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 INTELLECTUAL PROPERTY LAW PROFESSORS AND SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF THE RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Amici Intellectual Property Law Professors and Scholars write about intellectual property law and in particular patent law and policy.[2] We have no personal interest in the outcome of this case. Our interest in this case is to better explain the historical and policy context of existing doctrines and to contribute to the positive development of patent law and policy.

SUMMARY OF ARGUMENT

There is no paradox, no death of anything or otherwise a need for alarm. In this case, the Federal Circuit and the District Court have steadfastly followed the guidance from this Court on the most basic tenet of patent law: patent claims cannot exceed the disclosed invention. Patent law's disclosure requirements police this limit by comparing the claimed subject matter against the disclosed invention. Put simply, a patentee cannot claim more than their specification can prove that they invented. If there is any alarm or concern, it stems from the fact that the Petitioners and their supporting *Amici* have forgotten this basic foundational limit.

For more than 200 years the Court's upholding of this limit has served patent law well, allowing broad claims in some cases while limiting them in others.

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[1] *Amici* certify that no party, person, or entity other than *Amici* or their counsel authored this brief in whole or in part or made a monetary contribution to its preparation or submission. All parties have consented to the filing of this brief.

[2] Appendix A includes a list of the *Amici*.

Where a patentee invents broadly and discloses a multitude of varied solutions to some problem, the Court has allowed commensurately broad claims.

Yet not all inventions are broad. Where a patentee invents narrowly, meaning they find and disclose only a limited set of solutions *and* where they cannot provide a generalizable principle that unites a broader set of solutions, then that inventor has not invented broadly. Their claims have been limited to what was explicitly disclosed. Broader claims that reach beyond that limited set have been struck down. In each, the breadth of the disclosed invention determines the breadth of the allowed claims. The requirements of 35 U.S.C. § 112(a) police this critically important limit. Patentees must describe what they have invented as well as how to make and use that invention. And their claims cannot exceed that disclosed invention.

This case presents a classic example of a narrow invention that is coupled to overbroad claims. Calling it a narrow invention is not meant to imply that the actual invention disclosed is not important or beneficial; it is. But the trial-and-error screening that is at the heart of the disclosed methods for discovering Amgen's claimed antibodies is inherently a narrow way of inventing. Such inventions are *found* and they are a special class of inventions that are quite distinct from inventions that are conceived fully and broadly from the inventor's mind. Absent a disclosure that subsequently broadens such narrow discoveries, their claims must similarly be narrow. But Amgen did not limit its claims to the disclosed invention. As a result,

Amgen's claims fail the enablement requirement, and likely the written description requirement as well.

Currently the Court's focus is on enablement. Amgen has for sure enabled something. The question is whether Amgen enabled as broadly as it argues it has enabled. The patent explicitly discloses and enables a limited set of 26 antibodies. But the claims at issue in this case extend well beyond those 26 antibodies and any antibodies derived from them. To fill that huge gap, Amgen argues that its disclosed "roadmap" teaches how to 'make' all the claimed antibodies.

Though it seems innocuous, the above argument exposes a sleight of hand or, perhaps more generously, a fundamental misunderstanding. The "roadmap" may colloquially be a method of 'making' antibodies but it cannot support enablement. Enablement requires teaching others how to make and use that which the patentee has already invent*ed*. Amgen's "roadmap" does not do that. It is merely a research plan for random trial-and-error discovery of new antibodies. It categorically does not enable the making of something that was already invent*ed*. It does not direct a person of skill to make any definite or permanent thing that was conceived by Amgen. The stark gulf between what was enabled versus what was claimed led the courts below to correctly invalidate these overly broad claims for failing the enablement requirement.

Owing to the current unpredictability of protein folding, finding an antibody that binds PCSK9 provides almost no guidance towards predicting or

envisioning unrelated antibodies that will also bind to PCSK9. As knowledge of protein folding advances and this important field becomes more predictable, future immunologists will someday move beyond trial-and-error inventing and be able to disclose and claim their antibodies more broadly. However we have yet to reach that day. Amgen has improperly tried to claim well beyond what it had invented and its patent claims were properly invalidated.

ARGUMENT

I. Claims Are Limited to the Disclosed Invention

A. Patentees Can Only Claim What They Have Invented

This Court has held on numerous occasions that, at most, inventors can claim only that which they themselves invented. *See O'Reilly v. Morse*, 56 U.S. 62, 120-21 (1853) ("[The patentee] can lawfully claim only what he has invented…."); *Evans v. Eaton*, 20 U.S. 356, 430 (1822) ("it is clear that the party cannot entitled [sic] himself to a patent for more than his own invention").[3] The Court in *O'Reilly* concludes that "[i]n fine [Morse] claims an exclusive right to use a

[3] *See also Agawam Woolen Co. v. Jordan*, 74 U.S. 583, 602 (1868) ("No one is entitled to a patent for that which he did not invent …."); *Morey v. Lockwood*, 75 U.S. 230, 240 (1868) ("Several objections are taken to this reissued patent; among others, and which is the most material, that the claim is broader than the invention."); *Wyeth v. Stone*, 30 F. Cas. 723, 727 (C.C.D. Mass. 1840) (Story, J.) ("A claim broader than the actual invention of the patentee is, for that very reason, upon the principles of the common law, utterly void, and the patent is a nullity").

manner and process which he … had not invented…. The court is of opinion that the claim is too broad, and not warranted by law." 56 U.S. at 113.

The invention, "[t]he thing patented [,] is the particular means devised by the inventor by which [a] result is attained, leaving it open to any other inventor to accomplish the same result by other means." *Elec. R.R. Signal Co. v. Hall Ry. Signal Co.*, 114 U.S. 87, 96 (1885). "[T]he word 'invention' in the Patent Act unquestionably refers to the inventor's conception…." *Pfaff v. Wells Elec., Inc.*, 525 U.S. 55, 60 (1998). Expanding on the inventor's "particular means" for solving the problem at hand, conception is "the formation, in the mind of the inventor, *of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice*…." *Mergenthaler v. Scudder*, 11 App. D.C. 264, 276 (D.C. Cir. 1897) (citing 1 Robinson on Patents, Sec. 375). "Conception requires both the idea of the invention's structure and possession of an operative method of making it." *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (citing *Oka v. Youssefyeh*, 849 F.2d 581, 583 (Fed. Cir. 1988)).

B. 35 U.S.C. § 112 Requires Disclosing and Claiming the *Invented* Subject Matter

The statutory disclosure requirements of written description and enablement police this fundamental limit preventing claims from exceeding the disclosed invention. *See* 35 U.S.C. § 112(a). As discussed above, a complete conception includes both the definite and permanent idea of the invention as

well as an operative method of making and using that invention. The statute requires both of these components: a "written description of the invention" and "the manner and process of making and using [the invention]." *Id.*

There is nothing unfair or impossible in requiring the patent applicant to fully disclose their complete invention. After all, patent applicants swear that they are "the original and first inventor[s] of the process, machine, manufacture, or composition of matter, or improvement thereof, for which [they] solicit a patent." 35 U.S.C. § 115 (pre-AIA).[4]

Patent law's disclosure requirements quite reasonably just ask that applicants document their complete conception in their patent specification. In an important sense, the specification provides corroboration of the inventor's definite, permanent completed conception. And the disclosure requirements ensure that patent claims do not exceed that disclosed conception.

C. Broad Claims for Broad Inventions

The rule that limits patent claims to the disclosed invention or synonymously to the disclosed "definite and permanent" conception might seem to mandate narrow claims. But this is not so. This Court has allowed broad claims when the applicant discloses a broad invention. This is most true when an inventor supplies a general principle of the invention that

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[4] *See generally* Oskar Liivak, *Overclaiming is Criminal*, 49 Ariz. St. L. J. 1417 (2016) (describing the relationship between the patent oath and overclaiming).

allows envisaging a broad set of solutions. This principle details the essential structural features that unite a broad set of viable solutions. And though these disclosures leverage a generalized principle, the disclosure is still definite and permanent for all the claimed embodiments. In such cases, broad claims to all those solutions have been allowed. *See, e.g., Tilghman v. Proctor*, 102 U.S. 707, 726, 730-33 (1881) (disclosing a broad set of variations sufficient to broadly claim that same set of solutions); *see also id.* at 723-27 (discussing the English case of *Neilson v. Harford,* 151 Eng. Rep. 1266 (Exch. 1841), as an example of a disclosure of a broad set of solutions that then supported broad process claims).

D. Narrow Claims for Narrow Inventions; Trial-and-Error Inventing Is Inherently Narrow

Yet despite allowing broad claims in many cases, the Court has made clear that not every inventor has invented and disclosed broadly enough to merit broad claims. "Undoubtedly there may be cases in which the letters-patent do include only the particular form described and claimed." *Winans v. Denmead*, 56 U.S. 330, 343 (1853); *see also Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419 (1908) (describing the Court's opinion in *Snow v. Lake Shore & Mich. S. Ry. Co.*, 121 U.S. 617 (1887) as a case "where a claim was limited by a description of the device … [when] there was nothing in the context to indicate that the patentee contemplated any alternative….").

This Court's decision in *Consol. Elec. Light Co. v. McKeesport Light Co. (The Incandescent Lamp Case)* is such a case. 159 U.S. 465 (1895). In the search for useful incandescent light bulb filaments, progress had been made toward the suitable shapes and even the general construction of the filaments. But researchers were still hunting to find the best materials from which to construct the filaments. *See id.* at 471. The patentees, Sawyer and Man, disclosed in their patent that they had actually reduced to practice filaments made from both carbonized paper and wood carbon. *See id.* at 466. Their third claim was narrow, claiming only filaments "formed of carbonized paper." Yet, their first claim was much broader covering a filament constructed from any "carbonized fibrous or textile material." *Id.* Commenting on these two claims, the Court noted that "[i]nstead of confining [their claims] to carbonized paper, as they might properly have done, and in fact did in their third claim, they made a broad claim for every fibrous or textile material, when in fact an examination of over 6,000 vegetable growths showed that none of them possessed the peculiar qualities that fitted them for that purpose." *Id.* at 472.

The Court made it clear that Sawyer and Man could have in theory claimed more broadly *if* they had identified structural features that united various filaments that would work. The Court stated that "if the patentees had discovered in fibrous and textile substances a quality common to them all, or to them generally, as distinguishing them from other materials, such as minerals, etc., and such quality or characteristic adapted them peculiarly to incandescent conductors, such claim might not be too

broad." *Id.* Such a disclosure, if it provided enough detail to prove that they had invented a broad set of filaments, would have elevated the work of Sawyer and Man to the type of invention made by Neilson or by Tilghman. But Sawyer and Man could not generalize to other solutions. Their invention was narrow and their broad claim failed as a result. *See id.* at 477.

A survey of all these cases demonstrates that claim scope varies along a spectrum from broad to narrow that is commensurate with the breadth of the invention. *See* Oskar Liivak, *Finding Invention*, 40 Fla. St. Univ. L. Rev. 57 (2012). Inventions involving predictable technology often result in broad claims, as the inventor can, using their understanding of that predictable science, disclose a broad set of viable solutions. *See id.* at 76. They can disclose the essential structural features that make their invention function. In contrast, where trial-and-error searching is employed *to find* the invention, then a narrow invention will invariably result. *See id.* at 83-91 (explaining that discovery via random trial and error, like the methods used for finding monoclonal antibodies, is inevitably narrow).

II. Patent Policy Supports Limiting Claims to the Disclosed Invention

In addition to being in accord with 200 years of patent doctrine, this requirement that applicants must describe and teach how to make their invention, and can only then claim their invention (but no more than their invention) makes good patent policy.

A. Narrow Antibody Claims Have Led to More Innovation

Antibody technology and its corresponding patents have flourished in the past two decades. In fact, the number of antibody composition patents has steadily increased almost four-fold from 2004 (138 patents) to 2019 (541 patents).[5] While the number of antibody patents has increased, the scope of antibody claims has narrowed.[6] Over the past two decades, antibody claims shifted from broad genus claims directed to the antigen or epitope to narrower species claims defined by the antibody structure. This narrowing started at the patent office where patent examiners have recognized that broad genus claims are not typically enabled by the specification. In fact, enablement and written description rejections have increased from 20% in 2003 to 40% by 2018.[7] Narrowing of antibody claims has led to more innovation in the antibody space and more breakthrough therapies for patients.

Revenues for antibody technologies have also increased over the past decades. In 2021, four of the top six highest-selling drugs were monoclonal antibodies, taking home a staggering $54.4 billion.[8]

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[5] *See* S. Sean Tu and Christopher M. Holman, *Antibody Patents: Use of the Written Description and Enablement Requirements at the Patent & Trademark Office*, 38 Berkeley Tech. L. J. (Figure 8) (2023 forthcoming) (available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4025167).

[6] *Id.* at Figure 2.

[7] *Id.* at Figure 1.

[8] *See* Lisa Urquhard, *Top Product Forecasts for 2021*, 20 Nat. Rev. Drug Discov. 10 at 10 (2020).

Granting only narrow antibody claims allows for robust competition, resulting in a larger number of antibodies and therapies. For example in 2021, the world's best-selling drug was adalimumab (Humira®, $17.3 billion), a TNF-alpha antibody. Competitors have invented and brought to market four additional antibodies directed to TNF-alpha, which earned a total of $8.9 billion in 2021 alone.[9] All of these drugs show excellent efficacy with similar rates of clinical response and prevention of disease progression.[10]

TNF-alpha antibodies are hardly an isolated example. In the booming area of cancer immunotherapy, four different FDA-approved antibodies target the PD-1 protein. Pembrolizumab (Keytruda®) is projected to be the world's best-selling therapy in 2023, with worldwide sales of $23 billion.[11] Meanwhile, nivolumab (Opdivo®) will be the sixth best-selling therapy, with worldwide sales of $11 billion.[12] The two other FDA-approved PD-1 inhibitors, cemiplimab and dostarlimab, also enjoy significant sales. By having somewhat different therapeutic profiles, these competitor drugs can fill important unmet needs. For example, dostarmilab was granted accelerated approval by the FDA in 2021

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[9] Etanercept (Enbrel®, $4.4 billion), infliximab (Remicade®, $2.0 billion), golimumab (Simponi®, $1.1 billion), and certolizumab (Cimzia®, $1.4 billion). Revenue data from SSR Health.

[10] Helga Radner and Daniel Aletaha, *Anti-TNF in Rheumatoid Arthritis: An Overview*, Wien Med Wochenschr 165:3-9 (2015).

[11] Amy Brown, *Top Product Forecasts for 2023*, 22 Nature Biotechnology 8 (2023).

[12] *Id.*

because it addressed an unmet need (in mismatch repair deficient recurrent or advanced solid tumors).[13]

When it comes to antibodies, we get more innovation with narrower claims without harming the incentives to innovate. Narrower claims give competitors space, which in turn allows for development of alternative therapies. These antibodies can then compete in the marketplace offering patients a variety of different therapeutic options. Accordingly, we do not need overbroad claims to incentivize antibody innovation. In fact, broad antibody genus claims that are not supported by a properly disclosed broad invention may impede innovation and ultimately harm patient welfare.

B. Limiting Claims to the Invention Generally Supports Innovation

If we care about innovation, then we care about the inventions that actually get made and introduced to benefit the public. Society needs actual medicines; actual solutions to technical problems. The Petitioners in this case did give society the benefits of their actual invention, and claims covering those narrow inventions are reasonable. But why do Petitioners need more? Can Amgen start clinical testing on antibodies that it never even conceived? Antibodies that it never even discovered? No, it can't. For that

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[13] *See* U.S. Food & Drug Admin., https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-dostarlimab-gxly-dmmr-endometrial-cancer/ (last visited Feb. 5, 2023).

reason patent law has never allowed protection to extend beyond the actual invention.

If Amgen were to invent more later, the patent system will be there for it as Amgen can file for additional later patents on those later inventions. Accordingly, there has never been nor is there now any need for patent protection beyond what was invented. And a contrary rule is worse than simply unnecessary, rather it is affirmatively harmful. Such a misguided patent law would block others who later actually do the hard work of inventing from gaining protection for their later but equally important contributions to society. *See Consol. Elec. Light Co.*, 159 U.S. at 476 (noting that broad claims "operate rather to discourage than to promote invention."). Two hundred years of this Court's work has protected this fundamental limit against overclaiming by applicants.

III. Amgen's "Roadmap" Is a Research Plan for Trial-and-Error Discovery; It Is a Plan for Future Inventing

The patents in this case did disclose an invention, namely 26 antibodies that had actually been reduced to practice. Claims tethered to those antibodies would be fine, yet the actual claims in this case extend far beyond that. Petitioners have argued vehemently that their "roadmap" for making antibodies enables their extraordinarily broad claims. That argument was rejected below, and the Federal Circuit's judgment invalidating those claims should be affirmed.

A. The Specification Must Enable What Has (Already) Been Invented

In describing the relationship between the inventor's conception and patent law's description requirements, the Court has highlighted a fundamental chronology in patent law: conception precedes description. By focusing on the verb tense in the Court's discussions, this chronology is laid bare: "[The patentee] can lawfully claim only what he has invent*ed* and described, and if he claims more his patent is void." *O'Reilly*, 56 U.S. at 121 (emphasis added).[14]

Accordingly, the disclosure requirements focus attention on what the patent disclosure can prove *was invented* by the applicant (the written description requirement) and on whether the disclosure can teach how to make and use what *was invented* (the

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[14] *See also Ensten v. Simon, Ascher & Co.*, 282 U.S. 445, 452 (1931) (describing the "principle which forbids a patentee to assert a right to more than he has actually invent*ed*") (emphasis added); *O'Reilly*, 56 U.S. at 120 (describing the "the evil … if [a patentee] claims more than he has invent*ed* although no other person has invented it before him.") (emphasis added). Focusing on and limiting patent claims to that which was actually creat*ed* by the patentee is not surprising. It is woven deeply into the fabric of the patent system. *See Burrow-Giles Lithographic Co. v. Sarony*, 111 U.S. 53, 59 (1884) ("[W]hen [someone] has secured … a patent, the question of invention … of originality is always open to examination."); *see also* R. Carl Moy, MOY'S WALKER ON PATENTS § 1:15 (4th Ed. 2003) ("[in view of the Trade-Mark Cases, 100 U.S. 82 (1879)] … it appears that Congress's authority under the intellectual property clause is limited to the protection of subject matter that is original to the grantee.").

enablement requirement). And claims can cover only that which satisfies both of these requirements.

This hard limit focused on what was invent*ed* is not altered even when the patentee discloses all manner of other technical information that falls short of an invention. "[T]he end to be accomplished is not the subject of a patent. The invention consists in the new and useful means of obtaining it." *Carver v. Hyde*, 41 U.S. 513, 519 (1842). And the Court has explained that some disclosures may contribute to science generally, but for patent law the focus is the disclosure of inventions alone: "This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something 'useful'….[b]ut a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 535-36 (1966). Here, Amgen's patent disclosure with its "roadmap," is not disparaged for its contribution to scientific information, but it just does not disclose an invention that is as broad as Amgen has claimed. It is fundamental to patent law that the patent and its claims are for what the patentee did invent; not for what others might (one day) invent.

B. Amgen's "Roadmap" Is a Trial-and-Error Research Plan for Future Inventing

As noted above, for cases where the inventor has conceived broadly, a vast array of embodiments can be efficiently disclosed because the inventor has conceived a principle of the invention that animates

all these embodiments. In these cases, the inventor discloses structural features that are essential to the solution and discloses how to build them. When they do this, they can broadly claim these varied embodiments. And in these cases, the disclosure and the claims both can extend well beyond the embodiments that have been physically reduced to practice.[15] Yet despite that claim breadth extends to things that have not yet even been physically built, the claims are still limited to the disclosed invention. Because the inventor disclosed a broadly applicable principle of means that animates all these varied solutions, the claims still cover subject matter that the patentee invent*ed*. The broad disclosed conception proves that the invention is similarly broad.

But not all cases contain such broad disclosures. Narrow inventions, especially those arrived at by trial and error, are different. They lack the disclosure of a general principle that defines the essential structural features that unites a broad array of solutions. When a solution is found by trial and error, often we do not know why that particular embodiment works nor can we generalize to other

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[15] In fact in such cases of broad disclosure and thereby broad invention, the Court does not require patentees to actually reduce any embodiments to practice. Famously, for example, in *The Telephone Cases*, the Court noted that "[i]t is quite true that when Bell applied for his patent he had never transmitted telegraphically spoken words … but in his specification he did describe accurately, and with admirable clearness, his process … with sufficient precision to enable one of ordinary skill in such matters to make it…." *Dolbear v. Am. Bell Tel. Co.*, 126 U.S. 1, 535 (1888); *see also Pfaff*, 525 U.S. at 66 ("[O]ne can prove that an invention is complete … before it has actually been reduced to practice.")

related solutions. We just know it works and that is all that is needed to obtain a claim *to that particular embodiment*; but to claim further, the patentee must invent further. And often they cannot and the only solutions that are disclosed are those particular ones that were explicitly found. This peculiar narrowness of trial-and-error inventing and its difference from broader inventing has been noted for some time:

> In many inventions the act of conception is clearly distinct, in point of time, from that of reduction; …. In many others the work of conception and reduction goes forward almost simultaneously, so nearly so that no date can be fixed as that before which the conception was complete and after which the reduction to practice was begun. *This is true in nearly all inventions which are the result of experiment*,—where the inventor, instead of evolving the entire art or instrument out of his own thought, conjectures that such an act or substance will subserve a given purpose, and having tried it, finds that it accomplishes the end. The production of a new means by this method is, equally with the former, an inventive act, *but at no instant before the experiment succeeds can it be said that the conception of the invention exists in the inventor's mind*. Until that instant it is mere speculation, at most a probable deduction from facts already known; *and the same act which*

> *reduces it to practice gives to the conception its definite and final form*.

William C. Robinson, LL.D., THE LAW OF PATENTS FOR USEFUL INVENTIONS § 381 (Vol. I 1890) (emphasis added); *see also Alpert v. Slatin*, 305 F.2d 891, 895 (C.C.P.A 1962) (noting this doctrine of simultaneous conception and reduction to practice applies where "results at each step … are achieved empirically by what amounts to trial and error").

Because of this, a method of random trial-and-error inventing cannot enable beyond the embodiments that have actually been found and disclosed. Using such methods, a researcher sets off to find additional solutions from amongst a vast sea of randomly varied possibilities without knowing the structure of the solutions that it will yield. Conception does not occur until actual reduction to practice.

This is in sharp contrast to the broadest inventions where a patentee discloses embodiments of the invention straight from a conceptual understanding of the solution without ever needing to actually reduce any of them to practice. And this is also in contrast to an intermediate regime where initial embodiments may well be found by trial and error but, using an understanding of the problem, researchers can then start to conceive and enable subsequent embodiments that are derived from those initial ones.[16] Narrow invention via random trial-and-

[16] The antibodies derived by minor modifications to the 26 antibodies that were explicitly disclosed might fall into this class. We don't express an opinion on whether those antibodies are enabled. Even if they were, the claims at issue are still

error discovery is categorically different from these broader modes.

Prior to completing the random trial-and-error search, you just don't have the solution, nor can you teach others to make those solutions. Until the search has been completed, the inventor cannot yet have conceived, cannot yet have formed, a "definite and permanent idea" of the invention. This has fundamental implications for enablement and this case.

A method for 'making' things like Amgen's "roadmap," that uses random trial-and-error searching, cannot provide enablement support for the broad claims at issue. The "roadmap" does not provide a definite and permanent idea of a complete and operative antibody until after the "roadmap" search has been completed. In other words, the "roadmap" does not teach how to make a particular antibody that was already conceived by the patentee. It does not teach how to make something that was invent*ed* by the patentee.

Rather the "roadmap" is instead a broad research plan that teaches persons of skill *to invent on their own*. This is fatal for Amgen's reliance on its "roadmap." *See* William C. Robinson, LL.D., THE LAW OF PATENTS FOR USEFUL INVENTIONS § 493 (Vol. II 1890) ("[I]f … inventive skill on the part of the constructor or the user is necessary to render the invention available to practice, the Description is

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invalid without more as they extend far beyond antibodies that are structurally tethered to the 26 antibodies disclosed.

fatally ambiguous and the patent granted on the specification which contains it is invalid." (citing *Neilson v. Harford*)).

An analogy may be helpful. Imagine a combination lock with 100 tumblers, each of which can be set to 20 different positions.[17] Assume there are a number of correct combinations (say hundreds of them) yet those correct combinations are still rare compared to the vast number of possible combinations. Through trial and error, imagine that an inventor finds and discloses 26 different successful lock combinations. They clearly have invented those combinations and can describe and enable them. But imagine that the inventor tries to claim much more, namely all successful combinations. One way that this would be plausible is if the patentee had gained a deep technological knowledge of the lock and its inner workings and that this insight was such that the inventor could disclose the structural features shared by all solutions and could instruct how to make and use those structural features. That would be a broad invention and commensurately broad claims would be justified.[18]

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[17] The complementarity-determining regions (CDRs) of antibodies consist of sections totaling approximately 100 amino acid residues. And for each of those positions one could use 1 of 20 different amino acids.

[18] As noted above in connection with *Brenner*, partial knowledge about the lock isn't good enough for a broad invention. For example, imagine that the inventor had understood (and disclosed) that all successful lock combinations will be those where the tumblers are aligned to allow the lock bolt to freely be opened. But imagine that despite that insight, we still just do not understand the particular shapes of the tumblers well

But imagine this has *not* happened because we just don't understand these locks well enough yet to do that. Rather, imagine the patentee gives a different answer that still purports to teach others how to 'make' every solution. Imagine their "roadmap" just tells people to randomly try a large set of combinations and then record the successful ones. They tout that this method produces a successful combination "every time." And it could, over time, produce all (or nearly all) the possible solutions.

In a colloquial sense, this "roadmap" could be said to teach how to 'make' successful combinations; yet upon more careful consideration the argument has to be rejected. This "roadmap" does not teach a person of skill how to make combinations that the patentee has already found. It is instead a research plan for random trial-and-error discovery that will look for new combinations that have not yet been invented. It is different in kind from a method of making combinations that have already been found.

Because it involves random trial and error, no one knows what lock combination the "roadmap" will ultimately produce even if it is assured that this method will relatively easily and with certainty produce *a* successful lock combination. This is patent

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enough to predict all the correct combinations that would achieve that. In such a case, the inventor still has not conceived broadly nor have they enabled people of skill to make and use a broad set of correct combinations. The insights must lead to actual solutions. If the insight is new then it might be applauded as a matter of scientific knowledge, but if that knowledge still does not enable the inventor to envision a broad set of solutions then it hasn't yet become a broad invention.

law's doctrine of simultaneous conception and reduction to practice at work. Until the successful combination is found, we don't have a definite and permanent idea of what that solution is. This lock combination "roadmap" is really a method of inventing new combinations rather than a method of making combinations that have already been found. In an important sense, such a "roadmap" cannot enable under the patent laws.

Or to reframe this same concept with a non-technological analogy, imagine that you need a place to eat tonight. You ask a friend "Can you tell me how to get to a good restaurant in D.C.?" The friend answers "Sure. In fact, I can tell you how to get to every good restaurant in D.C.: Go forth, eat in a bunch of places, and when you like the food, then you have found a good restaurant. Keep going and you will find them all." Witty? Perhaps. Responsive to your actual question? Absolutely not.

And it should be emphasized that your dissatisfaction with the above answer remains even if your friend assures you that following their method *will* produce good restaurants 'every time' or that it *will* ultimately lead to 'all' the good restaurants in D.C.[19] Nor does it matter if your friend assures you

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[19] Petitioners argue that Amgen "presented evidence that following the patents' roadmap produces claimed antibodies *every time*, and that the roadmap could produce *all* antibodies within the claims." Pet. Br. at 3. The nonresponsive answer to the restaurant query could similarly be characterized as producing a restaurant every time and all the good restaurants if repeated but we would still deem the answer categorically

that the search is not that hard since they supplied you with some tips on how to make the search faster or more efficient. It is all still non-responsive to what you were asking. You want directions to a restaurant that your friend already knows is a good restaurant. You don't want to search. You want an actual answer; patent law does too.

Yet Amgen's "roadmap" is essentially this same unacceptable response even though it is dressed up in layers of seemingly impenetrable biological jargon. The "roadmap" involves trial and error in a number of its steps, but one critically important way stands above the others.[20] The initial step of the "roadmap" introduces an antigen like PCSK9 to a mammalian immune system (or equivalently a randomized library of antibody sequences can be used) and those randomized antibodies are then screened to discover antibodies that can bind to PCSK9. Like randomly searching for lock combinations or randomly sampling restaurants to find a good one, the roadmap starts *without knowing what antibodies the method will yield* much less which antibodies will work. It is necessarily a random trial-and-error method for discovery. The immune systems of mice and men work by producing a staggeringly large array of randomly varying antibodies. In large part that is why it works

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nonresponsive to the relevant question about directions to get to a good restaurant.

[20] In addition to step one of the "roadmap" there are other trial-and-error aspects to the "roadmap." Even once antibodies that bind to PCSK9 are found by trial and error, the "roadmap" further screens those to find the antibodies that bind to the sweet spot and then it screens for antibodies that block the binding of PCSK9 to LDLR.

so well at identifying pathogens both known and never seen before. But despite its jaw-dropping scale and its trappings of hard-to-fathom biochemistry, it really is just a system of random trial-and-error testing. And any "roadmap" that utilizes this random trial and error for discovery of antibodies cannot be a method that enables a person of skill to make something that should have been already invented. Amgen's "roadmap" is instead a method of inventing in the first instance.

C. The Federal Circuit and the District Court Understood Amgen's "Roadmap" as a Trial-and-Error Research Plan for Discovery

The District Court found and the Federal Circuit agreed that the "roadmap" was a trial-and-error method for discovery:

> As the district court noted, the only ways for a person of ordinary skill *to discover* undisclosed claimed embodiments would be through either "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*" according to a randomization-and-screening "roadmap."

Amgen Inc. v. Sanofi, 987 F.3d 1080, 1088 (Fed. Cir. 2021) (emphasis added). The District Court understood that this is a case of narrow invention where "only through experimentation, not prediction"

could the skilled artisan determine whether a particular antibody would meet the functional limitations of the claim. *Amgen Inc. v. Sanofi*, No. 14-1317, 2019 WL 4058927, at *13 (D. Del. Aug. 28, 2019) *aff'd sub nom. Amgen, Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021) (quoting *Idenix Pharms. LLC v. Gilead Scis., Inc.*, No. 14-846, 2018 WL 922125, at *23 (D. Del. Feb. 16, 2018). And the Federal Circuit agreed.

In addition the District Court found that, using the "roadmap," "a person of ordinary skill in the art attempting to obtain a claimed antibody that is not disclosed or is a variant of a disclosed antibody 'would have to do essentially the same amount of work as the inventors of the patents-in-suit.'" *Amgen*, 2019 WL 4058927, at *11, *12 (quoting *MorphoSys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354, 372 (D. Del. 2019)). In addition to the *amount* of work and experimentation that a person of skill has to expend, the discussion here emphasizes that it is fatally problematic that a person of skill has to invent at all in order to get results from the "roadmap". It is just not a method that enables something that has already been invented because it "is almost exactly the same as the patentee's initial research process to discover the twenty-six disclosed antibodies." *Amgen*, 2019 WL 4058927, at *12. An enabling disclosure must teach how to make something the patentee has invented; if it leaves the inventing or the discovering to others, then it is invalid for lack of enablement.

In prior cases the Federal Circuit has ruled that such research plans alone do not satisfy the disclosure requirements. "[T]he policy behind [the disclosure

requirements] … is to promote disclosure of inventions, not of research plans." *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993). Incomplete research plans "attempt to preempt the future before it has arrived." *Id.* at 1171. In this case, the Federal Circuit has properly underscored the fundamental failing that undergirds the invalidity of Amgen's genus claims: "Amgen, by asserting such broad, unsupported claims is … trying to control what it has not invented." *Amgen Inc. v. Sanofi*, 850 F. App'x 794, 796 (Fed. Cir. 2021).

D. Experiments to Find the Invention Are Distinct from Experimentation in the Making and Using of What Was Already Invented

In the Court's guidance on experimentation regarding the disclosure requirements, some statements might seem conflicting. After all, in *The Incandescent Lamp Case* the Court announced a strict rule about experimentation: "undoubtedly it would be the duty of the court to declare the patent void [if it was] … evident, on the face of the specification, that no one could use the invention *without first ascertaining, by experiment,* the exact proportion of the different ingredients required to produce the result intended to be obtained." 159 U.S. at 475 (emphasis added). In contrast, in *Minerals Separation, Ltd. v. Hyde* the Court seemed to retreat, making clear that claims were not invalid even though "preliminary tests must be made to determine the amount of oil and the extent of agitation necessary in order to obtain the best results." 242 U.S. 261, 270

(1916). It was not a problem to "leav[e] something to the skill of persons applying the invention." *Id.* at 271.

But there really is no conflict here. Experimenting to find the invention in the first place is distinct from some experimentation needed to apply bona fide instructions for making or using things already invented. As discussed above, where the goal of the experimentation is to *find* the invention in the first place, then patent law cannot abide much if any experimentation because that leaves the actual inventing to others, which is not permissible. As analogized by the trial-and-error method of finding restaurants, leaving you to search for restaurants yourself is just not an acceptable answer.

In contrast, once someone has invented and they are telling you how to make or use that invention, then experimentation can play a role. Imagine a friend does have a bona fide restaurant recommendation, and their directions included "to get to the specific restaurant in NW D.C. that I mentioned you could take Wisconsin or Connecticut Avenue; you're a person of skill regarding D.C. traffic, you decide what is best based on the time of day and day of the week." Such instructions, despite the need for some experimentation, enable you to arrive at the restaurant. As long as the directions are not unduly imprecise, we should be fine. The multi-factor balancing test from *In re Wands* is well suited for such determinations. 858 F.2d 731, 737 (1988).

But as shown by this case and the discussions above, this does not mean that experimentation should be allowed to unthinkingly enter all parts of

the disclosure analysis. Where the whole point of the random trial-and-error experimentation is to find the invention in the first, patent law must be more strict. To do otherwise, risks allowing patentees to claim what they did not invent.

CONCLUSION

In countless fields of technology, our understanding has followed a natural progression from unpredictable trial and error that then matures towards the predictable. The antibody technology at issue in this case is still in the early stages of that process. Truly promising strides in predictive protein folding have recently been made but, even with these advances which notably arrived some ten years after these patents were filed, we are still a long way from predictability. As further progress is made, patent claims can and should grow organically in concert with the broader inventions that will then be possible.

But until further progress is made, overly broad claims are improperly claiming the future before it has arrived. The courts below understood this dangerous failing and they properly policed this limit. The Federal Circuit's judgments on lack of enablement should be affirmed.

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February 10, 2023

APPENDIX

TABLE OF APPENDICES

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APPENDIX A – LIST OF SIGNATORIES

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