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

AMICUS CURIAE BRIEF OF GLAXOSMITHKLINE PLC. IN SUPPORT OF PETITIONERS

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INTERESTS OF AMICUS

Amicus GlaxoSmithKline ("GSK") is one of the largest pharmaceutical, consumer-healthcare, and vaccine companies in the world.[1] GSK spends billions of dollars annually—including more than $5 billion in 2019 alone—developing groundbreaking drugs and vaccines, and bringing them to market. Those efforts have yielded breathtaking new therapies to fight a wide variety of diseases, including HIV, cancer, shingles, meningitis, asthma, diabetes, malaria, COVID-19, and others: As of the second quarter of 2020, GSK has thirty-five new medications and fifteen new vaccines under development. Genus claims—that is, patent claims that encompass, for example, a family of chemical compounds—are critical to the protection of GSK's past innovations. Moreover, the protection afforded by genus claims encourages continued innovation and early-stage investment by research-oriented companies in the chemical, pharmaceutical, and biotechnological industries to achieve future groundbreaking advances. The Federal Circuit's *Idenix* decision imposes new restrictions on genus claims, casting aside almost two centuries of this Court's patent jurisprudence to radically curtail this important area of patent law.[2] GSK submits this brief to educate the Court

1. Amicus certifies that no counsel for a party authored this brief in whole or in part and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. All parties were given proper notice and consented to the filing of this brief.

2. Amicus takes no position on the validity of the particular claims at issue in *Idenix*, and submits this brief solely to encourage the Court to correct the Federal Circuit's erroneous legal framework.

on the realities of the industry, and to encourage the Court to take up this important petition.

SUMMARY OF ARGUMENT

Genus claims, or patent claims "which use functional language or generic formulas to cover embodiments of the invention that share a common attribute," have become "ubiquitous" in the chemical, pharmaceutical, and biotechnological industries.[3] That is because genus claims are critical to protecting innovation in those industries. Groundbreaking inventions developed by companies such as GSK often manifest as a family (or genus) of closely related compounds that contain common chemical structures. Discovery of such groups of compounds with common novel chemical structures may take years of effort and billions of dollars of investment. It is therefore particularly critical that patentees in such industries be granted the scope of patent protection to which their inventions entitle them. Application of arbitrary bright-line rules, as the Federal Circuit has done in *Idenix*, robs patentees of the entirety of their invention and denies companies that fund the underlying research the chance to recoup their investment through patent protection, licensing, or other business arrangements.

For more than 175 years, courts have recognized the validity of genus claims. In fact, the text of the Patent Act squarely allows for genus claims so long as the patent enables one of skill in the art to "make and use" the claimed invention. 35 U.S.C. § 112(a). Until recent cases such as *Idenix*, the litmus test for genus claims

3. *See* Sean Seymour, *Patenting the Unexplained*, 96 Wash. U. L. Rev., 707, 729 (2019).

has been the case-specific question of whether a patent sufficiently "enables" persons of ordinary skill in the art ("artisans") to "make and use" the invention without undue experimentation—rather than the rote determination of whether the patent's claims cover an arbitrarily bounded number of embodiments. But the Federal Circuit's *Idenix* decision adopted that latter, erroneous framework, all but eliminating—as a matter of law—patentees' ability to make use of genus claims and courts' ability to assess the details of a specific case in determining enablement. That upsets the chemical, pharmaceutical, and biotechnology industries' decades-long reliance on genus claims to protect their important inventions. Indeed, the Federal Circuit in *Idenix* invalidated genus claims simply because the genus in question included a large number of species, even though the jury had found that an artisan ***could*** "make and use" embodiments of the invention (which is the Patent Act's sole textual requirement). And *Idenix* put genus claims in further jeopardy by advancing another bright-line rule contrary to the Patent Act and precedent, that the patent must enable the making and using of each and every one of a genus claim's species for the claim to be valid.

This sea change threatens to devastate the incentives for companies like GSK to invest billions of dollars, and hundreds of thousands of research hours, in discovering breakthrough chemical structures. Instead of focusing its efforts on developing the next groundbreaking drug, GSK would be forced to seek narrow patent claims that underrepresent the full breadth of its inventions and its true contributions to the scientific community. Furthermore, without the protection of genus claims, companies would be less inclined to disclose the full scope of their inventions as soon as the breakthrough occurs.

They would instead delay disclosure until a product is well along in development and the company has made and tested nearly every plausible species within the genus (which deprives the world of knowledge of the invention for a longer period of time). And by forcing patentees to synthesize and test many species in order to have broad patent protection for their actual inventive contributions, the Federal Circuit's decision threatens to divert the attention of research-oriented companies away from developing the next groundbreaking drug. Thus, without a course-correction, the Federal Circuit's *Idenix* holding risks eviscerating the protections and concomitant incentives to innovate that the patent system was designed to provide.

The Court should reject the Federal Circuit's recent creation of bright-line rules imposing limits on genus claiming and should instead reaffirm the general availability of genus claims when they satisfy—based on the specific circumstances of the case—the statutory enablement requirement. That would be faithful to the law as written and would best protect the incentives of companies like GSK to focus their research efforts on the development of groundbreaking therapeutic regimens. In short, patentees should be granted patents over the true scope of their inventions.

ARGUMENT

I. LEFT UNDISTURBED, THE FEDERAL CIRCUIT'S *IDENIX* DECISION WILL HAVE A DEVASTATING EFFECT ON CRITICAL DRUG-DISCOVERY RESEARCH AND DEVELOPMENT EFFORTS.

Massive investments—especially in the early days of drug discovery when the risk of failure is arguably the greatest—are required to bring new therapeutic regimens to market. In 2019 alone, GSK invested roughly £4.3 billion pounds (over $5 billion U.S. dollars) in the research and development of new therapeutic regimens, including pharmaceutical drugs.[4] GSK's research efforts focus on some of the most pressing public health concerns in the United States and around the world, including on groundbreaking research in the treatment of HIV/AIDS, cancer, and respiratory illnesses such as chronic obstructive pulmonary disease (COPD), as well as on the development of vaccines to prevent serious medical conditions like malaria and meningococcal meningitis.[5] In addition, GSK is currently working on the development of a COVID-19 vaccine.[6]

Innovative companies in the pharmaceutical and biotechnology industries depend on the patent system to

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4. *See* https://www.gsk.com/en-gb/research-and-development/ (last accessed 11/15/2020).

5. *See* 2019 GSK Annual Report, at 17-25 (available at: https://www.gsk.com/media/5894/annual-report.pdf).

6. *See* https://www.gsk.com/en-gb/media/press-releases/sanofi-and-gsk-initiate-phase-12-clinical-trial-of-covid-19-adjuvanted-recombinant-protein-based-vaccine-candidate/ (last accessed 11/15/2020).

protect their investments in developing groundbreaking pharmaceuticals and therapeutics. For example, pharmaceutical development is a notoriously high risk endeavor; it is estimated that only 8% of drugs in development at a given time will ever reach the market.[7] By all but eliminating genus claiming—or, at the very least, drastically increasing the uncertainty that a given genus claim will be held valid—the Federal Circuit's ruling in *Idenix* will make it more difficult for companies like GSK to invest in and get compensated, through licenses or other business arrangements, for teaching the world about the full scope of their inventions.

Without the robust patent protection offered by genus claiming that protects the full scope of groundbreaking inventions, it is less likely that pharmaceutical companies will risk the huge initial outlays of effort and money those inventions demand. That risks stifling not only the current generation of drug development, but also potentially handicapping drug development for decades into the future. Furthermore, maintaining efficient and time-limited patent coverage for an inventor's entire invention through a genus claim incentivizes others to pursue new breakthroughs that meaningfully advance the pharmaceutical arts. Indeed, a competitor that discovers unexpectedly beneficial properties of a compound that is within an already patented genus can itself obtain patent coverage on that compound.[8]

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7. *See* GSK Public Policy Positions – Patents & Access to Medicines in Developing Countries, at 2 (available at: https://www.gsk.com/media/2958/patents-and-access-to-medicines-in-developing-countries-july19.pdf).

8. *See Application of Petering*, 301 F.2d 676, 683 (1962) (finding a species patentable over a genus claimed in the prior art because unexpected properties of the species were shown). *Cf.*

If genus claiming of novel chemical structures were effectively removed from our patent system, pharmaceutical companies would be deprived of the ability to claim their entire invention and would be forced to limit their patent protection to only a discrete number of species in the genus. But it is simply not feasible to individually claim each of the active variations of a new drug compound.

Allowing for a wide breadth of protection based on a genus of compounds is, as a practical matter, the only means to ensure that an inventor actually receives the period of exclusivity contemplated by our patent system. The existence of a genus claim does not mean that medicines developed by others that fall within the scope of the claim would be prevented from reaching the market. It simply means that the patentee would be fairly compensated. The patent system would be serving its purpose, providing reward for early and full disclosure of an innovation the world needs to know about.

II. THE FEDERAL CIRCUIT'S RECENT DECISIONS CAST ASIDE ALMOST TWO CENTURIES OF PATENT PRACTICE TO RADICALLY CURTAIL GENUS CLAIMING.

For the reasons noted above, chemical and pharmaceutical innovators depend upon properly

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Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1371 (Fed. Cir. 2007) (determining that species claim was obvious in view of prior art genus claim because of a lack of evidence of unexpected results); *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (stating that to claim a subset of a range disclosed in a prior art patent, the applicant must generally show that "the claimed range achieves unexpected results relative to the prior art range").

supported genus claiming to provide adequate and efficient protection for their inventions. Without correction, *Idenix*'s radical departure from that established mechanism—effectively removing genus claiming, however well-supported, as an option for the protection of chemical structures—not only forsakes the straightforward text of the patent laws, but also undermines the sound policies supporting those laws.

A. Courts Have Long Recognized That The Plain Text Of The Patent Act Allows For Genus Claiming Where The Claims Are Enabled.

The Patent Act requires that a patent "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 which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a). This "enablement" requirement is perfectly consistent with genus claiming,[9] provided that the patent disclosure enables artisans to "make and use" embodiments (or variations) of the claimed inventions.

As early as 1854, this Court acknowledged that patent protection could cover an entire genus, even while grappling with the appropriate circumstances of such

9. *See, e.g.*, *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) ("In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.").

protection. *See, e.g.*, *O'Reilly v. Morse*, 56 U.S. 62, 62 (1854) (concluding that the inventor of the telegraph was not entitled to a claim over every "use of the motive power of the electric or galvanic current . . . however developed . . . for making or printing intelligible characters, signs or letters at any distances" because not all of those "use[s]" fell within the scope the invention); *Consol. Elec. Light Co v. McKeesport Light Co.*, 159 U.S. 465, 472 (1895) (invalidating a claim over the use of "every fibrous or textile material" as an incandescent lightbulb filament because the inventors had not "discovered in fibrous and textile substances a quality common to them all," but noting that if they had, "such claim might not be too broad").

In 1916, the Court affirmed the validity of a genus claim directed toward a class of substances used to separate ores, finding that the patent was sufficiently enabling for an artisan to make use of the invention, despite "infinite[]" variations in the compositions of the ores themselves. *Minerals Separation v. Hyde*, 242 U.S. 261, 271 (1916). This "infinite[]" variation and the fact that some experimentation would be necessary for artisans to practice the invention was not fatal to the genus claim.

> Equally untenable is the claim that the patent is invalid for the reason that the evidence shows that when different ores are treated preliminary tests must be made to determine the amount of oil and the extent of agitation necessary in order to obtain the best results. ***Such variation of treatment must be within the scope of the claims, and the certainty which the law requires in patents is not***

> ***greater than is reasonable, having regard to their subject matter.*** The composition of ores varies infinitely, each one presenting its special problem, and it is obviously impossible to specify in a patent the precise treatment which would be most successful and economical in each case.

Id. at 270–71 (emphasis added). The Court appropriately recognized that enablement is an industry and case-specific inquiry and that "the certainty which the law requires in patents is not greater than is reasonable, ***having regard to their subject matter***." *Id.* at 270 (emphasis added). Additionally, the patentee was entitled to rely on the artisan's background knowledge and skill in describing how to practice the invention.

> The process is one for dealing with a large class of substances and the range of treatment within the terms of the claims, ***while leaving something to the skill of persons applying the invention***, is clearly sufficiently definite to guide those skilled in the art to its successful application, as the evidence abundantly shows. This satisfies the law.

Id. at 271 (emphasis added).

In 1928, the Court again confirmed the statutory availability of genus claims where the patentee had shown some "general quality common" to the members of the genus. *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 385 (1928) (but concluding that the inventor in that case could not claim the benefit of a genus of

chemical "accelerators" where too many species in the genus were "not accelerators at all"). Under these early cases, the touchstone of enablement for genus claims was simply whether the patent disclosure sufficiently enabled artisans—with whatever level of skill is typical in the industry—to "make and use" embodiments of the invention. That history should be unsurprising, because then—and now—that is exactly what the text of the Patent Act requires.[10]

The courts have also explained that the Patent Act "requires that the specification teach those in the art to make and use the invention without 'undue experimentation.'" *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). *Cf. Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257 (1928) ("One attempting to use or avoid the use of Perkins' discovery as so claimed and described functionally could do so only after elaborate experimentation."). Despite this, the text of the Patent Act does not impose any limitations on the number of species that may be contained within a genus claim.

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10. An earlier version of the statute contained substantially similar language to the modern Patent Act, so these early cases remain illustrative to the interpretation of the current version. The earlier version stated: "Before any inventor or discoverer shall receive a patent for his invention or discovery he shall make application therefor, in writing to the Commissioner of Patents, and shall file in the Patent Office a written description of the same and of the manner and process of making, constructing, compounding and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same." Rev. Stat. § 4888, ch. 230, § 26, 16 Stat. 201 (1870).

Recognizing that the Patent Act does not treat genus claims differently from other claims, the courts in the mid to late-twentieth century have repeatedly recognized the validity and appropriateness of genus claiming, especially in the chemical and pharmaceutical industries. Along the way, the courts rejected the notion that the text of the Patent Act requires a patentee to test and disclose the efficacy of every compound within the claimed genus. In 1960, for example, the Court of Customs and Patent Appeals ("CCPA"), the predecessor to the Federal Circuit, explained that a genus claim was permissible if "the disclosure teaches those skilled in the art what the invention is and how to practice it." *Application of Grimme*, 274 F.2d 949, 952 (C.C.P.A. 1960). In that case, there was nothing indicating that the compounds in the genus "differ[ed] radically from each other." *Id.* The court therefore found "that the examples given [we]re adequate to show those skilled in the art how the invention of the appealed claims is to be practiced," and confirmed the availability and validity of the issued genus claim. *Id.*

During that era, the CCPA, in a chemical catalyst patent case, also recognized that it would be unnecessary and indeed futile to require patentees to draft "a patent application or applications with thousands of examples," as well as "disclosure of thousands of catalysts along with information as to whether each exhibits catalytic behavior." *Application of Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976) (internal quotation marks omitted). "[S]uch a requirement," the court reasoned, would be undesirable "even in an unpredictable art" not only because it "would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments," but also because it "would tend to discourage inventors

from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed." *Id.* at 502–03. Likewise, "[a] potential infringer could readily avoid 'literal' infringement of such claims by merely finding another analogous catalyst complex.'" *Id.* at 503. Thus, the court recognized both the efficiency of genus claiming and the public policy and copying risks posed in its absence. Inventors would choose trade secret protection over public disclosure because filing for a patent over only ***some*** embodiments would enable copyists to make ***other*** embodiments, eviscerating the inventor's period of exclusivity. *Id.* at 502–03. That result either deprives the public of advances in knowledge, or the inventor of the benefits of her invention and investment.

In short, having weighed the benefits and costs of genus claiming—the same policy considerations affecting innovator companies such as GSK—this Court and the Federal Circuit's predecessor court endorsed without reservation the full breadth of genus claiming consistent with the Patent Act that the Federal Circuit has now curtailed in *Idenix*. As discussed further in Part II.B, the courts also recognized that enablement is a ***case-specific inquiry*** that must take into account industrial realities and the artisans' level of skill and background knowledge.

B. Pre-*Idenix* Case Law Applied A Case-Specific Enablement Analysis Appropriately Tailored To The Scope Of Genus Claims.

Following this Court's approach, the Federal Circuit developed case-specific tools applying the requirements of the Patent Act to ensure that genus claims appropriately

reflect the technological context, artisans' level of skill and background knowledge, and the scope of the patent disclosure. For instance, Federal Circuit case law has recognized that enablement of a genus claim does not depend on whether the patentee vets every embodiment for efficacy if that is not necessary for an artisan to make and use the invention. In *Atlas Powder*, for example, the patent challenger, Du Pont, "argue[d] that the patent disclosure lists numerous salts, fuels, and emulsifiers that could form thousands of emulsions but there is no commensurate teaching as to which combination would work." *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). "The disclosure," according to Du Pont, was "nothing more than 'a list of candidate ingredients' from which one skilled in the art would have to select and experiment unduly to find an operable emulsion." *Atlas Powder*, 750 F.2d at 1576. Rejecting this argument, the Federal Circuit instead concluded that "[e]ven if some of the claimed combinations were inoperative, the claims are not necessarily invalid." *Id.* According to the court, the key question was not whether every combination in the genus worked but whether an artisan could create a working embodiment without undue experimentation. *Id.* at 1576–77 (citations omitted). Because the disclosure was sufficient to enable an artisan to create working embodiments of the invention, the Patent Act allowed the genus claim.

The courts over time appropriately developed this fact-based "undue experimentation" inquiry into a non-exhaustive multi-factor inquiry. In particular, the courts take into account: (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. *See In re Wands*, 858 F.2d at 737. That framework appropriately recognizes the case-specific nature of the enablement analysis and that judges should not impose arbitrary bright-line rules.

The Federal Circuit has also correctly recognized that even in the so-called "unpredictable arts," like chemistry, enablement depends heavily on the circumstances of the case, and is not susceptible to bright-line rules. *See In re Vaeck*, 947 F.2d at 496 ("[W]e do not imply that patent applicants in art areas currently denominated as 'unpredictable' must never be allowed generic claims encompassing more than the particular species disclosed in their specification. It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art."). Instead, "the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." *Id.*

As the cases above demonstrate, federal courts have long understood that the enablement question should depend on the degree of experimentation that it would take for an artisan to create an embodiment of the invention, and not on the number of species within a claimed genus or on whether every embodiment disclosed works. That does not mean that a person can claim a very large genus where only very few embodiments work. "Of course, if 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*, 750 F.2d at 1576-77 (emphasis added). But where the proportion of inoperative embodiments is sufficiently small such that artisans can "make and use" the invention without undue experimentation, the patent should be valid. *Idenix*'s bright-line rule, which assesses enablement in light of the number of species within a claimed genus, ignores this important analysis—short-circuiting an important tool for patent protection without appropriate consideration of the specifics of the industry and of the case.

C. The Federal Circuit Has Recently Adopted Bright-Line Rules That Effectively Eliminated Patentees' Ability To Claim A Genus of Compounds.

Despite having reaffirmed the validity of genus claims for decades (consistent with the Court's precedents and the text of the Patent Act),[11] in recent years, the Federal Circuit has strayed from the plain text of the Patent Act to engraft additional conditions to the Act's "enablement" requirement. More specifically, contrary to the Patent Act and precedent, the Federal Circuit in *Wyeth* and *Idenix* imposed arbitrary numerical limits on the number of species that can exist in an enabled genus claim and required that the patent enable the reader to perform the

11. *See, e.g.*, *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1352 (Fed. Cir. 2011) (stating that "there is no categorical rule that a species cannot suffice to claim the genus"); *Utter v. Hiraga*, 845 F.2d 993, 998–99 (Fed. Cir. 1988) (rejecting argument that a genus claim was invalid due to unpredictability in the art).

unrealistic task of making and testing substantially every species within a genus claim.

Strikingly, in 2013, the Federal Circuit in *Wyeth* stated that "practicing the full scope of the claims . . . would require synthesizing and screening" thousands of compounds, and that the genus claims were therefore invalid for lack of enablement "as a matter of law." *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1385–86 (Fed. Cir. 2013). The court announced this numeric limitation on the scope of a genus claim without regard to the industry or case specific details of how easily an artisan could "make and use" a working embodiment of the invention. As described below, *Idenix* further solidified this and other erroneous bright-line rules undermining the viability of genus claims.

1. *Idenix* Codifies A Bright-Line Rule Creating A Numerical Limit On The Number Of Compounds In A Genus Claim.

Building on the unprecedented and atextual requirements it created in *Wyeth*, the Federal Circuit in *Idenix* has now all but eliminated the genus claim as an effective and reliable means of protecting intellectual property, particularly in the chemical arts. The court in *Idenix* affirmed a district court's grant of judgment as a matter of law that a genus claim was not enabled—overturning a jury verdict that had upheld the claims based on the specific facts of the case. *Idenix Pharm. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1165 (Fed. Cir. 2019). The court reasoned that its earlier decision in *Wyeth* compelled that result because "as here, [the *Wyeth*] claim [] encompassed millions of compounds made by varying

the substituent groups, while only a significantly smaller subset of those compounds would have the claimed functional effects," and "in both cases, 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 1162-63.

In reaching that conclusion, the court noted that the claim "encompass[es] at least many, many thousands of [compounds] which need to be screened for [] efficacy, the quantity of experimentation needed is large and weighs in favor of non-enablement." *Id.* at 1159. Yet the court also acknowledged that a reasonable juror could have concluded based on the evidence at trial that the "synthesis" and "screening" of an individual compound was largely "routine"; that "a[n artisan] could synthesize [a] particular compound in relativity short order"; and that "a significant number of nucleosides were available off-the-shelf in libraries." *Id.* at 1157-60. Despite recognizing facts that significantly reduced any experimentation required to "make and use" the invention, the court nonetheless found that because "there were at least many, many thousands of candidate compounds, many of which would require synthesis and each of which would require screening," that alone "constitutes undue experimentation." *Id.* at 1163. The court therefore held ***as a matter of law*** that the claim was invalid for lack of enablement. *Id.* at 1165.

2. *Idenix* Also Adds To The Court's Trend Toward A Bright-Line Rule That A Patentee Must Enable Every Single Species In A Genus Claim.

The decision in *Idenix* also advances the unfounded trend in the Federal Circuit's recent jurisprudence requiring each and every species within a genus claim to be enabled. The Patent Act does not require the patentee to enable artisans to "make and use" ***every*** embodiment of an invention. And longstanding case law has recognized that industry and case-specific details should be the focus of the enablement inquiry. As discussed above, when case-specific details were accounted for, courts routinely recognized that claims could be enabled despite the fact that some of their embodiments were not. Yet the *Idenix* decision seems to further push in the wrong direction, building on the erroneous reasoning in cases such as *Wyeth* and imposing arbitrary bright-line rules. Synthesizing and testing ***each and every*** embodiment of a claimed genus for efficacy requires a prohibitive amount of experimentation and is not a requirement in any other type of patent claiming, particularly in industries such as the chemical and pharmaceutical arts where the level of skill is high and results may be, in certain circumstances, predictable. The Federal Circuit's recent requirements would diminish incentives for companies such as GSK to invest in the research and development of groundbreaking pharmaceuticals.

CONCLUSION

Genus claims are critical to continued innovation in the chemical and pharmaceutical industries. That appropriately acknowledges that innovations in such industries often take the form of inventive related chemical structures that form a genus. But the Federal Circuit has recently invalidated such claims, ignoring the plain language of the Patent Act, and engrafting additional conditions on genus claiming that are not found in the Patent Act itself. It has also improperly focused on bright-line rules in assessing enablement rather than on the circumstance specific to the industry and the case in question. Those developments are bad law and threaten to upend the chemical and pharmaceutical industries' incentives to develop novel chemical structures and their ability to protect past and future innovation. The Court should take up the petition to correct these atextual legal developments and to reconfirm the availability and viability of genus claiming under the Patent Act.

Respectfully submitted,

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