No. 17-1480

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING, LTD., 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. 14-1317-SLR (Consolidated), Judge Sue L. Robinson

---

RESPONSE TO PETITION FOR REHEARING EN BANC

JOHN J. MOLENDA
VISHAL C. GUPTA
SIEW Y. CHONG
STEPTOE & JOHNSON LLP
1114 AVENUE OF THE AMERICAS
NEW YORK, NY 10036
(212) 378-7540

PAUL D. CLEMENT
Counsel of Record
GEORGE W. HICKS, JR.
NATHAN S. MAMMEN
KIRKLAND & ELLIS LLP
655 Fifteenth Street, NW
Washington, DC 20005
(202) 879-5000
paul.clement@kirkland.com

Counsel for Defendants-Appellants
(Additional Counsel Listed on Inside Cover)

February 6, 2018

RICHARD PRASEUTH
STEPTOE & JOHNSON LLP
633 WEST FIFTH STREET
LOS ANGELES, CA 90071
(213) 439-9460

CERTIFICATE OF INTEREST

Counsel for appellants certifies the following:

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

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

2. The name of the real party in interest represented by us is:

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

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

Sanofi has no parent corporation, and no publicly held company owns 10 percent or more of its stock. Sanofi is the parent corporation of sanofi-aventis and Aventisub LLC. Regeneron Pharmaceuticals, Inc. has no parent corporation. Sanofi, through Sanofi's directly and indirectly owned subsidiaries, owns 10 percent or more of Regeneron's stock.

4. The names of all law firms and the partners or associates that appeared for appellants in trial court or are expected to appear in this court are:

KIRKLAND AND ELLIS LLP, BANCROFT PLLC: Paul D. Clement, George W. Hicks, Jr., Nathan S. Mammen, Christopher G. Michel

STEPTOE & JOHNSON LLP: John J. Molenda, Vishal C. Gupta, Jeffrey C. Lee, Richard Praseuth, Robert Greenfeld, Siew Yen Chong, Cassandra Adams, Margaret P. Kammerud, Michael F. O'Brien

ASHBY & GEDDES: Steven J. Balick, Tiffany G. Lydon, Andrew C. Mayo

AKIN GUMP STRAUSS HAUER & FELD LLP: Dianne B. Elderkin, Steven D. Maslowski, Matthew A. Pearson, Angela Verrecchio, Jenna M. Pellecchia, Matthew G. Hartman, Jonathan J. Underwood, Michael P. Kahn, Michael N. Petegorsky

Dated: February 6, 2018

s/Paul D. Clement
Paul D. Clement
Counsel of Record
KIRKLAND & ELLIS LLP
655 Fifteenth Street, NW
Washington, DC 20005
(202) 879-5000
paul.clement@kirkland.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules and Regulation

Other Authorities

INTRODUCTION

In a unanimous and thorough opinion by Chief Judge Prost, the panel correctly decided the two issues that Amgen identifies without creating any conflict with this Court's precedent. As to the first issue—the validity of the so-called "newly characterized antigen" test for written description—the panel painstakingly explained why that test "is not legally sound and *is not based on any binding precedent*." Op.13 (emphasis added). The panel was correct on both counts. It correctly identified past statements as dictum and underscored the reality that this Court has *never once* relied solely on an antigen description to uphold the validity of an antibody patent. Furthermore, as the panel explained, the patent statute requires a "written description of *the invention*" (the claimed antibody), not a description of something else (an antigen). 35 U.S.C. §112(a) (emphasis added).

Similarly, as to the second issue—whether Appellants can introduce antibody evidence postdating the patents' priority date—Amgen claims a conflict with three inapposite decisions it barely mentioned in merits briefing. There is no conflict. Those decisions predated cases addressing antibody genus claims and did not adopt a categorical rule against post-priority evidence for all purposes. The use of such evidence is not only consistent with more recent and more salient cases, but also absolutely critical to ensuring the validity of broadly claimed genera and avoiding the absurd situation below where Appellants could not introduce the accused

product, Praluent, to demonstrate that it shared little in common with the disclosed species. None of this will prevent inventors from making adequately-supported genus claims or securing the fruits of their labor, but it will prevent overbroad genus claims that preempt the future before it arrives. The panel's decision is correct, is thorough, and provides no basis for en banc review.

ARGUMENT

I. The Panel's Rejection Of The Flawed Newly-Characterized-Antigen Instruction Does Not Warrant Rehearing En Banc.

A. The Panel's Decision Does Not Conflict With This Court's Precedent.

1. The panel's decision rejecting the "newly characterized antigen" instruction does not "create[] an intra-circuit conflict." Pet.5. The instruction has its roots in an "antibody example" found in the PTO's *Written Description Training Materials* ("*Training Materials*").[1] The *Training Materials* suggested that the PTO would find adequate written description "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." The Court first referenced this "antibody

[1] *Examination Guidance and Training Materials*, U.S. Patent & Trademark Office (archived 2008), http://bit.ly/2kLrTLa.

example" in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002), a case involving nucleic acid probes, not antibodies. The Court upheld the patent's validity based on the inventors' depositing the claimed nucleotide sequences in a public depository. *Id.* at 964-65. The Court's passing reference to the "antibody example" was not necessary to resolving the case, and the Court did not suggest otherwise. Any claim that the antibody example was the *ratio decidendi* of a case not involving antibodies is facially implausible.

Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004), actually considered antibody claims, but found them *invalid* because the patentee had not adequately described the claimed antibodies or the target antigen. *Id.* at 1349. In so holding, the Court referred to *Enzo*'s one-sentence invocation of the antibody example in the *Training Materials*. *Id.* The Court stated in dictum that if the patentee had "sufficiently described the ... antigen, he could have claimed its antibody by simply stating its binding affinity for the 'fully characterized' antigen." *Id.* But because the patentee had failed to do even that, the Court had no occasion to explore the possibility. *Id.* at 1349-50.

The Court again addressed antibody claims in *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011). Centocor argued that this Court's "decision in *Noelle* and the PTO written description guidelines support the view that fully disclosing" a particular protein "provides adequate written description for any

antibody that binds to" that protein. *Id.* at 1351. This Court squarely *rejected* that position, holding that Centocor's "suggestion is based on an unduly broad characterization of the guidelines and our precedent" and reversing the jury verdict finding the patent valid. *Id.* at 1351, 1353. The Court observed that *Noelle* only "discussed" the antibody example—which, it skeptically noted, "[r]eferenc[ed] only an immunology text published in 1976." *Id.* at 1351-52. The Court then explained that the example assumes a novel antigen and that production of the claimed antibodies is "conventional" and "routine," but because the antigen in Centocor's patents was "known in the literature," and generating the claimed antibodies was not routine, the antibody example was inapplicable. *Id.* at 1352.[2]

In sum, although this Court has thrice "discussed" the antibody example and "newly characterized antigen" theory in dictum, it has *never once* crossed the Rubicon and upheld the validity of antibody claims based merely on disclosure or description of something else, namely, a novel antigen.

2. Amgen nevertheless claims that en banc review is necessary because *Enzo*, *Noelle*, and *Centocor* were "precedential rulings," in that they "*articulated* the newly-characterized-antigen test; *applied* that test to the case before it; and *rendered*

[2] Notably, Chief Judge Prost authored the decisions in *Centocor* and this case and sat on the *Enzo* panel. Similarly, Judges Clevenger and Bryson sat on both the *Noelle* and *Centocor* panels and apparently did not perceive *Centocor*'s criticism of the newly-characterized-antigen test as threatening any holding in *Noelle*.

judgment based on the test." Pet.1,7. But the articulation of a pathway to adequate description—absent actually finding adequate description based on that supposed pathway—is a textbook example of dictum. *See, e.g.*, *United States v. Caraballo-Martinez*, 866 F.3d 1233, 1244 (11th Cir. 2017) ("[T]he 'holding' of a prior decision can reach only as far as the facts and circumstances presented to the Court in the case which produced that decision."). And debates about the Platonic boundaries of "precedent" and "dictum" are ultimately beside the point because Amgen cannot show what Rule 35 requires, which is an actual conflict in result between the panel's decision and a previous decision upholding an antibody patent based on an antigen's description. *See Atonio v. Wards Cove Packing Co.*, 810 F.2d 1477, 1478-79 (9th Cir. 1987) (en banc) (en banc review intended to resolve "*irreconcilable conflict*" (emphasis added)). There is simply no such case here.

Amgen begins its search for a holding with *Enzo*. Pet.5. But *Enzo* did not involve a claim to antibodies, so it could not possibly have "adopted" the newly-characterized-antigen test as its holding. What *Enzo* actually held is that "a deposit of a nucleotide sequence … in a public depository" satisfies the written description requirement. 323 F.3d at 965. *Enzo*'s passing reference to the "antibody example" was plainly "unnecessary to the decision in the case, and therefore not precedential." *Co-Steel Raritan, Inc. v. ITC*, 357 F.3d 1294, 1307 (Fed. Cir. 2004).

To be sure, the Court subsequently referred to *Enzo*'s dicta as "past precedent" in *Noelle v. Lederman*, 355 F.3d at 1349. But a panel referring to "past precedent" has no need to distinguish between holding and dicta, and the passage in *Noelle* is itself dicta. Simply repeating dicta does not convert that dicta into a holding, particularly when "the point … at issue was not fully debated." *Cent. Va. Cmty. Coll. v. Katz*, 546 U.S. 356, 363 (2006); *see* Lilly Amicus Br.14 (showing that neither party in *Noelle* disputed the antibody example). And neither *Noelle* nor *Centocor* upheld the validity of an antibody patent because the patent sufficiently described the antigen, but not the antibody. Thus, Amgen is left with what is best described as dicta, but is in all events short of the conflict required by Rule 35.[3]

Even worse, the dicta Amgen invokes no longer has a foundation, as the "antibody example" *Enzo* and *Noelle* invoked is no longer on the books. The *Training Materials* from which the antibody example originated have been "archived" given "changes in the law since 2008, including [those] relating to" §112.

[3] As the panel noted, the newly-characterized-antigen instruction permits a jury "to deem any antibody within the claim adequately described merely because the antibody could easily be 'produc[ed]'" and used. Op.16 (alteration in original). By "permitting a finding of adequate written description merely from a finding of ability to make and use," the instruction thus runs "afoul of what is perhaps the core ruling of" *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc)—that written description and enablement are independent requirements. Op.16. Therefore, even if *Enzo* and *Noelle* were "precedent" establishing the newly-characterized-antigen theory, the intervening *Ariad* en banc decision has fatally undermined the theory, permitting its abrogation by the panel.

See Training Materials, http://bit.ly/2kLrTLa. And the Manual of Patent Examining Procedure touted by Amgen, Pet.6, conspicuously *omits* the antibody example as a means of satisfying written description. MPEP §2163 ¶II.A.3(a) 8th ed., Rev. 5 (Aug. 2006), http://bit.ly/2BpE5cJ.

In short, the newly-characterized-antigen instruction is based on a misguided, withdrawn PTO example, which was incorporated into dicta, repeated in further dicta, and then undermined by subsequent precedent that rejected reliance on the instruction as "based on an unduly broad characterization of the guidelines and our precedent." *Centocor*, 636 F.3d at 1351. The panel here thus correctly held that the theory was "not central to the holding in either *Enzo* or *Noelle*," and that *Centocor* "questioned [its] propriety." Op.15.

B. The Panel's Decision is Correct.

The panel's decision not only fails to create an intra-circuit conflict but is eminently correct. The newly-characterized-antigen instruction has no basis in the patent statute or science.

The instruction's "essential" problem is that it "flouts basic legal principles of the written description requirement," Op.15,18. Section 112 requires a "written description *of the invention*," 35 U.S.C. §112(a) (emphasis added), but the instruction envisions a patent based on a description of something *that is not the invention*—an antigen, rather than the antibody that is the subject of the claims. It

would be like awarding a patent to an arrow—or worse yet, all arrows—based on a description of a target. The instruction contradicts the statutory text. And by granting patent rights for an invention based only on the disclosure of a non-invention, the instruction undermines the fundamental "*quid pro quo*" of the patent system: "one describes *an invention*, and, if the law's other requirements are met, one obtains a patent." *Ariad*, 598 F.3d at 1345; *see* Op.18.

This Court has properly refused to recognize exceptions to the statutory written description requirement based on the claims' subject matter. *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 925 (Fed. Cir. 2004). Congress, moreover, knows how to carve out an exception to the written description requirement, *see, e.g.*, 35 U.S.C. §162 (exempting plant patents from §112), but has not done so for antibody claims, underscoring that the ordinary rules, requiring description of the invention, apply.

Nor does the "underlying science" bridge the gap between producing an antibody from an antigen and adequately describing that antibody. Op.16. It is undisputed science that the chemical structure of, or binding site on, an antigen does *not* teach the structure of an antibody. Here, for example, Appellants' expert testified that knowing that an antibody binds to a particular site on PCSK9 (the antigen) "does not tell you anything at all about the structure of the antibody." Appx1241(549:5-6, 11). And when *Amgen's* expert was asked about Appellants' position that "you can't

predict" an antibody's structure based on an antibody's binding site, he responded, "My opinion is that they're right." Appx1314(836:9-11).[4]

C. Amgen Overstates the Implications of the Panel's Decision.

Amgen contends that the panel's decision "destabilizes … written-description law." Pet.2. But commentators disagree. By trimming back on dictum based on obsolete PTO guidance and refocusing on §112's text, the decision "makes the application of the written description requirement as applied to antibody claims *more consistent* with how the Court has applied §112 to other biotechnological inventions." Kevin E. Noonan, *Amgen Inc. v. Sanofi (Fed. Cir. 2017)*, Patent Docs (Nov. 19, 2017), http://bit.ly/2EzFkJ2 (emphasis added); *see also* Sarah A. Kagan, *Federal Circuit Discredits Special Disclosure Rule for Antibodies*, Banner & Witcoff IP Alert (Oct. 31, 2017), http://bit.ly/2A34xJf (decision "brings [antibody claims] back in line with all other technologies" and is "a gain for the integrity of the overall system").

Amgen repeatedly touts "reliance interests" and contends that "[w]ithout genus claims, patent protection for antibodies would be nearly worthless." Pet.1-2, 4, 9-11. But that alarmist claim is both wrong and premature. Amgen's genus claims have not been invalidated by the panel's decision. Like all patentees, Amgen can try

[4] The panel characterized the science as "hotly disputed," but, notably, cited only this same evidence, which unanimously supports *Appellants'* position. Regardless, even "disputed" science would preclude the instruction's use. Op.17.

to show on remand that its genus claims satisfy the written description requirement because they disclose either a "representative number of species falling within the scope of the genus" or "structural features common to the members of the genus." *Ariad*, 598 F.3d at 1350.

Finally, Amgen overstates the importance of this issue both generally and to this case. The newly-characterized-antigen concept was a vestige of antiquated science—the product of a time when it was "considered routine to obtain an antibody specific for an antigen" by "inoculating an animal and collecting antibodies made by the animal," and describing structure was difficult. Kagan, *supra*. Now, however, "antibodies are highly engineered and determining their structures is routine." *Id.* At the same time, Amgen could likely not even take advantage of the newly-characterized-antigen instruction referenced in cases like *Noelle*. That instruction at least demanded a newly-discovered antigen. The materially different instruction given below, however, did not require even that, and the antigen here, PCSK9, was well-known in the field and hardly newly described or discovered by Amgen—who, at best, discovered a newly-characterized epitope (*i.e.*, an antigen's binding site), not a newly-characterized antigen. Appellants' Br.42-45; Reply Br.14-15. Thus, not only does the newly-characterized-antigen issue not implicate a conflict, or have any basis in the statute; it would not even make any difference here.

II. The Panel's Decision Permitting Appellants To Introduce Post-Priority Evidence Of The Accused Product Does Not Warrant Rehearing En Banc.

A. The Panel's Decision Does Not Conflict With This Court's Precedent.

The panel's decision likewise did not "overturn[] decades of precedent" relating to post-priority-date evidence. Pet.11. Rather, the Court "ha[d] not ruled on" whether post-priority-date evidence of species that fall within the claimed genus is admissible to show that the patent lack adequate written description. Op.9. Indeed, the Court could not have addressed this question in *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977), *In re Koller*, 613 F.2d 819 (C.C.P.A. 1980), or *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247 (Fed. Cir. 1989)—the supposedly conflicting precedents—because, as Amgen concedes, the Court "introduced" the representative-species test for written description well after these decisions. Pet.15 (citing *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997)). Underscoring the decisions' irrelevance, Amgen's merits briefing cited *Hogan* all of twice and *U.S. Steel* and *Koller* once. *See* Amgen Br.34-36.

Regardless, the panel's decision is consistent with *Hogan*, *U.S. Steel*, and *Koller*. *Hogan* only addressed and prohibited using post-priority-date evidence to show "the post-priority-date state of the art." Op.10. There, the PTO rejected Hogan's application because it did not enable production of amorphous polypropylene, which, although encompassed by the claim, did not exist until years

after Hogan's priority date. 559 F.2d at 597-98, 601, 605. Reversing, this Court explained that enablement was determined by the state of the art as of the filing date, not on post-priority changes in the state of the art. *Id.* at 604-05. *U.S. Steel*, which involved the same patent family as in *Hogan*, simply repeated the same point. 865 F.2d at 1249, 1251-52. Likewise, this Court explained in *Koller* that post-priority-date discoveries could not be the basis for narrowly construing a key term in the priority application. 613 F.2d at 824. None of these cases prescribed a blanket prohibition on post-priority-date evidence. In fact, *Hogan* and *Koller* identified six examples where post-priority-date evidence was relevant. *Hogan*, 559 F.2d at 605 n.17; *Koller*, 613 F.2d 824 n.5.

Here, as the panel recognized, "Appellants were not offering post-priority-date evidence to show that [Amgen's] claimed genus is not enabled because of a change in the state of the art." Op.11. Rather, Appellants offered this evidence to show that under the state of the art existing at the time Amgen filed its application, Amgen's application fails to disclose a representative number of species to support the claimed genus.

Moreover, the Court has repeatedly cautioned against overreading *Hogan*, as Amgen does here. In *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003), the patentee invoked *Hogan* for the proposition that post-priority-date evidence could not be considered to evaluate enablement. *Id.* at 1340.

The Court rejected that argument, explaining, "*Hogan* simply held that one could not use a later-existing state of the art to invalidate a patent that was enabled for what it claimed at the time of filing." *Id.* Similarly, in *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004), the Court held that a claim to chimeric and humanized antibodies was inadequately described because chimeric antibodies did not exist when the patentee submitted the relevant application. The Court rejected the patentee's argument (invoking *Hogan*) that post-priority-date evidence was irrelevant to the adequacy of written description at the time of filing. *Id.* at 1254-55, 1260.

B. The Panel's Decision is Correct.

The panel's decision also is plainly correct. Section 112 requires a patentee to "convey in its disclosure that it 'had possession of the claimed subject matter as of the filing date.'" Op.7 (quoting *Ariad*, 598 F.3d at 1351). Amgen claims an "entire genus of antibodies that bind to specific amino acid residues on PCSK9 and block PCSK9 from binding to LDL-Rs." Op.4-5. A "sufficient description of a genus" requires disclosing either "a representative number of species falling within the scope of the genus" or "structural features common to the members of the genus" so that "one of skill in the art can 'visual or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350.

The most probative evidence of whether a claimed genus is supported by a representative number of species or common structural features will likely be evidence of species that fall within the scope of the claimed genus but are not described in the patent, including the accused antibody—here, Praluent, which the district court excluded. Op.8-9. After all, it is nearly impossible to prove in the abstract that a disclosure is inadequate. This evidence of non-disclosed antibodies "is likely to postdate the priority date" simply because if it "predated the priority date, it might well anticipate the claimed genus." Op.9.

As the panel recognized, this "common-sense logic of admissibility finds support in *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014)," where "Centocor argued the antibodies disclosed in AbbVie's patent were 'not representative of the entire genus,' … rel[ying] heavily on its own accused antibody to support the unrepresentativeness argument." Op.9. Although Amgen contends that "the relevant antibodies" in *AbbVie* "were not post-priority," Pet.14 n.3, the panel recognized the timing of the antibody was at least "unsettled" and that nonetheless "[t]he Centocor antibody … was a basis for the unrepresentativeness ruling without regard to whether it postdated the patent's priority date." Op.9-10.

The written description requirement protects against "attempt[s] to preempt the future before it has arrived." *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

Amgen's rule, however, would incentivize a patentee to try to do just that by immediately seeking broad genus claims defined by the function of where an antibody binds, even though the onerous task of identifying what antibodies perform that function (and whether they share structural similarity) remains. In fact, Amgen's rule would perversely make the most vulnerable genus claims—those in which the supporting disclosure contains few species—*more* difficult to challenge, because evidence of the vast array of omitted species would be excluded. Neither law nor logic supports that outcome.

C. Amgen Exaggerates the Decision's Implications.

The panel's decision does not "undercut[] incentives to develop and patent antibodies" or "discourage[] innovation." Pet.16-17. The facts here readily undermine that argument. Amgen and Appellants independently identified antibodies directed to PCSK9, and then obtained patents claiming their specific antibodies by amino acid sequence. *See* Appellants' Br.7-9. It was years *after* these patents issued—and after Amgen experimented with Appellants' antibody—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. In short, the prospect of obtaining an overly broad patent was unnecessary to spur development of either Amgen's or Appellants' original antibodies. Amgen simply wishes to

leverage a subsequent, broad, functional claim to corner the PCSK9-inhibitor market.

The panel's decision actually enhances research and development by rejecting "attempts to preempt the future before it has arrived" and "ensur[ing] … the right to exclude … does not overreach the scope of the inventor's contribution[s]" to the art. *Ariad*, 598 F.3d at 1353-54. It ensures that companies can invest billions to discover new, life-saving medicines—as Appellants did—without the risk that they will lose those investments simply because an earlier applicant claimed an overly broad genus of antibodies by their function, when that applicant never "actually perform[ed] the difficult work" of discovering a representative number of species fitting in that genus. *Id.* at 1353. The panel simply recognized that evidence of antibodies "within the scope of the claimed genus" but not disclosed—such as the accused product itself—can be important evidence in policing the written description requirement. *AbbVie*, 759 F.3d at 1299-1300. And validity is not transient, Pet.17, because "written description is judged based on the state of art as of the priority date." Op.8. Accordingly, rather than create uncertainty or require that an applicant "describe … every conceivable and possible future embodiment of [the] invention," Pet.18, the panel's decision "provides clarity on the proper use of post-priority-date evidence" for "genus claims in general" and "functional antibody claims in particular." Irena

Royzman & Andrew Cohen, *Fed. Circ. Clarifies Law for Functional Antibody Claims*, Law360 (Nov. 1, 2017), http://bit.ly/2DgfecO.

Nor does the panel's decision "portend[] serious problems for patent prosecution." Pet.18. There are many ways to obtain patent protection for antibody research and innovation without resorting to vast, unsupported functional genus claims, including by claiming the antibodies by amino acid sequence (as both Amgen and Appellants have done). Even for functional genus claims, the panel's decision does not expand the Patent Office's definition of material information, 37 C.F.R. §1.56, or relax this Court's demanding standard for proving inequitable conduct. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc). The decision does nothing more than reinforce the longstanding requirement that patent applicants must disclose what they claim, which is "part of the *quid pro quo* of the patent grant." *Ariad*, 598 F.3d at 1354.

CONCLUSION

The petition should be denied.

Respectfully submitted,

s/Paul D. Clement

PAUL D. CLEMENT
Counsel of Record
GEORGE W. HICKS, JR.
NATHAN S. MAMMEN
KIRKLAND & ELLIS LLP
655 Fifteenth Street, NW
Washington, DC 20005
(202) 879-5000
paul.clement@kirkland.com

JOHN J. MOLENDA
VISHAL C. GUPTA
SIEW Y. CHONG
STEPTOE & JOHNSON LLP
1114 AVENUE OF THE AMERICAS
NEW YORK, NY 10036
(212) 378-7540

RICHARD PRASEUTH
STEPTOE & JOHNSON LLP
633 WEST FIFTH STREET
LOS ANGELES, CA 90071
(213) 439-9460

Counsel for Defendants-Appellants

February 6, 2018

CERTIFICATE OF COMPLIANCE

1. This Response complies with the type-volume limitation of Federal Circuit Rule 32(a) because it contains 3,900 words, excluding the parts exempted by applicable rules.

2. This Brief complies with the typeface requirements of Rule 32(a)(5) and the typestyle requirements of Rule 32(a)(6) of the Federal Rules of Appellate Procedure because the Response has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman font.

Dated: February 6, 2018

s/Paul D. Clement
Paul D. Clement

CERTIFICATE OF SERVICE

I hereby certify that on February 6, 2018, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/Paul D. Clement
Paul D. Clement