No. 06-1291

In the Supreme Court of the United States

AMGEN INC.,

Petitioner,

v.

HOECHST MARION ROUSSEL, INC. (now known as AVENTIS PHARMACEUTICALS INC.) and TRANSKARYOTIC THERAPIES, INC. (now known as SHIRE HUMAN GENETIC THERAPIES, INC.),

Respondents.

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

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

The petition for a writ of certiorari presented two broad, recurring legal issues of profound importance to patent litigation and the judicial process. One of them – *de novo* review of claim construction – cries out for this Court's attention, as three Federal Circuit en banc decisions, mountains of scholarly and judicial criticism, and numerous amicus briefs in past cases attest.[1] The other issue has *already* twice come to this Court, yet the Federal Circuit continues to defy this Court's rulings.

Respondents' brief in opposition proceeds as if petitioner had raised only fact-bound, case-specific issues. By arguing at length the merit of their construction of the term "therapeutically effective,"[2] respondents hope to distract the Court from the issue raised by this petition, which is whether the Federal Circuit should defer to the fact-based determinations of district courts regarding patent claim construction. Respondents duck that issue by resting on the same flawed premise as did the panel majority, namely that claim construction is an arid textual or grammatical exercise that appellate judges are as competent as district judges to perform. But patent claims must be interpreted from the standpoint of a skilled practitioner of the relevant art (in this case, a competent physician) – something that a district court, not an appellate court, is far better equipped to determine. Respondents refuse to engage this point, implicitly *assume* that their paradigm is correct, and then attempt to show that, under their paradigm, they win. Those diversionary tactics should not succeed.

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[1] Amicus briefs are anticipated in the present case as well. They are due – and respondents' brief in opposition was due – April 25, 2007. Only because respondents filed their brief in opposition 19 days before the due date is this case being distributed before the amicus briefs are filed.

[2] Though respondents try to obscure this fact, their construction of "therapeutically effective" notably rests entirely on their parsing of one sentence of the specification that *did not even use* the phrase "therapeutically effective." See p. 7, *infra*.

1.a. This case produced six opinions dissenting from or concurring in the denial of rehearing en banc. Five of those opinions addressed whether the Federal Circuit should change its entrenched practice of reviewing *de novo* all aspects of claim construction. Pet. App. 596a-602a, 604a-609a. Yet respondents argue that that issue is not even *presented* in this case. They are wrong.

Respondents' main argument is that their claim construction is so clearly correct – and Judge Young's so clearly wrong – that they would have prevailed under any standard of review. But respondents' interpretation is not correct. See pp. 6-9, *infra.* The fact that at least five members of the Federal Circuit agreed with Judge Young's claim construction (Pet. App. 43a, 598a, 603a, 604a, 608a) belies respondents' contention that their construction is so transparently right that the standard of review could have made no difference. A deferential standard would have required the Federal Circuit to accept the district court's factual determinations on two critical issues: (i) how the state of the art informed a proper understanding of the specification, and (ii) the knowledge of a person skilled in the art of the differences between mere biological effects and a therapeutically effective result.

b. Respondents also argue (Br. in Opp. ("BIO") 9) that petitioner did not preserve its challenge to plenary *de novo* review of claim constructions. That assertion is utterly mystifying. The three-judge panel was bound by prior en banc decisions to apply *de novo* review, so petitioner had no reason to make a futile request that the panel itself do otherwise. Petitioner certainly argued that the district court's claim construction was correct and should have been affirmed. Petitioner's first opportunity to challenge the standard of review was after the panel used *de novo* review to adopt its own misguided claim construction.

The rehearing petition's first sentence was: "Once again, a divided panel of this Court has swept aside a meticulous and well-reasoned district court claim construction in favor of its

own de novo construction." Argument heading II.C of the rehearing petition was "The Majority Decision Transgresses the Boundaries of Appellate Review." That section explained that, even when an ultimate conclusion is reviewed *de novo*, "the Supreme Court has made clear that 'a reviewing court should take care * * * to review findings of historical fact only for clear error.'" After presenting a range of arguments for deferential review of the factual determinations undergirding a claim construction, the petition concluded (at 15):

> If allowed to stand, the majority's decision to substitute its de novo construction for that of the district court will send a powerful yet debilitating message to district courts and litigants alike: there is little or no point to careful and considered efforts to construe the meaning of disputed claim terms to those skilled in the art because the Federal Circuit will substitute its own claim construction irrespective of their efforts. * * * The Court should hear this issue en banc because the panel's decision is inconsistent with both Federal Circuit and Supreme Court precedent.

It is irrelevant that "[p]etitioner did not mention [most] of the law review articles it now cites," or some of the other authorities the certiorari petition cites. BIO 9. "Although the Court generally declines to review *issues* not pressed or passed upon in the lower courts, it has allowed petitioners to make new *arguments* in support of claims properly presented below. * * * [T]he ability to introduce such 'new arguments' [i]s a 'traditional rule' * * *." STERN ET AL., SUPREME COURT PRACTICE § 6.26, at 421 (8th ed. 2002) (quoting *Lebron* v. *Nat'l R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995)).

The Federal Circuit's judges understood that the rehearing petition called *Cybor* into question. *E.g.*, Pet. App. 596a (Michel, C.J., dissenting from denial of rehearing en banc) ("Rehearing this case en banc would have enabled us to reconsider *Cybor*'s rule of de novo review for claim construction in light of our eight years of experience with its application."). The issue is properly before this Court.

c. Also surprising is respondents' assertion that review is "entirely premature," BIO 9, because review of Federal Circuit decisions should await "the full airing of views that en banc consideration affords," BIO 2, 10. For one thing, none of the five patent cases in which this Court heard argument last Term and this Term was resolved en banc.[3] In any event, the views of Federal Circuit judges (and amici) on the propriety of *de novo* review of claim construction *have* been aired en banc – three times, not even including the separate opinions in this very case. *Markman* v. *Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995) (en banc), aff'd on other grounds, 517 U.S. 370 (1996); *Cybor Corp.* v. *FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc); *Phillips* v. *AWH Corp.*, 415 F.3d 1303, 1328 (Fed. Cir. 2005) (en banc), cert. denied, 126 S. Ct. 1332 (2006). The numerous majority, concurring, and dissenting opinions in all of these cases more than join issue on the merits of *de novo* review.

What is more, the consistent battle lines in these cases show that the en banc Federal Circuit is not going to revisit this subject. Respondents say that the willingness expressed by "several members" of the Federal Circuit to reexamine *Cybor* "flatly belie[s] petitioner's claim that *Cybor* is here to stay." BIO 9. In the twelve years since *Markman*, however, the dissenting faction's "several members" have never come close to assembling a majority. If respondents are trying to imply that three judges' "willing[ness] to reconsider limited aspects of the *Cybor* decision" in an "atypical case" (Pet. App. 606a) creates

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[3] See *AT&T Corp.* v. *Microsoft Corp.*, 414 F.3d 1366 (Fed. Cir. 2005), cert. granted, 127 S. Ct. 467 (2006); *Teleflex, Inc.* v. *KSR Int'l Co.*, 119 Fed. Appx. 282 (Fed. Cir. 2005), cert. granted, 126 S. Ct. 2965 (2006); *MedImmune, Inc.* v. *Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005), rev'd, 127 S. Ct. 764 (2007); *MercExchange, L.L.C.* v. *eBay, Inc.*, 401 F.3d 1323 (Fed. Cir. 2005), vacated, 126 S. Ct. 1837 (2006); *Metabolite Labs., Inc.* v. *Lab. Corp. of Am. Holdings*, 370 F.3d 1354 (Fed. Cir. 2004), cert. granted, 126 S. Ct. 543 and 126 S. Ct. 601 (2005), cert. dismissed, 126 S. Ct. 2921 (2006).

a possibility that at some future time the en banc Federal Circuit finally will fix its mistake, that prediction is groundless. As the petition explained (at 19), even if the views of Judge Gajarsa were to prevail en banc, the Federal Circuit's *de novo* standard of review *still* would be in place (except in the rare case in which a district court expressly rested a definition on disputed expert testimony), and *still* would be wrong.[4]

d. In yet another effort to pretend that this case does not even *present* the issue of *de novo* review of claim construction, respondents (echoing Judge Gajarsa's concurrence) conflate *reliance on extrinsic evidence* with *resolving issues of fact*. The fact that Judge Young "properly and 'carefully review[ed] the *intrinsic* record'" (BIO 4 & n.2, quoting and adding emphasis to Amgen C.A. Br. 12) in no way makes his determinations any less factual. Rather, this Court has *already* held in the context of obviousness determinations that ascertaining "the scope and content of the prior art," "differences between the prior art and the claim at issue," and "the level of ordinary skill in the pertinent art" are *factual* determinations – inherently, and not just when those determinations are made based on extrinsic evidence. *Graham* v. *John Deere Co.*, 383 U.S. 1, 17 (1966). Those determinations are no less factual when they underlie a claim construction such as Judge Young's in this case. See Pet. 18-21. Thus, it would not matter even if were true that Judge Young "was *not* relying on expert testimony or demonstrative exhibits," BIO 3.

In any event, respondents protest too much. Judge Young did in fact draw heavily on the extrinsic testimony – and repeatedly acknowledged that fact. See Pet. 7-8, 19-21. That he did so

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[4] Among other problems (see Pet. 19, 22), Judge Gajarsa's view treats the specification and prosecution history – merely because they are considered intrinsic rather than extrinsic evidence and are documentary in nature – as items to be interpreted *de novo* on appeal. But Federal Rule of Civil Procedure 52(a) and *Anderson* v. *Bessemer City*, 470 U.S. 564 (1985), require appellate deference to factual findings based on documentary evidence.

under the rubric of "understand[ing] the technology" rather than "defin[ing] the claim term" is simply a function of the rules of the claim construction road. Judge Young was trying to avoid the pitfall of merely accepting a particular expert's say-so as to the definition of a claim term. But claim construction is necessarily informed by technical understanding. In trying to discern how one of skill in the art would understand the claim in the context of the specification, the judge properly drew on extrinsic evidence. See also Pet. 18 & n.8.

e. Respondents' brief in opposition ultimately rests on the same fallacy that led the panel majority astray. That fallacy – sometimes called "hypertextualism," see Craig Allen Nard, *A Theory of Claim Interpretation*, *in* FOUNDATIONS OF INTELLECTUAL PROPERTY LAW 122, 124-125 (Robert P. Merges & Jane C. Ginsburg, eds. 2004) – is that claim construction is a mere textual or grammatical exercise that appellate judges are just as competent as district judges to perform. But see Pet. 22-24.

Respondent, for example, relies on *Arcadia, Ohio* v. *Ohio Power Co.*, 498 U.S. 73 (1990), as support for the proposition that courts should attend to the rules of grammar in construing legal instruments. BIO 7. But in that case the Court was interpreting an Act of Congress, not a document reflecting specialized technical understanding. And even in *Arcadia* a grammatical difficulty with a particular reading of a statute was just the starting point of analysis. The longer portion of the Court's opinion rejecting that interpretation tried to make overall sense of the statutory provision at issue. 498 U.S. at 80-85.

In construing a patent, a court may of course start with rules of grammar, but its task is otherwise different from statutory interpretation. As Chief Judge Michel explained below:

> In interpreting statutes, a judge, whether trial or appellate, essentially asks himself/herself, "What does the disputed term mean to me, the judge, as an artisan in the law?" With claim construction, on the other hand, the judge is supposed to inquire, essentially, "How would the average artisan in the relevant field of technology understand the

> disputed claim terms in the context of the rest of the patent, the prosecution history, and the prior art?"

Pet. App. 596a. "What seems clear to a judge may read otherwise to a skilled designer." *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 831 F. Supp. 1354, 1359 (N.D. Ill. 1993) (Easterbrook, J., sitting by designation).

Here, an artisan in the relevant field simply would not understand "therapeutically effective amount" to mean an amount that does *not* heal but merely produces biological effects listed in the specification. To begin with, although respondents claim that "the patentee had acted as its own lexicographer and, in a critical sentence of the specification, had given the phase 'therapeutically effective' a non-ordinary meaning," BIO 1, ***the single sentence of the specification that constitutes respondents' entire case does not use the term "therapeutically effective."*** See Pet. App. 92a. It is a strange act of "lexicograph[y]" that defines one term by using a *different* term in a supposedly non-ordinary way.

The sentence on which respondents rely is set forth – without the bracketed numbers misleadingly inserted by the brief in opposition (at 5) – in the margin.[5] The passage discusses *why and how* the invention is "suitable for use" in "therapy procedures." It does not redefine – or even *use* – the term "therapeutically effective," the word "amount," or the phrase "therapeutically effective amount." There is no effort to redefine the critical phrase used in Claim 1 of the '422 patent.

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[5] "Similarly, to the extent that polypeptide products of the invention share the in vivo activity of natural EPO isolates they are conspicuously suitable for use in erythropoietin therapy procedures practiced on mammals, including humans, to develop any or all of the effects herefore attributed in vivo to EPO, e.g., stimulation of reticulocyte response, development of ferrokinetic effects * * *, erythrocyte mass changes, stimulation of hemoglobin C synthesis (see, Eschbach, et al., supra) and, as indicated in Example 10, increasing hematocrit levels in mammals." Pet. App. 88a.

Respondents misrepresent the opinion below when they say that "the centerpiece" of Judge Young's claim construction was a misreading of a single sentence in the specification. BIO 1, 4. The centerpiece, if there was one, was the undisputed plain and customary meaning of the term "therapeutically effective," which Judge Young – in effect standing in the shoes of a competent physician reading the patent – determined was not altered by anything in the patent or its prosecution history, properly understood. Pet. App. 75a-109a. Respondents acknowledge that the phrase must be given a "non-ordinary meaning" (BIO 1) for them to prevail, even as they point to a sentence that does not use the phrase as their only support for departing from its ordinary meaning.

Without the technical understanding that Judge Young gained, the specification's association of "therapy procedures" with a set of biological effects might suggest that the effects themselves are a type of therapy. BIO 5-6. But, as Judge Young found, that reading rested on "a *factually* incorrect" proposition. Pet. App. 90a (emphasis added).[6] Amgen's reading, by contrast, "comport[ed] with the Court's understanding – developed over the course of two intensive trials – of what hematocrit actually measures" (*id*. at 91a). Moreover, the court came to understand what the skilled worker knew – that the biological responses listed in the specification were precursors to a therapeutic effect, but in and of themselves provided no benefit to a patient. These are the very factual findings to which the Federal Circuit should have deferred.

Respondents' mantra is that Judge Young's reading of the sentence was "ungrammatical," BIO 1, 5, 6, 7, 8, but not even the panel majority went that far, and for good reason. Omitting "and" before the last item in a list following "e.g." is familiar

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[6] Respondents describe Judge Young's factual finding as "debatable." BIO 7 n.3. Choosing one of two "debatable" versions of facts, however, is exactly the function of trial proceedings, so respondents' assertion only helps prove petitioner's point. Respondents do not suggest that the finding was clearly erroneous. See Fed. R. Civ. P. 52(a).

shorthand, and hardly renders a reading so "tortured," *id*. at 7, that the need to avoid it trumps the understanding in the technical field.[7] Even if "simple rules of grammar" are "no less familiar to hematologists than * * * to federal judges," *id*. at 8, there was unrebutted testimony from a physician who agreed with Amgen's reading of the specification. 11/3/03 Tr. 658-659 (The sentence at issue "go[es] from the in vitro effects to the in vivo biologic effects and then increasing hematocrit levels, *both the biologic and eventually a therapeutic effect*. * * * So I think it shows an evolution of the use of erythropoietin, from in the laboratory to biological effects to, *finally to potential therapy*.") (emphasis added).

2. Respondents' approach to the doctrine-of-equivalents issue is equally mistaken. As an initial matter, respondents conceded below and do not here dispute that, contrary to the court of appeals' practice, the factual findings underlying a determination under *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), should be reviewed deferentially. See Pet. 11, 29-30. Nor do respondents contest that, if the panel *had* displayed appropriate deference, it would have affirmed. What respondents call a "fact-bound application," BIO 11, is really an aggressive foray into matters best left to the district court, subject to review for clear error.

Even on the merits, however, respondents are mistaken. Respondents argue that, because petitioner deleted an interim amendment claiming EPO with reference to the sequence of Figure 6 "or a fragment thereof," petitioner has surrendered its claim to *any* EPO with fewer than 166 amino acids. BIO 12. But that is exactly the kind of rigid approach to estoppel that has become the Federal Circuit's hallmark and that this Court

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[7] Moreover, without Judge Young's "bifurcation," the sentence has a much larger textual problem. As Judge Young pointed out, Pet. App. 90a, the phrase "in mammals" in the last item of the series would be redundant with "practiced on mammals" earlier in the sentence.

rejected in *Festo* and *Warner-Jenkinson* v. *Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). Pet. 27, 28.

Even though Judge Young construed the claim as not literally including the 165-amino-acid sequence, he recognized the triviality of the distinction between 165 and 166 amino acids. (In fact, Amgen's own product is a 165-amino-acid polypeptide.) And he recognized, too, that the reasons for the amendments at issue – to avoid redundancy with another patent – had *nothing to do with* the distinction between 165 and 166 amino acids. Respondents' contentions to the contrary, like the panel's, make the tangentiality rebuttal criterion unattainable because respondents focus, circularly, only on the *result* of the amendment – which logically *must* be related to the distinction at issue – rather than on the *reason* for the amendment, which may in fact bear only a tangential relation to the distinction between the literal terms of the claim and the equivalent.

Respondents' treatment of the "some other reason" exception is similarly flawed. Respondents first misleadingly suggest that petitioner focused only on how a skilled practitioner would read the claims, not the prosecution history. BIO 13. But, as petitioner explained, Judge Young determined that one of skill in the art would not understand the amendments in the prosecution history as surrendering a claim to EPO with 165 amino acids. See Pet. 9, 28. Moreover, in asking only whether petitioner *could have* claimed EPO with 165 amino acids, BIO 13-14, respondents (like the panel) read the reasonableness element out of this criterion and collapse it into the foreseeability test, which has never succeeded on appeal. Pet. 29. It is thus respondents, not petitioner, who render this Court's precedents "meaningless," BIO 13.

CONCLUSION

For the foregoing reasons and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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