No. 21-757

IN THE

Supreme Court of the United States

AMGEN INC., *et al.*,

Petitioners,

v.

SANOFI, *et al.*,

Respondents.

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

BRIEF OF *AMICUS CURIAE* NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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INTEREST OF AMICI CURIAE[1]

This amicus curiae brief is submitted on behalf of the New York Intellectual Property Law Association ("NYIPLA" or the "Association").

The NYIPLA is a bar association of attorneys who practice in the area of patent, copyright, trademark, and other intellectual property ("IP") law. It is one of the largest regional IP bar associations in the United States.

The NYIPLA's members include various attorneys specializing in patent law, including in-house counsel for businesses that own, enforce, and challenge patents, as well as attorneys in private practice who advise a wide array of clients on patent matters and procure issuance of patents through the U.S. Patent & Trademark Office (the "Patent Office"). NYIPLA's members represent inventors, entrepreneurs, businesses, universities, and industry and trade associations.

The NYIPLA's members and their clients have a strong interest in this case and regularly participate in patent prosecution on behalf of applicants and in patent litigation on behalf of both plaintiffs and defendants in federal court. Thus, the NYIPLA brings the informed and well-balanced perspective of diverse stakeholders on

1. Pursuant to Supreme Court Rule 37.6, counsel for amicus curiae states that no counsel for a party authored this brief in whole or in part, and no one other than amicus curiae or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Under the revised rules of the Court, no consent of the parties is necessary and in any event the parties have provided blanket consents.

patent issues. The NYIPLA hereby submits its amicus curiae brief in support of neither party.[2]

SUMMARY OF THE ARGUMENT

The Federal Circuit's requirement for enablement of the full scope of the claimed invention has been in effect since at least *In re Hyatt,* 708 F.2d 712, 714 (Fed.Cir.1983). As applied to genus claims in biotechnology, because of the uncertainty of the science and the required functionality, this has required disclosure of every species in the genus. *Wyeth* v. *Abbott Laboratories*, 720 F.3d 1380, 1385 (2013) (finding lack of enablement on summary judgment because "practicing the full scope of the claims would require synthesizing and screening *each* of at least tens of thousands of compounds" and "having to synthesize and screen each of at least tens of thousands of candidate compounds constitutes undue experimentation." However, this requirement seems to run afoul of this Court's decision in *Minerals Separation* v. *Hyde*, 242 U.S. 261, 270-71 (1916). Further, its full scope requirement does

2. The arguments made in this brief were approved by an absolute majority of the officers and members of the NYIPLA's Board of Directors eligible to vote (excluding any officers or directors who did not vote for any reason, including recusal), but do not necessarily reflect the views of a majority of the members of the Association, or of the law or corporate firms with which those members are associated. After reasonable investigation, the NYIPLA believes that no officer or director or member of the Amicus Briefs Committee who voted in favor of filing this brief, nor any attorney associated with any such officer, director or committee member in any law or corporate firm, represents a party to this litigation. Some officers, directors, committee members or associated attorneys may represent entities, including other amici curiae, which have an interest in other matters that may be affected by the outcome of this litigation.

not comport with the literal language of the statute. 35 U.S.C. 112.

Nevertheless, the Federal Circuit is addressing a valid concern, i.e., that a patentee not be granted patent claim coverage that exceeds what the inventor has invented, as disclosed in the patent application. However, the lower court's full scope rationale leads to a number of practical difficulties that could lead inventors to disclose less than what they discovered, such as a functional relationship at the heart of why the invention works. Withholding such information inhibits the progress of science, contrary to the very core of the constitutional imperative to incentivize innovation and may cause a proliferation of patents that inhibit commerce.

The NYIPLA proposes a new rule which involves limiting Section 112 to its statutory language and requiring an applicant to disclose a reasonable number of species sufficient to give the Patent Office examiner confidence that the genus is supported. However, under our proposed rule, at the time of a trial for infringement the court would use a claim construction that limits the scope of the patent to only those species that could have been obtained without undue experimentation using the specification and the state of the art at the time the application was filed.

This proposal reduces the burden on the applicant and Patent Office in preparing the application and examining it. It promotes full disclosure of the principle of the invention that is the basis for the genus claim. The application also acts as prior art to those inventors who would come later and thus reduces the number of patents

that might be granted for a particular subject matter. Further, the first inventor gets to keep her patent even if all species do not work, but the public is free to use those species that prove to require undue experimentation to obtain them.

ARGUMENT

I. Background

On November 4, 2022, the US Supreme Court granted certiorari in *Amgen Inc.* v. *Sanofi* (No. 21-757). This case involves application of the enablement requirement of Section 112 to a so-called genus claim in the context of pharmaceutical applications.

The two patents in dispute, US Patents Nos. 8,829,165 (the '165 patent) and 8,859,741 (the '741 patent), relate to antibody drugs that reduce low-density lipoprotein ("LDL") cholesterol. The human body normally relies on LDL receptors in the liver to remove LDL cholesterol from the bloodstream. A naturally occurring protein (PCSK9) binds to and causes the destruction of the LDL receptors leading to higher levels of LDL cholesterol. The patented invention is for a technology that relies on antibodies that bind to the PCSK9, inhibiting it from binding to LDL receptors and leaving them free to extract cholesterol from the bloodstream. Respondents (plaintiff Sanofi) developed **Praluent**, the first FDA-approved PCSK9 antibody, and Petitioner (defendant Amgen) developed **Repatha**, another FDA-approved PCSK9 antibody. These antibodies differ in amino acid sequence and where they bind to PCSK9.

Amgen obtained the two patents that broadly claim the genus of all antibodies that bind to certain amino acids on PCSK9 (a first function) and block its binding to LDL receptors (a second function). For example, claim 1 of the '165 patent reads:

> 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].

The common specification for the patents discloses that Amgen used a trial-and-error method to generate and screen antibodies that meet the claim language. Using this process, Amgen identified 85 antibodies that meet the claim language, but the specification discloses only the amino acid sequences of about two dozen of these antibodies. The specification also provides the three-dimensional structure of only two of those antibodies.

At trial, Respondent introduced evidence that the claims had a scope that could cover millions of antibodies and that given the unpredictability of antibody science, a person skilled in the art would have to test every single antibody generated by Amgen's disclosed methods to determine whether it had the necessary functional properties and thus was encompassed by the claims. At a first trial the defendants conceded infringement and the Jury found the patents valid. On appeal the Federal Circuit, 872 F.3d 1367 (Fed. Cir. 2017), affirmed in part, reversed in part, vacated in part, and remanded. On remand, the jury found two of five asserted claims invalid for lack of adequate written description but found

the three remaining claims valid. The district court granted Respondents' motion for JMOL as to enablement, concluding that, under the Federal Circuit's long-established multi-factor test for evaluating enablement, *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), Amgen's patents require undue experimentation and thus are not enabled. The *Wands* factors are

> (1) the quantity of experimentation necessary,
>
> (2) the amount of direction or guidance presented,
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> (3) the presence or absence of working examples,
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> (4) the nature of the invention,
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> (5) the state of the prior art,
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> (6) the relative skill of those in the art,
>
> (7) the predictability or unpredictability of the art, and
>
> (8) the breadth of the claims. *Id.* at 737

On a second appeal, the Federal Circuit unanimously affirmed the district court observing that enablement is "a question of law ... review[ed] without deference, although the determination may be based on underlying factual findings, which we review for clear error." 987 F.3d 1080, 1084 (Fed. Cir. 2021). Considering the *Wands* factors, the court determined that "undue experimentation" was necessary to enable the "**full scope**" of Amgen's "double-function claims" *Id.* at 1087. Further, the evidence established that the relevant "field of

science" was "unpredictable," and there was "the conspicuous absence of nonconclusory evidence that the **full scope** of the broad claims can predictably be generated by the described methods." *Id.* "[U]nder these facts," the court explained, "no reasonable jury could conclude ... that anything but substantial time and effort would be required **to reach the full scope of claimed embodiments**." *Id.* at 1088. Thus, "weighing the *Wands* factors," the court concluded that, "undue experimentation would be required to practice the **full scope** of these claims." *Id.* In support of its "**full scope**" requirement, the Federal Circuit cited its earlier opinions in *Wyeth & Cordis Corp.* v. *Abbott Laboratories,* 720 F.3d 1380, 1385–86 (Fed. Cir. 2013)*; Enzo Life Sciences, Inc.* v. *Roche Molecular Systems, Inc.,* 928 F.3d 1340, 1345–48 (Fed. Cir. 2019) and *Idenix Pharmaceuticals LLC* v. *Gilead Sciences Inc.,* 941 F.3d 1149, 1160–63, 1165 (Fed. Cir. 2019). *Id.*

In response to a petition for rehearing, the Federal Circuit explained that the opinion had merely "examined the relevant *Wands* factors and their interaction in a case-specific manner" 850 Fed. App'x 794, 795 (Fed. Cir. 2021) and that what was "new" was "not the law, but generic claims to biological materials that are not fully enabled." *Id.* at 795. The enablement requirement precludes obtaining a patent "for inventions broader than are disclosed or enabled, and that were apparently not invented by the applicant." *Id.* at 796. Allowing such overly broad genus claims where an inventor has not done the work of filling in the gaps, the panel observed, "discourages invention by others." *Id.* When "properly supported," however, "[g]enus claims, to any type of invention ... are alive and well." *Id.* at 795.

In its petition for certiorari, Amgen argues that in this case the Federal Circuit applied a recent court-made "hurdle[]" to enablement[3], i.e., for "genus" claims like Amgen's, and ruled that it is not enough that the patent meet the statutory requirement that it teach skilled artisans to "make and use" the invention. 35 U.S.C. 112(a). Instead, the Federal Circuit required that the specification allow skilled artisans "*to reach* ***the full scope*** of claimed embodiments" *i.e.,* to cumulatively identify and make all or nearly all possible variations of the invention-without "substantial time and effort."

Further Amgen asserts that there was no dispute that Amgen's patented invention—monoclonal antibodies that dramatically reduce levels of "bad" cholesterol—was a breakthrough. There was no dispute the patents enabled skilled artisans to "make and use" those antibodies. 35 U.S.C. 112(a). They could make the 26 antibodies identified in the patent by amino-acid sequence and could make other antibodies within the claims by following the patents' step-by-step "roadmap," which employs methods routine

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3. Amicus notes that by 1983 the Federal Circuit had articulated its "full scope" requirement for enablement. *See In re Hyatt, 708 F.2d 712, 714 (Fed.Cir.1983)* ("The enabling disclosure of the specification [must] be commensurate in scope with the claim under consideration."). *See also*, *Genentech Inc.* v. *Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) ("[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561, (Fed.Cir.1993); S*ee also Amgen, Inc.* v. *Chugai Pharm. Co.,* 927 F.2d 1200, 1212, (Fed.Cir.1991); *In re Fisher,* 427 F.2d 833, 839 (CCPA 1970) ("[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.")

in the antibody arts. No one — neither Respondents nor their experts, nor the court, identified even *one* actual embodiment that could *not* be made following the patent's disclosures. (Amgen's Petition, p. 8)

II. Question to be Reviewed by the Court

The question to be reviewed by the Court is:

> Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. 112, or whether it must instead enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation—i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "time and effort."

III. Discussion

A. The Federal Circuit's Enablement Standard Goes Beyond the Literal Requirements of the Statute's Plain Language

35 USC 112a provides that:

> The specification shall contain a **written description of the invention**, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same …

Section 112b provides that: "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**."

Thus, the text of 112 only requires that the written description disclose the manner and process of making and using what is literally in the claims, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use what is described in the claims. *McRO, Inc.* v. *Bandai Namco Games America Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020) ("[The Section 112] statutory requirement is limited to what is claimed. Section 112 requires enablement of 'only the claimed invention,' not matter outside the claims. *Union Carbide Chemicals & Plastics Tech. Corp.* v. *Shell Oil Co.*, 308 F.3d 1167, 1186 (Fed. Cir. 2002) (citing *Durel Corp.* v. *Osram Sylvania Inc.*, 256 F.3d 1298, 1306–07 (Fed. Cir. 2001)); *Liquid Dynamics Corp.* v. *Vaughan Co.*, 449 F.3d 1209, 1224 & n.2 (Fed. Cir. 2006); *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (all that must be enabled is "the claimed invention"). For that reason, the "enablement inquiry necessarily depends on an interpretation of the claims." *Liquid Dynamics*, 449 F.3d at 1224 & n.2").

The requirement for enablement of the full scope of the claimed invention is not supported by the plain language of the statute and is contrary to this Court's holding in ***Minerals Separation* v. *Hyde***, 242 U.S. 261, 270–71 (1916), which stated that:

> 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 to determine the amount of oil and the extent of agitation necessary 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 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. This satisfies the law. *Mowry* v. *Whitney,* 14 Wall. 620; *Ives* v. *Hamilton,* 92 U. S. 426; *Carnegie Steel Co.* v. *Cambria Iron Co.,* 185 U. S. 403, 185 U. S. 436–437 (emphasis added).

Despite its age, this case and this language is still being cited. *See, e.g.*, *Cisco Systems Inc* v. *Arista Networks, Inc.*, 2016 WL 3277009, *3 (N.D. Cal., June 15, 2016); *FlatWorld Interactives LLC* v. *Samsung Electronics Co.*, 2014 WL 7464143, *11 (D. Del. Dec. 31, 2014)

B. Notwithstanding the Plain Language of the Statute, the Federal Circuit's Enablement Standard Does Address a Valid Concern

The Federal Circuit is trying to guard against a potential harm. It observed that "millions of candidates" for antibodies ***might*** fall within the claims, each of which would have to be "generate[d] and then screen[ed]" to determine whether it met the claims' requirements. *Amgen*, 987 F.3d at 1088.

The Federal Circuit also reiterated its position expressed in *McRO,* 959 F.3d at 1100, n2 that:

> In cases involving claims that state certain structural requirements and also require performance of some function (e.g., efficacy for a certain purpose), we have explained that undue experimentation can include undue experimentation in identifying, from among the many concretely identified compounds that meet the structural requirements, the compounds that satisfy the functional requirement.
>
> The Federal Circuit explained that "the evidence showed that the scope of the claims encompasses millions of candidates claimed with respect to multiple specific functions, and that it would be necessary to first generate and then screen each candidate antibody to determine whether it meets the double-function claim limitations." *Id.*

The issue then becomes whether it is permitted under the patent laws to allow an inventor to claim possibly millions of compounds when she has only fully described dozens of those compounds and processes for producing those dozens and perhaps some unidentified number of other compounds, in the context of a genus claim. It should be noted that the issue is not the difficulty of determining whether any particular antibody meets the functional limitations of the claim, but the sheer number of possible antibodies.

C. The Adverse Impact on the U.S. Patent System Resulting from How Patentees Would Behave if the Federal Circuit's Enablement Standard were Confirmed by This Court

As a practical matter for inventions based on physics, when a principle is discovered, it is reasonably likely that all physical elements, greater than the size of atoms, will perform according to that principle (predictable arts). The same is not necessarily true for inventions based on chemistry and biology where the behavior of materials such as antibodies, is uncertain because small deviations in structure can result in fundamentally different functional characteristics and where a clear determination of those characteristics requires testing (unpredictable arts). [4]

4. *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970) ("In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.")

The requirements for investments in developing chemical and biological inventions can be very substantial because of the required testing. If a few species with a beneficial property are discovered, the inventor may be able to propose a genus, i.e., a rule that other similar species have the same property. If the inventor is allowed to patent the genus, she will file for a patent on the genus and disclose it. This is very valuable for the advancement of the science since it gives the public an underlying theory or principle to explore, which stimulates innovation that is important for society. Notably, that exploration can be performed using available state of the art tools (which may in turn lead to innovation of new tools to facilitate exploration).

If the Federal Circuit's enablement standard as stated in *Amgen* is confirmed by this Court in modification of *Minerals Separation*, the inventor will have no incentive (or duty) to disclose the genus, which perhaps comprises the most important part of the discovery. Rather, the inventor would only disclose that which she has been able to test (to include her best mode). The rest will be kept from the public as a trade secret. A patent on the tested species would be valuable since it might be the first diagnostic or even treatment for a disease. In the meantime, the inventor would work in secret to find other valuable species, knowing the undisclosed principle. When a new workable species is found, the inventor could file for a new patent and get a new 20-year term, thus extending the patent protection beyond what it would have been had the genus been patented when the underlying principle was first discovered and made part of the public disclosure.

Further, a race is created between the first inventor and her competitors, although the competitors may not know that the race has begun until the first inventor publishes her discovery. Assuming a competitor discovers a species not covered by the first inventor's species patent, the competitor would get a patent and subject the public to at least two patents in this area, possibly raising the barrier to entry for other competitors who might seek a non-infringing alternative species. If the competitor also discovered the generic principle, she would have no motivation to disclose it. Like the first inventor she would work in secret to obtain more patents on newly discovered species, one by one.

The resulting consequences of adopting the Federal Circuit's standard, as outlined above, is contrary to what is intended by the U.S. Constitution Patent clause, Art. I, Sect. 8, Cl. 8, which has promoted the progress of science and innovation in America for over 235 years.

IV. Our Proposed Solution

The NYIPLA proposes a solution that allows patents to cover a genus, here, one of the molecules that reflects the scope of the innovation including its dual functional requirements, but limits the scope of the granted patent to only those species that can be obtained without undue experimentation, a test applied only when evaluating infringement as a means for construing the scope of the claims. *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Stated otherwise, amicus proposes using the scope of enablement to define the scope of the claims.

The Federal Circuit's "full scope" test establishes that no inventor should get a patent to a genus claim unless she has tested all of the species that could possibly make up that genus. This requires not just constructing, but also testing for functionality all possible species.

Your Amicus offers an alternative: grant a patent to the genus claim. If at the time of infringement, it is determined that undue experimentation was needed to make the species accused of infringement (here, a particular antibody with dual functionality), that species would be considered outside the scope of the patent claim and not infringing. On the other hand, if all the alleged infringer did was to follow the disclosure of the patent without undue experimentation, the accused species would be within the scope of the patent and an infringement.

The benefit of this solution is that the determination of undue experimentation as to the full scope of the claims (i.e., each species) is not required at the patenting stage and broad disclosure of inventions is encouraged.[5] As has been the case since the institution of the enablement statute, the Patent Office examiner will consider the disclosure in light of the state of the art and level of skill

5. Since 112 is a requirement for patentability, it must also apply at the prosecution stage. However, the applicant's burden to establish patentable enablement at the time of prosecution is lower because the Patent Office examiner lacks the resources to challenge the applicant's assertions of sufficient enabling disclosure to obtain the full scope of the claim, and thus the Office can rely on there being disclosure of a sufficient number of species to support an applicant's claim to the genus. On the other hand, an infringer's ability to challenge enablement invalidity in litigation is much greater, using expert witnesses who may have conducted extensive tests and may be able to explain the level of ordinary skill in the art against which the undue experimentation must be evaluated.

in the art at the time of filing and if a lack of enablement is found for a genus (or other) claim, reject that claim. *See* MPEP Section 2164.08 https://www.uspto.gov/web/offices/pac/mpep/s2164.html. This reduces the burden on the PTO and expense to applicants who would supply such disclosure as is deemed needed to support the species and any genus claims, but not compel constructing and testing of every discernable species within that genus, including those that may have no inherently unique characteristics or no incremental practical commercial benefit. Nor would it delay the filing of such an application while the applicant conducted further testing and verification. It also would avoid the potential filing of a voluminous specification or a vast multiplicity of applications on distinct species that the PTO would then need to administer and examine, and the applicant would need to prosecute and, if granted, maintain.

Only a very small percentage of issued patents are ever litigated. Any member of the public could determine whether there is infringement by following the specification and seeing if its antibody is obtained without undue further experimentation before going to market. If the discovered species required undue experimentation, the newcomer would have a defense against infringement, i.e., its product is beyond the scope of the patent. Machines capable of analyzing biologic material are improved every year. Something that might require undue experimentation today, may be trivial tomorrow. Thus, the newcomer to the field can use these machines to find new species, but a determination of infringement would remain based on the state of the art when the patent application was filed.

Further, the broad disclosure of the genus in a first patent would act as prior art to subsequent patents on species within that genus, except for those newly discovered species (e.g., an antibody) that are found to require undue experimentation based on the first patent's specification. Any such new species would not infringe the first patent and could be the subject of a subsequent patent should the inventor of the new species seek to patent the antibody.

Under the Federal Circuit's current formulation of the enablement standard, a genus claim which is not enabled by the specification to its "full scope" is invalid under Section 112. This is true even for those species that are enabled. With our proposal, those species that are enabled are still covered by a valid genus claim, which creates a quid pro quo for complete disclosure.

During prosecution, Section 112 works as a gatekeeper to block genus claims that the applicant cannot establish are enabled. However, the Patent Office examiner is ill equipped to challenge a patent applicant who asserts that the specification provides sufficient disclosure to make any species of the genus available to a person of ordinary skill in the art without undue experimentation. For example, in this case Amgen's application was 385 pages long, identified 85 antibodies that meet the claim limitation, and disclosed the amino acid sequences of about two dozen of these antibodies. The specification also provided the three-dimensional structure of two of the antibodies. In addition,

> Amgen points to expert testimony purportedly showing that a person of skill in the art can make

> all antibodies within the scope of the claims by following a roadmap using anchor antibodies and well-known screening techniques as described in the specification or by making conservative amino acid substitutions in the twenty-six examples. *Amgen*, 987 F.3d at 1085.

It is not possible for a Patent Office examiner to challenge this volume of evidence, particularly given the budgetary constraints and lack of technical or research resources within the Patent Office and the reality of the amount of time any examiner is given to examine an application.

The Patent Act already accounts for this apparent disparity in the application of the patent laws and for different requirements at prosecution and in litigation.[6] An applicant must satisfy Section 112 during prosecution, where the claim construction standard is the broadest reasonable interpretation (BRI) and the burden of proof is a preponderance of the evidence, to obtain her patent.[7]

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6. For example, while an applicant still must satisfy the "Best Mode" disclosure requirement at prosecution, the Patent Act as amended by the AIA eliminated failure to disclose the Best Mode as a basis to invalidate the patent in litigation.

7. *See AK Steel Corp.* v. *Sollac*, 344 F.3d 1234, 1245 (2003) ("Finally, we dispel the notion that the failure of the PTO to issue an enablement rejection automatically creates an 'especially weighty presumption' of compliance with 35 U.S.C. 112. AK Steel cites language in *Brooktree Corp.* v. *Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1574–75 (Fed.Cir.1993), to that effect. However, whether a patent complies with the enablement requirement depends upon a factually intensive inquiry regarding the amount of experimentation required, *see* [*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)], an issue to be evaluated on a case-by-case basis. Indeed, the presumption is far from determinative, and we have on occasion invalidated patent

Once granted, that patent has a presumption of validity, including validity under Section 112, that can be overcome only by clear and convincing evidence to the contrary at the infringement stage. 35 U.S.C. 282. Also, the evidence presented in litigation regarding enablement may shift if the genus claim scope is deemed narrower than it would be under the BRI as a result of claim construction under *Phillips*. However, if the doctrine of equivalents is used for determining infringement, the proper time for evaluating whether an accused element is equivalent to a claimed element is at the time of infringement, not at the time the patent was issued. Subsequent changes in the state of the art, such as technologies developed after the date of invention, will often challenge the definition of a previously essential element or limitation present in the original claimed invention. As the Federal Circuit stated in *Chiron Corp.* v. *Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004) (addressing whether an earlier filed application was enabling to support the continuation):

> Whether the earlier applications enable the claims of the '561 patent is determined as of **the filing date of each application**. *See Plant Genetic Sys.*, 315 F.3d at 1339. As noted above, a patent disclosure need not enable information within the knowledge of an ordinarily skilled artisan. Thus, a patentee preferably omits from the disclosure any routine technology that is well known at the time of application. *See Hybritech*, 802 F.2d at 1384. At the other end of the knowledge continuum, **a patent**

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claims as not having been enabled, despite the PTO's having allowed those claims. [citation omitted]")

> **document cannot enable technology that arises after the date of application.** The law does not expect an applicant to disclose knowledge invented or developed after the filing date. **Such disclosure would be impossible.** *See In re Hogan*, 559 F.2d 595, 605–06 (CCPA 1977). Nascent technology, however, must be enabled with a "specific and useful teaching." *Genentech, Inc.* v. *Novo Nordisk, A/S*, 108 F.3d 1361, 1368 (Fed.Cir.1997). The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology. *See, e.g., J.E.M. AG Supply, Inc.* v. *Pioneer Hi–Bred Int'l, Inc.*, 534 U.S. 124, 142, 122 S.Ct. 593, 604, 151 L.Ed.2d 508 (2001) (emphasis added).

The point of this amicus proposal is to apply the plain statutory language in the Patent Office for satisfying Section 112 during the patent examination stage. Allowance of the broad genus claim at that point would be under the assumption that based on the specification's disclosure, the covered species could be obtained without undue experimentation. During litigation, Section 112 would be used to limit the scope of the genus claim to cover only those species that are enabled, i.e., obtainable without undue experimentation. And, if the accused infringer can show that his species was not obtainable without undue experimentation, that species would not be covered by the broad genus claim and would not constitute infringement.

Thus, during prosecution the patentee would have to provide sufficient evidence to convince the Patent Office examiner that all of the species in the genus claim could be made without undue experimentation by following the specification. For example, the applicant might have to disclose at least one species of each broad range of species. However, the applicant would not have to disclose every single species covered by the broad genus claim. At trial, evidence that the accused species could not be obtained without undue experimentation would lead to a judgment of non-infringement, but the patentee would still have a valid genus claim covering those species that were directly disclosed in the specification or could be obtained without undue experimentation.

The scope of the genus claim at infringement would be determined by considering whether the accused product could be obtained without undue experimentation using the specification as a guide and the level of skill in the art, including technologies available, at the time of filing the application. It would be the accused infringer's burden to present evidence on these issues if he wants to avoid infringement.

In the present case, respectfully the Court should remand the case for a determination of whether the Sanofi antibody was obtainable from the disclosure in the Amgen patents with some — but not undue — experimentation at the time of the filing of the Amgen application.

CONCLUSION

For all these reasons, respectfully the Court should reverse and remand for further proceedings.

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Respectfully submitted,

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