No. 20-1074

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING, LTD., and AMGEN USA, INC.,

Plaintiffs-Appellants,

v.

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

Defendants-Appellees.

On Appeal from the United States District Court for the District of Delaware, No. 14-cv-01317, Judge Richard G. Andrews

APPELLEES' OPPOSITION TO PETITION FOR REHEARING EN BANC

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May 28, 2021

U.S. Patent No. 8,829,165 (Appx411-412)

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 S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.

19. The isolated monoclonal antibody of claim 1 wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO:3.

CERTIFICATE OF INTEREST

Counsel for Appellees Sanofi, Aventisub LLC, sanofi-aventis U.S. LLC, and Regeneron Pharmaceuticals, Inc. certify the following:

1. The full name of every party represented by counsel is:

   Sanofi, Aventisub LLC, sanofi-aventis U.S. LLC, and Regeneron Pharmaceuticals, Inc.

2. The names of the real parties in interest represented by counsel, and not identified in response to Question 3, are:

   Same as above.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the parties represented by counsel are:

   None.

4. The names of all law firms and the partners or associates that appeared for the parties represented by counsel 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:

   Wilks, Lukoff & Bracegirdle, LLC: David E. Wilks, Scott B. Czerwonka

   Ashby & Geddes, P.A.: Steven J. Balick, Tiffany Geyer Lydon, Andrew Colin Mayo

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*formerly

5. The titles and numbers of any cases known to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal are:

None.

6. Information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):

None.

Date: May 28, 2021 */s/ Matthew M. Wolf*

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INTRODUCTION

The panel's unanimous decision in this case broke no new ground. The panel merely applied this Court's precedent to the undisputed facts and held that Amgen's broad functional claims are not enabled—just as the district court held after applying that same precedent to the same undisputed facts. Amgen's effort to spin the panel's factbound conclusion into a supposedly anomalous, far-reaching holding that conflicts with precedents of this Court and the Supreme Court is unavailing. This is a run-of-the-mill enablement case that does not warrant further review. Amgen's petition for rehearing en banc should be denied.

Amgen first contends that the panel "announce[d] a new test" for enablement of functionally defined genus claims that "asks how much '"time and effort"' is required 'to reach the full scope of claimed embodiments.'" Pet.1, 7 (emphasis omitted). To identify this supposed "test," Amgen is forced to mine the depths of the panel's decision, and for good reason: the panel did not actually articulate any new test, standard, or principle but instead simply applied this Court's recent decisions addressing functional genus claims—specifically, *Idenix Pharms. LLC v. Gilead Scis., Inc.*, 941 F.3d 1149 (Fed. Cir. 2019), *reh'g en banc denied* (Fed. Cir. 2020), *cert. denied*, 141 S.Ct. 1234 (2021), *Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340 (Fed. Cir. 2019), *reh'g en banc denied* (Fed. Cir. 2019), *cert. denied*, 140 S.Ct. 2634 (2020), and *Wyeth & Cordis Corp. v. Abbott Labs.*, 720

F.3d 1380 (Fed. Cir. 2013), *reh'g en banc denied* (Fed. Cir. 2013). The panel then concluded that "[t]he facts of this case" are "analogous to" the facts in those decisions and thus held that Amgen's claims are non-enabled. Op.14.

Amgen acknowledges that the panel applied the principles articulated in *Idenix*, *Enzo*, and *Wyeth*, and it concedes that the panel eschewed categorical rules. Amgen's real complaint is with *Idenix*, *Enzo*, and *Wyeth*, but it does not challenge the reasoning of those controlling (and correct) decisions in its petition, presumably because this Court denied rehearing in all of them and recently reaffirmed their application to cases exactly like this one. Moreover, those cases were all decided in accordance with longstanding Supreme Court precedent. Amgen is left to contend that the panel's decision will wreak havoc on innovation, but those are the same exaggerated arguments this Court has repeatedly heard and rejected as recently as *Idenix*. In reality, the panel's decision promotes innovation by guarding against overbroad claims that seek to corner the market on groundbreaking therapeutics.

Amgen also contends that this Court should determine "[w]hether enablement is a question of fact." Pet.vi. But this Court and the Supreme Court have repeatedly denied review of that question, including, again, as recently as *Idenix*. Amgen merely offers the same arguments as the *Idenix* petition for rehearing, and those arguments remain wrong. Courts have long understood enablement to be a question of law with underlying factual questions, and Amgen cites no case holding that

enablement is purely a question of fact. Even if it were otherwise, it would make no difference here given the undisputed evidence that produced the panel's decision.

Finally, this case is a poor vehicle for en banc review because answering either of Amgen's enablement-related questions would not resolve this appeal. Before the panel, Sanofi/Regeneron also argued for invalidity given lack of adequate written description and for a new trial given evidentiary errors. Due to its enablement holding, the panel did not confront those alternative arguments. If this Court were ever inclined to address Amgen's questions, it should be in a case where the answers are outcome-determinative, rather than a prologue to further analysis.

The panel's decision is a straightforward application of well-established precedent, not a dramatic change to enablement law. The petition should be denied.

ARGUMENT

I. Amgen's First Question Presented Does Not Warrant En Banc Review.

A. The Panel Did Not Create a "New Test" for Enablement.

Amgen's first question presented contends that the panel created a "new enablement test for genus claims with functional limitations." Pet.v; *see also id.* at 1, 7, 12, 13. This assertion is incorrect and does not warrant en banc review.

What Amgen characterizes as a "new test" was simply the panel's application of this Court's well-established law governing enablement of claims with functional limitations. In three prior cases—*Idenix*, *Enzo*, and *Wyeth*—this Court held that

claims covering chemical compounds and their uses were not enabled as a matter of law because they required "undue experimentation" under *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). As the Court recently summarized, in these cases "involving claims that state certain structural requirements and also require performance of some function … undue experimentation can include undue experimentation in identifying … the compounds that satisfy the functional requirement." *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 n.2 (Fed. Cir. 2020) (citing *Idenix*, *Enzo*, and *Wyeth*).

Here, the panel merely applied this case law to conclude that Amgen's functional claims likewise require "undue experimentation" under *Wands* and are thus not enabled. *See* Op.9-14. The panel reached this conclusion after "weighing the *Wands* factors" and determining that "[t]he facts of this case are … analogous to those in *Enzo*, *Wyeth*, and *Idenix*, where we concluded a lack of enablement." *Id.* at 14. As Amgen concedes, *see* Pet.10, the panel repeatedly disclaimed any bright-line rules or tests, *see* Op.11 ("functional claim limitations are not necessarily precluded"); *id.* at 12 (that "the scope of the claims is broad … does not close the analysis"); *id.* at 13 ("some need for testing by itself might not indicate a lack of enablement"); *id.* ("We do not hold that the effort required to *exhaust* a genus is dispositive.")—which presumably explains why Amgen must cobble together scattered portions of the panel's decision to identify the purportedly new "test." *See,*

e.g., Pet.v, 1, 7 (quoting Op.11, 12, 14). At bottom, Amgen simply seeks factbound error correction of the panel's application of settled law to the facts of this case. That does not warrant further review.

While repeatedly asserting that the panel announced a "new" and "different test for genus claims with functional limitations," Pet.1, Amgen itself acknowledges that the so-called "different test" is what this Court already set forth in *Idenix*, *Enzo*, and *Wyeth*. In describing the panel's decision, Amgen observes that the panel "invoked an alternative test" derived from *Idenix*, *Enzo*, and *Wyeth*, and that the panel applied "that test" to the facts to hold that "'substantial time and effort' would be required to reach the full scope of claimed embodiments." *Id.* at 6-7 (quoting Op.14) (emphasis omitted). But that very same language—the "time and effort" required "to reach the full scope of claimed embodiments"—is what Amgen contends is the "new test" created by the panel. *See* Pet.v, 1, 3, 6-7, 7, 9, 10, 10-11, 11. Thus, even Amgen recognizes that the panel's so-called "new test" is really just the result of the panel's applying *Idenix*, *Enzo*, and *Wyeth* to the facts of this case.

In reality, Amgen's complaint is with *Idenix*, *Enzo*, and *Wyeth*, which control here. *See* Pet.1-2 (Amgen describing panel decision as "the culmination of recent cases"). Amgen has always known this, which is why it barely mentioned those cases in its opening brief, *see* Amgen.Br.67-68, sought to distinguish them in its reply brief after Sanofi/Regeneron invoked them, *see* Amgen.Reply.1, 2, 7-8, 14, 17,

19, 20, and filed an amicus brief supporting en banc review in *Idenix*, *see* Brief of *Amicus Curiae* Amgen Inc. in Support of Rehearing En Banc, *Idenix*, 941 F.3d 1149 (Fed. Cir. No. 18-1691) ("Amgen.*Idenix*.Amicus.Br."), ECF No. 85. But this Court denied rehearing in *Idenix*—and in *Enzo* and *Wyeth*. The same result should follow here, not least because those cases are all in keeping with prior Supreme Court precedent. *See Consol. Elec. Light Co. v. McKeesport Light Co. (The Incandescent Lamp Patent)*, 159 U.S. 465, 472-73 (1895) (invalidating claim to "the use of all fibrous and textile materials for the purpose of electric illumination" because specification left POSA to "experiment[] … among the different species of vegetable growth" to find those that are "suitable"); *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 256-57 (1928) (invalidating claim to all starch glues functioning like animal glue because specification only described one starch glue, and others could only be found "after elaborate experimentation."); *Bene v. Jeantet*, 129 U.S. 683, 684, 686 (1889) (invalidating claim to method of shrinking coarse hair by using "chemicals" because specification merely disclosed one chemical "solution" and thus did not "enable [the POSA] to use the invention without having to resort to experiments … to discover those [other] ingredients").

Notably, because Amgen is well aware that this Court denied rehearing in *Idenix*, *Enzo*, and *Wyeth*—and, in *McRO*, reaffirmed that those decisions govern when addressing functional claims like those here—Amgen does not directly

challenge them, thus forfeiting any contention that they were wrongly decided. Instead, Amgen contends that the panel here "fundamentally change[d]" the "test" set out in those cases. Pet.8-9. But that assertion contradicts Amgen's prior description of the panel having *applied* that very same "test." *Id.* at 6-7. Regardless, Amgen never actually explains how the panel "fundamentally" deviated from *Idenix*, *Enzo*, and *Wyeth*. At most, it briefly argues that the panel required examination of "the effort to find *every* embodiment." *Id.* at 9. But the panel said no such thing; it simply observed that it is "appropriate" to "look at the amount of effort needed to obtain embodiments outside the scope of the disclosed examples and guidance." Op.13. Amgen instead shifts to arguing (as it did before the panel) that this case is *distinguishable* from *Idenix*, *Enzo*, and *Wyeth*, citing its own evidence. Pet.9. But that is simply another factbound argument that the panel erred in applying *Idenix*, *Enzo*, and *Wyeth*, unworthy of en banc review.

Like the *Idenix* rehearing petition and Amgen's amicus brief supporting rehearing in *Idenix*, Amgen contends that the panel's decision conflicts with *Minerals Separation Ltd. v. Hyde*, 242 U.S. 261 (1916), and *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234 (Fed. Cir. 2003). *See* Pet.10-12. And just as in *Idenix*, there is no conflict here. Those cases recognize that determining the full scope of a claim is necessary for assessing whether the patent has enabled that full scope. *See Minerals Separation*, 242 U.S. at 270 (understanding all "variation of treatment" for

"different ores" to be "within the scope of the claims"); *AK Steel*, 344 F.3d at 1244 (understanding the "full scope of the claimed invention" to include all embodiments in claimed "range"). Furthermore, this Court has long recognized *Wands*' requirement that patents "teach those skilled in the art how to make and use the *full scope* of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Here, the panel concluded, on "[t]he facts of this case" and "after weighing the *Wands* factors," that "undue experimentation would be required to practice the full scope of these claims." Op.14.

Amgen also argues that "Sanofi-Regeneron failed to identify *even one embodiment* … that could not be made quickly and easily" and that the panel failed to consider the non-enablement of multiple embodiments that "are or *may* be within the claim." Pet.2, 5. The undisputed evidence demonstrates the opposite. As the panel explained, the "only ways for a person of ordinary skill to discover undisclosed claimed embodiments would be through either 'trial and error' … or else 'by discovering the antibodies *de novo*.'" Op.13. The panel also identified a range of non-enabled embodiments. *See id.* at 12 n.1 (noting that "there are three claimed residues to which not one disclosed example binds" and that "none of Amgen's examples binds more than nine"). Only Amgen's competitors, not Amgen, were able to make such antibodies. Appx4283; *see also* Appx3685-3686(206:18-210:5);

Appx3754(332:7-11); Appx3776(420:12-20); Appx3777(421:1-5).[1] In any event, Amgen's fact-intensive arguments reinforce that the panel's decision does not implicate any unsettled legal questions and thus does not warrant further review.

B. The Panel's Decision Does Not Threaten Innovation.

Amgen contends that the panel's decision "threatens patents for breakthrough inventions," "reduces a formerly practical inquiry into a numbers game" that is "practically impossible to satisfy for any genus of any nontrivial size," and portends "devastating consequences for biotech and pharmaceutical patents." Pet.12-13 (quotations omitted). These are the exact same arguments made in the *Idenix* petition for rehearing, where the petitioner (supported by Amgen as amicus) argued that the panel's decision "threatens disaster for innovation," created a "'numbers' test … hostile to genus claiming," and was "wrong and destructive to innovation," especially in the "pharmaceutical and biotechnology fields." Petition for Rehearing En Banc at 10-11, *Idenix*, 941 F.3d 1149 (Fed. Cir. No. 18-1691), ECF No. 66 ("*Idenix*.Pet."); *see also* Amgen.*Idenix*.Amicus.Br.7-8 (arguing that the decision

[1] Claims that encompass a range of embodiments not enabled by the specification have long been struck down by the Supreme Court, this Court, and its predecessor. *See O'Reilly v. Morse*, 56 U.S. 62, 112, 120 (1853); *Jeantet*, 129 U.S. at 684, 686; *In re Vaeck*, 947 F.2d 488, 495-96 (Fed. Cir. 1991); *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). This Court most recently reaffirmed that principle in *Pacific BioSciences v. Oxford Nanopore Technologies*, __ F.3d ___, 2021 WL 1880926, at *5 (Fed. Cir. May 11, 2021) ("[I]t is not enough for enablement here that relevant artisans knew how to perform *some* 'nanopore sequencing' …. What matters is the scope of the asserted claims[.]").

"threatens innovation," especially for "biological and chemical genus claims"). The argument is no more convincing the second time around.[2]

The facts of this case readily undermine Amgen's contention that the panel's decision will discourage innovation. Amgen and Sanofi/Regeneron independently identified antibodies directed to PCSK9, and then obtained patents claiming their specific antibodies by amino acid sequence. *See* Sanofi/Regeneron.Br.4-9. It was years *after* these patents issued that Amgen obtained the patents-in-suit, which functionally claim *all* antibodies that bind to certain residues on PCSK9 and block PCSK9's binding to LDL-Rs. *Id.* at 10-11. In short, the prospect of obtaining an overly broad patent was unnecessary to spur development of either Amgen's or Sanofi/Regeneron's original antibodies. Amgen simply wishes to leverage a subsequent, broad, functional claim to corner the PCSK9-inhibitor market.

The panel's decision actually encourages investment in research and development by ensuring that companies can invest billions to experiment and discover innovative, life-saving medicines—as Sanofi/Regeneron did—without the risk that they will lose those investments simply because an applicant claimed an

[2] Actually, the third time: Amgen's previous petition for rehearing *in this case* made the same sky-is-falling arguments. *See, e.g.*, Petition for Rehearing En Banc at 1, *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. No. 17-1480), ECF No. 163 (contending that "[i]f the panel decision stands, the consequences will be dramatic, particularly for groundbreaking biologic medicines").

overly broad genus of antibodies by their function. As commentators have recognized, had Amgen prevailed here, there would be "even more of a chilling impact on innovation," for other companies would have no incentive to develop new therapeutics within the scope of Amgen's broad functional claims—even if those therapeutics might ultimately prove more effective for patients. Jane Byrne, *Amgen v Sanofi ruling: It is time to kiss goodbye to broad, functional patent claims for antibodies*, BIOPHARMA-REPORTER.COM (Mar. 25, 2021, 14:29 GMT), https://bit.ly/3bZUVnp.

Swinging for the fences, Amgen contends that "*[a]ny* patent with a functional element, in *any* field, is now at risk of invalidation." Pet.14 (emphases added); *see also id.* at 1 (contending that decision will "invalidate virtually any genus claim with functional limitations"). But Amgen does not cite a single decision of any federal court invoking the panel's decision, much less to invalidate a patent. It cites only a single PTAB decision where the Board sustained an enablement rejection after applying the *Wands* factors and concluding that "undue experimentation would be required to make and use the full scope of the claimed invention." *Ex Parte Beall*, No. 2020-001026, 2021 WL 1208966, at *3 (P.T.A.B. Mar. 26, 2021). Nothing in that garden-variety reasoning turned on the panel's decision here, which the Board only cited at the end of its decision after its analysis. The Board certainly did not invoke or apply any supposed "new test" articulated here—including the one that

Amgen has stitched together—reinforcing that the panel broke no new ground, that its decision will not deter innovation, and that en banc review is not warranted.[3]

II. Amgen's Second Question Presented Does Not Warrant En Banc Review.

Amgen also seeks rehearing en banc to determine "[w]hether enablement is a question of fact." Pet.vi. This question, too, does not warrant further review.

Both this Court and the Supreme Court have repeatedly denied petitions raising this question. *See, e.g.*, *Idenix*, 141 S. Ct. 1234; *Johnson v. I/O Concepts, Inc.*, 537 U.S. 1066 (2002); *Musco Corp. v. Qualite*, 522 U.S. 814 (1997). Indeed, Amgen's arguments are (again) largely recycled from the *Idenix* petition for rehearing. In *Idenix*, the petitioner argued that enablement is a question of fact based on *Battin v. Taggert*, 58 U.S. 74 (1854); that "[b]efore 1982, regional circuits were largely in accord"; that this Court's decision in *Raytheon Co. v. Roper Corp.*, 724 F.2d 951 (Fed. Cir. 1983), improperly changed course; and that the panel "reversed implicit jury findings on [the] *Wands* factors." *Idenix*.Pet.3, 16-18. Amgen makes these exact same contentions here. *See* Pet.15-17. Amgen provides no reason why the Court should grant rehearing en banc here after having so recently denied en banc review of the same question, based on the same arguments, in *Idenix*.

[3] Amgen misleadingly introduces *Beall* with a "*see, e.g.*" signal, suggesting that other examples abound. To Sanofi/Regeneron's knowledge, however, *Beall* is the only PTAB decision to cite the panel's decision.

It is no secret why this issue is frequently-denied. Patent validity is often a question of law with underlying factual questions. *See, e.g.*, *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 96-97 (2011); *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 280 (1976); *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966). Enablement, as an invalidity defense, has also always been a question of law with underlying factual determinations. *See Seymour v. Osbourne*, 78 U.S. 516, 540 (1870) (observing that enablement is "open to legal construction as to [its] sufficiency"); *3M v. Carborundum*, 155 F.2d 746, 749 (3d Cir. 1946) (enablement is a "question of law, open to this court"); *Watson v. Bersworth*, 251 F.2d 898, 901 (D.C. Cir. 1958) (same, citing *3M*); *Carter-Wallace, Inc. v. Otte*, 474 F.2d 529, 547 (2d Cir. 1972) ("The adequacy of a patent application's disclosure is a mixed question of law and fact, on which the court must ultimately apply a legal standard to a complex set of facts."). None of Amgen's cases contradicts this well-established understanding or holds that enablement is *purely* a question of fact for the jury, as Amgen appears to contend. Indeed, one of its principal cases says the opposite. *See Wood v. Underhill*, 46 U.S. 1, 6 (1847) (observing that "when the specification of a new composition of matter gives only the names of the substances which are to be mixed together, without stating any relative proportion, undoubtedly it would be the duty of the court to declare the patent to be void"); *see also Great Atlantic & Pac. Tea Co. v.*

Supermarket Equip. Co., 340 U.S. 147, 155 (1950) (Douglas, J., concurring) (observing that "the question of validity of a patent is a question of law.").

Regardless, even if enablement were a purely factual question, it would make no difference here given the undisputed evidence that produced the panel's decision. Amgen wrongly contends that the panel "[r]epeatedly resolv[ed] disputed factual issues" regarding the *Wands* factors. Pet.6, 17. In reality, the panel's decision was based on undisputed facts, as the panel repeatedly emphasized. *See, e.g.*, Op.12 (discussing what "[o]ne of Amgen's expert witnesses admitted" and "[a]nother of Amgen's experts conceded"); *id.* at 13 (noting "the conspicuous absence of nonconclusory evidence that the full scope of the broad claims can predictably be generated by the described methods").

Amgen's contrary contentions misstate the decision or the evidence. For example, Amgen states that the panel "recognized" that the parties disputed "the size of the claimed genus." Pet.17. But the panel actually observed that the parties disputed "the exact number of embodiments falling within the claims," and proceeded to explain that "we are not concerned simply with the number of embodiments but also with their *functional* breadth." Op.12. Similarly, Amgen argues that its experts testified that POSAs "would be certain to make all of the claim's antibodies" from the specification. Pet.17-18. But it omits that those same experts conceded that "the only way to know" whether any generated antibody falls

within the claim's scope "is to test it," and testing the "millions" of antibodies generated by the disclosed methods would be "an enormous amount of work" that no "antibody scientist would even contemplate doing." Appx3768-3769(388:24-389:8); Appx3902(732:21-733:11); Appx3914(781:10-14). Even purely factual issues can be decided as a matter of law when a verdict is unsupported by substantial evidence. *See, e.g.*, *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1335-38 (Fed. Cir. 2016). Here, even if enablement were a purely factual question, a reasonable jury could only conclude that Amgen's narrow disclosure fails to enable the full scope of Amgen's broad claims.

III. This Case Is a Poor Vehicle for En Banc Review.

Finally, this case is a poor vehicle for rehearing Amgen's two enablement-related questions en banc because answering them would not resolve this appeal.

Before the panel, Sanofi/Regeneron sought affirmance of the district court's invalidity judgment not only for lack of enablement, but also on the alternative ground of lack of adequate written description. Additionally, Sanofi/Regeneron argued that even if invalidity were inappropriate on the admitted evidence, a new trial was necessary given the improper exclusion of key post-priority-date evidence demonstrating lack of enablement and written description. These were not passing contentions: they occupied fifteen pages in Sanofi/Regeneron's brief, Sanofi/Regeneron.Br.49-63; the written-description argument identified numerous

differences between Amgen's disclosed antibodies and other antibodies within the claims' scope (which the panel itself acknowledged, *see* Op.12 n.1); and the evidentiary argument concerned exclusion of critical evidence supporting enablement and written description—including the *very same* "missing epitope" document this Court considered in previously holding that the district court improperly excluded key evidence, *see* Sanofi/Regeneron.Br.10-16, 59-62.

The panel did not address these compelling alternative grounds for affirmance or new trial because it simply affirmed given lack of enablement. Thus, if the Court granted Amgen's petition and resolved either enablement-related question favorably for Amgen, this appeal would not be over; the written-description and evidentiary issues would still have to be addressed. But neither of these issues warrants en banc consideration, which would be imprudent regardless since the panel did not pass on them. If this Court were ever inclined to address either of Amgen's enablement-related questions, it should do so in a case where their resolution would definitively resolve the appeal, rather than—as here—serve as a precursor to confronting additional unaddressed issues. Indeed, if Amgen were correct that the panel's reasoning here will "invalidate virtually any genus claim with functional limitations," Pet.1, there should be no shortage of such better vehicles in the future.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served on this 28th day of May, 2021 by the Court's CM/ECF system on all counsel of record.

Dated: May 28, 2021

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CERTIFICATE OF COMPLIANCE

I certify that the foregoing document:

1. Complies with the type-volume limitation of Fed. Cir. R. 32 and the word limit of Fed. Cir. R. 35(e)(2). This brief contains 3,900 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b). Microsoft Word was used to calculate the word count.

2. Complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). This brief has been prepared in a proportionally-spaced typeface using Microsoft Word in 14-point Times New Roman type style.

Dated: May 28, 2021

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