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 HUMAN GENETIC THERAPIES, INC.),

Respondents.

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

BRIEF IN OPPOSITION

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BRIEF IN OPPOSITION

The decision below raises neither of the questions petitioner asks this Court to review. In its effort to demonstrate otherwise, petitioner misstates the basis of the district court's ruling on claim construction, and mischaracterizes the panel's ruling on prosecution history estoppel.

Petitioner asks this Court to overturn the Federal Circuit's *de novo* standard of review and mandate appellate deference to the "factual determinations" that supposedly underlie district court claim constructions because, petitioner asserts, district courts have "superior access" to "extrinsic evidence," including expert testimony, that "crucially inform[s]" such rulings. Pet. at i, 19. But, the district court's claim construction in this case did not rest on any "findings of fact," and the district court repeatedly *disavowed* reliance on expert testimony. The court did so because the meaning of the phrase "therapeutically effective" does not turn on "technological mastery" or "key insights" into the treatment of anemia, *id.* at 14, 19. Rather, its meaning turns on a sentence in the specification where, as a matter of simple grammar, the patentee expressly equated the phrase with certain biological effects of erythropoietin ("EPO").

The panel did not mistakenly believe that these biological effects are "sufficient[] to treat anemia," as petitioner wrongly claims. *Id.* at 21. Instead, the panel found that the patentee had acted as is own lexicographer and, in a critical sentence of the specification, had given the phrase "therapeutically effective" a non-ordinary meaning. Thus, while petitioner fulminates about the reversal of a "careful and scientifically well-informed district court" claim construction, *id.* at 2, the centerpiece of that construction was the district court's grammatically nonsensical revision of the plain language of the specification. No deference is owed to a district court's demonstrably artificial reading of a patent specification.

Consideration of this issue is also entirely premature. Petitioner cites law review articles and judicial statements criticizing *Cybor Corp.* v. *FATS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc), and challenges its *de novo* standard of review as inconsistent with decisions of this Court and the Federal Rules of Civil Procedures. Pet. at 15 & nn.5 & 6, 18 & n.8, 21-23. But petitioner launched no such attack on *Cybor* below. Now, after several judges have stated a willingness to re-examine *Cybor*, Pet. App. 596a, 602a, 606a, petitioner claims that the decision "is here to stay," Pet. at 16, and asks this Court to overrule it based on arguments never raised below. This Court should address the question, if at all, only after the full airing of views that en banc consideration affords, just as this Court has done when addressing other principles of patent law.[1]

Nor does the panel's application of prosecution history estoppel in this case merit review. This fact-bound ruling was entirely faithful to the principles established by this Court in *Festo*, and erected no insurmountable barriers to rebuttal of the presumption of estoppel. Petitioner's hyperbolic claims to the contrary are demonstrably incorrect. Certiorari should be denied.

1a. The central premise of the first question petitioner seeks to raise is that the district court's construction of the phrase "therapeutically effective" rested on factual "findings." To create this impression, petitioner stresses that Judge Young received "tutorials from an M.I.T. scientist, listened to 32 days of testimony from 35 scientists, and read countless pages of written submissions." Pet. at 19, see also *id.* at 5, 7. From this, petitioner claims, the judge developed a

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[1] The following landmark cases followed en banc consideration by the Federal Circuit: *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370 (1996), *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17 (1997), and *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).

"technological mastery" and "special familiarity" with the scientific field, *id.* at 14, that "crucially informed" his construction of the claim language. *Id.* at 19. "[D]rawing on all he had read, heard, and seen," *id.* at 14, petitioner claims that Judge Young made a "factual determination" that

> even though the specification associated certain biological changes with "therapy procedures" it would never occur to a *skilled practioner reading the specification* that (as the panel majority thought) an amount *merely* eliciting one of these changes would be a "therapeutically effective amount."

Id. at 21. Indeed, petitioner claims that Judge Young himself "repeatedly emphasized that his conclusions were informed by the expert testimony and his familiarity with the technology." *Id.* at 7-8.

Judge Young's decision flatly refutes this fanciful portrayal. In fact, he repeatedly emphasized that he was *not* relying on expert testimony or demonstrative exhibits to construe the claims. He explained that "[d]emonstrative exhibits were presented and references were made to expert testimony [during the *Markman* hearing], but extrinsic evidence was *not admitted*." Pet. App. 69a (emphasis added). This was because expert testimony "is extrinsic evidence to which resort ought to be had only *if necessary*." *Id.* at 76a (internal quotation marks omitted); see also *id.* at 81a n.25 (same); *id.* at 86a n.28 ("the Court cannot rely on expert testimony to help construe the term 'therapeutically effective' unless absolutely necessary"). And Judge Young made clear that it was not necessary to resort to such evidence. He stressed that, "[w]hile the expert testimony does support the plain and ordinary meaning of the term, . . . the Court *will not rely on it to construe the claim*." *Id.* at 85a n.27 (emphasis added). Instead, he used "extrinsic evidence . . . to understand the technology—*not to define the term*" "therapeutically effective." *Id.* at 89a n.29 (emphasis added). See also *id.* at 111a n.47 (noting that reliance on expert

testimony would have been "an alternate" interpretive route, which he had not employed). This is why, in its brief to the panel below, petitioner did not argue that Judge Young's claim construction was "crucially informed by . . . extrinsic evidence," Pet. at 19, and instead repeatedly stressed that he had properly and "carefully review[ed] the *intrinsic* record."[2]

Petitioner now quotes selectively and misleadingly from the opinion to try to show that, despite his statements and petitioner's own concession below, Judge Young did rely on expert testimony to construe the claims. Petitioner claims that the judge's claim construction "was based on [1] 'a careful review of the technology and its history' that [2] 'relied on extrinsic evidence,'" and that "his conclusions were informed by his [3] 'understanding of the technology.'" Pet. at 20. In the passage from which these three excerpts are lifted, however, Judge Young was not explaining his claim construction conclusions at all. He was rejecting *petitioner's argument* that, if "therapeutically effective" means the *in vivo* biological effects of EPO, two claims of a different patent would be redundant. Pet. App. 84a. In this very discussion, moreover, Judge Young emphasized, twice, that he was not relying on expert testimony "to construe the claim," but to understand the technology, *id.* at 84a-85a n.27, which illuminated the flaw in petitioner's redundancy argument.

More fundamentally, petitioner's misleading excerpts have nothing to do with the centerpiece of Judge Young's ruling—and the central flaw the panel majority identified in it. Because a patentee can serve as his or her own lexicographer and give terms non-ordinary meanings, Judge Young recognized that he had to make two determinations: "[w]hat is the plain and ordinary meaning of 'therapeutically effective,' and does the intrinsic evidence define the term differently than its plain and ordinary meaning?" Pet. App. 76a n.22.

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[2] Br. of Plaintiff-Appellee, Amgen Inc. at 12, No. 05-1157 (Fed. Cir. filed May 17, 2005) (emphasis added); *see also id.* at 16, 19, 28.

Petitioner tried to rely on expert testimony before Judge Young to show what the plain meaning of the term was. See *id.* at 72a, 76a. But the critical error the panel identified in Judge Young's claim construction concerned the second determination—his conclusion that the patentee did not give the phrase "therapeutically effective" a non-ordinary meaning in the specification. In so ruling, Judge Young made no "factual determination" about how skilled practioners would read the specification, cf. Pet. at 21. Instead, his conclusion rests on a grammatically nonsensical reading of a critical sentence in the specification.

That sentence provides that:

> "to the extent that the 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., [1] stimulation of reticulocyte response, [2] development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), [3] erythrocyte mass changes, [4] stimulation of hemoglobin C synthesis (see, Eschbach, et al., supra) and, [5] as indicated in Example 10, increasing hematocrit level in mammals."

Pet. App. 88a (emphases added and deleted).

The panel in the first appeal observed that this language appears to teach that all five of the listed responses are encompassed by the term "therapeutically effective," *id.* at 400a-01a, even though only a sustained increase in hematocrit actually cures disease. On remand, Judge Young conceded that "use of the words 'therapy procedures' supports the interpretation that a 'therapeutically effective amount' encompasses an amount that would result in the biological effects" listed, whether or not they heal or cure. *Id.* at 90a; see also *id.* at 89a (the specification "suggests" that "the

biological effects[] are a type of effective therapy"). But Judge Young rejected this clear meaning. He read the specification, in the following artificial manner, to describe the claimed EPO as "'conspicuously suitable for'":

> (a) "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, . . ." *and*,
>
> (b) "as indicated in Example 10, increasing hematocrit level in mammals."

Id. at 89a (ellipses in original). So viewed, he believed, the specification explains that the claimed EPO elicits "'any or all' of the effects that natural EPO does—*and more*." *Id.* at 90a (emphasis added).

As a matter of basic grammar, this reading is utterly untenable. The sentence identifies "any or all" of the five biological effects as "effects' of "therapy procedures." The patentee easily could have said that the claimed composition is suitable for use in therapy because, in addition to eliciting all of the non-curative biological effects of natural EPO, it elicits something more—a sustained increase in hematocrit levels. But the sentence manifestly does not say this. Nor does it "make[] clear that 'any or all' only modifies those effects previously attributed to natural EPO." *Id.* The phrase "any or all" plainly modifies all five of the listed effects. Judge Young's "reading" of this key sentence is not an interpretation of it at all; his "reading" re-writes the sentence.

Moreover, Judge Young's attempt to bifurcate, and thereby re-write, the sentence produces a clear grammatical error. As noted above, the specification lists five effects previously attributed *in vivo* to EPO: "[1] stimulation of reticulocyte response, [2] development of ferrokinetic effects . . . [3] erythrocyte mass changes, [4] stimulation of hemoglobin C synthesis (see, Eschbach, et al., supra) and, [5] as indicated in Example 10, increasing hematocrit level in mammals." *Id.* at

88a (emphasis omitted). If the patentee intended to create two distinct categories, there should be an "and" before the fourth effect, which, under Judge Young's "reading," is the last of the effects listed in the first category. As this Court has explained when addressing a similar attempt to re-write (through "interpretation") a similarly structured sentence, courts should eschew interpretations of binding legal instruments that produce such ungrammatical omissions. See *Arcadia, Ohio* v. *Ohio Power Co.*, 498 U.S. 73, 79 (1990) (rejecting interpretation of statute for this reason).

Just as important, the sentence, even when bifurcated, still does not exclude the listed biological effects of natural EPO from the roster of therapeutic effects. The first part of the bifurcated sentence still states that petitioner's product is "'conspicuously suitable for use in erythropoietin *therapy procedures* . . . to develop any or all of the effects'" listed in Judge Young's first category. Pet. App. 88a. By referring to the biological effects of natural EPO as effects of "therapy procedures," the specification inescapably deems these effects therapeutic, as Judge Young acknowledged. *Id.* at 90a.

No deference is owed to this tortured and ungrammatical reading of the specification, which, as the panel majority correctly explained, rests on an "artificial distinction between the first four effects listed . . . and the fifth effect." *Id.* at 14a. Judge Young plainly did not rest that reading on any "factual finding" about how "skilled practitioners" would read the sentence. In fact, he never refers to "skilled pracitioners" or a "person of ordinary skill in the art" anywhere in his lengthy discussion of the specification. See *id.* at 87a-97a.[3] And,

[3] In analyzing the specification, Judge Young referred briefly to extrinsic evidence, again "not to define the term," Pet. App. 89a n.29, but to support his statement that the natural reading of this key sentence led to a mistake: increased hematocrit levels, he stated, were not previously attributable to natural EPO. *See id.* at 89a-90a. This "mistake" is debatable: natural EPO isolates did increase hematocrit, but did not lead to *sustained* increases, something the specification does not identify as a

while petitioner baldly asserts that it "would never occur to a *skilled practioner reading the specification* that . . . an amount *merely* eliciting one of these changes would be a 'therapeutically effective amount,'" such a reading is compelled by simple rules of grammar, which are no less familiar to hematologists than they are to federal judges.

Nor is it true that the panel majority failed to appreciate a scientific principle that Judge Young gleaned from tutorials and expert testimony—*i.e.*, that the first four effects listed in the specification's key sentence are "early indicators of red blood cell generation [that] are necessary, but not sufficient, to treat anemia." Pet. at 21. The panel majority below nowhere suggested that it thought these "early indicators" were healing or curative. To the contrary, it concluded that the patentee had deemed certain biological effects "therapeutic" even though "[t]hose effects do not *necessarily* include curing disease." Pet. App. 15a.

In short, this case provides no opportunity for the Court to address the first question the petition purports to present. The district court's claim construction does not rest on factual determinations "crucially informed" by expert testimony or other extrinsic evidence to which district courts have superior access. It rests on a manifestly ungrammatical and untenable re-writing of a key sentence in the specification. The legal issue petitioner urges this Court to address, therefore, can have no effect on the judgment in this case. Even under the "clearly erroneous" standard of review petitioner advocates,

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previous effect. But even if the specification did erroneously identify an increase in hematocrit as an effect of natural EPO isolates, that would not justify Judge Young's re-writing of the sentence. First, another mistake lies at the very "heart of [petitioner's] invention," *id.* at 242a, *i.e.*, that mature EPO has a 166-amino acid sequence. Second, and more fundamentally, if it is factually inaccurate to state that increasing hematocrit was an effect previously attributed to EPO isolates, that inaccuracy is not avoided by Judge Young's re-writing of the sentence, which, even as he bifurcates it, still describes "increasing hematocrit" as an effect previously attributed to EPO isolates.

no deference would be owed the district court's tortured "reading" of the specification.

b. Not only is this issue not presented, but consideration of the issue is entirely premature. Petitioner launches a broad-based attack on the *Cybor* decision, citing criticisms of it by law reviews and members of the Federal Circuit, and claiming that its *de novo* standard of review conflicts with Rule 52 of the Federal Rules of Civil Procedure as well as with this Court's decisions in *Markman*, *Dennison Manufacturing Co.* v. *Panduit Corp.*, 475 U.S. 809 (1986) and *Graham* v. *John Deere Co. of Kansas City*, 383 U.S. 1 (1996). Pet. at 15 & nn.5 & 6, 18 & n.8, 21-23. But petitioner launched no such attack on *Cybor* below, and this Court should not be the first to entertain these arguments.

As noted, before the panel, petitioner did not advocate deference to a fact-based claim construction. Rather, it argued that Judge Young had properly construed the claim based on his review of the intrinsic record. Nor did petitioner challenge *Cybor* in its petition for rehearing en banc. It simply noted that *Markman* did not establish a standard of review and argued that *Cybor* itself required "[s]ome measure of appellate respect" for district court claim constructions.[4] Petitioner did not mention any of the law review articles it cites now. It did not cite or mention Rule 52 or the decisions in *Dennison* or *Graham*. And it identified no conflict between *Cybor* and *Markman*.

Despite these failures, several members of the Federal Circuit expressed a willingness to re-examine *Cybor*. Pet. App. 596a, 602a, 606a. Those expressions flatly belie petitioner's claim that *Cybor* "is here to stay." Pet. at 16. In light of that willingness, moreover, this Court should not entertain review of an important precedent based on

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[4] Plaintiff-Appellee, Amgen Inc.'s Combined Petition for Panel Rehearing and Rehearing *En Banc* at 12-13, No. 05-1157 (Fed. Cir. filed Aug. 17, 2006).

arguments never raised below. Instead, it should address the issue, if at all, only with the benefit of the full airing of views that en banc consideration affords.

This is particularly true given the facile nature of many of petitioner's attacks on *Cybor*. Petitioner claims, for example, that the "factual findings" underlying claim constructions are indistinguishable from those that underlie obviousness determinations, and should be subjected to the same clearly erroneous standard of review. Pet. at 18, 21. But this case underscores the questionable nature of this analogy. Federal judges have no independent ability to determine the scope and content of prior art, the differences between prior art and a claimed invention, the level of ordinary skill in the pertinent art, or what the prior art would "teach" to a person of such skill. See *Graham*, 383 U.S. at 17. But federal judges are fully competent to apply the rules of grammar, and there is no reason to suppose that persons of skill in a particular scientific field employ different grammatical rules, or would simply ignore such rules.

Indeed, in *Markman* itself, this Court recognized that the credibility of experts would typically be "subsumed within the necessarily sophisticated analysis of the whole document, required by the standard construction rule that a term can be defined only in a way that comports with the instrument as a whole." 517 U.S. at 389. In this case, for example, if an expert had claimed that no skilled practitioner would read the specification's key sentence to deem non-curative effects therapeutic, that testimony would not have been credible for the same reasons Judge Young's "reading" is incorrect. A "factual finding" based on such testimony should not be entitled to deferential review. Petitioner's suggestion, therefore, that there is no meaningful difference between claim constructions and obviousness determinations is mistaken.

Thus, while petitioner seeks to portray *Cybor*'s *de novo* standard of review as a failed experiment that has been

"lambasted for years by bench, bar and academy," Pet. at 2, there are strong reasons to doubt this critique and, as this case demonstrates, equally strong reasons to doubt the wisdom of the highly deferential standard of review petitioner advocates. Even in a case that squarely presented the question petitioner seeks to raise, these reasons would militate against review in the absence of en banc consideration. Here, where the question is not even presented, they simply underscore why review should be denied.

2. The panel's straightforward and fact-bound application of the prosecution history estoppel principles this Court established in *Festo* likewise raises no issues worthy of review. Indeed, there was no dissent from this part of the panel decision, and petitioner did not even mention it in its petition for rehearing and rehearing en banc. In seeking review of that ruling now, petitioner repeatedly mischaracterizes the decision below.

Petitioner claims that the panel's decision announces a "near abolition of the doctrine of equivalents in any case in which a patent has been amended," by converting *Festo*'s second basis for rebutting the presumption of estoppel into a "circular and insurmountable" barrier, and "destroy[ing] the residual *Festo* criterion." Pet. at 26, 28 (capitalization altered; internal quotation marks omitted). Even the most cursory reading of the panel decision refutes these hyperbolic claims. Far from announcing any sweeping standards, the panel undertook a careful and detailed examination of the file wrapper, petitioner's extrinsic evidence, the district court's reasoning and petitioner's arguments on appeal. Pet. App. 25a-40a. In finding that *Festo*'s exceptions did not apply, the panel announed no new rules or principles, nor any hostility towards the doctrine of equivalents.

Petitioner contended that it added a reference to "Figure 6" (which reflects an EPO with 166 amino acids) in order to limit the claims of its '080 patent to human EPO and thereby avoid a double-patenting rejection in light of another of its

patent ("the '933 patent"). The panel properly rejected this argument for two reasons. First, it explained that, in an interim amendment, petitioner had limited these claims to EPO with the 166 amino acids of Figure 6 "'or a fragment thereof.'" Pet. App. 37a. This amendment literally embraced defendants' 165-amino acid product, but did not avoid double-patenting, because "an incomplete amino sequence of Figure 6 (a 'fragment') was encompassed by both [petitioner's] application and the '933 patent." *Id.* Petitioner therefore deleted the phrase "or fragment thereof" to overcome the double-patenting problem. The panel correctly held that, where an amendment surrendering sequences of less than 166 amino acids was "central to the allowance" of the claims-in-suit, a claimed equivalent of 165 amino acids was not merely "tangential" to the purpose of the amendment. *Id.* at 37a-38a.

Petitioner is simply wrong in asserting that its need to avoid duplication has no significant relationship to the distinction between 165 and 166 amino acids. Petitioner chose to seek two distinct legal monopolies, the '933 and '080 patents; to do so, it agreed to limit the claims of the latter to products with 166-amino acids. Petitioner sued respondents under its other monopoly, the '933 patent, but the claims of the '933 patent asserted against respondents have been declared invalid. Petitioner now seeks to disavow the limits to which it agreed in order to obtain its second patent, the '080, and to reclaim, through the doctrine of equivalents, what it purposely surrendered in order to get two patents. This is a paradigmatic situation for use of prosecution history estoppel, and its application on these facts erects no "insurmountable" barrier to use of the doctrine of equivalents in future cases.

Second, the panel properly rejected petitioner's assertion concerning the "pupose" of the amendment. Petitioner argued that it sought to limit the claims of the '080 patent to "human" EPO. But it is undisputed that, when it added the reference to Figure 6, petitioner knew that mature human

EPO did not have 166-amino acids. Moreover, in interim amendments, petitioner added the word "human" when referring to EPO, but then deleted that language from the claims. In light of these facts, the panel correctly ruled that the purpose of an amendment specifying 166 amino acids was not to limit the claims to "human" EPO. *Id.* at 38a. This ruling, which is inherently fact-bound, "erect[s] [no] roadblock across the most important avenue for avoiding estoppel." Pet. at 28.

Finally, while petitioner accuses the panel of destroying *Festo*'s residual, "some other reason" exception, it is petitioner that proposes a radical, and improper, new role for this exception. Even though petitioner *knew* when it amended its claims that mature human EPO has 165, not 166, amino acids, petitioner claimed that it could not have reasonably been expected to claim a 165-amino-acid sequence because those skilled in the art would have interpreted the reference to the 166 sequence of Figure 6 to encompass a 165-amino acid equivalent. As the panel recognized, this turns the concept of estoppel on its head.

The relevant inquiry is not whether skilled practitioners reading claims to a polypeptide with 166 amino acids would assume it covered polypeptides with 165 amino acids. The question is whether such a person who reviewed the file wrapper and saw that petitioner deleted references to "human" EPO and "fragments" of a 166-amino acid sequence would think that the patentee nevertheless intended to claim a mature human EPO sequence of 165 amino acids. The answer to that question is obviously no unless the patentee comes forward with "some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Festo*, 535 U.S. at 741. If a patentee can simply assert that he did not think he needed to bother to claim a known substitute because it was an obvious equivalent, then the principle of prosecution history estoppel is rendered meaningless. Because Amgen

knew of the equivalent, "could have simply claimed mature human EPO," but "still chose to claim the incorrect 166-amino acid sequence," it had failed to meet *Festo*'s third exception. Pet. App. 39a-40a. That ruling is plainly correct, and raises no issues warranting this Court's attention.

CONCLUSION

For all of the foregoing reasons, the petition should be denied.

Respectfully submitted,

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