No. 17-1480

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellees

v.

SANOFI; SANOFI-AVENTIS U.S. LLC; AVENTISUB LLC, F/D/B/A AVENTIS PHARMACEUTICALS INC.; AND REGENERON PHARMACEUTICALS, INC.,

Defendants-Appellants

On Appeal from the United States District Court
for the District of Delaware
No. 14-CV-1317-SLR

AMGEN'S PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Appellees Amgen Inc.; Amgen Manufacturing, Limited; and Amgen USA, Inc. certifies the following:

1. The full names of the parties represented by me are Amgen Inc.; Amgen Manufacturing, Limited; and Amgen USA, Inc.

2. The names of the real parties in interest are Amgen Inc.; Amgen Manufacturing, Limited; and Amgen USA, Inc.

3. Amgen Inc. owns 10 percent or more of the stock of Amgen Manufacturing, Limited and Amgen USA, Inc. No publicly held company owns 10 percent or more of Amgen Inc.

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

   YOUNG CONAWAY STARGATT & TAYLOR: James L. Higgins

   McDERMOTT WILL & EMERY LLP: Michael V. O'Shaughnessy; Mandy H. Kim; Lauren Martin; Rebecca Harker Duttry; Bhanu K. Sadasivan

   KING & SPALDING LLP: Hon. Adam M. Conrad (no longer with the firm)

5. I am not aware of a case pending in this Court or another court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal.

December 6, 2017

/s/ Daryl L. Joseffer
Daryl L. Joseffer

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to at least the following precedents of this Court: *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011); *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002); *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247 (Fed. Cir. 1989); *In re Koller*, 613 F.2d 819 (C.C.P.A. 1980); *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977).

December 6, 2017

/s/ Daryl L. Joseffer
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PETITION FOR REHEARING EN BANC

The patent system cannot promote progress if the rules governing patentability are a moving target. In remanding a jury verdict of no invalidity, the panel decision here dispensed with decades of precedent that this Court has repeatedly applied; that the PTO incorporated into its written guidance long ago; and that innovators have relied on to obtain and defend the right to their inventions. If the panel decision stands, the consequences will be dramatic, particularly for groundbreaking biologic medicines needed to treat patients with serious and otherwise potentially fatal diseases.

First, the panel decision abrogates a critical legal standard implementing the Court's written-description requirement. For over 15 years, this Court has recognized that written description can be satisfied through the "newly-characterized antigen" test. For longer still, the PTO has directed patent examiners to use that test. While the panel acknowledged this Court's precedents, it dismissed them as "dictum." But the cases apply the test as the *ratio decidendi*. That is the opposite of dictum. If innovators, the PTO, patent prosecutors, and lower courts cannot rely on those precedential rulings, there is little

they can rely upon. The patent system can provide incentives to invest billions of dollars in new cures only if it is stable. The panel decision destabilizes not only written-description law, but also what it means to be "precedent."

Second, the panel decision upends four decades of precedent holding post-priority-date embodiments irrelevant to patent validity. Written description and enablement—just like novelty and obviousness—are judged as of the priority date. This Court therefore has precluded efforts to meet (or defeat) written description and enablement through evidence of embodiments discovered after the priority date. "[A]nalysis using later-filed references to determine the scope of enablement" or "description" is "impermissible." *In re Koller*, 613 F.2d 819, 825 (C.C.P.A. 1980). The panel in this case held the opposite: Later-created embodiments, it ruled, are relevant to whether the patentee met the Court's written-description requirement by disclosing representative species.

That ruling portends dire consequences for antibody innovation and for PTO examinations alike. If embodiments developed after the priority date bear on validity, patent prosecutors will need to disclose

them continually as they are discovered—on pain of inequitable-conduct claims. Because examiners will need to reconsider in light of each new embodiment, they "could never safely call a halt and pass an application to issue." *In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977). And subjecting genus claims to continual challenges based on later-arising embodiments threatens the value of antibody claims generally. No one can identify and disclose every future embodiment of an antibody (much less in a written description that is "concise," per §112).

Here, Amgen spent $2 billion to develop and bring to market pioneering therapeutic antibodies that lower cholesterol levels by blocking PCSK9 from interfering with the body's cholesterol receptors. Amgen discovered PCSK9's "sweet spot," a narrow area where antibodies must bind to block receptor-PCSK9 interaction. The patents describe the generation of hundreds of antibodies that bind the sweet spot and block PCSK9 strongly. The patents provide amino-acid sequences for 24 claimed antibodies with "quite extensive diversity," along with a comprehensive roadmap to make more. The panel's opinion would allow infringers to make antibodies *using Amgen's disclosures* and then use those later-developed embodiments to attack

the written description of Amgen's patents. Companies cannot invest the enormous resources and time needed to pursue difficult targets like PCSK9 if that is the reward for success. Breakthrough inventions deserve meaningful claim scope and shouldn't be undone by later embodiments falling within that scope.

Not long ago, this Court went en banc in *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010), to decide whether the Patent Act even has a written-description requirement separate from enablement (a decision from which neither party sought Supreme Court review). The panel decision destabilizes that once-modest requirement and converts it into an unnecessary impediment to innovation. En banc review is warranted.

I. The Panel's Abrogation Of The "Newly-Characterized Antigen" Test For Written Description Warrants En Banc Review.

The Supreme Court has emphasized that, when it comes to "property (patents)[,] … considerations favoring stare decisis are 'at their acme.'" *Kimble v. Marvel Comics Entm't, LLC*, 135 S. Ct. 2401, 2410 (2015). The panel decision in this case goes the opposite direction, dismissing 15 years of precedent as mere "dictum."

A. The Panel Decision Creates An Intra-Circuit Conflict.

This Court recognized the "newly characterized antigen" test in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002). Under that test, written description for "an antibody to [a] novel protein" is satisfied "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 Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1351-52 (Fed. Cir. 2011).

1. The Court has applied the newly-characterized-antigen test in case after case:

- *Enzo* "adopt[ed]" the newly-characterized-antigen test after being "persuaded" by PTO guidance "on this point." 323 F.3d at 964. Applying that test, the Court vacated a finding of no written description because the specification described the claimed sequences by their ability to hybridize (*i.e.*, bind) to a deposited substance—bacterial DNA. *Id.* at 968. The Court remanded with express instructions to apply the test in the PTO guidelines. *Id.*

- *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004), invoked *Enzo* as "precedent" on that point, declaring that inventors can claim an "antibody by its binding affinity to" a "*fully characterized antigen*." *Id.* at 1349. Applying that test, the Court rejected the claim because the relevant application "failed to disclose the structural elements" of the "antibody *or antigen*." *Id.* (emphasis added).

- *Centocor* applied the test, too. "[W]ritten description for certain antibody claims," it ruled, "can be satisfied by disclosing a well-characterized antigen." 636 F.3d at 1352. But it rejected the claims there for failure to meet the second requirement—that the "creation of the antibodies" be rendered "routine" under the then-existing "state of human antibody" knowledge. *Id.*

The PTO has followed that test for longer still. *Enzo* drew the test from PTO guidance. *See* 323 F.3d at 964. When *Centecor* was decided, the test was in the MPEP, not just PTO "training materials." *See* MPEP §2163 ¶II.A.3(a) 8th ed., Rev. 5 (Aug. 2006), http://bit.ly/2BpE5cJ. Today, the MPEP declares that "disclosure of an antigen fully characterized by its structure, formula," etc., "*provides an adequate written description* of an antibody claimed by its binding affinity to that antigen, if 'generating the claimed antibody is so routine that possessing the [antigen] places the applicant in possession of an antibody.'" MPEP §2163 ¶II.A.3(a) (emphasis added).

2. The panel dismissed this Court's precedents as "dictum," seemingly because the written descriptions were found inadequate in *Noelle* and *Centocor*. Slip Op. 13-15. But an "explication[] of the governing rules of law" is not dictum; nor is the "rationale upon which the Court based the results." *Seminole Tribe v. Florida*, 517 U.S. 44,

66-67 (1996); *Int'l Truck & Engine Corp. v. Bray*, 372 F.3d 717, 721 (5th Cir. 2004). Language "explain[ing] the Court's rationale" is instead "part of the holding." *United States v. Bloom*, 149 F.3d 649, 653 (7th Cir. 1998); *see also United States v. Title Ins. Co.*, 265 U.S. 472, 486 (1924) (even rationales in the alternative are "holdings").

In *Enzo*, *Noelle*, and *Centocor*, this Court *articulated* the newly-characterized-antigen test; *applied* that test to the case before it; and *rendered judgment* based on the test. That is hardly dictum. The "rationale upon which the Court based the results of its earlier decisions" is as binding as "the result[s]." *Seminole Tribe*, 517 U.S. at 66-67; *see* 21 C.J.S. Courts §223 (2006); *e.g.*, *Ryste & Ricas, Inc. v. Harvey*, 477 F.3d 1337, 1342 (Fed. Cir. 2007).

Enzo, moreover, invoked the newly-characterized-antigen test to *overturn* a finding of *no* adequate written description. 323 F.3d at 964-66. It was thus a "holding" even under the panel's view. While *Enzo* did not involve antibodies, it *extended* the newly-characterized-antigen test to additional compounds: Just as an antibody can be described through its propensity to bind to a fully characterized antigen, *Enzo* held, *other* substances can be described through their propensity to bind

with other fully described materials (in that case, by hybridizing to deposited genomic DNA). *Id.* at 960, 964, 968. Far from suggesting that *Enzo* can be distinguished because it involved different biologic material, the panel disclaimed the creation of special or different rules for antibodies. Slip Op. 18.

3. The clash with PTO guidance is equally square. The panel attempted to dismiss certain training materials as "archived." Slip Op. 13 n.4. The guidance, however, is in the MPEP—quoted above—which binds patent examiners. Numerous PTAB decisions follow the same rule. Amgen Br. 43. And current training materials still include the rule. http://bit.ly/2nMsWPU at p.17.

The conflict concerns fundamental principles. The panel rejected the newly-characterized-antigen test based on its view that the specification may not describe the thing claimed by describing something else. Slip Op. 18. But *Enzo*'s central holding was that a claimed substance *can* be described by reference to another substance to which it binds, hybridizes, or has an affinity. 323 F.3d at 966; *see Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 925 (Fed. Cir. 2004) (depending on the art, "disclosure of a DNA sequence might

support a claim to the complementary molecules that can hybridize to it"). The "specification satisfies the written description requirement" when it "conveys the necessary information—regardless of *how* it conveys such information." *Bd. of Trustees of Leland Stanford Jr. Univ. v. Chinese Univ. of H.K.*, 860 F.3d 1367, 1375 (Fed. Cir. 2017) (quotation marks omitted).[1] If the panel disagreed with that bedrock principle, the proper—and only—remedy was review en banc.

B. The Issue Is Exceptionally Important.

The reliance interests alone are staggering. The PTO has issued myriad patents under the newly-characterized-antigen test. *E.g.*, *In re Bicknell*, Appx6498-6501 (PTAB Jan. 8, 2016); *Ex Parte Dickson*, 2007 WL 5108541 (BPAI Nov. 5, 2007). Amgen alone devoted $2 billion and a decade of work to develop and secure regulatory approval for its invention. Amgen Br. 73. Innovators cannot invest in developing

[1] Nor is the panel correct that the newly-characterized-antigen rule requires only enablement. Slip Op. 16-17. Under *Enzo*, *Centocor*, and the jury instructions here, the jury must find that (1) the patentee provided a detailed description of the antigen to which the antibodies bind, *and* (2) it would be routine for a person skilled in the art, armed with the patent's disclosures, to make the claimed antibodies. *Centocor*, 636 F.3d at 1351-52; pp. 5-6, *supra*. The first requirement is crucial: It requires disclosure of a "newly-characterized antigen by its structure, formula, chemical name, or physical properties." Appx1580.

therapeutic agents absent confidence they can take this Court's precedents at their word, especially in an industry where the few successful medicines must also fund the many research dead-ends. The panel decision here—which overturns the *ratio decidendi* of three cases as "dictum"—gravely undermines that confidence.

Once an inventor identifies a useful therapeutic target and shows that antibodies can be developed against it, it is ordinarily trivial for others to produce additional antibodies that bind to the same target. *Centocor*, 636 F.3d at 1351 ("PTO guidelines characterize 'production of antibodies against a well-characterized antigen' as 'conventional' and 'routine,' given 'well developed and mature' antibody technology."); *Ex parte Flynn*, 2013 WL 3355938, at *5 (PTAB 2013) ("if in possession of an antigen, the ordinary artisan will be able to obtain an antibody"); *Bicknell*, Appx6500 ("[I]n 2003, the skilled artisan was easily able to generate antibodies to known antigenic sequences without undue experimentation."). The record here confirms that. Amgen Br. 44-46 (citing expert testimony). Simply put, knowing the antigen's structure lets skilled artisans use conventional methods to make claimed

antibodies, all of which share common structural features that allow them to bind to the target antigen. *See Flynn*, 2013 WL 3355938, at *5.

Without genus claims, patent protection for antibodies would be nearly worthless. Copyists "could … make a minor change to the sequence and thereby avoid infringement while still exploiting the benefits of [Amgen's] invention." *Enzo*, 323 F.3d at 966. No one would bother investing in targeting antigens, much less targeting difficult ones like PCSK9. This Court should not overturn 15 years of precedent and longer-standing PTO guidance designed to confer patent protection when an innovator demonstrates possession of antibodies directed to a new target.

II. The Panel Decision Overturns Decades Of Precedent Precluding Reliance On Post-Priority-Date Embodiments.

A. The Decision Conflicts With Controlling Authority.

The invention's priority date has long been the pivotal moment for validity, including for written description and enablement. *Ariad*, 598 F.3d at 1351. For decades, this Court has held that advances in the art after the priority date—such as new embodiments—are irrelevant. *Hogan*, 559 F.2d at 605; *see U.S. Steel Corp. v. Phillips Petroleum Co.*,

865 F.2d 1247, 1251-52 (Fed. Cir. 1989); *Koller*, 613 F.2d at 823-24.[2] The "law must be applied to each invention at the time it enters the patent process"; post-priority-date embodiments are "legally irrelevant." *Ariad*, 598 F.3d at 1351, 1355. That is true whether the evidence is invoked to support validity or defeat it: The rule cannot apply "in one manner with respect to the applicant and in a different manner with respect to the examiner." *Hogan*, 559 F.2d at 604.

That principle—the priority date is the critical moment for validity—resonates throughout patent law. Consistent with 35 U.S.C. §120, obviousness, anticipation, written description, and enablement are all judged based on the art as of the priority date. *Id*.

In *Hogan*, the Court rejected "application of later knowledge about later art-related facts . . . which did not exist on the filing date," holding it "impermissible." 559 F.2d at 605. The Court therefore overturned the PTO's rejection of a patent claiming a genus of homopolymers, and disclosing several species, based on an embodiment discovered years

[2] Of course, post-priority-date evidence illuminating *the state of the art on the priority date* remains relevant. *Hogan*, 559 F.2d at 605; *Chiron Corp. v. Genentech*, 363 F.3d 1247, 1260 (Fed. Cir. 2004). This includes later explication of inherent properties of compounds identified in a patent application as of the priority date. *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1423 (Fed. Cir. 1987).

later. *Id.* "The courts have consistently considered subsequently existing states of the art as raising questions of infringement, but never of validity." *Id.* at 607. In *U.S. Steel*, this Court ruled that a later-developed type of propylene could not be used to show that the patentee lacked possession of the full scope of the claimed invention. 865 F.2d at 1250-51. Such evidence, the Court held, is "immaterial to the Section 112, first paragraph inquiry." *Id.* at 1252. Evidence of a subsequent embodiment "relates to infringement, not to patentability." *Id.* at 1251.

The panel disputed none of that. It agreed, in particular, that evidence of later-discovered embodiments is generally irrelevant. Slip Op. 8-10. It nonetheless held that post-priority-date embodiments are relevant to whether "a patent fails to disclose a representative number of species." *Id.* at 10. But that falls squarely within what *Hogan* and *U.S. Steel* reject—the invocation of different embodiments, unknown on the priority date, to challenge written description and enablement. If a 1953 patent was properly issued considering "all art-related facts existing in 1953," then "a later change in the state of the art cannot change" validity. *Hogan*, 559 F.2d at 605.

The conflict with *Koller* is clearer still. *Koller* reversed the PTAB's ruling that an application did not adequately describe a claimed genus of "liquid medi[a]" because it did not describe water-immiscible solvents. 613 F.2d at 822-23, 825. Failure to describe this later-developed embodiment did not invalidate the genus. *Id.* at 823-25. "[A]n analysis using later-filed references to determine the scope of enablement" or "description," *Koller* declared, is "impermissible." *Id.* at 825. The panel here declared the opposite: Later-arising embodiments, it pronounced, are relevant to validity, and the sufficiency of representative species in particular.[3]

The panel upended the priority-date rule for enablement, too. *Hogan* declared that, once established with facts available on the priority date, "enablement [i]s established for all time." 559 F.2d at 605. The panel here held the opposite: Amgen's post-priority-date efforts to develop new embodiments are, it said, relevant to "undue

[3] The panel invoked *Abbvie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014). If *Abbvie* had addressed the issue, that would *underscore* the intra-circuit conflict. But *Abbvie* did not. The relevant antibodies there were not post-priority: The antibody later sold as Stelara was invented "[n]o later than April 30, 1998," *before* the March 25, 1999 priority date. *Abbott GmbH & Co. v. Centocor Ortho Biotech Inc.*, 870 F.Supp.2d 206, 217-18 (D. Mass. 2012).

experimentation." Slip Op. 11. But "undue experimentation" is just the test for enablement. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). It cannot be that post-priority-date embodiments are inadmissible for enablement but can be admitted for undue experimentation—which is to say, for enablement. *Hogan* specifically rejected the invocation of post-priority developments "as evidence to prove [the patent's] disclosure non-enabling for 'other species' of the claimed" genus. 559 F.2d at 604.[4]

Far from distinguishing these precedents, the panel decision eviscerates them. The representative-species test, introduced by the Court in *Regents of the Univ. of Cal. v. Eli Lilly & Co.,* 119 F.3d 1559, 1569 (Fed. Cir. 1997), did not invite after-arising species as evidence for challenging the scope of the genus or the adequacy of support for it. But the decision converts that means of proving written description *as of the priority date*—the provision of representative species—into an excuse

[4] *In re Corneil*, 347 F.2d 563 (C.C.P.A. 1965), considered post-priority evidence proffered without objection by both parties. But *Corneil* did not "establish[] a precedent for permitting use of a later existing state of the art in determining enablement." *Hogan*, 559 F.2d at 605 n.17. And *White Consolidated Industries v. Vega-Servo Control, Inc.*, 713 F.2d 799 (Fed. Cir. 1983), *see* Slip Op. 12, is irrelevant. That case involved expert testimony about the amount of experimentation required, not post-priority embodiments or other changes in the art.

for examining post-priority-date improvements to challenge validity. Indeed, a party challenging a written description or enablement can *always* argue that later-discovered embodiments are relevant to the validity of genus claims.

B. The Decision Is Important And Unsettles Patent Rights.

The panel's approach undercuts incentives to develop and patent antibodies to new targets. A follower can almost always rely on the innovator's patent to develop additional antibodies (which may be themselves patentable as species). Under the panel decision, those otherwise-infringing embodiments are now relevant to invalidating the innovator's patent on the theory that the patent's examples are not sufficiently "representative." Patent protection is transient at best, as the written description of the invention becomes both the target and the enabling means for the patent's potential demise. There is little reason for inventors to invest billions of dollars to address unknown and difficult targets. Why bother, if easier, subsequent developments—enabled by the patentee's own disclosures—can be the basis for invalidating the patent that made them possible? Just so here: Amgen's patent offered extensive disclosures for PCSK9 antibodies. It

described the target antigen in detail, offered numerous representative antibodies, and showed any potential followers how to make others. Amgen Br. 14-17.

The panel's approach hits the most groundbreaking inventions the hardest. "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. "To demand such restriction is merely to state a policy against broad protection for pioneer inventions." *Id.*

The panel decision also threatens to create a "zone of uncertainty" that "discourage[s] invention." *United Carbon Co. v. Binney & Smith Co.*, 317 U. S. 228, 236 (1942). Under it, validity may decline over time as the state of the art advances. A claim may be held valid before a new embodiment is found. But later advances (like new embodiments, even ones building on the innovator's patent) may now convince later factfinders of invalidity. That makes no sense. Patents are important property rights. Innovators and the public cannot rely on those rights if validity dissipates over time. And if an inventor has made the further investment to bring its invention to market, and to develop a market

where none existed before, the patent is at greatest risk of invalidity just when it may be most valuable.

The decision also portends serious problems for patent prosecution. If subsequent embodiments are relevant, applicants may need to disclose post-priority developments continuously as they arise. Failure to do so could spawn inequitable-conduct charges. *See* 37 C.F.R. § 1.56(a). If ongoing developments affect validity, "[a]n examiner could never safely call a halt and pass an application to issue." *Hogan*, 559 F.2d at 606. And challengers could routinely attempt to undermine the deference owed to PTO examinations by arguing that the PTO did not consider (and perhaps could not have considered) embodiments discovered after the priority date—indeed, after issuance. *Cf. Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 111 (2011) (PTO's "judgment may lose significant force" if it "did not have all material facts before it"). Before the panel decision, "[t]he law .... [did] not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention." *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc). The panel decision has upset that rule.

The panel expressed concern about over-claiming that might "preempt[] the future before it has arrived." Slip Op. 8. But *Ariad* holds that such concerns are addressed through application of written description "as of the filing date." *Ariad,* 598 F.3d at 1351, 1353. Advances in the art that bring an accused embodiment beyond the scope of an invention, on the other hand, are addressed by other means—claim construction, reverse doctrine-of-equivalents—not by requiring patentees to foresee and describe later-created embodiments. *See, e.g.,* Appx1033, n.3; *Hogan*, 559 F.2d at 607.

For decades, validity has hinged on the priority date. The panel decision throws a monkey-wrench into that, exempting post-priority-date embodiments for written description and enablement. This Court and its predecessor have rejected that as inconsistent with § 120 and the structure of the Patent Act as a whole. *See id.* at 604-05. En banc review is warranted to restore uniformity to Circuit law.

CONCLUSION

The petition should be granted.

Respectfully submitted,

Dated: December 6, 2017

/s/ Daryl L. Joseffer

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ADDENDUM

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.

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

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

entire genus of antibodies 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

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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.

compete with 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 repre-

sentative 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 unset-

tled: 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 representative 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

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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

"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 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.

Trademark Office, *available at* https://www.uspto.gov/patent/laws-and-regulations/examination-policy/examination-guidance-and-training-materials.

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 antibodies 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

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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).

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.

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 enable-

ment 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

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. Cir. R. 35(b)(2)(A), I certify that the foregoing petition contains 3,890 words, as counted by Microsoft Word 2013.

/s/ Daryl L. Joseffer
Daryl L. Joseffer

CERTIFICATE OF SERVICE

On December 6, 2017, I caused the foregoing to be filed with the Court electronically using the CM/ECF system, which will send a notification to all counsel of record.

December 6, 2017

/s/ Daryl L. Joseffer
Daryl L. Joseffer