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Amgen Inc. et al. v. Sanofi, et al.: What to Know About the Supreme Court Briefs and Oral Arguments

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BACKGROUND AND DISTRICT COURT AND FEDERAL CIRCUIT PROCEEDINGS

The patents at issue cover medications that help control blood levels of low-density lipoprotein (LDL) cholesterol using antibody technology. A naturally occurring protein called proprotein convertase subtilisin/kexin type 9 (PCSK9) can disrupt removal of LDL by binding to LDL receptors. In the 2000s, scientists hypothesized that antibodies could be made that bind to a certain region on PCKS9, which Amgen refers to as PCSK9's "sweet spot," thereby preventing PCSK9 from binding to LDL receptors, and allowing the liver cells to remove more LDL from the bloodstream.

In October 2011, Amgen obtained U.S. Patent No. 8,030,457 covering a specific antibody, identified by the amino acid sequence of its binding region, which binds to the PCSK9 sweet spot. The next month, Sanofi obtained U.S. Patent No. 8,062,640 covering a different antibody, identified by the amino acid sequence of its binding region, which binds to a different location on the sweet spot but likewise blocks PCSK9 from binding to LDL receptors. Amgen and Sanofi each obtained FDA approval for their antibodies and began marketing and selling them. Amgen's Repatha drug product and Sanofi/Regeneron's Praluent drug product, each covered by respective patents, do not have identical indications or dosages.

In 2014, Amgen obtained the two additional patents at issue before the Supreme Court: U.S. Patent No. 8,829,165 ('165 patent) and U.S. Patent No. 8,859,741 ('741 patent). Amgen sued Sanofi for infringement of the '165 and '741 patents. The parties stipulated to infringement but disputed validity.

The claims at issue together "claim antibodies that bind to one or more of" specified residues in the sweet spot "of the PCSK9 protein and block PCSK9 from binding to LDL receptors." The specifications of the two patents are identical, disclose amino-acid sequences of 26 different antibodies, and depict the three-dimensional structures of two of those antibodies. The specifications also describe two methods to produce other antibodies that bind to the PCSK9 sweet spot. The specifications explain that a POSITA could generate a random pool of antibodies (such as by injecting mice with PCSK9),

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test those antibodies to see if they bind to PCSK9, and then test if the antibodies also block interaction with LDL receptors. Alternatively, a practitioner could selectively replace the amino acids in an identified antibody with other amino acids exhibiting common properties – "conservative substitution" – and then test the resulting antibody for function.

The district court excluded certain evidence concerning post-priority date antibodies that Sanofi asserted was relevant to enablement. The jury found Sanofi had not proven lack of enablement. Sanofi appealed, and the U.S. Court of Appeals for the Federal Circuit reversed and remanded for a new trial, ruling that the excluded evidence was relevant to enablement because it might show that Amgen "engaged in lengthy and potentially undue experimentation to enable the full scope of the claims."[1]

On remand, the district court again excluded, as irrelevant and potentially confusing, certain post-priority date evidence about antibodies. Enablement was tried to a second jury, who ultimately upheld the patent claims.

Sanofi moved for judgment as a matter of law on enablement. The district court determined that "there does not appear to be a genuine dispute between the parties" that "millions" of antibodies "would need to be tested to determine whether they fell within the claims." It noted that both parties had acknowledged substantial uncertainty in the art, and that the patents lack "guidance on how to predict whether an antibody will bind." The district court observed that Amgen's experts testified that "the experimentation necessary to enable the full scope of the claims would take a substantial amount of time and effort." The court granted the motion, holding the claims invalid and concluding that "a reasonable factfinder could not fail to find that the experimentation required is 'undue.'"

The Federal Circuit affirmed. The Federal Circuit recited the standard that a patent claim is invalid for lack of enablement if "a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation,'" as determined in light of the *Wands* factors. The court also noted that a patent's disclosure "must be 'at least commensurate with the scope of the claims.'"[2]

The Federal Circuit specifically noted that the asserted claims are "defined, not by structure, but by meeting functional limitations." It concluded "that the claims are far broader in functional diversity than the disclosed examples," citing evidence that, "although the claims include antibodies that bind up to sixteen residues, none of [Amgen's] examples binds more than nine," and "there are three claimed residues to which not one disclosed example binds." The court noted "the conspicuous absence of non-conclusory evidence that the full scope of the broad claims can predictably be generated by the described methods," and observed that "it would be necessary to generate and screen" "millions" of potential antibodies to determine if the double-function claim limitations were met. The Federal Circuit determined that "no reasonable fact-finder could conclude that there was adequate guidance beyond the narrow scope of the working examples." While declining to hold "that the effort required to exhaust a genus is dispositive," the court found that "no reasonable jury could conclude under these facts that anything but 'substantial time and effort' would be required to reach the full scope of claimed embodiments" in Amgen's patents. The Federal Circuit thus affirmed "that undue experimentation would be required."

The Federal Circuit denied panel rehearing and rehearing en banc, with no recorded dissents. The panel issued an opinion on the denial of panel rehearing, stating that it had not "created a new test for enablement," but had applied longstanding patent-law principles.[3] The panel explained that if a claimed invention is "defined as a genus, that group is enabled by a disclosure commensurate with the scope of the genus." The panel stated that the enablement problem with Amgen's patents was "not simply that the claimed genus was numerous," or "that it would take a long time to collect the full set of each and every embodiment." Rather, it was that the genus "was so broad, extending far beyond the examples and guidance provided," and that "far corners of the claimed landscape that were particularly inaccessible" were not enabled given "the narrow and limited guidance in the specification."

The panel further observed that "[c]laims defining a composition of matter by function raise special problems because one may not know whether a species is within the scope of a generic claim until one has made it and one can ascertain whether it possesses the claimed function." The panel emphasized,

however, that "well-supported generic claims do not lack for enablement," and that "[g]enus claims, to any type of invention, when properly supported, are alive and well."

THE SUPREME COURT

Amgen petitioned for writ of certiorari, presenting two questions: (1) whether enablement is a question of fact to be determined by a jury or a question of law for the court to review without deference, and (2) whether a patent must enable one skilled in the art to reach "the full scope" of the claimed embodiments without undue experimentation.

The Court granted certiorari only on the following question:

> 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."

Amgen's Position

In its brief, Amgen primarily makes two arguments in support of its position against the Federal Circuit's "full scope" standard.

First, Amgen argues that the Federal Circuit's "full scope" standard has no textual, precedential, or historic support. Amgen points to Section 112(a), which states 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 . . . to make and use the same." Amgen argues the Federal Circuit's "full scope" standard is a clear departure from established law and that the Federal Circuit focuses on the "number of possible candidates" contained within the scope of the claims. Amgen relies on several Supreme Court cases holding that a patentee need not describe "all possible forms in which the claimed principle may be reduced to practice." These cases, along with longstanding enablement practices, Amgen argues, forecloses the Federal Circuit's "full scope" standard.

Second, Amgen discusses the policy implications of the "full scope" standard, arguing it defies patent law policy and harms innovation. Amgen's brief emphasizes that the patent system allows inventors to receive protection for their ideas in exchange for disclosing their inventions – the "full scope" standard upsets this exchange. Amgen asserts that the "full scope" standard denies an inventor a patent to a genus "simply because courts can speculate about the far corners of the genus." Amgen argues this will harm incentives for the creation of breakthrough inventions. Amgen then challenges the idea broad patent claims would "preempt the future" by deterring innovation by pointing out that protecting the "full breath" of an invention still allows others to obtain improvement patents.

Amgen further argues that a breakthrough invention with many applications would be unable to satisfy the "full scope" standard, and claims that cover only specific embodiments of the invention would not adequately protect the inventor's investment. As a result, in an attempt to maximize patent protection, inventors would delay disclosure and waste resources to identify all possible embodiments of the invention. Amgen states that "rote identification of permutations within an invention adds nothing to the understanding in the relevant field and only results in delayed patent filings and escalating costs – costs that may squeeze out smaller innovators entirely." Amgen asserts that the consequences of the "full scope" standard would not just affect the biotech and pharmaceutical industries but could affect genus claims in any field, resulting in devastating effects to patent system as a whole, a sentiment echoed by several of the amicus curie briefs filed in support of Amgen.

Amgen argues that it is the statutory "make and use" standard that should govern. Amgen asserts that the make and use standard provides a practical test that relies on real evidence rather than speculation. Amgen submits that this standard is consistent with precedent that found that the scope of enablement "must only bear a reasonable correlation to the scope of the claims." Amgen further supports the "make and use" standard by pointing out that this standard addresses the concerns articulated by the Federal Circuit regarding overbroad claims – still

providing a means to prevent inventors from claiming beyond what was invented.

Amgen concludes it brief by asserting that under any reasonable formulation of the enablement standard, its claims are enabled. Amgen argues that its patent provided a roadmap that allowed skilled artisans to generate the claimed antibodies using "routine and well-known methods." Furthermore, Amgen points out that neither Sanofi nor the Federal Circuit could identify any antibody that would require undue experimentation using the teachings of the patents. Amgen states the Federal Circuit's decision to review enablement without deference to the previous jury findings was improper, its ultimate conclusion was "legally erroneous," and the judgment should reversed.

Sanofi's Position

Sanofi's brief endeavors to put Amgen's arguments into context, not only with case history and the Federal Circuit's decision in the second appeal, but also in the context of Federal Circuit precedent. Sanofi argues that it was Amgen – not the Federal Circuit – that "raised the bar" for establishing enablement under 35 U.S.C. § 112. By virtue of laying claim to a functionally-defined genus, Amgen, Sanofi argues, is required under Section 112 to establish enablement of the entire genus.

Sanofi describes the line of cases implementing the "full scope" requirement to establish that the standard is "faithful" to Section 112's text and, particularly, the precedent including the decisions in *Wands*, *Idenix*, *Wyeth*, and *Enzo*. Sanofi states: "There is no special rule for functional or genus claims, but the more that is claimed the more that must be enabled." Sanofi argues that following these line of cases, where the facts established that a POSITA would have to perform a trial and error process, even if routine, where the art is unpredictable and the number of compounds within the claim is in the realm of tens of thousands, the claims were invalid for lack of enablement.

Amgen's patents, Sanofi argues, provide no guidance for preparing particular embodiments of the claims or any specific, undisclosed antibody, absent undue experimentation. Sanofi says a "clear case of non-enablement is when skilled artisans cannot predictably produce specific undisclosed embodiments of the claimed invention (or even entire classes of undisclosed embodiments) that they want or need without engaging in a trial-and-error process that could take years."

Sanofi challenges Amgen's characterization of the Federal Circuit's decision, down to the Question Presented, stating that the Federal Circuit did not require the patentee to expend effort to "cumulatively identify and make all or nearly all embodiments of the invention," and never once used the word cumulative in its decision. Sanofi goes on to argue that Amgen's "cumulative effort test" is strawman, and that Federal Circuit never defined or applied that test, and in fact disclaimed it.

Sanofi also challenges Amgen's supposedly novel "as needed" standard for enablement: whether the specification "sufficiently . . . guide[s] those skilled in the art to the 'successful application' of 'the invention.'" In doing so, Sanofi disspells and distinguishes the authorities that Amgen relies upon.

In terms of policy (echoed in several amicus briefs), Sanofi argues that the industry and patients will suffer if Amgen's claims stand. Finding the Amgen's claims are enabled will allow patent applicants to lay claim to an entire genus, such as the genus of antibodies claimed here, without establishing their composition or how to make and use them, thereby preempting others from developing different compounds in the same genus, which the patent applicants had never even contemplated. Focusing on timelines of the respective parties' development, Sanofi accuses Amgen of scheming the patent system. The timeline cuts against Amgen's argument that their genus claims spurred innovation. Amgen's genus claims were filed years after several companies (including Sanofi) had independently pursued and discovered PCSK9-inhibiting antibodies.

Amgen's Reply Brief

In its reply brief, Amgen first argues that despite Sanofi's assertion to the contrary, the Federal Circuit did apply a "cumulative effort test" in determining the enablement of Amgen's genus claims. Amgen states that "[w]hile Sanofi-Regeneron downplays the 'cumulative-effort standard' as a 'straw man' it was Sanofi-Regeneron that pressed that standard below." Furthermore, Amgen points out that the PTO and the lower courts recognize that the Federal Circuit has imposed a higher standard for enablement that looks to the "effort required to screen and identify all antibodies within the claims."

Amgen goes on to again assert that the "make and use" standard should govern the enablement analysis. This standard, Amgen argues, is supported by Section 112(a) and does not depend on the number of embodiments encompassed by a claim – it instead takes into consideration the nature and field of the claimed invention. Amgen argues that the "make and use" standard provides safeguards to prevent patentees from claiming more than they enable.

Amgen then challenges Sanofi's proposed "specific undisclosed embodiments standard" by asserting that this standard is not supported. Amgen points to the language of Section 112, noting that it does not pose any requirement that every embodiment one can hypothesize be predictably produced. Amgen further argues that Sanofi's proposed standard goes against reasonableness and instead focuses on "speculative outliers skilled artisans may never want or need." Amgen asserts that even if the court was to adopt this standard, Sanofi would still not prevail as it fails to establish non-enablement by clear and convincing evidence.

Amgen also addresses the government's arguments (see below). Amgen refutes the government's argument that Amgen's patents were not enabled because they covered more embodiments than what was exemplified in the specification by pointing to "centuries of law" that state that patents may guide skilled artisans on the application of embodiments not disclosed in the specification. Amgen goes on to state that the court has never held that the only way to enable a genus where a patent claims a genus of products is for the specification to describe a general quality in structural terms, this is. Nevertheless, Amgen asserts that its patents do describe the claimed genus in structural terms and should be found to be enabling.

Amgen then refutes the assertion that its patents only provide a trial and error process to produce the claimed antibodies. Amgen states that Sanofi and the government disregard the roadmap to produce the claimed antibodies contained within its patents. This roadmap, Amgen argues, allows skilled artisans "to start where Amgen's research ended" and that its patents "provide a wealth of previously unknown shortcuts and techniques."

Lastly, Amgen emphasizes the importance of genus claims in promoting innovation. Amgen argues that Sanofi and amici decry genus claims with functional elements despite protecting their own inventions with genus claims. Amgen emphasizes that genus claims are "critical to protecting and advancing innovation" and offers protection that the doctrine of equivalents cannot provide. Genus claims encourage companies to develop diverse therapies rather than creating minor variations to known inventions – this, Amgen argues, is the type of innovation that the patent system should promote.

Amicus Brief Of The United States

The United States filed an amicus brief supporting Sanofi's position.

The brief for the government begins with noting that the parties agree that there is no enablement if "undue experimentation" is required to produce the claimed invention, citing the *Wands* case for that standard. The government's argument focuses on the determination of undue experimentation as a fact-specific inquiry, which includes the context of the invention and the nature of the patent claim at issue. The government asserts that Amgen's specification does no more than recite 26 exemplar antibodies with structural information that allow reverse engineering of those exemplars, while claiming all antibodies that function to bind PCSK9 and block it from binding to LDL receptors. The government argues that Amgen's "roadmap for creating those additional antibodies" merely instructs researchers to run experiments to determine which PCSK9 antibodies exhibit the claimed functionalities. The government states that Amgen "may not evade an undue-experimentation problem merely by baking the need for experimentation into their roadmap." Finally, the government puts forth its position that by applying the *Wands* factors that both parties accept, the Federal Circuit decision invalidating the claims is correct and that the Federal Circuit did not announce a new "reach-the-full-scope" test that depends on the amount of time and effort needed to make products within the genus of the claimed subject matter.

Other Amicus Briefs

Numerous amicus briefs were filed, as noted in Table 1 outlining the amici and which party they supported, if any.

Some collective themes of the amicus briefs include discussions of policy regarding whether broad genius claims (including those defined

functionally, without structural features) promote or hinder innovation, and whether enablement should be determined by a test strictly limited to the words of the statute or should include additional concepts such as "undue experimentation" and the *Wands* factors. Several amicus briefs accept these additional concepts, but draw the line at any analysis requiring enablement of the "full scope" of claims.

Amicus Briefs in Support of Amgen

There were nine amicus briefs filed in support of Amgen, as indicated in Table 1. Notable briefs include those of major pharmaceutical companies such as Abbvie and GSK. The amicus briefs of those companies focuses on the need for genus claims that the amici argue are critical to innovation, as well as taking up the argument that the "full scope" test is nowhere in the statute and is contrary to the statutory language and the prior case law. An amicus brief by the Chemistry and Law Division of the American Chemical Society contends that the substantial investment in pharma and biotech research was encouraged by a "robust and predictable patent system" that is already represented by the "delicate balance" reflected in Section 112. A brief by fourteen Intellectual Property Professors asserts that "[t]he central feature of patent law in the life sciences industries is the genus claim" and argues that the Supreme Court should "return the law to its traditional moorings" because "the Federal Circuit has changed the law dramatically in recent years, to the point where it is no longer possible to have a valid genus claim in the chemical and biotechnology industries . . . because the genus contains thousands or millions of possible chemicals, unless the patent itself identifies exactly which of those myriad species will work" which the Professors argued is "an impossible burden." A joint brief filed by the Alliance of U.S. Startups and Inventors for Jobs and The Innovation Alliance states that "[t]he Federal Circuit appears oblivious to the actual impact" of its decision and argues that biotech startups and small companies require meaningful patent protection that requires genus claims but that "[a]s a result of this opinion, no well-advised inventor or patent lawyer can trust the Federal Circuit to uphold a genus claim."

Amicus Briefs in Support of Sanofi

As can be seen in Table 1, there were sixteen amicus briefs filed in support of Sanofi. Notable among these briefs include a joint brief from Genentech, AstraZeneca, Bayer, Gilead, and Johnson and Johnson arguing that the Federal Circuit applies a "flexible enablement standard, which properly requires a patentee to enable the full invention over which it claims exclusive rights" and that this standard is demanded by Section 112 and has been applied consistently. They further argue that this test appropriately balances adequate disclosure with artificial barriers to patenting and thereby promotes innovation. A brief the American Intellectual Property Law Association argues that the Federal Circuit's decision was based on established law, including the statute and case law, and requests that the Court affirm and confirm that the *Wands* factors are important in judging enablement. A brief by ten Intellectual Property Law Professors and Scholars (in contrast to the IP Professors in support of Amgen) sees "no cause for alarm" and contends this was "a classic example of a narrow invention that is coupled to overbroad claims." A brief for four small and medium biotechnology companies summarizes their position with "the ancient legal principle, if it ain't broke, don't fix it" and argues "[t]he Federal Circuit's longstanding enablement standard is consistent with the statutory text and [the Supreme Court's] precedent."

Nobel Laureate Sir Gregory Paul Winter and Interested Scientists filed a brief that is akin to an expert report. The Winter brief noted the importance of antibodies as treatments for disease and addressed from a scientific perspective three points: (1) the unpredictability of the antibody art; (2) the lack of guidance in Amgen's patents; and (3) the "devastating impact of over-broad, purely functional claims like Amgen's on antibody development and innovation for pharmaceutical drugs.

Amicus Briefs in Support of Neither Party

There were five amicus briefs filed in support for neither party, as indicated in Table 1. Notable among these were three briefs from Intellectual Property organizations: Intellectual Property Law Association of Chicago (IPLAC), Intellectual Property Owners Association (IPO), and New York Intellectual Property Law Association (NYIPLA). IPLAC argues the case should be vacated and remanded to be decided on the "time-honored standard" of "how to make and use the invention," and that cataloguing and teaching all possible embodiments is

not the law. IPO argues that assessing enablement is "a fact-specific, flexible analysis" that includes the technology and reflects "the understanding, knowledge, and abilities" of a POSITA. IPO argues the *Wands* factors were a helpful tool for conducting the analysis. NYIPLA proposes a new rule which would require disclosure of "a reasonable number of species sufficient to give the Patent Office examiner confidence that the genus is supported." In an infringement case, NYIPLA argues, "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." A brief by the High Tech Inventors Alliance (HTIA) and Computer & Communications Industry Association (CCIA) argues that this is an "inappropriate vehicle" to address Section 112 as the claimed embodiments have not been determined, and the claims at issue are "naked functional claims" that violate bedrock principles of patent law so that the Court should dismiss the grant of cert or limit the case to its specific facts.

Oral Argument

Oral argument took place in the Supreme Court on March 27, 2023. The United States (but none of the other amici) argued in addition to the parties. The Justices had a fairly good grasp of the complicated biotechnology, at least at a base level, and had little time for analogies offered by the parties regarding bats, paint, steam engines or metal airplanes. The Justices consistently focused on the invention and technology at hand. The Justice's questions and counsel's oral arguments did not make the ultimate decision clear but did clarify many likely issues to be addressed.

One fundamental question is whether there is even a dispute over the legal standard for enablement. Several justices, including Justice Gorsuch, asked whether there was a dispute on the legal standard or whether this case was factual. The questions included whether "cumulative effort" to make and use the claimed antibodies was dispositive, relevant, or irrelevant. Amgen argued the long-standing *Wands* factors "can be useful" but often becomes a checklist replacing the statutory test – namely, what is reasonable and important to a skilled artisan. Amgen also argued that although enablement might vary with claim scope, broad claims do not necessarily require difficult or lengthy experimentation. Sanofi argued that both the time and effort, as well as the nature of the experimentation required to practice an invention's full scope, are relevant. Sanofi conceded some play in the "undue experimentation" standard, and that "tweaks" would not doom a claim, especially where predictable.

A second, central question was, what is Amgen's claimed invention? The justices, particularly Justice Thomas, wanted a precise definition of the claimed invention, and its boundaries. Specifically, the Justices' questions were directed to whether the claims cover just the 26 antibodies with amino acid sequences in the patents or the approximately 400 antibodies that Amgen identified via mouse immunizations. Or, as Sanofi argued and the Federal Circuit noted, do the claims cover potentially millions of antibodies including those that might be made via conservative substitution? The Justices asked several questions that illuminated the tension created by functionally claiming a composition, as compared to process or product-by-process claims.

Amgen argued for a high burden for its granted patent, subjected to trial and upheld by two jury decisions, to be invalidated for lack of enablement, arguing there was not clear and convincing evidence of a failure to make even one antibody within the scope of the claims. Amgen proposed that claims are enabled unless there is both: (1) evidence of some category or class of claimed antibodies that required "painstaking" experimentation to be made, and (2) a reason why that would matter to the skilled artisan. On the first point, Amgen asserted there was no evidence that even a single antibody could not be easily made by a skilled artisan following the roadmap in its patents. On the second point, Amgen intimated that even if one antibody could not be made, that did not matter as many antibodies could be made and used. Amgen argued that the degree of experimentation to get all embodiments (plural) is irrelevant, and how to make any singular antibody was adequately disclosed in its patents.

Amgen also argued that companies would not invest billions of dollars to find new antibodies if genus claims were unavailable. Amgen referred to recent PTAB decisions applying the Federal Circuit's decision to require a higher showing of enablement for functionally-defined genus claims.

Sanofi argued the "heart" of the patent bargain (which requires more enablement for broader claims – the so-called full scope test) doomed Amgen's claims.

Table 1

Named Amicus Filers	Filed As In Support of
Abbvie Inc.	Amgen
Alliance of U.S. Startups and Inventors for Jobs (USIJ) and Innovation Alliance (IA)	Amgen
Chemistry and the Law Division (CHAL), American Chemical Society	Amgen
Diversified Researchers and Innovators	Amgen
GlaxoSmithKline plc (GSK)	Amgen
Instil Bio, Inc.	Amgen
Intellectual Property Professors	Amgen
National Association of Patent Practitioners, Inc. (NAPP)	Amgen
Nature's Fynd	Amgen
American Intellectual Property Law Association (AIPLA)	Sanofi
Arnold Ventures, The National Center for Health Research, and Certain Medical Doctors	Sanofi
Association for Accessible Medicines (AAM)	Sanofi
Eli Lilly & Co., Ipsen Bioscience, Inc., and Innovent Biologics, Inc.	Sanofi
Fresenius Kabi USA, LLC	Sanofi
Genentech, Inc., Astrazeneca Pharmaceuticals LP, Bayer AG, Gilead Sciences, Inc., and Johnson & Johnson	Sanofi
Intellectual Property Law Professors and Scholars	Sanofi
Law Professors Joshua D. Sarnoff, Sharon K. Sandeen, and Ana Santos Rutschman	Sanofi
Pfizer Inc.	Sanofi
Professor Robin Feldman	Sanofi
Public Interest Patent Law Institute (PIPLI)	Sanofi
Sir Gregory Paul Winter and Interested Scientists	Sanofi
Small and Medium Biotechnology Companies	Sanofi
Unified Patents, LLC	Sanofi
United States	Sanofi
Viatris Inc.	Sanofi
High Tech Inventors Alliance (HTIA) and Computer & Communications Industry Association (CCIA)	Neither
Intellectual Property Law Association of Chicago (IPLAC)	Neither
Intellectual Property Owners Association (IPO)	Neither
New York Intellectual Property Law Association (NYIPLA)	Neither
Regenxbio Inc., IGM Biosciences, Inc., and Adaptive Phage Therapeutics, Inc.	Neither

Sanofi asserted that Amgen's claims cover millions of antibodies, claim antibodies binding at sixteen residues, but only disclose embodiments that bind nine. Sanofi agreed the 26 antibodies identified by amino acid sequences (the recipe) were enabled but otherwise Amgen's patents merely identified a laborious (although routine) process with a "hope" for an acceptable antibody. Sanofi focused on the unpredictability in this art and touted the amicus brief by Nobel Laureate Sir Gregory Winters as a must-read for the Justices. Sanofi indicated that even Amgen

agreed that a single change on an antibody required retesting for the binding and blocking attributes.

The government jumped in where Sanofi left off, agreeing with all Sanofi had argued. Indeed, the government went further, proposing that amino acid sequences were (all but) required for enablement. As to the supposed death of genus claims, the government argued that if new rules were required, it was up to Congress, not the Court, and that standard enablement and doctrine of equivalents law was, and has been, adequate to protect innovation. The government argued that patent claims should cover only what is invented and not cover what still needs to be or could be invented, pointing out that it is not required to make a "better mousetrap" to obtain a patent just a "different" one.

The Justices and parties referred several times to the number of amicus briefs and arguments made in some of those briefs. The Justices asked Sanofi, why is "Lemley" wrong, referring to the serially cited law review article, D. Karshtedt, M. Lemley & S. Seymore, The Death of the Genus Claim, 35 Harv. J.l. & Tech. (rev. Apr. 19, 2021). Sanofi responded that the Federal Circuit has not foreclosed all genus claims, and the government went further to point to a more recent publication from Lemley suggesting that the very patents at issue are not enabled. The amicus brief of Sir Gregory Winters was also mentioned, almost akin to an expert opinion in support of Sanofi's position.

CONCLUSION

We will have to wait for the decision to see which of these arguments resonated most with a majority of the Court. Based on the fact-specific questions of the Justices, we expect the opinion to be similarly fact-based without a wide-sweeping pronouncement that dooms or upholds all genus claims.

Notes

1. Amgen Inc. v. Sanofi, 872 F.3d 1367, 1375 (Fed. Cir. 2017), cert. denied, 139 S. Ct. 787 (2019).
2. Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1084 (Fed. Cir. 2021) (quoting Crown Operations Int'l, Ltd. v. Solutia Inc., 289 F.3d 1367, 1379 (Fed. Cir. 2002)), cert. granted 143 S.Ct. 399 (2022).
3. Amgen Inc. v. Sanofi, Aventisub LLC, 850 F. App'x. 794 (Fed. Cir. 2021).