2020-1074

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING, LIMITED,
and AMGEN USA, INC.,

Plaintiffs-Appellants,

– v. –

SANOFI, AVENTISUB LLC, FKA AVENTIS PHARMACEUTICALS INC.,
REGENERON PHARMACEUTICALS INC.,
and SANOFI-AVENTIS U.S. LLC,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Delaware in Nos. 1:14-cv-01317-RGA, 1:14-cv-01349-RGA, 1:14-cv-01393, 1:14-cv-01414-RGA, Judge Richard G. Andrews

BRIEF FOR *AMICUS CURIAE* GLAXOSMITHKLINE PLC IN SUPPORT OF APPELLANTS' PETITION FOR REHEARING *EN BANC*

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APRIL 28, 2021

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 20-1074

Short Case Caption Amgen Inc. et al. v. Sanofi et al.

Filing Party/Entity GlaxoSmithKline plc.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 04/28/2021

Signature: /s/ John M. Desmarais

Name: John M. Desmarais

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

☐ Additional pages attached

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

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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☑ None/Not Applicable ☐ Additional pages attached

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

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INTEREST OF AMICUS

GlaxoSmithKline plc ("GSK") is one of the largest pharmaceutical and consumer-healthcare companies in the world.[1] GSK spends billions of dollars annually—including more than $6 billion in 2020 alone—developing groundbreaking drugs, vaccines, and therapies. Those efforts have yielded breakthroughs in the fight against HIV, cancer, shingles, meningitis, asthma, diabetes, malaria, and others. During fiscal year 2020, GSK had fifty-seven new medicines and vaccines under development. Genus claims are critical to protect innovations of companies like GSK, as well as smaller entities and academic institutions, and to encourage investment and collaboration in the chemical, pharmaceutical, and biotechnological arts. But the panel's decision entrenches a harmful trend of imposing new restrictions on genus claiming.[2] GSK submits this brief to educate the Court on the importance of genus claims to continued innovation.

[1] Amicus certifies that no counsel for a party authored this brief in whole or in part and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. All parties were given notice and consented to the filing of this brief.

[2] Amicus takes no position on the validity of the particular claims at issue, and submits this brief solely to encourage the Federal Circuit to correct the legal framework that the panel applied.

SUMMARY OF ARGUMENT

Genus claims have become "ubiquitous" in the chemical, pharmaceutical, and biotechnological industries.[3] Such claims are critical to protecting and advancing innovation. Groundbreaking inventions developed by companies and academic institutions often manifest as a genus after years of discovery efforts and significant expenditure. Patentees in such industries should therefore be granted broad patent protection[4] to incentivize continued investment.

The panel's decision joins other recent panel decisions in imposing obstacles that prevent innovators from recouping a fair return on their investments and for their contributions to science. Until recently, courts focused on whether a patent sufficiently "enables" persons of ordinary skill in the art ("artisans") to "make and use" embodiments of the invention without undue experimentation—rather than on whether the patent enables the "full scope" of its claims (i.e., enables every species of a genus). But the panel adopted that latter framework. *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1086 (Fed. Cir. 2021). Indeed, the panel invalidated

[3] *See* Sean Seymour, *Patenting the Unexplained*, 96 WASH. U. L. REV., 707, 729 (2019).

[4] Of course, a patent's scope should be commensurate with the contribution the patentee has made to the art. While "enablement" analysis under 35 U.S.C. § 112 is an important aspect of ensuring such proportionality, the panel decision risks robbing patentees of patent scope to which they are entitled and harming past and future investments.

the genus claims even though the jury had found that no enablement problem existed. *Id.* at 1084.

That sea change threatens to devastate the incentives for companies like GSK to invest billions of dollars and hundreds of thousands of research hours in discovering breakthrough drugs. GSK and other research-oriented companies will be forced to seek inequitably narrow patent claims that underrepresent the full breadth of their inventions or risk invalidation. But such narrow claims would not offer adequate protection. Thus, without a course-correction, the panel's holding risks eviscerating incentives to innovate that the patent system's *quid pro quo* was designed to provide.

The Court should therefore grant the petition to rehear this case *en banc* and reject the recent obstacles to genus claiming. That would be faithful to the text of the Patent Act and would better protect the incentives of research-oriented companies like GSK.

ARGUMENT

I. GSK'S RESEARCH AND DEVELOPMENT EFFORTS DEPEND ON GENUS CLAIMING.

Massive investments are required to move science forward and bring new therapies to market. In 2020 alone, GSK invested roughly £4.6 billion (over $6 billion) in the research and development of new therapies, including pharmaceutical

drugs.[5] GSK's research efforts focus on some of the most pressing public health concerns in the United States and around the world, including the treatment of HIV/AIDS, cancer, COVID-19, and respiratory illnesses such as chronic obstructive pulmonary disease (COPD); GSK also develops vaccines to prevent serious medical conditions such as malaria and meningococcal meningitis.[6]

Innovative companies in the pharmaceutical and biotechnology industries depend on the patent system, and in particular genus claims, to protect their investments in developing groundbreaking pharmaceuticals and therapeutics. For example, it is estimated that only 8% of drugs in development at a given time will ever reach the market.[7] Without the robust patent protection offered by genus claims, it is less likely that pharmaceutical companies will risk the huge initial outlays of effort and money those inventions demand. That risks handicapping drug development for decades into the future. Furthermore, maintaining efficient and time-limited patent coverage for an inventor's entire invention through a genus claim incentivizes others to pursue new breakthroughs. Indeed, a competitor that discovers

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[5] *See* https://www.gsk.com/en-gb/research-and-development/ (last accessed 4/22/2021).

[6] *See* 2020 GSK Annual Report, at 18-27 (available at: https://www.gsk.com/media/6662/annual-report-2020.pdf).

[7] *See* GSK Public Policy Positions – Patents & Access to Medicines in Developing Countries, at 2 (available at: https://www.gsk.com/media/2958/patents-and-access-to-medicines-in-developing-countries-july19.pdf).

unexpectedly beneficial properties of a compound that is within an already patented genus can itself obtain patent coverage on that compound.[8]

Allowing for a wide breadth of protection based on a genus of compounds is, as a practical matter, the only means to ensure that an inventor actually receives the period of exclusivity contemplated by our patent system. The existence of genus claims does not mean that medicines developed by others that fall within the scope of the claim would be prevented from reaching the market. It simply means that the patentee would be fairly compensated for its breakthrough. The patent system has checks and balances for validity and the use of patents. Even if an injunction is sought, it may not be granted. Thus, the patent system would be serving its purpose, providing reward for early and full disclosure of an innovation the world needs to know about and allowing others to build upon past innovations.

II. THE PANEL'S DECISION CASTS ASIDE A LONGSTANDING LEGAL FRAMEWORK THAT APPROPRIATELY PROTECTS GENUS CLAIMING.

The Court should rehear this case *en banc* because panel's decision forsakes the straightforward text of the Patent Act, and also casts aside a legal framework that is more faithful to the text and which embodies better policy.

[8] *See In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (stating that to claim a subset of a range disclosed in a prior art patent, the applicant must generally show that "the claimed range achieves unexpected results relative to the prior art range").

A. The Patent Act Allows Genus Claiming And Does Not Require "Full Scope" Enablement.

The Patent Act states that a patent must "contain a written description of the invention" 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." 35 U.S.C. § 112(a). This "enablement" requirement is perfectly consistent with genus claiming, provided that the patent disclosure enables artisans to "make and use" embodiments of the claimed inventions. This Court has explained that the Patent Act "requires that the specification teach those in the art to make and use the invention without 'undue experimentation.'" *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). Despite this, the text of the Patent Act does not impose any limitations on the number of species that may be contained within a genus claim or require "full scope" enablement. Indeed, recent panel decisions target patents in the chemical, pharmaceutical, and biotechnological industries, even though genus claims in other art areas, including the mechanical arts, also encompass innumerable variations.

B. This Court's Predecessor Recognized The Importance And Validity Of Genus Claiming.

Courts, until recently, have recognized the validity and appropriateness of genus claiming, especially in the chemical and pharmaceutical industries. Along the way, the courts rejected the notion that the text of the Patent Act required "full

scope" enablement. In 1960, for example, the Court of Customs and Patent Appeals ("CCPA") explained that a genus claim was permissible if "the disclosure teaches those skilled in the art what the invention is and how to practice it." *Application of Grimme*, 274 F.2d 949, 952 (C.C.P.A. 1960). The CCPA recognized that it would be futile to require patentees to draft "a patent application or applications with thousands of examples," as well as "disclosure of thousands of catalysts along with information as to whether each exhibits catalytic behavior." *Application of Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976) (internal quotation marks omitted). "[S]uch a requirement," the CCPA reasoned, would be undesirable "even in an unpredictable art" not only because it "would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments," but also because it "would tend to discourage inventors from filing patent applications in an unpredictable area." *Id*. at 502–03. Likewise, "[a] potential infringer could readily avoid 'literal' infringement of such claims by merely finding another analogous catalyst complex.'" *Id.* at 503.

Thus, decades ago, the CCPA recognized both the efficiency of genus claiming and the public policy and copying risks posed in its absence. Inventors would choose trade secret protection over public disclosure because filing for a patent over only ***some*** embodiments would enable copyists to make ***other*** embodiments. *Id*. at 502–03. That result either deprives the public of advances in

knowledge, or the inventor of the benefits of her invention and investment. In short, having weighed the costs and benefits of genus claiming—the same policy considerations that apply today—the CCPA endorsed genus claiming which the panel now curtails.

C. Earlier Federal Circuit Case Law Likewise Applied A Case-Specific Enablement Analysis.

Following the CCPA's approach, this Court developed case-specific tools to ensure that genus claims appropriately reflect the technological context and artisans' level of skill and background knowledge. For instance, this Court has recognized that enablement of a genus claim does not depend on whether the patentee vetted every embodiment. In *Atlas Powder*, for example, the patent challenger "argue[d] that the patent disclosure lists numerous salts, fuels, and emulsifiers that could form thousands of emulsions but there is no commensurate teaching as to which combination would work." *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). "The disclosure," according to Du Pont, was "nothing more than 'a list of candidate ingredients' from which one skilled in the art would have to select and experiment unduly to find an operable emulsion." *Id.* Rejecting this argument, this Court instead concluded that "[e]ven if some of the claimed combinations were inoperative, the claims are not necessarily invalid." *Id.* The key question was not whether every combination in the genus worked but whether an artisan could create working embodiments without undue

experimentation. *Id.* at 1576–77 (citations omitted). Because the disclosure was sufficiently enabling, the Patent Act allowed the genus claim.

This Court now takes into account: (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. *See In re Wands*, 858 F.2d at 737. That framework appropriately recognizes the case-specific nature of the enablement analysis and that judges should not impose arbitrary bright-line rules.

Federal courts have therefore long understood that the enablement question should depend on the degree of experimentation that it would take for an artisan to create embodiments of the invention, and not on the number of species within a claimed genus or on whether the "full scope" of the invention is enabled. "Of course" as this Court has recognized, "if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid." *Atlas Powder*, 750 F.2d at 1576-77 (emphasis added). But where artisans can "make and use" embodiments of the invention without undue experimentation and the claim scope reflects the breadth of the inventor's contribution to the art, the patent should be valid. The panel's decision, which assesses enablement in light of

the number of species within a claimed genus, ignores the specifics of the industry and of the case.

D. The Panel Decision Joins Other Recent Decisions Which Improperly Curtail Patentees' Ability To Claim A Genus of Compounds.

Despite having reaffirmed the validity of genus claims for decades,[9] in recent years, panels have strayed from the plain text of the Patent Act, engrafting additional conditions to the Act's "enablement" requirement. Panel decisions in cases such as *Wyeth* and *Idenix* effectively imposed limits on the number of species that can exist in an enabled genus claim and required that the patent enable artisans to practice the "full scope" of the claims. *See Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1385-86 (Fed. Cir. 2013) (stating that "practicing the full scope of the claims . . . would require synthesizing and screening" thousands of compounds, and holding that the genus claims were therefore invalid for lack of enablement "as a matter of law."); *Idenix Pharm. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1162-63 (Fed. Cir. 2019) (stating that "practicing the full scope of the claims would require synthesizing and screening tens of thousands of candidate compounds for the claimed efficacy."). *Amgen*, relying in part on *Wyeth* and *Idenix*, now further enshrines those cases. The panel also casts aside a jury verdict which upheld the genus claims as enabled,

[9] *See, e.g.*, *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1352 (Fed. Cir. 2011) (stating that "there is no categorical rule that a species cannot suffice to claim the genus").

solidifying the erroneous legal standards of *Wyeth* and *Idenix*. *Amgen*, 987 F.3d at 1084.

While the panel states that it is "not concerned ***simply with the number of embodiments***" and it does "not hold that the effort required to exhaust a genus is dispositive," both the number of embodiments within the genus claims and the effort required to make and test each species within the genus were clearly important considerations. *Id.* at 1087-88 (emphasis added). Indeed, in describing *Amgen*'s similarity to *Wyeth* and *Idenix* and distinguishing *Wands*, the court specifically notes: "Here, 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.* at 1088 (emphases added). These recent developments regarding enablement therefore threaten genus claims covering many embodiments even where those embodiments are all attributed to a single inventive breakthrough.

CONCLUSION

Genus claims protect continued innovation in the chemical, pharmaceutical, and biotechnological industries. But the panel in *Amgen* joins other recent panels in upending such protections. That development is bad policy, as it disincentivizes innovation. The Court should take up the petition to rehear this case *en banc* to

reaffirm the availability and viability of genus claims commensurate with a patentee's contribution to the art.

Dated: April 28, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of April, 2021 I served the foregoing BRIEF FOR *AMICUS CURIAE* GLAXOSMITHKLINE PLC IN SUPPORT OF APPELLANTS' PETITION FOR REHEARING *EN BANC*, on all counsel of record by filing the document with the United States Court of Appeals for the Federal Circuit using the CM/ECF system.

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a) and Fed. Cir. R. 35(g). Excluding any portions exempted by Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2), this brief contains: 2,560 words as counted by Microsoft Word 2016, the word-processing system used to prepare this paper.

The undersigned further certifies that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 and 14-point Times New Roman type.

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