No. 21-757

IN THE

Supreme Court of the United States

AMGEN INC., *et al.*,

Petitioners,

v.

SANOFI, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* PFIZER INC. IN SUPPORT OF RESPONDENTS

DIMITRIOS T. DRIVAS
JOHN P. SCHEIBELER
AMIT H. THAKORE*
WHITE & CASE LLP
1221 Avenue of the Americas
New York, NY 10020
(212) 819-8200
athakore@whitecase.com

Counsel for Amicus Curiae Pfizer Inc.

* *Counsel of Record*

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(800) 274-3321 • (800) 359-6859

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INTEREST OF *AMICUS CURIAE*[1]

Pfizer Inc. is a global biopharmaceutical company that discovers, develops, and markets innovative medicines, including monoclonal antibodies. Monoclonal antibodies are effective drugs for many diseases and an important aspect of clinical research in numerous therapeutic areas under investigation by Pfizer and others. The patents at issue claim a broad genus of monoclonal antibodies not by any structural terms or amino acid sequence, but solely by reference to their function of binding to a broadly defined target and the resulting effect of such binding. The claims encompass millions of antibodies having no identifiable common structural features. While genus patent claims are important for the life sciences industry, patent claims that define a genus of molecules solely by reference to functional characteristics threaten innovation and preempt future development and commercialization of novel therapeutics. The enablement requirement set forth in Section 112 of the Patent Act protects against overbroad functional claims that are not commensurate with the inventors' contribution to the field.

SUMMARY OF ARGUMENT

Amgen's U.S. Patent Nos. 8,829,165 and 8,859,741 are directed to monoclonal antibodies for use in treating hypercholesterolemia. The antibodies bind to the naturally-occurring protein PCSK9 and block it from binding to

1. No counsel for a party authored this brief in whole or part, and no person other than the *amicus curiae* and its counsel made any monetary contribution to this brief's preparation and submission.

the LDL receptor, thus affecting the levels of LDL in a patient. This was no pioneering invention. PCSK9 was known, its effect on LDL levels and its binding to the LDL receptor were known, and a number of pharmaceutical companies in addition to Amgen, such as Pfizer and the Respondents, Sanofi and Regeneron, were conducting independent, contemporaneous clinical research on anti-PCSK9 antibodies to treat hypercholesterolemia. Amgen's patents are an attempt to monopolize that highly competitive therapeutic market.

As the Federal Circuit observed below, "each appealed claim in this case is a composition claim defined, not by structure, but by meeting functional limitations." Pet. App. 12a. The first functional limitation concerns the region on PCSK9 to which the antibodies may bind. The region is not precisely defined in the claims; instead, only select amino acid residues in the region are listed. The claimed antibodies must bind to "at least one" or "at least two" of the listed residues. The second functional limitation is that when the antibody binds to PCSK9, it must block the binding of PCSK9 to the LDL receptor. The claims do not otherwise define the antibody in any structural terms and are not limited to the specific monoclonal antibodies the Amgen inventors made and disclosed in their patents. Such claims encompass an enormous genus of indeterminate scope and preempt future research and development far beyond the inventors' contribution. They do not comply with the statutory requirements of 35 U.S.C. § 112 and fail either alternative test for enablement set forth in the Question Presented.

In considering enablement, the Federal Circuit applied the factors set forth in its longstanding precedent, *In re*

Wands, 858 F.2d 731 (Fed. Cir. 1988). The Federal Circuit held that in an unpredictable field such as therapeutic antibodies, "it is important to consider the quantity of experimentation that would be required to make and use, not only the limited number of embodiments that the patent discloses, but also the full scope of the claim." Pet. App. 11a. This was not a "new" test for enablement. The Federal Circuit, in applying *Wands*, properly considered the overreaching broad scope of the purely functional claims that Amgen chose to define the "invention," and the comparatively limited number of examples and guidance in the patent specification. Pet. App. 14a. Thus, it is the undue breadth of the claims and the exclusive rights they seek to encompass, rather than a heightened standard for enablement of genus claims, which led the district court and the Federal Circuit to conclude that the claims are invalid as a matter of law.

The issue here is not the test that was applied. It is instead the overbroad, functionally-defined patent claims that are not commensurate with the inventors' contribution to the art. The analysis by the Federal Circuit adheres to the statutory requirements of 35 U.S.C. § 112. The Court should either dismiss this petition as improvidently granted or affirm the Federal Circuit.

ARGUMENT

I. THE ENABLEMENT REQUIREMENT PLAYS A CRITICAL ROLE IN THE PATENT SYSTEM

Pfizer and other research-based pharmaceutical companies rely on meaningful patent protection to help recoup the significant investment required to develop

new innovative medicines. Patents prevent copies of the innovator's drug from entering the market during the patent's term. However, patents like those at issue in this case with purely functional claims that are not commensurate with the patent's disclosure are not intended to merely prevent "copies." They are an unwarranted attempt to exclude competition. Such patents threaten the development of, and patient access to, promising new therapeutics in violation of the patent laws.

A. Section 112 of the Patent Act Establishes a Patent Bargain

Section 112(a) of the Patent Act sets forth the requirements for a patent specification: (i) it must contain a "written description of the invention," and (ii) it must describe "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." 35 U.S.C. § 112(a). Both "it" and "the same" refer to "the invention," which is defined by the patent's claims. 35 U.S.C. § 112(b). These requirements ensure that, in exchange for receiving a patent and the right to exclude others from practicing the invention, patentees disclose their invention to the public so that others in the field can make and use the invention defined by the claims, or improve upon it to make new inventions that can benefit the public. This "carefully crafted bargain" is at the heart of the U.S. patent system. *Pfaff v. Wells Elecs. Inc.*, 525 U.S. 55, 63 (1998); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989).

Section 112(a) strikes a delicate balance between rewarding innovators with patent rights and requiring inventors to fully disclose their invention to the public. The scope of the patent claims and the right to exclude others must be commensurate with the enabling disclosure in the patent specification. *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). Amgen agrees that patent claims must not "truly exceed what the patent enables." Pet. Br. at 21, 45. The enablement requirement therefore plays a critical role in preserving the patent bargain by requiring patentees to describe how to make and use "the invention" in "full, clear, concise, and exact terms." 35 U.S.C. § 112(a). When the claims of a patent extend too far beyond the inventors' actual invention and contribution to the field, the patent system is undermined.

B. Amgen's Purely Functional Antibody Claims Violate the Patent Bargain

Amgen did not hold up its end of the patent bargain. The patents at issue concern antibodies that bind to PCSK9, a naturally-occurring protein that was known to affect LDL cholesterol levels. Pet. Br. at 7. Amgen did not discover PCSK9; its amino acid sequence and three-dimensional structure were known before the January 2008 priority date of Amgen's patents. Nor did Amgen discover PCSK9's biological activity. Independent researchers had shown that certain mutations in PCSK9 interfered with its binding to the LDL receptor (LDLR), and that increasing PCSK9 levels decreases LDLR levels in the liver and consequently causes LDL cholesterol levels to rise. *See* C.A. App. 198 (U.S. Patent No. 8,829,165). The prior art had even suggested investigating antibodies that block the interaction between PCSK9 and LDLR as potential

therapeutics in the treatment of hypercholesterolemia.[2] As a result, numerous pharmaceutical companies, including Pfizer, were independently researching antibodies that could bind to PCSK9 and block its activity, long before the Amgen patents issued. In short, Amgen did not discover PCSK9, its sequence, or its function, nor teach the world that it was a therapeutic target for monoclonal antibodies.

What Amgen accomplished was to make a small number of antibodies that bound to PCSK9 and interfered with its interaction with LDLR. Amgen's patents disclose two antibodies in particular (21B12 and 31H4) that bind to particular amino acid residues on PCSK9 and block PCSK9 from binding to LDLR. The patents disclose the amino acid sequences of these two antibodies and a limited number of additional anti-PCSK9 antibodies made by the inventors (26 in total), and the conventional methods used to produce, screen, and test them. But the patents at issue do not claim those specific antibodies, or antibodies having a similar sequence or structure. Instead, they claim any and all monoclonal antibodies that exhibit two functions: (i) binding to at least one identified amino acid residue (at least two residues in some claims) within what Amgen now refers to as the "sweet spot" on PCSK9; and (ii) blocking PCSK9 from binding to LDLR.[3] In other

2. *See, e.g.*, Thomas A. Lagace et al., *Secreted PCSK9 decreases the number of LDL receptors in hepatocytes and in livers of parabiotic mice*, 116 J. Clinical Investigation 2995, 2995-3005 (2006).

3. Two of the asserted claims recite fifteen amino acid residues on PCSK9 and require binding to "at least two" of these residues, while the remaining asserted claim requires binding to at least one of two specified residues on PCSK9.

words, they claim the antibodies by what was every competitor's research goals at the time. As the district court found, the claims encompass an indeterminate number of possible antibodies, in the millions, with diverse structures and sequences that may bind to an unknown number of different targets, far beyond those actually disclosed in the patent.[4] Pet. App. 34a.

The binding and blocking functions recited in the claims invite undue experimentation by skilled artisans attempting to "make and use" the invention. For example, even if an antibody meets the first function of binding to "at least one" or "at least two" of the amino acid residues identified in the claims, this does not conclude the inquiry. The skilled artisan would then need to determine whether such an antibody meets the second function of blocking PCSK9 from binding to LDLR. There is no way to reasonably predict, based on the claims or the disclosure in the specification, whether a particular antibody *not disclosed* in the patents would exhibit both functional limitations of the claims. The skilled artisan can ascertain this only by making the antibody and then testing it. *See* Pet. App. 14a. This is the epitome of undue experimentation.

Notably, Amgen's lead inventor testified that an antibody that interacted with only one amino acid residue on PCSK9 "wouldn't have the binding strength" to meet the other functional limitation of blocking PCSK9's binding

4. Since the claims only require binding to at least one or at least two listed amino acid residues, they encompass an indeterminate number of possible binding targets (i.e., combination of specific residues) on PCSK9 that are different than the targets to which the disclosed antibodies bind.

to LDLR. C.A. App. 3806(540:19-21). A skilled artisan attempting to "make and use" the claimed invention based on the patent disclosure could make countless antibodies that do not satisfy both of the functions recited in the claims, leading to endless experimentation to identify antibodies that "work."

Amgen's identification of the amino acid residues on PCSK9 to which two antibodies (21B12 and 31H4) bind provides no insight into what sequence or structure any undisclosed antibody must possess, in order to meet the purely functional limitations of the claims. As Amgen's expert, Dr. Rees, admitted, predicting antibody function and three-dimensional structure from an antibody's amino acid sequence (and vice versa) is "not possible," and discovering how to make such predictions will "get a Nobel Prize." C.A. App. 3910 (765:10-19). Even now, more than a decade after Amgen filed its patent application, it is impossible to predict with certainty any precise correlation between antibody sequence and function. That day may come, but it has not yet arrived.

The patented invention is defined by what is claimed. Amgen previously obtained patents covering the specific monoclonal antibodies it made by claiming their known disclosed structures and amino acid sequences (*see, e.g.*, U.S. Patent Nos. 8,030,457 and 8,062,640). Those patents, which protect against "copies," are not at issue here. Amgen gambled that it could obtain additional patents covering a broad genus of antibodies using purely functional claims to assert against other innovators. The claims amount to a land grab attempt for an undeserving monopoly. Such functional claims are inherently vulnerable under the enablement requirement, and rightly

so, because they capture more than what the inventors actually invented and contributed to the public knowledge and state of the art. The claims, if valid, would give Amgen the right to exclude others from making and using any monoclonal antibody that meets the two claimed functions, irrespective of its isotype, structure, amino acid sequence, or superior efficacy. The enablement requirement provides a safeguard against such over-reaching claims and preserves the delicate balance created by the Patent Act.

C. Amgen's Patents Preempt Future Research and Innovation

Purely functional genus claims to therapeutic molecules based on a limited, narrow disclosure not only violate the patent bargain but also preempt future innovation. After securing claims that covered the specific antibody species disclosed in their specification, Amgen continued to prosecute and obtain the claims at issue in an effort to capture any and every anti-PCSK9 antibody that a competitor might develop in the future. Praluent® is one such antibody that was discovered by Respondents, Sanofi and Regeneron, and eventually brought to market in 2015. Pfizer was also investigating its own anti-PCSK9 antibody (bococizumab), but discontinued its clinical development in 2016. Contrary to Amgen's assertion, these anti-PCSK9 antibodies were independently invented without the benefit of Amgen's patents.[5] Unlike a generic

5. For example, bococizumab was discovered by Pfizer in 2008—several years before the patents at issue were granted. Pfizer continued to develop bococizumab for several years thereafter until Phase III clinical trials were ultimately discontinued in 2016.

or biosimilar drug, these anti-PCSK9 antibodies possess unique amino acid sequences not disclosed in Amgen's patents and bind to different residues on PCSK9 than Amgen's disclosed antibodies. *See* Resp. Br. at 15. Yet, they inevitably fall within the broad scope of the claims because they perform the claimed "double-function" of binding to PCSK9 at one or more of the specified residues and blocking PCSK9 from binding to LDLR. Pet. App. 12a. Amgen's purely functional claims serve no purpose other than to block competitors and "preempt the future before it has arrived." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010).

The Court has cautioned against the danger that certain patents may pose in preempting future research in therapeutics. The Court's decision in *Assn. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), is instructive. In that case, the Court was confronted with the issue of whether Myriad's discovery of the exact location and sequence of the BRCA1 and BRCA2 genes was patentable under 35 U.S.C. § 101. The Court remarked:

> "It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad's principle contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13."

Id. at 590. Distinguishing *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the Court concluded "[i]n this case, by contrast, Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention." *Id.* at 591.

Here, Amgen did not discover or characterize the naturally occurring PCSK9 protein, nor did they "create or alter" the binding site on PCSK9 which binds LDLR. At most, Amgen made a limited number of antibodies that bind to PCSK9 and block binding of PCSK9 to LDLR. The interaction between PCSK9 and LDLR "existed in nature," *id.* at 590, as did the "sweet spot" on PCSK9. Accordingly, Amgen could not obtain a patent claiming the "sweet spot" or the particular amino acid residues on PCSK9 responsible for binding LDLR. Instead, they claimed monoclonal antibodies that bind to "at least one" or "at least two" of these amino acid residues. While such claims may not violate Section 101's prohibition against claiming laws of nature and natural phenomena, because they nominally claim man-made monoclonal antibodies, in reality they are just another way of preempting research and development based on patent claims covering all monoclonal antibody therapeutics that target a known, naturally-occurring protein and block its known biological activity. Patentees should not be permitted to circumvent the patent laws in such a manner by functionally claiming a genus far broader than the inventors' contribution. Such functional claims "inhibit further discovery by improperly tying up the future use of laws of nature." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 69 (2012).

The enablement requirement plays a critical role in maintaining the delicate balance between rewarding innovation and ensuring that patents do not improperly claim more than what the inventors discovered and disclosed to the public. Patents such as those at issue here disrupt this "carefully crafted bargain" and preempt future innovation and discovery.

II. THE FEDERAL CIRCUIT'S TEST COMPLIES WITH THE STATUTE AND FURTHERS THE GOALS OF THE PATENT SYSTEM

The Federal Circuit determined that Amgen's functionally defined antibody claims are invalid because "the specification here did not enable the preparation of the full scope of these double-function claims without undue experimentation." Pet. App. 12a. In reaching this conclusion, the Federal Circuit panel noted that "[w]hile functional claim limitations are not necessarily precluded in claims that meet the enablement requirement, such limitations pose high hurdles in fulfilling the enablement requirement for claims with broad functional language." *Id*. The Federal Circuit's analysis comports with the statute and its purpose. Broad functional claims such as those at issue here necessarily "pose high hurdles" and "raise the bar" for enablement and must be scrutinized carefully to ensure that the inventors have provided a commensurate disclosure justifying their breadth. The district court and the Federal Circuit correctly found the claims in this case invalid as a matter of law.

A. The Specification Must Enable the Invention Defined by the Claims

Amgen argues that the Federal Circuit's enablement test finds no support in the statute because all that is required to satisfy enablement is that the specification teach the skilled artisan to "make and use" the invention. Pet. Br. at 22. However, the plain language of Section 112(a) requires that the specification describe and enable "*the invention*" in "full, clear, concise, and exact terms." 35 U.S.C. § 112(a). Accordingly, where the claimed "invention" is a broad, functionally defined genus of indeterminate scope, the patent specification must enable the skilled artisan to "make and use" that genus. The Federal Circuit's test is therefore entirely consistent with the statute. Contrary to Amgen's argument, it does not improperly "raise the bar" or create a "distinct test" for genus claims, as suggested in the Question Presented and as Amgen argues in its brief. *See, e.g.*, Pet. Br. at 25, 41. Rather, it ensures that inventors provide an "enabling disclosure . . . commensurate in scope with the claim under consideration." *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983). Requiring anything less would improperly *lower* the bar for enablement of functionally-defined genus claims.

Pfizer agrees with *amici* who contend that genus claims for truly "pioneering" inventions are important to the life sciences industry. *See, e.g.,* Brief of AbbVie Inc. as *Amicus Curiae* in Support of Petitioners at 1. However, Pfizer does not agree that the Federal Circuit formulated a "distinct" test for enablement of a genus claim specific to biologic inventions that is different from the test in other areas such as chemical drugs. Pioneering

or not, all claimed inventions must meet the statutory standard. The test applied by the Federal Circuit follows longstanding precedent and complies with the statutory requirement that the specification must describe how to make and use the claimed "invention" in "full, clear, concise and exact terms" so as to enable a person of skill in the art to practice the invention. 35 U.S.C. § 112(a); *see also* Resp. Br. at 4-6. Amgen's disclosure fails on each of these standards embodied in the statutory text: it is not full, clear, concise, or exact with regard to enablement of the claimed invention. As noted by the district court and the Federal Circuit, Amgen's disclosure, which it terms a "roadmap," is really just a "research plan," namely, make antibodies however you please, and then test them. Pet. App. 14a, 40a. The Federal Circuit properly found that it would require undue experimentation to prepare the full scope of monoclonal antibodies covered by Amgen's "double-function" genus claims. Pet. App. 12a.

B. The Federal Circuit's Enablement Analysis Was Correct

Amgen and its *amici*[6] complain that the Federal Circuit "turned enablement into a numbers game" by looking at the time and effort needed to reach "every (or nearly every) embodiment within the claim." Pet. Br. at 26, 28. This argument misses the mark. The claims here provide no sequence or structural limitations whatsoever for the claimed antibody and are of enormous breadth. Indeed, monoclonal antibodies of any kind, whether

6. *See, e.g.*, Brief of Diversified Researchers and Innovators in Support of Petitioners at 5 (arguing that Federal Circuit's decision "turns enablement into a counting exercise").

human, non-human, chimeric, etc. are all covered by the claims. The patent specification makes clear that the monoclonal antibodies covered by the claims can be of any one of the five functionally different, primary classes of antibodies (IgG, IgM, IgA, IgD, and IgE). Such antibodies have different shapes, sequences, and gross molecular structures, and consequently different activities and functions in different tissues in the body that would also affect how they could be used as therapeutic drugs:

> In humans, the IgA and IgD isotypes contain four heavy chains and four light chains; the IgG and IgE isotypes contain two heavy chains and two light chains; and the IgM isotype contains five heavy chains and five light chains . . . *The antibodies that are provided can have any of these isotypes and subtypes.*

C.A. App. 214-215 (U.S. Patent No. 8,829,165) (emphasis added). The monoclonal antibodies exemplified in the patent, however, belong exclusively to the IgG class. There is no disclosure of how to develop, produce, or identify an antibody of one of the other classes. Furthermore, as the Federal Circuit observed, the epitopes or binding sites to which Amgen's antibodies bind are a small subset of the broad range of possible binding sites on PCSK9 encompassed by the claims, since they require binding to only one or two listed amino acid residues on PCSK9. Pet. App. 13a. In view of the enormous breadth of the claims, and the comparatively limited number of examples and guidance provided in the patent's specification, the Federal Circuit properly considered the quantity of experimentation that would be required to make and use the "full scope" of the claimed genus. Pet. App. 11a.

The Federal Circuit's analysis is consistent with the approach outlined in its seminal decision in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Indeed, one of the factors for enablement identified in *Wands* is the breadth of the claims. *Id.* at 737. As Judge Newman pointed out concurring in part and dissenting in part with the majority in *Wands*, "the claims must be commensurate with the inventor's contribution," *id.* at 741, and it is "incumbent" on the patentee to "provide reasonable support for the proposed breadth of the claims," such that the results disclosed in the patent are "reasonably predictable within the scope of the claimed generic invention based on experiment and/or scientific theory." *Id.* at 742. The patents at issue provide no experiments or scientific theory to enable, for example, the claimed monoclonal antibodies of IgM, IgA, IgD, and IgE isotypes, or their utility as therapeutics. There is also no direction in the specification regarding antibody mutations that could be predicted to preserve the double function of the claimed antibodies. Pet. App. 14a. The Federal Circuit's *Wands* framework allows courts to account for such factual considerations in evaluating enablement.

The district court and the Federal Circuit also found that the invention is in an unpredictable field, another factor to be considered under *Wands*. Pet. App. 38a, 13a. The district court noted that the only ways for a person of ordinary skill to discover undisclosed claimed embodiments would be either through trial and error or by discovering the antibodies *de novo*. Pet. App. 41a. In affirming the district court, the Federal Circuit followed *Wands* and similarly concluded there was no evidence that the "full scope of the broad claims can predictably be generated by the described methods." Pet. App. 13a.

Amgen does not appear to challenge any of these findings and instead argues that it need only disclose how to make "individual embodiments *as needed*." Pet. Br. at 21 (emphasis in original). Such an unsupported interpretation of the statute would overturn decades of precedent and allow Amgen and others to preempt an entire field of research by essentially claiming "anything that works," while contributing little-to-nothing to advance the state of the art or improve one's ability to identify undisclosed embodiments that may differ significantly in structure or amino acid sequence, but function in a similar manner.

Contrary to Amgen's suggestion throughout its brief, the Federal Circuit did *not* find the claims at issue invalid merely because the specification did not disclose each and every "variation" of the disclosed antibodies, no matter how "cumulative" or trivial. *See, e.g.,* Pet. Br. at 2-3, 28-29.[7] As noted above, the claimed genus encompasses an unknown and indeterminate number of antibodies having different structural and functional characteristics. The specification, however, does not come close to disclosing antibodies representative of the potential breadth and diversity of the genus—let alone "variants" of the antibodies that are disclosed. Indeed, as the Federal Circuit noted, focusing on another deficiency in the patent, "the claims are far broader in functional diversity than the disclosed examples," as evidenced by the fact that *none* of the examples bind to three of the amino acid residues recited in the claims, or to more than nine of the

7. *See also* Brief of *Amicus Curiae* GSK PLC in Support of Petitioners at 7 (arguing that under the "full scope" test, the inventor must teach how to "*cumulatively* produce *all* the variants of her invention, to obtain a meaningful genus claim.") (emphasis in original).

fifteen listed residues. Pet. App. 13a. Such undisclosed embodiments are not mere "variants" of the disclosed antibodies—they are altogether different antibodies with different amino acid sequences, structures, and binding properties. Amgen's concerns regarding the "cumulative effort necessary to identify and make all or nearly all variations within the genus" (Pet. Br. at 26-27) distorts the Federal Circuit's holding and deflects the focus away from the enormous gap between the disclosure in the specification and the breadth of the purely functional claims.

Similarly, Amgen's assertion (echoed by several *amici*)[8] that the Federal Circuit's test "discourages breakthrough innovations by cutting off patent protection" for inventions that have "too many useful applications" dramatically overstates Amgen's actual invention and contribution to the field and ignores the fundamental problem with the claims at issue. Pet. Br. at 20. It is not that the claims have "too many useful applications." Rather, Amgen attempts to gain patent protection over every antibody, no matter how different in structure or sequence, that achieves the same applications, while

8. *See, e.g.,* Brief of AbbVie Inc. as *Amicus Curiae* in Support of Petitioners at 3 ("The 'full scope' test destroys the basic 'bargain' of patent law, because it does not give pioneering inventors adequate range of patent protection for breakthrough inventions with broad applicability"); Brief of *Amicus Curiae* GSK PLC in Support of Petitioners at 2 ("Without the ability to secure patent protection over a genus . . . a pioneer might be less likely to invest in discovery because disclosure of her full discovery would unfairly enrich mere copyists…); Brief of Diversified Researchers and Innovators in Support of Petitioners at 7 ("Potential breakthrough technologies risk wasting away on the shelf…").

having disclosed only a limited number of embodiments produced using conventional methods that bring the skilled artisan no closer to undisclosed species than trial-and-error research. *See* Pet. App. 39a, 14a. The Federal Circuit's test preserves the patent "bargain" and encourages, rather than discourages, competition and innovation. Amgen and its *amici*'s arguments to the contrary greatly exaggerate the impact of the Federal Circuit's enablement holding on the continued investment in research and development of novel therapeutics by Pfizer and other innovators. Striking down Amgen's claims has had, and will have, no effect at all on innovation in the life sciences.

Pfizer does not object to an innovator obtaining broad claims for genuine "breakthrough" inventions that satisfy the statutory requirements and are based on a disclosure that is commensurate in scope with the claims. However, the claims at issue are not commensurate with the inventors' contribution. They are a naked attempt to preempt future innovation and an unwarranted extension of the patent monopoly. *See Consol. Elec. Light Co. v. McKeesport Light Co.*, 159 U.S. 465, 476 (1895) ("to hold that one, who had discovered that a certain fibrous or textile material answered the required purpose, should obtain the right to exclude everybody from the whole domain of fibrous and textile materials, and thereby shut out any further efforts to discover a better specimen of that class than the patentee had employed, would be unwarranted extension of his monopoly, and operate rather to discourage than to promote invention"). The enablement requirement must be applied in a manner that ensures that patent claims do not exceed the inventors' actual invention and contribution to the field. The Federal Circuit's decision and reasoning achieves this goal.

CONCLUSION

The issue here is not the test for enablement for a broad genus claim. It is instead the purely functional language that Amgen chose to define the claimed genus. Amgen's claims should fail under any test for enablement. The Court should dismiss this petition as improvidently granted or alternatively affirm the Federal Circuit's judgment.

Respectfully submitted,

DIMITRIOS T. DRIVAS
JOHN P. SCHEIBELER
AMIT H. THAKORE*
WHITE & CASE LLP
1221 Avenue of the Americas
New York, NY 10020
(212) 819-8200
athakore@whitecase.com

Counsel for Amicus Curiae Pfizer Inc.

* *Counsel of Record*

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