No. 19-1131

IN THE
Supreme Court of the United States

ACTAVIS LABORATORIES, FL, INC.,
Petitioner,
v.

NALPROPION PHARMACEUTICALS LLC
Respondent.

On Petition for a Writ of Certiorari
To the United States Court of Appeals
For the Federal Circuit

BRIEF OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with safe and effective generic and biosimilar medicines at affordable prices. AAM regularly participates in litigation as *amicus curiae*.

AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet generics account for only 22% of total drug spending. Billions of generic prescriptions are filled in the United States annually, costing patients roughly one-seventh the price of brand-name alternatives. Individuals rely on this affordable access to life-sustaining medications, and States rely on the

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[1] Pursuant to this Court's Rule 37.2(a), *amicus* timely notified all parties of its intention to file this brief. Counsel for all parties have consented to the filing of this *amicus* brief. Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

billions of dollars of annual Medicare and Medicaid savings that generic medications generate.[2]

AAM and its members have a significant interest in the issues raised by this petition for certiorari. As the petition explains, the Federal Circuit's decision weakens and confuses the Patent Act's written description requirement. According to the opinion below, a patentee may expand patent coverage beyond its disclosed invention to reach undefined "substantial[] equivalents" for an ambiguous set of "resultant . . . parameter" or non-"operative" claim limitations. *See* Pet. App. 11a, 14a. Yet the panel's decision provides no test for determining "substantial equivalence;" it does not clearly define the kinds of claim limitations that qualify for this less-exacting treatment under written description law; and it certainly does not justify as a matter of law (or policy) the imposition of an amorphous two-tier system for evaluating the adequacy of the written description which contradicts both this Court's teachings and entire lines of established Federal Circuit authority.

What the dissent below called a "problematic[] . . . new rule for written description," Pet. App. 30a, is of particular concern to AAM and its members. Generic and biosimilar manufacturers seeking to develop competing alternatives to expensive brand-name drugs

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[2] *See Report: 2019 Generic Drug & Biosimilars Access & Savings in the U.S.*, Ass'n for Accessible Medicines, https://accessiblemeds.org/resources/reports/2019-access-and-savings-report (last visited Apr. 14, 2020).

already face substantial and well-documented challenges from large patent estates.[3] The panel's amorphous "substantial equivalence" standard now threatens to give drug company patentees license to expand their patent portfolio to cover competing products they *never invented*, including design-around generic alternatives to high-priced pharmaceuticals. When a patentee's invention is specific, then potential competitors can design around the specific claims. This is particularly important in the pharmaceutical industry, where design-arounds can enable the launch of generic alternatives to high-priced brand-name pharmaceuticals. But if brand-name drug companies can go back and get new claims, covering variants that they did not invent, they can block design-around competition.

This unprecedented freedom to claim broadly is particularly troubling in the context of continuation applications claiming variations of a drug claimed in a parent application. A patentee seeking new claims to cover a competing product can allege "substantial equivalence" to sidestep the new matter prohibition and maintain the parent application's priority date, barging in front of the competing product and defeating intervening would-be prior art. The ultimate victims of these tactics are patients, who will be deprived of cost-

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[3] *See, e.g.*, *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients*, Biosimilars Council 5-7 (June 2019), https://www.biosimilarscouncil.org/wp-content/uploads/2019/06/Biosimilars-Council-White-Paper-Failure-to-Launch-June-2019.pdf.

saving generic alternatives that were never invented (and perhaps never even conceived of) by the patentees.

A rule that deprives the public of the complete invention disclosures to which it is entitled—while simultaneously stifling good-faith efforts to develop competing products—disserves the purpose of the written description requirement. AAM respectfully urges this Court to grant certiorari to restore the written description requirement to its role of ensuring "that the inventor actually invented the invention claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *see also Atl. Works v. Brady*, 107 U.S. 192, 200 (1883) ("The design of the patent laws is to reward those who make some substantial discovery or invention, which adds to our knowledge and makes a step in advance of the useful arts"—not to grant exclusive privileges in exchange for merely "a shade of an idea.").

SUMMARY OF ARGUMENT

I. The decision below dangerously departs from well-settled law. By allowing patent coverage for undisclosed variants of an invention, the Federal Circuit's decision undermines the fundamental bargain underlying the patent system: public disclosure of an invention in exchange for temporary monopoly protection. In doing so, the decision below contravenes the governing statute and this Court's precedent, and it creates substantial discord in the law of the Federal Circuit.

II. The Federal Circuit's ill-conceived new rule will yield severe consequences for the generics and

biosimilars industry in particular. For one thing, the decision will allow patentees to block the introduction of lower-cost drug alternatives into the market through improper continuation patents that add claims reciting subject matter that was not disclosed in the specification. More fundamentally, the rule below imposes an amorphous new test that will deprive generics manufacturers of the legal predictability they need to make the major investments that new drugs require. The result will be fewer and higher-cost medicines for the public without any legal justification or countervailing public benefit.

ARGUMENT

I. The Federal Circuit's Decision Contravenes Both Supreme Court and Federal Circuit Precedent.

There is a well-established bargain underlying the written description requirement: "in exchange for being excluded from practicing an invention for a period of time," members of the public must "receive[] a meaningful disclosure" of that invention. *Ariad*, 598 F.3d at 1353-54; *see also Bilski v. Kappos*, 561 U.S. 593, 602 (2010) ("[I]n order to receive the Patent Act's protection the claimed invention must [be] fully and particularly described."). To enforce this bargain, the law demands that "what is claimed by the patent application must be the same as what is disclosed in the specification," *Ariad*, 598 F.3d at 1346-47 (quotation marks omitted), and the specification must contain "*precise* descriptions of the new characteristic for which protection is sought," *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938) (emphasis added). As this Court has recognized, "nothing can be

more just and fair, both to the patentee and to the public, than that the former should understand, and correctly *describe*, just what he has invented, and for what he claims [as] a patent." *Merrill v. Yeomans*, 94 U.S. 568, 573–74 (1876) (emphasis added).

The decision below repudiates this fair exchange. For the first time, the Federal Circuit has allowed patentees to claim an *undisclosed* variant—termed a "substantial[] equivalent"—of their alleged invention. Pet. App. 11a. In doing so, the Federal Circuit has contravened the governing statute, Supreme Court precedent, and the formerly-settled law of the Federal Circuit.

In this case, the patentee claimed an invention having a particular naltrexone dissolution profile as measured by a measurement technique called the "paddle method" (or "USP 2"), even though the key portion of the patent's written description disclosed only data measured by a different technique called the "basket method" (or "USP 1"). *See* Pet. App. 7a, 12a. Uncontroverted evidence established that the paddle method would not yield the same measure of the drug's dissolution profile as would the basket method. *See* Pet. App. 31a. Despite acknowledging that "as a general matter written description may not be satisfied by so-called equivalent disclosure," the Federal Circuit excused the patent's failure to disclose any invention of a naltrexone formulation using the claimed method and exhibiting the claimed dissolution profile. Pet. App. 13a–14a. It justified doing so on the ground that the disclosed basket method was "substantially equivalent" to the claimed paddle method. Rather than engage in any

analysis of statutory text or binding precedent, the court simply declared that "[r]igidity should yield to flexible, sensible interpretation." Pet. App. 11a, 14a.

The Federal Circuit's "flexible, sensible interpretation" purports to be an "interpretation" of 35 U.S.C. § 112. Pet. App. 14a. Yet, as the petition ably demonstrates, the statutory text cannot be reconciled with the Federal Circuit's conclusion. Actavis Pet. at 24. Section 112 speaks of a single "written description of *the invention*" articulated in "full" and "exact terms." 35 U.S.C. § 112(a) (emphasis added). And it makes clear that the same "invention" must be "*particularly* point[ed] out and *distinctly* claim[ed]." *Id.* § 112(b). There is simply no textual basis for the Federal Circuit's decision to replace these exacting requirements with "flexible" ones, or to replace the singular written description requirement with multiple requirements for different types of claim limitations. Pet. App. 14a.

On this ground alone, the decision below fails to abide by this Court's repeated direction in statutory interpretation cases. *See, e.g.*, *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (explaining in a patent case that this Court's "duty is to give effect to the text that 535 *actual* legislators (plus one President) enacted into law"); *Sebelius v. Cloer*, 569 U.S. 369, 376 (2013) ("[I]n any statutory construction case, we start, of course, with the statutory text, and proceed from the understanding that unless otherwise defined, statutory terms are generally interpreted in accordance with their ordinary meaning." (internal quotation marks and brackets omitted)); *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253–54 (1992) ("[C]ourts must presume that a legislature

says in a statute what it means and means in a statute what it says there.").

The decision below also conflicts with fundamental principles of patent law as articulated by the Supreme Court. On multiple occasions, this Court has recognized that an invention cannot be broken down into supposedly material and immaterial components. Rather, "[e]ach element contained in a patent claim is . . . material to defining the scope of the patented invention." *Warner-Jenkinson, Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997); *see also Limelight Networks Co. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014) ("[U]nder this Court's case law, the patent is not infringed unless *all* the steps are carried out." (emphasis added)). This principle has stood the test of time. *See, e.g.*, *Union Water-Meter Co. v. Desper*, 101 U.S. 332, 337 (1879) (reasoning that if a patentee "claims a combination of certain elements or parts, we cannot declare that any one of these elements is immaterial" because "[t]he patentee [has] ma[de] them all material by the restricted form of his claim.").

The Federal Circuit has applied this rule consistently for decades. No matter how great or small the differences between the disclosed invention and the claimed subject matter, a patentee may obtain a monopoly over only the invention that is actually disclosed in the specification. There is no exception for resultant "parameters" rather than "operative claim steps." Pet. App. 14a. Indeed, in language that could (and should) have been used in this case, the Federal Circuit has decried, as "exactly the type of overreaching the written description requirement was designed to

guard against," a claim for a method of treatment using an extended release drug having "a characteristic that is not discussed even in passing in the disclosure." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1327 (Fed. Cir. 2000); *see also* Pet. at 23 (discussing precedent rejecting the "obvious variant" theory); Pet. App. 30a (discussing this precedent in the dissenting opinion).

II. The "Flexible" Rule Adopted Below Will Hinder Innovation and Competition, Particularly for Generic and Biosimilar Alternatives.

The Federal Circuit's new standard is not just wrong on the law; it also will meaningfully curtail pharmaceutical innovation and competition, and thus ultimately result in fewer and higher-cost drug options for patients.

A. The Rule Below Will Wrongly Permit Patentees To Extend Patent Rights Through Continuation Patents by Adding Claims Not Found in the Specification.

A weakened written description requirement poses special harms for the development of generics and biosimilars in the context of continuation applications. In a continuation application, a patentee is allowed to add new claims to the patent and obtain the benefit of the original application date and prior art date, but *only* to the extent that the new claims are supported by the original specification. In other words, the written description requirement is meant to "prohibit[] new matter from entering into claim amendments." *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1379 (Fed. Cir. 2009).

Yet, the decision below all but guarantees that § 112 will no longer serve this key function. Even if not actually disclosed in the specification, a patentee under the Federal Circuit's new rule can secure patent claims in a continuation application directed to a competitor's later design-around by arguing that it disclosed a "substantial equivalent" in the written description. Particularly in the pharmaceutical field, where regulations require bioequivalence or biosimilarity and, thus, limit the extent to which a generic or biosimilar manufacturer can deviate from a patented drug, *see, e.g.*, 21 C.F.R. § 314.94(a)(7), the "substantial[] equivalent" standard grants the patentee ample opportunity to capture design-around efforts through continuation practice. *See* Actavis Pet. at 7–8, 29.

In fact, patent holders are already trying to use the decision below to extend their monopolies against generics. For example, in an ongoing inter partes review proceeding, the patent holder of a brand-name drug for opioid use disorder has argued that a claim in a continuation patent is entitled to the earlier priority date because the claim is the substantial equivalent to what was disclosed in the written description. *See* Patent Owner Response at 22, 32–33, *Dr. Reddy's Labs. v. Indivior UK Ltd.*, IPR 2019-00329 (P.T.A.B. Sept. 17, 2019) (citing *Nalpropion*); Patent Owner Sur-Reply at 15, *Dr. Reddy's Labs. v. Indivior UK Ltd.*, IPR 2019-00329 (P.T.A.B. Jan. 21, 2020) (same). The primary source of support for the patent holder's argument is the Federal Circuit's new standard in the decision below. *See generally* Patent Owner Response, *Dr. Reddy's Labs.*, IPR 2019-00329.

This problem is likely to grow over time. Studies have shown that the number of patents for each drug—including continuation patents—has increased continuously and significantly since the 1980s. *See* Lisa L. Ouellette, *How Many Patents Does It Take to Make a Drug – Follow-On Pharmaceutical Patents and University Licensing*, 17 Mich. Telecomm. & Tech. L. Rev. 299, 316, 320 (2010) (citing data showing a "statistically significant" increase). Moreover, the number of patents per drug is higher in absolute terms where pharmaceutical companies are "more concerned about generic competitors." *Id.* at 316. By 2018, for example, the twelve best-selling drugs in the United States had an average of seventy-one patents granted per drug. *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices*, I-MAK 2 (Aug. 2018), http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf. And since the law places no limit on the number of continuation applications that may be filed for a given medication, *see* Stephanie Plamondon Bair, *Adjustments, Extensions, Disclaimers, and Continuations*, 41 Cap. U.L. Rev. 445, 464 (2013), pharmaceutical companies will be encouraged by the Federal Circuit's new rule to ratchet up their continuation filings even further.

B. The Uncertainty Generated by the Rule Below About the Scope of Patent Rights Will be Particularly Harmful to Development of Generics and Biosimilars.

Perhaps the most invidious effect of the rule below is that it does not just weaken the written description

doctrine but muddies it. Prior to the Federal Circuit's decision, competitors had the tools to make investment decisions with a measure of predictability. They could look to the patent itself to determine the scope of its coverage. Now, the undefined concepts of "substantial equivalence" and "resultant parameter" will stymie industry efforts to determine which inventions courts will deem subject to a statutory monopoly.

The decision below provides no definition or test by which to determine whether a disclosure is a "substantial[] equivalent" or whether it applies to a "resultant parameter," even though those very concepts determined the outcome of the case. Pet. App. 11a, 14a. This lack of clarity will deprive generics manufacturers of a reliable way to assess brand-name drugs' patent coverage prior to making major investments. The consequences are increased unwarranted monopolies, higher drug prices, and reduced innovation.

Consider again the extended release medication at issue in this case. Before the Federal Circuit's new rule, the patentee would have been limited to claiming the dissolution profile (measured by the basket method) disclosed in the specification. *See* Pet. App. 30a. A generic competitor could design around this patent by, for instance, developing a drug exhibiting a superior dissolution profile as measured by the paddle method.

But now a generic competitor may well be dissuaded from investing resources for such an advance in patient treatment because of the risk that a court might conclude that a claim actually concerns a mere "resultant parameter" that reaches beyond what it says to encompass something "substantially equivalent." And

even if the competitor were to prevail under the Federal Circuit's rule, it would likely do so only after lengthy litigation over whether the claim falls within the exception created by this case. This litigation will take place while the generic company remains subject to a statutory stay of regulatory approval, *see, e.g.*, 21 U.S.C. § 355(j)(5)(B)(iii), and well after the company has gambled limited resources in hopes of a favorable outcome.

The competitor also faces uncertainty of the kind noted in the prior section: the competitor could invest in the advance only to find that the patentee claims the superior profile in a continuation patent. For a manufacturer attempting to develop a competing generic product, this undefined notion of "substantial equivalence" creates a degree of business uncertainty that is sure to affect a broad array of investment decisions.[4] *See Gen. Elec. Co*, 304 U.S. at 369 ("The limits

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[4] *See The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report*, Ass'n for Accessible Medicines 26 (2019), https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf ("[P]atent thickets chill competition by discouraging competitors from entering a market because of the exorbitant cost of litigating" when "brand-name drug companies attempt to . . . repackage existing inventions in later, secondary patents."); *see also* Masayuki Morikawa, *How Uncertainty Over Business Conditions Affects Investment Decisions*, World Econ. Forum (Apr. 15, 2016), https://www.weforum.org/agenda/2016/04/how-uncertainty-over-business-conditions-affects-investment-decisions ("Empirical studies generally support th[e] theoretical prediction

of a patent must be known for . . . the encouragement of the inventive genius of others.").

This uncertainty is potentially devastating for the generics and biosimilars industry, but the ultimate consequence will be to reduce public access to affordable medicines. Given generics' business model, manufacturers are likely to deem fewer medications worthy of production.[5] And the prices of those medications that do reach the market are likely to rise as a result of the increased litigation costs the Federal Circuit's amorphous standard will generate.[6] Public health ultimately will suffer as a result.[7] At a time when

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that uncertainty has a negative effect on . . . research and development (R&D) investment[.]").

[5] *See, e.g.*, *Ensuring the Future of Accessible Medicines in the U.S.* Ass'n for Accessible Medicines 8, https://accessiblemeds.org/sites/default/files/2018-02/AAM-Whitepaper-Ensuring-Future-of-Generic-Medicines.pdf (explaining that generics are "low-margin" products, and manufacturers "reevaluate product portfolios and discontinue certain medicines" in response to increased barriers to entry); *id.* at 15 ("market uncertainty forces generic manufacturers to reconsider production of lower-margin . . . medicines in order to ensure their continued corporate sustainability").

[6] *See Generic Medicines Save Money for Patients and Taxpayers*, Ass'n for Accessible Medicines 2, https://accessiblemeds.org/sites/default/files/2019-04/AAM-Generic-Medicines-State-Brief.pdf (recognizing that generic manufacturers "regularly adjust prices up and down to react to market conditions").

[7] *See, e.g.*, *Office of Generic Drugs: 2019 Annual Report*, U.S. Food & Drug. Admin iii (Feb. 2020), https://www.fda.gov/media/135329/download ("[G]eneric drugs play a vital role in the U.S. health care system. Affordable access to medicines is a public health priority,

access to affordable medicines is more important than ever, this case warrants Supreme Court intervention.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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and competition from generic drugs can help reduce prices and improve access[.]"); *Ensuring the Future of Accessible Medicines in the U.S.*, *supra* note 5, at 5 (explaining that the prescription abandonment rate for brand-name drugs is nearly three times as high as for generics, and non-adherence to proscribed medication is responsible for approximately 125,000 deaths and 10 percent of hospitalizations annually).