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

BRIEF OF BIOPHORE PHARMA INC.; NATCO PHARMA INC.; DEVA HOLDING A/S AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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INTEREST OF AMICUS CURIAE[1]

The amicus are generic pharmaceutical companies that seek FDA approval for and market generic drug products in the U.S. They are: Biophore Pharma Inc.; Natco Pharma Inc.; and Deva Holding A/S. They have an interest in ensuring that patent laws are robust enough to facilitate the Constitutional requirement of promoting the progress of industry. But underlying the promotion of industry, is that the patent laws must be fair; that is fairly construed to promote competition. As generic drug companies are often defendants in patent infringement suits, much litigation surrounds the proper and fair interpretation of the patent laws.

INTRODUCTION & SUMMARY OF THE ARGUMENT

This case presents the Court with an opportunity to clarify some fundamental principles of patent law, with respect to the "written description" and enablement requirements. Particularly, this case concerns statutory interpretation, not technical or scientific issues.

This brief explains the plain problem that needs resolving. The following facts are not in dispute. Novartis obtained FDA approval, on 07 July 2015, to

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[1] Under this Court's Rule 37.2, amicus states that counsel of record for all parties received notice of amicus's intent to file this brief more than ten days before the brief's due date. And under this Court's Rule 37.6, amicus states that no counsel for a party authored this brief in whole or in part, that no such counsel or party made a monetary contribution intended to fund the brief's preparation or submission, and that no person other than amicus and its counsel made such a monetary contribution.

market Entresto®, which is a *complex* of the molecules: sacubitril and valsartan. The underlying patent, the U.S. Patent No. 8,101,659 ("the '659 patent") claims a *combination* of the molecules. The '659 patent was filed (as a patent application) and issued long before the FDA approved Entresto. It is undisputed that after the '659 patent was filed, Novartis then discovered that the two molecules could be put together in a *complex*. By being in a complex, the molecules, are in a sense, joined together. It would be akin to two people almost holding hands versus they are clasping each other's hands. Once they are actually holding hands, the hands are joined together. The '659 patent was listed in the FDA's Orange Book on 06 Aug. 2015.

Now because Entresto was, per FDA characterization, a *complex* of the two molecules, generic companies that file the generic drug dossier (called the ANDA), must have the same molecules in the same structure. Hence MSN's proposed generic version must also be a complex. Again, there is no dispute that MSN's proposed generic version of Entresto is a complex. If it were not, then FDA could not approve MSN's generic version.

MSN filed its generic drug dossier seeking approval of its generic version. As is typical in the so-called Hatch Waxman Act ¶ IV Certification context, MSN filed a Paragraph IV certification against the '659 patent. Thereafter, Novartis sued MSN (among others) for patent infringement under the Hatch Waxman Act. The basic background of the Hatch Waxman Act scheme is described in Shashank Upadhye, Generic Pharmaceutical Patent and FDA, § 1:3, *Legal aspects of the generic drug development*

pathway for judges and lawyers (Westlaw 2024–25 ed.).

Novartis argued at trial during the so-called claim construction process that the claim language of "combination" in the '659 patent had to include a *complex* because that would be the only way to ensnare the MSN generic drug complex. Getting that claim construction would make MSN liable for patent infringement.

Be careful what you wish for, for it might come true. The district court noted that by arguing for the broad claim construction to ensnare an infringer, that might lead to patent invalidity because of a lack of written description under 35 U.S.C. §112. This was because the "complex" of the molecules was not described in the '659 patent specification. Nor could it. The complex was not discovered until years later so it could not have been described in the '659 patent specification. Accordingly, the trial court invalidated the relevant claims. It said that later-arising technology could not be described in an earlier specification and thus could not support the claim the claim that encompassed later-arising technology.

The Federal Circuit reversed. Because neither party appealed the actual claim construction, the Court only dealt with the invalidity issue. The Court stated that *for the purposes of invalidity*, after-arising technology could not be encompassed within the claim. And because of that, the claim construction for invalidity purposes excluded complexes. And when it excluded complexes, there was no need to describe something that was not required to be described. The Court, therefore, reversed the invalidity decision.

The problem with this construct is that case law

squarely states that claims are to be construed the same for infringement and for invalidity. The Court's ruling creates an unfair situation: for infringement a patentee can ask the court for a broader claim construction to ensnare the infringer through later developed technology, but then not suffer the consequence that such technology need not be described in the specification.

During the underlying litigation, the '659 patent expired due to its natural patent expiration. Novartis, therefore, enjoyed the full term (including any relevant term extensions) for the '659 patent. This expiration does not moot this case because MSN launched its generic version in the interim and could be on the hook for monetary patent damages.

Accordingly, this Court should grant the Petition to clarify the case law that after-arising technology, if used for infringement purposes, then must also be considered for invalidity purposes. By granting the Petition, it can clarify that the In Re Hogan-Entresto theory is not the law and should be rejected.

ARGUMENT

I. If An Invention Is Described By The Claims, Then That Invention Must, Under Section 112, Be Described In The Patent Specification.

A. Inventions are Described the Claims.

The current patent statute, 35 U.S.C. §112(b), requires that the invention be claimed. Indeed, § 112(b) requires that the claims identify what the inventor regards as his invention. Accordingly, there is no doubt that Novartis had to include claims to the

invention, and that invention must be what it regarded as its invention.

B. The Claimed Invention Must Comply With Section 112(a)

Even though the applicant has claimed an invention, it is not done. The invention claimed must also comply with the requirements of 35 U.S.C. § 112(a). Here, the statute commands that there must be a written description and enablement of the invention. And the statute commands the level of detail required: in full, clear, concise, and exact terms. Accordingly, scant details or missing details are not enough. Rather, there must be a full description.

Now for after arising technology, this is where it fails. One cannot fully, clearly, concisely, nor exactly define what is not yet even known or discovered. The Federal Circuit stated that the "written description requirement serves a teaching function, as a "quid pro quo" in which the public is given meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time." *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 922 (Fed. Cir. 2004). And in that case, the patent claims directed to COX–2 inhibitors were invalidated for lack of adequate written description because the existence of such inhibitors was merely "hypothesized"; no such inhibitors were yet known and none were described in the patent). *Id.* at 918, 923. Allowing yet-to-be-discovered after-arising technology to be swept up into a claim for infringement purposes denies the quid pro quo requirement that the public be educated on that. That is, how can after-arising technology be dedicated to the public upon patent expiration if that technology is

not even fully described in the patent specification? *Amgen Inc. v. Sanofi*, 598 U.S. 594, 605 (2023) ("So today, just as in 1790, the law secures for the public its benefit of the patent bargain by ensuring that, upon the expiration of [the patent], the knowledge of the invention inures to the people, who are thus enabled without restriction to practice it. *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933)*;* see also *Grant v. Raymond*, 31 U.S. 218, 219 (Marshall, C. J.) ("This is necessary in order to give the public, after the privilege shall expire, the advantage for which the privilege is allowed, and is the foundation of the power to issue a patent."); *Whittemore v. Cutter*, 29 F. Cas. 1120, 1122 (No. 17,600) (C.C.D. Mass. 1813) (Story, J.) ("If therefore [the disclosure] be so obscure, loose, and imperfect, that this cannot be done, it is defrauding the public of all the consideration, upon which the monopoly is granted.") (cleaned up).

This Court reaffirmed this principle in *Festo*. There the Court reaffirmed that patent holders are supposed to know what they own; and competitors are entitled to know what patentees do not own. And this comes from a full description of the invention that the patentee knows what he owns. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002) ("A patent holder should know what he owns, and the public should know what he does not. For this reason, the patent laws require inventors to describe their work in full, clear, concise, and exact terms as part of the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations,

creations, and new ideas beyond the inventor's exclusive rights.") (cleaned up).

A patent applicant is not penalized by this understanding. There is nothing unfair about this. For if the applicant (or another applicant) should invent or discover after-arising technology, nothing stops the applicant from filing a new patent application on that after arising technology and obtaining new and presumably longer-term patent protection (assuming the other aspects of the patent laws are met). Indeed, Novartis obtained two patents to the complex as U.S. Patent Nos.: 8,877,938; and 9,388,134.

II. If One Cannot Expressly Claim The After Arising Technology Because It Runs Afoul With Section 112(a), Then Axiomatically It Runs Afoul With Section 112(a) For Infringement Purposes.

Suppose Novartis during the patent application process expressly tried to claim the "complex". That claim would have certainly been rejected for a lack of written description.

Now, does it make sense that a patentee can assert a specific after-arising technological species for infringement purposes, and win the infringement side, yet not have been allowed that claim during the application process? No, it does not make sense, and it is unfair. This understanding would not provide any notice to any competitor about what activities it might undertake, as being in-bounds or out-of-bounds. *Festo*, 535 U.S. at 730–731 ("The monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote

progress"). And given that many of these claim construction and invalidity decisions are based on questions of law, or mixed questions of law and fact, it would ultimately be up to the Federal Circuit panel to decide these questions. That is, no question can be settled until the Federal Circuit panel says so. This will cost competitors years of litigation and millions of dollars. Generic drug companies, who are defendants in these pharma patent cases, seek to bring cheaper versions of the drugs to the market for patient and payor benefit. The millions of dollars spent and time lost affect competition and prices. And if this is a question of policy about fair notice to competitors versus rewards for inventors, Congress is best suited to resolve this. *SAS Institute, Inc. v. Iancu*, 584 U.S. 357, 368 (2018) ("Policy arguments are properly addressed to Congress, not this Court. It is Congress's job to enact policy and it is this Court's job to follow the policy Congress has prescribed.").

That after-arising technology can also be used for infringement purposes (to ensnare the competitor) but survive invalidity, upends the precedent that claims are to be construed the same for infringement and invalidity. *Amgen Inc. v. Hoechst Marion Roussel*, Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003) ("It is axiomatic that claims are construed the same way for both invalidity and infringement.").

Also, the situation of after arising technology being used for infringement purposes but suffering invalidity is a patentee's own fault. It is the patentee that argues, in the scope of litigation, that it needs a broader claim construction to ensnare the competitor for infringement purposes. See Shashank Upadhye, *The Perils of Broad Patent Claims: From Issuance to*

Invalidity, Upadhye Tang LLP (July 1, 2025), https://ipfdalaw.com/the-perils-of-broad-patent-claims-from-issuance-to-invalidity/ ("Patent owners often advocate for broad interpretations of claim terms in order to capture the accused product. But in doing so, they may find themselves hoisted by their own petard. … In their quest for litigation advantage, patent owners may stretch claim scope just far enough to capture the target and right into the jaws of invalidity. The very arguments used to broaden the claim for infringement purposes become the rope by which the claim is hanged under §112.").

III. To The Extent An Intra-Circuit Split Exists, This Court Should Resolve This Split.

In some decisions, including *In re Entresto*, the Federal Circuit has held that after-arising technology may never invalidate a patent. *See, e.g.*, *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1340 (Fed. Cir. 2003) (holding that "one [can]not use a later-existing state of the art to invalidate a patent that was enabled for what it claimed at the time of filing"); *In re Hogan*, 559 F.2d 595, 604 (C.C.P.A. 1977) ("It is quite another thing, however, to utilize the patenting or publication of later existing improvements to 'reach back' and preclude or invalidate a patent on the underlying invention.").

Other Federal Circuit decisions cast doubt on the premise that after-arising technology is necessarily unclaimed and thus may never expose a patent's invalidity. *See, e.g.*, *Innogenetics, N.V. v. Abbott Lab'ys*, 512 F.3d 1363, 1371–72 (Fed. Cir. 2008) ("Our case law allows for after-arising technology to be captured within the literal scope of valid claims that

are drafted broadly enough."); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) ("[T]he Chiron scientists, by definition, could not have possession of, and disclose, the subject matter of chimeric antibodies that did not even exist at the time of the 1984 application. Thus, axiomatically, Chiron cannot satisfy the written description requirement for the new matter …").

To the extent that *In Re Hogan* still represents good law, it is not being followed by later Federal Circuit panels. Because Federal Circuit panels are not applying its case law consistently, patentees can and are gaming the system. Gaming the system: (i) creates uncertainty for industry; (ii) unpredictability because the outcome can be Federal Circuit panel dependent; and (iii) ultimately the U.S. public is deprived of low-cost generic drugs.

This Court has not reviewed the patent law "written description" requirement under § 112, though it has reviewed Federal Circuit decisions involving the "enablement" requirement in *Amgen* and the "definiteness" requirement in *Nautilus*. And in both cases, this Court recognized the centuries long history of the written description requirement. Indeed, in *Nautilus*, this Court recognized that the full written description was the basis of the patent right; even before the statutes were amended to include the claims. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 902 (2014) ("Under early patent practice in the United States, we have recounted, it was the written specification that represented the key to the patent. Eventually, however, patent applicants began to set out the invention's scope in a separate section known as the

'claim.' The Patent Act of 1870 expressly conditioned the receipt of a patent on the inventor's inclusion of one or more such claims, described with particularity and distinctness. *See* Act of July 8, 1870, § 26, 16 Stat. 201 (to obtain a patent, the inventor must particularly point out and distinctly claim the part, improvement, or combination which [the inventor] claims as his invention or discovery).") (cleaned up).

This Court recognized that in "the area of patents, it is especially important that the law remain stable and clear." *Bilski v. Kappos*, 561 U.S. 593, 613 (2010). Thus, this Petition may be used to clarify the scope of after-arising technology, by overruling the *Hogan-Entresto* line of cases, reaffirming that patent specifications require a full written description of the invention as claimed, and reaffirming that the scope of the invention that forms the basis for infringement must parallel the scope of the claims for invalidity purposes.

CONCLUSION

The Court should grant the petition for writ of certiorari to clarify that after-arising technology cannot be used for infringement purposes to ensnare a competitor yet not be used for §112(a)'s compliance with written description or enablement.

Respectfully submitted,

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