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 LAW PROFESSORS JOSHUA D. SARNOFF, SHARON K. SANDEEN, AND ANA SANTOS RUTSCHMAN AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Amici are law professors who teach and write about intellectual property law.[2] *Amici* have no personal interest in the outcome of this case. *Amici* seek to better explain the historical and policy context of existing patent law doctrines and to contribute to patent law and policy.

SUMMARY OF ARGUMENT

For over two hundred years, the Patent Act has consistently required that an applicant for a patent actually conceive an invention and disclose what they have invented, in a manner that *also* enables skilled practitioners to make and use the invention conceived and disclosed. Courts have applied many different doctrines to invalidate patents or patent claims when applicants have sought to patent what they have not invented or disclosed, typically by claiming results or by claiming a genus of unenumerated structures that perform desired results or recited functions. Courts have made clear that such claims are not claims to "inventions" within the meaning of the Patent Act, because the applicants have not yet determined what structures would perform the desired or recited functions. Such invalid claims, where the applicant has failed to disclose a sufficient structural-functional relationship, have variously been referred to as not

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

[2] The Appendix includes a list of the *amici*.

invented, overbroad, functional at the point of novelty, research plans, or not enabled.

Under the enablement doctrine, applicants: (1) cannot shift to the public the burden of "inventing" the claimed genus; and (2) must provide sufficient information for the public to "make and use" a properly disclosed and claimed genus invention. Although the decision of the U.S. Court of Appeals for the Federal Circuit in this case was clearly correct under *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), this Court needs to provide guidance on both aspects of the enablement standard in order to support its further refinement. First, *how much* of a structural-functional relationship must be disclosed to validly support a genus claim without improperly shifting the burden of inventing to skilled artisans? Second, for an already invented and properly disclosed genus, how much *additional* information must an applicant provide to "enable" skilled artisans to "make and use" the claimed genus? This second requirement must consider how much time, money, and effort can be imposed by applicants on skilled practitioners in regard to the scope of the invention actually claimed. The current "undue experimentation" standard in *Wands*, however, does not provide any meaningful referent to guide such analysis ("undue" compared to what?), and improperly conflates these two required inquiries. Nevertheless, the evidentiary factors identified in *Wands* remain relevant to the second inquiry.

This Court and the Federal Circuit have identified numerous concerns underlying the various patent law doctrines that prohibit claiming a genus of

structures without disclosing a sufficient structural-functional relationship. In general, there are two important reasons not to permit such claims. The first is that granting such claims provides a disproportionate reward to applicants. Applicants are entitled to claim the particular structural species that they have identified that perform the desired functions. When they do so, applicants then may receive additional protection for functionally "equivalent" structures under the "doctrine of equivalents." If applicants *also* can identify a common structural-functional relationship that sufficiently assures that other structures will perform the required functions, then (and only then) can they validly claim a genus of structures that they have not identified individually. This assures commensurability between the invention made and the rights granted. The second reason is that claiming a result or a research plan blocks sequential innovation and commercialization of additional structures that the applicant has not yet identified to possess the desired result or recited function, but has claimed using structural or functional language. This excessive claiming is particularly pernicious given the constrained experimental use exception adopted by the lower courts.

The instant case is an "easy case" in view of the complete lack of disclosure connecting structure to function. The case involves broad genus claims based entirely on desired and claimed functions. There is no disclosure that would indicate what structures are even *likely* to exhibit the recited functions, while requiring structures falling within the claimed genus to do so. This case thus does not require the Court to

address *how much* of a structural-functional relationship must be identified and disclosed in order to invent, disclose, and properly claim a genus. Nor does this case require the Court to address the permissible amount of time, effort, and money that can be required of skilled practitioners to make and use a *properly disclosed and claimed genus*. The Court thus should affirm the decision below and invalidate the claims at issue without remand, while providing the required guidance for the lower courts to further develop the law of enablement.

ARGUMENT

I. To Properly Enable A Claimed Genus Invention, An Applicant Must Identify And Describe A Sufficient Structural-Functional Relationship, Rather Than Merely Claiming A Result Or A Research Plan.

A. The Statute Requires Disclosure of "the Invention," and It Is *that* Conceived, Disclosed and Properly Claimed "Invention" that Must Be Enabled.

Since the initial 1790 legislation, the Patent Act has required that an applicant seeking patent rights identify the invention that they have conceived ***and*** provide *additional* information that will enable skilled practitioners to "make and use" *the conceived, disclosed and claimed* invention. *See* 35 U.S.C. § 112(a) ("The specification shall contain a written description of *the invention,* ***and*** of the manner and process of making and using [*the invention*]…") (emphasis added); the Patent Act of Apr. 10, 1790, § 2, 1 Stat. 109 ("a specification in writing, containing a description … of the thing or things, *by him or them invented or discovered* … which specification shall be so particular … *to enable* a workman or other person skilled in the art or manufacture … *to make, construct, or use the same*, to the end that the public may have the full benefit thereof, after the expiration of the patent term") (emphasis added). *See also* 35 U.S.C. § 112(b) ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor *regards as the invention*.") (emphasis

added). Thus: (1) patents can only issue for "inventions," which requires *subjective mental comprehension* by applicants of what they claim to have invented;[3] (2) it is the *completed, objectively disclosed* inventions that must be enabled for others to "make and use"; and (3) the claims (to be proper) must correspond in scope to the inventions subjectively recognized by the applicant (*i.e.*, "regarded" as the invention). These limits assure that the grant of rights claimed by an applicant do not exceed the scope of the invention actually made by applicants and sufficiently disclosed to others.[4]

Petitioners thus have posed a false dichotomy that the Court must choose between the statutory standard for enablement on the one hand and enabling the full scope of the claimed invention on the

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[3] *See, e.g.,* William C. Robinson, *The Law of Patents for Useful Inventions*, Vol I, § 77, at 116, Vol I, § 79, at 121 (1890) (describing subjective and objective requirements of "invention"); *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (conception of an invention "requires both the idea of the invention's structure and possession of an operative method of making it"). Relatedly, in the context of 35 U.S.C. § 101, this Court has sought to draw lines between claims to mere abstract ideas and claims that rise to the level of patentable invention by requiring that the claim *applying* per se ineligible discoveries include an additional, "inventive concept," invalidating patents that claim more than the actual invention *See, e.g., Alice Corp. Pty. Ltd. v. CLS Bank Intern.,* 573 U.S. 208, 221 (2014); *Mackay Radio & Tel. Co. v. Radio Corp. of Am.,* 306 U.S. 86, 98 (1939); *O'Reilly v. Morse,* 56 U.S. 62, 120-21 (1853).

[4] *See, e.g., J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.,* 534 U.S. 124, 142 (2001) ("The disclosure required by the Patent Act is 'the *quid pro quo* of the right to exclude.'") (citation omitted).

other.[5] There is no dichotomy, because the statutory standard *requires* enabling the invention actually conceived, disclosed, and claimed. If an applicant claims a genus invention, the applicant must conceive and disclose a genus invention and enable others to make and use that (complete, claimed) genus. If the applicant claims a species or a smaller genus, then the applicant must disclose and enable only that species or that smaller genus. Thus, the statute *requires* enablement of the full scope of whatever is claimed, in order to assure that the claim is commensurate with the invention subjectively recognized by the claimant and objectively described in the specification.

Further, contrary to Petitioners' efforts to confuse the issues here,[6] courts—even in the present

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[5] *Compare, e.g.*, Pet. Br. at 6 ("'successful application' of '*the invention*'") (emphasis added; citations omitted) *with, e.g., id.* at 20-21 ("[T]he specification's instructions must be sufficiently robust to permit skilled artisans to reasonably make and use *individual embodiments* as needed.") (emphasis added and deleted). Throughout the brief, Petitioners seek to limit "the invention" that must be enabled to specific embodiments. *See, e.g.*, Pet. Br. at 27. Yet, even Petitioners acknowledge that "no one denies that a patent must reasonably enable the entire scope of the claim…." Pet. Br. at 28.

[6] *Compare, e.g.*, Pet. Br. at 41-42 ("That the patent's claims can be practiced *through more embodiments 'than the [patent's] disclosed examples,' … is itself of no moment.* '[D]escrib[ing] all possible forms in which' a claimed invention 'may be reduced to practice * * * belong[s] to the skill of the mechanic, not the inventor.'") (citations omitted and emphasis added) *with id.* at 42 ("The Federal Circuit's reach-the-full-scope rule abandons that 'practical focus on whether others could *make use of [a particular embodiment of] the claimed invention*' in 'favor of a fruitless

case[7]—have never required, for an adequate disclosure of a genus invention, that applicants reduce to practice (physically make) or recite in the specification *all* species of a claimed genus invention. Rather, applicants may validly claim a genus when they have identified and disclosed a *sufficient* structural-functional relationship among the species of the genus to *identify* the genus *as the invention* ***and*** when they have provided sufficient *additional information* to enable *that* genus to be made and used by others (with some unspecified degree of time, money, and effort).[8]

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search for the exact boundaries of that invention.'") (citation omitted and emphasis added).

[7] *See, e.g., Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1088 (Fed. Cir. 2021) (searching for "adequate guidance beyond the narrow scope of the working examples that the patent's "roadmap" produced" and "look[ing] at the amount of effort needed to obtain embodiments outside the scope of the disclosed examples and guidance" given that "[t]he functional limitations here are broad, [and] the disclosed examples and guidance are narrow.")

[8] *See, e.g., In re Wands,* 858 F.2d at 734, 740 ("The application on appeal claims methods … using monoclonal antibodies *such as those described* in the … patent…. Wands' disclosure provides considerable direction and guidance on *how to practice* their invention *and* presents *working examples.*") (emphasis added). *Cf. Univ. of Rochester v. G.D. Searle & Co.,* 358 F.3d 916, 927 (Fed. Cir. 2004) (the "patent does not disclose just '*which* "peptides, polynucleotides, and small organic molecules" have the desired characteristic … Without such disclosure, the claimed methods *cannot be said to have been described.*") (citation omitted and emphasis added).

B. The Courts and Congress Have Employed Numerous Doctrines to Assure that the Claimed Invention Corresponds to and Is Limited to a Conceived Invention that Is Sufficiently Disclosed.

In the seminal case of *O'Reilly v. Morse*, 56 U.S. 62 (1853), Samuel Morse overclaimed his invention based on his discovery in electromagnetism. In response, this Court invalidated that broad claim and clearly articulated that applicants cannot *properly* claim what they have not yet invented. Similarly, the Court explained that applicants cannot *describe* as an invention in their application what they have not yet conceived, even though they may find the structural or functional words to claim it. Rather, applicants are required to *disclaim* more than they have invented, if their claim language without such tailoring would apply to more than they have conceived and disclosed:

> In fine [Morse] *claims* an exclusive right to use a manner and process which he has not described and indeed *had not invented, and therefore could not describe* when he obtained his patent. The court is of opinion that the claim is too broad, and not warranted by law.
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> …
>
> Whether, therefore, the patent is illegal in part because he claims *more than he has sufficiently described, or more than he invented,* he must in either case

> *disclaim,* in order to save the portion to which he is entitled….

Id. at 113, 121 (emphasis added).[9]

One particular form of claim has drawn even greater concern regarding overclaiming of more than the invention actually conceived and disclosed.[10] That is the use of "functional" language in order to claim a result, without actually identifying a sufficient structural-functional relationship that constitutes an invention. Such claims thereby require further experimentation *in order to determine* what structures will perform the required function. This concern was first clearly articulated in regard to machines, where applicants were prohibited from claiming the "function of a machine."

> His patent having a title which claims a machine, and his specification describing a machine, to construe his claim as for the function, effect, or result of his machine, would certainly endanger, if not destroy, its validity. His claim cannot change or nullify his previous specification with safety to his patent. He cannot describe a machine which will

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[9] Congress subsequently revised the disclaimer doctrine to a claim-by-claim basis. *See* 35 U.S.C. § 288. Further, absent "error," applicants can obtain revised claims through a "reissue" application. *See* 35 U.S.C. § 251.

[10] *See generally, e.g.,* Mark A. Lemley, *Software Patents and the Return of Functional Claiming,* 2013 Wisc. L. Rev. 905 (2012); Paul R. Gugliuzza, *Early Filing and Functional Claiming,* 96 B.U. L. Rev. 1223 (2016).

> perform a certain function, and then claim the function itself, and all other machines *that may be invented* to perform the same function.

Corning v. Burden, 56 U.S. 252, 269 (1853) (emphasis added). Significantly, the Court indicated that even if applicants invent species within the genus of machines having the required function, they cannot claim all potentially functional species by claiming the genus of functional results, without first having actually *invented* all the structural machines being claimed by their function.

Similarly, in *Risdon Iron & Locomotive Works v. Medart,* 158 U.S. 68 (1895), this Court held in regard to process claims:

> There is somewhat of the same obscurity in the line of demarkation as in that between mechanical skill and invention, or in that between a new article of manufacture, which is universally held to be patentable, and the function of a machine, which it is equally clear is not.... It is equally clear, however, that a valid patent cannot be obtained for a process which involves nothing more than the operation of a piece of mechanism, or, in other words, for the function of a machine.... [T]his distinction between a process and a function has never been departed from by this court, and has been accepted and

> applied in a large number of cases in the circuit courts.

Id. at 71–72, 77, 79.

The same concern about claiming a result without actually identifying and disclosing a sufficient structural-functional relationship was also at the heart of this Court's holding in regard to *functional* claim language used to distinguish and define a claimed invention.

> Under these circumstances the broadness, ambiguity, and overhanging threat *of the functional claim* of Walker become apparent. What he claimed in the court below and what he claims here is that his patent bars anyone from using in an oil well any device heretofore *or hereafter invented* which combined with the Lehr and Wyatt machine performs the function…. Just how many different devices there are of various kinds and characters which would serve … we do not know…. In this age of technological development there may be many other devices beyond our present information or indeed our imagination which will perform that function and yet fit these claims. And unless frightened from the course *of experimentation* by broad functional claims like these, inventive genius may evolve many more devices to accomplish the same purpose. Yet if Walker's blanket claims be valid, no

> device … now known *or hereafter invented,* whether the device be an actual *equivalent* of Walker's ingredient or not, could be used in a combination such as this, during the life of Walker's patent. *Had Walker accurately described the machine he claims to have invented, he would have had no such broad rights to bar the use of all devices now or hereafter known….*"

Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1, 12-13 (1946) (emphasis added).[11]

In 1952, in response to *Halliburton,* Congress permitted the use of functional claiming language (even at the point of novelty), while simultaneously limiting such claims to *structural equivalents* to *disclosed structural embodiments* that achieved the required functions. *See* 35 U.S.C. § 112(f) ("An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts *described in the specification and equivalents thereof*.") (emphasis added).[12] Thus, Congress

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[11] *See also Gen. Elec. Co v. Wabash Appliance Corp.,* 304 U.S. 364, 371 (1938) ("But the vice of a functional claim exists not only when a claim is 'wholly' functional, if that is ever true, but also when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty.").

[12] *See also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 28 (1997) ("Section 112, ¶ 6, now expressly allows so-

specified the permissible limits of structural genus claiming using functional language, limiting claim scope to equivalent species of embodiments actually invented by the applicant and disclosed in the specification.[13]

The same concern about overclaiming a genus without identifying an adequate structural-functional relationship also applies to *chemical compositions* and to claims employing *structural* language. Shortly before the 1952 Act, this Court in *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.,* 336 U.S. 271 (1949), invalidated claims to a genus defined by *structure* that contained inoperative embodiments, and thus effectively claimed a result rather than an invention.

> The trial court looked at claims 24 and 26 alone and declined to interpret the terms 'silicates' and 'metallic silicates' therein as being limited or qualified by specifications to mean *only the nine metallic silicates which had been proved operative.* The District Court considered that the claims therefore were too broad

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called 'means' claims, with the proviso that application of the broad literal language of such claims must be limited to only those means that are 'equivalen[t]' to the actual means shown in the patent specification.").

[13] Had the lower courts in the instant case construed the functional claim at issue properly (as limited to disclosed structural embodiments and their equivalents), there would be no present dispute over enablement, Such claims would be no broader than a structural Markush claim reciting the same species, structural equivalents of which would then be protected under the current doctrine of equivalents.

> and *comprehended more than the invention.* The Court of Appeals considered that … [the District Court] should have construed the claims as thus narrowed and limited by the specifications.
>
> …
>
> While the cases more often have dealt with efforts to resort to specifications to expand claims, it is clear that the latter fail equally to perform their function as a measure of the grant *when they overclaim the invention. When they do so to the point of invalidity* and are free from ambiguity which might justify resort to the specifications, we agree with the District Court that they are not to be saved because the latter are less inclusive.

Id. at 276-77 (emphasis added).[14] At the same time, this Court affirmed the validity of *narrower* structural genus claims (to "alkaline earth metal" silicates as a major constituent of flux compounds), for which the structural-functional relationship *had* been identified

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[14] *See also id.* at 277-78 ("All process claims were held invalid by the District Court; those numbered 1, 3, 4, 7, 8 and 9, because they make no specific reference to the *essential chemical constituents* of the welding composition to be used in the claimed welding process, a conclusion with which we agree.") (emphasis added).

and disclosed.[15] Finally, in the more famous, subsequent decision in the same case, this Court allowed the patentee to enforce these *narrower,* valid genus claims even against *unclaimed* structural-functional "equivalents" to the enumerated and disclosed embodiments (the alkaline earth metal silicates) of the generically claimed flux inventions.[16] In other words, although the patent holder was not permited to overclaim his invention by a genus including inoperative structural species, his narrower genus claim was proper and that claim prohibited infringement by structural equivalents to species of the genus that he had actually invented and disclosed.

Further, this Court and the lower courts have also expressed concern that applicants must have developed their understanding of the relationship of structure and function beyond a mere research plan, under both the utility and written description doctrines. For example, in *Brenner v. Manson,* 383 U.S. 519 (1966), this Court held that research intermediates (whether products or processes, the discovery of which are highly valuable) are not

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[15] *See id.* at 275 (affirming the validity of flux claims 18, 20, 22, and 23) (citing *Linde Air Prods. Co. v. Graver Tank & Mfg. Co.,* 86 F. Supp. 191, 198 (N.D. Ind. 1947)).

[16] *See Graver Tank & Mfg. Co. v. Linde Air Prods. Co.,* 339 U.S. 605, 610, 612 (1950) (discussing whether "the substitution of the manganese which is not an alkaline earth metal for the magnesium … make the doctrine of equivalents inapplicable; or conversely, whether … the change was so insubstantial that the trial court's invocation of the doctrine of equivalents was justified…. [T]he trial court could properly infer that the accused flux is the result of imitation rather than experimentation or invention.").

"inventions" within the meaning of the Patent Act until concrete (specific) products having substantial social utility are developed, identified, and disclosed. Otherwise, the applicant could simply claim all functionally useful results of using a product or process to produce a valuable (but unspecified) set of products. Further, the reason to prohibit such claims is that they would block sequential innovation by others to *invent* those valuable products, using the identified intermediate products or processes. As the Court held:

> Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public.

Id. at 534.

The Federal Circuit similarly has employed the written description doctrine to prohibit claiming research plans without identifying a concrete invention already made. For example, in *Ariad Pharm., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336 (Fed. Cir. 2010) (en banc), the full Federal Circuit invalidated a broad genus claim because the applicant had not yet identified a sufficient structural-functional relationship or sufficient species possessing the required function to demonstrate that the applicant

had actually invented and disclosed the claimed genus.

> [A] generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result.... [T]he specification must describe an invention understandable to that skilled artisan and show that *the inventor actually invented* the invention claimed.

Id. at 1349-51 (emphasis added; citations omitted).[17] However, the Federal Circuit has not yet clearly

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[17] Note that the language of Section 112(b) requires "distinct claiming" of "the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). As the plain meaning of this language indicates, the applicant may only claim (distinctly) what the applicant subjectively regards as the invention. However, Federal Circuit case law has limited application of Section 112(b) in infringement litigation. *See Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372 (Fed. Cir. 2000). Thus, the Federal Circuit currently polices the correspondence of the claim to the applicant's subjective understanding of the invention (as objectively disclosed in the specification) through

articulated *when* sufficient species have been disclosed or when a *sufficient* structural-functional relationship is identified to justify that the applicant subjectively "possess[ed]" the genus of a claimed species, and thus invented rather than just claimed that genus.

> [A] sufficient description of a genus instead 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…. [T]he test for sufficiency is whether the disclosure of the application relied upon *reasonably conveys* to those skilled in the art *that the inventor had possession of the claimed subject matter* as of the filing date.

Id. at 1350-51 (emphasis added; citations omitted).[18]

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the "possession" test, under the "written description" requirement of Section 112(a) rather than under Section 112(b). *See* 35 U.S.C. § 112(a); *Ariad*, 598 F.3d at 1351.

[18] Note that the en banc Federal Circuit standard requires the applicant to objectively demonstrate *both* that *the applicant* "had possession" (*i.e.,* subjectively recognized the species) of the claimed genus (similar to the "regards as invention" requirement) *and* provide sufficient information for *skilled practitioners* themselves to "visualize and recognize" the members of the genus. The former should be addressed under written description doctrine; the latter under enablement doctrine.

C. This Court Has Articulated the Same Concerns Under the Enablement Doctrine, Requiring Conception and Disclosure of a Sufficient Structural-Functional Relationship Before Claiming a Genus As an Invention.

This Court has imposed similar requirements for the identification and disclosure of a sufficient structural-functional relationship of a claimed genus to qualify as an "invention" under the "enablement" doctrine. It is that *conceived and disclosed* (not just claimed) invention that the applicant must *then* enable others to "make and use." Applicants cannot shift to skilled practitioners the burden of *inventing* a genus by experimentation, and then claim that skilled practitioners are enabled to make the invention (actually to invent that invention).

As the Court held in *Consolidated Elec. Light Co. v. McKeesport Light Co.,* 159 U.S. 465 (1895):

> 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….
>
> From this it appears very clearly that *there is no such quality common* to fibrous and textile substances *generally*

> as makes them suitable for an incandescent conductor…. The question really is whether the imperfectly successful experiments … authorize the [patentees] to put under tribute the results of the brilliant discoveries made by others….
>
> If the description be so vague and uncertain that *no one can tell, except by independent experiments, how to construct the patented device,* the patent is void….
>
> [Absent a disclosure of the relative chemical proportions] in such cases it would be 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…. *And if, from the nature and character of the ingredients to be used, they are not susceptible of such exact description, the inventor is not entitled to a patent.*"

Id. at 472-75 (emphasis added; citations omitted). In short, even for "enablement," to validly claim a genus as an "invention" requires identification and disclosure *of the common structural features of the genus that will perform the required function* that are sufficient to assure that the inventor recognized *and* disclosed the claimed structures without forcing the public to "first ascertain[], by experiment" what is

claimed. *Id.* Without such identification and disclosure, the claim overreaches any invention actually made and disclosed.

Nor is the Court's holding in *Minerals Separation, Ltd. v. Hyde,* 242 U.S. 261 (1916), to the contrary.[19] Rather, the Court merely held that applicants need not reduce to practice (*i.e.*, physically create) and enumerate in the specification *all* of the generically claimed *species* embodiments in order to show what species within the claim *work best,* when (and only when) disclosure of a limited number of embodiments was sufficient to demonstrate that the applicant had identified the required structural-functional relationship. In contrast, the Court found that the required structural-functional relationship disclosure was lacking in regard to some of the claims.

> Equally untenable is the claim that the patent is invalid for the reason that the evidence shows that when different ores are treated preliminary tests must be made … in order to obtain *the best results.* Such variation of treatment must be within the scope of the claims, and *the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject matter.* The composition of ores varies infinitely, each one presenting its

[19] At most, *Minerals Separation* permits the applicant, having *disclosed* the requisite structural-functional relationship to identify the conceived invention, to avoid having to *reduce to practice* numerous species in order *to demonstrate* the required structural-functional relationship.

> special problem, and it is obviously impossible to specify in a patent the precise treatment *which would be most successful and economical in each case.* The process is one for dealing with a large class of substances and the range of treatment within the terms of the claims, *while leaving something to the skill of persons applying the invention, is clearly sufficiently definite to guide those skilled in the art to its successful application*, as the evidence abundantly shows. [20]…
>
> While we thus find in favor of the validity of the patent, we cannot agree with the district court in regarding it valid *as to all of the claims in suit*.... [Y]et … the patent must be confined to the results obtained by the use of oil *within the proportions often described in the testimony and in the claims of the patent as 'critical proportions,'* 'amounting to a fraction of 1 per cent on the ore,' and therefore the decree of this court will be that the patent … is invalid as to claims 9, 10, and 11.

Minerals Separation, 242 U.S. at 270-71 (emphasis added; citations omitted). Nothing in the first paragraph above suggests – and the second paragraph expressly contradicts – that applicants can leave to

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[20] Note that this follows the same principle as discussed by the Court in *Risdon Iron & Locomotive Works,* identifying "the same obscurity in the line of demarkation as in that between mechanical skill and invention." 158 U.S. at 71-72.

skilled practitioners the obligation *to invent.* Applicants cannot shift the burden of experimenting (by trial-and-error testing) to identify from a broader set of potential structures the more limited set that in fact have the required functional properties to qualify as species within a claimed genus.

D. The Enablement Doctrine Requires Both Disclosure of a Sufficient Structural-Functional Relationship to Validly Claim a Genus and Sufficient Additional Information to Make and Use that Invention.

The Court should provide guidance on *both* aspects of the enablement standard, in order to support its further refinement by the lower courts and the U.S. Patent and Trademark Office. First, courts (and others) must determine *how much* of an identified and disclosed structural-functional relationship will support a valid genus claim. This Court's prior cases, such as *Risdon*, *Graver Tank,* and *Consolidated Electric Light,* seem to suggest that: (a) a claimed genus is valid only if "mechanical" and not "inventive" skill (however distinguished) must be applied to identify the structures falling within the scope of the claim; (b) claiming *any* "[in]operative species" will invalidate even a structural (genus) claim; and (c) a generic claim must reflect a structural-functional relationship that is a "quality common to all of" the claimed species. *See supra.* Even if these strict standards are to be relaxed (without further guidance from Congress), this Court has yet to clearly identify what would be sufficient *to invent and disclose* a genus. For example, if the disclosure identifies *likely*

structures that, when tested for the required functions, meet functional claim limitations 80% of the time, would that be a sufficient disclosure of a genus of claimed structures? How about 20%? A fractional percentage?[21] Does it depend on how difficult it is to "make" and "test" the structures for the required functions? Does it depend on whether the genus comprises millions of potential structures or only a few? These are precisely the right questions to ask (in an appropriate case) *if* this Court seeks to alter the guidance from its precedents, where *any* degree of inventive skill, *any* inoperative embodiments (not disclaimed), or the lack of *any* disclosed structure-functional relationship will invalidate a genus claim. In other words, this court needs to provide guidance directing lower courts to distinguish "mechanical skill" from "invention" in regard to genus claims.

Further, the various evidentiary considerations described by the Federal Circuit in *Wands* (as developed by the Patent Office) would *then* be relevant to determining whether a *properly disclosed* genus can be "made and used" by skilled practitioners.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been

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[21] The instant case does not involve even a fractional percentage. Amgen tested 1500 antibody candidates obtained from injecting mice (reduced to 35 tested for amino acid sequences) and identified only a handful of species. But lacking *any* identified structural-functional relationship, there were an "astronomically large number of" candidates to make (with a potentially infinite number of mice) and *then* test *by trial and error* (like the proverbial monkeys and keyboards), C.A. App. 3759.

> summarized by the board.... They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

858 F.2d at 737.

Unfortunately, *Wands* conflates, under the "undue experimentation" standard for enablement, the inquiries of: (a) whether there is sufficient disclosure for *skilled practitioners to identify the species* of a claimed genus (without inventing them); and (b) whether skilled practitioners can make and use the properly claimed species of a genus without too much time, money, and effort. Much of the analysis of the first inquiry by the lower courts to date, moreover, has been performed under the "written description" doctrine, which should address whether the skilled practitioners can recognize that the *applicant* invented (subjectively recognized the species within) the scope of the claimed genus. *See, e.g., Ariad*, 598 F.3d at 1349-50.

Nevertheless, the first question for enablement is whether there is a sufficient disclosure to properly claim a genus (as indicated by *Consolidated Electric Light)*. This question is a predicate (*what* must be enabled) to the question of *whether* the disclosed and

claimed invention is enabled (*i.e.*, can be made and used by skilled practitioners). One simply cannot enable others to make and use an invention that one has not identified and disclosed. Rather, one can enable others to invent what has been (improperly) claimed.

The second question for enablement is for courts to determine if sufficient *additional information* is disclosed to enable skilled practitioners to make and use a properly disclosed and claimed invention, whether a genus, a subgenus, or a species. This second aspect of the enablement inquiry must consider how much time, money, and effort permissibly can be imposed by applicants on skilled practitioners in order for them to make and use what is claimed. Significantly, there may be a difference in regard to the time, money and effort required to make and use: (1) *undisclosed* (unenumerated) embodiments of a claimed genus that a skilled practitioner must first identify (particularly if functionally claimed, which then requires testing for the function if the structural-functional relationship is not exhibited 100% of the time), and (2) disclosed (enumerated) embodiments. The *Wands* evidentiary considerations may be relevant to this second inquiry, even if the *Wands* "undue experimentation" standard is not helpful to making such judgments.

The "undue experimentation" standard in *Wands,* moreover, fails to provide *any* meaningful referent to guide *either* the analysis of whether a genus is properly claimed or whether the applicant has provided sufficient information to make and use that genus ("undue" compared to what?). Similarly,

Minerals Separation's "reasonable[ness]" standard provides no basis to draw the line between insufficient instruction and sufficient instruction that "leav[es] something to the skill of persons applying the invention." 242 U.S. at 271. That line-drawing standard should be based on economic determinations that reflect an appropriate balance between initial discovery and disclosure and the scope of the claim's exclusive rights, and whether that promotes or restricts sequential innovation. *See generally* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope,* 90 Colum. L. Rev. 839 (1990); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law,* 5 J. Econ. Persp. 29 (1991); Bhaven Sampat & Heidi L. Williams, *How Do Patents Affect Follow-On Innovation? Evidence From the Human Genome,* 109 Am. Econ. Rev. 203 (2019); Janet Freilich & Sepehr Shahshahani, *Measuring Follow-On Innovation* (Nov. 4, 2022), at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4268690. In the absence of further legislative intervention, the Courts must develop these principles over time through precedents and analogical reasoning. This Court should instruct the lower courts to develop these precedents as much as possible on economic considerations and on the relevant evidence for specific fields.

II. The Enablement Doctrine Prevents Overclaiming Of Genus Inventions That Are Actually Research Plans Or Results.

This Court and the U.S. Court of Appeals for the Federal Circuit have identified numerous concerns

underlying the different patent law doctrines that prohibit claiming a genus of structures without disclosing a sufficient structural-functional relationship. First, granting such claims would provide a disproportionate reward to applicants. As noted in *O'Reilly,* claims to unspecified structures that perform the required functions but without disclosing a common structural-functional relationship are not "invented, and therefore could not [be] describe[d]." 56 U.S. at 113. Lacking such a disclosure, because the genus of functional structures is "not susceptible of such exact description, the inventor is not entitled to a patent." *Consol. Elec. Light,* 159 U.S. at 475. Similarly, in *Minerals Separation,* "the patent must be confined to the results obtained." 242 U.S. at 271. Limiting the claims to the structural-functional relationship discovered and disclosed assures that the "pro quo" of the patent right is commensurate with the "quid" of the actual invention.

This Court should not be concerned that applicants can claim only what they have invented and disclosed. Applicants are entitled to claim the particular, structural species (or any sufficiently related genus of species) that they have identified that perform the desired functions. When they do so, applicants then may receive *additional* protection for functionally *equivalent structures* under the doctrine of equivalents. *See Graver Tank*, 339 U.S. at 610. *If* applicants can *also* identify a common structural-functional relationship that sufficiently assures that other structures will perform the required functions, *then* (and only then) they can claim a (broader) genus of structures (using either structural or functional language) that they have not identified individually.

Again, this assures commensurability between the invention made and the rights granted.

The second reason the enablement doctrine prohibits such overbroad generic claiming is that claiming a result or a research plan (*i.e.,* claiming *future* inventions) blocks sequential innovation and commercialization of additional structures that the applicant has not yet identified to possess the required function.[22] Although the Court has addressed this concern under numerous doctrines (as demonstrated above), it is no less relevant to enablement concerns.[23]

Such excessive claiming is particularly pernicious in light of the constrained experimental use "exception" to infringement adopted by the lower courts. *See e.g., Madey v. Duke Univ.*, 307 F.3d 1351, 1355, 1362 (Fed. Cir. 2002) (restricting non-infringing experimental use whenever experiments to make or use a patented invention are performed with a commercial purpose). Thus, no sequential innovator may seek *to discover* any additional, functional species

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[22] *See, e.g., Halliburton Oil Well Cementing,* 329 U.S. at 12 ("frightened from the course of experimentation by broad functional claims"); *O'Reilly*, 56 U.S. at 113 ("[S]ome future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification..... But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.").

[23] *See supra* Part I.B. *Cf. Rochester,* 358 F.3d at 927, 929-30 ("In view of our affirmance of the district court's decision on the written description ground, *we consider the enablement issue to be moot* and will not discuss it further.") (emphasis added).

within the scope of the claims by making and testing embodiments of the claimed genus. To do so, they will need prior authorization of the patent holder, so long as they perform their experiments *intending* to commercialize those discovered species. This is true even if those species are non-obvious and qualify as separate, but subservient, patentable inventions.

The history of antibody claiming demonstrates the importance of not granting (and not enforcing where granted) such broad genus claims to research plans. Over the past two decades, antibody claims shifted from broad genus claims directed to the antigen or epitope (*i.e.,* binding function) to narrower species claims defined by the antibody structure. This narrowing started at the Patent Office, where patent examiners have recognized that broad claims are not typically enabled by the specification. *See* S. Sean Tu & Christopher M. Holman, *Antibody Patents: Use of the Written Description and Enablement Requirements at the Patent & Trademark Office,* 38 Berkeley Tech. L. J. (forthcoming 2023).

> As antibody technology matured from research and diagnostic tools to therapeutic medicines, courts and the PTO sought to narrow the scope of antibody claims to (1) better reflect that which the inventor disclosed and (2) prevent any one firm from hindering the development of antibodies. Thus, narrowing the scope of antibody patents allowed competitors to develop their own antibodies by "designing around" already patented antibodies.

> However, as antibody technology moved from diagnostic tools towards therapeutic uses that depended on specific binding sites, so too have patent claims moved from broad genus claims to narrow species claims.

S. Sean Tu & Christopher M. Holman, *Antibody Claims and the Evolution of the Written Description/Enablement Requirement,* 63 IDEA 84, 96 (2021). Had the early, broad, generic antibody claims been enforced against competitive therapeutics development or had similar therapeutic claims later been granted, we would not have obtained the many medically useful alternatives and the variety of antibody options that were developed, some of which are at issue in this case. Without freedom to operate within the (undisclosed) genus of functionally claimed results, scientists and small companies will be frightened from the course of inventing.

III. The Court Should Invalidate The Genus Claims At Issue While Providing Better Guidance For Future Cases.

In this case, Amgen claimed an entire genus of antibodies, using functional language at the point of novelty in two ways. For example,

> 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues [followed by a list of 15 amino acid residues], and wherein the monoclonal antibody blocks binding of PCSK9 to [LDL receptors].

U.S. Pat. No. 8,829,165, Cl. 1. First, the structural antibodies that fall within the scope of the claim must bind (sufficiently) to PCSK9, and must do so in the "sweet spot" identified in the claim. Second, those antibodies must block binding (sufficiently) of the PCSK9-antibody complex to the low-density lipoprotein receptors. As extensively discussed in the opinion below, such production and screening to *identify* structural species of the functional claim (at present) *necessarily* involves experimentation. *See Amgen,* 987 F.3d at 1088 (Fed. Cir. 2021) ("[T]he only ways for a person of ordinary skill to discover undisclosed claimed embodiments would be through either 'trial and error … or else 'by discovering the antibodies *de novo*' according to a randomization-and-screening 'roadmap.'"). Such random trial-and-error testing and screening must (in order to *identify* what structures are within the scope of a claimed genus) test a *potentially infinite* number of structures to determine which of them possess the required functions. Nothing in the patent's disclosure indicates *which* antibody structures are *likely* to possess the required functional properties, and thus might limit the amount of required testing.[24] Rather, the disclosure is simply an invitation for others to *invent* species that (through trial-and-error testing or random production screening) will turn out to fall within the scope of the functional limitations. This

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[24] In theory, developments in combinatoric chemistry and analysis of protein folding structures might *in the future* provide *some* indication of the *likely* antibody structures that might need to be tested for functionality, so as to determine the limits of the claim's scope. But we are not there yet. *See, e.g.,* Barry Robson, *De novo protein folding on computers. Benefits and challenges,* Comput. Biol. Medicine 143 (2022).

was precisely the problem with the claim in *Consolidated Electric Light,* given the limited species invention made and the lack of identification and disclosure of a structural-functional relationship.

Accordingly, the *generic* claims at issue pose an "easy case," which requires little thought and no difficult line-drawing in order to invalidate it on lack of enablement grounds (or on any of the other grounds discussed in Part I.B.). Further, the broad generic claims at issue are not enabled merely because the patentee disclosed *some* identified structures that perform the required functions, and also disclosed a methodology (a research plan) for making and testing additional structures to determine if they possess the desired functional limitations. Thus, the patentee has made only narrower, species inventions (or perhaps narrow genus inventions) and has identified a plan for performing the needed research *to invent* additional species (or perhaps a broader genus). Again, this Court need not be concerned that the patentee will be denied of any claim scope to which it is properly entitled, and the doctrine of equivalents will protect the applicant from structurally similar, functionally identical species identified by others.

CONCLUSION

Because this is an "easy case," the Court should affirm without remand while providing the needed guidance explained in Part I.D. to properly develop the law for innumerable, difficult enablement issues.

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APPENDIX

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