No.

IN THE
Supreme Court of the United States

AMGEN INC., AMGEN MANUFACTURING LIMITED, AND AMGEN USA, INC.,
Petitioners,

v.

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

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The 1952 Patent Act requires patents to "contain a written description of the invention, and of the manner and process of making and using it." 35 U.S.C. §112(a). The "written description" must be "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." *Ibid.* "The object of the statute is to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent." *Schriber-Schroth Co.* v. *Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938).

The Federal Circuit has construed §112(a) as imposing separate "written description" and "enablement" requirements subject to different standards. *Ariad Pharms., Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc). The Federal Circuit holds that the standard in §112(a)—"in such full, clear, concise, and exact terms as to enable" skilled artisans "to make and use" the invention—does *not* govern written description of the invention; it applies only to the "enablement" requirement ("the manner and process of making and using"). *Ibid.* For "written description of the invention," the Federal Circuit applies its own standard: The patent disclosure must demonstrate that the inventor "'had possession'" of the invention "'as of the filing date.'" App., *infra*, 7a (quoting *Ariad*, 598 F.3d at 1350). The Federal Circuit has announced (and then modified or rescinded) various specialized "possession" sub-tests, as well as the evidence relevant to "possession." The question presented is:

Whether the standard for determining the adequacy of the "written description of the invention" should be as the statute says—that the description must be "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"—or whether court-created standards should control instead.

PARTIES TO THE PROCEEDINGS BELOW

Petitioners Amgen Inc., Amgen Manufacturing Limited, and Amgen USA, Inc., were plaintiffs in the district court and appellees in the court of appeals. Respondents Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., and Sanofi-Aventis U.S., LLC, were defendants in the district court and appellants in the court of appeals.

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, petitioner Amgen Inc. states that it has no parent corporation and that no publicly held company owns 10% or more of its stock. Petitioners Amgen Manufacturing Limited and Amgen USA, Inc., state that they are fully owned by Amgen Inc.

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PETITION FOR A WRIT OF CERTIORARI

Amgen Inc., Amgen Manufacturing Limited, and Amgen USA, Inc., respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The court of appeals' opinion (App., *infra*, 1a-25a) is reported at 872 F.3d 1367. The district court's opinion denying motions for a new trial and judgment as a matter of law (App., *infra*, 26a-55a) is reported at 227 F. Supp. 3d 333; its evidentiary rulings (App., *infra*, 58a-68a) are unreported.

STATEMENT OF JURISDICTION

The Federal Circuit entered judgment on October 5, 2017 (App., *infra*, 1a-25a), and denied rehearing on Feb-

ruary 23, 2018 (App., *infra*, 69a-70a). On May 14, 2018, the Chief Justice extended the time to file a petition for a writ of certiorari to July 23, 2018. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant provisions of the Patent Act of 1952, 35 U.S.C. § 112, are set forth in the Appendix (App., *infra*, 71a-76a).

INTRODUCTION

This petition presents whether the sufficiency of patent disclosures should be evaluated under the standard provided by the Patent Act itself, or under the Federal Circuit's self-created "possession" standard. That court's "possession" jurisprudence has strayed too far from the statutory standard, imposes extra-statutory barriers to patent protection, and has resulted in a shifting array of uncertain sub-tests and evidentiary considerations that destabilize the incentives and certainty needed to drive the development of breakthrough inventions.

The patent laws reflect a bargain: In exchange for disclosing their inventions to the public—enabling others to make and use them—inventors receive the exclusive right to their inventions for a limited time. The Patent Act specifies the required disclosures: Patent applications must "contain *a* written description of the invention, and of the manner and process of making and using it." 35 U.S.C. § 112(a) (emphasis added). The Act thus requires a single written description covering two topics—the invention, and how to make and use it. The Act sets forth a single standard for the written description: It must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use" the invention. *Ibid.* The Act "require[s] the patentee to describe his invention so that others may construct

and use it after" the patent's expiration. *Schriber-Schroth Co.* v. *Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938).

The Patent Act thus requires "*a* written description," and imposes *one* standard for evaluating its sufficiency. But the Federal Circuit has gone a different direction. The Federal Circuit divides § 112(a) into distinct "written description" and "enablement" requirements, applying different standards for each. For "enablement," the Federal Circuit applies the statutory standard—the description must be "'in such full, clear, concise, and exact terms as to enable.'" *Ariad Pharms., Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc). For "written description of the invention," the Federal Circuit does not apply the statutory standard. The "prepositional phrase 'in such full, clear, concise, and exact terms as to enable,'" that court declared, "modifies only 'the written description . . . of the manner and process of making and using'" the invention. *Ibid.* The Federal Circuit therefore evaluates "written description of the invention" under a judge-made standard: The written description must prove the inventor "had possession" of the claimed invention "as of the filing date." *Id.* at 1351.

That standard defies the statute and precedent. Section 112(a) requires the "written description" to be "in such full, clear, concise, and exact terms as to enable." The text of § 112(a) nowhere sets forth—and this Court's precedents nowhere recognize—a nebulous requirement that the written description prove the inventor had "possession" of the invention. The "possession" standard, moreover, "has never been very enlightening." *Ariad*, 598 F.3d at 1351. Attempting to give it meaning, the Federal Circuit has developed an array of sub-tests (*e.g.*, the "representative-species" test, "structure-function"

test, and "common-structural-features" test). Those tests cannot be reconciled with statutory text either. Those evolving non-statutory standards impose heightened burdens on inventors, requiring them to provide proof on issues that § 112(a) does not make a condition for patent protection.

The Federal Circuit's approach was met with a wave of dissenting opinions and an outpouring of academic criticism. The Federal Circuit's tests, they urged, not only lack any statutory basis, but also deny legitimate patent protection and adversely impact innovation. The Federal Circuit therefore went en banc in *Ariad* to reconsider its approach. But the court "reaffirm[ed]" its position, again over vigorous dissents. *Ariad*, 598 F.3d at 1340. Since *Ariad*, the Federal Circuit's ongoing efforts with sub-tests implementing its "possession" standard have pushed patent law still further from the statute. The ever-shifting demands of those sub-formulations have left innovators no way of predicting what disclosures will be sufficient.

This case sets that instability in stark relief. The jury instructions on the "possession" sub-tests were lifted from 15 years of Federal Circuit precedent. Following those instructions, the jury upheld Amgen's patents on its breakthrough cholesterol-lowering antibodies. On appeal, the Circuit changed its mind; eliminated one of its own tests as inconsistent with its current view of its "possession" standard; and overturned settled relevance principles based on another sub-test. It required that, on remand, the written description in Amgen's patents be evaluated through the "representative-species" test or "structure-function" test—tests nowhere found in § 112.

The Federal Circuit's departure from § 112(a)'s standard—and the bargain the Patent Act provides—has

become intolerable. It does not promote research and investment required for the breakthrough inventions most deserving of patent protection; instead, incentives are shifted to narrow advances for which narrow patents can be obtained under the Circuit's sub-tests. The ever-evolving application of the "possession" standard has produced jurisprudential anarchy, leaving inventors uncertain whether disclosures are sufficient. Neither party sought this Court's review when the Federal Circuit reaffirmed its extra-statutory approach en banc in *Ariad*. Review is warranted now.

STATEMENT

I. STATUTORY FRAMEWORK

This Nation's patent laws reflect "a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology." *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). In exchange for disclosing their inventions, inventors are granted the exclusive right to those inventions for limited times. *Ibid.* That exchange—disclosure in return for a period of exclusivity—is the "*quid pro quo*" of patent law. *Universal Oil Prods. Co.* v. *Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944).

A. The Written-Description Requirement

1. To fulfill their side of the bargain, inventors must disclose the "process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired." *Universal Oil*, 322 U.S. at 484. Section 112 of the Patent Act of 1952 implements that requirement by requiring "a written description":

> 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 * * * .

35 U.S.C. § 112(a) (emphasis added).

Section 112(a) begins by mandating a disclosure: The "specification *shall* contain a *written description*." It then identifies the subjects of the written description: The description must be "*of* the invention, and *of* the manner and process of making and using it." Finally, the written description must be "in such full, clear, concise, and exact terms as to enable" those skilled in the art "to make and use the" invention. The patentee thus must "describe his invention" so "others may construct and use it." *Schriber-Schroth*, 305 U.S. at 57.

That written-description requirement has deep roots. Eighteenth-century cases addressing the sufficiency of patent disclosures often concerned "whether the specification described *the invention* well enough to allow members of the appropriate trade to reproduce it." *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 379 (1996) (emphasis added). The Patent Acts of 1790 and 1793—the Nation's first patent statutes—incorporated that requirement through language still found in current § 112. The 1793 Act provided that the inventor:

> shall deliver a *written description of [the] invention*, and of *the manner of using, or process* of compounding the same, *in such full, clear and exact terms, as* [A] to distinguish the same from all other things before known, and [B] *to enable* any person skilled in the art * * * to make, compound, and use the same.

Act of Feb. 21, 1793, ch. 11, §3, 1 Stat. 318, 321-322 (bracketed letters and emphasis added).

Like the current Patent Act, the 1793 Act began with a mandate ("shall deliver") for "a written description." Like the current Act, the written description had to be "of [the] invention" and "of the manner of" using or making it. And like the current Act, the written description had to be in sufficiently "full, clear and exact terms as * * * to enable." Unlike current law, the 1793 Act further required that the "written description * * * distinguish" the claimed invention from prior art. The 1790 Act was similar. See Act of Apr. 10, 1790, ch. 7, §2, 1 Stat. 109, 110-111.

2. The Patent Act of 1836 largely followed the same pattern. It, too, required inventors to provide "a written description" of the "invention or discovery, and of the manner and process of making, constructing, using, and compounding" it. Act of July 4, 1836, ch. 357, §6, 5 Stat. 117, 119. And it required "such full, clear, and exact terms * * * as to enable" skilled artisans to practice the invention. *Ibid.*

The 1836 Act, however, changed one function of the written-description requirement: It removed the obligation to "distinguish the invention from all other things before known." See §6, 5 Stat. at 119. Instead, the 1836 Act required "claims" that "particularly specify and point out the part, improvement, or combination [the inventor] claims as his own invention or discovery." *Ibid.* The 1870 Act was, in relevant respects, the same. See Act of July 8, 1870, ch. 230, §26, 16 Stat. 198, 201.

Section 112 of the 1952 Patent Act incorporates the same requirements, using similar language. Today, the written-description requirement appears at 35 U.S.C. §112(a). The requirement of claims that "particularly"

and "distinctly" recite "the subject matter" the inventor "regards as the invention" appears as § 112(b).

B. The Federal Circuit's Written-Description Precedent

For over a century, the federal courts applied § 112 directly, requiring the written description—"of the invention, and of the manner and process of making and using it"—to be "in such full, clear, concise, and exact terms as to enable" skilled artisans to practice the invention. See, *e.g.*, *Le Roy* v. *Tatham*, 63 U.S. 132, 138-139 (1860); p. 26, *infra*. By the 1980s, however, the Federal Circuit came to impose a separate standard for "written description of the invention."

1. In *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967), the Federal Circuit's predecessor affirmed the rejection of a patent application on written-description grounds. The claim was to a single, specific compound, but the patent disclosed a general chemical formula with many variables. *Id.* at 991-992. The formula encompassed "half a million [potential] compounds." *Id.* at 993. The court expressed no difficulty with a broad disclosure that supports a broad claim. But the court found that the general disclosure did "not constitute support for" the claim to an *individual* compound absent disclosures guiding the skilled artisan to select that compound over the myriad other options. *Id.* at 994. Because the disclosure failed to tell artisans *what* to make, it did not "enabl[e]" them to make it. *Id.* at 995. In rejecting the claim to a single compound, the court stated that the description failed to "disclose[ ]" that invention "specifically, as something [the inventor] actually invented." *Ibid.*

Later cases addressing "priority" questions (concerning the date of invention) construed *Ruschig* as creating an additional requirement beyond the statutory "such

full, clear, concise, and exact terms as to enable" standard. They construed it to require a written description of the invention demonstrating the inventor "was in possession of the invention" as of the filing date. *Vas-Cath Inc.* v. *Mahurkar*, 935 F.2d 1555, 1563-1564 (Fed. Cir. 1991) (emphasis omitted).[1] In *Regents of the University of California* v. *Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), the Federal Circuit applied that requirement outside the priority context, invalidating a patent because the "written description" did not show the inventor had possession. See *Ariad*, 598 F.3d at 1363 (Rader, J., dissenting-in-part); *id.* at 1370 (Linn, J., dissenting-in-part).

A raft of dissents ensued.[2] Precedent, they urged, precluded replacing the statutory standard with a poorly defined proof-of-possession test found nowhere in §112. See, *e.g.*, *Univ. of Rochester*, 375 F.3d at 1309-1311 (Rader, J., dissenting from denial of rehearing en banc); *id.* at 1326 (Linn, J., dissenting from denial of rehearing en banc).

2. In *Ariad Pharmaceuticals, Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010), the Federal Circuit went

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[1] See, *e.g.*, *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976) ("the description requirement is to ensure that the inventor had possession, as of the filing date of the application").

[2] See, *e.g.*, *Enzo Biochem, Inc.* v. *Gen-Probe Inc.*, 323 F.3d 956, 976 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing en banc); *id.* at 987 (Linn, J., dissenting from denial of rehearing en banc); *Moba, B.V.* v. *Diamond Automation, Inc.*, 325 F.3d 1306, 1322 (Fed. Cir. 2003) (Rader, J., concurring); *Univ. of Rochester* v. *G.D. Searle & Co.*, 375 F.3d 1303, 1307 (Fed. Cir. 2004) (Rader, J., dissenting from denial of rehearing en banc); *id.* at 1325 (Linn, J., dissenting from denial of rehearing en banc); *LizardTech, Inc.* v. *Earth Res. Mapping, Inc.*, 433 F.3d 1373, 1376 (Fed. Cir. 2006) (Rader, J., dissenting from denial of rehearing en banc).

en banc to reconsider its construction of § 112. Over vigorous dissents, the majority reaffirmed the court's position that "written description" and "enablement" are distinct requirements evaluated under different standards.

Everyone agreed that § 112(a) requires 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 make and use the same." See *Ariad*, 598 F.3d at 1344. But the majority held that the standard § 112(a) sets forth—"in such full, clear, concise, and exact terms as to enable"—does not govern "written description of the invention." *Ibid.* Instead, the majority held, the statutory standard "modifies *only* 'the written description . . . of *the manner and process of making and using* [the invention].'" *Ibid.* (brackets in original) (emphasis added).

The en banc court thus reaffirmed a two-requirement, two-standard approach. First, there is an "enablement" requirement subject to the statutory standard: The "written description * * * of the manner and process of making and using" the invention must be sufficiently "full, clear, concise, and exact as to enable" skilled artisans to practice it. Second, there is a "written description of the invention" requirement. That requirement is not evaluated under the statutory standard. Instead, "the test for sufficiency" is "whether the disclosure * * * reasonably conveys * * * that the inventor *had possession* of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351 (emphasis added). The court identified no term in § 112 supporting that standard. Judges Rader and Linn dissented. *Id.* at 1361-1367 (Rader, J.); *id.* at 1367-1372 (Linn., J.). No party sought this Court's review.

The Federal Circuit created sub-tests implementing its "possession" standard. For example, in *Eli Lilly*, the court held that, for patents claiming a "genus" of chemical materials, written descriptions may need to identify "a representative number of species within the genus" sufficient to show "'possession'" of the whole genus. 119 F.3d at 1568-1569. The Circuit endorsed that sub-test, and others, when reaffirming the "possession" standard in *Ariad*. 598 F.3d at 1349-1350. Since then, the Federal Circuit has "often applied" those sub-tests "to hold claims invalid." *Novozymes A/S* v. *DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346 (Fed. Cir. 2013).

II. Proceedings Below

This case arises from patents for Amgen's breakthrough innovation—genetically engineered antibodies that can dramatically lower "bad cholesterol" that causes heart disease and strokes.

A. Amgen Invents and Patents Antibodies That Can Lower Cholesterol by Binding to PCSK9's "Sweet Spot"

High levels of low-density lipoprotein ("LDL" or "bad") cholesterol cause cardiovascular disease—the world's leading cause of death. App., *infra*, 4a; C.A. App. 2417 (394:20-395:17). Typically, high cholesterol was treated using statins. App., *infra*, 4a. Too often, those are ineffective. C.A. App. 2420 (405:1-407:22). The patents at issue disclose Amgen's breakthrough—monoclonal antibodies that dramatically lower LDL levels. U.S. Patent No. 8,829,165 ("'165 Patent"), C.A. App. 153-537; and No. 8,859,741 ("'741 Patent"), C.A. App. 538-923.

1. The human body ordinarily removes LDL cholesterol from the bloodstream using receptors in the liver. App., *infra*, 4a. But a naturally occurring protein in the body, known as PCSK9, can bind to those LDL recep-

tors, interfering with their ability to attach to and remove LDL cholesterol. *Id.* at 4a-6a. The antibodies that Amgen invented target PCSK9 to prevent it from interfering with LDL removal. *Id.* at 4a. The antibodies bind to the specific region of PCSK9 that would otherwise bind to—and thus block PCSK9 from binding with—the liver's LDL receptors. C.A. App. 1166 (256:6)-1167 (258:24).

The invention required years of research and enormous investments. Amgen scientists designed unique protocols and specialized methods to generate and select antibodies that block PCSK9's interaction with LDL receptors. C.A. App. 1167 (259:8-261:18). By October 2006, Amgen had created and identified 3,000 antibodies that bind to PCSK9. *Id.* at 1167 (261:17)-1168 (265:8). Hundreds of those blocked the interaction between PCSK9 and LDL receptors "well." *Id.* at 1263 (638:1-3). At least 100 blocked the interaction by more than 90%. *Ibid.*; see App., *infra*, 39a. Amgen determined the amino-acid sequences of 24 strongly blocking antibodies. C.A. App. 168-207, 1169 (266:15-267:11). In August 2007, Amgen filed a 323-page provisional patent application disclosing that data. *Id.* at 1172 (281:6)-1173 (283:1), 2617.

Amgen scientists performed x-ray crystallography that provided atomic-level detail on the "sweet spot"—the region of PCSK9 to which LDL receptors bind, and to which Amgen's blocking antibodies bind as well. See C.A. App. 1173 (285:11)-1174 (287:3). The x-ray crystallography revealed that the sweet spot comprises only 15 out of PCSK9's 692 amino acids. See App., *infra*, 39a n.6, 50a; C.A. App. 379, col. 129 ("LENGTH: 692"). Amgen filed that data in a second, 351-page provisional application in December 2007, and a third, 711-page provisional in January 2008. C.A. App. 1174 (289:15)-1175 (291:14), 2940, 3291.

2. Amgen's '165 and '741 Patents issued in September and October of 2014. C.A. App. 153, 538. They disclose and claim a class of monoclonal antibodies that bind to PCSK9's "sweet spot," blocking PCSK9 from binding to LDL receptors. See *id.* at 153-537.[3] The patents map the "sweet spot" where the antibodies bind to PCSK9. *Id.* at 364 (100:5-10). The claims are directed to antibodies that bind to one (or more) of the specific amino acids or "residues" in the sweet spot. *Id.* at 528-529. For example, dependent claim 19 covers "an isolated monoclonal antibody" that "blocks binding of PCSK9 to LDL[ ]" receptors by "bind[ing] to at least two of" 15 listed amino acids—"S153, I154, P155," *etc.* *Id.* at 528 (427:47-53), 529 (429:7-12). The listed amino acids form the sweet spot. *Id.* at 364 (100:5-10).

One antibody identified in the patents became Amgen's product REPATHA®, which the FDA approved in August 2015. App., *infra*, 4a, 31a. REPATHA® is approved for patients with, among other things, dangerously high LDL levels despite taking the maximum doses of other medications. C.A. App. 2260-2261.

B. Proceedings Before the District Court

In October 2014, Amgen filed an infringement action against respondents Sanofi-Regeneron, which make and market Praluent. App., *infra*, 3a, 5a-6a. Like REPATHA®, Praluent is a monoclonal antibody that targets PCSK9 to prevent it from binding to LDL receptors. *Id.* at 5a-6a. Sanofi-Regeneron knew that Praluent had a "patent issue," C.A. App. 2365 (187:15)-2367 (193:24), and ultimately stipulated that Praluent infringes Amgen's patents, App., *infra*, 6a.

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[3] For simplicity, only the '165 Patent is cited.

1. Sanofi-Regeneron, however, disputed validity. App., *infra*, 6a. During the ensuing jury trial, § 112(a)'s written-description requirement loomed large. The district court recognized that *Ariad* had endorsed several sub-tests for "possession." See *id.* at 61a. The district court stated that, to show written-description "[s]upport for a genus claim," the patent must disclose "either a 'representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus.'" *Ibid.* (quoting *Ariad*, 598 F.3d at 1350).

The district court excluded evidence of PCSK9 antibodies developed after Amgen's patent applications were filed. App., *infra*, 59a-62a. Sanofi-Regeneron had sought to introduce that evidence as showing that the "representative species" disclosed in Amgen's patents were not fully "representative" of the genus Amgen had claimed. See *id.* at 8a-9a. The court recognized that disclosures are evaluated based on the art at the time of filing; post-priority-date evidence thus is not relevant. *Id.* at 62a. "[B]ecause the written description requirement is tested as of the filing date," evidence of "later-developed or later-discovered products" "should be excluded." *Id.* at 64a-66a (citing *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977)).

2. The court instructed the jury that written description could be shown by (1) disclosing a representative number of species within the claimed genus or (2) disclosing structural features common to the members of the genus. App., *infra*, 12a. Invoking Federal Circuit precedent, the court also instructed the jury that, for antibodies, the written-description requirement can be satisfied by disclosing a "newly characterized antigen" *if* "at the time of filing" the "production of antibodies

against such an antigen was conventional or routine." *Id.* at 13a; see *id.* at 61a (citing *Centocor Ortho Biotech, Inc.* v. *Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011)).

The jury ruled for Amgen, finding no claim invalid. App., *infra*, 28a. The district court entered injunctive relief, which was stayed pending appeal. *Id.* at 6a.

C. Proceedings Before the Federal Circuit

The Federal Circuit reversed in relevant part. App., *infra*, 7a-19a.

1. The court addressed § 112(a)'s written-description requirement at length. Although § 112(a) states that the written description must be "in such full, clear, concise, and exact terms as to enable," the court held that was not the proper standard. App., *infra*, 16a. Instead, "a patentee must convey in its disclosure that it 'had possession of the claimed subject matter as of the filing date.'" *Id.* at 7a (quoting *Ariad*, 598 F.3d at 1351).

The court of appeals held that the district court's "newly characterized antigen" instruction was error. App., *infra*, 12a-13a. It agreed that, for at least 15 years, Federal Circuit precedent had supported the rule that patentees can provide a written description for an antibody by fully describing the protein or antigen to which it binds, so long as generating the claimed antibody would be routine for anyone skilled in the art. See *id.* at 15a. But the court deemed that language "dicta." *Id.* at 14a. "[T]o satisfy the statutory requirement of a description of the invention," the court stated, "it is not enough for the specification * * * to enable it." *Id.* at 16a (citing *Ariad*). "Yet the instruction in this case invites just that improper equation." *Ibid.* The court of appeals instructed the district court to alter its jury instructions on remand,

limiting them to the "correct[]" representative-species and structure-function sub-tests. See *id.* at 12a-13a, 19a.

2. The Federal Circuit also overturned the district court's decision excluding post-priority-date antibodies from evidence. It acknowledged that, because "written description is judged based on the state of the art as of the priority date," courts had long disregarded evidence of embodiments developed after the invention's priority date. App., *infra*, 8a, 10a. But the panel invoked the "possession" test and sub-tests to overturn the exclusion of such evidence. A patent claiming a genus, the court stated, "must disclose 'a representative number of species falling within the scope of the genus or structural features common to the members of the genus.'" *Id.* at 8a (quoting *Ariad*, 598 F.3d at 1350). According to the court, post-priority-date antibody "species that fall within the claimed genus but are not disclosed by the patent" might be "relevant" if offered to show the written description "does not disclose a representative number of species." *Id.* at 8a-9a.

Rehearing and rehearing en banc was denied on February 23, 2018. App., *infra*, 69a-70a.

REASONS FOR GRANTING THE PETITION

This Court has repeatedly emphasized that the Patent Act is a statute and must be read as such. This case arises from the Federal Circuit's departure from that requirement—with devastating results for legal stability and innovation. The Patent Act provides an express standard for the "written description" required by 35 U.S.C. §112(a). The Federal Circuit displaced that standard in favor of its own tests. After a raft of dissents and intensive commentary, the Federal Circuit went en banc to reconsider—but reaffirmed its extra-statutory approach. *Ariad Pharms., Inc.* v. *Eli Lilly & Co.*, 598

F.3d 1336 (Fed. Cir. 2010) (en banc). Since then, the legal instability and resulting damage to the incentives to innovate have become acute—as the decision below illustrates.

By its terms, §112(a) requires "*a* written description of the invention, and of the manner and process of making and using it." It thus requires *a single* written description covering two topics. The Act provides *a single* standard for evaluating that written description: It must be "in such full, clear, concise, and exact terms as to enable" those skilled in the art to practice the invention. The Federal Circuit, however, has split the written-description requirement into "enablement" and "written-description" requirements, holding that the former is governed by the statutory standard but the latter is not. The Court's rationale for that result is grammatically impossible. And it has the bizarre effect of leaving §112(a) with *no* standard for evaluating written description of the invention.

Having unmoored itself from §112(a)'s standard, the court created a standard of its own. "'[W]ritten description of the invention,'" the court declared, requires inventors to demonstrate "'possession of'" the invention "'as of the filing date.'" App., *infra*, 7a (quoting *Ariad*, 598 F.3d at 1351). But that "proof the inventor had possession" standard is nowhere in §112(a)—or this Court's written-description precedent. The Federal Circuit has added further sub-tests (*e.g.*, the "representative-species" test, "structure-function" test, and "common-structural-features" test). Those sub-tests have no more basis in §112 than the "possession" standard. With no anchor in statutory text, they have proved unstable and uncertain.

The proceedings here prove the point. The district court instructed the jury under a longstanding written-description test repeatedly endorsed in Federal Circuit precedent. In the decision below, the court changed its mind about that test; abandoned it as contrary to its current view of the "possession" standard; and remanded for a new trial under different extra-statutory sub-tests. Based on those sub-tests, the panel also upended long-standing precedent on the relevance of embodiments developed after the patent's priority date, rendering the sufficiency of patent disclosures potentially transitory. Innovators cannot rely on the patent system if the standards for protection regularly shift after they make investments.

The extra-statutory standards make it increasingly difficult to patent breakthrough innovations, "impeding innovation," especially in "the biotechnology industry where patent protection is vital in moving new products to market." K. Stone, *Written Description After* Ariad v. Eli Lilly*: 35 USC § 112's Third Wheel*, 11 J. High Tech. L. 191, 228 (2010). The Patent Act offers a bargain: The inventor receives a period of exclusivity in exchange for "describ[ing] his invention so that others may construct and use it after the expiration of the patent." *Schriber-Schroth Co.* v. *Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938). The Federal Circuit has rewritten that bargain, replacing a clear statutory standard with changing burdens of uncertain scope. Review is warranted.

I. THE FEDERAL CIRCUIT'S "POSSESSION" STANDARD DEFIES TEXT, HISTORY, AND PRECEDENT

The Federal Circuit's § 112(a) standard contravenes text, history, and precedent.

A. The Federal Circuit's Approach Contradicts § 112(a)'s Text

Statutory construction must "[s]tart where the statute does." *SAS Inst. Inc.* v. *Iancu*, 138 S. Ct. 1348, 1355 (2018). Section 112(a) commands that inventors "shall" provide "a written description." 35 U.S.C. § 112(a). It specifies the subject of that written description: It must be "of the invention, and of the manner and process of making and using it." *Ibid.* Section 112(a) also sets out the standard for evaluating the written description's sufficiency: It must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use the" invention. *Ibid.* That standard applies whether the written description is identifying "the invention" or "the manner and process of making and using it."

1. Section 112(a)'s grammatical structure makes that inescapable. It imposes the requirement of "a written description," followed by three sequential prepositional phrases ([1]-[3] below):

> The specification
>
> [A] *shall* contain *a written description*
>
> [1] *of* the invention, and
>
> [2] *of* the manner and process of making and using it,
>
> [3] *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 * * * .

35 U.S.C. § 112(a) (emphasis, color, line breaks, and brackets added).

Each prepositional phrase modifies "written description." [1] The description must be "*of* the invention." [2] The description must also be "*of* the manner and process of making and using" that invention. [3] And the description must be "*in* such full, clear, concise, and exact terms as to enable" skilled artisans to practice the invention.

The compound prepositional phrase, "*of* the invention, and *of* the manner and process of making and using it," modifies "written description." See *Int'l Primate Prot. League* v. *Adm'rs of Tulane Educ. Fund*, 500 U.S. 72, 79-80 (1991). The next prepositional phrase—"*in* such full, clear, concise, and exact terms as to enable"—modifies the same grammatical subject, the "written description" that must be provided. It does so whether the written description is addressing "the invention" or "the manner and process of making and using it."[4]

2. The Federal Circuit has nonetheless divided the written-description requirement into separate "written-description" and "enablement" mandates, each subject to different standards. Insofar as the "written description" addresses "the invention," the Federal Circuit holds that the statutory "full, clear, concise, and exact" standard does not apply. *Ariad*, 598 F.3d at 1344. Instead, the Federal Circuit has stated, the "prepositional phrase 'in such full, clear, concise, and exact terms as to enable' * * *

[4] Grammatically, "in such full, clear, concise, and exact terms as to enable" must characterize "written description." It is natural to say that a "description" must be in "full, clear, concise, and exact terms." It is unnatural to say a "manner" or "process" of making and using—conduct or actions—must be in "full, clear, concise, and exact terms." It is the *written description* of the "manner and process"—and of the invention—that must be in "full, clear, concise, and exact terms."

modifies *only* 'the written description . . . *of the manner and process of making and using* [the invention].'" *Ibid.* (brackets in original) (emphasis added).

That does not merely defy grammar. It also disregards Congress's careful punctuation.[5] And it leads to a bizarre result: Under it, § 112(a) provides *no standard* for evaluating "written description *of the invention*." Written description "of the invention" "need not be full. It need not be clear. It need not be concise. It need not be exact. And, of course, it need not enable." *Ariad*, 598 F.3d at 1362 (Rader, J., dissenting-in-part) (citation omitted). That makes the statute into nonsense. If a specification does not identify "*what* to make and use," it is not full, clear, concise, and exact. *Id.* at 1363. Nor does it enable the skilled artisan to make and use the invention. *Ibid.*

3. The Federal Circuit's view is at war with § 112's entire structure. Section 112(a) starts with a command—the specification "shall contain." It sets forth what must be contained: "a written description of the invention, and of the manner and process" of using the invention. It then provides the standard for evaluating sufficiency:

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[5] Congress placed a comma after "of the manner and process of making and using it," separating it from the phrase "in such full, clear, concise, and exact terms as to enable." "A qualifying phrase separated from antecedents by a comma is evidence that the qualifier is supposed to apply to *all* the antecedents instead of only to the immediately preceding one." 2A N. Singer, *Sutherland Statutory Construction* § 47:33 (7th ed. 2017) (emphasis added). "All before that comma prescribes *what* shall be described. The phrase following the comma prescribes *how* and for *whom* it shall be described." *In re Barker*, 559 F.2d 588, 595 (C.C.P.A. 1977) (Markey, C.J., dissenting) (emphasis added). The Federal Circuit rendered that comma inexplicable. *Ariad*, 598 F.3d at 1363 (Rader, J., dissenting-in-part).

The written description must be "in such full, clear, concise, and exact terms as to enable."

Section 112(b), addressing "claims," follows the same pattern. It begins with a command: "The specification shall conclude with" specified content. It sets forth the required content: "one or more claims." Section 112(b) then provides the standard for evaluating the claims' sufficiency. They must "particularly point[ ] out and distinctly claim[ ] the subject matter" the inventor "regards as the invention."

The Federal Circuit makes hash of that pattern. Inventors are commanded to include a "written description of the invention, and of the manner and process of making and using it." They are directed to include "claims." For description of the "manner and process," and the "claims," the statute provides a standard—"full, clear, concise," or "particularly pointing out and distinctly claiming." But insofar as the inventor is describing "the invention," the statute provides no standard. That is nonsense.

4. The Federal Circuit's construction defies Congress's decision to precede "written description" with the singular article "a." Section 112(a) states that the specification "shall contain *a* written description"—a single written description—that covers two subjects (the invention and the manner and process of using it). The Federal Circuit bifurcates that single written description into two—the written description of the invention and the separate written description of making and using it. In the Federal Circuit's view, the statutory standard applies to "only '*the* written description . . . of the manner and process of making and using'" the invention. *Ariad*, 598 F.3d at 1344 (emphasis added). But the Act speaks of "*a*

written description"—not two written descriptions subject to two different standards.

B. The Federal Circuit's "Inventor-Had-Possession" Standard Has No Statutory Basis

Having rejected the statutory standard for "written description of the invention," the Federal Circuit created a standard of its own: The "test for sufficiency," it declares, is "whether the disclosure of the application * * * reasonably conveys * * * that the *inventor had possession* of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351 (emphasis added). That standard appears nowhere in § 112(a). "[M]ore than once," this Court has "cautioned" the Federal Circuit "that courts should not read into the patent laws limitations and conditions which the legislature has not expressed." *Bilski* v. *Kappos*, 561 U.S. 593, 602 (2010) (quotation marks omitted). Yet the Federal Circuit's construction does exactly that.

If Congress had intended the Federal Circuit's standards, § 112(a) would require two written descriptions: "a written description of the invention, in terms showing 'possession,'" *and* "a written description * * * of the manner and process of making and using [the invention] in such full, clear, concise, and exact terms as to enable" skilled artisans "to make and use" it. That is not the statute Congress wrote.

The Federal Circuit's "possession" standard, moreover, departs from § 112(a) conceptually. This Court has explained that, to constitute a written description "of the invention," the description must "identify" the invention, *Schriber-Schroth*, 305 U.S. at 57, or "describe[ ]" what the invention is, *The Telephone Cases*, 126 U.S. 1, 536 (1888). Further, the invention must be described in such terms

"as to enable" skilled artisans to make and use it. *Le Roy* v. *Tatham*, 63 U.S. 132, 138-139 (1860).

The Federal Circuit's "possession" standard is different in kind—as evidenced by the application of the judicial sub-tests it has spawned. For example, *Ariad* held that, where the claim covers a "genus" of pharmaceutical compounds, "possession" may be demonstrated by "disclosure of either" (1) "a representative number of species" (examples) within the scope of the claims or (2) "structural features common to the members of the genus." 598 F.3d at 1350. Those tests are not a different verbal formulation of §112(a)'s requirements. They demand that patentees disclose additional and different information from what is necessary for a skilled artisan to understand what the invention is and how to make and use it.

C. The Federal Circuit's Approach Defies History and This Court's Precedent

The Federal Circuit's construction defies §112(a)'s history and this Court's precedent. The written-description requirement in §112, and predecessors back to the 1790 Act, share similar language. See pp. 6-7, *supra*; App., *infra*, 71a-76a. But not one Patent Act in 230 years has included proof the "inventor had possession" as the written-description standard.

Nor have this Court's cases. To the contrary, they make clear that the statutory standard—in such "full, clear, concise, and exact terms as to enable"—governs written description of the invention. As this Court explained when construing the 1870 Act, "[t]he object of the statute is to require the patentee *to describe his invention* so that others *may construct and use it* after the expiration of the patent." *Schriber-Schroth*, 305 U.S. at 57 (emphasis added). Before the first Patent Act, 18th-cen-

tury "'enablement' cases" asked juries "to determine whether the specification *described the invention* well enough *to allow* members of the appropriate trade to reproduce it." *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 379 (1996) (emphasis added) (citing case from 1785). "Under the modern American system," patents must "contain[ ] a specification *describing the invention* 'in such full, clear, concise, and exact terms as *to enable* any person skilled in the art . . . to make and use the same.'" *Id.* at 373 (emphasis added). The patent system's "*quid pro quo*" is "disclosure of a process or *device in sufficient detail to enable* one skilled in the art to practice the invention." *Universal Oil Prods. Co.* v. *Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944) (emphasis added). The Federal Circuit's position that "written description of the invention" is *not* subject to the "full, clear, concise, and exact terms as to enable" standard—and is governed by a non-statutory "possession" standard instead—defies this Court's precedents.

This Court upheld Alexander Graham Bell's patent under the statutory standard. *The Telephone Cases*, 126 U.S. at 536. It was "enough," this Court declared, that the inventor "describe[d] his method"—there, a method for "transmitting speech telegraphically"—"with sufficient clearness and precision to enable those skilled in the matter to understand what the process is" and "some practicable way of putting it into operation." *Ibid.*; see *Le Roy*, 63 U.S. at 138-139 (sustaining patent where "the machinery described" was "sufficiently explicit to show

the nature of the invention" and how "to produce" the desired "result[ ]").[6]

Before the Federal Circuit's creation, the regional courts of appeals hewed to statutory text. They understood that §112 requires that "the patentee shall make a written description *of his invention* or discovery, 'in such full, clear . . . and exact terms as to enable any person skilled in the art . . . to make, construct . . . and use the same.'" *Donner* v. *Am. Sheet & Tin Plate Co.*, 165 F. 199, 206 (3d Cir. 1908) (emphasis added); see also *Philip A. Hunt Co.* v. *Mallinckrodt Chem. Works*, 177 F.2d 583, 585 (2d Cir. 1949) (similar); *Ill. Tool Works, Inc.* v. *Foster Grant Co.*, 547 F.2d 1300, 1309 (7th Cir. 1976) (similar). None imposed proof of "possession" as the written-description standard.

For at least a decade after the 1952 Act was enacted, the Federal Circuit's predecessor adhered to the statutory standard. See *Enzo Biochem, Inc.* v. *Gen-Probe Inc.*, 323 F.3d 956, 977 (Fed. Cir. 2002) (Rader, J., dissenting from denial of rehearing en banc). Early cases understood that the "essence" of §112 "is that a specification shall disclose *an invention* in such a manner as will enable one skilled in the art to make and utilize it." *In re Gay*, 309 F.2d 769, 772 (C.C.P.A. 1962) (emphasis added);

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[6] In the decision below, the Federal Circuit invoked *Schriber-Schroth* for its assertion that, to provide "a description of the invention, it is not enough for the specification to show how to make and use the invention, *i.e.*, to enable it." App., *infra*, 16a. But *Schriber-Schroth* held only that a written description could not be amended, under the guise of "clarification," to encompass an invention not covered—indeed, excluded—in the original disclosure. See 305 U.S. at 55, 58-59. *Schriber-Schroth* provides no support for the Federal Circuit's *sui generis* "possession" standard.

see pp. 8, 26, *supra*. The Federal Circuit's departure from text and precedent warrants review.

II. THE ISSUE IS EXCEPTIONALLY IMPORTANT

The Federal Circuit's "possession" standard has spawned a series of indeterminate and changing tests. It has provoked intense dissent and academic criticism. And its practical impacts are severe, especially for biotechnology. Since *Ariad*, those problems have intensified.

A. The Federal Circuit's Ever-Changing "Possession" Tests Impede Innovation

Seldom does the record speak so loudly to an issue's importance. Before *Ariad*, criticism of the Federal Circuit's written-description decisions, and extra-statutory "possession" standard, mounted. The earliest suggestions of divorcing "written description of the invention" from the statutory standard met fierce resistance: Congress specified, "in a single prepositional phrase, that the description of the invention, and the description of the manner of making and using it, shall *both* be in 'such full, clear, concise, and exact terms as to enable.'" *In re Barker*, 559 F.2d at 594 (Markey, C.J., dissenting).

After the Federal Circuit bifurcated written description and enablement, a wave of dissents followed. *Ariad*, 598 F.3d at 1361-1362 (Rader, J., dissenting-in-part); see p. 9 & n.2, *supra*. So did intense academic criticism. See *Univ. of Rochester* v. *G.D. Searle & Co.*, 375 F.3d 1303, 1314-1325 (Fed. Cir. 2004) (Rader, J., dissenting from denial of rehearing en banc) (identifying myriad articles). The "written description requirement is at worst indecipherable, and at best unruly." M. Janis, *On Courts Herding Cats: Contending With the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 Wash. U. J.L. & Pol'y 55, 106 (2000).

While *Ariad* "petrifie[d]" the "quixotic possession requirement" into place, 598 F.3d at 1362 (Rader, J., dissenting-in-part), it admitted the standard "has never been very enlightening," *id.* at 1351 (majority opinion). *Ariad*'s Delphic descriptions of that test, see *id.* at 1351-1352, leave courts and practitioners "'to trudge through a thicket of written description jurisprudence that provides no conclusive answers,'" *Anascape, Ltd.* v. *Nintendo of Am., Inc.*, 601 F.3d 1333, 1342 (Fed. Cir. 2010) (Gajarsa, J., concurring).

More problematic, the Federal Circuit's departure from §112(a)'s standard has led to the creation of unstable judicial sub-tests. For example, as discussed above, *Ariad* held that, where the claim covers a "genus" of pharmaceutical compounds, the patentee must disclose either "a representative number of species falling within the scope of the genus," or "structural features common to the members of the genus." *Ariad*, 598 F.3d at 1350. Section 112(a) does not require such disclosures. Yet, since *Ariad*, the Federal Circuit has "often applied those * * * concepts to hold claims invalid." *Novozymes A/S* v. *DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346 (Fed. Cir. 2013).

The Federal Circuit provides little guidance on how to satisfy its tests. For example, "a representative number of species" does not mean disclosure of some "number" of embodiments. *Ariad*, 598 F.3d at 1350. Instead, the applicant must demonstrate possession of the "structural diversity of the claimed genus" by identifying an array of sufficiently exemplifying embodiments. *AbbVie Deutschland GmbH & Co., KG* v. *Janssen Biotech, Inc.*, 759 F.3d 1285, 1301 (Fed. Cir. 2014). But patentees cannot reliably predict when the Federal Circuit will deem that satisfied. In "some cases," the Federal Circuit has found

that "broad or generic disclosures can adequately describe particular constituent species." *Novozymes*, 723 F.3d at 1347. But in *AbbVie*, the Federal Circuit held that describing the amino-acid sequences of 300 antibodies was insufficient because they did not "qualitatively represent other types of antibodies encompassed by the genus," 759 F.3d at 1300, a result the district court below characterized as a "dramatic change in perspective," App., *infra*, 68a n.3.

Path-marking innovations require billions of dollars and years of research and development. One of the justifications for the Federal Circuit's creation was to "reduce the * * * uncertainty of legal doctrine" that undermines incentives to innovate. *Christianson* v. *Colt Indus. Operating Corp.*, 486 U.S. 800, 813 (1988). Here, the Federal Circuit has exacerbated uncertainty. If innovators cannot predict the content that must be disclosed to secure patent protection, they will not invest in innovation, or will pursue other means of protecting inventions, such as trade-secret protection.

B. This Case Exemplifies the Federal Circuit's Destabilizing Approach

The Federal Circuit's extra-statutory standards are so unstable that they do not merely evolve; they get overturned—as happened here. Companies cannot make multi-billion-dollar investments or rely on patents if the legal landscape constantly changes.

1. Before the decision below, the Federal Circuit had repeatedly articulated and applied a specific written-description formulation for antibodies. Under the "newly characterized antigen" test, inventors could claim an antibody (1) by fully describing the antigen to which the antibody binds, (2) so long as generating the claimed antibody would be routine for those skilled in the art. App.,

infra, 13a-16a. The Federal Circuit invoked that test in several cases over 15 years. *Enzo*, 323 F.3d at 964; *Noelle* v. *Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004); *Centocor Ortho Biotech, Inc.* v. *Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011). The PTO followed that test for even longer, *Enzo*, 323 F.3d at 964; see MPEP §2163 (II)(A)(3)(a) ¶5 (9th ed., rev. July 2015), issuing thousands of patents based on it, *e.g.*, *Ex Parte Dickson*, No. 2007-4125, 2007 WL 5108541 (B.P.A.I. Nov. 5, 2007). The district court instructed the jury using language drawn directly from those precedents. App., *infra*, 12a-13a.

In the decision below, the Federal Circuit abandoned that test as "dicta." App., *infra*, 14a. According to the Federal Circuit, that test could allow a jury to find written description of the invention satisfied whenever the description is sufficiently full and clear to enable others to practice the invention. Under the possession standard, the court stated, "it is not enough for the specification to show how to make and use the invention, *i.e.*, to enable it." *Id.* at 16a. Failing to require proof of possession would "r[un] afoul of what is perhaps the core ruling of *Ariad*." *Id.* at 17a. The court remanded for a new trial with jury instructions under *Ariad*'s sub-tests requiring inventors to (1) "disclose 'a representative number of species falling within the scope of the genus,'" or (2) "'structural features common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus.'" *Id.* at 7a-8a (quoting *Ariad*, 598 F.3d at 1350). That about-face in precedent demonstrates the instability that departure from §112's text has wrought—instability that is at war with the incentive to innovate.

2. The decision below upset a second line of precedent, again based on the "possession" sub-tests. Validity

generally is determined based on the state of the art on the patent's "priority date." See 35 U.S.C. §120. Consequently, the Federal Circuit had long emphasized that evidence of *later*-developed embodiments of the invention—additional forms—has no bearing on written description. *E.g.*, *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977); *U.S. Steel Corp.* v. *Phillips Petrol. Co.*, 865 F.2d 1247 (Fed. Cir. 1989).

In the decision below, the Federal Circuit reversed course on that issue, too. The "possession" standard can be met here, it stated, by disclosing sufficient "representative * * * species." App., *infra*, 11a. Infringing embodiments developed after the priority date, the court ruled, might show the disclosed examples are not sufficiently "representative." *Ibid.* The panel therefore reversed the district court's exclusion of such evidence.

That ruling does not merely represent a second upheaval in the law. It makes patent protection transient. As the patent disclosures enable artisans to develop additional embodiments, the new embodiments become evidence that the disclosed examples were not sufficiently representative—potentially rendering a once-valid patent invalid. The Patent Act cannot foster progress if the sufficiency of disclosures is constantly changing. The Federal Circuit's creation of a vast "zone of uncertainty" that "discourage[s] invention" underscores the need for review. *United Carbon Co.* v. *Binney & Smith Co.*, 317 U.S. 228, 236 (1942).

The decision also creates serious disincentives to developing groundbreaking inventions. "If later states of the art could be employed as a basis for rejection * * * , the opportunity for obtaining a basic patent upon early disclosure of pioneer inventions would be abolished." *Hogan*, 559 F.2d at 606. Indeed, the district court below

described the approach as "impos[ing] the 'impossible burden' on inventors to 'at least describe some species representative of antibodies that are structurally similar to' unknown future embodiments." App., *infra*, 68a (footnote omitted).

C. The "Possession" Standard Has a Disparate Impact on Biotechnology

Although the Patent Act should be "a technology-neutral statute," *Moba, B.V.* v. *Diamond Automation, Inc.*, 325 F.3d 1306, 1327 (Fed. Cir. 2003) (Rader, J., concurring), the "possession" mandate and sub-tests impose unique barriers on biotechnology—barriers that would be "inconceivable in other industries." D. Burk & M. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1653-1654 (2003); see C. Nard & J. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 Nw. U. L. Rev. 1619, 1664 (2007) (tests "erect[ ] a more demanding disclosure standard for biotechnology-related inventions").

Antibodies, for example, are often composed of chains of hundreds of amino acids, many of which can be substituted without altering function. See *Moba*, 325 F.3d at 1325 (Rader, J., concurring). "Consequently," the Federal Circuit's proof of "possession" standard threatens to require "tedious" experimental development and "disclosure of thousands of potential permutations" just to prove the diversity of antibodies in the inventor's "possession." *Ibid.* Such requirements would be unthinkable for software inventions or mechanical arts. *Ibid.* They escalate costs and uncertainty—one must predict possible variants—pricing some innovators out of the field. *Id.* at 1326 (Rader, J., concurring); see C. MacDougall, *The Split over Enablement and Written Description:*

Losing Sight of the Purpose of the Patent System, 14 Intell. Prop. L. Bull. 123, 139-140 (2010).

This case proves the point. Amgen's patents identified the *precise residues* on PCSK9 to which the antibody must bind, provided 24 antibody examples, and disclosed the experiments and testing by which to make more. See pp. 12-13, *supra*. Once those disclosures were made, the development of additional antibodies became routine. If those patents do not satisfy the written-description requirement, it is difficult to imagine what would.

III. REVIEW IS WARRANTED HERE

This case squarely presents the issue for review. Although § 112(a) requires a written description of the invention "in such full, clear, concise, and exact terms as to enable," the decision below did not use that standard. "[T]o satisfy the statutory requirement of a description of the invention," the court stated, "it is not enough for the specification to show how * * * to enable it." App., *infra*, 16a. Instead, the court applied the "possession" standard and its sub-tests. "[A] patentee must convey in its disclosure that it 'had possession of the claimed subject matter as of the filing date.'" *Id.* at 7a (quoting *Ariad*, 598 F.3d at 1351).

Indeed, the Federal Circuit overturned the district court's jury instructions, and the Circuit's own prior tests, as contrary to its current view of the "possession" concept. Under the newly characterized antigen test and instruction, a written description of a fully characterized antigen may be sufficient if it enables others to make the claimed antibody through standard methods. See pp. 14-15, 29-30, *supra*. But the court held that instruction and standard improper because "permitting a finding of adequate written description merely from a finding of ability to make and use"—enablement—runs "afoul of what is

perhaps the core ruling of *Ariad*." App., *infra*, 17a. The court insisted that the jury be instructed on court-made sub-tests for "possession" of genus claims—*e.g.*, that the patent "must disclose 'a representative number of species falling within the scope of the genus or structural features common to the members of the genus.'" *Id.* at 8a (quoting *Ariad*, 598 F.3d at 1350).

The court's evidentiary ruling rested on the sub-test requiring disclosure of "a representative number of species." App., *infra*, 9a. Evidence of infringing embodiments developed after the priority date, the court held, can be relevant and admissible to show the disclosed examples are not sufficiently "representative." *Id.* at 11a; pp. 16, 31, *supra*. Everything the decision below held on written description rested on a possession standard and sub-tests that defy §112(a)'s text.

Although the Federal Circuit remanded for a new trial, review is warranted now. A case may be "reviewed despite its interlocutory status" where "there is some important and clear-cut issue of law that is fundamental to the further conduct of the case and that would otherwise qualify as a basis for certiorari." S. Shapiro *et al.*, *Supreme Court Practice* §4.18, at 283 (10th ed. 2013). That is plainly the case here. Overturning the Federal Circuit's standard would dramatically alter any remand—and return courts to faithful application of the statutory text.

CONCLUSION

The petition should be granted.

Respectfully submitted.

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JULY 2018

APPENDIX

APPENDIX A
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2017-1480

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

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Decided: October 5, 2017

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Before PROST, *Chief Judge*, TARANTO and HUGHES, *Circuit Judges*.

PROST, *Chief Judge*.

Appellants Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., and Sanofi-Aventis U.S., LLC (collectively, "Appellants") appeal from a final judgment of the district court holding U.S. Patent Nos. 8,829,165 ("'165 patent") and 8,859,741 ("'741 patent") not invalid and granting a permanent injunction enjoining sales of Appellants' Praluent® alirocumab ("Praluent").[1] In particular, Appellants argue that the district court improperly excluded evidence regarding written description and enablement, improperly instructed the jury on written description, improperly denied Appellants' motion seeking JMOL of no written description and no enablement, improperly granted Appellees' motion seeking JMOL of non-obviousness, and improperly issued the permanent injunction. Appellants' Br. 1. Because we conclude that the district court (i) erred by excluding Appellants' evidence regarding written description and enablement, and (ii) improperly instructed the jury on written description, we reverse-in-part and remand for a new trial on written description and enablement. We also conclude that Appellants are not entitled to JMOL of no written description and no enablement. We affirm the district court's grant of Appellees' JMOL of non-obviousness. Finally, we vacate the district court's permanent injunction.

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[1] Appellants stipulated to infringement of the '165 and '741 patents. Appellants' Br. 11.

I

A

The patents at issue generally relate to antibodies that help reduce low-density lipoprotein cholesterol (LDL-C), or "bad cholesterol." High levels of LDL-C in the bloodstream can cause heart attacks, strokes, and cardiovascular disease. Typically, high LDL-C is treated using small molecules called statins. In some cases, however, statins have adverse side effects or cannot reduce a patient's LDL-C to a healthy level, requiring alternative treatment. One such alternative treatment is a PCSK9 inhibitor—the medicine claimed by the patents at issue. PCSK9 is a naturally occurring protein that binds to and causes the destruction of liver cell receptors (LDL receptors, or LDL-Rs) that are responsible for extracting LDL-C from the bloodstream.

Appellees Amgen Inc., Amgen Manufacturing, Ltd., and Amgen USA, Inc. (collectively, "Appellees") first began studying PCSK9 in early 2005. This research resulted in the development of Appellees' drug Repatha™ which uses the active ingredient "evolocumab." Evolocumab is a monoclonal antibody that targets PCSK9 to prevent it from destroying LDL-R proteins. Appellees filed for FDA approval on August 27, 2014. The FDA approved Repatha in August 2015.

The two patents at issue, both of which share the same specification, are entitled "Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9)."[2] The '165 patent issued on September 9, 2014, and the '741 patent issued on October 14, 2014. The patents have an undisputed priority date of January 9, 2008. Appellants' Br. 12. The relevant claims cover the entire genus of an-

[2] All references are to the '165 patent unless otherwise indicated.

tibodies that bind to specific amino acid residues on PCSK9 and block PCSK9 from binding to LDL-Rs.[3] The patents do not specifically claim Repatha, or any other antibody, by amino acid sequence. Claim 1 of the '165 patent is representative. It recites:

> An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDL[-]R.

'165 patent col. 427 ll. 47-53.

The patents disclose the trial-and-error process Appellees used to generate and screen antibodies that bind to PCSK9 and block PCSK9 from binding to LDL-Rs. *Id.* at col. 73 l. 29-col. 124 l. 31. In particular, the specification explains that to discover the claimed antibodies, 3,000 human monoclonal antibodies were "rescreened for binding to wild-type PCSK9 to confirm stab[ility]," *id.* at col. 78 ll. 4-6, which were eventually narrowed to "85 antibodies that blocked interaction between the PCSK9 . . . and the LDLR [at] greater than 90%," *id.* at col. 80 ll. 35-37. The specification also discloses the three-dimensional structures, obtained via x-ray crystallography, of two antibodies known to bind to residues recited in the claims—21B12 (Repatha) and 31H4. *Id.* at fig. 3E, fig. 3JJ, col. 99 l. 29-col. 103 l. 60. Finally, the specification discloses the amino acid sequences of twenty-two other antibodies that "bin" with Repatha or 31H4, meaning they compete with

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[3] A "residue" is a particular amino acid along PCSK9's amino acid sequence. Thus, the residue "S153" refers to the amino acid serine, located at the 153rd position of PCSK9's sequence.

these antibodies for binding to PCSK9. *Id.* at figs. 2A-2D, figs. 3A-3JJ, col. 88 l. 30-col. 89 l. 37.

In September 2007, Appellants also started exploring antibodies targeting PCSK9. This research resulted in development of Praluent. The active ingredient in Praluent is a monoclonal antibody that targets PCSK9 to prevent it from binding to and destroying LDL-R proteins. The LDL-R proteins then extract LDL-C thereby lowering overall LDL-C levels in the bloodstream. In November 2011, the PTO issued Appellants a patent that claimed Praluent by its amino acid sequence. Appellants filed for FDA approval of Praluent in November 2014. The FDA approved Praluent in July 2015.

B

In October 2014, Appellees sued Appellants, claiming that Praluent infringed the patents in suit. Appellants stipulated to infringement but challenged the patents' validity on written description, enablement, and obviousness grounds.

Over the course of litigation, the district court made several rulings and decisions that are challenged here on appeal. First, the district court excluded all of Appellants' post-priority-date evidence proffered to show that the patents in suit did not provide adequate written description. Second, the district court instructed the jury, over Appellants' objection, that written description can be satisfied "by the disclosure of a newly-characterized antigen . . . if you find that the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against such an antigen was conventional or routine." J.A. 1580. Third, the district court denied Appellants' post-trial motions seeking JMOL on written description and enablement. Fourth, the district court excluded two purported prior

art references, Novartis and Schering, for being improper prior art and granted Appellees' motion seeking JMOL of non-obviousness. And fifth, the district court issued a permanent injunction removing Appellants' Praluent from the market.

This court stayed the injunction pending appeal.

II

A

We first review whether the district court improperly excluded Appellants' evidence about antibodies, including Appellants' infringing Praluent, developed after the patents' priority date of January 9, 2008. Appellants proffered this evidence to show that the patents lack 35 U.S.C. § 112 written description support. The district court excluded this evidence, concluding that because the evidence did not "illuminate[ ] the state of the art *at the time of filing*," it was not relevant "to determine whether there is sufficient disclosure of the claimed invention." *Amgen Inc.* v. *Sanofi*, No. 14-1317, 2016 WL 675576, at *2 (D. Del. Feb. 18, 2016); see also J.A. 1030 ("I concluded that, because the written description requirement is tested as of the filing date, such evidence should be excluded."). Because the district court's decision was based on a misapplication of the law, we reverse.

Section 112 states that "[t]he specification shall 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 . . . to make and use the same . . . ." This requirement ensures "that the inventor actually invented the invention claimed." *Ariad Pharm., Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). To show invention, a patentee must convey in its disclosure that it "had possession of the claimed subject matter as of the filing date." *Id.* at 1350.

Demonstrating possession "requires a precise definition" of the invention. *Id.* To provide this "precise definition" for a claim to a genus, a patentee must disclose "a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.*

Here, the parties dispute whether a court may rely on post-priority-date evidence to determine if a patent discloses "a representative number of species." *Id.* Appellants argue that because the "written description requirement protects against 'attempts to preempt the future before it has arrived,'" Appellants' Br. 28 (quoting *Fiers* v. *Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)), it "would make [no] sense if future innovators were barred from introducing evidence of their own innovations in written description challenges," *id.* Appellees counter that because "[w]ritten description and enablement are judged at the time of filing," Appellees' Br. 34 (citing *Ariad*, 598 F.3d at 1355), "post-priority-date evidence may be relevant only if it illuminates the state of the art at the filing date," *id.* (first citing *In re Koller*, 613 F.2d 819, 825 (CCPA 1980); then citing *In re Hogan*, 559 F.2d 595, 605 (CCPA 1977)). And because Praluent and the other antibodies Appellants proffered did not exist until after the priority date, "they [were] not part of the state of the art . . . and therefore cannot 'illuminate' it." *Id.*

Appellees are correct that written description is judged based on the state of the art as of the priority date. *Ariad*, 598 F.3d at 1355. Accordingly, evidence illuminating the state of the art subsequent to the priority date is not relevant to written description. *Id.* Appellants, however, are also correct that a patent claiming a genus must disclose "a representative number of species

falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* at 1351. Evidence showing that a claimed genus does not disclose a representative number of species may include evidence of species that fall within the claimed genus but are not disclosed by the patent, and evidence of such species is likely to postdate the priority date. If such evidence predated the priority date, it might well anticipate the claimed genus.

Here, Appellants sought to introduce evidence not to illuminate the state of the art on the priority date but to show that the patent purportedly did not disclose a representative number of species. Appellants' Br. 12. As a logical matter, such evidence is relevant to the representativeness question. Simply, post-priority-date evidence of a particular species can reasonably bear on whether a patent "fails to disclose a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350.

We have not ruled on that question to date, but the common-sense logic of admissibility finds support in *AbbVie Deutschland GmbH & Co.* v. *Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014). There, Centocor, the accused infringer of AbbVie's functional claim to a genus of antibodies, stipulated to infringement and challenged validity based on written description. Centocor argued that the antibodies disclosed in AbbVie's patents were "not representative of the entire genus," *id.* at 1298, and it relied heavily on its own accused antibody to support the unrepresentativeness argument, introducing evidence that its antibody "differ[ed] considerably from the

. . . antibodies described in [the asserted] patents," *id.* at 1300. The jury found that the patents lacked adequate written description, and both the district court and this court relied heavily on that evidence in upholding the invalidity verdict. See *AbbVie*, 759 F.3d at 1301; *Abbott GmBH & Co., KG* v. *Centocor Ortho Biotech, Inc.*, 971 F.3d 171, 176-80 (D. Mass. 2013). That is significant because, at the time of trial, the timing of Centocor's antibody in relation to AbbVie's priority date was unsettled: the PTO, in an interference, had found that Centocor's antibody postdated AbbVie's invention, as AbbVie argued, and the subsequent litigation of the question under 35 U.S.C. § 146 was unresolved. See *Abbott*, 870 F. Supp. 2d at 246. The Centocor antibody, in short, was a basis for the unrepresentativeness ruling without regard to whether it postdated the patent's priority date.

Appellees argue, and the district court held, that our predecessor court's decision in *In re Hogan* prohibits the use of post-priority-date evidence to show that a patent fails to disclose a representative number of species. See Appellees' Br. 34 ("[P]ost-priority-date evidence may be relevant only if it illuminates the state of the art at the filing date."); J.A. 1032 ("By giving its imprimatur to the jury's verdict [in *AbbVie*], the Federal Circuit arguably departed from its own precedent, established in *In re Hogan*, 559 F.2d 595 (CCPA 1977), that later-developed or later-discovered products should not be used to test compliance with 35 U.S.C. § 112[, ¶] 1."). But the district court and Appellees misread *In re Hogan* by conflating the difference between post-priority-date evidence proffered to illuminate the post-priority-date state of the art, which is improper, with post-priority-date evidence proffered to show that a patent fails to disclose a representa-

tive number of species. *In re Hogan* prohibits the former but is silent with respect to the latter.

In *In re Hogan*, the U.S. Patent and Trademark Office ("PTO") rejected an application directed to "Solid Polymer of Olefins" for failing to enable the claimed invention. 559 F.3d at 597. The relevant claim at issue recited, in its entirety, "[a] normally solid homopolymer of 4-methyl-1-pentene." *Id.* The application disclosed "a method of making the crystalline form" of the claimed homopolymer which was "the only then existing way to make such a polymer." *Id.* at 606. The PTO rejected the application, however, because the application did not disclose a second, "amorphous form" of making the polymer "which . . . did not exist" as of the priority date. *Id.* Our predecessor court reversed the PTO, holding that "[t]o now say that appellants should have disclosed in 1953 the amorphous form which on this record did not exist until 1962, would be to impose an impossible burden on inventors and thus on the patent system." *Id.* Further, because the applicant had claimed the homopolymer and not a particular method of making the polymer, the court further held that "[t]o restrict appellants to the crystalline form disclosed, under such circumstances, would be a poor way to stimulate invention, and particularly to encourage its early disclosure." *Id.*

Here, unlike in *In re Hogan*, Appellants were not offering post-priority-date evidence to show that Appellees' claimed genus is not enabled because of a change in the state of the art. Instead, Appellants offered Praluent and other post-priority-date antibodies to argue that the claimed genus fails to disclose a representative number of species. As explained above, the use of post-priority-date evidence to show that a patent does not disclose a representative number of species of a claimed genus is

proper. It was thus legal error for the district court to categorically preclude all of Appellants' post-priority-date evidence of Praluent and other antibodies. Accordingly, we reverse the district court's decision and remand for a new trial on written description.

For many of the same reasons, the district court's improper exclusion of post-priority-date evidence requires a new trial on enablement as well. Under the enablement requirement, "the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Genentech, Inc.* v. *Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). Appellants purportedly sought to introduce post-priority-date evidence showing that Appellees engaged in lengthy and potentially undue experimentation to enable the full scope of the claims. Such evidence could have been relevant to determining if the claims were enabled as of the priority date and should not have been excluded simply because it post-dated the claims' priority date. See, *e.g.*, *White Consol. Indus., Inc.* v. *Vega Servo-Control, Inc.*, 713 F.2d 788, 791 (Fed. Cir. 1983) (determining, based on post-priority-date expert evidence that "1½ to 2 man years of effort" would be needed to practice an invention, that patent claims were not enabled). Accordingly, we reverse the district court's decision excluding Appellants' post-priority-date evidence of enablement and remand for a new trial on enablement.

B

We next consider whether the trial court improperly instructed the jury on written description. The district court correctly instructed the jury that in order to satisfy the written description requirement, a patentee may disclose either a representative number of species falling

within the scope of the genus or disclose structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus. Additionally, however, the district court further instructed the jury that:

> In the case of a claim to antibodies, the correlation between structure and function may also be satisfied by the disclosure of a newly characterized antigen by its structure, formula, chemical name, or physical properties if you find that the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against such an antigen was conventional or routine.

J.A. 1580. Appellants argue that this instruction is erroneous because disclosing an antigen does not satisfy the written description requirement for a claim to an antibody. Appellees respond that the instruction was proper because it merely restates the law as set forth in *Enzo Biochem, Inc.* v. *Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002), *Noelle* v. *Lederman*, 355 F.3d 1343 (Fed. Cir. 2004), and *Centocor Ortho Biotech, Inc.* v. *Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011). As discussed below, the district court's instruction is not legally sound and is not based on any binding precedent. Accordingly, we conclude that the instruction was improper.

The district court's instruction traces its roots back to PTO guidelines first discussed by this court in *Enzo Biochem*. That case involved claims directed to nucleic acid probes that were defined by their function of selectively hybridizing to the genetic material of certain bacteria. *Enzo Biochem*, 323 F.3d at 960. We noted in that case that not "all functional descriptions of genetic material fail to meet the written description requirement." *Id.* at 964. Instead, we cited the PTO's Guidelines on written

description for the proposition that "functional characteristics when coupled with a known or disclosed correlation between function and structure" may satisfy the written description requirement. *Id.* (citing *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement* 66 Fed. Reg. 1099-01, 1106 ("Guidelines")).[4] We further noted, in dicta, that "the PTO would find compliance with 112, [¶]1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well-defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature." *Id.* (citing Synopsis of Application of Written Description Guidelines, at 60, *available at* https://web.archive.org/web/20041101121800/http://www.uspto.gov/-web/menu/written.pdf).

In *Noelle*, the patent owner claimed an antibody and sought to claim priority to an earlier filed patent. 355 F.3d at 1349. Noelle argued that "because antibodies are defined by their binding affinity to their antigens, he sufficiently described [the claimed antibody] by stating that

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[4] The Guidelines were first published on Feb. 28, 2000 as the Revised Interim Written Description Guidelines Training Materials. In March 2008, the training materials were revised and republished as Written Description Training Materials, Revision 1, available at https://www.uspto.gov/sites/default/files/web/menu/written.pdf. The PTO now notes that the Training Materials have been "archived" and that "[a] new version will be prepared to reflect changes in the law since 2008, including any required clarifications due to developments in the law relating to 35 U.S.C. 112." Examination Guidance and Training Materials, United States Patent and Trademark Office, *available at* https://www.uspto.gov/patent/laws-and-regulations/examination-policy/examination-guidance-and-training-materials.

it binds to [a disclosed antigen]." *Id.* We rejected this argument and concluded that the claims were not entitled to the earlier priority date because "Noelle failed to disclose the structural elements of [the] antibody or antigen in his earlier . . . application." *Id.* In reaching this conclusion, we acknowledged that according to *Enzo*, "as long as an applicant has disclosed a '*fully characterized* antigen,' either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen." *Id.* But because Noelle did not disclose structure for the antibody or the antigen, we did not rely on *Enzo* to find that the patentee had satisfied the written description requirement.

Then, in *Centocor*, we examined *Enzo* and *Noelle* as well as the PTO Guidelines and held that the antibody claims at issue were invalid for lack of written description. 636 F.3d at 1351-53. We noted that under the PTO's Guidelines, "an applicant can claim an antibody to novel protein X without describing the antibody when (1) the applicant fully discloses the novel protein and (2) generating the claimed antibody is so routine that possessing the protein places the applicant in possession of an antibody." *Id.* at 1351-52. The patentee there had claimed a "class of antibodies containing a human variable region that have particularly desirable therapeutic properties: high affinity, neutralizing activity, and A2 specificity." *Id.* at 1352. The claimed antibodies could bind to "the human TNF-α protein." *Id.* at 1351. The patentee there argued that under *Noelle* and the PTO Guidelines, "fully disclosing the human TNF-α protein provides adequate written description for any antibody that binds to human TNF-α." *Id.* We held, however, that

even though the patentee had disclosed the human TNF-α protein, the claims were still invalid. *Id.* at 1352-53. We questioned the propriety of the "newly characterized antigen" test and concluded that instead of "analogizing the antibody-antigen relationship to a 'key in a lock,'" it was more apt to analogize it to a lock and "a ring with a *million* keys on it." *Id.* at 1352.

Centocor is the only case where we examined the "newly characterized antigen" test in some detail. The test was not central to the holding in either *Enzo* or *Noelle* and neither case explored it in much depth. And in *Noelle*, we cautioned that "each case involving the issue of written description[ ] 'must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited.'" *Id.* at 1349 (quoting *Vas-Cath Inc.* v. *Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991)).

The essential problem with the jury instruction given in this case is that it effectively permitted the jury to dispense with the required finding of a "written description of the invention." 35 U.S.C. § 112. Our en banc decision in *Ariad*, reflecting earlier decisions such as *Schriber-Schroth Co.* v. *Cleveland Trust Co.*, 305 U.S. 47, 56-57 (1938), and *In re Ruschig*, 379 F.2d 990, 991-95 (CCPA 1967), made clear that, to satisfy the statutory requirement of a description of the invention, it is not enough for the specification to show how to make and use the invention, *i.e.*, to enable it. *Ariad*, 598 F.3d at 1345-46, 1347-48. Yet the instruction in this case invites just that improper equation. A jury would naturally understand the instruction to permit it to deem any antibody within the claim adequately described merely because the antibody could easily be "produc[ed]" (and, implicitly, used as an antibody). J.A. 1580 (requirement "may . . . be satisfied" if antigen is newly characterized and "production of anti-

bodies against such an antigen was conventional or routine"). Indeed, the instruction does not even require any *particular* antibody to be easily made; all it requires is that "production of *antibodies*"—some, not all—"against [a newly characterized] antigen" be conventional or routine. By permitting a finding of adequate written description merely from a finding of ability to make and use, the challenged sentence of the jury instruction in this case ran afoul of what is perhaps the core ruling of *Ariad*.

We cannot say that this particular context, involving a "newly characterized antigen" and a functional genus claim to corresponding antibodies, is one in which the underlying science establishes that a finding of "make and use" (routine or conventional production) actually does equate to the required description of the claimed products. For us to draw such a conclusion, and transform a factual issue into a legally required inference, we would have to declare a contested scientific proposition to be so settled as to be entitled to judicial notice. That we cannot do.

An adequate written description must contain enough information about the actual makeup of the claimed products—"a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials," which may be present in "functional" terminology "when the art has established a correlation between structure and function." *Ariad*, 598 F.3d at 1350. But both in this case and in our previous cases, it has been, at the least, hotly disputed that knowledge of the chemical structure of an antigen gives the required kind of structure-identifying information about the corresponding antibodies. See, *e.g.*,

J.A. 1241 (549:5-16) (Appellants' expert Dr. Eck testifying that knowing "that an antibody binds to a particular amino acid on PCSK9 . . . does not tell you anything at all about the structure of the antibody"); J.A. 1314 (836:9-11) (Appellees' expert Dr. Petsko being informed of Dr. Eck's testimony and responding that "[m]y opinion is that [he's] right"); *Centocor*, 636 F.3d at 1352 (analogizing the antibody-antigen relationship as searching for a key "on a ring with *a million* keys on it") (internal citations and quotation marks omitted).

A court may take judicial notice of a fact only when it is either "generally known" or "accurately and readily [discernible] from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b); see *B.V.D. Licensing Corp.* v. *Body Action Design, Inc.*, 846 F.2d 727, 728 (Fed. Cir. 1988) ("Courts may take judicial notice of facts of universal notoriety, which need not be proved, and of whatever is generally known within their jurisdictions." (citing *Brown* v. *Piper*, 91 U.S. 37 (1875))). Because the scientific premise behind the "newly characterized antigen" test stated in the instruction in this case was neither "generally known" nor "accurately and readily" ascertainable, we cannot take judicial notice of the premise and displace the required fact finding with what amounts to a rule of law. We are not required to conclude otherwise, and depart from the plain restriction on judicial notice, by the statement in *Enzo*, which was unnecessary to its holding, about what PTO Guidelines indicated the PTO would find.

Further, the "newly characterized antigen" test flouts basic legal principles of the written description requirement. Section 112 requires a "written description of the invention." But this test allows patentees to claim antibodies by describing something that is not the invention,

i.e., the antigen. The test thus contradicts the statutory "quid pro quo" of the patent system where "one describes an invention, and, if the law's other requirements are met, one obtains a patent." *Ariad*, 598 F.3d at 1345. Indeed, we have generally eschewed judicial exceptions to the written description requirement based on the subject matter of the claims. See *Univ. of Rochester* v. *G.D. Searle & Co.*, 358 F.3d 916, 925 (Fed. Cir. 2004) (noting that "the statute applies to all types of inventions"). And Congress has not created a special written description requirement for antibodies as it has, for example, for plant patents. See, *e.g.*, 35 U.S.C. § 162 (exempting plant patents from § 112 "if the description is as complete as is reasonably possible").

For those reasons, it was improper for the district court to instruct the jury as it did in the sentence at issue here. On remand, the district court should amend its jury instructions accordingly.

C

Next, we consider whether the district court improperly denied Appellants' post-trial motion seeking JMOL of no written description and no enablement. Appellants argue that the asserted patents fail to provide written description support because they merely teach "where an antibody binds to an antigen" which "tells one *nothing* about the structure of any other antibody." Appellants' Br. 53. Appellants also argue that the patents are not enabling because one must engage in several steps including a trial-and-error process of generating and screening antibodies, performing x-ray crystallography, and still potentially failing to "get a sufficient number of antibodies that enable the full scope of the claims." *Id.*

JMOL is proper when "a reasonable jury would not have a legally sufficient evidentiary basis to find for the

party." Fed. R. Civ. P. 50(a)(1). "A determination that a patent is invalid for failure to meet the written description requirement of 35 U.S.C. §112, ¶1 is a question of fact, and we review a jury's determinations of facts relating to compliance with the written description requirement for substantial evidence." *Ariad*, 598 F.3d at 1355 (citing *PIN/NIP, Inc.* v. *Platte Chem. Co.*, 304 F.3d, 1235, 1243 (Fed. Cir. 2002)). And "[t]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Genentech*, 108 F.3d at 1365 (internal quotation marks omitted). But "[e]nablement is not precluded by the necessity for some experimentation such as routine screening" of antibodies. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

Here, the jury did not hear relevant post-priority-date evidence regarding written description and enablement. This evidence may show, for example, that practicing the invention did not require undue experimentation or that the disclosed species are representative of the claimed genus. Because we are presented with an incomplete record on these issues, the court is unable to determine whether the jury would have a "legally sufficient evidentiary basis" to determine if the patents provide sufficient written description or if the claims are enabled. Fed. R. Civ. P. 50(a)(1). We therefore reject Appellants' arguments and conclude that Appellants are not entitled to JMOL of no written description and no enablement.

D

We next address whether the district court improperly granted Appellees' JMOL of non-obviousness. Because the district court correctly excluded Appellants' proffered references as improper prior art, we conclude that

the district court's grant of Appellees' motion seeking JMOL of non-obviousness was proper.

During litigation, Appellants sought to invalidate the asserted patents by proffering two published PCT applications: Novartis (WO 2008/12563) and Schering (WO 2009/055783). Neither reference predates the January 9, 2008 priority date of the asserted patents. But both applications claim priority to provisional applications that do predate the asserted patents' priority date.[5] In the district court, Appellants attempted to rely on these PCT applications as pre-AIA § 102(e)(1) art. 35 U.S.C. § 102(e)(1) (providing "an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent"). Appellees argued, however, that the references were not proper prior art because Appellants had not shown that the provisional applications provided written description support for the claims of the PCT applications. The district court agreed, excluded the two references, and granted JMOL of non-obviousness.

Appellants argue that the district court erred by misapplying our decision in *Dynamic Drinkware, LLC* v. *National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015). According to Appellants, that case only related to whether "a *patent* asserted as prior art under § 102(e)(2) was prior art as of the filing date of a parent application" but does not relate to whether "published patent *applications* asserted as prior art under § 102(e)(1)" were prior art as of the filing date of their provisional applications. Appellants' Br. 46. Appellants are incorrect.

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[5] It is undisputed that the provisional applications are not themselves prior art under § 102(e)(1) because they are not applications published under § 122(b).

In *Dynamic Drinkware*, we clearly explained that for a non-provisional application to claim priority to a provisional application for prior art purposes, "the specification of the *provisional* [application] must contain a written description of the invention . . . in such full, clear, concise, and exact terms, to enable an ordinarily skilled artisan to practice the invention claimed in the *non-provisional* application." 800 F.3d at 1378. Further, we have previously stated that "for the non-provisional utility application to be afforded the priority date of the provisional application, . . . the written description of the provisional must adequately support the claims of the non-provisional application." *New Railhead Mfg., L.L.C.* v. *Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002).

Here, Appellants challenged the district court's application of *Dynamic Drinkware*, but did not proffer any evidence showing that the provisional applications contained representative species or common structural elements sufficient to satisfy the written description requirement for the monoclonal antibodies claimed in the PCT applications. Similarly, Appellants provided no evidence that the claims of the PCT applications were enabled by the provisional application. Because the district court properly excluded Novartis and Schering under *Dynamic Drinkware*, the court's grant of JMOL of non-obviousness was proper.

E

Finally, we address the district court's permanent injunction removing Appellants' Praluent from the market. As noted earlier, we stayed this injunction pending resolution of this appeal. Because we vacate the district court's judgment as to written description and enablement and remand for a new trial, we also vacate the permanent injunction.

We write to note, however, that the district court's permanent injunction analysis in this case was improper for two distinct reasons. First, the district court misapplied *eBay, Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006). In that case, the Supreme Court explained that:

> [A] plaintiff seeking a permanent injunction *must satisfy* a four-factor test before a court may grant such relief. A plaintiff *must demonstrate*: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

Id. at 391 (emphases added). Here, the district court concluded that issuing a permanent injunction would disserve the public interest. Despite that finding, the court issued a permanent injunction. J.A. 33-34. That was in clear violation of *eBay*. If a plaintiff fails to show "that the public interest would not be disserved by a permanent injunction," then the district court may not issue an injunction. *eBay*, 547 U.S. at 391.

Second, the district court also erred in its analysis of the "public interest" factor. In reaching its conclusion that the injunction would disserve the public, the district court weighed "being a patent holder and a verdict winner" on the one hand and "taking an independently developed, helpful drug off the market" on the other. J.A. 33. It then "conclude[d] that the public interest of having a choice of drugs should prevail." J.A. 33-34.

But eliminating a choice of drugs is not, by itself, sufficient to disserve the public interest. Under such an approach, courts could never enjoin a drug because doing so

would always reduce a choice of drugs. That, of course, is not the law. See 35 U.S.C. § 271(e)(4)(B) ("[I]njunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product."). We previously rejected such reasoning in *WBIP, LLC* v. *Kohler Co.* and explained that:

> The district court's decision is based on its reasoning that having more manufacturers of a lifesaving good in the market is better for the public interest. But this reasoning is true in nearly every situation involving such goods, such that, if it alone is sufficient, it would create a categorical rule denying permanent injunctions for life-saving goods, such as many patented pharmaceutical products. As the Supreme Court has warned, categorical rules regarding permanent injunctions are disfavored.

829 F.3d 1317, 1343 (Fed. Cir. 2016). Just as a patent owner does not automatically receive an injunction merely by proving infringement, see *eBay*, 547 U.S. at 394, an accused infringer cannot escape an injunction merely by producing infringing drugs. Accordingly, a reduction in choice of drugs cannot be the sole reason for a district court to deny an injunction.

III

For the foregoing reasons, we conclude that the district court erred by (i) categorically excluding Appellants' evidence of written description and enablement, and (ii) improperly instructing the jury on written description. For these reasons we reverse the district court's decision to exclude Appellants' evidence of written description and enablement and remand for a new trial consistent with this opinion. We conclude that Appellants are not

entitled to JMOL of no written description and no enablement. We also conclude that the district court properly granted Appellees' JMOL of non-obviousness. Finally, we vacate the permanent injunction and remand for further proceedings consistent with this opinion.

REVERSED IN PART, AFFIRMED IN PART, VACATED IN PART, AND REMANDED

APPENDIX B

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CIV. NO. 14-1317-SLR

AMGEN INC., AMGEN MANUFACTURING, LIMITED; AND AMGEN USA, INC.,

Plaintiffs,

v.

SANOFI; SANOFI-AVENTIS U.S. LLC; AVENTISUB LLC f/d/b/a AVENTIS PHARMACEUTICALS INC.; AND REGENERON PHARMACEUTICALS INC.,

Defendants.

Melanie K. Sharp, Esquire and James L. Higgins, Esquire of Young Conaway Stargatt & Taylor, LLP, Wilmington, Delaware. Counsel for Plaintiffs. Of Counsel: William G. Gaede, III, Esquire, David L. Larson, Esquire, Eric W. Hagen, Esquire, Terry W. Ahearn, Esquire, Bhanu K. Sadasivan, Esquire, Sarah C. Columbia, Esquire, K. Nicole Clouse, Esquire, Lauren Martin, Esquire, Esther E. Lin, Esquire, Michael V. O'Shaughnessy, Esquire, and Rebecca Harker Duttry, Esquire of McDermott Will & Emery LLP.

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MEMORANDUM OPINION

Dated: January 3, 2017
Wilmington, Delaware

/s/Sue L. Robinson
ROBINSON, District Judge

I. INTRODUCTION

On October 17, 2014, plaintiffs Amgen Inc., Amgen Manufacturing Limited, and Amgen USA Inc. (collectively "plaintiffs") brought this action alleging infringement of U.S. Patent Nos. 8,563,698; 8,829,165 ("the '165 patent"); and 8,859,741 ("the '741 patent") against defendants Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, and Regeneron Pharmaceuticals, Inc. (collectively "defendants"). (D.I. 1) Plaintiffs filed an amended complaint on November 17, 2014. (D.I. 10) Defendants answered the complaint on December 15, 2014. (D.I. 18, 19, 20) The court held a *Markman* hearing on September 17, 2015, and issued a claim construction order on October 25, 2015 construing certain disputed limitations of the '165 and '741 patents. (D.I. 151) On January 29, 2016,

the court granted plaintiffs' motion to amend the complaint, which amended complaint was filed the same day consolidating into a single complaint plaintiffs' pleadings from four lawsuits (resulting in the addition of U.S. Patent Nos. 8,871,913; 8,871,914; 8,883,983; and 8,889,834). (D.I. 183, 184) Defendants answered the amended complaint on February 16, 2016. (D.I. 220) On February 22, 2016, defendants stipulated to infringement of the asserted claims of the patents-in-suit.[1] (D.I. 235) The court held a final pretrial conference on February 22, 2016.

The parties proceeded to trial on March 8, 2016, arguing the validity of the asserted claims. The court decided a series of evidentiary issues and *Daubert* motions before and during trial. (D.I. 226, 249, 250, 264, 269, 280) On March 16, 2016, the court granted defendants' judgment as a matter of law regarding willful infringement. (D.I. 302) On March 16, 2016, the jury returned a verdict finding the asserted claims of the patents-in-suit valid. (D.I. 304) Presently before the court are defendants' motions for a new trial and judgment as a matter of law on written description and enablement (D.I. 331, 332), and plaintiffs' motion to strike the opening brief in support of defendants' motion for judgment as a matter of law (D.I. 338). The court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a).

II. BACKGROUND

A. Parties

Amgen Inc. and Amgen USA Inc. are corporations organized under the laws of the State of Delaware, with a principal place of business in Thousand Oaks, California. Amgen Manufacturing, Limited is a corporation orga-

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[1] Claims 2, 7, 9, 15, 19, and 29 of the '165 patent and claim 7 of the '741 patent.

nized under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico. Sanofi is a company organized under the laws of France with its principal headquarters in Paris, France. Sanofi-Aventis U.S. LLC is a company organized under the laws of the State of Delaware with its principal place of business in Bridgewater, New Jersey. Aventisub LLC is a company organized under the laws of the State of Delaware having its principal place of business in Greenville, Delaware.[2] Regeneron Pharmaceuticals, Inc. is a corporation organized under the laws of the State of New York with its principal place of business in Tarrytown, New York. (D.I. 184 at ¶¶2-8, 12)

B. Technology

1. The patents-at-issue

The '165 patent issued on September 9, 2014 and the '741 patent issued on October 14, 2014 (collectively "the patents-at-issue"). (JTX 2, 3) The patents-at-issue are titled "Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9)" and share a specification.[3] Proprotein convertase subtilisin kexin type 9 ("PCSK9") is a specific antibody involved in regulating the levels of the low density lipoprotein receptor ("LDLR") protein. (1:57-59) Monoclonal antibodies have a known "Y-shaped" structure made up of "two identical pairs of polypeptide chains," each pair having a heavy chain and a light chain. The carboxy-terminal portion of each chain typically defines a constant region. "The ami-

[2] Aventisub is the surviving entity from a June 2014 merger involving Aventis Pharmaceuticals Inc. and has assumed the assets, liabilities, and/or responsibilities of Aventis Pharmaceuticals Inc. Aventis Pharmaceuticals Inc. was a Delaware corporation having a principal place of business in Bridgewater, New Jersey.

[3] All references are to the '165 patent unless otherwise indicated.

no-terminal portion of each chain typically includes a variable region of about 100 to 110 or more amino acids that typically is responsible for antigen recognition." This allows different antibodies to bind to different antigens. (33:1-27) The specification describes monoclonal antibodies that bind to a specific region of PCSK9. (3:5-6)

The specification provides that 3000 human monoclonal antibodies were "rescreened for binding to wild-type PCSK9 to confirm stable hybridomas were established," and "a total of 2441 positives repeated in the second screen." (78:4-6, 35) Of these, "384 antibodies . . . blocked the interaction between PCSK9 and the LDLR well [and] 100 antibodies blocked the interaction strongly," "inhibit[ing] the binding interaction of PCSK9 and LDLR [at] greater than 90%." (80:22-26) The "screen of the 384 member subset identified 85 antibodies that blocked interaction between the PCSK9 mutant enzyme and the LDLR [at] greater than 90%." (80:35-37) The specification provides the amino acid sequence of over two dozen of the identified antibodies. (Figures 2A-2D, 3A-3JJ, 15A-15D, 17:60-18:3, 20:1-8, 85:7-43) The specification describes the use of "epitope binning assays"[4] to characterize the different epitopes on PCSK9. 21B12 and 31H4 are representative members of two epitope bins that do not compete with each other for binding to PCSK9. (88:34-89:19) X-ray crystallography experiments were used to characterize the 21B12 and 31H4 binding sites. (99:56-103:60)

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[4] Epitope binning assays are used to determine the ability of an antibody to block another's binding to the antigen. Antibodies with similar blocking profiles are grouped into a bin, indicating these antibodies bind to the same or overlapping epitopes. (88:34-89:37; D.I. 344 at 799:7-800:16)

The claims reference specific amino acids at designated positions in SEQ ID NO: 1 and/or 3, which are specific amino acid sequences of PCSK9. (124-133) Claim 1 of the '165 patent recites:

> An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO: 3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.

(427:47-52) Claim 1 of the '741 patent recites:

> An isolated monoclonal antibody that binds to PCSK9, wherein the isolated monoclonal antibody binds an epitope on PCSK9 comprising at least one of residues 237 or 238 of SEQ ID NO: 3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.

('741 patent, 427:36-40) At trial, defendants argued that the asserted claims were invalid for lack of written description and enablement and were obvious in light of the prior art.

2. Repatha™ and PRALUENT®

Physicians recognize dyslipidemia caused by elevated LDL ("low density lipoprotein" or "bad" cholesterol) as a major risk factor for cardiovascular disease. Plaintiffs developed Repatha™ ("Repatha"), which uses an active ingredient "evolocumab" (identified as "21B12" in the specification). As described in the specification, evolocumab is a monoclonal antibody that targets PCSK9 to prevent it from engaging LDLR and ultimately lowers the levels of LDL in the blood. The FDA approved Repatha in August 2015. (D.I. 184; D.I. 342 at 241:15-24;

D.I. 362 at 5) Defendants developed PRALUENT® alirocumab ("Praluent"), a monoclonal antibody that reduces LDL cholesterol levels in the blood. The FDA approved Praluent in July 2015. (D.I. 342 at 347:6-9, 350:23-351:5; D.I. 362 at 5)

III. STANDARDS OF REVIEW

A. Renewed Motion for Judgment as a Matter of Law

The Federal Circuit "review[s] a district court's denial of judgment as a matter of law under the law of the regional circuit. *WBIP, LLC* v. *Kohler Co.*, 829 F.3d 1317, 1325 (Fed. Cir. 2016) (citation omitted). In the Third Circuit, a "court may grant a judgment as a matter of law contrary to the verdict only if 'the record is critically deficient of the minimum quantum of evidence' to sustain the verdict." *Acumed LLC* v. *Advanced Surgical Servs., Inc.*, 561 F.3d 199, 211 (3d Cir. 2009) (citing *Gomez* v. *Allegheny Health Servs., Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995)); see also *McKenna* v. *City of Philadelphia*, 649 F.3d 171, 176 (3d Cir. 2011). The court should grant judgment as a matter of law "sparingly," and "only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Marra* v. *Philadelphia Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007) (citing *Moyer* v. *United Dominion Indus., Inc.*, 473 F.3d 532, 545 n.8 (3d Cir. 2007)). "In performing this narrow inquiry, [the court] must refrain from weighing the evidence, determining the credibility of witnesses, or substituting [its] own version of the facts for that of the jury. *Id.* (citing *Lightning Lube, Inc.* v. *Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993)). Judgment as a matter of law may be appropriate when there is "a purely legal ba-

sis" for reversal "that does not depend on rejecting the jury's findings on the evidence at trial." *Acumed*, 561 F.3d at 211.

B. Motion for a New Trial

Federal Rule of Civil Procedure 59(a) provides, in pertinent part:

> A new trial may be granted to all or any of the parties and on all or part of the issues in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States.

Fed. R. Civ. P. 59(a). The decision to grant or deny a new trial is within the sound discretion of the trial court and, unlike the standard for determining judgment as a matter of law, the court need not view the evidence in the light most favorable to the verdict winner. See *Allied Chem. Corp.* v. *Daiflon, Inc.*, 449 U.S. 33, 36 (1980); *Leonard* v. *Stemtech Int'l Inc*, 834 F.3d 376, 386 (3d Cir. 2016) (citing *Olefins Trading, Inc.* v. *Han Yang Chem. Corp.*, 9 F.3d 282 (3d Cir. 1993)); *LifeScan Inc.* v. *Home Diagnostics, Inc.*, 103 F. Supp. 2d 345, 350 (D. Del. 2000) (citations omitted); see also 9A Wright & Miller, *Federal Practice and Procedure* §2531 (2d ed. 1994) ("On a motion for new trial the court may consider the credibility of witnesses and the weight of the evidence."). Among the most common reasons for granting a new trial are: (1) the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) newly-discovered evidence exists that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury's verdict was facially inconsistent. See *Zarow-Smith* v. *N.J. Transit Rail Opera-*

tions, 953 F. Supp. 581, 584-85 (D.N.J. 1997) (citations omitted). The court must proceed cautiously, mindful that it should not simply substitute its own judgment of the facts and the credibility of the witnesses for those of the jury. Rather, the court should grant a new trial "only when the great weight of the evidence cuts against the verdict and a miscarriage of justice would result if the verdict were to stand." *Leonard*, 834 F.3d at 386 (citing *Springer* v. *Henry*, 435 F.3d 268, 274 (3d Cir. 2006) and *Williamson* v. *Consol. Rail Corp.*, 926 F.2d 1344, 1352-53 (3d Cir. 1991)) (internal quotation marks omitted).

IV. MOTION FOR JMOL

A. Procedural Issue

Defendants renew their motion for JMOL on the issue of lack of written description and enablement, arguing that the evidence presented at trial was legally sufficient to show that the specification lacked written description and was not enabled. Plaintiffs challenge the propriety of the renewed motion as defendants did not formally move for JMOL under Rule 50(a) during trial. Fed. R. Civ. P. 50(a).

Rule 50(a) requires the movant to "specify the judgment sought and the law and facts that entitle the movant to judgment." Fed. R. Civ. P. 50(a). "The purpose of th[is] requirement is to afford the opposing party an opportunity to cure the defects in proof that might otherwise preclude the party from taking the case to the jury." See *DuroLast, Inc.* v. *Custom Seal, Inc.*, 321 F.3d 1098, 1105 (Fed. Cir. 2003). The caselaw indicates that a Rule 50(b) JMOL motion is properly founded where an oral Rule 50(a) motion was lodged; or a mere technical failure to comply with Rule 50(a) occurred, i.e., "the party clearly challenged the sufficiency of the evidence on the disputed issue at some point during trial, thereby alerting

the opposing party as to the grounds on which the evidence is allegedly insufficient." *Id.* at 1106. The level of specificity required to give the opposing party notice has been the subject of interpretation, and may vary depending on the circumstances of the case. See *Fresenius Medical Care Holdings, Inc.* v. *Baxter Intern., Inc.*, 2007 WL 518804, *5 (N.D. Cal. Feb. 13, 2007) (collecting Federal Circuit authority).

At the close of defendants' case, on March 10, 2016, the court indicated that the parties should move on to the rest of the case postponing any motion practice until the jury was excused. (D.I. 343 at 720:17-19) After resolving an evidentiary issue outside the presence of the jury, the court stated that "if [plaintiffs] want to do [their] placeholder motion, [plaintiffs] should just say [that they] make a motion, and I will reserve judgment. No need to do much more than that." Plaintiffs moved for JMOL arguing that defendants did not present a sufficient evidentiary basis for a reasonable juror to find for defendants with respect to their invalidity defenses of obviousness, lack of written description, and enablement relating to the . . . asserted claims of the patents-in-suit." The court reserved judgment, and stated that there was "[n]o need for defendants to even respond" to plaintiffs' motion. (D.I. 343 at 725:15-726:8) On March 14, 2016, after further discussion with counsel, the court granted plaintiffs' motion for JMOL on obviousness. (D.I. 345 at 1076:21-1077:6) With this grant, the court issued a short instruction to the jury to explain why the testimony of plaintiffs' expert was cut off. (*Id.* at 1110:9-17) Plaintiffs then rested their case. Defendants did not formally move for JMOL on the issues of written description and invalidity and moved on to their rebuttal case. (*Id.* at 1100:18-23)

"The district court [is] in the best position to judge the sufficiency of [a] Rule 50(a) motion in the context of the trial . . . ." *Gaus* v. *Conair Corp.*, 363 F.3d 1284, 1287 (Fed. Cir. 2004). Throughout the trial, the crux of the invalidity dispute was defendants' contention of lack of written description and invalidity. Indeed, only these issues went to the jury (defendants having stipulated to infringement and the court having resolved the issue of willful infringement and obviousness). Under the circumstances, the court concludes that plaintiffs were apprised during trial of defendants' allegations of insufficient evidence of written description and enablement, therefore, defendants may proceed with the renewed JMOL.[5]

B. Standard

The statutory basis for the enablement and written description requirements, 35 U.S.C. §112, provides in relevant part:

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

35 U.S.C. §112 ¶1. "The enablement requirement is met

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[5] In contrast, in *TruePosition Inc.* v. *Andrew Corp.*, 568 F. Supp. 2d 500 (D. Del. 2008) (cited by plaintiffs), the court found that defendant's pre-verdict JMOL motions regarding infringement (no offer for sale and failure of proof on claims 1 and 22) and damages, together with its counsel's statements, were insufficient to support the post-trial renewed JMOL motion on several other claims (willfulness; no lost profits damages based on the existence of non-infringing alternatives; government use; fraud; and promissory estoppel)).

where one skilled in the art, having read the specification, could practice the invention without 'undue experimentation.'" *Streck, Inc.* v. *Research & Diagnostic Systems, Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) (citation omitted). "While every aspect of a generic claim certainly need not have been carried out by the inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech, Inc.* v. *Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). The specification need not teach what is well known in the art. *Id.* (citing *Hybritech* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986)). A reasonable amount of experimentation may be required, so long as such experimentation is not "undue." *ALZA Corp.* v. *Andrx Pharmaceuticals, Inc.*, 603 F.3d 935, 940 (Fed. Cir. 2010).

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Martek Biosciences Corp.* v. *Nutrinova, Inc.*, 579 F.3d 1363, 1378 (Fed. Cir. 2009) (citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). The Federal Circuit has identified several factors that may be utilized in determining whether a disclosure would require undue experimentation: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (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 of the art; and (8) the breadth of the claims. *In re Wands*, 858 F.2d at 737. These factors are sometimes referred to as the "*Wands* factors." A

court need not consider every one of the *Wands* factors in its analysis, rather, a court is only required to consider those factors relevant to the facts of the case. See *Streck, Inc.*, 655 F.3d at 1288 (citing *Amgen, Inc.* v. *Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991)).

The enablement requirement is a question of law based on underlying factual inquiries. See *Green Edge Enterprises, LLC* v. *Rubber Mulch Etc., LLC*, 620 F.3d 1287, 1298-99 (Fed. Cir. 2010) (citation omitted); *Wands*, 858 F.2d at 737. Enablement is determined as of the filing date of the patent application. *In re '318 Patent Infringement Litigation*, 583 F.3d 1317, 1323 (Fed. Cir. 2009) (citation omitted). The burden is on one challenging validity to show, by clear and convincing evidence, that the specification is not enabling. See *Streck, Inc.*, 665 F.3d at 1288 (citation omitted).

A patent must also contain a written description of the invention. 35 U.S.C. §112, ¶1. The written description requirement is separate and distinct from the enablement requirement. See *Ariad Pharmaceuticals, Inc.* v. *Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2011). It ensures that "the patentee had possession of the claimed invention at the time of the application, i.e., that the patentee invented what is claimed." *LizardTech, Inc.* v. *Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005). The Federal Circuit has stated that the relevant inquiry—"possession as shown in the disclosure"—is an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351.

This inquiry is a question of fact; "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Id.* (citation omitted). In this regard, defendant must provide clear and convincing evidence that persons skilled in the art would not recognize in the disclosure a description of the claimed invention. See *PowerOasis, Inc.* v. *T-Mobile USA, Inc.*, 522 F.3d 1299, 1306-07 (Fed. Cir. 2008) (citation omitted).

C. Evidence

1. 21B12 and 31H4

The parties agreed that the patent described the screening of about 3,000 antibodies to determine which ones block the binding of PCSK9 to the LDL receptor. The inventors chose 384 antibodies, which blocked PCSK9 "well" for further testing. Of these, 100 antibodies were identified that blocked PCSK9 at over 90%. (D.I. 342 at 283; D.I. 343 at 637:18-639:3, 742) The parties also agreed that the patents-in-suit disclose two antibodies (21B12 and 31H4) that bind to a specific region (the "binding region") of PCSK9.[6] The inventors identified the binding region using X-ray crystallography of 21B12 and 31H4. (D.I. 342 at 283-286:11, 411:4-9, 415:15-21; D.I. 343 at 550:7-17; D.I. 344 at 881:19-882:4, 916:6-8) The specification only provides X-ray crystallography data for 21B12 and 31H4. (D.I. 342 at 283:10-14; D.I. 343 at 645:4-13; D.I. 344 at 882:5-8, 937:24-938:6)

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[6] The court will refer to this region as "the binding region," rather than the list of names used by the various witnesses including, but not limited to: region, zone, hot zone, central patch, patch, specific area, and sweet spot.

2. Defendants' evidence

Defendants' expert, Dr. Michael Eck ("Dr. Eck"), testified that the patent disclosed the topography of PCSK9 and the fifteen residue binding region, as well as the crystal structure. (D.I. 343 at 562:19-563:4, 579:1-11; see also D.I. 344 at 633:22-634:22, 676:2-677:10) He explained that 21B12 and 31H4 "bind to very defined spots on the surface of PCSK9, [21B12] on one spot, sort of at the edge . . . of the [binding] region [and] 31H4 on the opposite edge." (D.I. 343 at 540:9-541:2; D.I. 345 at 1114:5-1116:13) He stated that 21B12 "probably interacts with probably eighteen amino acids on the surface," four of which are in the binding region. 31H4 interacts with about thirty amino acids total and three in the binding region. (D.I. 343 at 556-557) There are residues in the "middle" of the binding region that are not bound by either 21B12 or 31H4. (D.I. 343 at 546:4-19, 556:4-557:4; D.I. 345 at 1115:10-13) He opined that there are "many different positions on the surface of PCSK9, including this region in the middle, where one would expect antibodies to [be] able to bind, and we see here in [plaintiffs'] patent exactly two examples of antibodies that we know bind in this general vicinity, both on the edge." (D.I. 343 at 541:3-10) There is no example of an antibody "that interacts with the middle and binds [S]153 or likewise D238 or I369 or V380." (D.I. 345 at 1118:14-1119:12) Defendants' other expert, Dr. Donald Siegel ("Dr. Siegel"), similarly concluded that the patents-in-suit do not show the structure of an antibody that binds centrally to the binding region and opined that such an antibody "would have to have a different amino acid sequence or structure than either" 21B12 or 31H4. Moreover, it "would be interacting in a different way." (D.I. 343 at 634:6-25, 645:14-24)

Dr. Eck further explained that there are other possible antibodies, which would have different structures and mechanisms of binding with the binding region. Such antibodies "[m]ight interact with many of the same residues on PCSK9, but [also with] a few different residues." That a certain antibody binds to a particular amino acid on PCSK9 "does not tell you anything at all about the structure," "only about its function." Moreover, there are no developed methods for working back from a binding target "to reliably predict how to make an antibody to bind there." (*Id.* at 547:18-549:16, 564:14-17) Nor can one predict where an antibody would bind on PCSK9 from its structure. (*Id.* at 558:6-9, see also 684:3-18) For example, one would expect that "many antibodies with very different chemical structures could bind to PCSK9 and" bind to "D238, but do it in very different ways, with many different antibody structures." (D.I. 343 at 580:11-22, 587:20-588:3, 588:18-590:5)

Dr. Eck testified that the specification disclosed eleven other antibodies that have essentially the same sequence as 21B12. He opined that if the multiple copies of 21B12 are "binding at all, they have to be binding right where [21B12] is." (D.I. 343 at 558:12-559:1) Dr. Eck also testified that there are "on the order of thousands of different versions of . . . 21B12," and the patent does not describe any "examples of antibodies that bind centrally across the middle" of the binding region. (D.I. 345 at 1112:24-1113:19) Dr. Eck briefly described that an antibody may "contact" an amino acid without binding to the amino acid, such that 21B12 contacts the middle amino acid of the EGF-A region (the region of the LDL receptor that binds and interacts with PCSK9). (D.I. 343 at 557, 565:1-18)

Yet another of defendants' experts, Dr. Jeffrey Ravetch ("Dr. Ravetch"), testified that the antibody technology was extremely well developed and a "mature technology." The use of "transgenic mice and phage display," as well as other laboratory methods, were routine techniques. (D.I. 342 at 409:7-11, 413:3-20, 414-415) Dr. Siegel explained that the asserted claims were not limited to human antibodies, but could be mouse or camel antibodies. The structures of such non-human antibodies would be "much different" than human antibodies. (D.I. 343 at 632:20-633:12) He also explained that the asserted claims (excepting claim 29 of the '165 patent) do not specify a particular level of blocking, such that "any small amount of blocking would define an antibody that fit in the genus of antibodies." (*Id.* at 632:15-19)

Dr. Eck explained that to determine similarities of antibodies, a person of ordinary skill considers "their chemical structure, their composition, their primary amino acid sequence and their three-dimensional structure." (*Id.* at 577:21-578:4) He concluded that there are "many antibodies that will meet [the asserted] claims that have nevertheless very diverse and different three-dimensional structures and primary amino acid sequences." He could not "visualize or recognize" these based on the teachings of the specification. Further, "having the expectation that there are many antibodies that will bind [to the binding region] is different than being able to know precisely what those structures are and to be able to realize and make and use any of those structures." (*Id.* at 583:13-584:14) The specification does not offer "clear evidence" of antibodies binding to the "many ways one could have antibodies binding, covering this central region, as well, for example, as binding to the north edge, or binding to the south edge." (D.I. 345 at 1117:2-21)

Dr. Siegel explained that the claims of the patents-in-suit "are very broad" and "cover a large number of antibody structures, not limited in any way." He opined that the specification does not "provide a description of [the] invention." (D.I. 343 at 612:9-17) Moreover, the claims reciting an antibody that binds to at least one residue (for example D238), do not provide information about the structure or sequence of such antibody. (*Id.* at 630:9-12) He testified that there are no "common structural features . . . described that would make one understand . . . the structures of other antibodies." (*Id.* at 659:3-22) Dr. Siegel concluded that the two antibodies are not representative of antibodies that would bind in the middle of the binding region. (*Id.* at 650:24-651:10) He also opined that the 20 or more sequences reported in the specification are insufficient to represent the diversity of antibodies covered by the asserted claims. (*Id.* at 707:18-22)

As to the enablement requirement, Dr. Siegel testified that it would not be possible to start with the amino acid sequences listed in the specification and make "the full diversity of antibodies that are covered by the claims," because "[i]t's a very unpredictable process" and would require trial and error. (*Id.* at 662:19-663:10) He stated that the methods were known (*id.* at 664-668:9) but, in his opinion, the process would involve undue experimentation, as "there are a lot of steps involved" and there is nothing in the specification to help a researcher "hone in on an antibody that satisfies the claims." (*Id.* at 668:10-669:13) The specification has not disclosed a "quick way of doing" the research, or "taught . . . anything special." (*Id.* at 701:4-8) That the binding region is known is not useful in making the antibodies, as the antibodies must be made and tested to determine where they bind. (*Id.* at 672:22-673:20, 714:10-12) He stated that "even today,

we're talking about how immature the art is where you can't take an antigen and figure out how to make an antibody that will bind to it." (*Id.* at 695:5-9)

3. Plaintiffs' evidence

Plaintiffs' scientific director, Dr. Simon Jackson ("Dr. Jackson"), testified that the crystallography data "showed . . . the specific amino acids that were . . . binding" and "that the antibodies were binding in a small region side by side on PCSK9." (D.I. 342 at 285) Plaintiffs' expert, Dr. Gregory Petsko ("Dr. Petsko"), testified that when the antibodies bind, they cover "a footprint." (D.I. 344 at 799) Dr. Petsko disagreed with the characterization of 21B12 and 31H4 as "edge binders." He described the antibodies as "very large objects" with "a pretty big footprint on the" binding region, that "don't really hang onto the edge at all." (*Id.* at 805) He explained that the 15 residues that constitute the binding region are covered "virtually perfectly, including . . . [F]379" by 21B12 and 31H4. (*Id.* at 806) On cross-examination, Dr. Petsko was asked: "Based on the information available in the patent as of January 9, 2008, one cannot determine that any of the antibodies disclosed bind to PCSK9 in between where 21B12 and 31H4 bind; is that correct?" He explained that "when a scientist hears the word 'determined,' a scientist often thinks about doing experiments." He responded that without experiments, however, he didn't "know for sure that there are any such antibodies." (*Id.* at 862: 19-863: 15)

Dr. Petsko testified that example 11 in the patent describes the blocking data for the antibodies, i.e., the ability of the antibody to prevent the LDL receptor from binding to PCSK9. Example 3 of the patent discloses that the inventors were in possession of 85 antibodies that blocked at more than 90%. He explained that the

384 member subset blocked quite reasonably. (*Id.* at 796-797) Dr. Jackson explained that "[b]inning is a way to group antibodies . . . depending on how they bind and where they bind to the protein, in this case PCSK9." (D.I. 342 at 267) Antibodies that co-bin cannot bind "at the same time," instead they "compete against each other for binding to the site." (*Id.* at 269) The specification uses 21B12 as a representative antibody for bin 1 and 31BH4 for bin 3. (D.I. 344 at 270) Dr. Petsko testified that "binning experiments . . . tell you whether antibodies have overlapping footprints on the surface of PCSK9." (*Id.* at 798:15-17) He explained that bin 1 (containing seventeen antibodies) and bin 3 (containing seven antibodies) "represent the collection of antibodies that co-bin with 21B12 and the collection that co-bin with 31H4," respectively.[7] (*Id.* at 798-802)

Chadwick King ("King"), one of the named inventors on the patents-in-suit, testified that the screening process used in the patent allowed plaintiffs to "identify . . . antibodies that are highly active, have a function of interest, but also have sequence diversity." Sequence diversity helps ensure that there are "enough molecules [so] that one of them can potentially make it through the later stage steps of drug development . . . [and] testing." He opined that the panel of thirty antibodies "had nice sequence diversity" and "cover[ed] multiple epitopes." He concluded that "comparisons of [the] antibody sequences to the germline consensus region" resulted in "good diversity in germline usage." (D.I. 343 at 744-746)

According to Dr. Petsko, 21B12 and 31H4 are sufficiently representative of the asserted claims, as they

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[7] Dr. Siegel answered a short series of questions regarding co-binning on cross examination, and conceded that the "epitopes would overlap if [the antibodies] co-bin." (D.I. 343 at 688:14-691:25)

provide "all the information" needed "to define the part of PCSK9 where the antibodies need to bind in order to block." (D.I. 344 at 806-807, 811) He described generally how an antibody comes together with PCSK9 and that there are different types of chemical interactions possible with an amino acid (for example D238). (*Id.* at 808-809) Dr. Petsko agreed that antibodies could have different kinds of chemical interactions with a particular residue, but disagreed with the characterization that such differences result in a significant difference in structure. (*Id.* at 808:24-809:23) Using S153 as an example, Dr. Petsko described "the noncovalent interaction that contributes to the affinity of the antibody for PCSK9." (*Id.* at 815-16) He reasoned that 21B12 binds to S153, R194, R237, D238, D374, T377, and F379 and, therefore, falls within the scope of claims 2, 7, 19, and 29 of the '165 patent and claim 7 of the '741 patent. 31H4 binds to D374 and V380, with a possibility of binding to S381 and, therefore, falls within the scope of claims 15, 19, and 29 of the '165 patent.[8] (*Id.* at 817)

Dr. Petsko explained that using the binning and blocking data, it is "more likely than not that one or more of those [antibodies] are going to make interactions with the residues" of the binding region. He identified which of the co-binned antibodies identified in the patent would "more likely than not" meet the claim limitations of claims 19 and 29 of the '165 patent. (*Id.* at 818-21, 824-25, 827) He opined that although the specification does not disclose "a crystal structure [for] an antibody that binds to I369," the inventors were in possession of such an antibody, because the patent discloses a list of "strong

[8] Dr. Eck disagreed with the detail of Dr. Petsko's analysis (but can "understand where he's coming from") that 21B12 and 31H4 interact with D374. (D.I. 345 at 1120:5-10)

blockers," which would contain antibodies that are likely to bind I369. (*Id.* at 830-32) In other words, the "inventors are in possession of a large number of antibodies and we've described two that cover quite a bit of the [binding region], and we've also indicated the likely presence of antibodies that will interact with even more residues in the [binding region]." (*Id.* at 831-32)

Dr. Petsko testified that, although one could not sit at a desk and write out all the sequences, a scientist would use the information provided to find antibodies that bind to the binding region on PCSK9. (*Id.* at 836:5-837:14) The specification provided sufficient information to conclude that 21B12 and 31H4 are representative. (*Id.* at 818-819) On cross-examination, Dr. Petsko agreed that there could be "many antibodies that recognize the same epitope," and the specification does not provide "the formula" for all of them, but added that "nobody could do that." (*Id.* at 869:14-23) He also conceded that whether an antibody would bind with a particular residue is "not certain at all" from co-binning data. (*Id.* at 880-881, see also D.I. 343 at 594:23-595:6, 600:22-601:3) Dr. Jackson concluded that using the X-ray crystallography of 21B12 and 31H4 and the binning data, plaintiffs "knew that the other antibodies were binding in" the binding region. (D.I. 342 at 291-292)

Another of plaintiffs' experts, Dr. Anthony Rees ("Dr. Rees"), also described using binning data to make antibodies and screening them against 21B12 to see if they compete. (D.I. 344 at 917-18) He testified that, from a scientific perspective, making additional antibodies did not require undue experimentation. With "a particular series of steps . . . to follow," it is "routine experimentation with some surprises along the way, but which [a person of ordinary skill] can solve in routine ways." (*Id.* at

920) He evaluated the diversity of the patent's antibodies and concluded that the sequences, which lead to differences in protein sequence and structure, result in "seven different families." He reasoned that this was "quite an extensive diversity." (*Id.* at 923-26) He concluded that a skilled person in the art "would understand that [plaintiffs'] antibodies are representative of the" antibodies of claim 19, based on the disclosure of "detailed three-dimensional structure" of 21B12 and 31H4, and the twenty-two "other antibodies that are disclosed with respect to their competition or their binning behavior." (*Id.* at 937:17-938:6)

As to a structure-function relationship, Dr. Petsko opined that antibodies can bind through "noncovalent interactions," which "hold them together more often than not." (*Id.* at 791-92) He explained that a "different amino acid sequence might approach a particular residue from a different direction . . . to make a noncovalent interaction with the residue," but this does not affect the structure-function relationship. (*Id.* at 838-40) Dr. Petsko concluded that the specification describes a structure-function relationship by "describing structure characteristics that the antibodies in the genus have in order to carry out the function of binding to PCSK9, blocking the binding of the LDL receptor." More specifically, the "structure function relationship is binding to specific residues on the" binding region. (*Id.* at 783:25-784:19) The specification provides a person of skill in the art the ability to visualize and recognize antibodies falling within the claims based on crystal structures and binning experiments. (*Id.* at 836:22-837:23)

Dr. Rees opined that when an antibody binds to PCSK9, it takes on a unique structure and precisely fits together. So "all the antibodies . . . that bind to this re-

gion must share structural features . . . that allow them to get the shape fitting that is required." (*Id.* at 908:10-24, 902:22-903:14, 905:23-906:10) For example, two different amino acid sequences, which bind to the antigen region from influenza may have a different structure, but still share the structural feature of binding to the region. (*Id.* at 910:13-911:18) The "antibodies that fall within the scope of the claims have common structural features." These structural features lead "to the functions of binding and blocking" in order to block the binding of PCSK9 to its LDL receptor. "[T]he consequence of that is there must be a correlation between structure and function." (*Id.* at 912:8-22) On cross-examination, Dr. Rees agreed that the amino acid sequences defined the antibody and the detailed interactions of the amino acids lead to the folded structure. (*Id.* at 986:9-24)

As to the well characterized antigen test, Dr. Petsko testified that he used the term antigen to describe the binding region (part of PCSK9) and that the binding region could be considered a "newly characterized antibody." Dr. Petsko explained how to design more antibodies from the disclosures in the patent—by using 21B12 as a reference, performing binning experiments, testing to see whether the antibodies block the binding to the LDL receptor, and then using developed techniques to screen the antibodies. (*Id.* at 834:17-836:4, 871:10-20; see also 915:13-922:24, 937:11-16)

As to enablement, Dr. Rees testified that the state of antibody and engineering sciences is "mature and well established," with well-known methods for creating antibodies, such as those described in the specification. In his opinion, the scope of the claims "is pretty narrow," as they describe "antibodies that bind to a rather small region on the surface of PCSK9." He opined that the speci-

fication is a "comprehensive roadmap to how to make . . . [the] antibodies." (*Id.* at 940-41; see also D.I. 342 at 401:23-402:7, 417:10-21) He explained that a researcher does not use the binding region to make the antibodies, but the specification teaches "how to analyze for antibodies that bind to" it. (D.I. 344 at 942) Dr. Rees explained that other types of antibodies are well known, including mouse monoclonal antibodies, rat antibodies, and camel antibodies. Moreover, those types of antibodies, as well as fragments, may be made using the information in the specification and routine methods known in the art. (*Id.* at 942-43) On cross-examination, Dr. Rees agreed that the examples of the specification did not describe mouse or camel antibodies. (*Id.* at 981:21-982:12) As to the degree of blocking, Dr. Petsko opined that if an antibody bound to one of the residues, it would be likely that "the big molecule" (with a "pretty big footprint") would cause some blocking. Moreover, the patent disclosed certain "low blocking" antibodies. (*Id.* at 840:5-25) Dr. Petsko agreed that a small amount of blocking would suffice to meet the requirements of certain of the asserted claims. (*Id.* at 870: 11-24)

D. Analysis

The jury was asked to consider whether defendants presented clear and convincing evidence that the asserted claims of the patents-in-suit lacked written description and enablement. The court instructed the jury that the specification could disclose either "a representative number [of] species falling within the scope of the claimed invention," or "structural features common to the members of the genus, so that a person of ordinary skill in the art can 'visualize or recognize' the members of the claimed invention." The jury was also instructed that "[i]n the case of a claim to antibodies, the correlation between

structure and function may also be satisfied by the disclosure of a newly-characterized antigen by its structure, formula, chemical name, or physical properties if" the creation of such "antibodies against such an antigen was conventional or routine." (D.I. 299 at 24-25)

The parties and their experts largely agreed on what the specification discloses—a screening process used to select 384 antibodies, which blocked PCSK9 "well" for further testing; a certain subset of antibodies that blocked PCSK9 at over 90%; two antibodies (21B12 and 31H4), which underwent X-ray crystallography analysis; a binding region on PCSK9 of fifteen residues that is the target of such antibodies. The parties' experts also agreed that the art discloses the research techniques necessary to perform antibody development and screening.

The parties' experts analyzed the specification's disclosures and formulated conclusions. Defendants' experts focused on the "middle" portion of the binding region and concluded that insufficient data and examples were disclosed in the specification. Plaintiffs' experts argued the opposite, that is, the examples and disclosures in the patent sufficiently described two antibodies which bind to a large portion of the binding region. An antibody that would bind to the part of the binding region that is not specifically bound by 21B12 and 31H4 is logically within reach using the disclosures of the specification (including the blocking and binning data).

The jury is the finder of fact and is tasked with weighing the evidence and credibility of the witnesses. The parties' experts provided the jury with competing testimony on the interpretation of the data available in the specification. The jury concluded that the asserted claims were not invalid for lack of written description or

enablement. Defendants' post-trial arguments essentially ask the court to reevaluate the experts' testimony and reach the opposite conclusion. For example, defendants argue that the two antibodies (21B12 and 31H4) are "plainly insufficient" to represent the genus, and the twenty-two other antibodies that "bin" with 21B12 and 31H4 are not value added as "binning does not allow a person of ordinary skill in the art to determine with any certainty what amino acid an antibody binds to." According to defendants, their experts testified that "nothing disclosed in the [specification] allowed one to visualize or recognize the structures of the claimed antibodies and to distinguish the claimed antibodies from others." According to defendants, plaintiffs' experts "gave purely conclusory testimony" that the specifications did allow such visualization or recognition. (D.I. 367 at 7, 15)

On the record at bar, plaintiffs' experts provided more than conclusory testimony in order to explain their respective conclusions to the jury. The jury credited such testimony over that of defendants' experts. The court declines to re-weigh the evidence or the credibility of the experts. Viewing the record in the light most favorable to plaintiffs, substantial evidence supports the jury's verdict.[9, 10] For these reasons, defendants' renewed motion for JMOL is denied.

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[9] Defendants argue that *Regents of the Univ. of California* v. *Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), requires a finding that the disclosure is insufficient to meet the representative species test. However, the procedural posture of that case, as well as the facts, are different. Reviewing the district court's findings following a bench trial, the Federal Circuit held that the written description requirement was not met. It reasoned in part that the specification disclosed "only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B

In the alternative, defendants requested a new trial should the court deny the renewed motion for JMOL on written description and enablement. Defendants' request is premised on the same arguments as its renewed motion for JMOL. Defendants again ask the court to "substitute its own judgment of the facts and the credibility of the witnesses," and reach the opposite conclusion as the jury. For the reasons discussed above, the jury's verdict is not against the clear weight of the evidence, therefore, the court denies defendants' request for a new trial.

V. RECONSIDERATION

In their motion for a new trial, defendants argue that the erroneous exclusion of post-January 2008 evidence substantially prejudiced their defenses of lack of written description and enablement; the jury was erroneously instructed on the test for written description (with respect to the court's "well-characterized antigen" instruction); and the court's grant of JMOL as to obviousness was based on an erroneous interpretation and misapplication of *Dynamic Drinkware* v. *National Graphics*, 800 F.3d 1375 (Fed. Cir. 2015). While filed as part of a motion for a new trial, defendants essentially request reconsideration of each of the above issues.

A motion for reconsideration is the "functional equivalent" of a motion to alter or amend judgment under Federal Rule of Civil Procedure 59(e). See *Jones* v. *Pitts-*

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chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin." *Id.* at 1567.

[10] The jury's verdict is supported by the evidence on the "representative number of species" or "common structural features" tests, therefore, whether the jury credited the evidence on the "well-characterized antigen" test is not dispositive.

burgh Nat'l Corp., 899 F.2d 1350, 1352 (3d Cir. 1990) (citing *Fed. Kemper Ins. Co.* v. *Rauscher*, 807 F.2d 345, 348 (3d Cir. 1986)). The standard for obtaining relief under Rule 59(e) is difficult to meet. The purpose of a motion for reconsideration is to "correct manifest errors of law or fact or to present newly discovered evidence." *Max's Seafood Cafe ex rel. Lou-Ann, Inc.* v. *Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999). A court should exercise its discretion to alter or amend its judgment only if the movant demonstrates one of the following: (1) a change in the controlling law; (2) a need to correct a clear error of law or fact or to prevent manifest injustice; or (3) availability of new evidence not available when the judgment was granted. See *id.* A motion for reconsideration is not properly grounded on a request that a court rethink a decision already made and may not be used "as a means to argue new facts or issues that inexcusably were not presented to the court in the matter previously decided." *Brambles USA, Inc.* v. *Blocker*, 735 F. Supp. 1239, 1240 (D. Del. 1990); see also *Glendon Energy Co.* v. *Borough of Glendon*, 836 F. Supp. 1109, 1122 (E.D. Pa. 1993). It goes without saying, therefore, that a motion under Rule 59(e) that advances the same arguments already thought through and rejected by the court—rightly or wrongly—should be denied. See, *e.g.*, *Lazaridis* v. *Wehmer*, 591 F.3d 666, 669 (3d Cir. 2010); *Savage* v. *Bonavitacola*, 2005 WL 730679 (E.D. Pa. Mar. 29, 2005), at *1 (citing *Glendon Energy Co.* v. *Boroough of Glendon*, 836 F. Supp. 1109, 1122 (E.D. Pa. 1993)); *Brambles USA, Inc.* v. *Blocker*, 735 F. Supp. 1239, 1240 (D. Del. 1990).

As to the exclusion of post-January 2008 evidence, the complexity of the matter mandated that the court draw lines and stick to them. (D.I. 345 at 1076:6-1077:25) The court entertained both argument and briefing on this

dispute, and issued written orders in support of its decision. (D.I. 226, 249) As to the inclusion of the "well-characterized antigen" jury instruction (D.I. 299 at 25), again the parties were provided opportunity to present argument and briefing, which the court considered. (D.I. 291; D.I. 344 at 1063:5-1065:21) As to the courts' grant of JMOL on obviousness, the court fully considered defendants' arguments as to the applicability of the *Drinkware* case, both before and during trial. (D.I. 250, 282; D.I. 345 at 1076:21-1077:6, 1089:14-17) While defendants disagree with the court's decisions and request that it rethink them, the court declines to do so. The court did not arrive at any of these decisions lightly; indeed, it considered fulsome arguments and briefing. Defendants' request for reconsideration of these issues is denied, as is the motion for a new trial.

For the foregoing reasons, the court denies defendants' motions for a new trial and judgment as a matter of law on written description and enablement (D.I. 331, 332); and denies as moot plaintiffs' motion to strike the opening brief in support of defendants' motion for judgment as a matter of law (D.I. 338). An appropriate order shall issue.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CIV. NO. 14-1317-SLR
(CONSOLIDATED)

AMGEN INC., AMGEN MANUFACTURING, LIMITED; AND AMGEN USA, INC.,

Plaintiffs,

v.

SANOFI; SANOFI-AVENTIS U.S. LLC; AVENTISUB LLC f/d/b/a AVENTIS PHARMACEUTICALS INC.; AND REGENERON PHARMACEUTICALS, INC.,

Defendants.

Final Judgment Following Post Trial Motion Practice Pursuant to Fed. R. Civ. P. 54(b)

For reasons stated in the court's memorandum opinion and order of January 3, 2017;

IT IS ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of plaintiffs Amgen, Inc., Amgen Manufacturing, Limited and Amgen USA Inc. and against defendants Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, and Regeneron Pharmaceuticals, Inc.

/s/ Sue L. Robinson
United States District Judge

Dated: 1/3/2017

/s/ Nicole Nolt
(By) Deputy Clerk

APPENDIX D

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CIV. NO. 14-1317-SLR
(CONSOLIDATED)

AMGEN INC., *ET AL.*,
Plaintiffs,

v.

SANOFI, *ET AL.*,
Defendants.

MEMORANDUM ORDER

At Wilmington this 18th day of February, 2016, having reviewed the various papers submitted by the parties in connection with their pretrial evidentiary issues;

IT IS ORDERED that:

1. **The UTSW PCSK9 handout** is excluded as being disclosed untimely. In this regard, it would take further discovery to flesh out whether it is prior art, as the facial indicia of such is not sufficient to pass muster. If not prior art, the handout is cumulative and likely to lead to mischief if admitted to demonstrate the state of the art.

2. ***Daubert* motions: standard of review.** A qualified expert may testify in the form of an opinion if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods,

and (3) the witness has applied the principles and methods reliably to the facts of the case.[1] Fed. R. Evid. 702. As summarized by the Third Circuit in *Elcock* v. *Kmart Corp.*, 233 F.3d 734 (3d Cir. 2000), "Rule 702 embodies three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit." *Id.* at 741. The burden of persuading the judge to allow the expert to testify is on the party tendering the expert, and is by a preponderance of the evidence. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743-45 (3d Cir. 1994). As noted by the Supreme Court, "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumbo Tire Co.* v. *Carmichael*, 526 U.S. 137, 152 (1999).

3. **Cross *Daubert* motions regarding post-priority date evidence.** Both parties have filed *Daubert* motions to exclude post-priority date evidence. Plaintiffs' motion seeks to exclude expert testimony regarding the structure of post-priority date antibodies that were not disclosed in the selected patents. (D.I. 191) Defendants' motion seeks to exclude expert testimony that relies on later-developed evidence to demonstrate the structure of the disclosed antibodies. (D.I. 185) Although characterized differently, both motions relate to defendants' written description defense.

4. In this case, the patent claims[2] asserted against defendants are directed to genuses of antibodies. Claim 1 of the '165 patent, for example, recites:

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[1] Of course, an expert must be qualified as well, an issue not in dispute presently.

[2] Selected claims of U.S. Patent Nos. 8,829,165 ("the '165 patent"), 8,859,741 ("the '741 patent"), and 8,871,914 ("the '914 patent").

> 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S81 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.

Defendants argue that such claims as that recited above are invalid for lack of written description pursuant to 35 U.S.C. § 112, ¶ 1 because: (1) the claimed antibodies are defined by their function, not by their structure; (2) although the patents identify representative examples of the antibodies encompassed by the asserted claims, the examples are identified only by their amino acid sequences, not by their structure; (3) information about their structure is necessary to determine where these antibodies bind to PCSK9; (4) the only structural information provided by plaintiffs is comprised of post-priority date x-ray crystallography analysis. Plaintiffs respond in kind as follows: (1) the claims "clearly recite several structural features;" (2) the structure of the selected antibodies is an "inherent property" of where they bind to PCSK9; (3) "inherently disclosed properties" are deemed present in the specification. (D.I. 202 at 1, 3)

4. To satisfy the written description requirement, "the applicant must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate that by disclosure in the specification of the patent." *Carnegie Mellon Univ.* v. *Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) (citation omitted); see also *Centocor Ortho Biotech, Inc.* v. *Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011). "[T]he hallmark of written description is disclosure," and "the level

of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad Pharm., Inc.* v. *Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). A written description of an invention involving a chemical genus "requires a precise definition, such as by structure, formula, [or] chemical name" of the claimed subject matter sufficient to distinguish it from other materials. *Regents of Univ. of Cal.* v. *Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Support for a genus claim requires either a "representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350; *Regents*, 119 F.3d at 1568. "[A]n applicant can claim an antibody to novel protein X without describing the antibody when (1) the applicant fully discloses the novel protein and (2) generating the claimed antibody is so routine that possessing the protein places the applicant in possession of an antibody." *Centocor*, 636 F.3d at 1351-52. Because "each patented advance has a novel relationship with the state of the art from which it emerges," the written description inquiry "is a question of fact" with the law being "applied to each invention at the time it enters the patent process." *Ariad*, 598 F.3d at 1351. As explained by the Federal Circuit in *Ariad*, "requiring a written description of the invention limits patent protection to those who actually perform the difficult work of 'invention'—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public." *Id.* at 1353.

5. The case law cited above gives broad leeway to the court in terms of admitting evidence that illuminates the state of the art **at the time of filing** in order to determine whether there is sufficient disclosure of the claimed invention, in this case, a genus. Given the complexity of the technology at issue and the "considerable leeway" I have as a judge to determine whether an expert's knowledge will help the jury understand the evidence and determine issues of fact, I conclude that the clearest, most consistent result is to grant both motions and preclude the use of any such evidence in connection with the issue of written description.

6. ***Daubert* motions relating to damages.** As per the normal course of events, both plaintiffs and defendants accuse the opposing experts of basing their economic analyses on inappropriate data. Both experts agree that there are no comparable bare license agreements. In order to base their respective opinions on some modicum of real-world data, plaintiffs' expert resorted to using distributor fees as relevant comparables and defendants' expert resorted to using collaboration agreements and cross-license agreements as relevant comparables. With the exception of the Dezima acquisition agreement and the Genentech/Regenron settlement agreement,[3] I am satisfied that the experts have adequately explained in their reports the relevance of their respective data vis a vis the various *Georgia-Pacific* factors.[4] Therefore, de-

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[3] Identified by Dr. Stevens. I will preclude these business arrangements as being too far afield from a bare patent license to be relevant comparables.

[4] Including those factors relating to the parties' licensing practices and the fact that plaintiff "does not out-license its patent rights to a competitor where the technology covered by the patent rights is technology that Amgen itself intents to commercialize in the same

fendants' motion as to the reasonable royalty opinions of Dr. Meyer (D.I. 185) is denied, and plaintiffs' motion to exclude the expert testimony of Dr. Stevens (D.I. 187) is granted in part and denied in part.

/s/ Sue L. Robinson
United States District Judge

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geographic area and for the same therapeutic use." (D.I. 188, ex. 4, ¶ 146)

APPENDIX E

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CIV. NO. 14-1317-SLR
(CONSOLIDATED)

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

Plaintiffs,

v.

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

Defendants.

MEMORANDUM ORDER

At Wilmington this 2nd day of March, 2016, having heard argument on the motion for reargument filed by defendants, and having reviewed the papers filed in connection therewith;

IT IS ORDERED that said motion (D.I. 231) is granted to the extent I have entertained further argument on the issues presented, but denied as to its substantive request, for the reasons that follow:

1. I issued a memorandum order on February 18, 2016 that addressed various pretrial evidentiary issues in the above captioned litigation, including whether evidence regarding the structure of antibodies that did not exist at

the time of filing (and, therefore, were not disclosed in the patents-in-suit) should be excluded for purposes of defendants' written description defense. I concluded that, because the written description requirement is tested as of the filing date, such evidence should be excluded. Defendants contend that my decision is contrary to the law, particularly, the Federal Circuit's reasoning in *AbbVie Deutschland GmbH & Co., KG* v. *Janssen Biotech, Inc. and Centocor Biologics, LLC*, 759 F.3d 1285 (Fed. Cir. 2014). The Court in *AbbVie* upheld a jury's finding of invalidity of genus claims that were functionally defined based on lack of written description. The Court reasoned that

> [w]hen a patent claims a genus using functional language to define a desired result, "the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented a species sufficient to support a claim to the functionally defined genus." . . . We have 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 so that one of skill in the art can 'visualize or recognize' the members of the genus."

Id. at 1299 (citations omitted). The question presented was whether the patents at issue described representative species to support the entire genus. Without apparent objection, defendant "presented expert testimony that the antibodies described in the patents were structurally similar, but that they differed from [the accused

antibody] in many respects." *Id.* at 1293. According to the Federal Circuit,

> the jury heard ample evidence that AbbVie's patents only describe one type of structurally similar antibodies and that those antibodies are not representative of the full variety or scope of the genus .... [More specifically, the accused antibody] differs considerably from the Joe-9 antibodies described in AbbVie's patents. . . . Centocor's expert testified that antibodies with 80% sequence similarity to J695 could bind to completely different antigens, . . [.] thus illustrating the significant structural differences between [the accused antibody] and the Joe-9 antibodies and the unpredictability of the field of invention. Centocor also presented evidence of other differences between [the accused antibody] and the Joe-9 antibodies, such as CDR length and epitope binding site.

Id. at 1300. The Court concluded that there was "no evidence to show any described antibody to be structurally similar to, and thus representative of [the accused antibody]. There is also no evidence to show whether one of skill in the art could make predictable changes to the described antibodies to arrive at other types of antibodies such as [the accused antibody]." *Id.* at 1301.

2. By giving its imprimatur to the jury's verdict, the Federal Circuit arguably departed from its own precedent, established in *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977), that later-developed or later-discovered products

should not be used to test compliance with 35 U.S.C. § 112.[1] In this regard, the Court in *Hogan* reasoned that,

> to now say that appellants should have disclosed in 1953 the amorphous form which on this record did not exist until 1962, would be to impose an impossible burden on inventors and thus on the patent system . . . .
>
> The business of the PTO is patentability, not infringement. . . . The courts have consistently considered subsequently existing states of the art as raising question of infringement, **but never of validity.**

Id. at 607 (emphasis added). See also *United States Steel Corp.* v. *Phillips Petroleum Co.*, 865 F.2d 1247 (Fed. Cir. 1989); *Schering Corp.* v. *Amgen, Inc.*, 222 F.3d 1347 (Fed. Cir. 2000); *Amgen, Inc.* v. *Hoechst Marion Roussel Inc.*, 314 F.3d 1313 (Fed. Cir. 2003); *Scripps Clinic & Research Foundation* v. *Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991); *Chiron Corp.* v. *Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004); *Biogen Idec, Inc. & Genentech, Inc.* v. *Glaxo Smith Kline LLC*, 713 F.3d 1090 (Fed.

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[1] It is important to keep in mind that the district judge in the *AbbVie* case had consolidated an infringement action filed by AbbVie with an appeal by Centocor from an interference proceeding in which AbbVie's [6,914,128] patent was awarded priority over Centocor's patent application covering the accused antibody. In other words, it may not be surprising that the *AbbVie* record does not contain the kind of evidentiary issues that have arisen instantly, and that the Federal Circuit simply decided the issues presented—on the record presented—without attending to the more significant question of whether it is ever or always appropriate to use post-priority evidence of an embodiment that was not known or even in existence at the time of filing to invalidate a patent based on lack of written description support.

Cir. 2013). See also Goldstein, Jorge, "*AbbVie Deutschland* and Unknown Embodiments: Has the Written Description Requirement for Anitbodies Gone Too Far?," 9 LSLR 399 (Bloomberg BNA, Apr. 3, 2015). This leaves me between a rock—the written description requirement has always been anchored in the state of the art at the time of filing—and a hard place—*AbbVie* arguably has imposed the "impossible burden"[2] on inventors to "at least describe some species representative of antibodies that are structurally similar to" unknown future embodiments. *AbbVie*, 759 F.3d at 1301.

3. Without a specific recognition by the Court in *AbbVie* that it was so dramatically changing the law on written description, I choose to interpret it narrowly and limit it to its unusual facts and procedural posture. Therefore, while I appreciate the arguments made by defendants, I decline to change my ruling precluding the admission of any post-priority date evidence on written description.[3]

/s/ Sue L. Robinson
United States District Judge

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[2] *Hogan*, 559 F.2d at 606.

[3] I note in closing that this significant issue was not addressed during claim construction or in the context of infringement which, absent the dramatic change in perspective arguably foretold by the *AbbVie* decision, would be the most sensible way of addressing broad genus claims and future embodiments not foretold and described in the specification.

APPENDIX F

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,

2017-1480

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.

ON PETITION FOR REHEARING EN BANC

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

PER CURIAM.

ORDER

Appellees 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 appellants Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., Sanofi-Aventis U.S., LLC. 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:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on March 2, 2018.

FOR THE COURT

February 23, 2018
Date

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

APPENDIX G

RELEVANT STATUTORY PROVISIONS

1. The Patent Act, 35 U.S.C. § 1 *et seq.*, provides in relevant part:

§ 112. Specification

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

2. Section 2 of the Act of April 10, 1790, 1 Stat. 109, 110-111, ch. 7, provided:

Sec. 2. *And be it further enacted*, That the grantee or grantees of each patent shall, at the time of granting the same, deliver to the Secretary of State a specification in writing, containing a description, accompanied with drafts or models, and explanations and models (if the nature of the invention or discovery will admit of a model) of the thing or things, by him or them invented or discovered, and described as aforesaid, in the said patents; which specification shall be so particular, and said models so exact, as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art or manufacture, whereof it is a branch, or wherewith it may be nearest connected, to make, construct, or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term; which specification shall be filed in the office of the said Secretary, and certified copies thereof, shall be competent evidence in all courts and before all jurisdictions, where any matter or thing, touching or concerning such patent, right, or privilege, shall come in question.

3. Section 3 of the Act of February 21, 1793, 1 Stat. 318, 321-322, ch. 11, provided:

Sec. 3. *And it be further enacted*, That every inventor, before he can receive a patent, shall swear or affirm, that he does verily believe, that he is the true inventor or discoverer of the art, machine, or improvement, for which he solicits a patent, which oath or affirmation may be made before any person authorized to administer oaths, and shall deliver a written description of this invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same. And in the case of any machine, he shall fully explain the principle, and the several modes in which he has contemplated the application of that principle or character, by which it may be distinguished from other inventions; and he shall accompany the whole with drawings and written references, where the nature of the case admits of drawings, or with specimens of the ingredients, and of the composition of matter, sufficient in quantity for the purpose of experiment, where the invention is of a composition of matter; which description, signed by himself and attested by two witnesses, shall be filed in the office of the Secretary of State, and certified copies thereof shall be competent evidence, in all courts, where any matter or thing, touching such patent-right, shall come in question. And such inventor shall, moreover, deliver a model of his machine, provided, the secretary shall deem such model to be necessary.

4. Section 6 of the Act of July 4, 1836, 5 Stat. 117, 119, ch. 357, provided:

Sec. 6. *And be it further enacted*, That any person or persons having discovered or invented any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter, not known or used by others before his or their discovery or invention thereof, and not, at the time of his application for a patent, in public use or on sale, with his consent or allowance, as the inventor or discoverer; and shall desire to obtain an exclusive property therein, may make application in writing to the Commissioner of Patents, expressing such desire, and the Commissioner, on due proceedings had, may grant a patent therefor. But before any inventor shall receive a patent for any such new invention or discovery, he shall deliver a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same; and in case of any machine, he shall fully explain the principle and the several modes in which he has contemplated the application of that principle or character by which it may be distinguished from other inventions; and shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery. He shall, furthermore, accompany the whole with a drawing, or drawings, and written references, where the nature of the case admits of drawings, or specimens of ingredients, and of the composition of matter, sufficient in quantity for the purpose of exper-

iment, where the invention or discovery is of a composition of matter; which descriptions and drawings, signed by the inventor and attested by two witnesses, shall be filed in the Patent Office; and he shall moreover furnish a model of his invention, in all cases which admit of a representation by model, of a convenient size to exhibit advantageously its several parts. The applicant shall also make oath or affirmation that he does verily believe that he is the original and first inventor or discoverer of the art, machine, composition, or improvement, for which he solicits a patent, and that he does not know or believe that the same was ever before known or used; and also of what country he is a citizen; which oath or affirmation may be made before any person authorized by law to administer oaths.

5. Section 26 of the Act of July 8, 1870, 16 Stat. 198, 201, ch. 230, provided:

Sec. 26. *And be it further enacted*, That before any inventor or discoverer shall receive a patent for his invention or discovery, he shall make application therefor, in writing, to the commissioner, and shall file in the patent office a written description of the same, and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same; and in case of a machine, he shall explain the principle thereof, and the best mode in which he has contemplated applying that principle so as to distinguish it from other inventions; and he shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery; and said specification and claim shall be signed by the inventor and attested by two witnesses.