Original Paper

Journal of Generic Medicines

Journal of Generic Medicines
2021, Vol. 17(2) 77–83

DOI: 10.1177/17411343211013572
journals.sagepub.com/home/jgm
SAGE

Idenix v. Gilead: The enablement and written description limits of a genus claim

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Abstract

In *Idenix Pharms. LLC v. Gilead Sci. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019), the Federal Circuit affirmed a judgment of invalidity of a patent claiming methods for treating Hepatitis C virus for, inter alia, lack of enablement. The Supreme Court denied Idenix's petition for a writ of certiorari, meaning that the Federal Circuit decision stands, and genus claims covering thousands of compounds that were supported by an insufficient number of examples have failed the enablement test not once, but twice. See *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013). This case report presents the context surrounding the Federal Circuit's Idenix decision and the Supreme Court's decision not to hear the case.

Keywords

Idenix, Gilead, insufficient support, enablement, examples, genus

Introduction

In *Idenix v. Gilead*, a divided panel of the Federal Circuit held that a patent claiming methods for treating Hepatitis C Virus ("HCV") by administering certain compounds was invalid for lack of enablement and inadequate written description under 35 U.S.C. § 112. *Idenix Pharms. LLC v. Gilead Sci. Inc.*, 941F.3d 1149 (Fed. Cir. 2019) ("Fed. Cir. Op."). The court found that the claims at issue encompassed "tens if not hundreds of thousands" of compounds, and that the patent specification provided no meaningful guidance on which compounds would be effective to treat HCV. *Id.* at 1164. Without more, the court found lack of enablement, and rejected Idenix's argument that the four working examples disclosed in the specification were sufficient to enable the claim. Moreover, because the court agreed that the field of art was unpredictable, the court also rejected Idenix's argument that a skilled artisan would have independently understood the claim to encompass only compounds that inhibit NS5B polymerase. Rather, a patent applicant "cannot simply rely on the knowledge of a person of ordinary skill," and even if it could, it was "not enough to identify a 'target' to be the subject of future testing." *Id.* at 1161. For the same reasons, the Federal Circuit also separately found inadequate written description.

Idenix Pharmaceuticals LLC petitioned for rehearing at the Federal Circuit, which the court denied on 24 April 2020. On 21 September 2020, Idenix petitioned the Supreme Court for a writ of *certiorari* on two questions: (1) "Whether, as the Federal Circuit has held, a genus claim is not enabled 'as a matter of law' if it encompasses a large number of compounds—or whether, as the Supreme Court has recognized, enablement is a context-specific jury question"; and (2) "Whether, as the Federal Circuit has held, § 112 (a) contains a separate 'possession' requirement—or whether, as the statute provides, § 112(a) sets forth a single substantive requirement of 'a written description of the invention' sufficient 'to enable any person skilled in the art . . . to make and use the same."

The Supreme Court denied Idenix's petition for a writ of certiorari on 19 January 2021, leaving the written description requirement intact and the scope of an enabled genus claim unclear. While it is unclear whether, as Idenix argued in its petition, Federal Circuit precedent has established that a genus claim is not enabled as a matter of law if it encompasses a large number of compounds, genus claims covering thousands of compounds that were supported by an

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insufficient number of examples have failed the enablement test not once, but twice. In an earlier case that the Federal Circuit found directly on point, a claim covering thousands of compounds was similarly found invalid for lack of enablement as a matter of law. *See Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013). Accordingly, patent applicants should be aware of this case law when drafting such claims.

Background

Idenix v. Gilead involved a dispute over Idenix's U.S. Patent No. 7,608,597 ("the '597 patent"), which claims methods for treating Hepatitis C Virus ("HCV") using certain antiviral compounds. HCV is a serious chronic liver disease that, at the time of the invention, affected approximately 170 million people worldwide and accounted for 8,000–12,000 deaths per year in the United States. '597 patent col. 1 ll. 23–26. At that time, the best available treatments for HCV included combination treatments known to cause significant side-effects such as hemolysis, flu-like symptoms, anemia, and fatigue. *Id.* at col. 2 l. 8–col. 3 l. 4.

HCV is an "RNA virus," and throughout the 1990s, research to fight RNA viral infection focused on using modified nucleosides as antiviral agents. *Idenix Pharms. LLC v. Gilead Scis., Inc.*, No. CV 14-846-LPS, 2018 WL 922125 at *2 (D. Del. 16 February 2018) ("JMOL Op."). Some of these antiviral agents, called "chain terminators," bind to and disable the enzymes that allow the target virus to replicate. *Id.* In 2000, Idenix discovered what it termed an improvement to state-of-the-art "chain terminators" by placing a methyl group at the nucleoside's 2' up position. *Id.* It subsequently filed a provisional patent application directed to related methods and compositions for treating HCV covering this discovery, which formed the priority basis for a series of patents, including the '597 patent at issue in this case. *Id.*; U.S. Pat. App. No. 60/206585.

Around the same time, Pharmasset, Inc., which was later acquired by Gilead Sciences Inc., created the allegedly infringing compound, sofosbuvir, the active ingredient in Gilead's SOVALDI®. *Id.* According to Gilead, this modification resulted in a highly effective treatment that lacked the unfortunate side-effects caused by prior treatments. *Id.*

Following Sovaldi's launch, Idenix and Gilead fought numerous patent suits around the world. *Id.* The suit in question began in 2013 when Idenix sued Gilead for infringement of the '597 patent and U.S. Patent No. 6,914,054 ("the '054 patent"), also directed to methods and compositions for treating HCV. *Id.* Because Idenix dropped the '054 patent after claim construction, the ensuing litigation focused on the claims of the '597 patent. *Id.* Claim 1 is the only independent claim of the '597 patent, and recites: "A method for the treatment of a hepatitis C virus infection, comprising administering an effective amount of a purine or pyrimidine β-D-2'-methyl-ribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof." ("Claim 1"). *Id.*

The '597 specification clarifies that β-D-2'-methyl-ribofuranosyl nucleosides contain a sugar ring having five carbon atoms, numbered 1'–5' with a substituent atom or group of atoms added to each carbon in either an "up" or "down" orientation. Fed. Cir. Op. at 1154. Sofosbuvir, the active ingredient in Sovaldi, comprises the five-carbon sugar ring with a fluorine in the 2' down orientation. *Id.* at 1155 (Figure 1(b), below). After the district court construed Claim 1 as encompassing any "non-hydrogen substituents at the 2' down" position, *Idenix Pharms., Inc. v. Gilead Scis., Inc.*, No. CV 13-1987-LPS, 2015 WL 9048010 at *6 (D. Del. 16 December 2015) (emphasis added), Gilead stipulated that its 2'-methyl-up 2'-fluoro-down nucleoside infringed. JMOL Op. at *1. However, Gilead argued, *inter alia*, that the '597

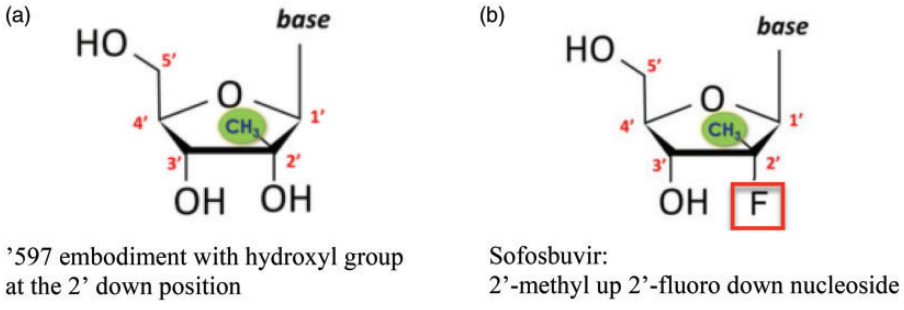

Figure 1. (a) '597 embodiment with hydroxyl group at the 2' down position; (b) Sofosbuvir: 2'-methyl up 2'-fluoro down nucleoside.

patent's specification primarily described a hydroxyl group at the 2'-down position (Figure 1(a), above) and therefore did not describe or enable sofosbuvir, let alone every β-D-2'-methyl-ribofuranosyl nucleoside with a non-hydrogen substituent in the 2' down position.[1] Fed. Cir. Op. at 1155.

Jury decision and judgment as a matter of law opinion

Following a two week trial in December 2016, a jury determined that Gilead failed to prove invalidity of the asserted claims and awarded Idenix $2.54 billion. JMOL Op. at *1. In a renewed motion for judgment as a matter of law, Gilead urged the district court to set aside the jury's verdict. *Id.* Siding with Gilead, the district court judge overturned the jury's verdict finding that the '597 patent was not enabled. *Id.* at 25.

To be enabling, a specification must teach a POSA to make and use the full scope of the claimed invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Courts use the *Wands* factors[2] to guide their analysis as to whether a specification has taught a POSA to make and use the invention without undue experimentation. Here, the court relied heavily on the *Wands* factors in finding Claim 1 invalid for lack of enablement. With respect to the first factor—the quantity of experimentation necessary—the court explained that the broad "non-hydrogen" language adopted during claim construction forced Idenix to concede that "billions" of compounds satisfied Claim 1's structural limitations. JMOL Op. at *12. While a POSA would rely on "common sense" to narrow this number, the court determined that the claim encompassed "likely, millions or at least many, many thousands" of compounds. *Id.* at 13.

Because the district court had construed the preamble, "[a] method for the treatment of a hepatitis C virus infection," as a narrowing functional limitation, it found that a POSA would need to screen every compound encompassed by the claim to determine which were effective in treating HCV. *Id.* at 11. While Idenix's expert established that his lab "tested 18,000–20,000 compounds in the HCV replicon assay" during a three month period in 2000, the judge remained convinced that screening would be a "significant rate-limiting factor" in light of the millions of compounds that required testing. *Id.* at 19. Because many of the compounds were not commercially available, a POSA would need to first synthesize—a process the court considered "neither routine nor simple" even for a single compound. *Id.* at 16.

Turning to the second factor—the amount of direction or guidance presented—the court noted the specification's lack of guidance as to how a POSA could screen for nucleosides capable of treating HCV. *Id.* at 22. In briefing, Idenix explained that the key to effectiveness lies in a compound's ability to target NS5B polymerase. *Id.* at 20. The court, however, found that the specification provided insufficient guidance because it failed to teach a POSA to target NS5B polymerase and sofosbuvir had not been disclosed. *See id.* at 11, 24.

In weighing the third and fourth factors—the presence or absence of working examples and nature of the invention—the court cited an absence of adequate examples in light of: (i) the specification's failure to direct a POSA to the NS5B polymerase; (ii) the claim's inclusion of numerous inoperable 2'-methyl up embodiments; and (iii) the specification's failure to disclose fluorine in the 2' down position. *Id.* at 22. Finally, the court decided the fifth and sixth factors—the state of the prior art and relative skill of a POSA—in favor of non-enablement, explaining that although "nucleoside chemistry was a well-studied field populated with highly skilled POSAs, the use of such compounds to treat HCV constituted a novel, highly unpredictable endeavor." *Id.* at 22.

Notably, the court likened the present case to *Wyeth*, 720 F.3d 1380. *Id.* at 23. *Wyeth* considered the validity of a claim directed to treating restenosis using a genus of compounds called rapamycins. *Id.* The court noted that although *Wyeth* involved a genus claim, the patent only disclosed "one rapamycin species," called sirolimus. *Id.* (quoting *Wyeth*, 720 F.3d at 1382). Similar to Idenix, the patent-holder, Wyeth, admitted that the number of effective compounds would be "significantly smaller" than the "millions of compounds" encompassed by its claim's structural limitations. *Id.* Wyeth also argued that a POSA's common sense would help reduce the range of candidates. *Id.* The Federal Circuit rejected Wyeth's arguments, observing that even if a POSA's common sense would impose implicit limitations, there were still "'at least tens of thousands of candidates' to screen; the specification was 'silent about how to structurally modify sirolimus;' it would be necessary to 'first synthesize and then screen *each* candidate' to determine effectiveness; and the record and specification offered no guidance as to which 'particular substitutions' at substituent positions might be 'preferable' or would preserve sirolimus's effective properties." *Id.* (quoting *Wyeth*, 720 F.3d at 1385-86 (emphasis in original)).

The district court found "striking" similarities between *Wyeth* and the present case. *Id.* at 24. It observed that "[a]s in *Wyeth*, Idenix claimed a new use for an existing class of compounds, but the patent contain[ed] limited disclosure of functional

species." *Id.* (quoting *Wyeth*, 720 F.3d at 1384). Much of the court's *Wands* analysis followed *Wyeth*, but it specifically noted that the "chemical arts remain generally unpredictable" and it compared the "infancy" of treating HCV with nucleosides to "the 'limited knowledge of treat[ing] [] restenosis [with] sirolimus.'" *Id.* The court also noted that both specifications required POSAs to commit extensive time and effort to synthesize and screen compounds potentially meeting the respective limitations. *Id.* In light of these shared shortcomings, the court concluded that "a patent that merely provides 'a starting point' 'to engage in an iterative, trial-and-error process to practice the claimed invention,' lacks enablement." *Id.* (quoting *Wyeth*, 720 F.3d at 1386).

Appeal to the Federal Circuit

On appeal, Idenix argued that the district court erred in granting judgment as a matter of law for lack of enablement. Fed. Cir. Op. at 1153. The panel sided with Gilead and affirmed the district court's grant of judgment as a matter of law on invalidity for non-enablement.[3] *Id.* at 1165.

Echoing the district court's analysis, the Federal Circuit panel confirmed that the factual record weighed heavily in favor of a finding of non-enablement. The panel focused on the specification's failure to guide POSAs in screening for effective compounds. Specifically, the panel noted that the 2'-methyl up limitation alone was not "commensurate in scope with the claim" because not every 2'-methyl up compound could effectively treat HCV, and the panel remained unpersuaded that a POSA would understand NS5B to be the target enzyme. *Id.* at 1160-61 (quoting *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983)). Moreover, even if a POSA understood NS5B to be the target, the court explained that "it is not enough to identify a 'target' to be the subject of future testing." *Id.* at 1161. The court explained that an applicant must include this information in its specification, not rely on a POSA to "serve as a substitute for the missing information." *Id.* (quoting *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010)). The panel therefore concluded that a specification that requires a POSA to "engage in an iterative, trial-and-error process to practice the claimed invention' does not provide an enabling disclosure." *Id.*

The panel also endorsed the district court's reliance on *Wyeth*, and likewise noted "striking" similarities with the present case. *Id.* at 112. In both, "scientific testimony confirmed that practicing the full scope of the claims would require synthesizing and screening tens of thousands of candidate compounds for the claimed efficacy." *Id.* at 1163. And even if the process was "routine" for an individual compound, the claim in *Wyeth* was not enabled because at least tens of thousands of candidates would need to be screened and synthesized. *Id.* Ultimately, the panel held that "[a] reasonable jury could only have concluded that there were at least many, many thousands of candidate compounds, many of which would require synthesis and each of which would require screening. That constitutes undue experimentation." *Id.* The panel rejected Idenix's attempts to distinguish *Wyeth* based on improvements in the "state of the arts of screening and synthesis between 1992, when the *Wyeth* patent application was filed, as compared to 2000, when Idenix's first application was filed." *Id.* The panel explained that in both cases the patent would fail to enable even if screening were routine because the respective decisions "rest[] on the 'limits of permissible experimentation,' not on the relative time that experimentation would take.'" *Id.* (quoting *Wyeth*, 720 F.3d at 1386).[4]

Idenix's petition for rehearing en banc

Idenix filed a petition for rehearing en banc on 15 January 2020, arguing that the panel's decision announced new enablement rules that "radically heighten the enablement standard." Appellants' Petition for Rehearing En Banc, at 8 ("Appellant Pet."). Idenix questioned the panel's reliance on *Wyeth* and argued that its opinion could be read to support an untenable proposition: a genus claim with a large number of candidate compounds that must be synthesized and screened for effectiveness requires undue experimentation as a matter of law regardless of the nature of the art or whether an ordinary artisan would view such testing as routine. *Id.* at 2.

Idenix argued that the Federal Circuit failed to adequately consider two *Wands* factors: the state of the art and whether an ordinary artisan would consider synthesis and screening a routine part of practicing the invention. *Id.* at 7, 10. According to Idenix, synthesis and screening in large quantities was routine in pharmaceutical and biotechnology fields at the time of the invention, thus specifications that disclose a representative number of embodiments should satisfy the enablement requirement even for claims encompassing many thousands of compounds. *Id.* at 10–11. Idenix also distinguished *Wyeth* on this point, arguing that it did not justify this court's "numbers" test for enablement because Wyeth's specification disclosed only one operative embodiment, and Wyeth conceded that there was no "guidance" suggesting other operative embodiments. *Id.* at 11 (quoting *Wyeth*, 720 F.3d at 1385-86).

Idenix further argued that the decision will negatively impact innovation. *Id.* It explained that

breakthrough medical treatments often require genus claiming and frequently "yield 'at least thousands' of embodiments." *Id.* According to Idenix, the question should be "whether the artisan's work in practicing the patent is routine," not how long it would take an artisan to synthesize and test every embodiment (*id.* at 9), particularly where, as in the pharmaceutical and biotechnology fields, "synthesis and screening—even in large quantities—are routine" (*id.* at 11).

Two parties filed amicus briefs in support of Idenix's petition for rehearing *en banc*. Amgen, Inc.'s amicus brief warned that *Idenix* has the potential to negate genus claiming altogether, which will harm innovators and the public. Brief of Amicus Curiae Amgen Inc. in Support of Rehearing En Banc ("Amgen Br."). Amgen characterized the panel's opinion as requiring the disclosure of each species within a genus claim to be an enabling disclosure. Amgen Br. at 6. Amgen called for a flexible, context-specific test to analyze invalidity under Section 112. *Id.* at 12.

RegenxBio Inc. and Professor Hugh C. Hansen (collectively, "RegenxBio") also submitted an amicus brief in support of rehearing *en banc*. RegenxBio argued that the panel's decision effectively "judged compliance with the written description and enablement requirements not on the basis of the patent's disclosure itself, but rather on what it did not disclose about the accused product." Brief of Amici Curiae RegenxBio, Inc. and Professor Hugh C. Hansen in Support of Petition for Rehearing *En Banc* ("RegenxBio Br.") at 3. With respect to enablement, RegenxBio argued that the panel erroneously turned the enablement question into a "mere numbers game." *Id.* at 9. With respect to written description, RegenxBio argued that the panel's decision effectively required a specific disclosure of an accused infringing product. *Id.* at 7.

Gilead's opposition to rehearing en banc

After receiving an invitation to respond, Gilead filed its opposition on 9 April 2020. Appellee's Response in Opposition to Rehearing En Banc ("Appellee Pet."). Gilead argued that Idenix's petition mischaracterized the panel's opinion. According to Gilead, the panel did not heighten the enablement standard, rather it correctly applied the fact-based standard for an enablement analysis that has governed since *In re Wands*. *Id.* at 7 (citing 858 F.2d 731 (Fed. Cir. 1988)).

Gilead argued that Idenix's petition, which accused the court of creating a "numbers-based" rule, Appellant Pet. at 11, largely ignored the court's 14-page *Wands* analysis, which "laid bare" numerous flaws with the '597 patent. *Id.* at 9–10. Specifically, Gilead pointed to the court's findings that: (i) using modified nucleosides to treat HCV was an unpredictable art; (ii) Idenix's claim covered "at least 'many, many thousands' of candidate compounds;" and (iii) Idenix's specification offered no "meaningful guidance" on how to determine which compounds would be effective. *Id.* at 8 (quoting Fed. Cir. Op. at 9, 17–18). Gilead argued that these "case-specific" findings justified the court's non-enablement holding, but did not suggest an intention to create a "*per se*" rule in which practicing a patent requires undue experimentation whenever a claim encompasses "many thousands" of embodiments. *Id.* at 12. Gilead conceded, however, that one *Wands* factor did favor enablement: synthesizing and screening individual nucleosides was "largely routine" at the time of the invention. *Id.* at 9. Nevertheless, Gilead contended that this factor did not negate Idenix's obligation to provide *some* guidance. *Id.* According to Gilead, the specification failed to provide any guidance and instead provided a mere "starting point" for further research because POSAs would be forced to "perform 'an iterative, trial-and-error process' to discover useful compounds." *Id.* at 9 (quoting Fed. Cir. Op. at 16–17).

Gilead also contended that Idenix "wildly overread []" the panel's "*Wyeth* epilogue." *Id.* at 12 (citing Appellant Pet. at 8, 9). According to Gilead, Idenix unjustifiably interpreted the Federal Circuit's endorsement of *Wyeth* as an endorsement of a rule in which "'synthesizing and screening tens of thousands of candidate compounds for the claimed efficacy' *always* constitutes undue experimentation, 'regardless of case-specific considerations.'" *Id.* at 12 (citing Appellant Pet. at 8, 10). Gilead further asserted that the case embodied the exact opposite of a numbers-based rule in light of the panel's thorough, 14-page *Wands* analysis. *Id.* Ultimately, Gilead argued that the panel properly focused on whether the amount of experimentation was "*incommensurate* with the patent's limited teachings," and did not, as Idenix argued, create a rule that finds high-volume experimentation *per se* excessive. *Id.* (emphasis added).

Finally, Gilead remained unpersuaded by Idenix and its supporting amici's contention that this holding "poses a 'dire' 'threat' to 'genus claiming.'" *Id.* at 13 (citing Appellant Pet. at 8; Amgen Br. at 1–4). Gilead acknowledged that genus claims should not be found invalid "when they provide commensurate teachings that guide an artisan to effective compounds, even if they require a significant amount of experimentation.'" *Id.* at 13 (quoting *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576-77 (Fed. Cir. 1984)). However, Gilead explained that experimentation is undue for claims like the one at issue here, which "merely prompt 'further iterative research in an unpredictable and poorly understood field.'" *Id.* at 14

(quoting *Wyeth*, 720 F.3d at 1386). According to Gilead, such claims require undue experimentation, fail to uphold the patent system's *quid pro quo*, and should therefore be invalidated. *Id.*

The Federal Circuit denied Idenix's petition for rehearing *en banc* on 24 April 2020.

Petition for certiorari

On 21 September 2020, Idenix petitioned the Supreme Court for a writ of *certiorari*. Idenix identified the following two questions:

> 1. Whether, as the Federal Circuit has held, a genus claim is not enabled "as a matter of law" if it encompasses a large number of compounds—or whether, as the Supreme Court has recognized, enablement is a context-specific jury question; and
>
> 2. Whether, as the Federal Circuit has held, § 112(a) contains a separate "possession" requirement—or whether, as the statute provides, § 112(a) sets forth a single substantive requirement of "a written description of the invention" sufficient "to enable any person skilled in the art . . . to make and use the same.

Idenix Petition for a Writ of Certiorari ("Cert Petition"). In its petition, Idenix characterized the panel opinion as rewriting the law to create "bright-line rules that make it nearly impossible for genus claims to satisfy § 112(a)." *Id.* at 2. Idenix claimed that the Federal Circuit had set a rule for enablement that invalidated a genus sheerly based on numbers, "even if the evidence shows, and a jury finds, that making and screening thousands of compounds is 'largely routine.'" *Id.* at 3. Idenix also challenged the Federal Circuit's ruling in a 2011 opinion as creating a separate written description requirement for validity where § 112(a) did not require one. *Id.*

Gilead's opposition to the petition for writ of *certiorari* characterized the panel decision quite differently. Gilead pointed out that for enablement, the panel decision walked through each of the *Wands* factors, including the unpredictability of the field of art, before reaching a conclusion on enablement. Brief in Opposition to Petition for Certiorari ("Cert Opp.") at 1–2. Thus, Gilead challenged Idenix's assertion that the Federal Circuit had created a bright-line rule for enablement or written description based on mere numbers. *Id.* Gilead further emphasized that far from the conservative "thousands" that Idenix claimed its patent covered, the claims at issue actually "purport to monopolize *billions* of untested and largely unmade candidate compounds" (emphasis in original). *Id.* at 1.

A number of *amici* filed briefs, all in support of Idenix, including Amgen, Inc. ("Amgen"), GlaxoSmithKline PLC ("GSK"), and a group of 14 intellectual property professors ("IPP"). These *amici* supported Idenix's characterization of the panel decision as turning the § 112 analysis into a "numbers game." Brief of IPP In Support of Petitioners at 12. GSK sounded an alarm that the panel decision "all but eliminated the genus claim as an effective and reliable means of protecting intellectual property, particularly in the chemical arts." Brief of GSK In Support of Petitioners at 17. Amgen argued that § 112 supports one written description requirement, which the Federal Circuit improperly separated into two: enablement and written description, thus creating a separate written description requirement. According to Amgen, the Federal Circuit's heightened enablement requirement and separate "possession" requirement for written description chills life-saving innovation, particularly in biotechnology. Brief of Amgen In Support of Petitioners at 17–18.

Idenix's reply in support of its petition reiterated its arguments that the Federal Circuit had reduced the Section 112 analysis to a numbers game, and that there should be no separate written description "possession" requirement. Idenix acknowledged, as Gilead pointed out, that "the panel marched through the *Wands* factors." Idenix Reply at 4. However, Idenix asserted that "a rule drove [the panel's] decision about how to balance those factors in cases involving a large genus in unpredictable fields like biotechnology or pharmaceuticals" – a rule that depended on the genus's numbers. *Id.* This rule, Idenix warned, would have "devastating consequences for fields like biotechnology and pharmaceuticals." *Id.* at 1.

On 19 January 2021, the Supreme Court denied Idenix's petition for a writ of *certiorari*.

Conclusion

The Federal Circuit's panel decision does not appear to break new ground with respect to § 112 law. Following *Wyeth*, now reaffirmed in *Idenix*, a genus claim found to encompass thousands of embodiments, even if limited by structural and functional limitations, risks invalidation for lack enablement and inadequate written description. The Federal Circuit's refusal to rehear this case *en banc*, and the Supreme Court's denial of *certiorari*, leaves this precedent intact. Although these decisions do not set a bright line for how small a genus must be or the number or type of examples needed to satisfy § 112, *Idenix* and *Wyeth* serve as strong reminders to draft genus claims with enablement (and written description) in mind.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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Notes

1. Although Gilead argued that Claim 1 was invalid for lack of written description and enablement, this article discusses only the issue of enablement.
2. These factors include: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *In re Wands*, 858 F.2d at 737.
3. The court also held the patent invalid for lack of written description. Fed. Cir. Op. at 1153.
4. For substantially the same reasons, because of the specification's failure to guide POSAs in identifying effective compounds, the panel separately found inadequate written description.

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