No. 24-2325

IN THE
United States Court of Appeals for the Federal Circuit

WYETH LLC,

Plaintiff-Appellant,

v.

ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA AB,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Delaware
No. 1:21-cv-01338-MFK, Hon. Matthew F. Kennelly

BRIEF OF REGENERON PHARMACEUTICALS, INC. AND SANOFI-AVENTIS U.S. LLC AS AMICI CURIAE IN SUPPORT OF APPELLEES

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 24-2325

Short Case Caption Wyeth LLC v. AstraZeneca Pharmaceuticals LP

Filing Party/Entity Regeneron Pharmaceuticals, Inc.; Sanofi-Aventis U.S. LLC

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Date: 03/20/2025

Signature: /s/ Irena Royzman

Name: Irena Royzman

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Regeneron Pharmaceuticals, Inc.		None
Sanofi-Aventis U.S. LLC		Sanofi

☐ Additional pages attached

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

☑ None/Not Applicable ☐ Additional pages attached

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

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

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☑ None/Not Applicable ☐ Additional pages attached

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STATEMENT OF INTEREST[1]

Amici curiae Regeneron Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC are leading innovators in the biopharmaceutical industry. They discover, develop, and commercialize medicines to treat patients facing challenging, complex, and often life-threatening illnesses. At various times, they are both plaintiffs and defendants in patent disputes. And they rely on both the disclosure of inventions and the protection provided by the patent system to support their businesses.

The written description and enablement requirements are critical to maintaining the patent system. They ensure that an applicant cannot claim (and thus exclude others from working with) subject matter the applicant did not actually invent. Allowing an applicant to exclude other companies from broad areas of scientific endeavor using functional genus claims without providing a commensurate description and enabling disclosure in the specification undermines the quid pro quo that underlies the patent system.

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[1] No party's counsel authored this brief in whole or in part. No party, party's counsel, or any person other than amici or their counsel contributed money intended to fund preparing or submitting this brief.

Amici therefore request that the Court clarify that a disclosure such as that at issue in this case falls far short of what is required to support broad functional genus claims.

INTRODUCTION

The patent system is founded on the premise that in exchange for a limited term monopoly, innovators will disclose their discoveries to the public. In furtherance of that exchange, the Patent Act imposes two significant disclosure obligations: (1) patents must "contain a written description of the invention" (the written description requirement); and (2) patents must disclose "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person of skill in the art … to make and use the same" (the enablement requirement). 35 U.S.C. § 112(a).

Both the Supreme Court and this Court have cautioned that broad genus claims, especially when functionally defined, pose a heightened risk of violating the written description and enablement requirements. *See Amgen Inc. v. Sanofi*, 598 U.S. 594, 613 (2023) ("[Patentee] seeks to monopolize an entire class of things defined by their function.… That poses … a challenge.… [T]he more a party claims, the broader the

monopoly it demands, the more it must enable."); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1345, 1349 (Fed. Cir. 2010) (en banc) ("The [written-description] problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus.").

The claims at issue in this case are broad, functionally-defined genus claims. They purport to cover a category of molecule with an enormous number of members defined *only* by what they *do*. Against these broad claims, the specification provides only three examples—all of which use similar structural elements (which Wyeth said were not required and which are not found in the accused product) and fail to satisfy the claims. And nothing in the specification provides *guidance* that would allow a person of ordinary skill in the art (POSA) to recognize or identify the members of the claimed genus without extensive trial-and-error experimentation. Put simply, there is *nothing* in the specification to suggest that the applicant was in possession of the *full scope* of what it claimed or that a POSA armed with the specification could readily make and use the full scope of that alleged invention.

The Court should, therefore, affirm the district court's decision on the additional ground that the Wyeth patents lack written description and enabling support for their claims to a broad, functionally-defined genus—namely, claims covering any compound, regardless of structure, that irreversibly inhibits epidermal growth factor receptor (EGFR), binds to a particular protein structure, and can be used to treat certain kinds of cancer via daily administration.

ARGUMENT

I. Wyeth's Overbroad Functional Genus Claims Are Invalid Under § 112.

Both written description and enablement serve critical roles in ensuring the patent system's basic "*quid pro quo*"—namely, that in return for a limited monopoly, the public receives a fulsome disclosure of the invention. *Ariad*, 598 F.3d at 1345; *see also Amgen*, 598 U.S. at 604 ("In exchange for bringing 'new designs and technologies into the public domain through disclosure,' so they may benefit all, an inventor receives a limited term of 'protection from competitive exploitation.'" (citation omitted)).

A. Wyeth's patent claims lack written description.

As this Court has explained: "A description of the claimed invention allows the United States Patent and Trademark Office … to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights." *Ariad*, 598 F.3d at 1345.

As a result, to fulfill the written description requirement, a patent must provide a robust disclosure of the claimed invention. Indeed, this Court has repeatedly made clear "that an adequate written description of a claimed genus claim requires more than a generic statement of the invention's boundaries"—especially in the biopharmaceutical field, which is notoriously unpredictable. *Id.* at 1349; *see AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301 (Fed. Cir. 2014) ("Functionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and

function for the whole genus or to predict what would be covered by the functionally claimed genus.").

For example, in *Regents of the University of California v. Eli Lilly & Co.*, this Court held that claims which "*generically*" claimed recombinant DNA plasmids that encode insulin were invalid for lack of written description where the patent described only "one species of [the claimed] genus." 119 F.3d 1559, 1567-68 (Fed. Cir. 1997). Likewise, in *Ariad*, this Court held that genus claims may "distinguish the genus from other materials in any way except by function" and that it is not enough to "provide[] 'only a definition of a useful result rather than a definition of what achieves that result.'" 598 F.3d at 1350 (quoting *Eli Lilly*, 119 F.3d at 1568). Accordingly, "a sufficient description of a genus" generally "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." *Id.* (citation omitted).

The patents here are directed to methods for treating "gefitinib and/or erlotinib resistant cancer" using "an irreversible epidermal

growth factor receptor (EGFR) inhibitor." U.S. Patent No. 10,603,314, abstract; *accord* U.S. Patent No. 10,596,162, abstract. The patents' claims are directed to a broad functional genus: They recite "[a] method for treating gefitinib and/or erlotinib resistant non-small cell lung cancer" by "administering daily to the patient … a pharmaceutical composition comprising a unit dosage of an irreversible epidermal growth factor receptor (EGFR) inhibitor that covalently binds to" a particular protein residue on EGFR. '314 patent, claim 1; *accord* '162 patent, claim 1 (claiming the same method, applied to treat "gefitinib and/or erlotinib resistant non-small cell lung cancer having a T790M mutation").

In other words, the patents claim using ***any*** compound that (i) has the ***function*** of irreversibly inhibiting EGFR, (ii) has the ***function*** of covalently binding to a particular protein residue, (iii) has the ***function*** of treating certain kinds of cancer, and (iv) can ***functionally*** be administered to a patient on a daily basis. Thus, the claims at issue here are *expressly* and *explicitly* defined by their functions. They are functional genius claims.

The genus is also both broad and unbounded. AstraZeneca and its expert contended that the genus contains "a vast universe of chemical compounds of varying structures—literally *hundreds of billions*" of possible members that may meet the claims' functional requirements. *See, e.g.*, AstraZeneca's Mot. for Judgment as a Matter of Law, *Wyeth LLC v. AstraZeneca Pharms. LP*, No. 1:21-cv-01338-MFK (D. Del. May 17, 2024), Dkt. 448 at 6. Wyeth disputed the breadth of the genus, but that dispute revealed that no one even *knows* all the members of the genus—indeed, one *cannot* know all the compounds that might eventually be found to satisfy the claims' functional requirements. *See also* AstraZeneca's Response Br. ("RB") at 17-28 (discussing trial evidence); *accord id.* at 53-54.

In contrast to this sweeping claim scope, the disclosure in the patents is narrow. As the patents recognize, identifying an appropriate irreversible EGFR inhibitor is highly unpredictable, and gefitinib and/or erlotinib resistant non-small cell lung cancer is difficult to treat. *See* '314 patent, 3:19-39; *accord* '162 patent, 3:24-44. But the patents provide only three exemplary compounds for use as an irreversible EGFR inhibitor to treat the relevant cancer. *See* '314 patent, abstract

("EKB-569, HKI-272, HKI-357"); *accord* '162 patent, abstract. All three have the same cyanoquinoline scaffold, a chlorine on the aniline ring, and the same Michael acceptor warhead, as illustrated below:

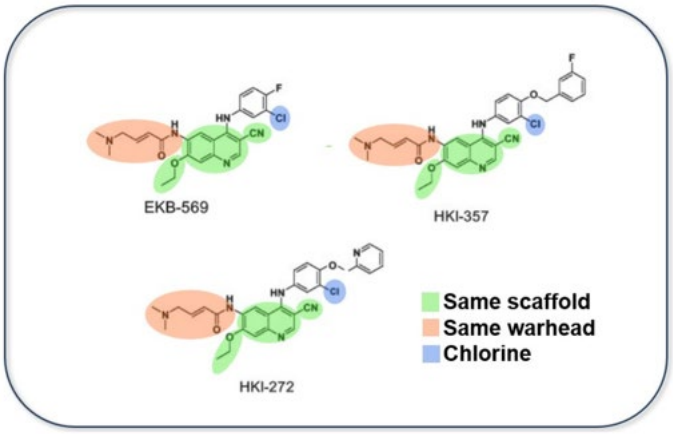

Figure 1. The three compounds disclosed in the Wyeth patents.

But Wyeth took the position that *none* of these structural elements were necessary to or limitations on the scope of the genus. Indeed, Wyeth *had* to take that position because, as illustrated below, the accused product does not contain ***any*** of those features.

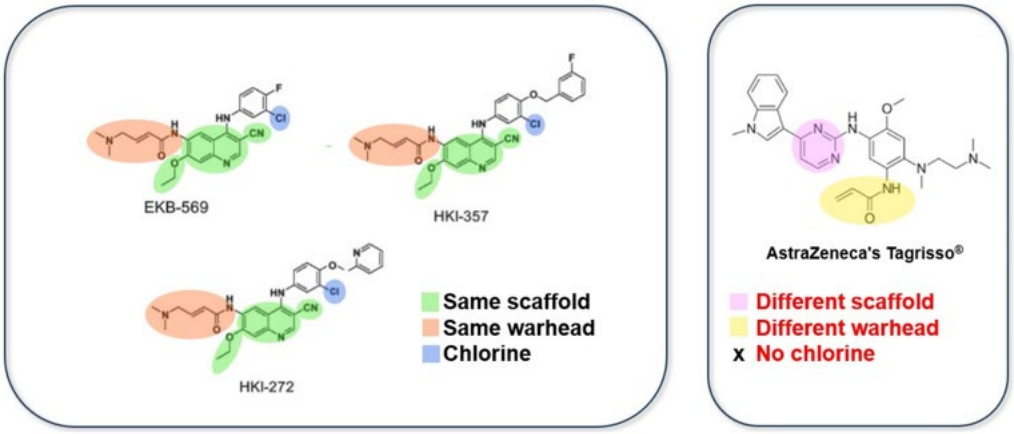

Figure 2. Comparison between disclosed and accused compounds.

In and of itself, this should be sufficient to strike down the patents. Wyeth is asserting a claim covering a method of using *any compound* that satisfies certain functional requirements, while simultaneously arguing that the structural elements of the three disclosed embodiments are irrelevant to written description and enablement because they do not give any information that would allow a POSA to recognize or identify all other members of the genus. Because Wyeth is *literally* asserting that its only examples do not provide guidance—and there is no other guidance in the patents—the inventors did not and could not possess the full scope of the genus they sought to claim. *See Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1337 (Fed. Cir. 2021) (affirming that a patent was invalid for lack of written description where the "patent provide[d] nothing to indicate that the inventors possessed the full scope of the genus that they chose to claim.").

Put differently, the patents' specifications here do not provide enough information to allow a POSA to "visualize or recognize" the entire claimed genus. *Ariad*, 598 F.3d at 1349-50 (citation omitted). And "whether a compound is claimed *per se* or a method is claimed that

entails the use of the compound [as here], the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods." *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004). The Wyeth patents do no more than "draw[] a fence around the outer limits of a purported genus," *Ariad*, 598 F.3d at 1350, based on just three examples, all of which involve the same (allegedly irrelevant) structural elements and all of which we *know* do not even satisfy the claims, *see* Appx59-61 (JMOL decision); *see also* RB 2-3, 7-8, 14-15, 60-61.

The Court should also note that the U.S. Patent and Trademark Office (PTO) has now agreed that the claims lack written description. Wyeth filed a continuation application (U.S. App. No. 17/820,519) claiming a narrower genus of irreversible EGFR inhibitors. The PTO rejected those claims for lack of written description, noting: "[T]he disclosure [of] EKB-569, HKI-272, and HKI-357 which all have chloride moieties [] at position 3 of the aniline group and bind to … EGFR fails to provide adequate support for the broader genus of irreversible EGFR

inhibitors … because the genus includes a myriad compounds that are distinct in structure from the disclosed … compounds and the three species are insufficient to describe the newly claimed genus of irreversible EGFR inhibitors." Final Office Action Summary at 12 (Dec. 10, 2024).

This Court should affirm that the patent claims are invalid for lack of written description.

B. Wyeth's patent claims lack enablement.

Since the 1790 version of the Patent Act, Congress has required that a patent's specification "enable a workman or other person skilled in the art or manufacture … to make, construct, or use" the claimed "invention or discovery." *Amgen*, 598 U.S. at 604-05 (citation omitted). The modern Patent Act continues to impose an enablement requirement, "[s]o today, just as in 1790, the law secures for the public its benefit of the patent bargain by ensuring that, 'upon the expiration of [the patent], the knowledge of the invention [i]nures to the people, who are thus enabled without restriction to practice it.'" *Id.* at 605 (citation omitted). The result is a "simple statutory command": "If a patent claims an entire class of processes, machines, manufactures, or

compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class." *Id.* at 610.

The Supreme Court has cautioned that the enablement requirement is particularly important in the context of genus claims—and especially functional genus claims—because of the wide scope of exclusivity that they involve. For example, in *Amgen*, the patents "claim[ed] a monopoly over all antibodies" that "bind to specific amino acids on a … protein known as PCSK9, and … block PCSK9 from impairing the body's mechanism for removing [low-density lipoprotein] cholesterol from the bloodstream." *Id.* at 599. In other words, the patents did not "seek protection for any particular antibody described by amino acid sequence," but rather, "'the entire genus' of antibodies that" perform a particular function. *Id.* at 602. Amgen disclosed only 26 antibodies (*i.e.*, species) within the genus and two "trial-and-error process[es] of discovery" for "generating additional antibodies with the same functions." *Id.* at 603-04. But the patents "claim[ed] for Amgen's exclusive use potentially *millions* more antibodies than the company had taught scientists to make." *Id.* at 599 (emphasis added). The

district court, this Court, and, ultimately, the Supreme Court all agreed that the claims were invalid for lack of enablement.

In affirming this Court, the Supreme Court held "that the more a party claims for itself the more it must enable." *Id.* at 616; *see also id.* at 610 ("The more one claims, the more one must enable"). "[A] specification may call for a reasonable amount of experimentation to make and use a patented invention," but "[w]hat is reasonable in any case will depend on the nature of the invention and the underlying art." *Id.* at 612. The specification's disclosure cannot "amount to little more than … research assignments" or a "trial-and-error method for finding" species that meet the functional limitations. *Id.* at 614. At bottom, a specification that "leave[s] a scientist … to engage in 'painstaking experimentation' to see what works … is not enablement"—"it is 'a hunting license.'" *Id.* (citations omitted).

The art at issue here is highly unpredictable. *Supra* 5. That matters, because the more unpredictable the art, the more the specification must disclose to satisfy the enablement requirement. The Wyeth patents, however, provide no more than the same kind of "research assignment" found insufficient in *Amgen*. *See Amgen*, 598

U.S. at 614. In particular, nothing in the Wyeth patents provide guidance that would help a POSA determine which compounds fall within the claims, and even if you were lucky enough to identify (through trial and error) an irreversible EGFR inhibitor, multiple follow-up experiments would be required. For example, to obtain irreversible EGFR inhibitors within the scope of the claims, scientists would need to generate *millions* of compounds and test to see if they bind irreversibly to EGFR; then, they would need to test those irreversible EGFR inhibitors to see if they treat gefitinib and/or erlotinib resistant non-small cell lung cancer; and then they would need to determine a unit dosage for each of those compounds that had a therapeutic effect that could be given to a patient on a daily basis, if any such dosage was possible. In other words, the Wyeth patents send a scientist not just on one hunting expedition, but on an extended series of nested trial-and-error experiments. That is not an enabling disclosure.

II. This Court's Clear Instruction On The Invalidity Of Overbroad Functional Genus Claims Is Necessary To Protect Innovators From Drawn-out And Unnecessary Litigation.

This Court's instruction to district courts that overbroad functional genus claims are invalid and impermissible is especially critical now. A strong message from this Court could help prevent the drawn-out and unnecessary litigation to which innovators like *amici* and AstraZeneca have been subjected as a result of broad functional genus claims.

Recall that this case arises from a judgment as a matter of law decision—that is, a vacatur of a jury verdict. AstraZeneca was forced to litigate all the way through trial before Wyeth's patent claims were invalidated by the court. That will *sometimes* be necessary, but it should not be the norm. And in *amici's* view, it continues to be increasingly common for patentees in the biopharmaceutical space to assert these kind of broad functional genus claims. *See, e.g.*, *Lindis Biotech, GmbH v. Amgen Inc.*, No. 1:22-cv-00035-GBW (D. Del.) (denial of summary judgment followed by trial, defendant's motion for judgment as a matter of law at the close of plaintiff's case-in-chief, and a jury verdict of infringement, with litigation still ongoing).

The threat of long and costly litigation is a hefty weight that allows patentees to force independent innovators like *amici* into the difficult decision between fighting invalid claims for years in litigation or licensing invalid claims. This Court should use this opportunity to provide additional guidance to district courts on the relationship between functional genus claims, written description, and enablement in order to further empower them (where appropriate) to address this kind of claim earlier in the litigation and discourage applicants from asserting facially invalid claims.

CONCLUSION

The Court should affirm the district court's decision.

March 20, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. Cir. R. 29(b), because this brief contains 3009 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word for Microsoft 365 in Century Schoolbook 14-point font.

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