No. 25-225

IN THE

Supreme Court of the United States

MSN PHARMACEUTICALS, INC., *ET AL.*,

Petitioners,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Respondent.

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

REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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INTRODUCTION

The panel below held that after-arising technology "cannot be used to 'reach back' and invalidate" a patent. App. 18a-19a. But in other cases, the Federal Circuit has held that after-arising technology can be used to invalidate a patent. *See, e.g.*, *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019) (invalidating patent where at-issue embodiment arose "after the application was filed"); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) (same, where at-issue technology "did not even exist at the time of the … application"). Yet the Federal Circuit's predecessor denied that "later states of the art could be employed as a basis" to invalidate patents, *In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977)—even though this Court invalidated Sawyer and Man's patent on the basis of Edison's after-arising bamboo-filament technology in *Incandescent Lamp Patent*, 159 U.S. 465, 471-72 (1895). Against this backdrop, Novartis insists that "[t]here is no conflict between the decision here and other circuit precedent." BIO at 18.

Novartis stands alone. Scholars, practitioners, think tanks, industry groups, and other pharmaceutical companies have all concluded that the Federal Circuit's after-arising technology decisions "contradict[]" one another, thereby "leading patentees, accused infringers, innovators, and counsel to a different conclusion depending on which line is followed." *E.g.*, Unified Patents Br. at 13; *see also* Pub. Int. Patent Inst. Br. at 10; IP Law Prof. Br. at 6.

In response, Novartis urges that these decisions involved "the same rule," applied only to "different facts." BIO at 20. Not so. When some cases say that "later-existing state of the art … may not be properly

considered" in the validity analysis (App. 18a), and other cases say that it can, there are two different—and conflicting—rules. That difference is precisely what the question presented asks this Court to resolve: "Whether, in a patent-infringement suit, a court may consider after-arising technology to hold that the patent is invalid." Pet. at i.

Nothing Novartis says changes that understanding. For one, Novartis argues that this case does not implicate the question presented because the Federal Circuit held that "the patent at issue here does not claim" the complex. BIO at 3. But that logic is circular. The panel held that the '659 patent did not claim the complex because the panel presumed, under *Hogan*, that after-arising technology is an improper consideration in the validity analysis and falls outside claim scope for validity as a matter of law. App. 15a-16a & n.5, 18a-19a. Had the panel followed *Incandescent Lamp* over *Hogan*, it would have ruled differently. Novartis may not dodge the question presented by begging it.

Novartis also urges that this case does not implicate the question presented because the valsartan-sacubitril complex is a mere "improvement" on the '659 patent, rather than an after-arising invention. BIO at 2, 4, 31-32. Below, however, Novartis "argu[ed] that a complex of valsartan and sacubitril *was* an after-arising invention." App. 11a (emphasis added). It got it right the first time. No pharmaceutical company sells patients mere physical mixtures of valsartan and sacubitril—the only species available at the time of the patent's filing. App. 4a. Instead, the commercial product is the "complex[ed]" form, "which combines the two drugs into a single

unit-dose-form through weak, non-covalent bonds." App. 4a. That complex was the culmination of over a thousand experiments, and at the endeavor's outset, scientists had no idea whether they could do it, calling it a "loooong shot." App. 64a.

In other words, this is not a case of A+B+C. Rather, the after-arising complex constituted not an improvement but a fundamentally new product, the equivalent of transforming a few stray letters into words and sentences. Indeed, like Edison's bamboo, the complex is the sort of special embodiment that—under ordinary patent-disclosure principles—would expose the patent's invalidity by revealing that the patent failed to describe and enable the full scope of the claimed genus. As *Incandescent Lamp* teaches, when this happens, the original, overbroad "patent is void." 159 U.S. at 474.

This case is a "clean opportunity for this Court to clear up" a longstanding and significant conflict in patent law. Sigmapharm Br. at 7-8. That conflict is significant not just for the pharmaceutical industry, but for all stakeholders in our patent system. This Court should grant review and reverse.

ARGUMENT

I. The Federal Circuit's Decisions on After-Arising Technology Are Incompatible.

A. For decades, the Federal Circuit has declined to give a consistent rule on whether after-arising technology can invalidate a patent. Some decisions hold it can, because after-arising technology is a proper consideration in the written-description and enablement inquiries for validity. *See Idenix*, 941 F.3d at 1164-65; *Chiron,* 363 F.3d at 1254-55 (written

description); *Plant Genetic Sys., N.V. (PGS) v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1341 (Fed. Cir. 2003) (enablement). Other decisions apply a categorical rule rejecting consideration of after-arising technology from the validity analysis. App. 18a-19a (citing *Hogan*, 559 F.2d at 605); *see also* Jorge A. Goldstein, U.S. Biotechnology Patent Law § 6:26 (Aug. 2025) ("The *Entresto* rule overrules *sub silentio* the conclusion reached in *Chiron* … .").[1]

Those propositions cannot both be true. So it should come as no surprise that parties in after-arising technology cases have repeatedly asked the Federal Circuit en banc to settle the doctrine. Pet. at 15 (collecting petitions). Because the en banc court has declined each time, this Court should answer the call.[2]

B. Although Novartis asserts that *Idenix* "did not involve any question about after-arising technology" (BIO at 19), the panel there invalidated a patent that failed to describe and enable a method that was invented "a year or so after the application was filed," 941 F.3d at 1164. To state the obvious, something that is invented a year after an application is filed is after-arising technology. In *Chiron*, likewise, the panel

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[1] Meanwhile, some decisions broadly construe claims to cover after-arising technology, *see SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 878 (Fed. Cir. 2004), while other decisions do the opposite, *see Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1353 (Fed. Cir. 2000).

[2] Contrary to Novartis's contention about § 112(a) (BIO at 5), the 2011 Leahy-Smith America Invents Act ("AIA") did not change the language of § 112's written-description and enablement requirements; it simply put them in a subsection (a). *See, e.g.*, *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1364 (Fed. Cir. 2023) (citing § 112(a) while addressing pre-AIA patent).

invalidated a patent that failed to describe technology that "did not even exist at the time of the … application." 363 F.3d at 1254. And in *PGS*, the panel invalidated a patent that failed to enable "a later development." 315 F.3d at 1341.

While Novartis tries to distinguish this trilogy on the ground that those cases involved functional claims (BIO at 20), that distinction makes no difference. *Hogan* held—without mentioning functional language—that after-arising technology may not reach back and invalidate patents, *see* 559 F.2d at 605-06, and neither Judge Newman's *Idenix* dissent nor Judge Bryson's *Chiron* concurrence (on enablement) mentioned the claims' functional language as reasons why the majority was wrong to depart from a *Hogan-Entresto* approach, *see* Pet. at 16-20. The question now is whether the *Hogan-Entresto* line should be excised from the doctrine because it clashes with *Incandescent Lamp*, *Amgen v. Sanofi*, 598 U.S. 594 (2023), and other decisions; it should be.

C. While *Amgen* did not involve after-arising technology, that does not mean the Federal Circuit has license to recognize an after-arising-technology exception to the validity inquiry. Rather, *Amgen*'s fundamental holding—"[t]he more one claims, the more one must enable," *id.* at 616—is a universal one. And by granting review here, on *Amgen*'s heels, this Court's consequent decision—*Amgen 2.0*—can unify disclosure doctrine across contexts.

II. The Decision Below Is Wrong.

A. Under the panel's reasoning, a patentee like Novartis may weaponize a claim to block an after-arising invention even when the patentee has neither described nor taught that invention. Yet *Incandescent*

Lamp held that Sawyer and Man could not weaponize their claim for "carbonized fibrous or textile material" to block after-arising technology that they did not describe or teach: the bamboo filament. 159 U.S. at 466, 468. *Holland Furniture* explains why: claims that "extend[] beyond the invention" "foreclose efforts to discover other and better types." *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257-58 (1928).

To be sure, if there were nothing special about after-arising bamboo, it could not have reached back and invalidated the patent. But bamboo was a superior species of the claimed fibrous-textile genus; a skilled artisan with access to the specification could not have invented that embodiment without "elaborate experimentation." *See Amgen*, 598 U.S. at 610 (quoting *Holland Furniture*, 277 U.S. at 257). So it made sense—and harmonized with bedrock patent-disclosure principles—to hold that after-arising bamboo had exposed the patent's invalidity. The bamboo embodiment revealed that the patent had failed to describe and teach the full scope of the claimed fibrous-textile genus.

In Tolkienian terms, if a patent claimed a genus of metal gears, after-arising mithril would reach back and invalidate the patent if a skilled artisan could not use the specification to make mithril gears without elaborate experimentation: "additional work is what renders [the] patent insufficient to warrant stretching her claim to include mithril within its scope." Masur & Ouellette Br. at 9-10. Novartis is thus wrong that, without the categorical *Hogan-Entresto* rule, there is no limiting principle to stop technological advances from wiping out swaths of patents. BIO at 31-32. In some cases, after-arising technology can soundly reach

back and invalidate a patent; in other cases, it cannot. A *per se* rule excluding after-arising technology from the validity analysis is misguided.

B. This case is on all fours with *Incandescent Lamp*. Novartis does not meaningfully say otherwise. BIO at 30. Like Sawyer and Man's fibrous-textile patent, Novartis's '659 patent claimed a genus: valsartan-sacubitril combinations. App. 56a. But at the time of filing, valsartan and sacubitril could be combined only as a "physical mixture" of two separate components. App. 55a. Akin to Sawyer and Man's lamp, that physical mixture never came to market. Instead, as with bamboo, the key advance for commercial success was the discovery, through elaborate experimentation, of a special embodiment of the genus: the complex, which links valsartan and sacubitril via non-covalent bonds. App. 56a.

Novartis's attempt to trivialize the complex (at 2, 4, 31-32) as a minor improvement is at loggerheads with its representations below. As the district court found—based on Novartis's evidence—Novartis's scientists "conduct[ed] over one thousand separate experiments" in their endeavor to discover a complex. App. 64a. The scientists described their task as a "loooong shot," an "Out-of-the-box (Irrational?) Approach," "wild"—they "did not know whether it was possible" or "feasible" to turn the theoretical idea into reality. *Id.* Through elaborate experimentation, however, they did. *Id.* And as Novartis itself has explained to the FDA, that complex, compared with the combination, has a "distinct chemical structure," "releases higher concentrations," is "more bioavailable," has "higher solubility," and has a "more favorable dissolution profile." *See In re Entresto*, No.

1:20-md-02930, Doc. 1778-1 (D. Del. Feb. 14, 2025), at 16-20. Novartis's patent for the complex also touts "different properties that make it particularly useful for manufacturing and therapeutic applications." C.A. App. 5074-75 (8,877,938 patent).

Given this record, the valsartan-sacubitril complex is one species of the valsartan-sacubitril combination genus that a skilled artisan, with access to the '659 patent's specification, could not have developed without "elaborate experimentation." *See Holland Furniture*, 277 U.S. at 257. It would be an "injustice" for Novartis to reap complex-related benefits from the '659 patent "in view of the experiments made, and continued" long after that patent's filing. *See Incandescent Lamp*, 159 U.S. at 472-73. The complex is thus the sort of after-arising technology that can expose the '659 patent's invalidity. The complex reveals that the '659 patent failed to describe and teach the full scope of the claimed combination genus. The panel below therefore erred in holding that the after-arising complex was an improper consideration for the validity analysis and in reversing the invalidity finding on that ground—assuming that *Hogan* is wrong, which this Court should confirm. Pet. at 31-34.

C. While Novartis stresses that its scientists invented the complex (BIO at 1, 31), that fact is a red herring. Novartis is deploying its '659 patent—for the entire genus of valsartan-sacubitril combinations—to foreclose "other and better types," *see Holland Furniture*, 277 U.S. at 257, including generic versions of the after-arising complex, such as MSN's product. Although settled patent doctrine ordinarily forecloses the strategy of lassoing loose claims to block competition, the *Hogan-Entresto* line enables

patentees to employ that strategy in cases of after-arising technology—to the detriment of patients' access to affordable medicines in the pharmaceutical context, and to the detriment of innovation in other contexts. *See* Ass'n of Affordable Med. Br. at 13; Biophore Br. at 10; Pub. Int. Patent Inst. Br. at 12-16.

D. Novartis's prior representations about the complex also undermine its attempt to shoehorn this case into an A+B+C framework. The complex is not an additional ingredient to add to a valsartan-sacubitril combination—the C to an A+B. The patent claims all permutations where "valsartan and sacubitril are administered in combination," whether in separate or complexed form. App. 8a. That makes Novartis's valsartan-sacubitril combination claim a genus claim. Physical mixtures are one species in that genus. Complexes are another. Or, to use Novartis's analogy: complexes are one type of A+B (and, in commercial terms, the type that works), and physical mixtures are a different type of A+B.

E. The cases Novartis marshals in opposition do not change this calculus. *Cantrell v. Wallick*, 117 U.S. 689, 694 (1886), concerned "an improvement" that did not materially change the underlying product; as this Court noted, "[i]t would baffle the ingenuity of the most skilled expert to show a substantial difference between the invention claimed by the plaintiff and that which it is conceded that the defendants use." *Id.* at 694-95. *Cochrane v. Deener*, 94 U.S. 780, 787 (1876), similarly involved an "improvement[]" to a product that "was itself capable of beneficial use, and was put to such use." And *Temco Electric Motor Co. v. Apco Manufacturing Co.*, 275 U.S. 319, 328 (1928), involved an "improvement" on an existing patent whose

"usefulness was demonstrated by 10 years' use in such large numbers and by such profitable business."[3]

In none of these cases did the improvement turn a previously unsold product into a commercially viable one. And in none did this improvement take years of painstaking experimentation. When these circumstances are present, after-arising technology is properly part of the validity analysis—consistent with *Incandescent Lamp*, and contrary to *Hogan*.

III. This Case Is an Ideal Vehicle.

This case is an ideal vehicle to determine whether to close the *Hogan-Entresto* exception to the ordinary patent-disclosure rules on validity. That loophole, from the premise that after-arising technology is irrelevant to the validity analysis, permits patentees to block after-arising inventions even if the claims do not describe or enable them. Apart from the BIO, Novartis has recognized this case's capacity to answer this question. C.A. App. 4219 ("Allowing a later-discovered embodiment to reach back in time and invalidate a previously valid patent would cause substantial uncertainty."); C.A. App. 4230 (advocating for "enablement exception for unknown technology").

MSN's stipulation to *infringement* is not a vehicle problem. BIO at 33. Quite the contrary, the infringement stipulation isolates the question

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[3] In passing, Novartis also cites *Winans v. Denmead*, 56 U.S. 330 (1853), and *Morley Sewing Mach. Co. v. Lancaster*, 129 U.S. 263 (1889). Those cases concern the doctrine of equivalents—which militates *for* review, not against it. Under that doctrine, even if the *Hogan-Entresto* loophole is closed, patentees may categorically block after-arising copycats. It is one of several doctrinal tools to maintain a balanced patent system. Pet. at 31.

presented, which concerns the *validity* analysis and its implications. And MSN's stipulation is effective only "to the extent that claims 1-4 of the '659 patent are valid." D.C. Dkt. 406 at 3. If these claims are found at any point to be invalid, the stipulation becomes inapplicable and drops from the case. This Court therefore can and should resolve this case by following "the better practice [of] inquiring fully into the validity of [a] patent," rather than "dispos[ing] of" it on infringement or other grounds. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330 (1945).

Novartis next contends that "the D.C. Circuit appears to have recognized that MSN's product is primarily 'not a complex' of valsartan and sacubitril." BIO at 34 (quoting *Novartis Pharms. Corp. v. Kennedy*, 2025 WL 2737402 (D.C. Cir. Sept. 26, 2025)). But the quoted language comes from the D.C. Circuit's recitation of Novartis's argument. *Id.* at *5 ("According to Novartis … ."). The D.C. Circuit did not hold that MSN's product is not a complex. More fundamentally, the point remains that the Federal Circuit here held that Novartis could use its '659 patent for combinations to block all competitors' after-arising complexes—and all other after-arising species within the genus. That holding is deeply flawed.

* * *

Contrary to Novartis's contentions, this case is an ideal vehicle for review. Like prior cases that have merited review, this case involves a "significant disagreement within the Court of Appeals for the Federal Circuit" over a legal issue. *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997); *see also WesternGeco LLC v. ION Geophysical Corp.*, 585 U.S. 407, 412 (2018). Like prior

cases, it presents an issue where the petitioner sought, but the Federal Circuit denied, rehearing. *See United States v. Arthrex, Inc.*, 594 U.S. 1, 11 (2021); *Cuozzo Speed Techs. v. Com. for Intell. Prop.*, 579 U.S. 261, 271 (2016). And like prior cases, the economic stakes and the consequences for scientific innovation are substantial. *See Amgen*, 598 U.S. at 598.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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