NOTE: This order is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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**AMGEN INC., AMGEN MANUFACTURING, LIMITED, AMGEN USA, INC.,**
*Plaintiffs-Appellants*

**v.**

**SANOFI, AVENTISUB LLC, FKA AVENTIS PHARMACEUTICALS INC., REGENERON PHARMACEUTICALS INC., SANOFI-AVENTIS U.S. LLC,**
*Defendants-Appellees*

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2020-1074

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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-RGA, 1:14-cv-01414-RGA, Judge Richard G. Andrews.

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JEFFREY A. LAMKEN, MoloLamken LLP, Washington, DC, filed a petition for rehearing en banc for plaintiffs-appellants. Also represented by SARAH JUSTINE NEWMAN, MICHAEL GREGORY PATTILLO, JR.; SARA MARGOLIS, New York, NY; EMILY JOHNSON, ERICA S. OLSON, STEVEN TANG, STUART WATT, WENDY A. WHITEFORD, Amgen Inc., Thousand Oaks, CA; KEITH HUMMEL, Cravath Swaine & Moore LLP, New York, NY; WILLIAM G. GAEDE, III, McDermott

Will & Emery LLP, Menlo Park, CA; CHRISTOPHER B. MEAD, Schertler Onorato Mead & Sears LLP, Washington, DC; JAMES L. HIGGINS, MELANIE K. SHARP, Young, Conaway, Stargatt & Taylor, LLP, Wilmington, DE. Plaintiff-appellant Amgen Inc. also represented by SARAH CHAPIN COLUMBIA, McDermott, Will & Emery LLP, Boston, MA; LAUREN MARTIN, Quinn Emanuel Urquhart & Sullivan LLP, Boston, MA.

MATTHEW WOLF, Arnold & Porter Kaye Scholer LLP, Washington, DC, filed a response for defendants-appellees. Also represented by VICTORIA REINES; DAVID K. BARR, DANIEL REISNER, New York, NY; DEBORAH E. FISHMAN, Palo Alto, CA; GEORGE W. HICKS, JR., NATHAN S. MAMMEN, CALVIN ALEXANDER SHANK, Kirkland & Ellis LLP, Washington, DC. Defendants-appellees Sanofi, Aventisub LLC, Sanofi-Aventis U.S. LLC also represented by STEPHANIE DONAHUE, Sanofi, Bridgewater, NJ. Defendant-appellee Regeneron Pharmaceuticals Inc. also represented by LARRY A. COURY, LYNDA NGUYEN, Regeneron Pharmaceuticals Inc., Tarrytown, NY.

MARK A. LEMLEY, Stanford Law School, Stanford, CA, for amici curiae Ann Bartow, Timothy Richard Holbrook, Mark David Janis, Dmitry Karshtedt, Mark A. Lemley, Stephen McJohn, Robert P. Merges, Sean B. Seymore.

JEFFREY PAUL KUSHAN, Sidley Austin LLP, Washington, DC, for amici curiae Biogen Inc., Bristol-Myers Squibb Company, Corning Incorporated, Merck Sharp & Dohme Corp. Also represented by STEVEN J. HOROWITZ, Chicago, IL; SUE WANG, San Francisco, CA.

JOHN M. DESMARAIS, Desmarais LLP, New York, NY, for amicus curiae GlaxoSmithKline PLC. Also represented by ELIYAHU BALSAM, TODD LAWRENCE KRAUSE.

**ON PETITION FOR REHEARING EN BANC**

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Before MOORE, *Chief Judge*[*], NEWMAN, LOURIE, DYK, PROST[**], O'MALLEY, REYNA, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.[***]

LOURIE, *Circuit Judge*, with whom PROST and HUGHES, *Circuit Judges*, join, authored a separate opinion on the denial of the petition for panel rehearing.

PER CURIAM.

**O R D E R**

Amgen Inc., Amgen Manufacturing, Limited, and Amgen USA, Inc. filed a petition for rehearing en banc. A response to the petition was invited by the court and filed by Sanofi, Aventisub LLC, Sanofi-Aventis U.S. LLC, and Regeneron Pharmaceuticals Inc. A group of intellectual property professors; GlaxoSmithKline plc; and Biogen Inc., Bristol-Myers Squibb Company, Corning Incorporated, and Merck Sharp & Dohme Corp. requested leave to file briefs as amici curiae, which the court granted. The petition was first referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

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[*] Chief Judge Kimberly A. Moore assumed the position of Chief Judge on May 22, 2021.

[**] Circuit Judge Sharon Prost vacated the position of Chief Judge on May 21, 2021.

[***] Circuit Judge Evan J. Wallach assumed senior status on May 31, 2021, and did not participate in the decision on the petition for rehearing en banc.

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on June 28, 2021.

FOR THE COURT

June 21, 2021
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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**AMGEN INC., AMGEN MANUFACTURING, LIMITED, AMGEN USA, INC.,**
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**v.**

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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-RGA, 1:14-cv-01414-RGA, Judge Richard G. Andrews.

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LOURIE, *Circuit Judge*, with whom PROST and HUGHES, *Circuit Judges*, join, authoring a separate opinion on the denial of the petition for panel rehearing.

Amgen has petitioned for panel rehearing. The petition is denied.

Amgen argues that we have created a new test for enablement. That is incorrect. It has always been, or at least has been since the Patent Act of 1870, that a patent applicant must enable one's invention, whatever the invention is. *See* Section 26, Patent Act of 1870, 16 Stat. 198 (1870), (R.S. § 4888). A composition of matter, whether a chemical compound or biological material, accordingly, must be enabled, as must other types of inventions.

If the invention is a group of compositions, defined as a genus, that group is enabled by a disclosure commensurate with the scope of the genus. For years, before biological materials were often claimed, chemical genus claims were enabled by actual or constructive (often called prophetic) examples. Chemical patent specifications were filled with examples of compounds that had been prepared, generally shown by use of the past tense to describe the procedures, with melting points or other physical constants obtained by actual reductions to practice. Constructive examples were described in the present tense, with starting materials and process details resulting in named compounds within the scope of the claims. Whether actual or constructive, those examples enabled the full scope of the claims. Such well-supported generic claims do not lack for enablement, or written description. Amici and others bemoaning the so-called death of generic claims are therefore off-base. Genus claims, to any type of invention, when properly supported, are alive and well.

What is new today is not the law, but generic claims to biological materials that are not fully enabled. Enablement is required, even for generic claims to biological materials. But, as with genus claims to chemical compounds, if they encompass more subject matter than just a few species, they need to be enabled accordingly. Biological compositions not actually prepared need to be described constructively, if required to enable the full scope of the claims, with procedures and names of resultant compositions, as with chemical compositions.

Amgen and amici argue that requiring that broad generic claims in the biotechnology field be supported by disclosure enabling the full scope of the claims will make it impossible to obtain proper protection for biotechnology inventions. But all that the enablement requirement precludes is obtaining protection for inventions broader than are disclosed or enabled, and that were apparently not invented by the applicant or patentee, as shown by a lack of enabling disclosure. If the genus had been invented by the time of filing, it would have been fully enabled in the patent.

Entitlement to broad genus claims thus requires disclosure and enablement of species supportive of the genus that a patentee claims to have invented. That requirement is based on the concept that in order to have invented a genus, one needs to have invented species that constitute the genus. Drawing a broad fence around subject matter, without filling in the holes, is not inventing the genus. It in fact discourages invention by others. If one has disclosed or enabled only a small number of invented species, then one has not invented a broad genus. Invention of a genus means to conceive and reduce to practice a reasonable number and distribution of species constituting the genus. Mere statement of a genus does not demonstrate that one has invented a generic concept, without the enablement of constituent species.

Amici insist that this court has recently adopted a "numbers-based standard" to evaluate enablement, asking not whether experimentation is undue but how long it would take to make and screen every species. IP Professors' Amicus Br. 7. That mischaracterizes our law, and our opinion specifically resisted what might be termed a simple "numerosity" or "exhaustion" requirement. Consistent with our law, the opinion examined the relevant *Wands* factors and their interaction in a case-specific manner. The problem was not simply that the claimed genus was numerous—it was that it was so broad, extending far beyond

the examples and guidance provided. Likewise, it was not that it would take a long time to collect the full set of each and every embodiment—it was that the narrow and limited guidance in the specification made far corners of the claimed landscape that were particularly inaccessible or uncertain to make unenabled.

Amgen and its amici argue that our decisions on enablement (just as it was once argued with respect to written description) threaten innovation and will "devastate" the incentives to invest in drug discovery. It seems to them that the sky is falling. But enablement is part of our law, and for good reason. One should not gain exclusivity over claimed subject matter without disclosing how to make and use it. And if one considers that one has invented a group of compositions defined by a genus but does not know enough to fully enable that genus, one would suppress innovation if one were able to claim such a broad genus, not enhance it. Amgen, by asserting such broad, unsupported claims is doing just that, by trying to control what it has not invented. And, contrary to assertions by amici that broad, unenabled claims are necessary to protect investment, claims to materials properly supported by inventive work and disclosure can be protected. Amgen in fact has separate patent protection on the PCSK9 antibody that it has invented and additionally purports to cover by the generic claim we have invalidated. *See* U.S. Patent 8,030,457. Thus, the failure to obtain unsupported, unenabled claims has not deprived it of patent protection on the fruits of its investment.

Additionally, if another party invents a species not described or enabled by a first inventor, and hence not able to be encompassed by a properly enabled generic claim, that party has promoted the progress of the useful arts. Yet if that compound is so close to species disclosed and claimed by a first entrant as to be an equivalent, there is the doctrine of equivalents to protect the innovator. And, of course, that second comer may encounter the expensive

hurdle of having to meet its own regulatory requirements, if it does not qualify for ANDA or biosimilar status.

Claims 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, hence that it has been enabled. In such cases, it is circular; enablement comes only with success, which depends upon enablement. It is not the law that one can put forth an idea, or a result or function, and claim all methods of achieving it; one cannot claim everything that works.

This court has already considered the impact of functional means claim limitations on whether a disclosure is commensurate in scope with the claim. The answer is that single means claims claim too much. *See In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983) (Rich, J.) ("The proper statutory basis for the rejection of a single means claim is the requirement of the first paragraph of § 112 that the enabling disclosure of the specification be commensurate in scope with the claim under consideration. The long-recognized problem with a single means claim is that it covers every conceivable means for achieving the stated result, while the specification discloses at most only those means known to the inventor."). Multiple means claims simply compound the problem.

Amgen argues that we should overrule case law that holds that enablement is a question of law, albeit based on underlying factual findings. But we are bound by our precedent and decline to recommend to the court that it go en banc to overrule longtime precedent simply because a party has questioned it. One can reasonably ask, as Amgen does, why enablement is a question of law when written description, which sits side by side with the enablement requirement, is not. They both relate to the disclosure in the patent specification. But our precedent is long in the tooth,

dating back before the establishment of this court. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960 n.6 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) (citing *In re Hogan*, 559 F.2d 595, 604 (C.C.P.A. 1977) (stating that "Courts should not treat the same *legal question*, enablement under § 112, in one manner with respect to the applicant and in a different manner with respect to the examiner.") (emphasis added); *In re Brandstadter*, 484 F.2d 1395, 1406 (C.C.P.A. 1973) (analyzing whether certain affidavits could be considered when evaluating "the ultimate *legal question* of enablement.") (emphasis added)); *see also Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1216 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 856 (1991) (citing *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1268 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987)) ("We review a determination of enablement as a *question of law*.") (emphasis added); *Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003) (citing *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369 (Fed. Cir. 1999)) ("[W]hether a disclosure is enabling . . . is a *question of law* . . . .") (emphasis added); *McRO, Inc. v. Bandai Namco Games Am., Inc.*, 959 F.3d 1091, 1096 (Fed. Cir. 2020) (citing *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013)) ("[W]hether a patent satisfies the enablement requirement is a *question of law* . . . .") (emphasis added). The much-cited *Wands* case is the signature authority on the issue. *See In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988) (explaining that "we review enablement as a *question of law*.") (emphasis added).

Indeed, despite being repeatedly asked over the decades this court has existed, the Supreme Court has not seen fit to take up this question. It has, however, made clear that interpretation of claim scope, a question inexorably intertwined with enablement, is a question of law. Obviousness, which involves comparing claim scope with the prior art, is similarly a question of law. And so it is no

surprise that enablement, which involves interpreting the specification and the scope of the claims, is also a question of law, if one that accommodates underlying factual inquiries where applicable. Thus, the principle is indelibly embodied in and consistent with our law, and we see no reason to change it, especially where the arguments that Amgen makes provide no compelling reason to introduce such a seismic shift.

Accordingly, the petition for panel rehearing is denied.