No.

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

PETITION FOR A WRIT OF CERTIORARI

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March 13, 2020

QUESTION PRESENTED

Under 35 U.S.C. § 112, a patent's specification must "contain a written description of the invention." That requirement, a cornerstone of federal patent law, ensures that an inventor can claim patent protection only for what she actually invented.

Consistent with this Court's longstanding directive that every element of a patent claim must be treated as material, the Federal Circuit has long held that *all* elements of a patent's claims must *actually* be disclosed in the patent's specification. But the Federal Circuit has now broken from that established rule. In the 2-1 decision below, the Federal Circuit announced for the first time that for some claim limitations, a "substantially equivalent" disclosure will do. Here, although the claims expressly require testing using one specific method identified by name, the court held that the written description's disclosure of a *different* testing method was good enough. The court grounded its change of heart not in statutory text or precedent, but in the court's view that "[r]igidity should yield to flexible, sensible interpretation."

The question presented is:

Whether § 112 requires a patent's specification to contain a written description of all of the limitations of a patent's claims, not just a "substantially equivalent" disclosure.

PARTIES TO THE PROCEEDING

Petitioner, defendant-appellant below, is Actavis Laboratories FL, Inc.

Respondent, plaintiff-appellee below, is Nalpropion Pharmaceuticals LLC.

This suit was originally filed in the district court by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals International GmbH, Takeda Pharmaceuticals USA, Inc., and Takeda Pharmaceuticals, America, Inc. (collectively, "Takeda") and Orexigen Therapeutics, Inc. ("Orexigen"). While the case was pending in district court, Orexigen acquired all of Takeda's patent rights pertaining to this suit, and the district court allowed Takeda to withdraw from the action. *See* D. Ct. Dkt. No. 92. During the appeal, Orexigen filed for bankruptcy under Chapter 11 of the Bankruptcy Code, and Nalpropion Pharmaceuticals, Inc., acquired all of Orexigen's patent rights pertaining to this suit. The Federal Circuit granted a motion to substitute Nalpropion Pharmaceuticals, Inc., for Orexigen. *See* C.A. Dkt. No. 32. Thus, Takeda and Orexigen are no longer parties to this action. *See* Pet. App. 3a n.1.

Nalpropion Pharmaceuticals, Inc., then converted to a limited liability company, and the court granted an unopposed motion to substitute respondent Nalpropion Pharmaceuticals LLC as plaintiff-appellee. *See* C.A. Dkt. No. 112.

CORPORATE DISCLOSURE STATEMENT

Actavis Laboratories FL, Inc., is a wholly owned subsidiary of Andrx LLC. Andrx LLC is a wholly owned subsidiary of Actavis Holdco US, Inc. Actavis Holdco US, Inc., is a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc. Teva Pharmaceuticals USA, Inc., is co-owned by Orvet UK Unlimited and Teva Pharmaceutical Holdings Coöperatieve U.A. (the latter of which, in turn, is owned by IVAX LLC, which is owned by Teva Pharmaceuticals USA, Inc.). Teva Pharmaceuticals USA, Inc., and Orvet UK Unlimited are wholly owned subsidiaries of Teva Pharmaceuticals Europe B.V. Teva Pharmaceuticals Europe B.V. is a wholly owned subsidiary of Teva Pharmaceuticals Industries Ltd., a publicly traded company.

Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Actavis Laboratories FL, Inc.

RELATED PROCEEDINGS

Orexigen Therapeutics, Inc. v. *Actavis Laboratories FL, Inc.*, D. Del. No. 15-cv-451 (Oct. 26, 2017).

Nalpropion Pharmaceuticals, Inc. v. *Actavis Laboratories FL, Inc.*, Fed. Cir. No. 18-1221 (Aug. 15, 2019).

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes:

Other Authorities:

Actavis Laboratories FL, Inc., respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-32a) is reported at 934 F.3d 1344. The district court's post-trial opinion (Pet. App. 33a-80a) is reported at 282 F. Supp. 3d 793.

JURISDICTION

The court of appeals entered judgment on August 15, 2019. A petition for rehearing was denied on December 16, 2019 (Pet. App. 81a-82a). This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

The pre-2012 text of 35 U.S.C. § 112, first paragraph, provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, 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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[1]

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[1] Section 112 was amended in ways not relevant here by the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, § 4(c), 125 Stat. 284, 296 (2011). The only changes to the first paragraph of § 112 were stylistic and non-substantive. *See Nautilus, Inc.* v. *Biosig Instruments, Inc.*, 572 U.S. 898, 902 n.1

INTRODUCTION

Under 35 U.S.C. § 112, a patent's specification must "contain a written description of the invention." That is a straightforward requirement that has long been read to mean what it says: the specification must disclose *the invention*, not some variant of it. That holds the patentee to the statutory bargain—it may obtain a patent only for the inventions it discloses to the public. But the divided Federal Circuit panel in this case, breaking with longstanding precedent, has adopted a new rule: now disclosing something "substantially equivalent" can suffice.

That new rule replaces a complete and workable test for assessing the sufficiency of a patent's written description with an amorphous inquiry grounded in neither statutory text nor applicable precedent. That sudden change will spell confusion and harm the public, by making it easier for patentees to improperly broaden their patents to claim more than they disclosed in their specifications. The result will be less competition, less disclosure, less access to needed technologies—and more windfalls for patentees.

(2014). In particular, the AIA gave the previously undesignated first paragraph a caption—"(a) IN GENERAL"—and replaced the words "contemplated by *the inventor* of carrying out *his* invention" with the words "contemplated by *the inventor or joint inventor* of carrying out *the* invention." AIA § 4(c)(1), 125 Stat. at 296 (emphases added). If there were any difference, the pre-AIA text would apply, because the application for the patent at issue in this case was filed before the effective date of the AIA. *See id.* § 4(e), 125 Stat. at 297 (35 U.S.C. § 111 note).

This case exemplifies those perverse consequences. All respondent's other patent claims have been invalidated as obvious. Respondent got this one final patent claim, and overcame the obviousness bar, only by claiming a chemical formulation with a *particular* "dissolution profile," measured using a "*specific* dissolution test." C.A. App. 7039 (emphasis added). Yet that test is mentioned nowhere in the patent's specification, which reports data obtained using *different* testing methods. Over Chief Judge Prost's dissent, the Federal Circuit upheld respondent's patent despite this divergence between the claim and the specification, based solely on its new rule that a "substantially equivalent" disclosure can satisfy § 112. And unless this Court reverses, respondent's brand-name drug will be insulated from generic competition until 2030.

Requiring a patent to contain sufficient written-description support ensures that a patent-holder cannot assert a broader monopoly than what "the inventor actually invented." *Ariad Pharm., Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). An adequate written description is also necessary "to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not." *Permutit Co.* v. *Graver Corp.*, 284 U.S. 52, 60 (1931).

Given these important functions, the Federal Circuit has long held that a patent's claims—the precise rights asserted by the patent-holder—must be *the same as* the invention disclosed in the patent's specification. In other words, the Federal Circuit has repeatedly rejected the notion that the "claimed inven-

tion" can merely be "an obvious variant of that which is disclosed in the specification." *Lockwood* v. *Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). And it has consistently held that "*all* the limitations" of the patent's claims "must appear in the specification." *Id.* (emphasis added).

Not anymore. Under the new rule, "substantially equivalent" disclosure can be good enough. "While as a general matter written description may not be satisfied by so-called equivalent disclosure," the majority held, it would abandon that rule for disclosures related to what it deemed non-"operative" claim steps. Pet. App. 13a-14a. For that subset of claim limitations, the majority explained, a "substantially equivalent" disclosure can now satisfy the written-description requirement. Pet. App. 13a-14a. As Chief Judge Prost explained in dissent, however, that holding "adds what appears . . . to be a new rule to this court's long-standing written description jurisprudence." Pet. App. 25a.

This Court should review and reverse that holding. The Court has previously admonished the Federal Circuit to "be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). Yet here the Federal Circuit renounced years of established precedent. And it did so largely without analysis. The majority's conclusion rested not on the text of § 112 or relevant judicial decisions, but on a single line of *ipse dixit*: "Rigidity should yield to flexible, sensible interpretation." Pet. App. 14a. An unadorned maxim is no basis to discard a well-worn legal rule.

This case is an excellent vehicle for the Court's review. Only a single patent claim is at issue. It claims a method that concededly is not disclosed in the specification. The Federal Circuit's new rule therefore is outcome-determinative: without it, Actavis could bring its generic to market forthwith, instead of being blocked for another full decade.

The Court should grant certiorari.

STATEMENT

A. The Written-Description Requirement.

1. The rule that an inventor must furnish a written description of a claimed invention is one of the oldest in American patent law—indeed, it has existed practically since the Founding. The first Patent Act required a recipient of a patent, at the time his patent was granted, to "deliver to the Secretary of State a specification in writing, containing a description . . . of the thing or things . . . invented or discovered." Act of Apr. 10, 1790, ch. 7, § 2, 1 Stat. 109, 110. Such a "specification shall be so particular," the Act instructed, as to "distinguish the invention or discovery from other things before known and used." *Id.*

Three years later, the Patent Act of 1793 refined and reaffirmed the written-description requirement. In language remarkably similar to the present-day § 112, that Act provided:

> That every inventor, before he can receive a patent, . . . shall deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms, as to distinguish the

> same from all other things before known, and to enable any person skilled in the art or science, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same.

Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321. The same requirement appeared in successive Patent Acts and, in 1952, was codified in Section 112. Act of July 19, 1952, ch. 950, § 1, 66 Stat. 792, 798.

2. The written-description requirement fulfills at least two important functions. First, and most critically, it ensures that an inventor does not claim patent protection for something broader than what he or she has invented by the time of filing the patent application. And second, the description effectuates the patent bargain: what the inventor claims, and secures a monopoly over, he or she must describe.

a. This Court articulated the rule that an inventor may not claim more than he has invented as early as *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62 (1853), in which the Court considered the eight claims in Samuel Morse's patent for the invention of the telegraph. The first seven claims of that patent recited specific aspects of Morse's invention. But the eighth claim purported to cover *every* means of electronically transmitting letters or symbols over a distance—as Morse candidly wrote, "I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims." *Id.* at 112. Citing the written-description requirement, *id.* at 118, the Court found that portion of the patent invalid because Morse "claim[ed] an exclusive right to use a manner and process *which he*

has not described and indeed had not invented, and therefore *could not describe* when he obtained his patent." *Id.* at 113 (emphasis added); *see also id.* at 119-120 ("[T]his claim can derive no aid from the specification filed. It is outside of it, and the patentee claims beyond it.").

By making an inventor "recount his invention in [sufficient] detail," therefore, the written-description requirement "guards against the inventor's overreaching." *Vas-Cath Inc.* v. *Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991) (quoting *Rengo Co.* v. *Molins Mach. Co.*, 657 F.2d 535, 551 (3d Cir. 1981)). And because applicants can amend their claims after filing the written description, the requirement ensures that the only "future claims" the inventor will press in that chain of patent applications are those "encompassed within his original creation." *Id.* (quoting *Rengo*, 657 F.2d at 551).

That function is particularly important when it comes to questions of patent priority. An applicant for a patent can often file a "continuation" application, seeking to get more claims than the applicant initially sought. The applicant may be able to maintain the benefit of the earlier filing date for the original application—which removes from the scope of "prior art" anything that postdates the original application—but only if the newly claimed invention was "disclosed in the manner provided by the first paragraph of section 112" in the original application. 35 U.S.C. § 120 (2006); *accord* 35 U.S.C. § 120 (same, updating the cross-reference to read "section 112(a)"). The written-description requirement thus provides a necessary check: It "prohibits *new* matter from entering into claim amendments, particularly

during the continuation process." *Agilent Techs., Inc.* v. *Affymetrix, Inc.*, 567 F.3d 1366, 1379 (Fed. Cir. 2009) (emphasis added).

b. The written-description requirement also serves an important teaching and public-notice function. It consummates the "*quid pro quo*" of the patent grant—"in exchange for being excluded from practicing an invention for a period of time," the public ultimately "receives a meaningful disclosure" of that invention. *Ariad*, 598 F.3d at 1354. And the *quid* and the *quo* must match up: "[w]hat is claimed by the patent application must be the same as what is disclosed in the specification." *Festo*, 535 U.S. at 736. That also allows "other inventors [to] know what part of the field of invention is unoccupied." *Gill* v. *Wells*, 89 U.S. (22 Wall.) 1, 25-26 (1874).

Given these important functions, a patent that issues without an adequate written description is invalid. *See* 35 U.S.C. § 282(b)(3)(A).

B. Contrave And The '195 Patent.

1. Nalpropion markets Contrave, an extended-release tablet containing a combination of two drugs—naltrexone and bupropion.[2] Contrave is FDA-approved for chronic weight management in adults who are obese or overweight and who suffer from weight-related disorders such as type 2 diabetes

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[2] Contrave was developed and originally marketed, and this lawsuit was initiated, by Nalpropion's predecessors-in-interest. *See* Pet. App. 3a n.1; p. ii, *supra*. For ease of reference, this petition refers to the patent owner and marketer of Contrave as "Nalpropion."

or hypertension. Pet. App. 34a. Contrave has been on the market since 2014, and no generic alternative is yet available. A year of Contrave costs more than $1100.

Nalpropion did not invent naltrexone or bupropion, or discover their weight-loss effects. Rather, bupropion was known to produce weight loss as early as 1995, Pet. App. 35a, and naltrexone's weight-loss effects have been documented at least since 1985, when a study observed that "naltrexone or similar drugs may have a role in the clinical treatment of obesity," Pet. App. 19a (quoting C.A. App. 8950); *see* Pet. App. 15a n.4. Nor did Nalpropion invent the combined use of naltrexone and bupropion: at least as early as 2003, publicly available sources "[taught] a combination of effective amounts of sustained-release bupropion and naltrexone for minimizing weight gain." Pet. App. 20a; *see* Pet. App. 55a.

2. Nalpropion secured three patents purporting to cover Contrave. This petition focuses on the third one to issue—the last one remaining after the relevant claims of the first two patents were declared invalid.

a. The first two patents issued in 2008. U.S. Patent No. 7,375,111 (the '111 patent) claims a formulation combining bupropion and naltrexone in a single, sustained-release oral dose. Pet. App. 5a-6a. U.S. Patent No. 7,462,626 (the '626 patent) claims a method of treating overweight or obesity by administering bupropion and naltrexone. Pet. App. 3a-4a. Those patents would both have expired by 2025 even if not invalidated.

b. The patent at issue here extends Nalpropion's patent monopoly to 2030. That patent, U.S. Patent No. 8,916,195 (the '195 patent), issued in 2014. Like the '626 patent, the '195 patent claims a method of treating overweight or obesity using a formulation containing bupropion and naltrexone. Pet. App. 3a-4a. But it contains a limitation that the other two patents do not: the specific "dissolution profile" of the naltrexone in the formulation. Pet. App. 4a-5a. A "dissolution profile" measures how quickly a drug dissolves in water (or another liquid). *See, e.g.*, C.A. App. 11347. That information is important because a drug's dissolution profile under lab conditions (or "in vitro") can serve as a predictor of how the drug will be absorbed by a person's body (or "in vivo"). *See, e.g.*, FDA, Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral Dosage Forms 2 (Aug. 1997), *available at* https://www.fda.gov/media/70936/download. In other words, a drug's dissolution profile—not just its chemical composition—may be an important element of the drug's formulation.

The claim asserted here is claim 11 of the '195 patent, which calls for the twice-daily administration of approximately 16 mg of naltrexone and 180 mg of bupropion in a sustained-release formulation. Pet. App. 99a-100a; *see* Pet. App. 4a-5a. More specifically, the language of claim 11 calls for the naltrexone to be administered as a sustained-release formulation that achieves:

> an in vitro naltrexone dissolution profile in a dissolution test of USP Apparatus 2 Paddle Method at 100 rpm in a dissolution medium of water at 37° C. of:

> a) between 39% and 70% of naltrexone released in one hour,
>
> b) between 62% and 90% of naltrexone released in two hours; and
>
> c) at least 99% in 8 hours . . . .

Pet. App. 99a-100a.[3]

As this language makes clear, claim 11 requires naltrexone's dissolution profile to be measured using a specific test—the "USP Apparatus 2 Paddle Method" (or "USP 2"). Pet. App. 99a-100a. Under USP 2, a tablet is placed in a container of water and a paddle is used to move the water over the surface of the tablet, releasing the active ingredient while the tablet remains on the bottom of the container. C.A. App. 11315, 11349-11350.

USP 2 contrasts with the "USP Apparatus 1 Basket Method" (or "USP 1"), in which a tablet is placed in a basket suspended in the water in the middle of the container; the basket rotates in the water, releasing the drug from the tablet. *Id.* Put simply, USP 2 moves the water around the tablet, while USP 1 moves the tablet through the water.[4]

These two dissolution tests produce different results in practice because of the different flow dynamics involved in the two apparatuses. That is, each

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[3] The full text of the '195 patent's claims, including claim 11, is reproduced at Pet. App. 97a-101a.

[4] A side-by-side visual comparison of the two USP methods is available on YouTube at http://youtu.be/tHqPkAYp17E (last visited March 12, 2020).

method will result in a different dissolution profile for the same tablet. C.A. App. 11319-11321; *see also* C.A. App. 11356-11358. In fact, the named inventor of the '195 patent testified that the two tests are not "comparable," and that when he tested the naltrexone-bupropion tablet from claim 11 he obtained different results for the in vitro dissolution of naltrexone depending on which method he used. C.A. App. 11312, 11319-11321.

While claim 11 of the '195 patent unambiguously requires a naltrexone dissolution profile measured using USP 2, the '195 patent's specification does not disclose a naltrexone-bupropion formulation that matches claim 11 and is measured using USP 2. As relevant here, two examples in the specification—Examples 2 and 3—report dissolution testing data at specified time points. Pet. App. 92a-97a; *see also* Pet. App. 9a-10a. But Example 2 unambiguously provides dissolution data obtained using USP 1: the specification itself makes clear that the testing in that example was "completed using a 10-mesh basket[]." Pet. App. 92a; *see* Pet. App. 9a; *see also* C.A. App. 11322 (testimony of the named inventor of the '195 patent conceding the point). Example 3, for its part, is silent as to whether the relevant data were obtained using USP 1 or USP 2. Pet. App. 95a-97a; *see* Pet. App. 9a.

Other portions of the '195 patent's specification briefly discuss dissolution tests that differ from USP 2 as set forth in claim 11—but those passages do not alter claim 11. The "Definitions" section of the patent, for example, defines the term "release rate" and provides that "[a]n in vitro release rate is determined by a 'standard dissolution test[,]' conducted according

to [USP 2] at a spindle rotation speed of 100 rpm and a dissolution medium of water, at 37° C., or other test conditions substantially equivalent thereto." Pet. App. 87a. The "Formulations" section, meanwhile, provides that "[i]n vitro release rate is determined by a standard dissolution test as described above." Pet. App. 89a. Notably, however, the defined term "release rate" appears nowhere in claim 11. Pet. App. 99a-100a.

3. The requirement that the claimed naltrexone-bupropion formulation have a dissolution profile as specifically measured using USP 2 was critical to the issuance of the '195 patent. *See* Pet. App. 27a-28a (Prost, C.J., dissenting). Under federal patent law, the PTO must reject a patent application if the "prior art"—*i.e.*, the publicly available teachings in the relevant subject area—discloses the claimed invention or makes it "obvious" to "a person having ordinary skill in the art." 35 U.S.C. §§ 102, 103. Here, the patent examiner repeatedly rejected the application for the '195 patent in light of a naltrexone-bupropion formulation disclosed in a prior, publicly available patent application by Weber et al. *See* C.A. Supp. App. 3751, 3755-3757, 3784-3793, 3835, 3838-3847, 3875-3886.

To remedy this problem, the examiner suggested that the applicants "define the formulation and/or patient population in order to distinguish the claimed method from the teachings of Weber et al." C.A. Supp. App. 3897. The applicants, in response, proposed a new claim that was identical to the later-issued claim 11 except that it recited a "standard dissolution test" rather than USP 2. C.A. App. 3976-3977 (claim 79). The claim was again rejected. *See*

C.A. Supp. App. 6987, 6994-6998. The applicants then amended the claim to require that the dissolution profile be measured using USP 2, arguing that adding "the specific dissolution test conditions" overcame Weber. C.A. App. 7039; *see* C.A. App. 7034-7035 (claim 79).

This time the examiner allowed the claim, expressly referring to the addition of USP 2 as a reason for allowance. "Weber et al.'s teachings," the examiner concluded, "do not direct one to obtain [the] claimed method with . . . a sustained-release formulation of naltrexone . . . *having an in vitro naltrexone dissolution profile in a standard dissolution test of USP Apparatus 2 Paddle Method* at 100 rpm in a dissolution medium of water at 37° C [with the ranges] claimed in the instant application." C.A. Supp. App. 7094-7095 (emphasis added) (underscoring omitted).

C. This Litigation.

1. Actavis seeks to market a generic version of Contrave. Because Actavis's product and Contrave have the "same active ingredients" and are "biologically equivalent," the Hatch-Waxman Act permits Actavis to seek FDA approval for its product through an expedited process known as an Abbreviated New Drug Application (ANDA). *FTC* v. *Actavis, Inc.*, 570 U.S. 136, 142 (2013); *see* 21 U.S.C. § 355(j). As part of the ANDA process, "the Hatch-Waxman Act sets forth special procedures for identifying, and resolving, related patent disputes" between the generic and brand-name manufacturers. *Actavis*, 570 U.S. at 143. Here, Actavis filed a "paragraph IV certification" with its ANDA, certifying that any patents cov-

ering Contrave "are invalid or will not be infringed by the manufacture, use, or sale of" Actavis's generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Filing that application is treated as an artificial act of infringement, 35 U.S.C. § 271(e)(2)(A), and Nalpropion brought suit alleging that Actavis's generic product would infringe the '195, '111, and '626 patents once approved and marketed.

In response, Actavis argued these three patents were invalid. With respect to the '195 patent, Actavis explained that claim 11 lacked adequate written-description support. With respect to the '111 and '626 patents, meanwhile, Actavis explained that it would have been obvious to a person of ordinary skill in the art to combine bupropion and naltrexone and to use them as a weight-loss treatment.

2. After a bench trial, the district court held that the patents-in-suit were not invalid and would be infringed by Actavis's product. *See* Pet. App. 80a.

The district court first rejected Actavis's written-description argument. The court focused primarily on Example 3 of the '195 patent, which describes a particular naltrexone-bupropion combination, and the accompanying Table 10, which sets forth the dissolution data for that combination. Pet. App. 43a-44a; *see* Pet. App. 95a-97a. According to the district court, the values in Table 10—*i.e.*, 67% of naltrexone released after one hour, 85% after two hours, and 99% after eight hours—"fall squarely within the ranges in claim 11." Pet. App. 43a. And that was true, the district court reasoned, even though the specification was silent as to whether the data were obtained using USP 1 or USP 2: in the district court's

view, "a person of ordinary skill would understand that the inventors had possession of the claimed invention *regardless of whether the USP Apparatus 2 method or a 'substantially equivalent' method* were used." Pet. App. 44a (emphasis added). "Therefore," the district court concluded, "whether the dissolution data reported in the specification was obtained using the basket method [USP 1] or the paddle method [USP 2] is not relevant to whether the inventors had possession of the invention." Pet. App. 45a.

The district court also rejected Actavis's obviousness arguments with respect to the '111 and '626 patents. *See* Pet. App. 63a.

3. A partially divided panel of the Federal Circuit affirmed in part and reversed in part. The panel unanimously held the relevant claims of the '111 and '626 patents obvious over the prior art. Pet. App. 14a-24a. But by a 2-1 vote, the panel held that claim 11 of the '195 patent survived. And because that is the last-expiring patent, that means Contrave is protected from generic competition until 2030.

The majority concluded that the '195 patent's specification provided adequate written-description support for claim 11. Beginning with the claim language, the majority observed that claim 11 "requires that the claimed naltrexone formulation have an in vitro dissolution profile in a dissolution test of USP Apparatus 2 Paddle Method." Pet. App. 9a. Turning to the specification, the majority acknowledged that Example 2 reported data obtained using "10-mesh baskets" (*i.e.*, USP 1), while Example 3 and the accompanying Table 10 were "silent as to whether the data were obtained using USP 1 or USP 2." Pet.

App. 9a. Nevertheless, the majority held that the specification's failure to disclose this element of claim 11 was irrelevant in light of the district court's finding that USP 1 and USP 2 were "substantially equivalent" methods for testing dissolution profile. Pet. App. 11a.

In reaching that conclusion, the majority observed that claim 11's requirement that the dissolution profile be measured by USP 2 "relates only to the measurement of resultant in vitro parameters, not to the operative steps to treat overweight or obesity." Pet. App. 11a. "While as a general matter written description may not be satisfied by so-called equivalent disclosure," the majority held, it would make an exception here: the relevant limitation did not concern what the majority called "operative claim steps," but "relate[d] only to resultant dissolution parameters." Pet. App. 13a-14a. According to the majority, such an exception to the ordinary rule against equivalent disclosure was warranted because "[r]igidity should yield to flexible, sensible interpretation." Pet. App. 14a.

Chief Judge Prost dissented from this portion of the judgment, stating that she would have found claim 11 invalid for lack of adequate written description. As she explained, the majority had created "a new rule" by holding "that a 'substantially equivalent' disclosure may satisfy the written description requirement when the relevant claim limitation recites only 'resultant dissolution parameters rather than operative claim steps.'" Pet. App. 25a. That "'substantially equivalent' rule," Chief Judge Prost observed, "is inconsistent with [the Federal Circuit's] precedent." Pet. App. 26a. In particular, the Federal

Circuit's en banc decision in *Ariad* and its decision in *Lockwood* make clear that "[a] substantially equivalent disclosure, even if it would render the claim limitation obvious, cannot satisfy the written description requirement." Pet. App. 30a. Yet the majority's "substantially equivalent" rule permits exactly that. Pet. App. 30a.[5]

4. The Federal Circuit denied Actavis's petition for rehearing. Pet. App. 81a-82a.

REASONS FOR GRANTING THE WRIT

Before the Federal Circuit's decision in this case, the written-description requirement of § 112 was clear. Under longstanding Federal Circuit precedent, "*all* [of a claim's] limitations" needed to "appear in the specification." *Lockwood* v. *Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (emphasis added). Just disclosing enough to "merely render[] the invention obvious," in other words, was not enough to "satisfy the requirement." *Ariad Pharm., Inc.* v.

[5] Chief Judge Prost's dissent also interpreted the majority opinion as implicitly holding that the USP 2 element of claim 11 is non-limiting, *i.e.*, does not form part of the metes and bounds of the claim. *See* Pet. App. 26a-27a. But the district court and the parties uniformly agreed that this element *is* limiting—and Nalpropion acknowledged as much in opposing rehearing en banc. *See* Nalpropion Resp. to Pet. for Reh'g 3 ("[T]he parties and Court agree that the USP 2 clause limits the claims."); *see also id.* at 16 ("[T]he parties, District Court, and [Federal Circuit] majority agree that the USP term limits the claims."). In short, while the Federal Circuit majority said that the USP 2 element of claim 11 was non-"*operative*," there is no basis to conclude that it made a separate, silent, *sua sponte* determination that the element is non-*limiting*, too. *See* Pet. App. 14a.

Eli Lilly & Co., 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc). As this Court summarized the rule, "[w]hat is claimed by the patent application must be *the same as* what is disclosed in the specification." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (emphasis added).

Now, however, there are two competing rules, depending on whether a claim limitation is deemed to be an "operative step" or something else. For "operative" steps, the old rule still applies, and the specification must disclose what is *actually claimed*. But for non-"operative" steps, the new rule announced below controls, and the specification need only show that the inventor possessed something "substantially equivalent" to the claimed invention.

That dual-track approach is incorrect. It is inconsistent with the statutory text and this Court's precedent—indeed, the Federal Circuit fashioned it from whole cloth. And its consequences are grave. One need look no further than this case to see its pernicious effects: Nalpropion is insulated from generic competition for another full decade based on a single patent claim that extends beyond the scope of its actual innovation. The rule will also spell confusion as the PTO and the courts struggle to sort operative from non-operative claim limitations and to determine when a disclosure is close enough to count as "substantially equivalent."

This case is an ideal vehicle to forestall these problems. It presents a clean opportunity to address the validity of the Federal Circuit's new rule, which was outcome-determinative below. The Court should grant certiorari to confirm that there is only one

written-description test—the one that the statutory text compels and that courts have applied for years.

A. The Federal Circuit's New Rule Breaks From The Long-Accepted Approach To § 112.

1. The Federal Circuit has long read § 112 to require a patent's specification to disclose all of a claim's limitations—and to do so with precision.

In *Lockwood*, for example, a patent-holder contended that although the specification in its patent application failed to describe the claimed invention, that invention "would have been apparent to one skilled in the art"—*i.e.*, would have been obvious—based on what *was* disclosed. 107 F.3d at 1572. The Federal Circuit rejected that argument. As the court explained, "[t]he question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification," but whether the specification "describe[s] [the] invention, and do[es] so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented *the claimed invention*." *Id.* (emphasis added).

Similarly, in *Lucent Techs., Inc.* v. *Gateway, Inc.*, 543 F.3d 710 (Fed. Cir. 2008), the Federal Circuit held that a patent lacked adequate written-description support because the claimed invention—a method of compressing digital audio files—required the use of particular type of data known as "modified discrete cosine transform coefficients" (MDCTs), while the specification did not mention MDCTs. *Id.* at 714, 719. As the Federal Circuit emphasized, "[e]ven if the implementation of MDCTs into the claimed technology would have been obvious to one

of skill in the art, . . . a demonstration of obviousness is not sufficient to show possession." *Id.* at 719.

The Federal Circuit reached the same conclusion in *ICU Medical, Inc.* v. *Alaris Medical Systems, Inc.*, 558 F.3d 1368 (Fed. Cir. 2009). There, the court considered a patent for valves in intravenous medical equipment. *Id.* at 1372. The patent's claims recited valves both with and without "spikes," but nothing in the specification indicated that the inventor possessed a valve without a spike. *See id.* at 1372, 1377-1378. The Federal Circuit held that the "spikeless claims" lacked adequate written-description support, rejecting the patentee's argument that it was "enough that it would have been obvious to a person of ordinary skill that a [valve] could be used without a spike." *Id.* at 1379.

Meanwhile, in *Vas-Cath Inc.* v. *Mahurkar*, 935 F.3d 1555 (Fed. Cir. 1991), the Federal Circuit stated that a specification that does not *describe* the claimed invention does not satisfy the written-description requirement even if the specification would *enable* a skilled artisan to practice the claimed invention. *Id.* at 1561-1562. As the court explained, when a specification discusses "*only* compound A," it does not describe an invention of compounds B and C, even if the specification might "enable one skilled in the art to make and use compounds B and C." *Id.*

These decisions are hardly outliers. Time and again the Federal Circuit has reaffirmed the principle that all of a claim's limitations—and not merely obvious variants of those limitations—must be disclosed in a patent's specification. *See also, e.g.*, *D Three Enters., LLC* v. *SunModo Corp.*, 890 F.3d

1042, 1052 (Fed. Cir. 2018) ("[A]dequate written description does not ask what is permissible, rather, it asks what is disclosed."); *PowerOasis, Inc.* v. *T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) ("The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification." (citation omitted)); *Regents of the Univ. of Cal.* v. *Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997) ("[A]n applicant complies with the written description requirement by describing the invention, with all its claimed limitations, not that which makes it obvious . . . ." (citation omitted)).

Unsurprisingly, the same view is reflected in the PTO's own guidelines for patent examiners. In setting forth the "methodology for determining adequacy of written description," the PTO instructs its examiners to "review the entire application to understand how [the] applicant provides support for the claimed invention including *each element and/or step*." Manual of Patent Examining Procedure § 2163(II)(A)(2) (emphasis added; capitalization omitted). As those guidelines emphasize, "[t]he claim as a whole, including *all limitations* found it the preamble, the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement." *Id.* § 2163(II)(A)(1) (emphasis added; citation omitted).

2. The decision below creates a new rule that hopelessly muddies what previously was clear and cannot be reconciled with the court of appeals' previous decisions.

Under the majority's rationale, a patent satisfies § 112 so long as its specification discloses a "substan-

tially equivalent" invention to the one recited in the claims. Pet. App. 13a-14a; *see* pp. 16-17, *supra*. That rule is impossible to square with the court's prior invalidation of claims directed to "obvious variants" of the disclosed invention. *See Lockwood*, 107 F.3d at 1572; *Lucent*, 543 F.3d at 719; *ICU Medical*, 558 F.3d at 1379; *D Three*, 890 F.3d at 1052; *PowerOasis*, 522 F.3d at 1306; *Regents*, 119 F.3d at 1566. Indeed, the decision below effectively acknowledged the inconsistency with prior Federal Circuit precedent: the panel conceded that "as a general matter written description may not be satisfied by so-called equivalent disclosure." Pet. App. 13a-14a.

To be sure, the Federal Circuit has previously recognized that a patent's specification need not use identical *wording* to the claim. *See, e.g.*, *Lockwood*, 107 F.3d at 1572 ("[T]he exact terms need not be used *in haec verba* . . . ."). But the difference the panel overlooked here was not one of language alone—the '195 patent's specification disclosed an entirely different method of measuring dissolution rates from that which was claimed, and the unrebutted evidence was that the different methods produced different results. *See* pp. 11-12, *supra*. In short, by accepting a disclosure that was "substantially equivalent"—*i.e.*, different but close enough—the Federal Circuit departed from years of consistent decisions to the contrary.

B. The Federal Circuit's New Two-Track Approach Is Incorrect.

Seeking to explain its newly created exception, the majority stressed the fact that the USP 2 element of claim 11 does not relate to an "operative

claim step[]." Pet. App. 14a. But it cited nothing for the proposition that a different written-description rule can apply where the undisclosed claim limitation is deemed less important than the "operative" steps of a method claim. Nor could it have done so: the statutory text and this Court's clear precedent both foreclose such a rule. Instead, the majority focused solely on a single policy interest—"flexib[ility]." Pet. App. 14a. But even if it were appropriate to turn to policy here, the policy underlying § 112 cuts *against* the majority's new, two-track approach to written description.

1. Begin with the statutory text. The first paragraph of § 112 provides that a patent's "specification shall contain a written description of *the invention*." 35 U.S.C. § 112 (emphasis added). The second paragraph then spells out exactly what is meant by "the invention." According to that paragraph: "The [patent's] specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant *regards as his invention*." *Id.* (emphasis added).[6] Thus, "the invention" for purposes of the written-description requirement is the "subject matter" that is set forth in detail in the patent's claims.

A rule that applies the written-description requirement more "flexibly" to some subset of seemingly less important claim limitations is inconsistent with that statutory text. For one thing, the second

[6] The post-AIA language of the second paragraph of § 112—now designated § 112(b)—is materially identical. *See* 35 U.S.C. § 112(b); *see also* n.1, *supra*.

paragraph of § 112 defines the invention as that which is "*particularly* point[ed] out" and "*distinctly* claim[ed]" in the patent's claims. *Id.* (emphasis added). Yet the Federal Circuit's rule allows the specification to provide a written description of something less than all of the invention's particular and distinct aspects. More generally, the first and second paragraphs of § 112 set forth a *single* definition of "the" invention, subject to a *single* written-description requirement. Only by "reading words or elements into [the] statute"—a practice courts "ordinarily resist"—is the Federal Circuit's two-tiered approach possible. *Dean* v. *United States*, 556 U.S. 568, 572 (2009) (citation omitted).

2. The Federal Circuit's new, bifurcated approach to written description is contrary not only to the statutory text, but also to how this Court has read and applied it. This Court has always treated *every* claim limitation as mattering equally. The Court has explained, for example, that "a patent is[] the conferral of rights in a particular claimed set of elements," such that "*[e]ach element* contained in a patent claim is . . . material to defining the scope of the patented invention." *Limelight Networks, Inc.* v. *Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014) (emphasis added) (quotation marks omitted) (quoting *Warner-Jenkinson*, *Inc.* v. *Hilton Davis Chem. Co.,* 520 U.S. 17, 29 (1997)). "[I]f [a patentee] claims a combination of certain elements or parts, we cannot declare that any one of these elements is material. The patentee has made them all material by the restricted form of his claim." *Water-Meter Co.* v. *Desper*, 101 U.S. 332, 337 (1880). In other words, the Court has

already rejected the notion that some claim steps are less important than others.

The Federal Circuit has rejected that premise, too. In addition to the body of written-description case law already discussed above (pp. 20-23, *supra*), the Federal Circuit and its predecessor have recognized in other contexts as well that "[c]laim limitations defining the subject matter of an invention are *never* disregarded." *In re Sabatino*, 480 F.2d 911, 913 (C.C.P.A. 1973); *see also, e.g.*, *Exxon Chem. Patents, Inc.* v. *Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995) ("We must give meaning to all the words in Exxon's claims."). Thus, for example, in innumerable cases, the Federal Circuit has reaffirmed that for a single prior-art reference to invalidate a patent under 35 U.S.C. § 102, it must contain "each and every limitation" claimed in the patent. *E.g.*, *Nidec Motor Corp.* v. *Zhongshan Broad Ocean Motor Co.*, 851 F.3d 1270, 1273 (Fed. Cir. 2017) (citation omitted). Put simply, these is no basis for distinguishing between a set of major—or "operative"—claim steps entitled to enhanced protection and a set of minor claim steps entitled to lesser protection.

And if there were some set of minor claim steps, there is nothing minor about the USP 2 limitation at issue here, which was essential to the issuance of the patent. As this Court has emphasized, all limitations are material, but "especially such as were introduced into an application after it had been persistently rejected." *Hubbell* v. *United States*, 179 U.S. 77, 83-84 (1900). There is no way to read "the invention" to exclude a limitation whose addition allowed the patent to issue.

3. In the end, the Federal Circuit did not even try to reconcile its test with the language of § 112, with this Court's precedent, or even with its own. Instead, it offered a single, citationless aphorism: "Rigidity should yield to flexible, sensible interpretation." Pet. App. 14a. But even if naked policy were a sufficient basis to rewrite § 112, the Federal Circuit's purported "flexib[ility]" in fact makes a hash of the written-description test's policy aims.

As described above, the written-description test serves two important functions. First, it polices the scope of the patent-holder's power to exclude, ensuring "that the inventor invented the claimed invention." *Lockwood*, 107 F.3d at 1572; *see* pp. 6-8, *supra*. And second, it provides public notice—informing others of the scope of the patent-holder's monopoly and teaching the invention to the public in exchange for that limited monopoly. *See* p. 8, *supra*. The Federal Circuit's "flexible" test (read: a test that leaves others guessing how it will be applied in any given case) only undercuts those aims. The Federal Circuit entirely failed to consider these objectives of the written-description requirement, or to explain how they align with its new rule.

C. The Question Presented Is Important, And This Case Is An Ideal Vehicle To Resolve It.

1. The question presented warrants this Court's attention. Section 112's written-description requirement—and in particular its demand that patent applicants disclose *all* claim limitations—is a bedrock principle of federal patent law. The Federal Circuit's contrary decision risks significant harm to

both the inventing community and the general public.

a. First, the Federal Circuit's new rule is incoherent. The majority premised its new rule on a desire to avoid "[r]igidity" and a preference for a "flexible, sensible interpretation." Pet. App. 14a. But the majority replaced a clear, readily applied rule—if a claim term is limiting, it requires written-description support in the specification—with an essentially ad hoc distinction. Now, limitations that are deemed important must be in the written description, while limitations that are deemed less important need only have a "substantially equivalent" disclosure.

That amorphous rule makes written-description disputes far more complex and less predictable. Under the decision below, if a patent's claims reach something similar to—but substantively different from—what is disclosed in the specification, a court must make the further judgment as to whether the undisclosed claim limitation is important enough to require actual disclosure (the only rule to date) or just "substantially equivalent" disclosure (the new rule announced below).

The Federal Circuit's decision provided no guidance about how to make that determination—*i.e.*, how to decide whether a claim limitation is minor or non-"operative"—nor did it explain how to assess whether a disclosure is "substantially equivalent." Thus, applying the decision below will require the development not just of *one* new doctrine, but *multiple* new doctrines—doubling the uncertainty the decision has created by cutting loose from the statutory

text and setting sail with only "flexibility" to navigate by.

b. Second, even if the rule were clear, it would still be flawed, because it allows patentees to broaden their claims beyond what they possessed at the time of filing. A patent's priority date is important because it establishes what constitutes the "prior art" against which an invention's novelty is judged. The patent may not issue until years after filing. And during that time, intervening teachings in the relevant subject area are not considered when determining whether the application's claims are obvious—but only so long as the claims are supported by the written description of the original patent. 35 U.S.C. § 120.[7]

Until now, "[t]he written description doctrine [has] prohibit[ed] new matter from entering into claim amendments, particularly during the continuation process," *Agilent Techs., Inc.* v. *Affymetrix, Inc.*, 567 F.3d 1366, 1379 (Fed. Cir. 2009), ensuring that applicants do not smuggle previously undisclosed new claims into a patent application while simultaneously maintaining the benefit of an original filing date. But if merely "substantially equivalent" disclosures can support new claims not disclosed in the specification, applicants can expand their claims beyond their invention "and date [the new matter] back

[7] The practice of seeking new claims that supposedly reach back years to the original patent application is particularly prevalent in the pharmaceutical and biotechnology fields. *See* pp. 6-8, *supra*; Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. Rev. 63, 69 (2004).

to their original filing date, thus defeating an accurate accounting of the priority of invention." *Chiron Corp.* v. *Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004). Put simply, the majority's new written-description standard encourages precisely what the written-description requirement is intended to prevent.

c. The dispute surrounding the '195 patent is a case-in-point illustrating the problems that the Federal Circuit's new rule will create. The weight-loss effects of naltrexone and bupropion had been known for years by the time Nalpropion applied for the '195 patent—Nalpropion did not discover them. *See* p. 9, *supra*. Nor was Nalpropion the first to combine naltrexone and bupropion to manage weight gain; that combined use, too, had been publicly taught well before Nalpropion submitted its patent application. *See* p. 9, *supra*. Indeed, the Federal Circuit declared both the '111 patent, which covers the combination of naltrexone and bupropion, and the '626 patent, which covers their use to treat overweight or obesity, invalid because they are obvious over the prior art. *See* p. 16, *supra*.

Instead, Nalpropion secured the '195 patent by persuading the PTO that its claims were novel because they covered a chemical formulation with a *particular* dissolution profile measured (as Nalpropion put it) using a "*specific* dissolution test"—USP 2. C.A. App. 7039 (emphasis added). Yet that test is nowhere to be found in the patent's specification: the only identifiable test in the specification is USP 1. *See* p. 12, *supra*. In other words, there is nothing in the patent to show that Nalpropion actually had possession of the claimed invention as of the filing date.

Based on that single patent claim, the Federal Circuit's new "substantially equivalent" rule allows Nalpropion to foreclose generic competition to Contrave for another decade—until 2030—even though the composition and its use have already been known for years. Without this Court's intervention, that story will play itself out over and over again, reducing the public's access to cost-effective treatments in the pharmaceutical space and needed technologies more generally.

2. This case is an ideal vehicle to resolve the question presented. The Federal Circuit's determination that claim 11 of the '195 patent is not invalid rested *solely* on its conclusion that a "substantially equivalent" disclosure is enough to satisfy § 112. Without an exception for "substantially equivalent" disclosures, that is, Nalpropion has no argument that USP 2 is somehow supported in the '195 patent's specification. The validity of claim 11 thus rises or falls on the Federal Circuit's new rule.[8]

Moreover, not only is the Federal Circuit's new rule dispositive of the validity of claim 11 of the '195 patent, but the validity of claim 11 is in turn dispositive of Actavis's ability to market its generic product

[8] The validity of the Federal Circuit's new rule is a purely legal question. At times the decision below invoked the clear-error standard and discussed the district court's factual finding that USP 1 and USP 2 are "substantially equivalent." Pet. App. 11a-14a. But that is not the issue: what matters is not whether USP 1 and USP 2 are *in fact* "substantially equivalent," but whether—even if they *are* substantially equivalent—disclosing one is enough to claim the other, under the correct reading of § 112.

before 2030. The Federal Circuit unanimously held that the two other patents covering Contrave—the '111 and '626 patents—are invalid as obvious over the prior art. Pet. App. 14a-24a. Thus, the *only* thing preventing Actavis from marketing its product—and therefore the *only* thing keeping Nalpropion from facing generic competition for its product until 2030—is a single claim of a single patent. In light of that fact, a decision by this Court to affirm or reject the Federal Circuit's new rule would plainly be outcome-determinative.

This issue does not require further percolation. The Federal Circuit is the only court of appeals with jurisdiction to consider the scope of § 112 and the written-description requirement. *See* 28 U.S.C. § 1295. Especially in light of the substantial confusion and other detrimental consequences that will arise from that rule, *see* pp. 22-23, 27-31, *supra*, there is no reason to await further decisions.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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March 13, 2020

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