United States Court of Appeals for the Federal Circuit

05-1157

AMGEN INC.,

Plaintiff-Appellee,

v.

HOECHST MARION ROUSSEL, INC.
(now known as Aventis Pharmaceuticals Inc.)
and TRANSKARYOTIC THERAPIES, INC.,

Defendants-Appellants.

Lloyd R. Day, Jr., Day Casebeer Madrid & Batchelder LLP, of Cupertino, California, filed a combined petition for panel rehearing and rehearing en banc for plaintiff-appellee. With him on the petition were Edward M. O'Toole, McCracken & Frank, of Chicago, Illinois; Michael F. Borun, Marshall, Gerstein & Borun LLP, of Chicago, Illinois; and Stuart L. Watt, Amgen Inc., of Thousand Oaks, California.

Carter G. Phillips, Sidley Austin LLP, of Washington, DC, filed a response to the petition for defendants-appellants. With him on the response was Joseph R. Guerra.

Appealed from: United States District Court for the District of Massachusetts

Judge William G. Young

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Defendants-Appellants.

ON PETITION FOR PANEL REHEARING
AND REHEARING EN BANC

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, Circuit Judges, CLEVENGER, Senior Circuit Judge,[*] RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges.

O R D E R

A combined petition for panel rehearing and rehearing en banc was filed by the Appellee, and a response thereto was invited by the court and filed by the Appellants. The petition for rehearing was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition for panel rehearing is denied.

[*] Senior Judge Clevenger, who was on the original panel, participated only in decision on the petition for panel rehearing.

(2) The petition for rehearing en banc is denied.

(3) The mandate of the court will issue on November 29, 2006.

MICHEL, Chief Judge, with whom RADER, Circuit Judge, joins, dissents in the denial of the petition for rehearing en banc in a separate opinion.

NEWMAN, Circuit Judge, dissents in the denial of the petition for rehearing en banc in a separate opinion.

LOURIE, Circuit Judge, concurs in the denial of the petition for rehearing en banc in a separate opinion.

RADER, Circuit Judge, dissents in the denial of the petition for rehearing en banc in a separate opinion.

GAJARSA, Circuit Judge, with whom LINN, and DYK, Circuit Judges, join, concur in the denial of the petition for rehearing en banc in a separate opinion.

MOORE, Circuit Judge, dissents in the denial of the petition for rehearing en banc in a separate opinion.

FOR THE COURT

_____ _____

Date Jan Horbaly
Clerk

cc: Lloyd R. Day, Jr., Esq.
Carter G. Phillips, Esq.

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(now known as Shire Human Genetic Therapies, Inc.),

Defendants-Appellants.

MICHEL, Chief Judge, and RADER, Circuit Judge, dissenting from the denial of the petition for 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. I have come to believe that reconsideration is appropriate and revision may be advisable.

In my view, four practical problems have emerged under the Markman-Cybor regime: (1) a steadily high reversal rate; (2) a lack of predictability about appellate outcomes, which may confound trial judges and discourage settlements; (3) loss of the comparative advantage often enjoyed by the district judges who heard or read all of the evidence and may have spent more time on the claim constructions than we ever could on appeal; and (4) inundation of our court with the minutia of construing numerous disputed claim terms (in multiple claims and patents) in nearly every patent case.

Our standard of review of no deference to the trial judge's claim constructions, expressed in Cybor, rests upon the premise that claim construction is always a purely legal exercise, devoid of factual content. We have likened claim construction to statutory construction. I believe that this analogy is open to serious question. 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?"

It seems to me that the claim construction question often cannot be answered without assessing, at least implicitly, what the average artisan knew and how she thought about the particular technology when the patent claims were written. To make such determinations, the trial judge necessarily relies upon prior art documents and other evidence concerning the skill of the ordinary artisan at the relevant time. Indeed, trial judges are arguably better equipped than appellate judges to make these factual determinations, especially in close cases. In such instances, perhaps we should routinely give at least some deference to the trial court, given its greater knowledge of the facts. Or, perhaps other adjustments to our current practice should be considered.

Whatever our resolution, however, I believe the time has come for us to re-examine Cybor's no deference rule. I hope that we will do so at our next opportunity, and I expect we will.

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Defendants-Appellants.

NEWMAN, Circuit Judge, dissenting from denial of the petition for rehearing *en banc*.

The issue for rehearing *en banc* is the Federal Circuit's rejection of the district court's construction of the claim term "a therapeutically effective amount." My concern is with this court's methodology and rationale of claim construction, and with the sources on which the panel majority relied (or failed to rely) in arriving at its changed claim construction. The district court had correctly applied this court's precedent, requiring affirmance.

I

In brief, the panel majority construed the claims more broadly than the invention that was patented; thus the court ignored the patentee's purpose of writing claims that avoid the prior art -- a purpose essential to every claim in every patent -- by now construing the claims so that, as the panel majority recognized, they may read on the prior art. The

patentee's purpose of including the critical limitation to "a therapeutically effective amount" of the genetically engineered erythropoietin (EPO) was to distinguish the prior art EPO isolates, which were not therapeutically effective to "heal or cure," in the district court's words. Thus this court's claim construction diverges from the specification and the prosecution history, and presents a claim construction that impinges on the prior art and thereby fosters invalidity. From this analytic method of claim construction and the denial of rehearing *en banc* I must, respectfully, dissent.

The methodology of claim construction that the court has here adopted raises issues that were laid to rest in Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005), where the *en banc* court disavowed the view that a patent claim can be construed more broadly than the invention to which it gives legal effect. In Phillips that unwarranted breadth was found in claim construction based on general dictionary definitions of claim terms, rather than relying on the specific technical usage in the specification; in this case the unwarranted breadth is found in the court's claim construction that may embrace the prior art, despite the exclusion of that subject matter by the prosecution history.

The district court, construing the claims in light of the specification and the prosecution history, construed "a therapeutically effective amount" as "a quantity that produces a result that in and of itself helps to heal or cure." That construction was the basis on which the patentee distinguished its genetically engineered EPO from the chemically identical EPO in known isolates of naturally occurring EPO, for the prior art product contained insufficient EPO to heal or cure. Thus the claim limitation to "a therapeutically effective amount" of EPO was critical to allowance. During an extensive prosecution, the applicant stated that

> naturally occurring human erythropoietin is not a viable human therapeutic product; human recombinant erythropoietin, on the other hand, has been proven to be clinically effective, and is the first therapeutic product which can be used to effectively treat the hundreds of thousands of patients who suffer from anemia and other disorders involving low blood counts.

App. No. 113,178, Amendment under Rule 16 at 4, June 5, 1989 (emphasis in original).

The record in the district court contains evidence, presented by persons experienced in this field of science, that the limitation to "a therapeutically effective amount" distinguishes the genetically engineered EPO from known EPO isolates. The district court construed the claims from the viewpoint of the skilled artisan, upon reading and understanding the specification and the restrictions flowing from the prosecution history. My concern about this court's methodology is that the panel majority does not apply these standard tools of claim construction. The court's holding that "a therapeutically effective amount" includes any amount of EPO that exhibits a physiologic effect, whether or not the amount of EPO is adequate to provide therapy for any disorder, imparts to the claims the scope that was excluded during prosecution.

Although this court has urged caution in construing claims in order to preserve their validity, no precedent or logic requires that when more than one claim construction is available, the court must choose the broader one although it may invalidate the claim. See Phillips, 415 F.3d at 1327 (court may not construe claims as would be appropriate to preserve their validity unless "after applying all the available tools of claim construction . . . the claim is still ambiguous"); see also Smith v. Snow, 294 U.S. 1, 14 (1935) ("if the claim were fairly susceptible to two constructions, that should be adopted which will secure to the patentee his actual invention"); Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1556 (Fed. Cir. 1996) ("When claims are amenable to more than one

construction, they should when reasonably possible be interpreted so as to preserve their validity.").

Here, the specification and prosecution history make clear that the claimed invention is the "therapeutically effective amount" of engineered recombinant EPO. As was explained to the patent examiner and again in the district court, the prior art isolates of EPO were ineffective to heal or cure. Just as the prosecution record cannot enlarge the claims beyond what the inventor has presented as his invention, so the court cannot enlarge the claims beyond the limitations imposed by the patentee. See Phillips, 415 F.3d at 1319 (rejecting definitions broader than the technical usage specific to the invention). The court in this case has departed from these fundamental principles. We should speak *en banc* to clarify that it is appropriate, and necessary, to look at what has in fact been invented, prosecuted, and patented, and construe the claims accordingly.

II

I do not share the view, expressed here by some colleagues, that this court should not intrude upon panel decisions when major errors of claim construction are pointed out on petition for rehearing *en banc*. The Federal Circuit has a special obligation to provide predictability and consistency in patent adjudication, for our panel decisions are of nationwide effect; indeed, this obligation was a justification for the court's holding, a decade ago, that the district court's claim construction receives non-deferential review on appeal. This appellate position imposes on us the obligation to state the correct law, even on rehearing *en banc*. If the meaning of "therapeutically effective amount" is treated as a question of law, its correct definition as well as the methodology by which it is defined are squarely within the criteria for rehearing *en banc*. And if the meaning is recognized as a

case-specific finding of fact, appellate review warrants deference to the trier of fact, a deference here lacking.

III

I continue to believe that findings of science/technology-based facts in patent cases should receive appellate review on the same basis as other science-based findings, guided by Daubert and the Court's ensuing elaborations. The Court's and our own precedent require the trial judge to evaluate scientific evidence and expertise from the viewpoint of a person experienced in the field of science, a framework that aptly fits evaluation of the technologic content and scope of patents, an analysis whose intermingling of fact and law is well served by the procedures and the adjudicatory skill of the district courts. The Federal Circuit's position that patent interpretation requires more rigorous appellate review than other fact/law issues has not well withstood the test of experience. It is time to reopen the question and to rethink, *en banc*, the optimum approach to accuracy, consistency, and predictability in the resolution of patent disputes, with due attention to judicial structure, litigants' needs, and the national interest in invention and innovation.

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Defendants-Appellants.

LOURIE, Circuit Judge concurring.

I concur in the decision of the court not to rehear this case en banc. I do so, even though I agree that the panel erred in construing the claim limitation "a therapeutically effective amount." In my view, the panel dissent by Chief Judge Michel was correct, as was the decision by the district court and the current dissent by Judge Newman. However, I do not believe that every error by a panel is enbancable. A panel is entitled to err without the full court descending upon it.

Federal Rule of Appellate Procedure 35(a) provides that "[a]n en banc hearing or rehearing is not favored and ordinarily will not be ordered unless: (1) en banc consideration is necessary to secure or maintain uniformity of the court's decisions; or (2) the proceeding involves a question of exceptional importance." Our Internal Operating Procedures ("IOPs") state that "[a]mong the reasons for en banc actions are: (1) necessity of securing or maintaining uniformity of decision; (2) involvement of a question of exceptional importance; (3) necessity of overruling a prior holding of this or

a predecessor court expressed in an opinion having precedential status; or (4) the initiation, continuation, or resolution of a conflict with another circuit." IOP 13(2).

This issue is thus enbancable only on the uniformity or exceptional importance grounds. However, the interpretation of "a therapeutically effective amount" with respect to this particular patent specification seems to me to be case-specific, and it does not therefore raise a question of uniformity of decision or exceptional importance. The term, while in my view incorrectly construed by the majority of the panel, does not necessarily apply to specifications of other patents. In addition, while the result may be of exceptional importance to the parties, it does not seem to be so to the law.

I therefore concur in the decision of the court not to rehear the case en banc, although I disagree with the majority's holding.

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Defendants-Appellants.

RADER, Circuit Judge, dissenting from denial of the petition for rehearing en banc.

I agree with the reasoning of Chief Judge Michel's and Judge Newman's dissents. Like them, I urge this court to accord deference to the factual components of the lower court's claim construction. Under current law, this court accords no deference whatsoever to a district court's claim construction. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1451, 1455-56 (Fed. Cir. 1998) ("[C]laim construction, as a purely legal issue, is subject to de novo review on appeal."). The Supreme Court recognized that, far from a "purely legal issue," claim construction "falls somewhere between a pristine legal standard and a simple historical fact." Markman v. Westview Instruments, Inc., 517 U.S. 370, 388 (1996).

Quoting the Supreme Court, this court agreed with the Supreme Court's recognition that "the fact/law distinction at times has turned on a determination that, as a matter of sound administration of justice, one judicial actor is better positioned than another to decide the issue in question." Cybor, 138 F.3d at 1455. In this case, the

district court's analysis of "therapeutically effective amount" deserved greater deference. As is often the case, the district court was better positioned than this court to reach the proper construction. After all the district court has more tools, more time, and more direct contact with factual evidence than this appellate body. Id. at 1477 (Rader, J., dissenting) ("Trial judges can spend hundreds of hours reading and rereading all kinds of source material, receiving tutorials on technology from leading scientists, formally questioning technical experts and testing their understanding against that of various experts, examining on site the operation of the principles of the claimed invention, and deliberating over the meaning of the claim language. If district judges are not satisfied with the proofs proffered by the parties, they are not bound to a prepared record but may compel additional presentations or even employ their own court-appointed expert."). Indeed, in this case, the trial court held a nine-day trial, including testimony of artisans informed of the meaning of "therapeutically effective amount" at the time of invention. The trial court, while noting that it did not rely on expert testimony to construe the claim, specifically noted that such testimony offered during the trial fully supported the district court's claim construction. Given this court's rule toward limited reliance on extrinsic evidence in claim construction, Forest Labs., Inc. v. Abbott Labs., 239 F.3d 1305, 1311 (Fed. Cir. 2001) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 (Fed. Cir. 1996)), district court judges have learned to disclaim any reliance on expert testimony. Yet, in this case the trial court took testimony for nine days – hardly necessary if the judge was merely reading and relying upon the intrinsic patent document alone.

The district court's construction of "therapeutically effective amount" also falls in line with prior opinions of this court and suggests that artisans in this field would accord the term its customary usage. Geneva Pharm. v. GlaxoSmithKline, 349 F.3d 1373, 1383 (Fed. Cir. 2003) (finding that "effective amount" is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite); Abbott Labs. v. Baxter Pharm. Prods., Inc., 344 F.3d 1274, 1278 (Fed. Cir. 2003) (Because the patentee did not deviate from the accustomed meaning of the disputed claim term, the term "effective amount" is construed in view of its ordinary and customary meaning). Thus, I would grant en banc review.

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Defendant-Appellants.

GAJARSA, LINN and DYK, Circuit Judges, concurring in the denial of the petition for rehearing en banc.

We concur in the denial of rehearing en banc. Our concurrence should not be read as an endorsement of the panel's claim construction in this particular case, nor as an unqualified endorsement of the en banc decision in Cybor Corp v. FAS Techs., Inc., 138 F.3d 1448 (Fed. Cir. 1998). In an appropriate case we would be willing to reconsider limited aspects of the Cybor decision. In our view an appropriate case would be the atypical case in which the language of the claims, the written description, and the prosecution history on their face did not resolve the question of claim interpretation, and the district court found it necessary to resolve conflicting expert evidence to interpret particular claim terms in the field of the art. This is not such a case.

In this case the district court explicitly and repeatedly disavowed reliance on extrinsic expert evidence in construing the claim term "therapeutically effective." The district court noted that "[d]emonstrative exhibits were presented and references were made to certain expert testimony, but extrinsic evidence was not admitted." Amgen Inc. v. Hoechst Marion Roussel, Inc., 339 F. Supp. 2d 202, 222 (D. Mass. 2004). Ultimately, the district court concluded:

> While the expert testimony does support the plain and ordinary meaning of the term since it defines what 'cure' means in the context of anemia patients, the Court will not rely on it to construe the claim, because even the Altiris [Inc. v. Symantex Corp., 318 F.3d 1363 (Fed. Cir. 2003)] court made clear that it was looking to expert testimony merely to understand the technology—not to construe the term itself.

Amgen, 339 F. Supp. 2d at 230 n.27; see id. at 233 n.29 (noting that extrinsic evidence was not being used "to define the term").[1]

The district court proceeded to construe the claim "therapeutically effective" without resort to extrinsic expert evidence. It first "look[ed] to the plain and ordinary meaning of the words of the patent claim," id. at 229, then "review[ed] the specification to determine whether the patentee has used terms in a manner inconsistent with the ordinary meaning or has become his own lexicographer," id. at 232, and finally "consider[ed] the prosecution history to determine whether the applicant ha[d] made any express representations regarding the claim's scope," id. at 238. No deference is due a district court's legal interpretation of the claim language, written description, and prosecution history that an appellate court is equally competent to interpret.

[1] See also id. at 226 (noting that expert testimony "is extrinsic evidence to which resort ought to be had only 'if necessary'"); id. at 231 n.28 ("[T]he Court cannot rely on expert testimony to help construe the term 'therapeutically effective' unless absolutely necessary.")

Since the district court did not rest its interpretation on factual findings concerning conflicting expert evidence and neither the panel majority nor the dissent addressed this issue, we do not believe that this is the appropriate case in which to reconsider aspects of the Cybor decision.

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MOORE, Circuit Judge, dissenting from the denial of the petition for rehearing en banc.

I dissent from this court's denial of the petition for rehearing en banc. First, let me begin by saying that under the court's present standard of de novo review, in my opinion the district court's construction of "a therapeutically effective amount" was correct. I need not articulate all the reasons that the claims, specification, prosecution history, and extrinsic evidence all support the interpretation given by the district court—the district court's own opinion and the panel dissent by Chief Judge Michel effectively do so. If the only issue were one of case-specific mistake, I would concur in the decision not to hear the case en banc. Federal Rule of Appellate Procedure 35(a) and our Internal Operating Procedures limit the use of en banc.

I dissent because I believe this court should have taken this case en banc to reconsider its position on deference to district court claim construction articulated in Cybor Corp. v. FAS Tech., Inc., 138 F.3d 1448, 1454-55 (Fed. Cir. 1998) (holding that claim construction was purely a matter of law and therefore subject to de novo review). Five judges of this court have written opinions in this case expressing disagreement

with the two judge panel majority's claim construction even under the de novo standard of review.

In this case, the district court construed the term "a therapeutically effective amount" with the assistance of a technical advisor (an MIT Professor) and a Special Master. The district court opinion explains that the term was construed using the patent claims, the specification, the prosecution history, three different dictionaries, and prior art.[1] The opinion also explains that the claim construction is supported by the expert testimony presented by the parties in this case,[2] but then disavows using it to "define the term" or "construe the term" instead stating that it is being used to "understand the technology."[3]

I commend the district court for its thorough, detailed, thoughtful, and competent efforts in construing this claim limitation. The district court did everything we have asked it to do, and in my opinion, did it correctly. While this may not be a basis for taking the case en banc, reconsideration of the deference accorded to the district court in this case would have been. Therefore, I would grant en banc review.

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[1] Dictionaries, technical treatises, and prior art disclosures are extrinsic evidence relied upon by the district court to construe this term. See Amgen, Inc. v. Hoechst Marion Roussel, Inc., 339 F. Supp.2d 202, 226-228 (D. Mass. 2004) (detailing the dictionary definitions); Id. at 244 n.46 (explaining that the prior art disclosed to the patent examiner also supports the district court's interpretation). When the district court disavows use of extrinsic evidence, it seems to be focusing on expert testimony.

[2] Id. at 244-45 n.47 (finding that "two crucial witnesses for the defense conceded" points which support the district court's claim construction).

[3] The district court goes on to point out that the Federal Circuit precedent has created a "conundrum" by: "discouraging resort to extrinsic evidence while at the same time urging courts to begin claim construction by considering the plain and customary meaning of a term as understood by one skilled in the art." Id. at 226 n.23.