2017-1480

United States Court of Appeals for the Federal Circuit

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

Plaintiffs-Appellees

v.

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

Defendants-Appellants

Appeal from the United States District Court for the District of Delaware in Nos. 1:14-cv-01317-SLR, 1:14-cv-01349-SLR, 1:14-cv-01393-SLR, 1:14-cv-01414-SLR, Judge Sue L. Robinson.

BRIEF OF AMICUS CURIAE BRISTOL-MYERS SQUIBB COMPANY, BAVARIAN NORDIC, AND ENZO BIOCHEM, INC. IN SUPPORT OF APPELLEES' PETITION FOR EN BANC REHEARING

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Dated: December 20, 2017

FORM 9. Certificate of Interest **Form 9**
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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING LIMITED, AMGEN USA, INC., **v.** SANOFI, AVENTISUB LLC, REGENERON PHARMACEUTICALS INC., SANOFI-AVENTIS U.S., LLC

Case No. 17-1480

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ☐ (appellee) ■ (amicus) ☐ (name of party)

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

none

12/20/2017
Date

/s/ Jorge A. Goldstein
Signature of counsel

Please Note: All questions must be answered

Jorge A. Goldstein
Printed name of counsel

cc: all counsel via CM/ECF

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Bavarian Nordic A/S	none	none

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1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
ENZO BIOCHEM, INC	none	none

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

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12/20/2017
Date

/s/ Jorge A. Goldstein
Signature of counsel

Please Note: All questions must be answered

Jorge A. Goldstein
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AMICI'S STATEMENT UNDER RULE 29

Pursuant to Federal Rule of Appellate Procedure Rule 29(c)(5)(A)-(C), the amici confirm that no party's counsel involved in the litigation below authored this brief, in whole or in part. Counsel for the amici confirm that, while they are counsel for Party Amgen on other matters, they are not counsel in the present matter. The amici also confirm that no party or party's counsel, or any other person other than the amici, contributed money that was intended to fund preparing or submitting this brief.

INTEREST OF AMICUS CURIAE

The amici are innovator biopharmaceutical companies that research targeted treatments for human diseases: including cancer and autoimmune therapies for Bristol-Myers Squibb Company, infectious disease and cancer therapies for Bavarian Nordic, and immune modulators for Enzo Biochem. Collectively, the amici devote billions of dollars in research and development to create cutting edge therapies for areas of high unmet medical need. The amici rely on patents to protect their groundbreaking inventions, and to justify the huge expense and risk in seeking to cure or treat disease.

They are concerned that the Panel's decision fundamentally alters existing law under 35 U.S.C. §112, ¶1,[2] in a way that undermines a reasonable scope of patent coverage – and thus threatens the efficacy of the patent system – for such treatments and the molecules involved. They worry that they and others in their position will lose their previously-held patent protection. Without meaningful patent scope,

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[2] We refer to §112, ¶1, because the patents-in-suit were filed under pre-AIA law, but our arguments apply equally to post-AIA §112(a).

research and development of new treatments will be impaired, innovation will slow, and the patient community will suffer.

Modern therapies, ranging from treating heart disease to cancer, start with first understanding and then modulating the biological targets and pathways that give rise to disease, e.g., identifying molecular receptors involved in signaling a cell's growth or death. These critical innovations may take place in academic institutions, start-ups, or established biopharmaceutical companies. The ability to block or activate targets and pathways with agents such as monoclonal antibodies can provide important new medicines that improve the standard of care. The central quest for targeted medicines lies in uncovering targets and pathways, and the elucidation of their physiological significance. Such research is where the innovators spend most of their time, investment, and intellectual capital.

Given the lack of eligibility of natural materials and phenomena (e.g., *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 566 U.S. 902 (2012), *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012)), patent protection is not available for the underlying molecular targets and pathways. Instead, it is the innovative *molecules,*

such as antibodies, that interact with these targets and modulate these pathways that are patent-eligible. And the incentives to invest in the discovery of novel targets and pathways will be severely diminished if innovators are only able to protect a single molecule or a very narrow set of molecules. This is the likely impact if the Panel's decision stands.

Narrow patent protection will place the amici's antibodies, or other similar biomolecules, and their uses in the hands of the public without the corresponding reward of robust patent protection to offset considerable investments. Narrow protection will allow after-arriving competitors and copyists to quickly (and much less expensively) benefit unfairly from the pioneers' research. Such an outcome frustrates those who were willing to make the necessary research investments in the first place. Without the reward of patent protection of an adequate scope, innovators will be dis-incentivized from developing the next generation of biotech therapies. Moreover, the unpredictability of strong patent protection will decrease investment and partnering, dis-incentivizing companies and research institutions from pursuing cutting edge research.

The amici fear that the Panel's decisions on 35 U.S.C. §112 will result in major harm to further innovation in the burgeoning field of antibody therapeutics. And the harm caused by allowing after-arising embodiments to undermine §112 support will also extend well beyond the field of antibodies to other areas where genus protection is critical (such as in Bavarian Nordic's development of cancer antigens or Enzo's development of immune modulators). *En banc* review is necessary to ensure adequate patent protection for innovators.

ARGUMENT

I. The Panel Upends the Amici's Reasonable Reliance on Long-Established Case Law under 35 U.S.C. §112, ¶ 1.

A. The Rule in *Noelle v. Lederman* on Sufficient Written Description of a Genus of Antibodies to a Newly Characterized Antigen is Sound and Can Only be Overturned by the Court, *en banc*.

The Panel has all but cast aside the rule of *Noelle* (also a panel decision) that, to describe a genus of routinely-made antibodies to a newly-characterized antigen it is sufficient to describe the antigen, not the antibodies that bind to it. The amicus curiae are greatly concerned that undermining *Noelle* is incorrect as matter of both science and law.

If *Noelle* is undermined, innovators in the field of antibody-based therapies will be left with nothing but easily-avoidable claims.[3]

In *Deckers Corp. v. United States,* 752 F.3d 949 (Fed. Cir. 2014), this Court warned about the binding effect of previous panel decisions: "In this Circuit, a later panel is bound by the determinations of a prior panel, unless relieved of that obligation by an en banc order of the court or a decision of the Supreme Court." *Id.* at 959. The Panel in the present case did not go as far as stating that it overruled *Noelle*; but given its strong critique and dismissal of the previous panel's decision, it is hard not to conclude otherwise. Only the full court can do that.

Specifically, the Panel denigrated *Noelle's* "newly-characterized antigen" rule, viewing it as a non-statutory "antibody exception" to the written description requirement. Slip op. at 18. But *Noelle* is neither an exception to, nor does it flout, the written description requirement. It is grounded in the structure/function correlation test of *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997)), i.e., the *structure* of the well-characterized antigen determines the

[3] Amicus curiae will not repeat Amgen's legal arguments in support of *Noelle* articulated in Amgen's Petition for Rehearing *en banc*.

binding *function* of its complementary antibodies. It is also based on a sound understanding of antibody science, where – in contrast to organic chemistry – an antibody genus can be fully described by describing the structure of its antigen, without the need to exemplify the easily-obtainable and large number of antibody sequences that will perform binding.

We provide an example. In chemistry, a purely functional claim term like "a drug that lowers blood pressure" carries no meaning without structure, because there are large variations in the structures of such small molecule drugs. Most chemical product claims are therefore routinely defined by structural formulas having a basic core with a variety of functional groups, or by Markush groups providing a list of compounds.

Things are different in the biological world of antibodies to newly-characterized antigens. All antibodies are proteins that have a common scaffold of two heavy chains, two light chains, and all of them assemble to create the CDRs (Complementarity-Determining Regions) that bind antigen. *A priori*, the antibodies claimed in Amgen's patents share a common counter-molecule, their binding partner PCSK9.

To argue that a person of ordinary skill in the art does not have possession of the genus of antibodies that bind a well-characterized antigen until she has provided detailed sequence information of multiple representative CDR sequences (all of which *a priori* bind the antigen), is an unwarranted extrapolation from organic chemistry. Once the structure of the antigen is well characterized and disclosed by the inventor, her disclosure plus routine methods of making antibodies, puts the full genus of antibodies in the hands of the public. To show possession, the specific CDR sequences are not as critical to antibody scientists as the structures of small molecules are to organic chemists.[4]

B. Examination of After-Arising Embodiments to Evaluate Enablement and Written Description of Claims to a Genus of Molecules Flies in the Face of Settled Precedent.

Having gutted *Noelle*, the Panel turned its attention to the "representative examples" test of *Regents* and *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010). In *Ariad*, this Court

[4] See, e.g., Example 13 in the USPTO 2008 Written Description Guidelines, which cites to Elvin A. Kabat, Structural Concepts In Immunology And Immunochemistry, 2nd Ed. (Holt, Rinehart and Winston 1976) for its conclusion that: "It does not appear that persons of skill in the art consider knowledge of the amino acid sequence of the variable regions critical for purposes of assessing possession of an antibody." Page 46.

held "that a sufficient description of a genus … requires the disclosure of either *a representative number of species* falling within the scope of the genus or structural features common to the members of the genus …".[5] The Panel then remanded for examination of after-arising embodiments as a way to evaluate the representativeness of specification-described examples. But the Panel's reliance on after-arising embodiments is incorrect.

For forty years, *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977) has been authority for the proposition that after-arising embodiments, unknown at the filing date, cannot be used to hold claims invalid for lack of enablement. The Court of Customs and Patent Appeals (CCPA), reversing a USPTO decision, held that the later state of the art could not be used to test an earlier application for compliance with 35 U.S.C.

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[5] This Court has upheld the representativeness test when evaluating genus claims to antibodies to *well-characterized* antigens. *See, e.g.*, *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1353 (Fed. Cir. 2011); or *AbbVie Deutschland GmbH & Co., KG v Janssen Biotech, Inc.*, 759 F.3d 1285, 1300-02 (Fed. Cir. 2014). *Cf.* Precedents based on *uncharacterized* antigens, such as*, e.g.*, *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004) are inapposite to the case at hand, where the antigen is newly-characterized.

§ 112. The CCPA remanded for evaluation of the claims under the state of the art *at the time of the initial application*. It added:

> The courts have consistently considered subsequently existing states of the art as raising questions of infringement, *but never of validity*.

Hogan, 559 F.2d at 607 (emphasis added). The *Hogan* rule is clear: One cannot be expected to enable embodiments that were not known on the filing date, and one should not be penalized for failing to do so.

The rule of *Hogan* has been applied consistently over the years. *In re Koller,* 613 F.2d 819 (C.C.P.A. 1980) affirmed *Hogan* and extended its rule to written description: "In *Hogan*, an analysis using later-filed references to determine the scope of enablement was found to be impermissible. *Similarly, it cannot be allowed when, as here, the description requirement is an issue*." *Id.* at 825 (emphasis added). And in *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247 (Fed. Cir. 1989) this Court found a claim to crystalline polypropylene not invalid over a later discovered improved polypropylene. *Id.* at 1252. In addition, the courts have been consistent in following the *Hogan* edict *sub silentio* when reviewing lower court decisions: they have considered after-

arising embodiments only when evaluating infringement, but not validity. Examples include *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1354 (Fed. Cir. 2000) and *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1097 (Fed. Cir. 2013), where validity over after-arising embodiments never even came up.

The amici have long relied on this settled case law to protect their pharmaceutical inventions. They have prosecuted and enforced claims to biological molecules and their uses with the expectation that these claims will not be attacked for failing to enable or describe after-arising embodiments.[6] Any interpretation of *Hogan* that allows evidence of after-arising embodiments for challenging validity would be a dramatic change in the law that should not be adopted without full consideration by this Court, *en banc*.

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[6] Amici take no issue with the introduction of post-filing evidence to demonstrate reproducibility or lack thereof of a *method of production at the filing date. See, e.g.*, *In re Wands et al* 858 F.2d 731 (Fed. Cir. 1988) (this Court cited approvingly to a post-filing declaration repeating described procedures to confirm enablement. *Id,* at 739-40). Proving or disproving repeatability of procedures at the filing date is very different than allowing evidence of lack of enablement or written description by citing after-arising embodiments.

A rule that would allow evidence of after-arising embodiments as a way to undermine the enablement and/or written description of a genus claim would upend long-held expectations. It would severely affect the time and effort invested by amici into finding novel targets and pathways, and developing new molecules to interact with them.

II. Gutting *Noelle* and Allowing Evidence into After-Arising Embodiments to Test Compliance with 35 U.S.C. § 112 Will Profoundly Burden Innovators in Molecular Medicine.

The Panel's assault on *Noelle* places an unnecessary burden on scientists that, to obtain genus protection for antibodies to newly-characterized antigens, they need to provide an exhaustive list of sequences that bind the antigen. The fact that a patent specification may not identify *in advance* all *specific* sequences of antibodies that bind to the antigen does not mean that scientists invent narrowly and should be precluded from obtaining claims of meaningful scope. Moreover, listing multiple specific sequences (or providing deposits) does not offer any more disclosure to the public — or show any more possession — than does characterizing the antigen. Any other conclusion puts form over substance and is unfair to innovators. It indicates a

misunderstanding of antibody science and a disconnect with the policies underlying a patent system designed to reward pioneering inventors.

When — beyond *Noelle* — a patent holder chooses to rely on the tests of *Regents* and *Ariad*, the Panel's decision allowing after-arising embodiments to undermine the representativeness of exemplified molecules will force innovators to carry out unnecessary multiple actual reductions to practice ahead of filing. This will channel their valuable time and investment away from patients and onto patents.

Such a change in the law would require never-ending pre-filing actual reductions to practice, a situation critiqued eloquently in *In re Angstadt*, 537 F.2d 498, 502-03 (C.C.P.A. 1976) (the law must not "force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments."). Smaller businesses and not-for-profit institutions that invent new therapeutics typically cannot afford to expend time and resources to provide extensive actual reductions to practice simply to confirm for patent purposes that the inventor has possession of a broad invention. And even larger innovator companies would be forced to divert resources away from developing new therapies and toward using routine methods to generate multiple

actual reductions to practice simply for patent purposes. Such a scheme results in increased research and development costs in exchange for an uncertain reward given the current vulnerability of biologics patents under the Panel's approach to written description.

Gutting *Noelle* and forcing patent applicants to carry out a prohibitive number of actual reductions to practice ahead of filing will not prevent an ingenious challenger from later producing additional, unexemplified embodiments, and playing "gotcha!" Allowing a challenger to introduce such evidence (selected with the full benefit of hindsight) is an invitation to mischief. It provides ever-changing grounds to argue that the exemplified embodiments were not sufficiently "representative." And it provides the late-comers with all the benefits of the innovator's pioneering work and uncertain investments, while leaving the innovator vulnerable to having her patent protection be stripped away in view of after-arising embodiments developed based on her own invention.

Perniciously, a rule allowing evidence of after-arising embodiments would not be limited to antibodies, but rather would undermine innovation in multiple therapeutic areas. The effect of such

change would be so detrimental to innovation that the full Court, as guardians of the patent laws, must carefully reconsider the Panel's decision.

CONCLUSION AND RELIEF SOUGHT

For the foregoing reasons, amicus curiae request that this Court vacate the Panel's decision and reconsider the issue *en banc*.

Dated: December 20, 2017

Respectfully submitted,

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for Amici Bristol-Myers Squibb, Bavarian Nordic, Enzo Biochem

(State whether representing appellant, appellee, etc.)

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