

No. 18-1691

IN THE
United States Court of Appeals for the Federal Circuit

IDENIX PHARMACEUTICALS LLC AND
UNIVERSITA DEGLI STUDI DI CAGLIARI,
Plaintiffs-Appellants,

v.

GILEAD SCIENCES INC.,
Defendant-Appellee.

On Appeal from the United States District Court
for the District of Delaware
No. 1:14-cv-00846-LPS, Hon. Leonard P. Stark

RESPONSE IN OPPOSITION TO REHEARING EN BANC

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.

Case No. 18-1691

CERTIFICATE OF INTEREST

Counsel for the:

(petitioner) (appellant) (respondent) (appellee) (amicus) (name of party)

Gilead Sciences Inc.

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Gilead Sciences Inc.	None	None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

None

4/9/2020

Date

/s/ E. Joshua Rosenkranz

Signature of counsel

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Printed name of counsel

Please Note: All questions must be answered

cc: Counsel of Record

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INTRODUCTION

The panel majority and dissent agreed on the bottom-line result in this case: Idenix was not entitled to a \$2.5 billion award for a lifesaving cure for Hepatitis C virus (HCV) that it did not invent. The majority held that Idenix’s patent is invalid for two independent reasons. It does not enable, nor does the specification meaningfully describe, the particular genus of compounds Idenix claims. The dissent would have salvaged Idenix’s patent by sua sponte adopting a new construction on appeal to drastically narrow the claims to what the patent does enable—but under that construction, Gilead’s drug would not infringe the patent. Those multiple independent grounds for reversing the judgment make this case an exceedingly poor candidate for en banc review.

Moreover, the panel correctly applied this Court’s settled § 112 precedent to the largely undisputed facts of this case.

Idenix’s attacks on the panel’s holdings are an exercise in selective omission. Idenix disregards this Court’s longstanding § 112 cases, which prevent patentees from offering “only a starting point, a direction for further research” in an unpredictable field, and then

taking credit when others follow through. Op. 16 (quoting *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010)).

Idenix then outright ignores most of the panel’s actual decision, which applies the traditional *Wands* factors on enablement to the facts here (Op. 8-20), and concludes with a brief analogy (Op. 20-21) to *Wyeth v. Abbott Laboratories*, 720 F.3d 1380 (Fed. Cir. 2013). Idenix overlooks critical facts in that analysis, like its own expert’s admissions that the field of treating HCV with nucleosides was highly unpredictable, such that anti-HCV activity could be determined only through nucleoside-by-nucleoside testing of the vast universe of compounds the patent discloses. Op. 7, 14. Meanwhile, Idenix’s patent contained only “exceedingly narrow” working examples, limited to just “a single sugar” in four variations. Op. 17. Instead of acknowledging and grappling with those facts, Idenix’s petition emphasizes that the *tools* for the research necessary to bring the invention to life—methods for making and screening compounds—were routine. *See* Pet. 6, 7, 10-11, 12; Op. 15, 21 (acknowledging same). But while it may be “routine” to pan for gold or randomly guess at a multi-character password, patentees cannot

claim the yet-to-be-realized results of that labor. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc).

Only by jettisoning all that can Idenix accuse the panel of inventing strict “new enablement and written-description rules” that pose a “disaster for innovation.” Pet. 2-3. Read in full, the decision correctly invalidated Idenix’s overbroad claims under established law. Far from threatening the legitimate use of genus claiming, the decision *protects* that practice—which has flourished under this Court’s § 112 jurisprudence—from abuse that would fence off vast fields of legitimate, novel research like Gilead’s. Indeed, notwithstanding Idenix and its amici’s sky-is-falling prognostications, nothing in the panel’s analysis casts doubt on properly supported genus claims. This Court has allowed, and will continue to allow, genus claims where the full scope of the claim is enabled and described by the specification. *E.g.*, *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 662-63 (E.D. Tex. 2017), *aff’d*, 739 F. App’x 643 (Fed. Cir. 2018); *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1338 (Fed. Cir. 2006). The panel’s factbound application of this Court’s enablement and written description cases does not warrant further review.

As for Idenix’s brief suggestion that this Court should recast enablement as a question of fact and eliminate the separate written description requirement, this Court has correctly rejected both arguments. And because the judgment rests on alternative grounds, this case is hardly “well-suited to revisiting [those] issues.” Pet. 3. The petition for rehearing should be denied.

BACKGROUND

Modifying nucleosides to inhibit HCV is an unpredictable field. Nucleosides, which comprise a five-carbon sugar ring attached to a base, are the building blocks of genetic code. Op. 4. They can be modified in limitless ways, by substituting new molecules at several different positions on the sugar and base. *Id.* Certain modifications may stop a virus—like HCV—from replicating. *Id.* But, as an “Idenix expert testified,” “you don’t know whether or not a nucleoside will have activity against HCV until you make it and test it.” Op. 14; *see* Appx37441. One change at any position could drastically alter the compound’s antiviral effect. “Idenix’s expert agreed that the field of modifying nucleosides for anti-HCV activity was ‘in its infancy’ and

‘unpredictable’” when Idenix and Gilead’s predecessor, Pharmasset, began their race for a cure. Op. 14; *see* Appx37736.

Idenix discovered that four nucleosides sharing the same modified sugar ring—substituting methyl at the 2'-up position, but leaving all other positions unchanged—were active against HCV in preliminary tests. Op. 17. But it then claimed much, much more: the genus containing *every* active nucleoside with methyl at 2'-up and virtually *any conceivable modification* at the other positions. Billions of compounds fit those structural limitations. Op. 7; *see* Appx37545; Appx37734. And, as the panel explained, even giving Idenix every benefit of the doubt, a skilled artisan would have concluded that “many, many thousands” of compounds stood a chance of exhibiting the required antiviral activity. Op. 14.

But which of those many thousands would be active? The unpredictability of nucleosides made it impossible to intuit. And the specification shows only one type of working nucleoside: 2'-methyl-up, with no other modifications. Op. 17; Appx37548; Appx37550. Beyond that, the specification merely “provides eighteen position-by-position formulas” describing compounds with modifications at other positions

that “*may* treat HCV.” Op. 23 (emphasis added). Those formulas encompass “tens if not hundreds of thousands of ‘preferred’ 2'-methyl-up nucleosides that would need to be tested for efficacy against HCV.” Op. 17. The specification does not “explain” what would make any of them “effective, or why.” Op. 24. Nor does it indicate “that any nucleosides outside of those disclosed in its formulas”—like the specific nucleoside Pharmasset discovered and Gilead brought to market—“could be effective to treat HCV.” Op. 23.

The minimal teachings in the patent, combined with the unpredictability in the art, meant—as Idenix’s expert put it—that “screening” was required “to ‘actually cut down on the number of compounds, by removing all inactive ones to a few interesting ones.’” Op. 14. And the proportion of inactive compounds was substantial: Idenix eventually tested hundreds of 2'-methyl-up candidate compounds and recorded that 90% were inactive. Appx50155-50216; *see* Appx37513-37514. It was a search “for a needle in a haystack.” Op. 19.

Gilead and Pharmasset, not Idenix, discovered the cure within that uncharted universe of possibilities: a nucleoside with methyl at 2'-up *and* fluorine substituted at 2'-down, among other modifications.

Idenix admitted it had not conceived of such a compound when it filed for patent protection, Op. 22, and so left it “conspicuously absent” from the billions of combinations described in the specification, Op. 24. The groundbreaking nucleoside was the invention of a Pharmasset chemist, who purposefully conducted his inventive research in areas Idenix’s disclosure did *not* cover. Appx40; *see also Storer v. Clark*, 860 F.3d 1340 (Fed. Cir. 2017) (awarding invention of the 2'-methyl-up, 2'-fluorine-down nucleoside to Pharmasset/Gilead over Idenix).

ARGUMENT

I. The Panel Correctly Applied This Court’s Settled Enablement Precedent To The Facts Of This Case.

A. The panel correctly held that the undisputed evidence established nonenablement as a matter of law. The panel broke no new ground, much less invented a “radically heightened” standard. Pet. 8. It applied the standard for enablement that has governed since *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Idenix barely mentions *Wands*, even though the panel’s thorough *Wands* analysis spans 13 pages—more than half the majority opinion.

The panel correctly applied each *Wands* factor to the facts of this case. It concluded that Idenix’s claims far outstripped the scope of its

teachings, and so those claims required an “undue” level of experimentation. Op. 8. In light of Idenix’s concessions, “a reasonable jury could only have concluded that the use of modified nucleosides to treat HCV was an unpredictable art” (*Wands* factor 5). Op. 17. Yet the broad structural limitations of Idenix’s claims swept in “at least ‘many, many thousands’ of candidate compounds” that required synthesis and screening for anti-HCV activity (factor 7), a “quantity of experimentation” that could only be classified as “very high” (factor 1). Op. 9, 18. Given the field’s unpredictability, a skilled artisan would have had no idea where to begin. And Idenix’s specification offered no “meaningful guidance” on which compounds would be effective. Op. 17. It identified only one type of working nucleoside, a “very narrow” disclosure that shed no light on where to find other effective compounds within the “wide breadth of the claims” (factor 3). *Id.* (quoting *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 (Fed. Cir. 1999)). The remainder of the specification was no help, either (factor 4). It never explained why its “tens if not hundreds of thousands” of “preferred” candidate compounds—let alone those outside the formulas,

like the one Gilead/Pharmasset discovered—might actually work. Op. 17.

The panel’s *Wands* analysis laid bare the enablement problem with Idenix’s claims: They provided “only a starting point, a direction for further research” regarding which 2'-methyl-up nucleosides would fight HCV. Op. 16 (quoting *ALZA*, 603 F.3d at 941). The panel acknowledged—as Idenix emphasizes throughout its petition—that the *tools* for that research were well-developed: The “level of ordinary skill” was “high,” Op. 9, such that methods for synthesizing and screening individual nucleosides were “largely routine,” Op. 16. But an unbounded research plan is not an enabled invention. As the panel explained, the patent system’s *quid pro quo* requires more than an invitation for others to perform “an iterative, trial-and-error process” to discover useful compounds. Op. 17 (quoting *ALZA*, 603 F.3d at 941). There is nothing “practicable,” *The Telephone Cases*, 126 U.S. 1, 536 (1888), or “sufficiently definite,” *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916), about “identify[ing] a ‘target’” for a skilled artisan without any “meaningful guidance” on how to reach it, Op. 17.

Then, in a short coda to its *Wands* analysis, the panel noted that the shortcomings in Idenix’s enabling disclosure—including the paucity of working examples and guidance in an unpredictable field—paralleled those held invalidating in *Wyeth*. Op. 20-21. That is why the panel unanimously concluded that Idenix’s claims were not “precisely commensurate” with Idenix’s “contribution” to the art. Pet. 12. The majority and dissent *agreed* that Idenix’s claims, as construed by the district court, vastly overreached its contribution. *See* Op. 20; Dissent 11-12.

B. In response, Idenix invents a different opinion and factual record and attacks those instead. Those inapposite arguments do not support further review.

First, Idenix pretends that the panel’s *Wands* analysis—all 13 pages of it—never happened. The petition acknowledges that *Wands* and its progeny define the correct standard for determining whether “the artisan’s work in practicing the patent is routine (or, conversely, ‘undue’).” Pet. 9. That is precisely what the panel said. Op. 4. But Idenix inexplicably contends that the “panel decision went against all these authorities.” Pet. 10. Idenix even asserts (at 10-11) that the

panel disregarded several *Wands* factors discussed at length in the decision: the level of “knowledge” in the field (*but see* Op. 17-18), the scope of working “representative embodiments” (*but see* Op. 16-17), and the “artisan’s skill” (*but see* Op. 15-16).

Second, Idenix rewrites the undisputed record on unpredictability. Repeating an erroneous assertion it made for the first time at oral argument, *see* Op. 13-14, Idenix contends there was “*no evidence* that any significant portion of 2'-methyl-up ribonucleosides (if any at all), including variations at 2'-down, would stymie the artisan by not working.” Pet. 12. But, as the panel explained, “Idenix’s own evidence” established that “only a ‘small’ group of candidates ... effectively treats HCV.” Op. 14, 19. And Idenix’s test logs showed a success rate of just *10 percent*. *Supra* 6. “[I]f the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid.” *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576-77 (Fed. Cir. 1984). That is the case here.

Third, Idenix wildly overreads the panel’s brief *Wyeth* epilogue, arguing that the panel used that case to “cement[]” a “narrow, numerical approach” at odds with *Wands*. Pet. 8, 10; see REGENXBIO Br. 8-10. In Idenix’s telling, the panel held that “synthesizing and screening tens of thousands of candidate compounds for the claimed efficacy” *always* constitutes undue experimentation, “regardless of” case-specific considerations like the field’s unpredictability or the extent of the patent’s teachings. Pet. 8, 10. The panel did no such thing. Its enablement analysis hinged on precisely those case-specific considerations, including the unpredictability of anti-HCV efficacy, the sheer size of the universe of candidate compounds, and the specification’s inadequate guidance. *Supra* 8. These factors show that on *these* facts—which closely resemble *Wyeth*—synthesizing and screening many thousands of candidate compounds was an amount of experimentation incommensurate with the patent’s limited teachings. But the panel’s decision—like *Wyeth*—does not purport to define that volume of experimentation as *per se* excessive.

C. Idenix and its amici also warn that the panel opinion poses a “dire” “threat[]” to “genus claiming.” Pet. 8; Amgen Br. 1-4. That contention lacks merit.

There is no question that genus claims can serve scientific advancement and may be “patentable” even if they require some experimentation. Pet. 8; *see* Amgen Br. 3-4. But they can pose a risk of *overclaiming*: In just a few words, patentees can claim every functional compound within a limitless universe of untested candidates, with the attendant danger that claim scope will far outstrip the specification’s teachings. *See Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1346 (Fed. Cir. 2019), *cert denied*, No. 19-1073 (March 30, 2020). Reflecting the need to balance those considerations, this Court upholds genus claims when they provide commensurate teachings that guide an artisan to effective compounds, even if they require a significant amount of experimentation by skilled artisans,¹ but it has not hesitated to hold that experimentation becomes undue when genus

¹ *E.g.*, *Atlas Powder*, 750 F.2d at 1576-77; *In re Cook*, 439 F.2d 730, 735 (C.C.P.A. 1971).

claims merely prompt “further iterative research in an unpredictable and poorly understood field.”²

The different results simply reflect the different facts of each case. But the rule has been—and remains—stable: Extreme outliers that abuse the patent system’s *quid pro quo* by seeking credit for future discoveries within an uncharted universe of untested compounds are invalid. And Idenix’s claims are as extreme as it gets. Far from “chilling” innovation, this vital check prevents patentees (like Idenix) from stalling progress (like Gilead’s development of a life-saving drug) by claiming rights to the prospective inventive labor of others. Pet. 3.

II. The Panel Correctly Applied This Court’s Settled Written Description Precedent To The Facts Of This Case.

A. The panel’s written description decision was equally faithful to precedent. As with enablement, this Court has struck a “balance” when it comes to written descriptions for genus claims. *Ariad*, 598 F.3d at 1353. The panel reaffirmed that § 112 “does not require ‘a nucleotide-by-nucleotide recitation of the entire genus.’” Op. 24 (quoting *Ariad*, 598 F.3d at 1352); *contra* Amgen Br. 5-10. But it *does* require adequate

² *Wyeth*, 720 F.3d at 1386; *see Enzo Life Scis.*, 928 F.3d at 1346; *Enzo Biochem*, 188 F.3d at 1372, 1374.

blaze marks: “either a representative number of species falling within the scope of the genus or structural features common to the members of the genus.” Op. 22-23 (quoting *Ariad*, 598 F.3d at 1350). This standard ensures that genus claims afford “patent protection” only “to those who actually perform the difficult work of ‘invention,’” rather than offer untested “theories” and leave the “downstream research” to others. *Ariad*, 598 F.3d at 1353.

Applying the blaze marks test to the uncontested record, the panel correctly found Idenix’s written description legally insufficient. Idenix’s claims cover “the specific subset of 2'-methyl-up nucleosides that are effective in treating HCV.” Op. 23. But a skilled artisan reading Idenix’s patent could not “visualize or recognize the members of the genus,” *Id.* (quoting *Ariad*, 598 F.3d at 1350), because the specification neither identifies what structural features are active against HCV nor discloses species that are representative of the full scope of the claims. Instead, the specification merely “provides eighteen position-by-position formulas” describing certain candidate compounds that “*may* treat HCV,” subject to synthesis and screening. Op. 23 (emphasis added). That disclosure offers “no indication that any nucleosides outside of” the

formulas, like Gilead’s 2'-methyl-up, 2'-fluorine-down nucleoside, “could be effective to treat HCV—much less any indication as to *which* of those undisclosed nucleosides would be effective.” *Id.*

Said otherwise, even if Idenix theorized that some 2'-methyl-up nucleosides outside its formulas would be effective against HCV, it did not “actually perform the difficult work” of identifying their features—or, more importantly, pass along that knowledge to those of ordinary skill. *Ariad*, 598 F.3d at 1353. As the panel emphasized, “[t]he written description requirement specifically defends against such attempts to ‘cover any compounds later actually invented and determined to fall within the claim’s functional boundaries.’” Op. 24 (quoting *Ariad*, 598 F.3d at 1353).

B. Idenix again largely ignores the panel’s sound analysis and attacks another strawman. It contends that the panel invalidated the patent for offering “too much disclosure without specifically disclosing the infringing product.” Pet. 7. Neither half of that statement is correct. First, the panel never suggested Idenix offered “too much” description—or “too many” “examples,” Pet. 14—of the claimed genus. Nor did it find that the specification contained “a detailed disclosure of

embodiments ‘similar[]’ to the accused product.” Pet. 15. Just the opposite. The panel made clear that the specification offered “*no indication*” that non-formula nucleosides like Gilead’s could have anti-HCV activity and “*no method* of distinguishing effective from ineffective compounds.” Op. 23 (emphases added). There is thus no “‘too much, too little’ fallacy” in the panel’s § 112 analysis. Pet. 5.

Second, contrary to Idenix’s implication, the panel did not require actual disclosure of the accused product. Pet. 5; *see also* REGENXBIO Br. 5-8. The panel correctly noted that undisclosed species (including accused products) *can* be adequately described by sufficiently representative blaze marks. Op. 22-23. Idenix’s claims, however, failed to provide those blaze marks to *any* undisclosed species, leaving the skilled artisan without “meaningful guidance into what compounds” outside the formulas would “treat HCV.” Op. 24.

The panel used the lack of guidance toward 2'-fluorine-down nucleosides as an example of a compound that (1) falls within the scope of the claims, but that the specification (2) scrupulously omits and (3) provides no suggestion would be effective. Op. 24-25. And that example was particularly illustrative because the “absence of 2'-fluoro-

down” was “conspicuous” in a way that *discouraged* a skilled artisan from visualizing it as part of the claimed genus. *Id.* That discussion did not create any legal rule requiring disclosure of the accused product in every case.

Once again, then, Idenix’s warnings of “innovation communities at sea,” Pet. 15, ring hollow. This Court has long stressed that a genus claim is invalid if it constitutes a mere “hunting license” in a nascent field. *Ariad*, 598 F.3d at 1353. That describes Idenix’s overbroad claims to a tee. By affirming their invalidity, the panel hewed to precedent and protected legitimate genus claiming from abuse.

III. The Panel Respected The Jury’s Role.

Relying on the same misreadings of the panel opinion, Idenix argues that the panel’s decision “guts” the jury’s factfinding role and “leaves little room for the jury’s historic fact-deciding authority.” Pet. 15, 18; *see* Amgen Br. 10-12. But the panel opinion accepts the jury’s finding on every issue where facts were actually in dispute. In applying *Wands*, for example, it declined to endorse several of the district court’s conclusions that could arguably have gone the other way, like the question of how difficult nucleoside synthesis would be. *See* Op. 15.

The panel’s nonenablement holding was driven instead by the *undisputed* evidence on the unpredictability of the field, the scope of the claims, and the absence of guidance in the specification.³

Similarly, having misread the panel’s written description analysis to hinge on a finding that “the specification discloses *too many* compounds without also disclosing the infringing one,” Idenix argues that the decision “evaporates” the “jury’s right to decide” the issue. Pet. 16. Again, the panel’s actual reasoning was driven by uncontested—and legally dispositive—facts about the specification’s lack of guidance about which compounds were effective and which were not. The panel properly granted judgment as a matter of law because, given the undisputed record, “a reasonable jury would not have had a legally sufficient evidentiary basis to find for” Idenix. Op. 3 (citations omitted).

Idenix also accuses the panel of assessing enablement and written description from the perspective of “judges, not skilled artisans.” Pet.

³ Idenix appears to now suggest that evidence on predictability was contested. Pet. 18. But it never disputes that its own experts described treating HCV with nucleosides as “unpredictable” and “in its infancy.” Op. 14 (quoting Idenix’s expert). And nothing Idenix cites actually suggests a person of skill could use the specification to predict which compounds would be effective.

18. That cannot be squared with the decision, which repeatedly invoked the skilled artisan’s point of view. *E.g.*, Op. 7 (enablement); Op. 23 (written description).

IV. This Is Not An Appropriate Case To Revisit This Court’s § 112 Jurisprudence.

Finally, Idenix briefly suggests a much more adventurous course: overturning decades of § 112 precedent that treat enablement as a question of law and written description as a distinct requirement. *See* Pet. 3, 17. Those cursory arguments for a jurisprudential revolution do not merit rehearing—and especially not in this case.

This Court has long construed enablement as a legal question whose “factual underpinnings” are reviewed deferentially for “substantial evidence.” Op. 4; *see Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960 n.6 (Fed. Cir. 1983) (enablement a question of law). Thus, as Idenix acknowledges, this Court already treats enablement as “factually intensive,” Pet. 17, with a standard of review to match. Formally reclassifying the ultimate question as a question of fact would not change the outcome here, given the overwhelming, uncontested evidence of nonenablement, and as evidenced by the Court’s prior

holding that Idenix did not enable a 2'-methyl-up, 2'-fluorine-down nucleoside. *Storer*, 860 F.3d at 1350-52.

As for the separate written description requirement, the en banc Court already explained at length why it is compelled by the text of § 112. *Ariad*, 598 F.3d at 1343-54. And the Supreme Court has recently and repeatedly rejected concerted efforts to overturn this Court's written description cases. *See Amgen Inc. v. Sanofi*, 139 S. Ct. 787 (2019); *Janssen Biotech, Inc. v. Abbott Labs.*, 565 U.S. 1197 (2012). Besides, Idenix does not explain what it can achieve by eliminating the separate written description requirement when it also failed to enable the claims.

CONCLUSION

The petition for rehearing should be denied.

Respectfully submitted,

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This brief complies with the type-volume limitation of Fed. Cir. R. 35(e)(4) because this brief contains 3871 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 35(c)(2).

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