AMGEN V. HMR: A CASE FOR DEFERENCE IN CLAIM CONSTRUCTION

Andrew S. Brown *

TABLE OF CONTENTS

I. INTRODUCTION ..............................................................................479
II. BACKGROUND ..............................................................................480
   A. Facts and Procedural History ..................................................480
   B. Construction of “Therapeutically Effective Amount” ..........482
   C. Denial of En Banc Rehearing ..................................................483
III. THE MARKMAN-CYBOR REGIME ..................................................486
   A. De Novo Review in Claim Construction.................................486
   B. The Arguments Against De Novo Review .................................488
IV. ANALYSIS ...................................................................................492
   A. Claim Construction Accuracy in the Federal Circuit ..........492
   B. The Future of Markman-Cybor ................................................494
   C. Supreme Court Review .............................................................496
V. CONCLUSION................................................................................498

I. INTRODUCTION

In Amgen Inc. v. Hoechst Marion Roussel, Inc. (Amgen V),1 the Court of Appeals for the Federal Circuit was once again faced with the difficult question of the proper standard of review in claim construction appeals. The case went back and forth between the district court and the Federal Circuit multiple times before eventually narrowing on the construction of a single claim term. Ultimately, a petition for rehearing en banc was filed arguing that the Federal Circuit panel should have afforded more deference to the district court’s claim construction. The petition was denied, but a number of dissenting and concurring opinions underscored the conflict among the Federal Circuit judges. Subsequently, a petition for a writ of certiorari was filed.2

* Harvard Law School, Candidate for J.D., 2008. Special thanks to Bryan Choi, Yixin Tang, the Harvard Journal of Law & Technology Student Writing Committee, and Dr. Kevin Noonan for their insightful feedback on earlier drafts.

1. Amgen Inc. v. Hoechst Marion Roussel, Inc. (Amgen V), 469 F.3d 1039 (Fed. Cir. 2006), denying reh’g and reh’g en banc of 457 F.3d 1293 (Fed. Cir. 2006), petition for cert. filed, 2007 WL 906697 (U.S. Mar. 22, 2007) (No. 06-1291).
Currently, claim construction is reviewed de novo on appeal. This rule was first announced in *Markman v. Westview Instruments, Inc.* (*Markman I*), and was confirmed by the Federal Circuit in *Cybor Corp. v. FAS Technologies, Inc.* But the rule has not been without detractors, especially given the high reversal rate in claim construction cases. Both academics and jurists have criticized the holding in *Cybor* and called for increased deference to district court claim constructions.

One of the most basic assumptions often made in the debate about the proper standard of review in claim construction cases is that the district court erred when a Federal Circuit panel reverses a district court claim construction. There is reason, however, to doubt this assumption. The Federal Circuit is certain to confront the *Markman-Cybor* rule again, but the exact adjustments it will make remain unclear. Ultimately, though, the Federal Circuit is unlikely to do enough. For this reason, Supreme Court review is warranted.

II. BACKGROUND

A. Facts and Procedural History

Amgen is the owner of several patents that cover the production of erythropoietin (“EPO”), a naturally-occurring hormone that regulates red blood cell production. Amgen sells EPOGEN, an embodiment of the patented EPO, to be used in treating anemia. U.S. Patent No. 5,955,422 (“the ’422 Patent”), the patent at issue, was issued to Kirin-Amgen on September 21, 1999. Claim 1 of the ’422 Patent reads: “A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture.”

In April 1997, Amgen filed a declaratory judgment action in district court alleging that an Investigational New Drug Application filed...
by Hoechst Marion Roussel (now known as Aventis Pharmaceuticals, Inc.) and Transkaryotic Therapies, Inc. (collectively, “HMR”) infringed several of Amgen’s EPO patents. In October 1999, Amgen amended the complaint to add the ’422 Patent and one other patent that had issued after the suit was filed. In January 2001, after an extensive trial, the district court issued a lengthy opinion in which it held three patents, including the ’422 Patent, valid and infringed.

HMR appealed to the Federal Circuit on several grounds, arguing in part that the district court’s validity determinations were erroneous. In reference to the ’422 Patent, the Federal Circuit panel held that the district court had erred in failing to construe explicitly the term “therapeutically effective,” which the panel deemed necessary to determine whether the ’422 Patent was anticipated by a prior art clinical study. On remand, the district court construed “therapeutically effective amount” as “a quantity that produces a result that in and of itself helps to heal or cure” a certain class of patients. Accordingly, it upheld its prior decision finding the ’422 Patent valid and infringed.

HMR appealed once again, contesting all of the district court’s rulings, and the Federal Circuit panel reviewed de novo the district court’s construction of the term “therapeutically effective amount.” In August 2006, a divided panel reversed the district court’s claim construction. The panel held that a “therapeutically effective amount” was an amount that elicited any one of several in vivo effects described in the patent, including, but not limited to, an increase in hematocrit, with no requirement that the amount be useful for healing or curing. The case was once again remanded to the district court to

10. Amgen II, 314 F.3d at 1319.
11. Id.
13. See Amgen II, 314 F.3d at 1320.
14. See id. at 1352–53. “Assumedly viewing [the term] ‘therapeutically effective’ as not in dispute,” the district court did not construe the term at the Markman hearing in Amgen I. Id. Instead, the district court implicitly construed the claim in discussing a prior art reference. Id.
16. See id. at 327–36.
17. Amgen Inc. v. Hoechst Marion Roussel, Inc. (Amgen IV), 457 F.3d 1293, 1297 (Fed. Cir. 2006).
18. Id. at 1301–03.
19. See id.
20. Id. at 1303. But see infra Part II.C (discussing criticism of the panel’s claim construction).
determine the issue of validity in light of the new claim construction.\footnote{Id. at 1317. Judge Newman, dissenting from the denial of rehearing en banc in Amgen V, indicated that the patent will likely be found invalid on remand. See infra note 134 and accompanying text.}

\textbf{B. Construction of “Therapeutically Effective Amount”}

To construe the term “therapeutically effective amount,” the panel majority relied heavily on a passage in the patent specification that states:

\begin{quote}
[T]o 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 [before] attributed in vivo to EPO, e.g., stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals.\footnote{Amgen IV, 457 F.3d at 1301–03 (quoting ‘422 Patent col.33 ll.11–22).}
\end{quote}

The majority read this section as defining all of the effects that the claimed invention could be used to produce in therapy.\footnote{See id. at 1302.} Accordingly, the majority concluded that the term “therapeutically effective” did not require the claimed EPO to increase hematocrit nor cure disease, but simply to elicit one or more of these effects.\footnote{Id. at 1302–03.}

Chief Judge Michel dissented, urging adoption of the district court’s construction.\footnote{See id. at 1317–21 (Michel, C.J., dissenting).} He argued that causing one of the effects of therapy is not the same as therapeutic effectiveness.\footnote{Id. at 1318. One common dictionary definition of effective is “producing a . . . desired effect.” \textit{Merriam-Webster’s Collegiate Dictionary} 368 (10th ed. 1993). The “desired effect” in this case would be the therapeutic purpose — treating disease — not merely the intermediate effects.} “Therapeutically effective,” according to Chief Judge Michel, was used by the patentee in the “ordinary sense of the phrase to mean promoting ‘healing’ or ‘curing.’”\footnote{Id. at 1317–21 (Michel, C.J., dissenting).} Rather than alter that meaning, the patentee affirmed it by listing certain effects previously attained by prior art EPO, with the addition that the claimed EPO also increases hema-
No. 2] Amgen v. HMR: Deference in Claim Construction 483
tocrit, which is necessary for healing. For this construction, Chief Judge Michel relied in part on the relationship between an increase in hematocrit and the other biological effects listed in the specification. As the district court stated, in most cases “an increase in hematocrit is accompanied, if not preceded, by ‘any or all’ of the biological effects listed in the specification.” By listing both, the patentee intended “to claim EPO that (1) causes the same in vivo biological effects as the natural EPO; and also (2) increases hematocrit.”

As additional support, Chief Judge Michel pointed out that one of the passages relied upon by the majority referred to analogs of EPO and not the claimed EPO. Therefore, the passage should not have been used to limit the claim. Finally, Chief Judge Michel argued that his construction of “therapeutically effective” was supported by the prosecution history, where the patentee differentiated the claimed EPO from the prior art by pointing to its ability to treat patients.

C. Denial of En Banc Rehearing

In response to the decision in Amgen IV, Amgen filed a petition for rehearing en banc, arguing that the majority erred in the construction of “therapeutically effective amount” and should have afforded more deference to the district court’s construction. Although Amgen’s petition was denied, four of the twelve Federal Circuit judges dissented and urged reconsideration of the Markman-Cybor rule of de novo review of claim construction. Three other judges concurred in

28. See id. Using the specification to depart from the ordinary meaning requires that the specification reveal a “special definition” given to the term by the patentee. Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc). The district court also did not find any such special definition. Amgen III, 339 F. Supp. 2d 202, 239 (D. Mass. 2004).

29. See id. at 234.

30. See Amgen IV, 457 F.3d at 1319 (Michel, C.J., dissenting) (“When a compound . . . ‘heals’ or ‘cures’ . . . a blood disorder, it necessarily increases hematocrit as well as causes one or more of the other listed in vivo biological effects.”).

31. Amgen III, 339 F. Supp. 2d at 234. These effects are also called “surrogate marker[s],” as they indicate that a “therapeutic effect, i.e., one that actually helps to heal or one that makes the patient feel better, is going to follow.” Id. at 329; see also Posting of Kevin Noonan to Patently-O, Noonan’s Corner Office: Amgen v. HMR, http://www.patentlyo.com/patent/2006/08/noonans_corner.html (Aug. 13, 2006) (“[A]ll of the recited properties are related to the clinical measurement of hematocrit, since they are all part of the biological developmental pathway leading to an increase in the number of red blood cells in blood.”).

32. Amgen IV, 457 F.3d at 1319 (Michel, C.J., dissenting).

33. See id. at 1320.

34. See id.

35. See id.


37. See id.
the denial of rehearing en banc but expressed a willingness to reconsider the rule given an appropriate case.38

Chief Judge Michel, who had dissented in the original panel decision, reiterated his dissent and was joined by Judge Rader.39 He first pointed to four practical problems created by the Markman-Cybor regime: (1) a high reversal rate of claim construction; (2) a lack of predictability, which confounds trial judges and discourages settlements; (3) loss of the comparative advantage held by district court judges; and (4) inundation of the Federal Circuit with the minutiae of claim construction.40 Next, he questioned the traditional analogy between claim construction and statutory interpretation, noting that claim construction necessarily involves factual determinations and that trial judges may be better equipped to make such determinations.41

In her dissent, Judge Newman first argued that the panel majority had misconstrued “therapeutically effective.”42 Thereafter, she stated her belief that the Federal Circuit should grant en banc review to correct errors of claim construction because the Federal Circuit has an obligation to provide consistency in construing claims.43 She wrote that since claim construction is treated as a matter of law, the correct construction falls squarely within the criteria for rehearing en banc.44 Ultimately, she suggested that the Federal Circuit’s review of findings of the technology-based facts inherent in claim construction should be guided by the Supreme Court’s Daubert45 decision.46 She indicated that providing due deference to findings based on factual evidence would take advantage of the district court’s procedures and adjudicatory skills, which are better suited to such mixed questions of law and fact.47

---

38. See id.
39. Id. at 1040 (Michel, C.J., dissenting).
40. Id.; see also infra notes 109–18 and accompanying text.
41. Amgen V, 469 F.3d at 1040–41 (Michel, C.J., dissenting).
42. Id. at 1041–42 (Newman, J., dissenting). Judge Newman’s arguments were similar to the ones made by Chief Judge Michel in his dissent to the panel decision. See supra notes 25–35 and accompanying text.
43. Amgen V, 469 F.3d at 1042–43 (Newman, J., dissenting). But see infra notes 48–50 and accompanying text (examining Judge Lourie’s arguments against rehearing en banc).
44. Amgen V, 469 F.3d at 1043 (Newman, J., dissenting).
46. Amgen V, 469 F.3d at 1043 (Newman, J., dissenting). In Cybor, Judge Newman cited Daubert to support her assertion that “[t]he Federal Circuit’s ruling that extrinsic evidence must be restricted unless there is a facial ambiguity in the meaning of the claim is an unnecessary restraint on potentially useful evidence.” Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1480 (Fed. Cir. 1998) (Newman, J., additional views) (citation omitted). She then explains that trial judges should admit extrinsic evidence when it meets the Daubert thresholds of relevance and reliability, and that “factual findings with respect to evidence relevant to claim interpretation should be treated, on appeal, like any other finding of the trial court.” Id. at 1481.
47. Amgen V, 469 F.3d at 1043 (Newman, J., dissenting).
Judge Lourie concurred in the denial of rehearing en banc.\textsuperscript{48} Although he agreed with the decision of the district court, the panel dissent by Chief Judge Michel, and Judge Newman’s dissent on the construction of “therapeutically effective,” he reasoned that “[a] panel is entitled to err without the full court descending upon it.”\textsuperscript{49} Judge Lourie argued that the Federal Rules of Appellate Procedure and the Federal Circuit’s Internal Operating Procedures did not allow en banc rehearing in this case because the case-specific construction of a claim term did not raise an issue of uniformity of decision or exceptional importance.\textsuperscript{50}

Judge Rader wrote that he agreed with the dissents of both Chief Judge Michel and Judge Newman, and he also dissented separately.\textsuperscript{51} Judge Rader found support for reconsideration of the \textit{Markman-Cybor} rule in the Supreme Court’s exhortation that the fact-law distinction often turns on a determination of which judicial actor is best positioned to decide the issue in question.\textsuperscript{52} He especially noted that the district court was better positioned to reach a proper claim construction because it has “more tools, more time, and more direct contact with factual evidence than [the Federal Circuit].”\textsuperscript{53} The trial court would not, he suggested, have taken testimony for nine days if the judge were relying upon the patent document alone.\textsuperscript{54}

Judges Gajarsa, Linn, and Dyk concurred in the denial of rehearing en banc but expressed a willingness to reconsider \textit{Cybor} given an appropriate case.\textsuperscript{55} They wrote that their 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 \textit{Cybor}.”\textsuperscript{56} They argued that in this case the court did not rely on, and in fact disavowed reliance on, any extrinsic evidence.\textsuperscript{57} An appropriate case in which they would be willing to reconsider \textit{Cybor} would involve a claim construction that could not be resolved by intrinsic evidence, requiring the district court to decipher conflicting expert evidence.\textsuperscript{58}

Judge Moore, in her first written opinion, dissented. She first stated that she disagreed with the panel majority’s claim construction for the reasons set forth in the district court opinion and Chief Judge

\textsuperscript{48} \textit{Id.} at 1043 (Lourie, J., concurring).
\textsuperscript{49} \textit{Id.}
\textsuperscript{50} \textit{Id.}
\textsuperscript{51} \textit{Id.} at 1044 (Rader, J., dissenting).
\textsuperscript{52} \textit{Id.}
\textsuperscript{53} \textit{Id.}
\textsuperscript{54} \textit{Id.}
\textsuperscript{55} \textit{Id.} at 1045 (Gajarsa, Linn, & Dyk, JJ., concurring).
\textsuperscript{56} \textit{Id.}
\textsuperscript{57} \textit{Id.}
\textsuperscript{58} \textit{Id.}
Michel’s panel dissent.59 Much like Judge Lourie, however, if it were only a matter of case-specific mistake, she would concur in the decision not to hear the case en banc.60 Instead, she commended the district court for its “thorough, detailed, thoughtful, and competent efforts” to construe the claim term, and suggested that the deference given to the district court in this case should be reconsidered.61 Judge Moore highlighted the many tools used by the district court to construe the claim62 and mentioned the “conundrum” that Federal Circuit precedent creates 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.”63

III. THE MARKMAN-CYBOR REGIME

A. De Novo Review in Claim Construction

The Federal Circuit’s rule of de novo review in claim construction has its roots in the seminal Markman decisions.64 In two decisions, the Federal Circuit and the Supreme Court addressed the role of the jury in claim construction.65 In Markman I, the Federal Circuit, sitting en banc, settled inconsistent precedents and held that claim construction was a matter of law for determination by a judge.66 In support of this conclusion, the court cited a number of rationales. First, the court pointed to the fundamental principle of American law that the construction of a written document is “exclusively with the court.”67 Second, claim construction essentially “defines the federal legal rights created by the patent document.”68 Thus, claims should be construed by a judge because “defining legal rights” is typically a legal matter left to courts.69 Finally, competitors can only understand the scope of a patentee’s rights by “applying established rules of con-

59. Id. at 1045–46 (Moore, J., dissenting).
60. Id. at 1046.
61. Id.
62. See id.
63. Id. at 1046 n.3 (citing Amgen, Inc. v. Hoechst Marion Roussel, Inc. (Amgen III), 339 F. Supp. 2d 202, 226 n.23 (D. Mass. 2004)).
65. See Burgess, supra note 64, at 771–72.
66. Markman I, 52 F.3d at 979.
67. Id. at 978 (quoting Levy v. Gadsby, 7 U.S. 180, 186 (1805)). In this discussion, the Markman I court also stated that “[t]he patent is a fully integrated written instrument.” Id.
68. Markman I, 52 F.3d at 978.
69. See id.
Trained in the law, a judge is best able to apply those rules to ensure a true and consistent scope of the claims. The Markman I court recognized that extrinsic evidence plays a part in claim construction but held that, because the claim construction is ultimately based on the patent and prosecution history, the construction was still entirely a matter of law. Tangentially, the court stated that because claim construction is a matter of law it should be subject to de novo review on appeal.

The Supreme Court granted certiorari and affirmed the Federal Circuit’s ruling in Markman v. Westview Instruments, Inc. (Markman II). However, the Court only considered the narrow question of whether the Seventh Amendment required claim construction to be tried by a jury. In holding that it did not, the Supreme Court acknowledged that claim construction is a “mongrel practice,” neither clearly law nor fact, and relied on a balancing of which judicial actor, judge or jury, was best positioned to construe claims.

In Cybor Corp. v. FAS Technologies, Inc., an en banc Federal Circuit returned to the “no deference” rule, rejecting a divergent line of cases that had relied on Markman II to provide clear error deference in claim construction. The majority concluded that the Supreme Court’s Markman II decision did not disturb the Federal Circuit’s holding in Markman I that claim construction was strictly a matter of law to be reviewed de novo. It dismissed the Supreme Court’s characterizations of claim construction as a “mongrel practice” as mere “prefatory comments.” The Federal Circuit reiterated its earlier reasoning from Markman I that claim construction is a pure issue of law; even credibility determinations “will be subsumed within the necessarily sophisticated analysis of the whole document.” Thus, Cybor definitively drew the bright-line rule of de novo review of claim construction that is currently applied.

70. Id. at 978–79.
71. Id. at 979.
72. Id. at 981.
73. Id. at 979.
75. Id. at 372; see Burgess, supra note 64, at 772.
76. Markman II, 517 U.S. at 378.
77. Id. at 388–90; see also Matthew R. Hulse, Note, Cybor Corp. v. FAS Technologies, Inc., 14 BERKELEY TECH. L.J. 87, 90 (1999).
79. Id. at 1451.
80. Id. at 1455.
81. Id. at 1456 (quoting Markman II, 517 U.S. at 389); see also Hulse, supra note 77, at 92–93.
82. See Burgess, supra note 64, at 773.
The most recent en banc decision by the Federal Circuit involving the Markman-Cybor rule was Phillips v. AWH Corp. 83 A decade after Markman I, claim construction reversal rates were high and still increasing. 84 Some scholars hoped that Phillips would clarify claim construction and fulfill Markman’s promise of certainty. 85 Perhaps unsurprisingly, though, after limited briefing and argument on the matter, the Phillips court decided not to address the issue of deference and left the ruling in Cybor untouched. 86

The Federal Circuit’s formalist approach 87 to the standard of review in claim construction has not left much room for policy arguments in these cases. Others, however, have defended de novo review on the basis of policy considerations, more in line with the Supreme Court’s decision in Markman II. 88 These analyses typically look at the issue as a tradeoff between certainty and accuracy. 89 They recognize the problems caused by de novo review, 90 but argue that it increases accuracy in claim construction. 91 Reaching the right result, they argue, is more important than other considerations and justifies the Markman-Cybor rule. 92

B. The Arguments Against De Novo Review

Views regarding Markman-Cybor have been less than harmonious, even within the Federal Circuit. Federal Circuit decisions regarding the standard of review in claim construction have regularly been accompanied by dissents. 93 Academics and practitioners have also found much to dislike in the de novo rule. 94

85. See, e.g., Moore, supra note 84, at 246–47.
86. Phillips, 415 F.3d at 1328. The Federal Circuit had asked the parties to brief the question of whether according deference in claim construction would be consistent with Markman II and Cybor, thus framing the question as one of interpretation, rather than reconsideration, of Cybor. See id.
87. See infra note 164 and accompanying text.
88. See supra notes 74–77 and accompanying text.
90. The primary problem is a high reversal rate, which necessarily leads to other difficulties. See infra notes 109–17 and accompanying text.
91. See, e.g., Moore, supra note 89, at 28. But see infra Part IV.A (arguing against the assumption of accuracy).
92. See Moore, supra note 89, at 28.
The first objection to the de novo rule is that it does not follow from Supreme Court precedent. It could be argued that *Cybor* directly contradicted the Supreme Court’s ruling in *Markman II*, or at least went beyond the *Markman II* ruling and misconstrued its dicta.95 Nothing in *Markman II* required that claim construction be treated as a pure matter of law.96 Indeed, the Supreme Court chose not to follow the reasoning of *Markman I*.97 Unless claim construction is a pure matter of law, Federal Rule of Civil Procedure 52(a), which calls for clear error deference to factual findings, requires that deference be given to the claim constructions of district courts.98

Second, some of the questions underlying claim construction seem to be treated differently in the context of patent enablement. As in claim construction, enablement requires evaluating the perspective of a “person of ordinary skill in the art.”99 The final determination of enablement is reviewed de novo on appeal, but, unlike claim construction, underlying factual inquires such as the level of ordinary skill in the art are reviewed under a clear error standard.100

Third, the *Markman-Cybor* rule is inconsistent with other analogous areas of law. For example, contract law requires a similar construction of a written document.101 In contract law, “interpretation” is the ascertaining of the meaning of words in a contract and is considered a factual issue.102 “Construction” is giving those words legal effect and is a matter of law reviewed de novo.103 Determining the meaning of claim terms, then, is similar to interpretation and would,
in the contract law context, be an issue of fact subject to clear error review.\textsuperscript{105} A fourth objection is that the Markman-Cybor rule grants an inappropriate level of power to the Federal Circuit. The debate about the proper standard of review may have reached its rhetorical high point in Judge Mayer’s dissent in Phillips where he argued just that.\textsuperscript{106} The tendency of the Federal Circuit to take on roles typically reserved for district courts has been termed “judicial hyperactivity” by some.\textsuperscript{107} Although judicial hyperactivity may seem expedient in some circumstances, such as with claim construction, it also tends to undermine confidence in the judicial process.\textsuperscript{108}

Finally, de novo review in claim construction has led to high reversal rates of claim construction on appeal. The exact rate is disputed,\textsuperscript{109} but in 2001, then-Professor Moore released a study suggesting a reversal rate of approximately one-third.\textsuperscript{110} In a recent pre-Phillips update, she found that the reversal rate was increasing.\textsuperscript{111} Although it is too early to know conclusively, there is a sense that the reversal rate has not been decreasing post-Phillips and may even be continuing to climb.\textsuperscript{112}

A high reversal rate, itself perhaps unobjectionable, may cause several problems. First, a high reversal rate could have the effect of

\begin{thebibliography}{11}
\bibitem{Markman I} Markman I, 52 F.3d 967, 1000–01 (Fed. Cir. 1995) (Newman, J., dissenting).
\bibitem{Markman Cybor} See FED. R. CIV. P. 52(a). Arguably, however, contract law is more fixed than patent law, which regularly deals with new technologies and new terms.
\bibitem{Phillips} Phillips v. AWH Corp., 415 F.3d 1303, 1330 (Fed. Cir. 2005) (Mayer, J., dissenting) (“[W]e have . . . focused inappropriate power in this court. In our quest to elevate our importance, we have, however, disregarded our role as an appellate court; the resulting mayhem has seriously undermined the legitimacy of the process, if not the integrity of the institution.”).
\bibitem{Gajarsa} See id. at 752. This is especially true when the Federal Circuit is effectively acting as a court of last resort. See Arthur J. Gajarsa & Lawrence P. Cogswell, III, The Federal Circuit and the Supreme Court, 55 AM. U. L. REV. 821, 822–23 (2006) (“In the twelve terms preceding [Markman II], the Supreme Court had heard only four patent cases.” (citation omitted)).
\bibitem{Moore 1} Moore, supra note 89, at 2.
\bibitem{Moore 2} Moore, supra note 84, at 245–47.
\end{thebibliography}
demoralizing district court judges.\textsuperscript{113} Trial judges are essential to building a complete evidentiary record, but if a trial judge believes that he is likely to be reversed on appeal irrespective of his actions, the judge is less likely to devote time and resources to what he views as a lost cause.\textsuperscript{114}

Additionally, the high reversal rate has led to increased uncertainty in patent litigation.\textsuperscript{115} Litigants who can rely on uncertainty at the Federal Circuit will be less likely to settle and more likely to appeal.\textsuperscript{116} If the district court is merely a “trial run” before the actual claim construction in the Federal Circuit, tremendous waste occurs in the form of squandered judicial resources and increased litigation costs.\textsuperscript{117}

The increase in appeals due to a de novo review regime could also arguably hinder the development of patent doctrine. Federal Circuit resources that could be used to promote uniformity in patent law are instead “inundat[ed] . . . with the minutia[e] of construing numerous disputed claim terms (in multiple claims and patents) in nearly every patent case.”\textsuperscript{118} It also seems that providing more deference to trial courts might benefit claim construction doctrine by inviting narrower Federal Circuit opinions that clearly explicate district court errors in claim construction.

\textsuperscript{113} The trial judge in this case, Chief Judge William G. Young of the Federal District Court of Massachusetts, has said:

\begin{quote}
I have had nine of my cases appealed to the Federal Circuit . . . . I have been reversed in seven. That does not relieve me — and I am not proud of that. I don’t throw that out as a challenge to anyone — far from it. My duty is to predict what they are going to say and follow the law. But I haven’t had noticeable success in dealing with these matters.
\end{quote}


\begin{quote}
Frankly, I don’t know why I’m so excited about trying to bring this thing to closure. It goes to the Federal Circuit afterwards. You know, it’s hard to deal with things that are ultimately resolved by people wearing propeller hats. But we’ll just have to see what happens when we give it to them. I could say that with impunity because they’ve reversed everything I’ve ever done, so I expect fully they’ll reverse this, too.
\end{quote}


\textsuperscript{114} Apparently this was not the case in \textit{Amgen III}. See \textit{Amgen V}, 469 F.3d 1039, 1046 (Fed. Cir. 2006) (Moore, J., dissenting) (commendng the district court for its “thorough, detailed, thoughtful, and competent efforts” in construing the claim limitation).

\textsuperscript{115} Moore, \textit{supra} note 89, at 27.

\textsuperscript{116} \textit{Id}. at 27–28.

\textsuperscript{117} See Phillips v. AWH Corp., 415 F.3d 1303, 1334 (Fed. Cir. 2005) (Mayer, J., dissenting).

\textsuperscript{118} \textit{Amgen V}, 469 F.3d 1039, 1040 (Fed. Cir. 2006) (Michel, C.J., dissenting).
IV. ANALYSIS

A. Claim Construction Accuracy in the Federal Circuit

Most current analyses of claim construction doctrine and the interplay between district courts and the Federal Circuit rely on the assumption that Federal Circuit panels are typically getting claim construction “right” and that the high reversal rate is attributable to district court error.119 This assumption is justified by pointing to the much greater experience of Federal Circuit judges in construing claim terms.120 Yet given the continued high rate of reversal in claim construction cases, alternative possibilities should be explored.

The first possibility is that there might not be a single “correct” construction of any given claim term.121 A patent is a grant of rights by the government, and courts “defin[e] the federal legal rights created by the patent document.”122 A natural outgrowth of this approach is the belief that a court is capable of finding the single correct construction to the exclusion of others. Recognizing that this is mere legal fiction, however, suggests that reasonable minds could disagree without being wrong about the construction of a claim.123 Under this view, while the Federal Circuit is not erring in its claim constructions, it is unnecessarily reversing equally plausible constructions made by the district courts.

Alternatively, it is possible that Federal Circuit panels are creating erroneous claim constructions in a significant number of cases. Although claim construction relies primarily on intrinsic evidence, such as the claim itself and the patent’s specification, extrinsic evidence may also be considered.124 Indeed, a basic inquiry into extrinsic evidence seems necessary to determine what the meaning of a term

119. See, e.g., Moore, supra note 89, at 17–18.
120. Id. at 18. Then-Professor Moore also looked at the construction of individual claim terms and found that reversal rates were not significantly affected by several characteristics of the presiding judges — level of technical background, patent experience prior to joining the court, or political party of the appointing president. Id. at 21–27. Professor Moore also found that most of the panels were unanimous in their decisions. Id.
121. In at least one example, two separate panels of the Federal Circuit unanimously construed the same term from the same claim differently. See id. at 18–21 (discussing CVI/Beta Ventures, Inc. v. Custom Optical Frames, Inc., 92 F.3d 1203 (Fed. Cir. 1996) and CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146 (Fed. Cir. 1997)).
122. Markman I, 52 F.3d 967, 978 (Fed. Cir. 1995).
123. Even when Federal Circuit judges agree with the particular procedure followed to construe a claim, they do not necessarily agree with the result. In Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc), the en banc majority overturned the panel majority, and adopted the panel dissent’s claim construction. Dissenting in the en banc opinion, the panel majority expressed consternation that the en banc majority had done so despite discrediting the procedure followed by the panel dissent and endorsing the procedure followed by the panel majority. Phillips, 415 F.3d at 1329 (Lourie, J., dissenting).
124. See id. at 1314.
would be to a “person of skill in the art.” To this end, trial judges devote extensive time and other resources to examining such evidence. It is naïve to think that judges do not utilize this evidence in construing claims, even if they do not explicitly rely on it in their written opinions.

In this capacity, trial judges should be more competent than appellate judges. Although all of this evidence is a part of the record on appeal, which the Federal Circuit panel may consider, only the trial judge is able to direct its accumulation. Additionally, it is doubtful whether Federal Circuit panels are able to devote the immense amount of time afforded district courts in examining evidence, which may be essential to build the technological knowledge necessary to properly construe a claim. Compared to appellate judges, district court judges are more accustomed to fact finding, presumably making them more accurate. While Federal Circuit judges may be vastly more experienced at interpreting intrinsic evidence and construing claims, that skill is of dubious value when the determinations that need to be made are, at their root, factual and variable with each patent. In light of these factors, it may be as reasonable to assume that the Federal Circuit errs when reversing a claim construction as it is to assume that the district court errs when making the construction in the first place.

In *Amgen IV*, the panel majority significantly misread a single passage of the specification to alter an otherwise easily understood claim term, possibly invalidating the patent in the process.
that reason, Amgen seems to provide an excellent example of a Federal Circuit panel overemphasizing and, in this case, misreading intrinsic evidence to come to a facially reasonable claim construction that does not correspond with reality.135 In contrast, the district court judge, who was immersed in the case and technology, correctly recognized what the term would mean to a person having ordinary skill in the art and that the patentee was using that ordinary meaning.

B. The Future of Markman-Cybor

The Markman-Cybor doctrine was contentious well before the denial of rehearing en banc in Amgen V, and the arguments presented against de novo review of claim construction are familiar.136 However, the denial of rehearing en banc serves as the most comprehensive display, to date, of the lines that are calcifying in the fight over review of claim construction. Consideration of the opposing and overlapping doctrinal blocs evident in the various dissenting and concurring opinions might be useful in forecasting the future of the standard of review in claim construction.

Even absent explicit reconsideration of Cybor by the Federal Circuit, deference to claim constructions by district courts may increase. Concurring in Cybor, Judges Bryson and Plager137 noted that de novo review does not require throwing out all of the district court’s work and that common sense would suggest assigning some weight to the trial judge’s construction.138 Although some post-Cybor cases cited to these concurrences, they gained very little precedential weight.139 In the aftermath of the Amgen V denial of rehearing en banc, however, some Federal Circuit panels have used a similar strategy in announcing de novo review but conceding some deference to the trial court.140

this case expressing disagreement with the two judge panel majority’s claim construction even under the de novo standard of review.”).
134. The newly broadened claim term will likely be found to have been anticipated by a prior art reference. See Amgen V, 469 F.3d at 1041 (Newman, J., dissenting) (stating that the claims as construed may read on the prior art, “thereby foster[ing] invalidity”).
135. See Posting of Noonan, supra note 31 ("[Amgen IV] provide[s] a nice illustration that Phillips has not changed the [Federal Circuit’s] capacity for arriving at its own idiosyncratic construction . . . . [B]y cherry-picking the language of the specification, the [court] was able to arrive at a facially-reasonable claim construction that seems to run contra to clinical reality.").
136. See supra Part III.B.
137. Judge Bryson did not file a separate opinion in Amgen V. Judge Plager retired to senior status in 2000, before Amgen V.
138. See Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1462 (Fed. Cir. 1998) (Plager, J., concurring); id. at 1463 (Bryson, J., concurring). But see Burgess, supra note 64, at 787 (stating that the concurrences contradict the clear holding of Cybor).
139. Burgess, supra note 64, at 786–87 (citing Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709 (Fed. Cir. 1998)).
Given the many dissents in *Amgen V*, it is possible that, absent reconsideration of *Cybor* in an en banc decision, this tactic will see more frequent use by Federal Circuit panels. Unfortunately, providing limited deference to trial courts does too little to attenuate the mischief of de novo review if the actual degree of deference remains subject to the complete discretion of the appellate panel.

Eight of the twelve judges on the Federal Circuit have now indicated support for reconsidering *Cybor* given an appropriate case, so it seems only a matter of time until the Federal Circuit directly confronts the issue en banc. Conceivably, after full briefing and oral argument, the court could either reverse or severely revise *Cybor* and provide substantial deference to district court claim constructions. Yet such a result seems unlikely. Although a majority of the Federal Circuit supports reconsideration of *Cybor*, a balance of that majority only supports a very limited reconsideration.

Even among those judges who have questioned the current standard of review, the degree of their discontent with the *Cybor* standard varies considerably. Furthermore, no alternative solution has
emerged from the dissents as a clear front-runner to replace the Markman-Cybor rule. The most likely outcome from a Federal Circuit reconsideration of Cybor would be a rule of limited deference to district courts in cases that rely explicitly on extrinsic evidence for claim construction, particularly conflicting testimony. These cases would fall into the exception envisioned by the concurrence of Judges Gajarsa, Linn, and Dyk in Amgen V. Such an approach should easily capture a majority of the votes of Federal Circuit judges. Unfortunately, it would not change the status quo for the more typical cases, which do not explicitly rely on extrinsic evidence but are still afflicted by high reversal rates and the other complications of de novo review.  

Suggestions for a number of extra-judicial reforms have emerged to remedy the problems of de novo review of claim construction. These include, for example, administrative claim construction or a specialized district court. In a similar vein, a bill recently passed by the House of Representatives would set up a pilot program assigning patent cases to designated district court judges and providing them with additional training in patent law. Nevertheless, assuming that the Federal Circuit does not drop its de novo review standard, reforms like these will only be successful at lowering the reversal rate if district courts are, at present, truly erring in the construction of claim terms, and appellate panels are truly getting it right.

C. Supreme Court Review

The Supreme Court should grant certiorari to consider the Markman-Cybor regime. The Supreme Court historically has been cau-
tious about granting certiorari on Federal Circuit decisions, perhaps because the Federal Circuit’s exclusive jurisdiction over certain substantive areas precludes certiorari-prompting intercircuit splits. However, the Court has recently developed a new interest in reviewing patent cases. Markman-Cybor has all the markings of an issue ripe for Supreme Court review.

The Supreme Court Rules allow for broad discretion in decisions to grant certiorari. Some authorities suggest that an intracircuit split, especially where there is disagreement among different panels of the Federal Circuit, could be sufficient to trigger Supreme Court review. Although Supreme Court review of intracircuit splits is generally disfavored, the Federal Circuit presents a somewhat unusual case because it holds exclusive appellate jurisdiction over all patent matters. Accordingly, a traditional intercircuit split, a common trigger for a grant of certiorari, is all but unheard of in matters involving the Federal Circuit. Therefore, sufficiently strong disagreement within the Federal Circuit might be likened to an intercircuit split. The many dissents and concurrences in Amgen V indicate a divergence of viewpoints that should be sufficient to warrant grant of certiorari.

In addition to circuit splits, the Supreme Court Rules allow grants of certiorari if a court of appeals “has decided an important question

pened after the Supreme Court took up the issue of the Federal Circuit’s obviousness test in KSR International Co. v. Teleflex, Inc., 126 S.Ct. 2965 (argued Nov. 28, 2006) (mem.). For an example of one Federal Circuit panel response, see DyStar Textilfarben GMBH & Co. v. C.H. Patrick, 464 F.3d 1356, 1367 (Fed. Cir. 2006). “It is difficult to see how our suggestion test could be seen as rigid and categorical given the myriad cases over several decades in which panels of this court have applied the suggestion test flexibly.” Id. A similar revision to the standard of review would look like discretionary deference. See supra notes 137–41 and accompanying text.

153. See Gajarsa & Cogswell, supra note 108, at 822–23; see also infra notes 157–59 and accompanying text.


155. SUP. CT. R. 10 (“The following . . . neither contro[l] nor fully measur[e] the Court’s discretion . . . .”)


161. Cf. id. at 1523. The absence of an opinion defending the Markman-Cybor rule, however, might cut against Supreme Court review.
of federal law that has not been, but should be, settled by this Court, or has decided an important federal question in a way that conflicts with relevant decisions of this Court.” This portion of the Rules provides an even better basis for Supreme Court review of Markman-Cybor.

Some have argued that the Federal Circuit’s decision in Cybor conflicts with Markman II in that it rejects the mixed-law-and-fact nature of claim construction. The current bright line Markman-Cybor rule exemplifies the formalism that dominates the Federal Circuit’s reasoning. Straying from Supreme Court precedent, especially toward bright line rules, seems to have been a common trigger in recent grants of certiorari over patent cases.

Even assuming that Cybor does not conflict with Markman II, the Supreme Court still has good reason to review the Cybor doctrine. Arguably, the Supreme Court has never settled this important question of federal law. The closest the Supreme Court came was in Markman II, but that decision was limited to the Seventh Amendment question and did not directly address the question of standard of review. Since the Federal Circuit has a tendency to accumulate decisional power for itself, it may be desirable to have a more detached institution review decisions affecting the scope of the Federal Circuit’s power. Here, the issue should be settled by the Supreme Court because of the Supreme Court’s unique ability, by virtue of its position, to arbitrate institutional claims of power within the patent system.

V. CONCLUSION

The rule of de novo review in claim construction has caused serious practical problems for the patent system. High reversal rates demoralize trial courts, lead to uncertainty, greatly increase litigation costs, hinder the development of patent doctrine, and ultimately undermine faith in the patent system. The Markman-Cybor regime is not

---

163. See supra notes 95–97 and accompanying text.
165. See supra notes 106–08 and accompanying text (discussing the concentration of power in the Federal Circuit); see also John F. Duffy, The Festo Decision and the Return of the Supreme Court to the Bar of Patents, 2002 Sup. Ct. Rev. 273, 303 (2002).
166. See supra notes 74–77 and accompanying text.
168. See Duffy, supra note 167, at 302–03.
169. See id.
justified by Supreme Court precedent and grants an inappropriate level of power in the Federal Circuit.

It is far from clear that giving deference to district courts would result in less accurate claim constructions. District court claim constructions may actually be more accurate. Considering the highly factual nature of determining how a person having ordinary skill in the art would understand a technical term, district courts seem to be in the best position to construe claims. Amgen is only the most recent example of the deleterious effect de novo review can have on claim construction.

The Federal Circuit is unlikely to solve the problem on its own. Although the problems caused by de novo review of claim construction affect nearly every patent case, the Federal Circuit only seems likely to afford deference to district court claim constructions in an extremely limited subset of cases. Structural reforms of the sort currently contemplated by Congress are similarly not up to the task because they are aimed only at improving claim construction prior to appeal.

It is appropriate and advisable for the Supreme Court to grant certiorari to reconsider Cybor. As in Markman II, policy considerations should take center stage when allocating decisional power over an issue that is neither clearly law nor fact. Placing claim construction in the hands of district courts would benefit the patent system by lowering the reversal rate and increasing claim construction accuracy.