe proponents of means-plus-function antibody claims are seeking broad, generic patents that are similar to those invalidated by *Amgen*. The idea of

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[209] Amgen Inc. v. Sanofi, 850 Fed. Appx. 794, 797 (Fed. Cir. 2021) (citing *In re Hyatt*, 708 F.2d at 714).

[210] Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

[211] *Enfish*, 9 F. Supp. 3d at 1128–29 (citing *Fiers*, 984 F.2d at 1171).

[212] No tribunal accused Xencor of drafting a single means claim. Indeed, Claim 9 of Xencor's application appears to include two elements: "a) means for binding human C5 protein; and b) an Fc domain comprising amino acid substitution M428L/N434S as compared to a human Fc polypeptide e . . . ." *See* U.S. Patent Application 16/803,690 (filed Feb. 27, 2020).

[213] *In re* Hyatt, 708 F.2d 712, 715 (Fed. Cir. 1983).

using a means-plus-function format to claim antibodies has arisen amid a perception among some scholars that it has become "nearly impossible to maintain a valid genus claim" in the chemical and biological arts.[214] Three of this viewpoint's leading proponents published *The Death of the Genus Claim* in 2021, arguing that:

> The Federal Circuit has abandoned a practical focus on whether others could make and use the claimed invention, instead favoring a fruitless search for the exact boundaries of that invention. This "full-scope possession" theory invalidates a genus claim unless the patentee can show exactly which species within the genus will work as intended—an impossible task for a genus of any nontrivial size.[215]

Death includes a limited discussion of functional antibody claims:

> In this Article, we don't want to get into the particular question of whether functional claiming of such antibodies is appropriate. But functional antibody claims that read on any antibody binding to a specific epitope on an antigen may fail the traditional enablement requirement if those of skill in the art can't identify and make antibodies within the scope of the claims without undue experimentation. But it is that question, not the question of "did you identify all of them?", that should resolve cases like *Sanofi*." (internal citations omitted).[216]

Two of *Death's* authors (Mark Lemley and Sean Seymore) joined an amicus brief on behalf of Amgen at the Supreme Court. The brief echoes *Death's* hypothesis and cites the paper four times.[217] For example:

> The Federal Circuit has changed the law dramatically in recent years, to the point where it is no longer possible to have a valid genus claim in the chemical and biotechnology industries. Under this new approach, it no longer suffices that the patent gives enough information that the PHOSITA can "make and use" the invention, as § 112(a) requires. Rather, the Federal Circuit now rejects claims as invalid because the genus contains thousands or millions of possible chemicals, unless the patent itself identifies exactly which of those myriad species will work.[218]

Regarding *Amgen*, the brief explains that:

> Ultimately, whether Amgen disclosed enough information to enable a PHOSITA to make and use Amgen's broader invention is a

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[214] Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 HARV. J. L. & TECH. 1, 1 (2021).
[215] *Id.* at 4.
[216] *Id.* at 57. *Sanofi* refers to *Amgen. v. Sanofi*.
[217] Brief of Intellectual Property Professors as Amici Curiae in Support of Petitioners at iv, Amgen Inc., et al., v. Sanofi, et al., 598 U.S. 594 (2023) (No. 21-757), 2023 WL 120178.
[218] *Id.* at 2.

> question that depends on the facts of the case. Amici do not express an opinion on the question of how much experimentation would be required to identify any particular species within the genus. But we believe that is the correct question, and that the Federal Circuit erred by requiring more.[219]

Lemley offered more perspective on antibody patents in *The Antibody Patent Paradox*, co-written with Jacob Sherkow (one of the authors of the amicus brief) and published shortly before oral arguments in *Amgen*. *Paradox* suggests that:

> Very few, if any, functional antibody patents are going to survive *Amgen*'s and *Juno*'s revolutions on enablement and written description. Post-*Amgen*, the enablement standard for antibodies has become, if not an impossible barrier, at least an impractical one, especially for the myriad antibody claims issued before *Amgen* was decided.[220]

Paradox originated the idea of applying means-plus-function claims to antibody patents. It suggests that the format may be "The key to saving some antibody genus claims"[221]:

> For antibodies, the means-plus-function claim format offers an intriguing intermediate possibility between pure functional claims and narrow species claims. If a patent owner claims "means for binding to antigen X," that claim would presumably not be invalid under the Federal Circuit's current written description or enablement precedents because it would be interpreted to cover only those means for binding to antigen X that are disclosed in the patent plus other means that are equivalent to the ones disclosed.[222]

Paradox acknowledges the difficulty of determining "what antibodies are 'equivalent' to the ones the inventor disclosed," noting that "the formulation typically used for such assessments is not terribly helpful,"[223] but it reasons, we think tellingly, that:

> An antibody claim written in means-plus-function format should cover other antibodies that achieve the same function even if they are structurally quite different. The structural differences likely don't matter to the function-way-result test, and they avoid the invalidity problems that plagued *Amgen* and *Juno*.[224]

This idea has guided Xencor's strategy. Xencor says its "approach to claiming

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[219] *Id.* at 17.
[220] Lemley & Sherkow, *supra* note 52, at 1034.
[221] *Id.* at 1055.
[222] *Id.* at 1057.
[223] *Id.* at 1058.
[224] *Id.* at 1059.

is exactly what Mark Lemley and Jacob B. Sherkow encourage in their recent article."[225] Its opening brief quotes *Paradox*:

> Claim 9 'cover[s] only those means for binding to [C5] that are disclosed in the patent plus other means that are equivalent to the ones disclosed,' i.e., 5G1.1 and its structural equivalents. It does not cover an enormous number of candidates, only 5G1.1, the structure disclosed in the specification (and any structural equivalents) (internal citations omitted).[226]

Lemley, Sherkow, and others subsequently filed an amicus brief on behalf of Xencor, explaining the scope of means-plus-function antibody claims: "means-plus-function claims for antibodies would not be so narrow that patentees would necessarily be limited to only a single embodiment of their invention; means-plus-function claims for antibodies literally encompass equivalents."[227]

Lemley and Sherkow's proposal presents several challenges. A means-plus-function format—if drafted and applied how we believe they propose—would likely yield patents covering antibodies that are not enabled. Lemley and Sherkow argue that these claims would meet the enablement requirement because "a [skilled artisan] could make or use the disclosed embodiments…even though the claim would extend to equivalents."[228] They similarly explain in their amicus brief that the format "satisf[ies] enablement because the scope of a means-plus-function antibody claim…would require only that an inventor teach a person having skill in the art to make and use the *disclosed* antibodies (emphasis in original)."[229]

We think this reasoning disregards the meaning of *Amgen*. In our reading, Lemley, Sherkow, and Xencor seek means-plus-function antibody claims that cover a range of species, but they propose enablement by disclosing only one species. This may be acceptable for a means-plus-function patent (although *Sitrick* and *Auto. Techs., Int'l., Inc.* suggest otherwise), but not under the rules in *Amgen*. The only way for an artisan to make and use the undisclosed antibodies of Xencor's patent (the 'equivalents') would be the same method required to make and use the undisclosed embodiments of Amgen's patent: "'trial and error, by making changes to the disclosed antibodies and then screening those antibodies for the desired binding and blocking properties,' or else 'by discovering the antibodies de novo.'"[230]

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[225] *Xencor's Appeal Brief*, *supra* note 134, at 34.
[226] *Id.* at 35 (quoting Lemley & Sherkow, *supra* note 52, at 1057).
[227] Brief of Patent Law Professors as Amicus Curiae Supporting the Appellant and Reversal at 11, *In re* Xencor, Inc., 2024 U.S. App. LEXIS 1462 (Fed. Cir. Jan. 23, 2024) (No. 2023-2048).
[228] Lemley & Sherkow, *supra* note 52, at 1057.
[229] Brief of Patent Law Professors as Amicus Curiae Supporting the Appellant and Reversal at 9–10, *In re* Xencor, Inc., 2024 U.S. App. LEXIS 1462 (Fed. Cir. Jan. 23, 2024) (No. 2023-2048).
[230] Amgen Inc. v. Sanofi, 987 F.3d 1080, 1088 (Fed. Cir. 2021) (quoting Amgen Inc. v. Sanofi, No. 14-1317-RGA, 2019 U.S. Dist. LEXIS 146305, at *31–32 (D. Del. Aug. 28, 2019)).

This may be acceptable in some arts,[231] and the enablement requirement permits some degree of experimentation.[232] However, in antibody science, where the structures do not clearly predict the function, the number of equivalents can be enormous and making a new embodiment is unpredictable.[233] *Amgen* recognizes the complexity of antibody science by requiring the enablement to be representative of the scope.[234] Referencing a single antibody to claim an entire genus is almost certainly inadequate to meet the enablement requirement under *Amgen*.

We also note a secondary problem with Lemley and Sherkow's proposal: they encourage patentees to assert means-plus-function antibody claims alongside the function/way/result test of the traditional doctrine of equivalents.[235] As noted in Part II, however, the propriety of applying the doctrine of equivalents to means-plus-function claims is uncertain,[236] an issue that the Federal Circuit implicitly observed in *Dawn Equipment Co. v. Kentucky Farms, Inc*.[237] The outcome of *Dawn Equipment* did not depend on the applicability of the doctrine of equivalents to means-plus-function claims, but each judge wrote separately to express thoughts on the issue. Only Judge Newman advocated applying the doctrine of equivalents to means-plus-function claims, and purely based on stare decisis.[238] Judge Michel questioned whether applying the doctrine of equivalents to means-plus-function claim contradicts the purpose of § 112 ¶ 6,[239] and Judge Plager called the law on this topic

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231 *See* Amgen Inc. v. Sanofi, 598 U.S. 594, 611–12 (2023).

232 *Id.* at 612.

233 *Id.* at 600.

234 *See e.g.*, *Amgen*, 987 F.3d at 1088 (Fed. Cir. 2021) ("[W]e agree with the district court that '[a]fter considering the disclosed roadmap in light of the unpredictability of the art, any reasonable factfinder would conclude that the patent does not provide significant guidance or direction to a person of ordinary skill in the art for the full scope of the claims.'"); *see also Amgen*, 598 U.S. at 613 (2023) ("Amgen seeks to monopolize an entire class of things defined by their function . . . this class of antibodies does not include just the 26 that Amgen has described by their amino acid sequences, but a "vast" number of additional antibodies. . . .That poses Amgen with a challenge. For if our cases teach anything, it is that the more a party claims, the broader the monopoly it demands, the more it must enable.").

235 Lemley & Sherkow, *supra* note 52, at 1059 n.411 ("Means-plus-function equivalence also encompasses those later-developed technologies by applying the traditional doctrine of equivalents on top of the equivalent structures that the law views as literally infringing, creating the possibility of an equivalent (under the doctrine of equivalents) to an equivalent (under § 112(f)).").

236 Hodge, *supra* note 125, at 210.

237 *See* Dawn Equip. Co. v. Kentucky Farms Inc., 140 F.3d 1009, 1015 n.2 (Fed. Cir. 1998).

238 *Id.* at 1022 (Newman, J., additional views) ("The proposed elimination of recourse to the doctrine of equivalents for claim elements described in means-plus-function form would markedly diminish the scope of the doctrine. This step has no support in precedent. Whether or not further restriction on the doctrine of equivalents will be warranted as, in the fullness of time, more is learned of its role in the larger system of national innovation policy, it is inappropriate for this court to undertake such a major step sua sponte.").

239 *Id.* at 1023 (Michel, J., additional views) ("I wonder [if affording the patentee additional protection under the doctrine of equivalents conflicts with the very language and intent of 35 U.S.C. § 112(6) (1994), which covers only those 'equivalents' disclosed in the specification . . . . Is it contrary to

"confusing" and argued that the doctrine of equivalents should not apply to means-plus-function claims.[240]

Even *Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc.* (cited by Lemley and Sherkow to prove the doctrine of equivalents can be applied to means-plus-function claims[241]) explains that a finding of nonequivalence under § 112 (f) precludes a finding of equivalence under the doctrine of equivalents if the accused technology existed at the time of invention.[242] While *Chiuminatta* may not entirely negate Lemley and Sherkow's approach (since the goal of using the doctrine of equivalents is claiming after-arising technologies), it and *Dawn Equipment* reveal the Federal Circuit's hesitance applying the doctrine of equivalents to means-plus-function patents.

In sum, we believe proponents of means-plus-function antibody claims are attempting to use procedure and language to bypass a substantive limit. Their approach is reminiscent of 'do it on a computer' claims that were commonplace before *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*.[243] "Do it on a computer" claims made abstract ideas patentable by describing a process or system and noting that each step was "implemented by a computer" or "program." Though the Federal Circuit's subject matter eligibility jurisprudence of the time tolerated these claims,[244] as the

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section 112(6) to expand the protection for inventions claimed partly in means-plus-function format by also applying the doctrine of equivalents to limitations claimed in that format, when protection for some but not all equivalents has already been incorporated into the statute itself and when doing so further diminishes the notice function of the patent?]").

240 *Id.* at 1022–23 (Plager, J., additional views) ("In that light, and consistent with that purpose, I believe that the practice of claiming under § 112, P 6 would be much improved if we adhered to the proposition that the 'equivalents' of 'structure, material, or acts described in the specification' are those found to be within the scope of that term as it is used in § 112, P 6, and not elsewhere. Accordingly, the separate judicially created doctrine of equivalents would have no application to those aspects of limitations drawn in means-plus-function form.").

241 Lemley & Sherkow, *supra* note 52, at 1058.

242 Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus. Inc., 145 F.3d 1303, 1309 (Fed. Cir. 1998).

243 Alice Corp. Pty. Ltd. v. CLS Bank Int'l., 573 U.S. 208, 223 (2014) ("[T]he mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention."). Abstract ideas have been held unpatentable since the nineteenth century. *See e.g.*, Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (citing Rubber-Tip Pencil Company v. Howard, 87 U.S. 498, 507 (1874)).

244 Federal Circuit jurisprudence pretermitted these claims. Prior to 1994, the Federal Circuit had analyzed the patent eligibility of software inventions with the *Freeman-Walter-Abele* test, which required that the abstract idea behind a piece of software, like a mathematical algorithm, be tied to a physical element or process. *See* Arrhythmia Rsch. Tech., Inc. v. Corazonix Corp., 958 F.2d 1053, 1058 (Fed. Cir. 1992). *See also* Ognjen Zivojnovic, *Patentable Subject Matter after Alice—Distinguishing Narrow Software Patents from Overly Broad Business Method Patents*, 30 BERKELEY TECH. L. J. 807, 815 (2015). After the mid-1990s, however, the Federal Circuit replaced the *Freeman-Walter-Abele* test with the more permissive "useful, concrete, and tangible result" test. *See In re* Allapat, 33 F.3d 1526, 1544–45 (Fed. Cir. 1994) (holding that a computer program for controlling pixels on a television was patentable because it produced a tangible result on a machine); *see also* State Street Bank & Trust Co. v. Signature Fin. Grp., Inc.,149 F.3d 1368, 1373–74 (Fed.

Supreme Court ultimately recognized, generic computer implementation does not "provid[e] any 'practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself.'"[245]

An illustrative example is US 7,062,251, issued in 2004. The patent claimed a method and system for gathering and redisplaying bedside data in critical care wards.[246] As the Federal Circuit noted when it used *Alice* to strike down US 7,062,251, even the specification explained that such data collection was routinely done on pen-and-paper, and the "invention" therefore only automated an abstract process.[247] Back in 2004, however, the patent issued because the draughtsman appended "do it on a computer" language to the familiar process.

Functional antibody claims with limited enablement are unpatentable just as abstract ideas are unpatentable. Appending "means-for" to an antibody function should not allow a patentee to claim the function any more than appending "do it on a computer" should allow a patentee to claim an abstract idea. We acknowledge that means-plus-function claiming has a specific statutory basis, unlike "do it on a computer" claims, but 35 U.S.C § 112(f) does not validate every claim using "means for." A linguistic workaround is a linguistic workaround regardless of whether the language comes from the Patent Act.

Finally, we acknowledge that means-plus-function antibody claims would not operate identically to traditional functional claims and that proponents describe them as an "intermediate" between pure functional claims and narrow species claims.[248] However, we still believe they constitute a linguistic and procedural workaround; they need not perfectly replicate claims like *Amgen*'s to violate the substantive limits from that case. This was also true of "do it on a computer claims"; US 7,062,251 did not claim every implementation of the abstract process of collecting data in critical care wards, much like Xencor does not claim all C5-complement antibodies with the Fc domain modification.[249] But, in both cases, the practical effect of the asserted

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Cir. 1998) (holding that a program which determined the share price of a mutual fund was patentable because it produced a useful and tangible result and abrogating the *Freeman-Walter-Abele* test). These rulings led to a deluge of software patents, particularly those directed to business processes. *In re* Bilski, 545 F.3d 943, 1004 (Fed. Cir. 2008) (Mayer, J., dissenting) (noting a tenfold increase, a "tsunami," in business method applications after *State Street*). This permissive jurisprudence began eroding after *In re Bilski* in 2008, which clarified the "machine or transformation" test and began a trilogy of eligibility cases at the Supreme Court culminating in *Alice. See* Ognjen Zivojnovic, *Patentable Subject Matter after Alice—Distinguishing Narrow Software Patents from Overly Broad Business Method Patents*, 30 BERKELEY TECH. L. J. 807, 815–16 (2015).

245 *Alice*, 573 U.S. at 224 (2014) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 77 (2012)).

246 U.S. Patent No. 7,062,251 (filed Jun. 13, 2006).

247 Univ. of Fla. Rsch. Found., Inc. v. GE Co., 916 F.3d 1363, 1367 (Fed. Cir. 2019) (citing U.S. Patent No. 7,062,251 col. 1 l. 21–23 (filed Jun. 13, 2006)).

248 Lemley & Sherkow, *supra* note 52, at 1057.

249 *See* U.S. Patent No. 7,062,251 col. 13 l. 59 (filed Jun. 13, 2006) (claiming only implementation through "bedside machines." We acknowledge that the means-plus-function format can limit the scope of the antibody monopoly compared to a traditional functional claim.).

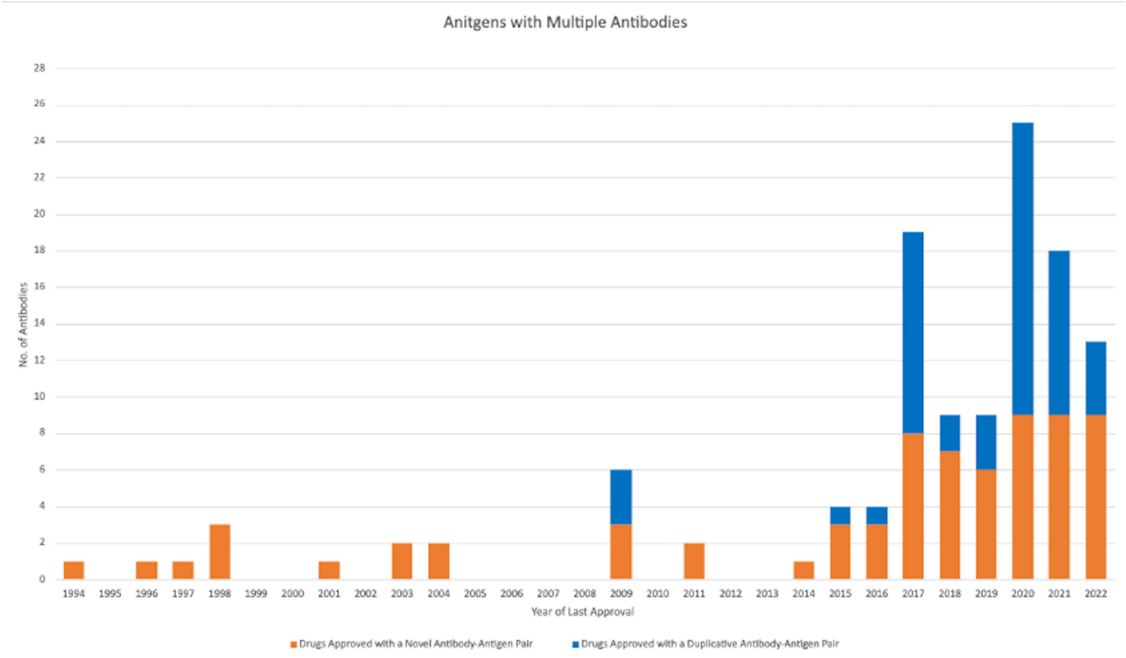
claims is *similar enough* to the clearly prohibited form of claiming to make the asserted claims essentially attempts to obtain nonstatutory patents using language.

D. Means-Plus-Function Antibody Claims Would Harm Innovation and Care

Patients have benefitted from narrower antibody patents that permit them to select from multiple therapeutics targeting the same antigen. Drugs like Praluent®, Herceptin®, and Enbrel® offer enhanced effectiveness or additional treatment indications compared to the reference antibodies targeting the same antigen.[250] Alternative epitope antibodies enable doctors to use new therapies for patients in whom the repeated administration of the brand antibody caused immunogenicity or simply did not work for that particular patient.[251]

The growth in FDA approvals for alternative epitope antibodies underscores their rising importance. As shown in Figure 2, alternative epitope antibodies constitute a large and increasing portion of the antibody drugs receiving FDA approval. (This total *excludes* FDA-approved biosimilar antibodies, which must use the same epitope as the brand biologic.)

Figure 2



[250] S. Sean Tu et al., *supra* note 8, at 1641–42.

[251] Brief of Sir Gregory Paul Winter and Interested Scientists as Amici Curiae in Support of Respondents, Amgen Inc., et al., v. Sanofi, et al., 598 U.S. 594 (2023) (No. 21-757), 2023 WL 2167707, at *30–31.

The proliferation of alternative epitope antibodies and the benefits it has offered patients would be impossible if broad genus claims like Amgen's were allowed. Means-plus-function claims might be narrower than functional genus claims that do not invoke 35 U.S.C. § 112(f). But claims where the equivalents can include a range of structures can still block or deter innovation.

Proponents of means-plus-function antibody claims might argue that these claims would not encompass alternative epitope antibodies like Praluent® because an antibody that offered unique therapeutic properties might work in a different way and thus would not be covered by a means-plus-function claim. As Lemley and Sherkow explain, "antibodies that bind to a different epitope, or do so with different binding characteristics, likely don't work in substantially the same way and so would not be infringing."[252]

While this may theoretically be true, applying an "insubstantial difference" standard to monoclonal antibodies would be difficult. Requiring equivalents to work in "substantially the same way" is far more ambiguous than a bright-line rule requiring two things to work *identically*. The Supreme Court has noted that "insubstantial difference" is a poor yardstick for non-mechanical inventions.[253] Indeed, determining if two antibodies work in "substantially the same way" is much more complex than comparing their target epitopes and "binding characteristics."[254] It would require evaluation of additional properties of monoclonal antibodies including functional affinity (how strong the bond is), the structural arrangement when binding, the biological half-life, the specificity (how well the antibody discriminates between one antigen and another), the selectivity (how well the antibody binds in a heterogenous mixture), and others.[255] Would an equivalent antibody have to be completely identical in all of these properties?

This uncertainty threatens innovation even if alternative epitope antibodies remain available. Determining whether a new antibody was encompassed by an existing means-plus-function claim would create great uncertainty for competitors. Firms would not only be forced to test the new structure for functional limitations but also decide whether the new structure's function is "identical enough" which is a term fraught with uncertainty.

Adding the doctrine of equivalents into this analysis, as Lemley and Sherkow propose, would increase the ambiguity associated with an already uncertain test. The Supreme Court has acknowledged that under the doctrine of equivalents "it may be difficult to determine what is, or is not, an equivalent," and "competitors may be deterred from engaging in legitimate manufactures outside [the patent's] limits."[256]

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[252] Lemley & Sherkow, *supra* note 52, at 1059.
[253] Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40 (1997).
[254] Lemley & Sherkow, *supra* note 52, at 1059.
[255] M. Lewis, *Affinity Vs Avidity*, JACKSON IMMUNORESEARCH LABORATORIES INC. (Feb. 20, 2022), https://www.jacksonimmuno.com/secondary-antibody-resource/technical-tips/affinity-vs-avidity/.
[256] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722, 732 (2002).

Determining whether biologics like monoclonal antibodies infringe under the doctrine of equivalents could be especially difficult.[257] As D. Alan White explained.

> If applying the doctrine of equivalents to the example of changing a single nucleotide in a simple DNA sequence . . . makes for difficult academic analysis, one must sympathize with attorneys, judges, and juries that are forced to apply the doctrine to the complex panoply of nucleotide sequences, proteins, antibodies, engineered cell lines, vaccines, and viruses that constitute the current array of biologic pharmaceuticals.[258]

The risk to innovation is not theoretical. In *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, the Federal Circuit affirmed a finding of infringement under the doctrine of equivalents between processes for producing two distinct biologics for treating Mystery Swine Disease. Although both used monkey kidney cells, the accused product, Schering's VR2525 virus, was significantly different from Boehringer's older virus, VR2332; structurally, the two viruses differed by least seventy-three nucleotides; functionally, VR2332 was a pathogenic virus (meaning it made inoculated pigs sick) while VR2525 was not.[259] While the Federal Circuit found no *literal* infringement, it did find infringement under the doctrine of equivalents because "VR2525 plays the same role as VR2332 in performance of the claimed method [producing an attenuated virus]," (internal citations omitted).[260] [A]ny differences between the two [viral genomes] are insignificant."[261] *Boehringer* underscores how applying the doctrine of equivalents may threaten innovation. The plaintiff was awarded a broad class of viruses grown in a particular cell type, blocking the commercialization of products that were functionally distinct from its invention.

The potential for infringement could deter research and create challenges for biotech companies to finance antibody development. In such a world, established industry players may use means-plus-function claims to secure broad patents covering any useful antibody-antigen pairing. Nebulous in scope, these patents would effectively discourage the development of new alternative epitope therapeutics for known targets.[262]

E. The Normative Solution: Maintain the Status-quo Under *Amgen*

Means-plus-function antibody claims can exist, but they should not be immune

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[257] D. Alan White, *The Doctrine of Equivalents: Fairness and Uncertainty in an Era of Biologic Pharmaceuticals*, 60 EMORY L.J. 751, 751 (2011).

[258] *Id.* at 763.

[259] Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1351–52 (Fed. Cir. 2003).

[260] *Id.*

[261] *Id.* at 1352.

[262] Brief of Sir Gregory Paul Winter and Interested Scientists as Amici Curiae in Support of Respondents, Amgen Inc., et al., v. Sanofi, et al., 598 U.S. 594 (2023) (No. 21-757), 2023 WL 2167707, at *30.

from the substantive limits established in *Amgen*. Their equivalents should encompass no more than what they enable. If Xencor invented a means for achieving all its functional limitations and explained how to apply it to on a diverse set of structures, its patent should encompass a range of antibodies. However, that is not what Xencor has done. A patentee like Xencor, which uses a means-plus-function claim and enables one structure, should not be able to claim different structures merely because they work like the disclosed structure. That would allow patentees to use a procedural tool (means-plus-function claim language) to circumvent the substantive enablement requirement announced in *Amgen*: a patent must enable the scope of what it claims.

A patent claiming every antibody that binds to an antigen within functional limitations is similar to a patent claiming "all things that fly higher than 15,000 ft."[263] If the specification of the flying machine patent describes only zeppelins, it would be unreasonable to say the patent encompassed jetliners, helicopters, rockets, drones, satellites, and everything else that flies above 15,000 ft. For the same reason, a functional antibody patent should not encompass an antibody it does not describe or enable just because that antibody binds to the antigen mentioned in the claim.

This analogy extends to functional claims invoking 35 U.S.C. § 112 (f). While patent claiming "a means for flying higher than 15,000 ft" that discloses only zeppelins may not be so broad as to encompass jetliners, drones, and satellites, if evaluated without appropriate attention to enablement, it could encompass any means of flying that works *like* a zeppelin, such as blimps and hot air balloons. The flying machine patent would also include a helium-based flying car if someone invented one during prosecution because the equivalents of a means-plus-function claim are determined based on the date of issuance, not filing (the date from which enablement and written description are analyzed). Hot air balloons and zeppelins may be more alike than spaceships and zeppelins, but saying a zeppelin patent encompassed hot air balloons merely because it uses "means for" in the claims would still be overly broad.

Similarly, an antibody patent claiming a "means for binding to antigen A" that discloses only antibody X should not encompass antibody Y simply because X and Y work "substantially similarly." The inventor of antibody Y deserves their own patent unless they could use the specification disclosing antibody X to make antibody Y.

The analogy underscores why means-plus-function antibody claims must be held to the standards in *Amgen*. Under *Amgen*, a patent that describes zeppelins gets zeppelins, and a patent that describes an antibody X gets that antibody X. The words "means for" should not allow the same specification to cover a greater scope.

V. Conclusion

Xencor is attempting to turn back the clock on antibody patent law. It wants

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[263] *Id.* at 23.

dominion over a range of anti-C5 antibodies, yet its only provable invention is a two amino acid substitution that works on one antibody.

Xencor defends its application by arguing that it is using a means-plus-function format. It is true that means-plus-function claims encompass only the disclosed structure and its equivalents, but even with this limitation, Xencor's claim could still include many C5-complement antibodies, potentially every species that works in the same way as 5G1.1, including after-arising examples through the doctrine of equivalents.

Exactly how broad Xencor's claim would be is hard to predict. The Federal Circuit has applied inconsistent tests for statutory equivalence across its rulings, and the applicability of the doctrine of equivalents in this analysis is debatable. The loose and unpredictable relationship between an antibody's structure and function and the array of measurable properties that monoclonals have adds uncertainty. These patents may or may not encompass distinct alternative epitope antibodies. Regardless, their uncertain scope these patents would likely deter researchers and investors from attempting to develop them.

Xencor's patent Examiner and the Patent Trials and Appeals Board recognized the possibility that the scope of a means-plus-function antibody claim would be out of proportion with the specification. They accordingly rejected Claim 9 for lack of written description. Concerningly, the PTO through its Appeals Review Panel disagreed, indicating that a single representative structure may be enough to provide written description support for a means-plus-function antibody claim. If Xencor's claim passes *written description* muster, antibody patentees could use the phrase "means for" to broaden the scope of their patent without increasing their disclosure.

Fortunately, *Amgen* offers a solution. It protects innovation from the uncertainty and breadth of functional antibody claims by requiring that antibody patents *enable* the full scope their claims, freeing researchers to pursue alternative epitope antibodies. The patent system should prevent overly broad patents that threaten innovation and care by applying the substantive enablement standards from *Amgen* to means-plus-function antibody claims.