No. 20-380

IN THE

# Supreme Court of the United States

IDENIX PHARMACEUTICALS LLC ET AL.,
*Petitioners*,

*v.*

GILEAD SCIENCES, INC.,
*Respondent.*

ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

## BRIEF IN OPPOSITION


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## QUESTION PRESENTED

Idenix discovered that a *single type* of modified ribonucleoside inhibits the Hepatitis C virus. Yet it sought a patent covering a vast *genus* of billions of untested and largely unmade compounds that might later prove to have similar effect. The court of appeals held those patent claims impermissibly overbroad for two independent reasons, yielding two questions presented:

1. The court found that the claims are not enabled—that is, the patent does not "teach those in the art to make and use the invention without undue experimentation," *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), as required by 35 U.S.C. § 112(a). Invoking the multi-factor *Wands* enablement standard it established decades ago (which Idenix does not challenge), the court held that the patent's limited teachings in an unpredictable field fail to enable the claims' vast scope. Did the court soundly apply the multi-factor standard to the facts of this case when it considered a variety of case-specific considerations?

2. The court separately held that the patent claims fail to satisfy § 112(a)'s distinct "written description" requirement, holding that when Idenix applied for the patent, it had not discovered and described the full scope of what it claimed. Was the court correct to follow more than 50 years of precedent holding that § 112(a) contains a separate written-description requirement?

## CORPORATE DISCLOSURE STATEMENT

Gilead Sciences, Inc. has no parent corporation and no publicly held company owns 10% or more of its stock.

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## INTRODUCTION

This case is about Gilead's breakthrough cure for the Hepatitis C virus (HCV), which Idenix claims to have invented. Idenix has sought credit for that cure—a modified nucleoside called sofosbuvir—in at least nine different agencies, courts, and tribunals around the world. But a basic problem has plagued Idenix at every turn: Its patents did not enable a person of skill to make and use sofosbuvir. So Idenix has lost. Nine times. *See, e.g.*, *Storer v. Clark*, 860 F.3d 1340 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 1598 (2018).

This tenth installment broke no new ground. Indeed, the shortcomings of the patent asserted here are particularly acute. Idenix's sweepingly broad claims, filed at the dawn of ribonucleoside research, purport to monopolize *billions* of untested and largely unmade candidate compounds, including sofosbuvir. But the patent does not even describe many of those candidate compounds, let alone teach other scientists how to make and use them. And the minimal information it *does* provide leads squarely away from sofosbuvir's pioneering structure. The Federal Circuit affirmed the district court's thorough determination that Idenix's patent claims fail the "enablement" requirement of 35 U.S.C. § 112(a), which requires patents to enable others to make and use the claimed invention. That is because of the gross mismatch between the sweeping scope of Idenix's genus claims and the paucity of guidance in the specification—particularly given the unpredictability of the field. In addition, the Federal Circuit held Idenix's patent also fails § 112(a)'s

"written description" requirement, under which the patent must describe the claimed invention.

Idenix's Petition presents no sound basis for review. Its first Question Presented depends entirely on a false premise: that the Federal Circuit abandoned the longstanding, multi-factor enablement standard set forth in *In re Wands* in favor of a supposed "bright-line" rule—namely, that a genus claim covering "a large number of compounds" is never enabled. *E.g.*, Pet. i, 2, 17. The Federal Circuit said no such thing. It analyzed enablement in a comprehensive, 14-page discussion that thoroughly considered each of the *Wands* factors. It (of course) considered the massive scope of the genus to which Idenix laid claim—but did so alongside other factors like the unpredictability of ribonucleoside modifications and the absence of meaningful guidance in Idenix's patent specification. It is Idenix that invented the supposed "bright-line rule," not the Federal Circuit.

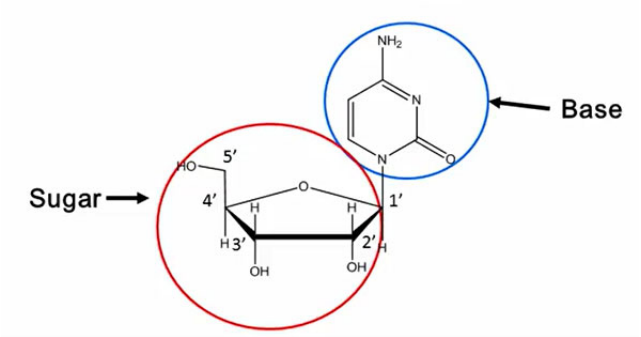
But Idenix has an even bigger problem: The Federal Circuit invalidated its patent on two, fully independent grounds. So Idenix is forced to ask the Court to also grant review on a second, separate question: whether to jettison § 112(a)'s distinct written-description requirement. This question, which would upend decades of settled expectations, has been repeatedly raised and recently denied by this Court—four times in the last 16 years, and most recently last year. With good reason: The written-description requirement is well-settled; Congress has chosen not to revisit it despite extensive revisions to the Patent Act; and Idenix presents no sound justification for the Court to intervene now.

The Petition should be denied.

## STATEMENT OF THE CASE

### In The Early 2000s, Modifying Ribonucleosides To Treat HCV Was A New And Unpredictable Field

One cannot appreciate the extraordinary breadth of Idenix's patent claims without understanding something about the chemistry of ribonucleosides—including the unpredictable ways in which the slightest modification can fundamentally change their properties. Ribonucleosides are the building blocks of RNA, which encodes a virus's genetic information. There are four naturally occurring ribonucleosides, each with the same sugar attached to a different base:




C.A. App.[1] 6386. The sugar has five carbon atoms, which are numbered from 1' to 5'. Each of those carbons is also bound to "substituents" (atoms or groups of atoms), which may be in the "up" or "down"

[1] Citations to "C.A. App." refer to the joint appendix filed in the court of appeals.

position. Pet. App. 6a-7a. For instance, in the illustration above, the sugar has a hydrogen atom (H) at the 2'-up position and a hydroxyl group (OH) at the 2'-down position.

To make a person sick, a virus like HCV must replicate itself and ribonucleosides play a pivotal role. To form new viral genes, HCV must build a copy of its own RNA by linking together ribonucleosides that are already present in the host's cells. C.A. App. 6372. Several enzymes are involved in that process, including NS5B, which selects the ribonucleosides to use when the virus replicates. *Id.*

In the early 2000s, scientists turned to modified ribonucleosides as a potential treatment for HCV. The deadly virus afflicted hundreds of millions of people worldwide, but patients' best hope entailed a grueling regimen of injections lasting 6-12 months, which had a low success rate and severe side effects. C.A. App. 37416-17. When that regimen failed, patients faced grim prospects: HCV damages the liver and eventually leads to cirrhosis, liver failure, and liver cancer. *Id.*

Scientists hoped to employ a new strategy: trick a viral enzyme (like NS5B, among others) into accepting a specially modified ribonucleoside that would jam the replication process. C.A. App. 37544. But while the concept was promising, the search for effective compounds was daunting. There are infinite ways to alter a nucleoside. Any of thousands of potential substituents can be added at any of the up or the down positions on the sugar, as well as at several positions on the base—and these innumerable changes can be

made alone or in combination. C.A. App. 7970, 37545. Moreover, because the field of treating HCV using ribonucleosides was in its "infancy," the antiviral effect of any such modification was highly unpredictable. In the words of Idenix's own chemist, "'you don't know whether or not a nucleoside will have activity against HCV until you make it and test it.'" Pet. App. 17a.

**Idenix Itself Focuses On A Single Type Of Ribonucleoside, But Claims *Every* Effective Ribonucleoside Within A Genus Of Billions Of Untested Compounds**

Faced with that unpredictable field, Idenix turned to a known quantity. Decades earlier, ribonucleosides with a single modification—substituting methyl (Me) at 2'-up—had shown activity against certain viruses and cancer enzymes. C.A. App. 52906-09. These ribonucleosides were unaltered at any other position, including, importantly for present purposes, the OH at 2'-down. That OH group was believed to be essential to trick HCV into using the modified ribonucleoside in its replication process. C.A. App. 49653. Idenix tested the same 2'MeOH ribonucleosides against a surrogate for HCV and found them to be active—that is, to inhibit viral reproduction in a laboratory setting. It immediately filed for patent protection. Ultimately, however, 2'MeOH compounds—including those that Idenix developed—performed poorly in clinical trials and never reached the market. C.A. App. 37105. Many turned out to be entirely inactive against HCV. C.A. App. 37421, 37513-14. And the FDA repeatedly placed 2'MeOH drugs on "clinical hold" because they were "very toxic" and cured virtually no one. C.A. App. 37105, 37412.

When Idenix sought patent protection, it claimed exponentially more than the "particular set of [2'MeOH] compounds" (Pet. 4) it had found to be active in the laboratory. Idenix's claims covered a huge swath of the untested universe of modified ribonucleosides: *every* ribonucleoside that inhibits viral reproduction in a laboratory and features methyl at 2'-up and *any conceivable* modification at virtually *any other* position. The scope of this monopoly is staggering: Billions of modified ribonucleosides meet the claims' structural limitations. Pet. App. 10a. Indeed, these candidates are covered if they inhibit *any* HCV enzyme—not merely NS5B, which the Petition mistakenly characterizes as the "target." *Compare* Pet. 11 *with* Pet. App. 23a ("'NS5B activity is *not* a claim limitation'").

The teachings of Idenix's patent, however, were not remotely commensurate with the patent's scope. The patent specification discloses just one working modification: adding Me at 2'-up in an otherwise natural ribonucleoside, the approach that Idenix had actually tested. Pet. App. 20a-21a. Beyond that, the specification falls back on 18 "formulas" that identify "tens if not hundreds of thousands of 'preferred' 2'-methyl-up nucleosides" that "*may*" turn out to inhibit HCV. Pet. App. 21a, 28a. The Petition calls these "covered compounds," Pet. 11, but they were merely candidates for further testing. The patent does not "explain" what would make any of the compounds covered by the formulas "effective, or why." Pet. App. 28a. Nor does it indicate "that any nucleosides *outside* of those disclosed in its formulas could be effective to treat HCV." *Id.* (emphasis added). As noted above, the patent does not even single out NS5B as the target for

inhibition. Instead, it broadly notes that any candidate "would need to be tested for efficacy against HCV," Pet. App. 13a, and provides methods for testing whether a compound inhibits any of three different viral enzymes, C.A. App. 76, 139.

**Gilead Discovers The Cure For HCV**

Gilead and its predecessor, Pharmasset, took a different path from Idenix. When it came to 2'MeOH compounds, Pharmasset was discouraged by lackluster antiviral performance and wary of a potential "patent conflict" with Idenix. C.A. App. 37171, 37199. Far from "press[ing] ahead" with 2'MeOH structures, Pet. 8, Pharmasset quickly abandoned them. C.A. App. 37171, 37199. Instead, Pharmasset chemist Jeremy Clark set out to create a compound that no one had ever synthesized before: a ribonucleoside with methyl added at 2'-up and fluorine (F) substituted for the signature OH at 2'-down.

Pharmasset approved the project only after reviewing Idenix's patent and concluding that 2'MeF ribonucleosides were not covered. That was why Clark at one point held Idenix's patent "in hand." Pet. 4. He and Pharmasset's chief scientist noted that 2'MeF compounds were excluded from the patent's expansive formulas, as well as all claims at the time. *See* C.A. App. 37322-33, 47949-8021. And the omission appeared to be "on purpose." C.A. App. 37322. Even as the patent omitted fluorine from 2'-down, it included every other member of the fluorine family (called "halogens") at that spot, and it included fluorine at other positions like 2'-up—all of which suggests that the inventors did not think fluorine at 2'-

down even worth exploring. *Id.* Idenix later was forced to acknowledge that it had not conceived of a 2'MeF structure when it filed for patent protection. Pet. App. 27a.

Synthesizing a 2'MeF ribonucleoside proved difficult. Clark tried "at least three" approaches over a period of several months. C.A. App. 37319. Finally, after several failures, Clark discovered the groundbreaking reaction that yielded a 2'MeF compound. The reaction itself may only have taken "fifteen minutes," Pet. 21, but the arduous process of discovering it stretched far longer. Tests showed high antiviral efficacy and low toxicity. Pharmasset had found the needle in the hayfield, and subsequently received a patent for its breakthrough. C.A. App. 49548.

Years of additional development followed. Pharmasset first focused on converting Clark's compound into a drug that could reach the liver in an effective form. That was a challenge, requiring a modified structure—called a prodrug—that could withstand the body's metabolic processes. C.A. App. 37338-39. The eventual solution, sofosbuvir, is a unique compound that links the sugar portion of Clark's ribonucleoside to a different base and a suitable prodrug. *Id.* Gilead then undertook the separate challenge of completing rigorous clinical trials and presenting the results to the FDA for approval, as part of an application spanning "a quarter of a million pages." C.A. App. 37425.

Gilead released the first sofosbuvir-based drug, Sovaldi®, in 2013. C.A. App. 37430. It was revolutionary. The HCV virus that had eluded reliable therapies

for decades could suddenly be cured in over 90% of patients in a matter of weeks, without significant side effects. C.A. App. 37425.

**Idenix Sues, But The District Court Invalidates Idenix's Overbroad Claims**

While Gilead developed its groundbreaking 2'MeF ribonucleosides, Idenix continued pursuing its failed drug candidates, as did larger companies like Merck, which eventually acquired Idenix. To date, Idenix has not itself found a single compound that safely and effectively treats HCV in humans within the billions of compounds its patent purports to cover.

Instead, having failed in its own drug development efforts, Idenix tried to cash in on Gilead's success. When Clark sought to patent Gilead's breakthrough discovery, Idenix opposed his application in an interference proceeding, arguing that it had discovered the 2'MeF breakthrough first. The Patent Office and the Federal Circuit disagreed. *Storer v. Clark*, 860 F.3d 1340 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 1598 (2018). Idenix pursued its strategy across the globe and was universally rebuffed. C.A. App. 7240. Idenix's eventual parent, Merck, also sued. Its lawsuit came to an ignominious end with a finding that its patents were unenforceable because it engaged in "deceptive dealing" and "unconscionable" and "outrageous" behavior in the course of its business dealings with Pharmasset, and in patent prosecution and litigation. *Gilead Scis., Inc. v. Merck & Co.*, No. 13-CV-04057-BLF, 2016 WL 3143943, at *29-33 (N.D. Cal. June 6, 2016), *aff'd*, 888 F.3d 1231 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 797 (2019).

Specifically, Merck narrowed its patent claims to zero in on Pharmasset's invention after its in-house patent prosecutor attorney lied about his role at the company and improperly accessed confidential information showing Clark's invention. *Id.*

That leaves this case, which met the same fate as the others. During trial, Idenix's experts did not dispute that the structural requirements encompassed by the patent claims cover billions of candidates; that many of those candidates, including 2'-MeF structures, fell outside the patent specification's formulas; or that the specification identifies only one type of working example. C.A. App. 37513, 37545; *see* Pet. App. 12a, 21a, 27a. One expert contended that a skilled artisan could eliminate some of those candidates as untenable. C.A. App. 37734. But Idenix's counsel conceded that the remaining compounds to be tested would number, at a bare minimum, in the "thousands." C.A. App. 40013. Moreover, Idenix's own witnesses conceded that the field of treating HCV with ribonucleosides was "in its infancy" and "unpredictable." C.A. App. 37736-37. Consequently, "you don't know whether or not a nucleoside will have activity against HCV until you make it and test it." C.A. App. 37441. Despite those concessions, the jury found for Idenix.

The district court vacated the verdict, granting judgment as a matter of law for Gilead because Idenix's claims are not enabled. The court went out of its way to emphasize that chemical genus claims are not "automatically non-enabled or inherently suspect." Pet. App. 85a n.13. But a genus claim—like any other claim—is not enabled if it requires undue

experimentation under *Wands*. That multi-factor test considers facts including the "unpredictability of the art," the "breadth of the claims," the "quantity of experimentation necessary," and "the amount of direction or guidance presented" in the patent, including "working examples." Pet. App. 77a (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)).

In a comprehensive 33-page analysis, the district court explained that, viewing the evidence "in the light most favorable to Idenix," Pet. App. 88a, these factors weigh decisively against enablement. The evidence shows that modifying ribonucleosides for anti-HCV activity was highly unpredictable, with "seemingly minor changes to active or effective compounds" yielding "inactive or even toxic" compounds. Pet. App. 61a, 99a. Not surprisingly, therefore, many of the candidate compounds that satisfied the claims' structural requirements were "inoperable." Pet. App. 87a. Identifying the relatively "few" active compounds within the broad universe of compounds covered by the patent claims would require screening (and often synthesizing) many thousands of ribonucleosides at a bare minimum. Pet. App. 101a. And the patent specification, with its single working modification, provided virtually no "guidance" about which ones would work. Pet. App. 85a n.13, 107a.

In short, whatever the importance of Idenix's discovery, its sweepingly broad genus claims far outstripped its contributions to a nascent field. The court explained that Idenix did not deserve credit for—and a monopoly over—"'the later patentable inventions of others,'" including Gilead's pioneering work on 2'MeF ribonucleosides. Pet. App. 109a-110a (quoting *Ariad*

*Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc)).

**The Federal Circuit Holds That Idenix's Overbroad Claims Fail § 112(a)'s Enablement And Written Description Requirements**

On appeal, the Federal Circuit affirmed the district court's non-enablement holding, and separately and independently invalidated Idenix's claims for lack of written description.

The panel first agreed that, on this record, the *Wands* factors overwhelmingly establish non-enablement. The panel emphasized that Idenix's own experts "testified … that the field was new and unpredictable." Pet. App. 22a. Despite that uncertainty, the claims swept broadly, thereby requiring a skilled artisan following the patent to screen a huge number of ribonucleosides, relatively "few" of which would be effective. Pet. App. 15a-16a, 21a. The court assumed for the sake of its analysis that a skilled artisan could have trimmed the number of viable candidates to "many, many thousands," in line with Idenix's concession. Pet. App. 15a. But this figure was "conservative," with the record showing that the true number was "likely orders of magnitude higher." *Id.* & n.5. Either way, Idenix's patent "fails to provide meaningful guidance" for that "broad" experimentation, identifying only "a single sugar" that worked. Pet. App. 21a. Absent more "specific guidance," Idenix's patent offered "'only a starting point, a direction for further research.'" Pet. App. 20a (quoting *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010)).

The panel took account of the full record. It recognized that some *tools* for further research in the field were well-developed. It also recognized that the "level of skill" in ribonucleoside synthesis was high, such that "a jury could have found that the synthesis of an individual compound was largely routine." Pet. App. 18a, 24a. Those considerations "weigh[ed] against a finding of non-enablement" to some degree. Pet. App. 19a. But that did not remedy the fatal overbreadth of Idenix's claims in this unpredictable field. In light of the patent's paucity of guidance and the sheer scope of the claims, Idenix offered nothing more than a plan for further research, and that plan did not become enabled (and therefore patentable) merely because other companies employed skilled researchers. Pet. App. 23a-24a.

Next, the court concluded that Idenix's patent claims are invalid for the separate reason that they are not supported by an adequate written description. Pet. App. 26a. To satisfy that requirement, "the specification must describe an invention … and show that the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351. The court emphasized that when it comes to chemical genus claims, an adequate written description need not contain "'a nucleotide-by-nucleotide recitation of the entire genus.'" Pet. App. 29a (quoting *Ariad*, 598 F.3d at 1352). Rather, it is enough to provide "relatively few representative examples or formulas to support a claim on a structurally similar genus," as long as that information provides "sufficient blaze marks to direct" a skilled artisan how to distinguish "the specific subset" of compounds that work from the multitude that do not. Pet. App. 27a-29a.

Here, however, the court explained that Idenix's patent plainly lacks such "blaze marks" that would tell an artisan where to search within the billions of candidate compounds for ones that might be effective. Idenix's patent specification does include 18 formulas—but, the Federal Circuit explained, even those formulas encompass hundreds of thousands of ribonucleosides that have methyl at 2'-up and only "*may*" be effective against HCV. Pet. App. 21a, 28a. And there are a huge number of candidate compounds that are encompassed by the sweeping patent claims but *not* covered by the 18 formulas—including Gilead's 2'MeF ribonucleosides. Pet. App. 28a-29a.

That mismatch between the scope of the patent claims and the written description in the specification is particularly "conspicuous," the court explained, because the formulas blaze a trail *away* from 2'MeF structures: As Pharmasset had observed, the formulas cover fluorine at several *other* positions, including 2'-up, but omit it from 2'-down. *Id.*; C.A. App. 37322. Ultimately, Idenix's patent specification "provides *no* indication that *any* nucleosides outside of those disclosed in its formulas could be effective to treat HCV—much less any indication as to *which* of those undisclosed nucleosides would be effective." Pet. App. 28a (first emphases added). The written description requirement bars Idenix from claiming monopoly rights over those "later … invented" compounds. Pet. App. 29a.[2]

[2] Judge Newman wrote separately in an opinion styled as a dissent. But she did not disagree with the majority's analysis of

The Federal Circuit denied rehearing en banc without any judge calling for a vote. Pet. App. 2a.

## REASONS FOR DENYING CERTIORARI

### I. The First Question Presented Is Premised On A Supposed "Numbers-Based Enablement Rule For Genus Claims" That Appears Nowhere In The Decision Below.

#### A. The Petition distorts the court of appeals' reasoning.

Idenix has no quarrel with the multi-factor *Wands* test the court of appeals has developed for deciding whether a patent claim is enabled. Instead, Idenix's first Question Presented rests principally on a false premise: that the court of appeals abandoned that multi-factor test in favor of an improper "bright-line rule" that "a genus claim fails *as a matter of law* if it covers too many compounds." Pet. 15, 17.

The court did no such thing. It properly articulated the longstanding *Wands* standard for enablement, a "case-specific" inquiry that balances seven factors, including "the nature and predictability of the field," "the amount of guidance presented in the patent," the scope of "working examples," "the scope of

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the patent's validity as the claims were construed. Pet. App. 11a. Instead, she would have addressed claim construction *sua sponte*, and construed Idenix's claims more narrowly to exclude Gilead's invention from their scope, thereby avoiding an enablement or written description problem. Pet. App. 32a-33a. Under that construction, Idenix's claims would not be infringed. Pet. App. 47a-48a.

the claimed invention," and "the quantity of experimentation necessary." Pet. App. 11a; *see Wands*, 858 F.3d at 737. The court then applied that test, assessing all seven factors in a comprehensive analysis spanning 14 pages in the Petition Appendix. Pet. App. 11a-24a. Only by ignoring half of that discussion could Idenix—and the amici that parrot its argument—maintain there is a bright-line rule based on the number of candidate compounds.

In truth, the panel did not even list the number of candidate compounds as a *Wands* factor, much less as a test unto itself. Pet. App. 11a. The panel merely treated that number as one element of the analysis, which informed just two of the seven factors: "the quantity of experimentation," Pet. App. 11a, and "the scope of the claims," Pet. App. 22a. Certainly, those factors "favor[ed] a finding of non-enablement." Pet. App. 12a. Idenix does not dispute that the number is at least relevant to those factors. It would have been absurd to ignore the massive breadth of what Idenix sought to monopolize. But these factors were not dispositive on their own—and the panel never said they were.

The court relied on multiple other factors that the Petition simply ignores. For one, the court noted the undisputed evidence that most 2'-methyl-up ribonucleosides will not work against HCV. It noted Idenix's expert testimony that there were just "a few interesting ones," and counsel's concession that "'not all 2' methyl up ribonucleosides will be effective to treat HCV.'" Pet. App. 17a (internal citation omitted). That means that the "patent leaves a [skilled artisan] searching for a needle in a haystack to determine

which of the large number of 2' methyl up nucleosides falls into the small group of candidates that effectively treats HCV." Pet. App. 23a. Idenix does not dispute that this factor is relevant to the degree of experimentation required. Yet, Idenix ignores it.

The panel also emphasized that researchers considering a candidate had no easy way to distinguish the universe of candidates that were effective from those that were not. Pet. App. 17a. The art of modifying ribonucleosides to treat HCV was—in the words of Idenix's expert—in its "infancy" and "unpredictable." *Id*. Changing a single atom at any position could change the compound's behavior so drastically that, an Idenix chemist testified, "you don't know whether or not a nucleoside will have activity against HCV until you make it and test it." *Id.* Idenix does not dispute that "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). And the nascent field could hardly have been more unpredictable. This was a critical factor in the court's enablement analysis. Yet the Petition ignores it.

Next, the court of appeals explained how little guidance Idenix's patent specification provides to distinguish the ribonucleosides that would work from those that would not. Idenix's patent offered just one "exceedingly narrow" working modification—adding methyl at 2'-up while retaining natural substituents at every other position. Pet. App. 21a. The specification offered no guidance about what would happen if the substituents at the other positions were modified; undisputedly, many would not work, and Idenix's

expert testified that screening would identify just "a few interesting ones." Pet. App. 17a; *see* Pet. App. 22a-23a. Idenix does not dispute that "[a]n enabling disclosure must 'be commensurate in scope with the claim.'" Pet. App. 20a (quoting *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983)). As the court of appeals concluded, there was no such proportionality here given the dearth of "meaningful guidance" in the specification. Pet. App. 21a. The Petition ignores this too.

Ultimately, the Petition suggests that the court of appeals somehow erased all of that careful *Wands* analysis by citing *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013). Idenix argues that *Wyeth* eschewed *Wands* to create the purported "numbers-based approach to enablement," and that the panel blindly followed that approach here. Pet. 17. But Idenix said the opposite in its rehearing petition, correctly describing *Wyeth* as "an unexceptional application of settled precedent." C.A. Reh'g Pet. at 11. As Idenix acknowledged then, but ignores now, *Wyeth* did not depart from *Wands*. Like this case, *Wyeth* involved a patent that disclosed a single working example of a compound that could treat a disease, but claimed *all* other effective compounds with *any other* structural substitutions. 720 F.3d at 1383. *Wyeth* held that a combination of unpredictability, expansive claim scope, and negligible guidance established non-enablement as a matter of law under the multi-factor *Wands* test. *Id.* The panel below cited *Wyeth* only as an example of a sound *Wands* analysis on "striking[ly]" "similar[]" facts. Pet. App. 24a.

Ultimately, it is the Petition—not the court of appeals—that tacitly seeks to replace the longstanding

*Wands* standard with an improper bright-line rule. Disregarding factors like the unpredictability of the field and the scope of the patent's teachings, Idenix suggests that the experimentation required by its claims could not have been "undue" solely because the *tools* for experimentation were "routine." Pet. 17-18, 22. It insists that all that really matters for enablement is that "follow-on scientists" had the technology to "rapidly generate other compounds" and see if they worked. Pet. 20. On the contrary, this Court has been clear that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 536 (1966). The court of appeals was therefore correct that "'a direction for further research'" is not an enabled invention. Pet. App. 20a (quoting *ALZA*, 603 F.3d at 941). That is no less true if the *methods* for hunting are routine, particularly when, as here, the record reflects that using those "routine" methods to randomly synthesize and screen compounds would have required at least a year of labor. Pet. 20-21. Idenix's patent claims nothing more than a research plan, and the Patent Act requires more.

### B. The Federal Circuit's analysis poses no threat to sound genus claims.

The Petition—again parroted by certain amici—repeatedly claims that the decision below will harm the biopharmaceutical industry. *E.g.*, Pet. 3, 15, 28, 32. It principally relies on the unpublished draft of an article co-authored by amici here. *See* Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim* (Aug. 5, 2020), https://tinyurl.com/yxkb8sc9; Professors' Br. 25. The Petition

and the article both rely on the same mistaken premise described above—that the court of appeals created an "arbitrary numerical threshold" on genus claims.

No one disputes that innovators in the chemical arts sometimes "must rely on 'genus' claims." Pet. 1. Gilead does this too; indeed, its patents on 2'MeF ribonucleosides use genus claims. *Storer*, 860 F.3d at 1344. An "arbitrary numerical threshold" on the size of those claims would certainly defy the "text" of § 112(a) and might well prove problematic for "life sciences innovation." Pet. 18, 28. But no matter how many times Idenix asserts it, the court of appeals has not established any such threshold. Instead, it considers whether the patent's disclosure is "'commensurate'" with the scope of the claims. That makes sense—if your patent claims more, then you must enable more. But this is not an impossible or unforgiving standard; the court of appeals emphasizes that "[e]ven a considerable amount of experimentation is permissible." *Wyeth*, 720 F.3d at 1386 (quotation marks omitted). Applying that standard, the court has upheld genus claims both before and after *Wyeth*. *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). There has been no "'fundamental … change in patent doctrine,'" Pet. 18, and there is no risk that pharmaceutical innovators must limit their claims to "individual compounds," Pet. 2.

The court of appeals' enablement decisions merely prevent patentees from abusing genus claims by trying to monopolize far more than they invented.

Legitimate genus claims afford commensurate protection for the "full scope" of a pharmaceutical "discovery." Pet. 3. But overbroad genus claims can become "hunting licenses" on an immense scale, stretching far beyond the patentee's actual contribution and preemptively claiming every compound within a massive, poorly understood universe of candidate structures.

This case demonstrates the danger: After screening just four barely modified ribonucleosides, Idenix claimed *all* successful compounds among *billions* of untested structures, without explaining why any particular modification might work. *Supra* 6. The very existence of that patent is bound to deter others from pursuing any of those candidates. Thus, a patent like Idenix's is antithetical to the patent bargain and poses grave risks to scientific innovation. Overbroad genus claims threaten to stop lifesaving discoveries like Gilead's sofosbuvir in their tracks. Invalidating such overreach does not herald the "'death of the genus claim.'" Pet. 4. It ensures that genus claims will promote rather than hinder innovation.

That is why, as the article featured by the Petition must concede, "innovation and even patent litigation seem to be proceeding apace in the pharmaceutical industry." *The Death of the Genus Claim*, *supra*, at 94. The article is at pains to reconcile the flourishing of the industry with the supposed "death of the genus claim." Ultimately it insists that the "[b]usinesspeople" in charge of leading pharmaceutical companies must be oblivious to "what the law says." *Id.* at 102. The far likelier explanation, however, is that seasoned executives running billion-dollar companies,

advised by experienced patent lawyers and responsible to their investors, are aware of the law governing their patents. Pharmaceutical "investment" and "patenting" continue apace, *id.* at 1, because legitimate genus claims are alive and well.

In a final bid to establish a threat to genus claiming, the Petition suggests (at 19) that the court of appeals' reasoning conflicts with and would invalidate the genus claim this Court upheld a century ago in *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261 (1916). If *Minerals Separation* had been so important, Idenix would have featured it prominently below. But Idenix cited it just once, in passing, for a boilerplate proposition. C.A. Idenix OB at 72. That is because, far from clashing with the decision below, *Minerals Separation* provides a telling contrast. The claims asserted there covered the use of a specific process to separate metals from a range of ores, using oil and air bubbles. 242 U.S. at 265. There was no dispute that every variation of this process worked—unlike Idenix's infinite universe of candidate compounds. Experimentation was required merely to *optimize* the claimed method for each ore by fine-tuning it "in order to obtain the best results"—that is, the "most successful and economical" application of the invention. *Id.* at 270-71. Claims covering such modest adjustments would not "plainly fail" under the decision below. Pet. 19. The court of appeals invalidated Idenix's claims only because they demand far more than optimization; they require skilled artisans to discover, without meaningful guidance, which compounds work *at all*.

### C. This case presents no question about the jury's role.

Sprinkled through the Petition are suggestions that this case implicates the role of the jury. No such question is presented.

*First*, Idenix asserts that a "bright-line legal rule" focused exclusively on the size of a genus would "subjugate[] juries" by disregarding their findings on the *Wands* factors. Pet. 22. Again, there is no such rule. And the panel carefully and faithfully parsed the jury's implicit findings on each of the *Wands* factors. Pet. App. 11a-24a.

*Second*, Idenix suggests in passing that there is disagreement about whether enablement is a question of law or of fact. Pet. 22-23. But Idenix did not seek certiorari on that question. *See* Pet. i. And, even if the question were properly presented, it would be a near-impossibility for the parties to meaningfully brief it, given that the Petition already asks the Court to grant review on two significant questions: the supposed bright-line rule for enablement and whether to do away with written description. Nor does the question make any practical difference here. Enablement rests on "factual underpinnings" (the *Wands* factors) reviewed only for "substantial evidence." Pet. App. 6a; *see Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960 n.6 (Fed. Cir. 1983). Here, the panel analyzed what facts reasonable jurors could and could not have found in Idenix's favor on a wide range of specific issues relevant under *Wands*. Pet. App. 12a-26a. Judgment as a matter of law was appropriate because the record contains overwhelming, uncontested evidence of non-

enablement. Idenix disagrees with the panel's analysis of the record. *E.g.*, Pet. 21 (asserting, without explanation, that the patent's working examples were "numerous"). Such fact-specific disputes do not warrant this Court's attention.

* * *

At bottom, this case simply does not present the enablement question that Idenix purports to raise. And even it did, this case would be the wrong vehicle for resolving that question. Enablement is just one of two independent grounds for invalidating Idenix's claims. A ruling on that issue could not change the judgment unless the Court also resolved the second question presented in Idenix's favor, to which we turn next.

## II. The Court Has Recently And Repeatedly—And Correctly—Denied Requests To Upend 50 Years Of Settled Doctrine Concerning Written Description.

Idenix's first Question Presented is inconsequential unless this Court also takes on Idenix's second question. There is no good reason to do so. Settled law reads 35 U.S.C. § 112(a) as embodying a written-description requirement separate from enablement. Whereas enablement asks whether the patent discloses enough for a person of ordinary skill in the art to *make and use* the claimed invention, written description asks whether the inventor *described* the invention in sufficient detail to show that she actually invented it. *Ariad*, 598 F.3d at 1352. Idenix's second question asks this Court to upend that long-settled

interpretation. This Court has recently and repeatedly denied petitions presenting this same question. *See Amgen Inc. v. Sanofi*, 139 S. Ct. 787 (2019); *Janssen Biotech, Inc. v. Abbott Labs.*, 565 U.S. 1197 (2012); *Chiron Corp. v. Genentech, Inc.*, 543 U.S. 1050 (2005); *Univ. of Rochester v. G.D. Searle & Co.*, 543 U.S. 1015 (2004).

It should do so again here. A written-description requirement has been a feature of the patent system for over 200 years, and, since their inception, the Federal Circuit and its predecessor have consistently interpreted § 112 as containing such a requirement. Idenix offers no compelling reason for the Court to abolish this requirement, particularly given the numerous occasions on which Congress has amended the Patent Act—including § 112—without doing so. And there is good reason not to take this radical step.

### A. The written description requirement is "firmly embedded."

The Petition insinuates that the written-description requirement is of recent vintage. Pet. 24. It is not. As the United States has explained, the written-description requirement is "firmly embedded in the operation of the patent system" and "only the most extraordinary justification could warrant" "upsetting statutory interpretations as settled as this." Brief for United States as Amicus Curiae ("*Ariad* U.S. Br."), *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (2010) (No. 2008-1248), 2009 WL 4832140, at 25-26, also available at https://tinyurl.com/USAriad.

A separate written-description requirement has been a crucial feature of patent law for over 200 years. From the Patent Act of 1793 through every subsequent revision, Congress has required inventors to provide *both* "a written description of [the] invention, *and* of the manner of using … the same." Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321-22 (emphasis added); *see* Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119; Act of July 8, 1870, ch. 230, § 26, 16 Stat. 198, 201; 35 U.S.C. § 112. This requirement "plays a vital role in curtailing claims" where the patent may be sufficiently enabling (e.g., because techniques for experimentation are known), yet the full scope of the claims "ha[s] not been invented, and thus cannot be described." *Ariad*, 598 F.3d at 1352.

Since at least 1853, this Court has recognized and applied that requirement. It refused a patent to Samuel Morse for every conceivable way of printing characters using an electric current because Morse claimed "an exclusive right to use a manner and process *which he has not described and indeed had not invented*, and therefore could not describe when he obtained his patent." *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-13 (1853) (emphasis added). It likewise invalidated claims for a gas engine with "flexible webs" because "that was not the invention which [the patentee] described by his references to an extremely rigid web." *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 56-59 (1938); *see Permutit Co. v. Graver Corp.*, 284 U.S. 52, 60 (1931); *Gill v. Wells*, 89 U.S. (22 Wall.) 1, 25-26 (1874).

This requirement is now codified in 35 U.S.C. § 112(a), which provides that the "specification shall

contain a written description of the invention, *and* of the manner and process of making and using it … and shall set forth the best mode contemplated by the inventor … of carrying out the invention" (emphasis added). This Court has read § 112(a) as establishing three separate requirements that "must be satisfied": "the patent application must [1] describe, [2] enable, *and* [3] set forth the best mode of carrying out the invention." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (emphasis and numbering added).[3] Likewise, the Federal Circuit "[s]ince its inception … has consistently held that § 112 … contains a written description requirement separate from enablement." *Ariad*, 598 F.3d at 1351. So did its predecessor, more than 50 years ago. *In re Ruschig*, 379 F.2d 990, 995-96 (C.C.P.A. 1967). Ten years ago, the full Federal Circuit, sitting en banc, reaffirmed this requirement, relying on, among other things, the plain statutory text, this Court's precedents, and statutory stare decisis. *Ariad*, 598 F.3d at 1343-54.

Congress has repeatedly acquiesced in this reading "'when it re-enact[ed] [the] statute without change'" some 50 times. *Forest Grove Sch. Dist. v. T.A.*, 557 U.S. 230, 239-40 (2009) (quoting *Lorillard v. Pons*, 434 U.S. 575, 580 (1978)); *Graham v. John*

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[3] *Festo* and the history recounted immediately above belie Idenix's unelaborated assertion that this Court has "long understood § 112(a) … to demand a single inquiry." Pet. 26. Nothing it cites contradicts these authorities. Its lead citation, for example, held that the inventor "did describe accurately, and with admirable clearness, his process." *The Telephone Cases*, 126 U.S. 1, 535 (1888).

*Deere Co.*, 383 U.S. 1, 10 (1966). Especially notable is Congress's revision in 2011, just one year after the full court of appeals reaffirmed the written-description requirement in *Ariad*. As part of a thorough revamping of the Patent Act, Congress revised *other* aspects of § 112—in particular, changing § 112's "best mode" requirement—but it did not touch the written description requirement. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 15, 125 Stat. 284, 328 (2011).

For years inventors, innovators, and the Patent Office have relied on the written-description requirement in crafting patents and preventing overbroad claims from stifling innovation. *See Ariad* U.S. Br. 20-23 (explaining reliance). This Court should be loath to reconsider this long-settled question of statutory interpretation where "stare decisis has special force." *Watson v. United States*, 552 U.S. 74, 82 (2007).

### B. Idenix presents no sound reason to revisit the "firmly embedded" written description requirement.

Idenix's principal argument is that this longstanding interpretation is wrong. Pet. 23-26. But the text defeats Idenix's position and its policy arguments are wrong and misdirected.

**1.** Tellingly, Idenix spends just one paragraph discussing the statutory text. Pet. 25-26. Here is the text of the provision in full, in the form in which it has appeared since 1952:

> The specification shall contain

> a written description of the invention,
>
> and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same,
>
> and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

35 U.S.C. § 112(a) (line breaks added). When Congress established that the patent specification must describe both "the invention … *and* … the manner and process of making and using it," Congress plainly established two distinct requirements, and added "best mode" as a third.

Idenix concedes, as it must, that § 112(a) requires a patentee to describe three things: "the invention, the manner and process of making and using it, and the best mode contemplated by the inventor … of carrying it out." Pet. 25-26. But Idenix effectively nullifies the first requirement by compressing it into the second. Its theory is that the modifying clause—"in such, full, clear, concise and exact terms as to enable"—establishes a single standard that modifies both of the first two requirements, and thereby melds them together. Pet. 25-26.

Idenix's interpretation violates the basic rule that "a limiting clause or phrase … should ordinarily be read as modifying only the noun or phrase that it

immediately follows." *Barnhart v. Thomas*, 540 U.S. 20, 26 (2003); *see Jama v. ICE*, 543 U.S. 335, 343-44 (2005). Idenix inappropriately reads the modifying clause to modify not just the immediately preceding phrase (about "the manner and process of making and using" the invention) but also the requirement to describe "the invention."

The longstanding reading of § 112 also "follows from the parallelism of the language." *Ariad*, 598 F.3d at 1344. Both the modifying clause and the underlying requirement (i.e., to describe "the manner and process of making and using") repeat the same "make and use" language. This is strong evidence that they are to be read together. Had Congress intended to make a single, unified requirement about how to use the invention, it would have chosen a much simpler formulation, such as: "The specification shall contain a written description of the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same." *Id.*

Idenix and its amicus Amgen also argue that the court of appeals' written-description requirement is wrong because it focuses on "possession," a word the text does not use. Pet. 25-27. But the court itself has explained that the "term 'possession'" is a misnomer. *Ariad*, 598 F.3d at 1351. Rather, "the hallmark of written description is disclosure": "the specification must describe an invention understandable to [a] skilled artisan and show that the inventor actually

invented the invention claimed." *Id.* This is exactly what the statute requires.[4]

**2.** Idenix argues that the "separate 'written description' rule has faced consistent judicial and academic criticism." Pet. 27. Of course, in the world of patent law, with its well-established battle lines—pro-patent vs. anti-patent; big tech vs. big pharma; innovators vs. generics—every doctrine has its detractors. Besides, the criticism Idenix highlights is unremarkable. It cites a handful of decisions that predate the en banc decision in *Ariad* and dissents written by the same two judges who dissented in *Ariad*. Pet. 27-28 n.6, 31. More notable is that the court of appeals decided *Ariad* by a lopsided vote of 9-2. And since *Ariad*, there has been marked agreement on a court with frequent dissenting views. As for the academy, the only recent criticism Idenix cites is the same unpublished manuscript co-authored by amici. *Supra* 19.

Idenix is also incorrect in asserting that, before the creation of the Federal Circuit, three courts rejected a separate written-description requirement.

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[4] Idenix also suggests that the court of appeals has adopted an atextual subtest for genus claims that requires describing "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus." Pet. 25. But there is nothing improper about a court elaborating on the evidence that may satisfy a statutory requirement. Tellingly, Idenix did not argue to the court of appeals (and therefore failed to preserve the argument) that its approach omits a relevant consideration or avenue for an inventor to show that it actually invented a claimed genus.

Pet. 27. In two of those cases the courts applied the written-description requirement and held the patents *invalid* because they failed to describe and disclose the full scope of the invention. *Donner v. Am. Sheet & Tin Plate Co.*, 165 F. 199, 206 (3d Cir. 1908) ("The evidence satisfies us the problem of continuous sheet-rolling was *neither solved nor disclosed* by this patent.") (emphasis added); *Philip A. Hunt Co. v. Mallinckrodt Chemical Works*, 177 F.2d 583, 585-86 (2d Cir. 1949) (holding claims invalid where "the disclosure" did not adequately define "the proper limits of the 'invention'"). The third case, from the Seventh Circuit, analyzed only the "'how to make' requirement of paragraph one of" § 112; it did not hold that that was all § 112 required. *Ill. Tool Works, Inc. v. Foster Grant Co.*, 547 F.2d 1300, 1309 (7th Cir. 1976).

**3.** Finally, Idenix argues that the written-description requirement will stifle innovation in the biotechnology industry because many discoveries involve broad genuses of compounds, and it can be difficult or tedious to describe every species in a genus that can achieve the claimed function. Pet. 32-33.

Idenix's concerns are groundless. Confronted with the same argument in *Ariad*, the court of appeals found "no evidence of any discernable impact on the pace of innovation" caused by the written-description requirement. 598 F.3d at 1353. And, as noted above, Idenix's favorite manuscript agrees that "innovation … seem[s] to be proceeding apace in the pharmaceutical industry." *The Death of the Genus Claim*, *supra*, at 94. In fact, in *Ariad*, companies from multiple sectors filed amicus briefs arguing that the written-description requirement is vital to innovation—

including leading pharmaceutical companies like Abbott Labs, Amgen, and GlaxoSmithKline. *See Ariad*, 598 F.3d at 1338-39.[5]

Even if Idenix's policy concern were valid, its recourse in seeking a subject-matter-specific rule is with Congress. For example, Congress passed the Plant Patent Act to address the concern that plant patents were "not amenable to the 'written description' requirement of the patent law." *Diamond v. Chakrabarty*, 447 U.S. 303, 312 (1980); 35 U.S.C. § 162. Congress created no such carveout here.

Ultimately, Idenix's policy concerns are rooted in a misapprehension of the court of appeals' standard for written description. Idenix says that now, in order to claim a genus, a patent must disclose nearly every possible species within the genus. Pet. 33. But the court of appeals said the opposite en banc and repeated it in this very case: Section 112 "does not require 'a nucleotide-by-nucleotide recitation of the entire genus.'" Pet. App. 29a (quoting *Ariad*, 598 F.3d at 1352). Instead, the law reasonably requires an inventor to provide sufficient "blaze marks" to show the public that it discovered the full scope of what it claimed to invent. The Federal Circuit has allowed, and will continue to allow, genus claims where the full scope of the claim is described by the specification

[5] Amicus Amgen, which has a pecuniary interest in ongoing litigation, has now changed its position on written description. Amgen Br. 1. Amicus GlaxoSmithKline does not urge revisiting that requirement.

without disclosing every species. *E.g., UroPep*, 739 F. App'x 643; *Monsanto*, 459 F.3d at 1338.

Of course, the more an inventor tries to claim in an unpredictable field, the harder it will be to satisfy that requirement. That is how it should be. In a larger, darker, denser forest, more blaze marks are needed—as this case vividly illustrates. Idenix made a particular discovery: that one modification to four natural ribonucleosides had some effectiveness against HCV in the laboratory. What Idenix claimed, however, was vastly broader: a genus encompassing billions of potential species with thousands of novel untested modifications, many of which were not virally effective. *Supra* 16-18. And the only guidance Idenix provided was a list of "formulas describing 'principal embodiments' of compounds that *may* treat HCV." Pet. App. 28a (emphasis added). Those formulas provided no evidence that Idenix had discovered any other effective compounds. Pet. App. 28a-29a. And critically, they omitted—and failed to blaze a trail toward—a huge swath of the candidate species, including 2'MeF compounds, because Idenix admittedly did not conceive of that swath. On the contrary, the court of appeals explained that the formulas pointed directly *away* from 2'MeF compounds by permitting fluorine as a substitution at other positions while omitting it as an option at 2'-down. Pet. App. 29a-30a. As the United States has cautioned, such broad and poorly described genuses harm innovation by "effectively foreclos[ing] others from pursuing 'efforts to discover a better specimen of [the] class' than the applicant has actually invented and described." *Ariad* U.S. Br. 24 (quoting *Consol. Elec. Light Co. v. McKeesport Light Co.*, 159 U.S. 465, 476 (1895)).

Nor are overbroad claims like Idenix's necessary to protect true inventions. When Gilead's predecessor discovered the cure, it secured a narrow patent directed only to its specific invention. *See Storer v. Clark*, 860 F.3d at 1343-44 (comparing Pharmasset's patent to Idenix's). And that patent has provided ample protection against copycat treatments because this is not a field where a comparable treatment can be had merely "by commercializing a substantively similar compound." Pet. 2. Were that so, Idenix would have had a treatment by now—given that its patent claims billions of supposed possibilities.

### C. Idenix is incorrect that this case presents a better vehicle than prior cases to revisit written description.

Idenix does not dispute that this Court has recently and repeatedly denied petitions presenting this same question. It tries to explain those other denials away by asserting that they had vehicle problems. As to *Amgen*, Idenix argues that the petition was interlocutory and the question might have been mooted by a trial. Pet. 35. But there was no chance of mootness because the petitioner had agreed to stay any trial, and the written-description requirement presented a pure question of law "fundamental to the further conduct of the case." Cert Reply, *Amgen Inc. v. Sanofi*, 139 S. Ct. 787 (2019) (No. 18-127), 2018 WL 6382975, at *11-12.

Regarding *Janssen Biotech*, Idenix argues that the case "implicated the distinct 'written description' requirement for later-added claims." Pet. 35. But there is no such distinct requirement. There is a

single written-description requirement that does not distinguish between original and later-added claims. 35 U.S.C. § 112(a); *see Ariad* U.S. Br. 24 (there is no "textual basis for limiting the doctrine in this fashion"). If anything, *Janssen* was a *better* vehicle: The written description "issue arises primarily in cases involving priority," *Ariad*, 598 F.3d at 1349, which was true of that case but not this one.

And for the reasons discussed above, this case has a major vehicle problem that those cases did not: the existence of two separate and independent holdings invalidating Idenix's patents. Idenix tries to turn this vice into a virtue, repeatedly suggesting that the Court can comprehensively address § 112. *E.g.*, Pet. 5 ("two sides of the same coin"). But each issue is a hefty merits case unto itself. The court of appeals' 20-page analysis of whether these claims are enabled on this record, Pet. App. 6a-26a, was entirely distinct from the statutory-construction question whether there is a separate written description requirement. These issues each deserve and would require full briefing and argument, rather than the demi-version that granting both of Idenix's Questions Presented would require. Indeed, two of Idenix's three amici declined to urge review of the written description requirement. *See* Professors Br. 25 n.4; GlaxoSmithKline Br. (discussing only enablement).

If the Court wishes to revisit the longstanding rule that written description is a separate requirement, there will be plenty of opportunities. As Idenix itself contends, "the Federal Circuit regularly resolves § 112(a) on 'written description' grounds without reaching enablement." Pet. 32.

## CONCLUSION

For the foregoing reasons, the Petition should be denied.

Respectfully submitted,

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